Drivers of large-scale change in complex health systems: a rapid review

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An **Evidence Check** review brokered by the Sax Institute for the NSW Agency for Clinical Innovation

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This rapid review was brokered by the Sax Institute.

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Abbreviations and terms

ABLe	Above and Below the Line (change framework)
ARCC	Advancing Research and Clinical practice through close Collaboration
CAS	Complex Adaptive Systems
CDC	Centres for Disease Control and Prevention (USA)
CPM	Clinical Practice Model
EICP	Enhancing Interdisciplinary Collaboration in Primary Health Care
EPOC	(Cochrane) Effective Practice and Organisation of Care (Review Group)
ICCC	Innovative Care for Chronic Conditions
IHI	Institute for Healthcare Improvement
ISF	Interactive Systems Framework for Dissemination and Implementation
KP	Kaiser Permanente
NHS	National Health Service (UK)
PDSA	Plan-Do-Study-Act
PI	Performance Improvement
QI	Quality Improvement
QUERI	Quality Enhancement Research Initiative
VA	Veterans Affairs (USA)
VHA	Veterans Health Administration (USA)
WHO	World Health Organisation

EXECUTIVE SUMMARY

Background

Large gaps between evidence and practice, variable performance in the safety and quality of care, inequitable patterns of utilisation, consumer dissatisfaction and unsustainable cost increases have contributed to the call for transformational change in healthcare systems.[1,2] Our understanding of how to achieve large-scale change in advanced health systems is evolving, however the evidence base to guide change efforts is limited.

The purpose of this rapid review was to determine the evidence for critical enablers of, and barriers to, successful and sustainable large-scale change in complex health systems and to identify implementation frameworks that can guide system change initiatives. This review will be valuable to organisations charged with designing and implementing large-scale evidence-based programs to improve health service provision, quality and consistency of care and patient experiences and outcomes.

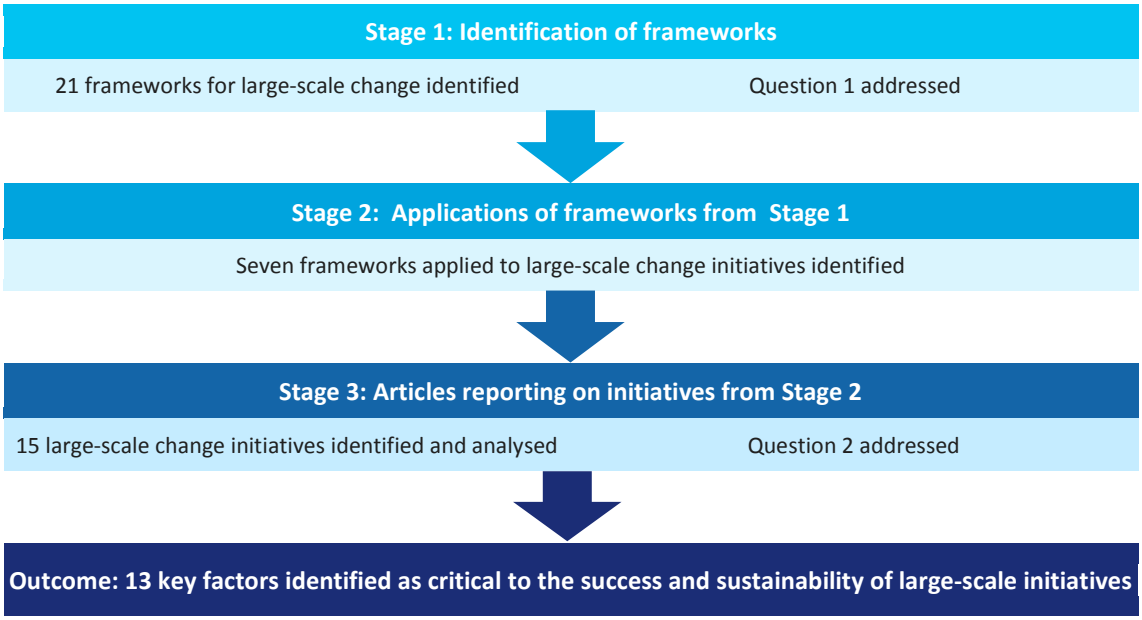
The three questions addressed in this review were:

1. What are the common and diverging features of implementation frameworks for scaling up initiatives to improve the quality of health service delivery across a complex system?
2. What key factors have been identified as critical enablers of, and barriers to, successful large-scale change?
3. To what extent does the successful implementation and sustainability of large-scale change depend on standardisation versus flexibility in implementation and post-implementation phases?

Method

Three stages of searching were conducted for all relevant articles published between January 2000 and July 2013 (refer Figure 1). Articles were identified from EBM reviews, Cochrane Database of Systematic Reviews, PubMED (which includes MEDLINE and life science journals), PsychINFO, Web of Knowledge, EMBASE, CINAHL, ScienceDirect, AUSThealth, Global Health and Google Scholar databases. Relevant agency reports, policy documents and bibliographies of peer-reviewed and grey literature were reviewed to identify any additional relevant material and ensure completeness of included literature.

Figure 1: Flowchart outlining search strategy



A coding matrix was used to identify the important elements of each of the frameworks included in this review and provide a visual comparison of their commonalities and differences. Only frameworks developed for high income countries with similar socio-political features to Australia were included (e.g. UK, Western Europe, Canada, US, NZ). In addition, published and grey literature not meeting Cochrane criteria for research quality but detailing large-scale change initiatives guided by an included framework were scanned for 'lessons learned' and 'key drivers.' These were synthesised using a content analysis approach (mindful of context) to draw out the barriers and critical enablers of successful and sustainable large-scale change. Existing systematic reviews and meta-narrative syntheses of change initiatives not necessarily limited to the health sector or to the scale of change that was of interest in the current review were used to compare and validate findings.

Results

A total of 21 relevant frameworks were found of which seven had been applied to guide large-scale change initiatives to improve the quality of health service delivery (refer Table 1). The remaining 14 frameworks appear to have been developed conceptually on the basis of research evidence and/or experience in conducting large-scale change initiatives in complex health systems. Searches for large-scale change initiatives using the identified seven frameworks yielded a total of 90 relevant titles and abstracts. On examination of the full documents, only 15 relevant papers were found detailing large-scale change initiatives guided by the seven different frameworks. The lack of papers detailing the application of many of the frameworks appears to be a consequence of their more recent development with nine frameworks published since 2010.

Table 1: Large-scale change initiatives analysed to derive the key factors critical for successful large-scale change

Framework	Institution/Location	Large-scale change initiative
Centers for Disease Control and Prevention (CDC) Replicating Effective Programs	International	Packages to scale up evidence-based interventions in a number of countries to reduce risky behaviours related to HIV[3]
Clinical Support Systems Model	Australia	Towards a Safer Culture (TASC) initiative to improve the translation of evidence-based guidelines for cardiac and stroke management into clinical practice[4,5]
Hybrid Model for Quality Improvement	Ontario, Canada	Quality improvement initiative to implement routine screening for cancer patients seen in Regional Cancer Centres throughout the province[6]
	New Mexico, US	Quality improvement initiative in school-based health centres across New Mexico[7]
Institute for Healthcare Improvement (IHI) Framework for Execution of Strategic Improvement	University of Washington Health System, US	Initiative to achieve sustainable elimination of healthcare associated infections across a five-state region[8]
	Kaiser Permanente Health System, US	Initiative to embed improvements into operations throughout the entire organisation[9]
Institute for Healthcare Improvement (IHI) Framework for Spread	Veterans Health Administration, US	Advanced Clinic Access Initiative to reduce wait times in more than 1800 clinics by spreading improvements in operational systems[10,11]
	Mayo Clinic Health System, US	Initiative to develop an institution-wide venous thromboembolism prophylaxis program[12]
	Institute for Healthcare Improvement, US	100,000 Lives Campaign to avoid 100,000 unnecessary deaths in US hospitals[13,14]
Quality Enhancement Research Initiative (QUERI) Framework	Veterans Health Administration, US	QUERI initiative to implement collaborative care for depression on a national scale[15]
Veterans Affairs (VA) Systems Improvement Framework	Veterans Health Administration, US	VA Mental Health System Redesign Initiative[16]
	Veterans Health Administration, US	Quality improvement initiative to improve inpatient flow and reduce waiting times in emergency departments[17]

The synthesis of lessons learned from initiatives included in this review identified 13 key factors that are vital to the success and sustainability of large-scale change initiatives. The factors are summarised in Table 2.

Table 2: Factors influencing large-scale change in healthcare

Antecedents of change: factors that need to be in place prior to roll-out of the large-scale change initiative	**1. Leadership structures and management support**	**Enablers of change:** • Establishment of a leadership structure appropriate for the intended scale of the initiative. This should include both overarching and local management structures • Engaged and supportive leadership with clinical and managerial expertise to oversee the change process **Barriers to change:** • The sole use of quality experts (e.g. quality or risk management consultants) rather than shared governance with operational leaders
	2. Microsystem capacity: ensuring frontline staff have sufficient training and resources to implement initiatives that are effective and sustainable	**Enablers of change:** • A robust induction process, a system for ongoing training and customised coaching and a structure for peer interaction and learning **Barriers to change:** • Limited skills and training among frontline staff in the implementation of initiative components
	3. Infrastructure	**Enablers of change:** • Adequate human resources, communication and data infrastructure at the local level to implement the initiative • Carefully planned and standardised data collection systems (developed by an experienced database designer) that are piloted, refined and put in place prior to roll-out of the initiative **Barriers to change:** • Time restrictions of frontline staff and failure to factor 'in kind' support into resource allocations • Overly complex and untested centralised data systems that cause confusion, delays in reporting and resistance to uptake
	4. Alignment: between initiative goals and organisational priorities	**Enablers of change:** • Alignment of objectives at all levels from the strategic goals of the overarching organisation to the daily improvement priorities of local management **Barriers to change:** • Project fatigue resulting from opportunistic selection of quality improvement initiatives and poor alignment of multiple competing priorities
	5. Systems perspective and broad engagement of stakeholders	**Enablers of change:** • Systems mapping exercises conducted by leadership to: locate and exploit critical pathways in patient care; help prioritise, sequence and align multiple initiatives; expose the scale of resource infrastructure required; and identify key stakeholders to engage • Partnerships between practitioners, operations experts, universities, health departments and the private sector **Barriers to change:** • System-level barriers that are beyond the ability of frontline staff to influence
	6. Credibility of evidence-based initiative	**Enablers of change:** • Development of an evidence-based initiative in collaboration with stakeholders that includes information systems, protocols and tools to support implementation **Barriers to change:** • Lack of consensus on the effectiveness of an initiative due to insufficient credible evidence

