PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program comprises four ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, interface with stakeholders, and address urgent evidence needs. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee composed of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

This topic was developed in response to a nomination from the VA Office of System Redesign and Improvement (10E2F). The scope was further developed with input from Operational Partners (below), the ESP Coordinating Center, the review team, and the technical expert panel (TEP). The ESP consulted several technical and content experts in designing the research questions and review methodology. In seeking broad expertise and perspectives, divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Ultimately, however, research questions, design, methodologic approaches, and/or conclusions of the review may not necessarily represent the views of individual technical and content experts. Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.


This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the VA Greater Los Angeles Health Care System, Los Angeles, CA, directed by Isomi Miake-Lye, PhD and Paul Shekelle, MD, PhD, and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development.

The findings and conclusions in this document are those of the author(s) who are responsible for its contents and do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.
ACKNOWLEDGMENTS

Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

Vince Watts, MD
Interim Director
VA Office of System Redesign and Improvement (10E2F)

Technical Expert Panel (TEP)

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

David Ganz, MD, PhD
Associate Director, VA HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy, VA Greater Los Angeles Healthcare System
Professor of Medicine, UCLA School of Medicine

Laura Damschroder, MPH, MS
Research Investigator, VA Ann Arbor Center for Clinical Management Research
Project Principal Investigator, Personalizing Options through Veteran Engagement Quality Enhancement Research Initiative (QUERI)

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Elizabeth Yano, PhD, MSPH
Director and Senior Research Career Scientist, VA HSR&D Center for the Study of Healthcare Innovation & Policy, VA Greater Los Angeles Healthcare System
Adjunct Professor of Health Policy & Management, University of California Los Angeles Fielding School of Public Health

Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.
EXECUTIVE SUMMARY

INTRODUCTION

As part of its mandate to optimize health outcomes for Veterans, the Department of Veterans Affairs (VA) has an incentive to improve the quality and safety of health care. Standardizing a process improvement methodology and training across the entire VA has the potential to expand resources for local improvement activities and improve the quality and efficiency of care delivery.

Continuous quality improvement frameworks are system-level approaches to improving the quality and safety of health care through systematic data-guided activities, iterative development and testing of processes, and designing with local conditions in mind. Lean Management (Lean) has subsequently been applied to a variety of medical and industrial settings and is one of the most popular continuous quality improvement frameworks in health care settings