Process of change: factors to consider during the implementation phase	**7. Engagement and peer support**	**Enablers of change:** • Continual process of engagement, orientation and peer support • Cultivation of clinical champions and other forms of leadership and relationships such as the physician-administrator relationship **Barriers to change:** • Poor leadership support, heavy clinical loads and limited opportunities for participation • Lack of occasions for frontline staff to share experiences in personal face-to-face mode • Frequent turnover of staff and key clinical leaders
	8. Attention to changing organisational culture	**Enablers of change:** • Fostering a culture of accountability through a number of strategies including promotion of local ownership and strengthening of internal and external social systems **Barriers to change:** • Obstructive organisational culture
	9. Approach to roll-out of initiative	**Enablers of change:** • Selection of a scaling up approach that is compatible with the complexity of the initiative being implemented and allows initial experimentation with the implementation system and capitalisation on lessons from previous change phases
	10. Intervention fidelity with implementation flexibility	**Enablers of change:** • Achieving balance between allowing local customisation to fit the culture and processes of each setting and maintaining adequate fidelity to the evidence-based components of the intervention
	11. Equipping frontline staff with tools for problem solving	**Enablers of change:** • Providing frontline staff and local-level leaders with a variety of tools/methodologies to solve local implementation problems early and often (such as Plan-Do-Study-Act, communication tools, flow charting and systems mapping)
	12. Monitoring and evaluation of progress	**Enablers of change:** • Accurate, reliable and systematic data systems to track progress, identify target areas for improvement and build a track record of the initiative's success • Simple electronic data-collection processes focussing on a vital few performance indicators • A rigorous evaluation framework to assess progress on: the implementation process, intervention fidelity at the organisational and patient level, impact on patient outcomes, and return on investment **Barriers to change:** • Lack of integration of performance data into daily operations. • No systematic recording of indicators across the system which threatens the validity of aggregated data and undermines the credibility of initiative outcomes
Maintenance and evolution: preparing for sustainability	**13. Integration of the change into routine practice**	**Enablers of change:** • To build a foundation for lasting change, messages should shift from creating a sense of urgency (important for initial engagement) to encouraging institutionalisation of the change **Barriers to change:** • Without integration into the culture, structure and processes of an organisation, initial clinical improvements can be lost when organisational attention shifts to a new priority

Discussion

This rapid review identified 21 frameworks for large-scale change in health systems. Frameworks can provide an overarching structure and common language by which critical enablers of success can be communicated and implemented at all levels of the system to optimise the chance of success.

The synthesis of lessons learned from large-scale change initiatives yielded 13 key factors vital to the success and sustainability of initiatives. The lack of rigorous scientific evidence means it is not currently possible to determine which factors are more or less important than others. It is probable that the importance of each will vary in different contexts and for different change initiatives.

One important message in the literature was that large-scale implementation of quality improvement initiatives requires a balance between centralised strategic planning and coordination, and autonomy and empowerment at the local level to generate innovation and more sustainable engagement. Investing in the skills and resources of clinical microsystems (the frontline of clinical care) is vital but needs to be supported by an overarching body that can provide: high-level strategic alignment; large-scale coordination; consistent provision of standardised and specialised resources and training; and the removal of obstacles that are beyond the ability of local departments.[6,9–12]

Another newly emerging message is the importance of addressing systems issues in the design and implementation of large-scale change.[7,9.12,18] Initiatives often ignore systemic issues that can undermine their success.[18,19] By targeting only local-level barriers and motivators to change, achievements are inadvertently limited to local-level outcomes or 'first-order shifts' in the system.[18] To achieve sustainable change in large and complex systems, solutions should target the root causes of barriers to change rather than symptomatic problems, both during the design phase and iteratively throughout implementation as the system evolves.[18,19]

Only one study of a large-scale change initiative investigated the initiative's impact with sufficient rigor to meet Cochrane quality standards, reflecting the difficulty of rigorously evaluating large-scale change in complex and dynamic systems. This study demonstrated a lack of effectiveness of the change initiative in achieving sustainable performance improvements and suggested the importance of factors such as alignment between the initiative and organisational priorities, integration of the change into routine practice and standardisation of processes for future initiatives.[17] Non-traditional integrative research methods and new approaches to data linkage, modelling and simulation may be required to gain new insights and solutions for transformational change in the future.

Applicability of findings to the Agency for Clinical Innovation

To achieve large-scale change across the NSW health system, it is recommended that the Agency for Clinical Innovation (ACI):

- ***Align strategies for large-scale change to the 13 critical factors.*** The 13 critical factors identified appear to be relevant to the NSW context and should be viewed as a practical tool for guiding the development of strategies to optimise the success of large-scale change initiatives
- ***Leverage its unique position to pioneer innovative research.*** While it is not possible to determine which of the 13 critical factors are more or less important in the context of the NSW health system, the analysis suggests that individual factors alone (such as funding incentives or engaging clinical champions) are unlikely to achieve and sustain large-

scale change. Research is crucial to determining the mix of factors that are most important in different clinical contexts within the NSW health system, for different initiatives (e.g. models of care or improving IT systems) and for different stages of change. Through rigorous evaluations of the effectiveness of its work, the ACI has an opportunity to contribute important evidence on the drivers of large-scale change. To create new knowledge in large-scale change and position themselves as pioneers in this field, it is recommended that the ACI should: conduct routine evaluation of initiatives, including the development of appropriate key performance indicators and data collection systems; and compare approaches to scaling up in relation to setting, context and the type of change being addressed. The scope of evaluations should include: the implementation process; intervention fidelity at the organisational and patient level; impact on patient outcomes; and return on investment

- ***Use existing structures to support centralised planning and decentralised implementation.*** This analysis suggests the importance of a degree of centralised strategic planning and coordination for large-scale implementation of quality improvement initiatives, for which the ACI is well-positioned to provide. In particular, the ACI could be instrumental in the strategic alignment of objectives across all levels of the system, providing standardised resources and training to support change, and identifying and removing systems-level obstacles, all of which have been identified as important for successful large-scale change. However, given the multiple variably independent organisational units that comprise the NSW health system, this analysis would suggest that a top-down approach to implementation is unlikely to be effective. A degree of local flexibility is critical to enable local adaption and innovation. The relationships the ACI and its Clinical Networks, Institutes and Taskforces, have with their partners, such as Local Health Districts, could provide this local capacity and guide the formation of implementation teams with multidisciplinary representation at all levels of the health system hierarchy
- ***Use innovation from non-health sectors.*** Systems science has been widely applied to sectors such as engineering, economics, ecology and business since its inception in the mid-1950s. Learning from applications in these non-health sectors, systems science methodologies have been used to help map and understand complex public health problems such as childhood obesity[20], diabetes[21], and heart disease[22], as well as optimise operational aspects of healthcare capacity and delivery such as patient flows in emergency[23,24], disease screening[25], demand for services[26,27], and workforce requirements.[28,29] Systems methodologies can systematically analyse a range of initiatives and organisational policies and solutions prior to implementation and identify leverage points in the system (places to intervene) where small inputs result in large impacts.[30] They can also be used to identify and analyse key stakeholders and linkages with non-health sectors and to explore critical relationships between networks or organisations and individuals that can drive or block the successful scaling up of initiatives. A systems approach to guide the ACI and their clinical partners in strategic planning, ongoing decision making and research to support system change initiatives holds promise. To achieve large-scale change, a systems approach requires: an in-depth knowledge of the organisations in which it is being applied, including management and funding arrangements; a clear outline of the specific problem being addressed; engagement of stakeholders representing each of the components of the system being mapped and/or modelled; and consultants/researchers with expertise in systems approaches to facilitate co-development of credible, feasible and effective evidence-based initiatives.

1 Background

The introduction of evidence-based practice in Australia in the 1990s aimed to incorporate increasing scientific information into clinical practice to improve patient outcomes, reduce variation in healthcare delivery and ensure the efficient use of limited health resources.[31] Despite decades of developing evidence, there remains slow and haphazard uptake of evidence-based practice and failures to achieve system-wide improvements in the quality of care.[32] Large gaps between evidence and practice, variable safety and quality standards, inequitable patterns of utilisation, consumer dissatisfaction and unsustainable cost increases have contributed to the call for transformational change in the healthcare system.[1,2] Our understanding of how to achieve large-scale change in advanced health systems is evolving as their complexity is elucidated; however, the evidence base to guide change efforts is lacking.

Implementation scholars and practitioners have identified many influences on implementation success including intervention fidelity, dosage, diffusion approaches used, and at least 23 personal, organisational and community factors.[33–35] Added to these many influences are the challenges presented when scaling up implementation across large and complex health systems. Scaling up goes beyond implementation, as the focus is not only on putting an effective program into place in a new location. Scaling up also aims to increase the depth of a program by offering new and different services and/or increase the number of recipients of a program.[36] There are a number of approaches to scaling up that should be considered individually or in combination when planning large-scale change initiatives. These include the:

A. Extension Agent Approach – mobile health workers or community leaders spread ideas and best practice and provide coaching and supervision

B. Affinity Group Approach (developed by Ascension Health) – alpha sites are established to develop and test a superior model of care and lead change on behalf of the system. Early improvements are said to simulate 'viral' spread of successful practices to other locations hoping to emulate similar results

C. Collaborative Approach – developed by the Institute for Healthcare Innovation (IHI) in the US, it emphasises peer-to-peer learning between teams as they exchange their improvement experiences. Further information about this approach can be found in Box 1

D. Wave Sequence Approach – a systematic approach to rapid spread of multi-level interventions that are systemic and cross tertiary, secondary and primary care settings. It is applicable when the full scale cannot be achieved all at once and there are limitations to human and financial resources. This approach builds on the Collaborative Approach and emphasises the use of clinical champions and a trained health system workforce from earlier spread phases to drive subsequent spread phases

E. Campaign Approach – has its origins in electoral campaigns and is applicable when the nature of the intervention is straightforward, easy to 'sell', aligns with other national initiatives, has a galvanising target and connects with the public. It builds on a platform and comprises broad communications, distributed field operations and a simple measurement system.

Box 1: IHI Collaboratives

In order to address the gap between research evidence and clinical practice, the Institute for Healthcare Improvement (IHI) in the US developed the Breakthrough Series to assist healthcare organisations make 'breakthrough' improvements in the quality of healthcare while reducing costs. The IHI Breakthrough Series Collaboratives were short-term (6- to 15-month) networks that provided a structure within which multidisciplinary teams from hospitals or clinics could work together to share information and materials in order to facilitate change and improve practice. Since 1995, IHI has sponsored over 50 Collaborative projects ranging in size from 12–160 organisational teams involving more than 1000 organisations. Learning Sessions, where team members from each organisation meet, assist in sharing knowledge of best practices and facilitating improvements in local organisations.[35,36]

Lessons from IHI Collaboratives: Collaboratives were successful in changing processes at individual organisations, but were successful to a lesser extent for Collaboratives as a whole. Successful implementation required the identification of local sub-practices, development of specific recommendations and strategies and the use of tools developed as templates for organisations, however many organisations lacked the resources to implement this structure. Evaluation was also challenging as reporting on key measures of success was often irregular and infrequent. Furthermore, the relatively short timeframe and complexity of the context of the Collaborative initiatives made it difficult to measure the true impact of the initiatives. In order to be successful, Collaboratives addressed topics that were relevant to stakeholders. Presenting strong evidence in support of the practices proposed often by an expert in the field was necessary to bring change. Teams that actively participated in the initiative, particularly by communicating information effectively, attending Collaborative meetings and having the support and engagement of senior management, were more successful at implementing change than those that did not. Strong leadership that supported organisational culture change was essential. Teams that utilised the Plan-Do-Study-Act cycle were more successful, although the use of this tool proved to be more challenging than anticipated. By ensuring the engagement of all stakeholders, particularly the support of senior management, Collaboratives can be a powerful way to motivate and support change in health care organisations and disseminate information across health systems.[36]

In addition to determining a context-appropriate approach for scaling up, a framework to provide practical guidance for the planning and execution of large-scale implementation efforts should also be considered.[34] Frameworks can help plan, implement and evaluate sustainable large-scale change efforts in health systems.[37] They assist with organising a set of ideas and practices that influence the implementation process in a manner that is easy to communicate to others, identifies essential elements of success and highlights mistakes that should be avoided.[34] Scale up approaches and frameworks need to be chosen according to the stage of change and context to have maximum utility and impact.[38] The research-to-practice gap in health service delivery and failures of large-scale change initiatives have been attributed to a lack of application of a framework for implementing effective initiatives in real-world settings which can assist with maintaining intervention fidelity while optimising transferability in different contexts.[3,39–41] Box 2 provides a portrait of an unsuccessful large-scale change initiative.

Box 2: Portrait of an unsuccessful change initiative

"Upper leadership announces a new program or initiative that will bring major change. It calls for a shift in money allocation for the work at hand, and many other programs and initiatives are placed on hold. There is an increase in role demands; all energy is focused on the effort; there are shifts in accountabilities; and hours of planning and multiple meetings take place. Timelines with clear expectations of outcomes are delineated. Some people immediately buy in and get on the train, whereas others are sceptical. There is focus and energy around getting something fixed. Some people are excited about the new project; others are not. It is easy to see that the desired outcomes of the project are honourable, for example, the desire to increase customer satisfaction or safety. Therefore, resistance of any sort is seen as negative, and those not supporting are either weeded out or become silent. Initial successes are reported and celebrated. However, over time the staff satisfaction starts to fall, and the high customer satisfaction achieved also starts to decline. One administrator comments, 'We spent over one million dollars on this effort; what is wrong with this picture.' The effort to fix certain problems is successful for a while but not sustained over time. In fact, the energy and focused effort leads to negative fallout. Why, in the face of such good intention and much intense effort, are the desired or positive outcomes of intense work not apparent or able to be sustained?"[42(p20)]

The purpose of this rapid review is to identify existing implementation frameworks that can guide large-scale change initiatives to improve the quality of health service delivery in complex systems. In addition, it aims to identify the critical enablers of, and barriers to, successful and sustainable large-scale change. The three questions addressed in this review were:

1. What are the common and diverging features of implementation frameworks for scaling up initiatives to improve the quality of health service delivery across a complex system?
2. What key factors have been identified as critical enablers of, and barriers to, successful large-scale change?
3. To what extent does the successful implementation and sustainability of large-scale change depend on standardisation versus flexibility in implementation and post-implementation phases?

This review will be of value to organisations charged with designing and implementing large-scale evidence based programs to improve health service provision, the quality and consistency of care as well as patient experiences and outcomes.

2 Search methods

Rapid reviews streamline traditional systematic review methods and apply search limitations to conduct the review in a shortened timeframe.[43] Completeness of the review is determined by time constraints and synthesis of findings in narrative and tabular format in order to assess what is known about a topic.[44] The subject of this rapid review is broad and hence the scope and search strategy was determined by time limitations, the guidelines provided by the commissioning agency and subsequent consensus meetings to refine the scope.

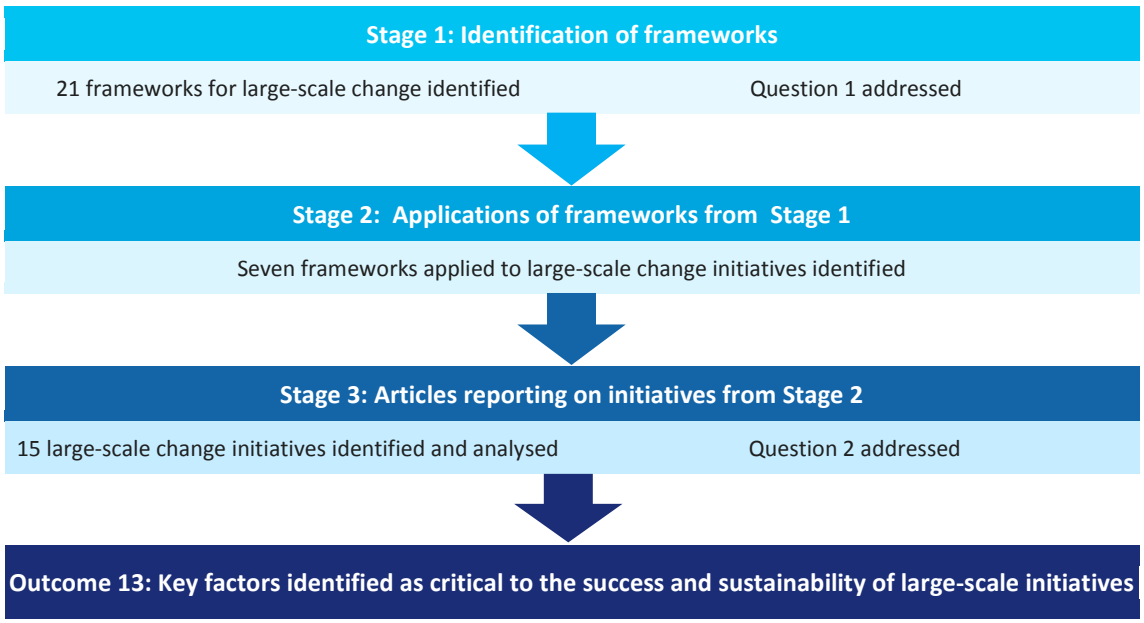
2.1 Information sources

A search was conducted of all relevant articles published between January 2000 and July 2013, identified from EBM reviews, Cochrane Database of Systematic Reviews, PubMED (which includes MEDLINE and life science journals), PsychINFO, Web of Knowledge, EMBASE, CINAHL, ScienceDirect, AUSThealth, Global Health and Google Scholar databases. Relevant agency reports and policy documents were reviewed to identify any additional relevant material. Review of bibliographies of papers was also carried out to ensure completeness of inclusion of all relevant literature.

2.2 Search strategy

In order to find relevant papers, three stages of searching were conducted (refer Figure 1).

Figure 1: Flowchart outlining search strategy



Initially, databases were searched with both keywords and subject headings specific to each database using the following search terms: 'framework OR approach OR model OR strategy OR mechanism OR policy' AND 'scale-up OR system transformation OR system change OR system strengthening OR implementation OR reform' AND 'health' AND 'innovation OR intervention OR evidence based practice OR quality improvement OR model of care OR practice guideline OR service delivery.' This first stage of searching identified relevant frameworks for addressing Question 1 of the rapid review. The second stage of searching used the name of each relevant framework to search for their applications in large-scale initiatives. Finally, searching was conducted under the names of specific initiatives known to have been guided by an included framework in order to identify relevant studies, papers and agency reports documenting lessons learned and predictors of success. This process relied heavily on 'snowball' methods (pursuing references of references and citation tracking) and sought advice on sources from experts in the field. Results of the second and third level searches were used to address Questions 2 and 3 of the rapid review. Both American and English spellings of key search terms were used. The search was limited to English language publications.

2.3 Study selection

Papers eligible for inclusion to address Question 1 were those describing implementation frameworks for large-scale change initiatives to improve the quality of health service delivery across a complex system. Frameworks were included regardless of whether they were described conceptually or were applied in a real-world context. Only frameworks developed for high income countries with similar socio-political features to Australia were included in the review (e.g. UK, Western Europe, Canada, US, NZ). Papers eligible for inclusion to address Questions 2 and 3 were those describing or evaluating large-scale change initiatives that applied any of the frameworks identified in Question 1. Minimum scale for roll-out of an initiative was at a state or provincial level or equivalent expansive organisational delivery in the private sector. For papers that reported an included initiative that was rigorously evaluated (i.e. where a randomised controlled trial, controlled before and after study or interrupted time series design was used), findings were extracted and analysed separately to case studies, observational studies and reports from grey literature.

2.4 Quality assessment, data coding and synthesis

A coding matrix was developed and independently verified by each member of the research team. It assisted with unpacking the important elements of each of the frameworks included in this review and provided a visual comparison of their commonalities and differences. It was also used to code the lessons learned provided by observational studies and case reports of large-scale change initiatives. In the absence of a 'gold standard' critical appraisal tool applicable across multiple study designs, quantitative studies evaluating large-scale change initiatives guided by included frameworks were subjected to the quality guidelines for inclusion outlined by the Cochrane Effective Practice and Organisation of Care (EPOC) review group.[45] A summary of frameworks relevant to guiding large-scale change initiatives to improve the quality of health service delivery (whether purely conceptual or applied), including a breakdown of the important elements they each emphasised, were used to address Question 1. Observational studies and case studies/reports detailing large-scale change initiatives guided by a relevant framework were scanned for 'lessons learned' and 'key drivers.' These were synthesised using a content analysis approach (mindful of context) to draw out the barriers and critical enablers of successful and sustainable large-scale change and were used to addressed Questions 2 and 3. Existing systematic reviews and meta-narrative syntheses of change initiatives not necessarily limited to the health sector or to the scale of change that was of interest in the current review were used to compare and validate findings. All references were entered into EndNote for reference

management. The process of study selection to address Question 1 is summarised in Appendix A and study selection for Questions 2 and 3 is summarised in Appendix B.

3 Results

A total of 21 relevant frameworks were found of which seven had been applied to guide large-scale change initiatives to improve the quality of health service delivery. The remaining 14 frameworks appear to have been developed conceptually on the basis of research evidence and/or experience in conducting large-scale change initiatives in complex health systems. It is possible that one or more of the remaining 14 frameworks have been applied; however, literature on these applications was not located. Searches for large-scale change initiatives using the identified seven frameworks yielded a total of 90 relevant titles and abstracts. On examination of the full documents, only 15 relevant papers were found detailing large-scale change initiatives guided by the seven different frameworks. The lack of papers detailing the application of many of the frameworks appears to be a consequence of their more recent development with nine frameworks published since 2010.

3.1 Question 1: What are the common and diverging features of implementation frameworks for scaling up initiatives to improve the quality of health service delivery across a complex system?

In the absence of quantitative evidence on the essential elements for successful large-scale change in complex health systems, a qualitative synthesis of literature detailing successful examples of such initiatives was carried out by Perla et al. (2013) using a modified Delphi technique.[46] The drivers of large-scale change proposed by these authors formed the architecture for unpacking the important elements of frameworks included in this rapid review. Table 3 lists the 21 frameworks suitable for guiding large-scale change initiatives, highlighting the emphasis they place on any of the primary drivers outlined by the systematic review.[46] A description of the composition of each driver can be found in Appendix C.

Frameworks commonly emphasised the importance of strategic plans for spread and consideration of individual, group and organisational factors important for large-scale change. Less commonly, they emphasised attention to ongoing process of change factors, performance measures and evaluation. Fewer than half of the frameworks included in this review placed emphasis on important elements such as infrastructure, systems influences and alignment between strategic goals of the macrosystem and priorities of the microsystem.

Only one study of a large-scale change initiative guided by one of the 21 frameworks investigated the initiative's impact with sufficient rigor to meet EPOC standards. Glasgow et al. (2012) evaluated the experience of 130 Veteran Health Administration (VHA) hospitals in the US that were participating in a large-scale quality improvement initiative guided by the Veterans Affairs Systems Improvement Framework.[17] As part of this initiative, a Collaborative was convened requiring mandatory involvement of participating hospitals. Each of the five US regions represented had a leadership team that consisted of two co-directors (with overarching leadership responsibility) and two coordinators (who oversaw day-to-day management of the initiative). Quality Improvement (QI) coaches were also recruited to work with hospital QI teams to facilitate change and provide feedback throughout the change journey.[17] Representatives from each hospital attended 1.5–2-day learning sessions focusing on the technical elements of the change initiative and the framework being used to guide the translation of key principles (identified by the Collaborative) into local solutions to improve inpatient flow problems.[17] This study used an interrupted time series design to determine whether participation in the initiative

resulted in sustained improvements in inpatient hospital flow through the continuum of inpatient care.

This study found considerable variability in performance across hospitals. In addition, marked enterprise-wide improvements seen during the initiative were not sustained once the Collaborative ended. The analysis also showed 28% of hospitals exhibiting no statistical trend on the two primary outcomes. Glasgow et al. (2012) suggested that these results were a consequence of a lack of standardised care processes across hospitals, highlighting the importance of processes that perform predictably and consistently before they can be successfully improved. In considering contextual explanations for the mixed results, it was noted that Veteran Health Administration hospitals regularly participate in national and local hospital led QI projects which present competing demands for participation. As such, if the goals of multiple national and local initiatives are not aligned, sustaining outcomes for a particular initiative will be difficult.[17] In addition, the Collaborative was mandated which may have influenced engagement by teams and hospitals, resulting in performance variation that may not have been present if participation had been voluntary.[17] Although the study demonstrated a lack of effectiveness of this initiative in sustaining performance improvements beyond the initiative period, it suggests the importance of factors such as alignment, integration and standardisation of processes, and the need for rigorous combined qualitative and quantitative evaluation that can identify key sources of variation. These issues will be discussed further in the following sections that respond to Questions 2 and 3 of the review. It is likely that the effectiveness of different frameworks will be determined by the context in which a framework is to be applied and hence recommendation for use of a particular framework is not deemed to be appropriate for this review.

Table 3: Frameworks mapped against drivers of large-scale change proposed by Perla et al. 2013*

Framework	Country (date published)	Strategic planning [A]	Infrastructure [B]	Individual and Group Dynamics [C]	Organisational factors [D]	System factors [E]	Process of change [F]	Performance measures [G]	Evaluation [H]	Alignment [I]
ABLe Change Framework[18]	US (2012)	✓		✓	✓	✓	✓			✓
ARCC model [47]	US (2010)			✓	✓		✓			
Complex Adaptive Systems (CAS) Framework[19]	US (2012)	✓		✓	✓	✓		✓	✓	
CDC Replicating Effective Programs[3]	US (2007)	✓	✓	✓				✓	✓	
Clinical Support System Model[48]	Australia (2004)			✓	✓		✓	✓	✓	
CPM Professional Practice Framework[1]	US and international consortium (2011)	✓		✓	✓	✓	✓			
EICP Framework[49]	Canada (2006)	✓	✓	✓					✓	✓
Framework for Action (WHO)[50]	Switzerland (2007)	✓		✓	✓	✓		✓	✓	✓
Framework for Organisational Transformation[51]	US (2007)	✓	✓	✓	✓	✓	✓			✓
Hybrid Model for Quality Improvement[6]	Canada (2012)	✓		✓			✓	✓	✓	
ICCC Framework (WHO)[52]	Switzerland (2012)		✓	✓	✓	✓				
ISF Framework[53]	US (2008)	✓	✓	✓	✓	✓	✓		✓	
IHI Framework for Execution of Strategic Improvement[54]	US (2007)	✓	✓	✓	✓	✓	✓	✓		✓

Framework	Country (date published)	Strategic planning [A]	Infrastructure [B]	Individual and Group Dynamics [C]	Organisational factors [D]	System factors [E]	Process of change [F]	Performance measures [G]	Evaluation [H]	Alignment [I]
IHI Framework for Spread[10]	US (2005)	✓	✓	✓	✓		✓	✓	✓	✓
NHS Change Model[55]	UK (2012)	✓		✓	✓	✓	✓	✓	✓	✓
QUERI Framework[56]	US (2008)	✓	✓	✓	✓		✓	✓	✓	✓
The Five C's of Culture Change framework[57]	US (2006)			✓				✓	✓	
The Multilevel Framework for Change[58]	USA and UK (2001)			✓	✓	✓				
The 'Territory of Change' concept map & 'Change Framework' [38]	Canada (2012)	✓			✓		✓		✓	
VA Strategic Framework for Quality Management[59]	US (2001)	✓		✓				✓	✓	✓
VA Systems Improvement Framework[60]	US (2010)	✓		✓	✓		✓	✓	✓	✓

*Elaboration on each of the elements can be found at Perla RJ, Bradbury E, Gunther-Murphy C. Large-scale improvement initiatives in healthcare: a scan of the literature. J Healthc Qual 2013;35(1):30–40, with systems factors supplemented by Paina L, Peters DH, Understanding pathways for scaling up health services through the lens of complex adaptive systems. Health Policy Plan 2012;27(5):365–373. These factors are summarised in Appendix C.

3.2 Question 2: What key factors have been identified as critical enablers of, or barriers to, successful large-scale change?

The 15 relevant papers found relating to this question were primarily case studies/case reports detailing large-scale change initiatives from the USA, Canada and Australia. No quantitative studies meeting EPOC criteria for rigor and quality were found, however two observational studies (one of which included a qualitative component) were included and synthesised alongside the case studies. To differentiate between the many enablers and barriers that were listed and those considered critical to success, emphasis was placed on the results of the observational studies and any key factors reported by case studies/reports as being vital to driving large-scale change. Table 1 provides a summary of the initiatives used to derive the enablers and barriers critical for successful large-scale change.

Table 1: Summary of large-scale change initiatives analysed to derive the key factors critical for successful large-scale change

Framework	Institution/Location	Large-scale-change initiative
Centers for Disease Control and Prevention (CDC) Replicating Effective Programs	International	Packages to scale up evidence-based interventions in a number of countries to reduce risky behaviours related to HIV[3]
Clinical Support Systems Model	Australia	Towards a Safer Culture (TASC) initiative to improve the translation of evidence-based guidelines for cardiac and stroke management into clinical practice[4,5]
Hybrid Model for Quality Improvement	Ontario, Canada	Quality improvement initiative to implement routine screening for cancer patients seen in Regional Cancer Centres throughout the province[6]
	New Mexico, US	Quality improvement initiative in school-based health centres across New Mexico[7]
Institute for Healthcare Improvement (IHI) Framework for Execution of Strategic Improvement	University of Washington Health System, US	Initiative to achieve sustainable elimination of healthcare associated infections across a five-state region[8]
	Kaiser Permanente Health System, US	Initiative to embed improvements into operations throughout the entire organisation[9]
Institute for Healthcare Improvement (IHI) Framework for Spread	Veterans Health Administration, US	Advanced Clinic Access Initiative to reduce wait times in more than 1800 clinics by spreading improvements in operational systems[10,11]
	Mayo Clinic Health System, US	Initiative to develop an institution-wide venous thromboembolism prophylaxis program[12]
	Institute for Healthcare Improvement, US	100,000 Lives Campaign to avoid 100,000 unnecessary deaths in US hospitals[13,14]
Quality Enhancement Research Initiative (QUERI) Framework	Veterans Health Administration, US	QUERI initiative to implement collaborative care for depression on a national scale[15]
Veterans Affairs (VA) Systems Improvement Framework	Veterans Health Administration, US	VA Mental Health System Redesign Initiative[16]
	Veterans Health Administration, US	Quality improvement initiative to improve inpatient flow and reduce waiting times in emergency departments[17]

Synthesis of initiatives identified the following critical enablers of, and barriers to, successful large-scale change organised under the three essential change components of: antecedents of change; process of change; and maintenance and evolution.

Antecedents of change

Strategic planning for large-scale change initiatives is essential and requires consideration of both the structural and cultural antecedents of change.[4] The key antecedents identified were:

1. *Leadership structures and management support*: Having an adequately engaged and supportive leadership to oversee the change process has long been recognised as an important determinant of success and its absence was reported as a major barrier in the current review.[5,9] The sole use of quality experts (e.g. quality or risk management consultants) rather than shared governance with operational leaders was another important barrier identified.[9] Experienced and effective leaders with the necessary clinical and managerial expertise as well as excellent communication skills were critical to uptake and innovation of spread initiatives.[8,9,12] However, leadership required for large-scale change entails more than personal expertise, commitment and advocacy.[6,11] Strategic planning and establishment of leadership architecture appropriate to the intended scale of the initiative prior to its commencement is vital, and should include both overarching and local management structures and processes.[6,11] It is suggested that these structures be geared towards supporting change at the frontline of care.[13,14] This support should include: elevating the visibility of the initiative; incorporating it into organisational priorities; providing clear roles and guidelines for accountability and reasonable expectations for performance targets; identifying and supporting clinical champions; facilitating regular communication and cooperation between silos within hospital systems; and removing implementation obstacles through appropriate resource acquisition and targeting that is beyond the ability of local departments.[4,11,13,14] Collaboratives have been successfully used as an overarching structure to drive change; however, a more long-term, sustainable and integrative structure to support the spread of operational systems was suggested to be required to reach a wider audience.[10] Kaiser Permanente's (KP's) experience with embedding quality improvement throughout their health system emphasised the pivotal role of clinical microsystems (frontline teams), and this led them to place the majority of personnel and resources at the local level. This investment was supported by an overarching body (the 'KP Improvement Institute') that provided specialised resources and training in leadership, new skills and approaches including 'systems thinking,' data management and analysis, Lean and Six Sigma methodologies and Plan-Do-Study-Act (PDSA) change cycles.[9] Further details of this initiative can be found in Box 3.

Box 3: The Kaiser Permanente experience

Kaiser Permanente (KP) is the largest not-for-profit health plan in the United States and has a history of innovation in prevention and population care. When senior leadership realised there were variations in the quality, safety and efficiency of health services, they developed and implemented a performance improvement (PI) system that was scaled up across all 35 medical centres nationwide. This included the creation of a data dashboard with a few vital high-level measures of performance which enabled executives to gauge their medical centres' performance against best-in-class organisations.

Outcomes: Between the second quarter of 2008 and the first quarter of 2009, performance across all facilities improved on the dashboard metrics. Performance on a Joint Commission composite measure improved from the national average to between the 75th and 90th percentiles. The prevalence of hospital-acquired pressure ulcers, a key performance indicator, decreased by more than 50%. Below are some of the key factors that contributed to the success of this large-scale change initiative.

ANTECEDENTS OF CHANGE:

***Leadership structures and management support*:** Leaders at all levels of the organisation and system received training on how to assess and support PI efforts. Interdisciplinary leadership teams were formed at each medical centre to provide regular oversight of improvement portfolios. Teams comprised the chief executive officer, chief medical officer, medical group administration, union staff, finance leaders and others. Leadership champions reviewed the progress of improvement portfolios weekly. At the regional level, experts in improvement were hired to mentor medical centre leaders for up to two years.

***Microsystem capacity*:** Key staff were trained as improvement advisors (IAs). IAs took portfolios of 90- to 120-day initiatives and implemented them with frontline staff in order to achieve system-level results. Through the development of strong unit-based teams, significant organisational energy and resources were devoted to providing clinical microsystems with skills to measure daily work performance. IAs were often promoted to operations and leadership positions, which in the long run ensured leadership had PI knowledge and skills.

***Infrastructure*:** The KP Improvement Institute helped executives develop their PI systems and implementation plans to align with operational structures. IAs had dedicated time to continually expand PI efforts and report to senior operational leaders. As little as 0.2 full-time equivalent (FTEs) employees were sufficient to complete initial projects.

***Alignment*:** Senior leaders shared common goals: engage all staff, from frontline carers through to senior executives; and focus on achieving organisational performance goals. Facilities were able to independently set goals and leaders were able to set direction to reduce variation in quality of care across sites.

Systems perspective and broad engagement of stakeholders: Medical centre leaders, leadership teams and IAs were mentored in applying systems thinking methodologies and developing infrastructure to implement strategically important efforts. Systems mapping helped leaders identify factors influencing organisation- and system-wide performance. Clinical staff were encouraged to understand how improvement initiatives impacted patient care and system performance.

Credibility of evidence-based initiative: During the planning phase, five high-performing organisations were benchmarked for best practices. Six capabilities of high-performing organisations formed the basis of the PI system.

PROCESS OF CHANGE:

Engagement and peer support: Shared accountability in integrating PI initiatives was critical. Frequent internal communications promoted shared responsibility for organisational performance.

Efforts focused on incremental improvement were primarily performed by frontline staff. Managers communicated how different departments worked together to avoid making changes that inadvertently interfered with another team's project. Leaders were asked to continually plan for expansion of PI activities rather than view projects as one-off initiatives.

Attention to changing organisational culture: Ownership of quality and service performance shifted from quality-content experts to operational leaders and managers and frontline staff. Leaders' perspective shifted from viewing projects in isolation to incorporating the interactions of systems and infrastructure in improving overall performance. Training focused on building leadership rather than the use of specific tactics. Understanding the link between implementing initiatives and system-wide improvement was essential for the engagement of frontline staff.

***Approach to roll out of initiative*:** The PI system was rolled out using a wave sequence approach. By capitalising on what was learnt in previous phases, the process of scaling up proceeded much quicker than if the program had been rolled out all at once.

Intervention fidelity with implementation flexibility: Medical centre leaders collaborated with their teams to use the dashboard data to identify potential areas of opportunity at the facility level that align with regional and national strategic priorities.

***Equipping frontline staff with tools for problem solving*:** Individualised road maps were provided to guide leaders to choose priorities and work collaboratively to make initial incremental changes before moving on to more complex strategies. Checklists helped leaders support execution of strategic goals. By training IAs on a number of approaches, they were able to apply tools in the most appropriate way to achieve results.

***Monitoring and evaluation of progress*:** The online data dashboard provided consistent, timely and actionable data that could be viewed at the national, regional and facility levels. Leaders and managers frequently communicated the relationship between the efforts of frontline staff and larger organisational goals.

MAINTENANCE AND EVOLUTION:

Integration of change into routine practice: Clinical teams had a sense of ownership of improvement initiatives as they implemented and assessed their efforts. With the benefit of collaborative learning across sites, frontline teams used existing knowledge to develop and refine initiatives in specific departments.

2. ***Microsystem capacity (training and resources for frontline staff):*** Limited skills and training of frontline staff in the implementation of initiative components was a key barrier to success.[13–15] Even when adequate initial training is provided, high staff turnover can affect the forward momentum of initiatives.[13–15] Since the knowledge and skills of frontline staff have been reported as a strong predictor of implementation success[11], a robust induction process, a system for ongoing training and customised coaching and a structure for peer interaction and learning were recommended to ensure faithful and effective replication of the intervention, adoption of a quality improvement culture and building of skills for local innovation.[3,9,11,13,14] An interactive training model that meets the immediate information needs of staff and supports a knowledge-to-action process was reported to be superior to a didactic learning approach where staff are overloaded with information.[9] It was also suggested that training be iterative, with staff empowered to make small improvements in the first instance and develop capacity over time to address more complex issues.[9]

3. ***Infrastructure (human resources and data and communication systems):*** Local contextual factors such as time demands of staff and level of resources were significant predictors of the extent of implementation.[11] A common barrier to participation in large-scale change initiatives and development of a culture of improvement among frontline staff was the time commitment

required by them in addition to their regular duties and concurrent projects.[4–6,9,10] There has been significant and profound concern among clinicians in some initiatives that their time was not factored into resource allocations and they were apprehensive about the possibility that implementation of an evidence-based initiative may identify additional patient issues for which there would be inadequate time and resources to address.[4,6] The types of 'in kind' support expected by initiatives included attendance at regular meetings, involvement in local customisation of interventions, recording of performance data and development of a local system to recruit and train staff to support the work.[4,10] These expectations may have significant implications for the sustainability of large-scale change initiatives. Successful implementation requires adequate human resource infrastructure at the local level to address barriers.[4,6] The strategy used by one initiative to achieve this was the development of a business case for resources needed to successfully undertake the initiative, which included a financial analysis of the costs associated with retaining the status quo.[8] It was recommended that initiatives with limited resources prioritise skill development of frontline staff, allocate rostered time for junior staff to contribute to activities and develop more advanced expertise within service lines.[4,9]

It is vital that data systems and electronic platforms to measure baseline and performance progress are piloted, refined and put in place prior to roll-out of large-scale initiatives. Overly complex, untested and centralised data systems can become a significant stumbling block to effective implementation as a result of confusion around too many data points and indicators, delays in reporting and resistance to uptake.[4,6] However, carefully planned, standardised data collection systems that can measure the spread and impact of the initiative and are refined prior to roll-out of the initiative can facilitate uptake by creating a common language for comparison across the system and motivation for ongoing participation.[10,12] To achieve this, an experienced database designer and manager should be engaged from the outset to ensure that database systems are integrated, adequately supported, flexible enough to accommodate new variables (although these should be avoided) and have safety checks on data fields to minimise data entry errors.[4] Data management and statistical experts are valuable for developing and implementing evaluation plans, data analysis, problem solving and communication of results to frontline staff and leadership.[12]

In addition to data systems, strategic planning should include consideration of communication systems. Communication infrastructure promoted by initiatives in this review included: telehealth and site visits for rural and remote areas; websites to spread messages, disseminate scientific findings, resources and success stories; publications and newsletters; and social media sites as platforms for knowledge exchange and to support the creation of a 'learning organisation.[7,9,10,15]

4. *Alignment:* Project fatigue or the perception of 'death by a thousand initiatives' was reported as a barrier to the uptake and sustainability of large-scale change. Project fatigue results from opportunistic selection of quality improvement initiatives, poor alignment of multiple competing priorities and lack of a systems perspective by frontline staff.[9,4] To prevent this, clearly identified, simple aims that are aligned with strategic objectives of the organisation are critical.[6,8–10,13,14] Alignment at all levels, from the strategic goals of the macrosystem to the daily improvement activities of the microsystem is important.[9] When this alignment is achieved, many other operational structures of an organisation can be improved and directed towards supporting the spread process.[9,10]

5. *Systems perspective and broad engagement of stakeholders:* In the implementation of initiatives, a range of barriers can arise that are beyond the project's ability to influence. When this occurs, frontline staff can become frustrated by the lack of ability to work through and resolve these issues.[4] Large-scale implementation of complex QI initiatives in a range of settings requires system-level factors to be addressed and staff to be provided with a systems perspective before large-scale improvements in clinical practice become feasible.[7] A systems perspective can assist with framing quality problems as a consequence of imperfect, unreliable and often chaotic systems that cause confusion and frustration and lead to poor outcomes in care, rather

than a result of poor performance of clinicians.[13,14] Systems mapping exercises conducted by leadership at all levels can: locate and exploit critical pathways in patient care; help prioritise, sequence and align multiple initiatives; expose the scale of resource infrastructure required to achieve goals; and identify key stakeholders to engage.[9,12] Providing frontline staff with a systems perspective helps to cultivate ownership and commitment to performance improvement.[9] Box 4 presents the perspective of large-scale change through the lens of Complex Adaptive Systems (CAS).

Box 4: A systems perspective for large-scale change[19]

Health systems as Complex Adaptive Systems: Complex Adaptive Systems (CAS) comprise many components that interact in complex, non-linear and unpredictable ways. They have the capability to self-organise, adapt and learn from experience. Such systems can create problems for decision makers attempting to control them through conventional means. Health systems are comprised of highly heterogeneous groups of actors intervening at multiple levels through a variety of services and functions. The interconnectedness of actors and dynamic interactions across the health system resemble a CAS. The systems perspective has been underutilised in understanding health system processes such as scaling up.[19]

Scaling up in health entails a set of processes that lead to expanded and sustained coverage of health services and involves strengthening the capacity of delivery organisations, increasing robustness of funding and management arrangements and growing the systems' overall capability to add or integrate services. Using a CAS lens can deepen our understanding of how to effect change in health systems including scaling up evidence-based initiatives but requires a shift in thinking from aiming to 'engineer' change to being focused on creating the conditions within which change will emerge. CAS methodologies such as network analysis, systems mapping and dynamic modelling can be used to achieve this and guide the more conventional cycles of program planning, implementation and monitoring and evaluation.[19]

Planning: During this phase, CAS methodologies can be used to identify and analyse key stakeholders and linkages with non-health sectors and to explore critical relationships between networks or organisations and individuals that can drive or block successful scaling up. CAS methodologies also allow scenario-building and testing activities to be undertaken that can engage decision makers in the process of identifying critical leverage points for change and planning for unpredictability.[19]

Implementation and monitoring: Understanding of CAS by local leaders and frontline staff allows adaption, learning and flexibility to address emerging issues, rather that strict adherence to initial plans. Adaption and innovation is perceived as an iterative process guided by local responses and monitoring of intended and unintended outcomes. CAS methodologies facilitate inclusive engagement, relationship-building and provide a platform for transparent dialogue among diverse actors.[19]

Evaluation: Analysis of CAS phenomena in scaling up provides a valuable complement to the traditional evaluation focus by providing rich insights to the processes through which intended and unintended consequences manifest themselves in a health system.[19]

Broad multilevel engagement, which includes quality, operations and clinical experts, professional bodies, the private sector and researchers, was identified as an essential component of success.[5,6,9,10] Partnerships between practitioners, universities and health departments were also suggested as strategies to overcome some of the barriers of the scale of operations for systems change and through co-development of credible, feasible and effective evidence-based initiatives.[7,15]

6. *Credibility of the evidence-based initiative:* Complex clinical innovations are potentially disruptive initiatives that represent a significant departure from current practice. They may require new roles for clinical staff and collaboration between previously independent services.[15] Such initiatives may experience uptake resistance due to the level of commitment required to enact the change and the considerable demand for system resources and a lack of consensus on the chosen initiative.[6,15] Insufficient credible evidence of the effectiveness of an initiative and lack of guidance for its implementation have also been identified as barriers to spread.[12] These issues require consideration during the strategic development phase with time and resources devoted to the development of the initiative (in collaboration with multi-level stakeholders) that are compatible and replicable across facilities but can be customised and make efficient use of local resources.[3,10,15] Initiatives need to include information systems, protocols and tools to support implementation and influence staff attitudes, capabilities and behaviour to encourage routine uptake.[4]

Process of change

Initial strategic planning and implementation do not negate the need for ongoing attention to the process of change and the inevitable evolution that occurs as initiatives are scaled up. Important factors identified in the review were:

7. *Engagement and peer support:* Key barriers reported during the process of change included: staff resistance; low leadership support; difficulties finding a common meeting time across disciplines; lack of time to nurture important relationships; lack of opportunity for project participants to share experiences in the more personal face-to-face mode; and frequent turnover of frontline staff and key clinical leaders.[4,5,7,15,16] These barriers can result in lost momentum, regression of progress and a waste of invested resources.[7] Initial engagement does not secure ongoing commitment to the change initiative, highlighting the importance of ensuring that engagement, orientation and peer support opportunities are an iterative process.[7,15] Difficulties were reported in engaging junior medical staff who have heavy clinical loads and Visiting Medical Officers (VMOs) who are often disenfranchised within the hospital system.[4,5] Strategies need to be explored to maximise the opportunities for their participation. It was also reported that reliance on clinical champions, while important for initiating activities and engaging peers, became a major hindrance to genuine and sustained cultural change (i.e. if the leader is removed, the system reverts back to its initial state).[4] It was therefore suggested that emphasis be placed on nurturing and valuing other forms of leadership and relationships. Cultivation of the physician-administrator relationship was highlighted as essential, as failure to do so was a major barrier to effecting change within the clinical setting.[4,5]

Key enablers for large-scale change reported in the literature were: collaboration by multidisciplinary project teams; ongoing engagement and involvement of senior leadership; clinical champions to initiate adoption of initiatives; organisational fostering of mechanisms that allow peer interaction; and knowledge sharing and change-team functioning.[4–6,8] Peer support was a crucial component of the IHI 100,000 lives campaign. Without mentor hospitals, peer support and IHI nurturing of that process, it was reported that the initiative would have been incapable of achieving outcomes.[13,14] Early momentum of initiatives, celebrating successes and shining a spotlight on top performers all contributed to positive peer pressure and incentive for ongoing participation.[10,13,14]

8. *Attention to changing organisational culture:* Staff resistance was described as being embedded in a culture of 'it's always been done this way'.[16] Considerable effort is required to change obstructive organisational culture to a culture of accountability.[4,8] An observational study identified an organisational culture of accountability as a key driver of success of large-scale change initiatives.[8] Strategies that have been used to create that environment include: promoting ownership of the goal by all staff; no option to 'opt out'; using strong, evidence-based solutions; realistic allocation of staff and resources; strengthening multidisciplinary internal and

external social systems to encourage learning from the efforts of others; oversight by an experienced project leader and project manager; and regular use of transparent real-time data to track progress, supported by a robust communication strategy.[8,10,11]

9. ***Approach to roll-out of initiative:*** Phased implementation or a wave sequence approach was suggested in a number of papers to be an approach that contributed to success.[9,10,15] Benefits of the wave sequence approach were that it supported: initial experimentation with the implementation system and capitalisation on lessons from previous change phases; use of the success of previous implementation waves to leverage support for larger scale roll-out; and shared accountability to permeate the organisation more gradually.[9,10,15]

10. ***Intervention fidelity with implementation flexibility:*** Fidelity of an intervention may change over the months and years following initial training and dissemination of the initiative and/or as a result of organisations being at different stages of readiness for adoption. A reported critical enabler of success was the ability to achieve balance between allowing local customisation of implementation to fit the culture and processes of each setting, and maintaining adequate fidelity to the evidence-based components of the initiative. This will be discussed in further detail in response to Question 3.[3,6,10–12]

11. ***Equipping frontline staff with tools for problem solving:*** A number of initiatives reported that the change process was driven by providing frontline staff and local-level leaders with a wealth of quality improvement tools and methodologies (such as PDSA, communication tools, flow charting and systems mapping) along with teaching, coaching and specialised advice which allowed them to solve local implementation problems and address barriers to implementation early and often.[6,13,14,16] This was particularly useful given the inevitable variation in readiness, commitment and quality improvement skills that exist between implementation contexts.[13,14]

12. ***Monitoring and evaluation of progress:*** Continuous feedback of transparent and credible performance data across the system is a vital component of successful large-scale change.[8,9] Accurate, reliable and systematic data systems are required to support frontline staff to maintain a sense of how well they are tracking and know where to target changes that will lead to improvements.[6,7,10] Performance data can create a sense of competition between settings that encourages participation and provides leaders with information that will assist with refinement of the spread strategy.[6,7,10] It was also reported that building a track record of the initiative's successful application is important in conferring credibility.[9] While sophisticated monitoring methods can help improve program content and delivery[7], it was recommended that simple electronic data collection processes be implemented that focus on a vital few performance indicators.[4–6,9,13,14] This reduces ambiguity and confusion and avoids burdening personnel with administrative requirements that would discourage participation.[4–6,9,13,14] Also important is the need to capture all multidisciplinary teams in project databases so that their contributions are recognised and feedback can inform their practice.[4] Under a shared ownership model, the selection of indicators should be carried out in consultation with organisational, clinical, operational and financial leaders.[9]

An important lesson provided by one initiative was the difficulty in developing an effective measurement system for timely data feedback. Form-reading software used in the pilot worked successfully, however, significant problems were encountered during scale up when attempting to merge local-level data into a central database.[5] The initiative crossed three Australian states with different computer systems and as a result, administrative datasets could not be obtained electronically.[5] Integrating performance data into daily operations has also been reported to be an ongoing challenge, particularly due to a lack of local-level personnel with the skills to automate reports for timely feedback.[5,9] In addition, a lack of systematic recording of indicators across the system can result in measurement bias which threatens the validity of aggregated data that are fed back to leaders and frontline staff and can undermine the credibility of performance ratings and reported outcomes of the initiative.[7,9]

A formative evaluation framework is recommended for ensuring accuracy and rigor of all assessments of progress and can be used to meet local monitoring and feedback requirements, while also serving a research function to answer more sophisticated questions to guide system-wide dissemination.[15] It was suggested that four key areas be included in any evaluation of large-scale change: the implementation process; intervention fidelity at the organisational and patient level; impact on patient outcomes; and return on investment (to build a business case for expansion).[3]

Maintenance and evolution (preparing for sustainability)

Unsustained change squanders invested resources, has costs associated with missed opportunities and affects organisational morale which may be detrimental to initiation of future change initiatives.[16] Planning for sustainability is vital and should not be an afterthought. An exploratory analysis of cross-sectional survey data from the Veterans Health Administration Advanced Clinic Access Initiative found three significant predictors of sustainability: tracking outcomes over time; regular reporting of system redesign results to leadership; and ongoing use of rapid performance improvement tools such as the PDSA change cycles that allow change to be an adaptable process.[16] Descriptions of these enablers have been reported in previous sections of this report. Other reported influences on sustainability include the demonstration of positive clinical outcomes, strong institutional support to continue the program, trained staff and continued funding sources to support implementation.[15]

13. ***Integration of the change into routine practice:*** By far the most commonly reported factor to consider when preparing for sustainability is moving beyond the initial large-scale improvement or redesign initiative to the step of integrating the innovation into routine practice.[5–7,9–11] Without integration into the culture, structure and processes of an organisation, initial clinical improvements can be lost when organisational attention shifts to a new priority.[11] To build a foundation for lasting change, messages should shift from creating a sense of urgency (important for initial engagement) to institutionalisation of the change.[9] Unless system drivers are aligned so that they collectively support the change, improvements are unlikely to be sustainable once initial resources are removed. Strategies used to achieve integration included: negotiating central funding for maintenance activities[5]; tying initiative goals into enterprise bargaining agreements, annual performance reviews and incentive plans[9,10]; promoting shared accountability[9]; and changing other local processes to support the initiative goals (e.g. changing the length of patient appointment times to allow completion of a screening tool).[6]

3.3 Question 3: To what extent does the successful implementation and sustainability of large-scale change depend on standardisation versus flexibility in implementation and post-implementation phases?

There was general consensus among papers reviewed that successful and sustainable large-scale change is best achieved through a balance between top-down, strategic system-wide goal setting and bottom up learning and application.[4,6,7,9–14] As discussed previously, system-wide aims and a common purpose reached through broad stakeholder engagement is important for ensuring alignment of quality improvement initiatives being scaled simultaneously. Systematic and standardised approaches to large-scale change were reported to maintain intervention fidelity, prevent project fatigue, reduce performance variation and increase the effectiveness and efficiency of care provision while also improving the systems that support the provision of high quality care.[3,7,13,14] Standardisation of strategic and operational elements of implementation importantly provided initiatives with: a common language across multiple disciplines and settings;

consistency of messaging and branding to provide credibility; common workflows and guidance for decision making; and a suite of specialised resources to support high-level coordination of large-scale implementation.[6,9,10,12] A support centre or agency well recognised and revered by stakeholders at all levels of the system, with the necessary technical skills and resources, may be best placed to provide these important elements.

A strong message conveyed by a number of papers, however, was that externally generated solutions imposed on clinical and administrative staff, delivered with a strong fidelity message increases the likelihood of resistance to initiative uptake.[3,4,11] In addition, local contexts vary enormously meaning no solution has uniform applicability.[4] Multifaceted and complex change initiatives require local customisation and innovation to optimise their effectiveness.[3,10,11] In order to broaden the potential for change and maximise creativity, three strategies were suggested to achieve fidelity of evidence-based initiatives while allowing them to be customised to improve their cultural relevance and acceptability in each context:

1. Encourage consensus building through multi-level engagement and shared decision-making in the design and succinct packaging of evidence-based initiatives.[6,15]
2. Standardise the core elements of an initiative but allow flexibility in the mechanisms by which interventions are operationalised across organisations.[3,4,10,12] Being able to readily test changes to organisational systems and refine implementation accordingly, facilitates creativity, innovation and ownership at the local level.[4,10]
3. Carefully select a spread team with the appropriate technical and interpersonal skills to liaise with frontline staff across the system and assist with customising the initiative while ensuring the core elements remain evidence based.[12]

A structure that provides overarching strategic alignment of goals, specialised resources and operational support, but can accommodate flexibility and innovation for local-level implementation, will be more likely to maximise resource efficiency and generate the system-level changes necessary to improve the quality of patient care.[4]

4 Discussion

This rapid review identified 13 key factors that are vital to the success and sustainability of large-scale change initiatives in health care. In addition, 21 frameworks were identified, applicable in many contexts, that can provide an overarching structure and common language by which these factors can be communicated and implemented at all levels of the system to optimise the chance of success. No rigorous scientific evidence was found to identify which of the 13 factors (or others) have a clear impact on success or sustainability of large-scale change. While search methods were systematic and verifiable within the limitations of a rapid review timeframe, the published and grey literature were vast and complex, making the database searches and 'snowball' methods used to identify relevant documents prone to serendipitous discovery. In addition, the nature of the 'evidence' makes findings vulnerable to subjective judgement both at the level of interpretation by initial authors of case studies and by authors during the analysis of the current review. Nonetheless, the lessons learned from national and international examples of large-scale initiatives provided many common messages relating to the barriers and enablers of success.

One important message was that large-scale implementation of quality improvement initiatives requires a balance between centralised strategic planning and coordination, and autonomy and empowerment at the local level to generate innovation and more sustainable engagement. Investing in the skills and resources of clinical microsystems is vital due to their pivotal role in initiating and sustaining change at the grassroots.[9] However, in order to transform a system, this investment needs to be supported by an overarching body that can provide: high-level strategic alignment; large-scale coordination and consistent provision of standardised and specialised resources and training; facilitation of information exchange; and the removal of obstacles that are beyond the ability of local departments.[9,10,6,11,12]

Another newly emerging message is the importance of addressing systems issues in the design and implementation of large-scale change if system transformation is to be realised.[7,9,12,18] Initiatives often ignore systemic issues that can undermine their success. By targeting only local-level barriers and motivators to change, achievements are inadvertently limited to local-level outcomes or 'first-order shifts' in the system.[18] To achieve sustainable change in large and complex systems, solutions should target the root causes rather than symptomatic problems, both during the design phase and iteratively throughout implementation as the system evolves.[18,19] In addition, it is essential to create positive conditions for change by creating an environment that harnesses the capacity of individuals in a system and their effective relationships.[61]

The 13 factors identified by this review that should be considered when embarking on large-scale change initiatives are summarised in Table 4. It is not possible to determine which are more or less important and it is probable that differential emphasis on these factors will be required in different contexts and for different change initiatives. Experience also suggests that critical factors for success vary over time even within the same settings.

Table 4: Factors influencing large-scale change in healthcare

Antecedents of change: factors that need to be in place prior to roll-out of the large-scale change initiative	Leadership structures and management support
	Microsystem capacity
	Infrastructure
	Alignment
	Systems perspective and broad engagement of stakeholders
	Credibility of evidence-based initiative
Process of change: factors to consider during the implementation phase	Engagement and peer support
	Attention to changing organisational culture
	Approach to roll-out of initiative
	Intervention fidelity with implementation flexibility
	Equipping frontline staff with tools for problem solving
	Monitoring and evaluation of progress
Maintenance and evolution: preparing for sustainability	Integration of the change into routine practice

The findings of this review are consistent with those of other systematic and meta-narrative reviews of large-scale spread initiatives in health and other sectors that may or may not have been guided by the use of an implementation framework.[37,46,61,62] Each of these key reviews and their findings are briefly described below to highlight the differences in the timeframes and focus of each review and the emphasis they placed on the factors influencing large-scale change identified by this current review. A common feature of all reviews was the lack of rigorous quantitative evidence to support findings.

A commissioned systematic review by the UK Department of Health focusing primarily, but not exclusively, on studies of healthcare, used a meta-narrative review methodology to answer the question: "*How can we spread and sustain innovations in health service delivery and organisation?*"[62] The review was a large and comprehensive undertaking spanning 14 months that culminated in the development of a unifying conceptual model of diffusion. This model draws attention to the key factors thought to influence diffusion which include: characteristics of the innovation; system antecedents and readiness for change; the implementation process; individual and organisational characteristics; communication and influence; and external influences such as the socio-political climate and environmental stability.[62] Useful detailed descriptions of these constructs are provided by authors, from which similarities to the findings of the current review can be drawn.

Doebbeling and Flanagan (2011) combined case study synthesis with expert discussion to determine a core set of components required for successful system redesign.[37] These were: the use of a CAS framework; fostering local-level engagement and dynamic intervention adaption; development of appropriate performance measures and incentives; creating continuous learning organisations; and integrating information, technology and communication into practice.[37] The authors emphasise the importance of investment in research and development that is embedded in the change process and identified research priorities in each of these key areas.[37]

In a third review, the authors conducted a scan of published and grey literature on large-scale spread efforts in hospitals and healthcare systems using a modified Delphi approach. The search yielded 39 relevant documents which were analysed by an expert panel.[46] The drivers of large-scale change identified closely resemble the 13 factors identified in the current review. Important recommendations made by these authors and endorsed by the authors of this review include: the development of more systematic approaches to evaluating the impact of initiatives; further work to understand the economic and infrastructure requirements of large-scale spread, including what might be the structural levers for change; further guidance on what might be the characteristics of effective learning networks; and the creation of a repository of approaches and examples of large-scale spread to reduce the fragmented nature of the availability of this information.[46]

Finally, a recent systematic review commissioned by the Saskatchewan Ministry of Health in Canada synthesised research, theory and practice knowledge to make inferences about the factors influencing large-scale change.[61] This synthesis used a realist analytic approach nested in a macro framing of CAS to identify five 'simple rules' of transformational change that were likely to augment the success of initiatives: These were: 1) engage individuals at all levels in leading change efforts, ensuring alignment, and include both distributed leadership (shared accountability/collective governance) and designated (overarching) leadership; 2) establish feedback loops (continuous measurement of carefully selected indicators and judicious disclosure of progress to both internal and external stakeholders); 3) attend to history (conduct a careful analysis of what has gone before as an important preliminary step); 4) engage physicians (taking into account contextual influences on engagement such as alignment between professional and regulatory drivers, incentive structure, level of guidance and professional directives); and 5) include patients and families.

In conclusion, this review synthesised and affirmed well-described themes in health services and organisational and systems change literature. Rather than representing definitive answers, the 13 critical factors identified by this review should be used as a practical tool for guiding the development of strategies to optimise the success of large-scale change initiatives. The findings highlight the complex and dynamic process of systems transformation. The lack of empirical evidence reflects the difficulties in rigorously evaluating large-scale change in complex systems. Non-traditional integrative research methods and new approaches to data linkage, modelling and simulation are required if we are to gain new insights and solutions for transformational change in the future.[37]

5 Applicability of findings to the NSW Agency for Clinical Innovation

To achieve large-scale change across the NSW health system, it is recommended the NSW Agency for Clinical Innovation (ACI):

- ***Align strategies for large-scale change to the 13 critical factors:*** This review has attempted to confine itself to organisational arrangements that have some similarity to the NSW health system (large with multiple internal components) but, even so, there are major organisational and funding differences that could impact on the applicability of any model. Nonetheless, the 13 critical factors identified would appear to be relevant to the NSW health system, or at least there are no a priori reasons to assume that they would not be relevant. Rather than representing definitive answers, these 13 critical factors should be viewed as a practical tool for guiding the development of strategies to optimise the success of large-scale change initiatives
- ***Leverage its unique position to pioneer innovative research:*** While it is not possible to determine which of the 13 critical factors are more or less important in the context of the NSW health system, the analysis suggests that individual factors alone (such as funding incentives or engaging clinical champions) are unlikely to achieve and sustain large-scale change. Research is crucial to determining the mix of factors that are most important in different clinical contexts within the NSW health system, for different initiatives (e.g. models of care or improving IT systems) and for different stages of change. Through rigorous evaluations of the effectiveness of its work, the ACI has an opportunity to contribute important evidence on the drivers of large-scale change. To create new knowledge in large-scale change and position themselves as pioneers in this field, it is recommended that the ACI should: conduct routine evaluation of initiatives, including the development of appropriate key performance indicators and data collection systems; and compare approaches to scaling up in relation to setting, context and the type of change being addressed. The scope of evaluations should include: the implementation process; intervention fidelity at the organisational and patient level; impact on patient outcomes; and return on investment
- ***Use existing structures to support centralised planning and decentralised implementation:*** This analysis suggests the importance of a degree of centralised strategic planning and coordination for large-scale implementation of quality improvement initiatives, for which the ACI is well-positioned to provide. In particular, the ACI could be instrumental in securing strategic alignment of objectives across all levels of the system, providing standardised resources and training to support change and identifying and removing systems-level obstacles, all of which have been identified as important for successful large-scale change. However, given the multiple variably independent organisational units that compromise the NSW health system, this analysis would suggest that a top-down approach to implementation is unlikely to be effective. A degree of local flexibility is critical to enable local adaption and innovation. The relationships the ACI and its Clinical Networks, Institutes and Taskforces have with partners, such as Local Health Districts, could provide this local capacity and guide the formation of implementation teams with multidisciplinary representation at all levels of the health system hierarchy
- ***Use innovation from non-health sectors:*** Systems science has been widely applied to sectors such as engineering, economics, ecology and business since its inception in the mid-1950s. Learning from applications in these non-health sectors, systems science methodologies have been used to help map and understand complex public health problems such as childhood obesity[20], diabetes[21], and heart disease[22], as well as optimise

operational aspects of healthcare capacity and delivery such as patient flows in emergency[23,24], disease screening[25], demand for services[26,27], and workforce requirements.[28,29] The utility of systems methodologies lie in their ability to systematically analyse a range of initiatives and organisational policies and solutions prior to implementation and identify leverage points in the system (places to intervene) where small inputs result in large impacts.[30] They can also be used to identify and analyse key stakeholders and linkages with non-health sectors and to explore critical relationships between networks or organisations and individuals that can drive or block successful scaling up. A systems approach to guide the ACI and their clinical partners in strategic planning, ongoing decision making and research to support system change initiatives holds promise. To achieve large-scale change, a systems approach requires: an in-depth knowledge of the organisation in which it is being applied, including management and funding arrangements; a clear outline of the specific problem it aims to address; engagement of stakeholders representing each of the components of the system being mapped and/or modelled; and consultants/researchers with expertise in systems approaches to facilitate co-development of credible, feasible and effective evidence-based initiatives.

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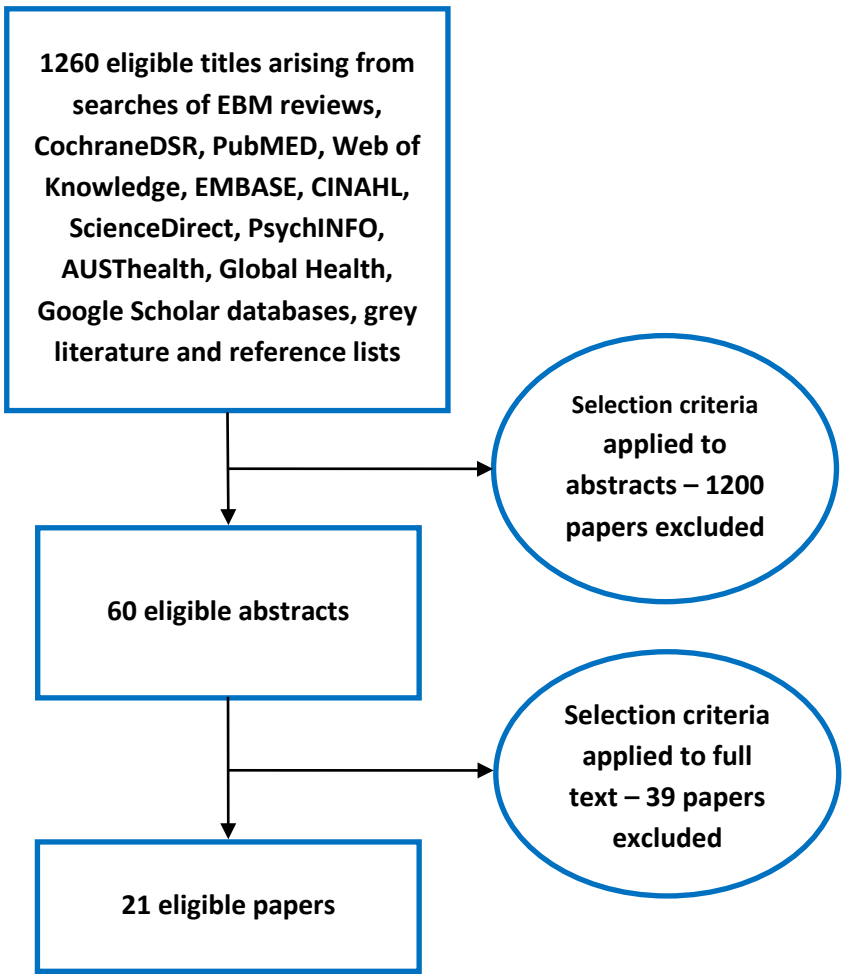
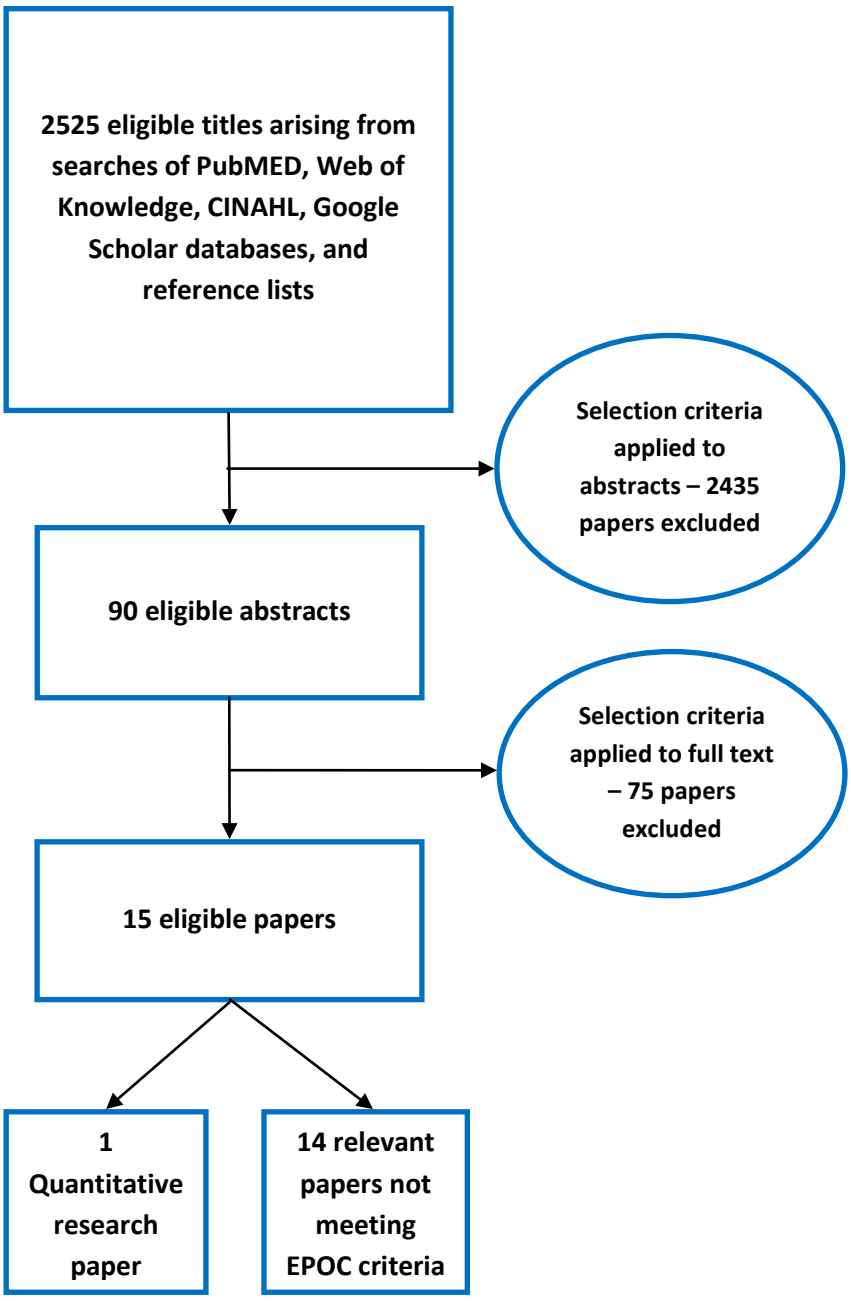
7 Appendices

Appendix A: Flow chart of paper selection process to address Question 1



Please note: there may be duplications in the number of eligible titles found such that the actual number of titles found may be less than 1260.

Appendix B: Flow chart of paper selection process to address Questions 2 and 3



Please note: there may be duplications in the number of eligible titles found such that the actual number of titles found may be less than 2525.

Appendix C: Summary of elements proposed as important for successful large-scale change in complex health systems that were used to code frameworks

A. ***Strategic planning:*** Emphasis on identification of priority changes and development of a compelling vision and aim; development of an intervention that can be modified for compatibility with each context without losing fidelity; planning structure for management and support of implementation (considering top down and bottom up approaches); state-wide mandates/policy for large-scale implementation; and planning for monitoring and evaluation systems at outset

B. ***Infrastructure:*** Sufficient resources and infrastructure for effective large-scale change including personnel, project management, time and funding; program marketing; workforce development/education; technical and informatics support for implementation and sustainability; and information technology and communication infrastructure

C. ***Individual and group factors:*** Stakeholder engagement at all levels (including providers, professional organisations, other sectors, government staff and consumers) through system-wide taskforces, continuous learning/knowledge exchange/implementation networks, conferences; attention to factors that influence individual adaption of innovation and flexibility at local level to address these factors; engaging managerial and clinical champions of change; a cadre of leaders equipped to effect change; and consideration of incentives for change

D. ***Organisational factors:*** Attention to positive and negative organisational culture; and organisational redesign to become more outward looking and externally connected as well as internally fostering innovation, enhancing partnerships, communication, teamwork and trust

E. ***System factors:***[19] Consideration of system influences and alignment of system drivers with aims of change; conceptualisation of system complexity and attention drawn to the basic rules or principles of the dynamic action of a system and its environmental parameters. Phenomena such as path dependence, feedback loops, emergent behaviours and phase transitions are explored during the planning and implementation of large-scale change initiatives allowing anticipation of unintended consequences that can undermine scaling up efforts, and in doing so, allow iterative problem-solving and adaption

F. ***Process of change:*** Attention to the extent of active pushing of change and the delivery mechanisms (e.g. data sharing, learning and site visits or collaborative methodology or campaign structure); and matching of delivery mechanisms to the problem

G. ***Performance measures:*** Attention to data processes and infrastructure to collect reliable and valid data that can be linked to the change initiative; and consensus on appropriate indicators of success (adoption of initiative/patient outcomes) as well as indicators for quality and fidelity of scaled intervention

H. ***Evaluation:*** Attention to methodological rigor in evaluation design and data analysis; and timely feedback of progress data to stakeholders and care-providers to motivate further change

I. ***Alignment:*** Alignment of initiatives to be scaled (including implementation plans, processes, resource decisions, policies etc) with common purpose/overarching strategic goals for systems change.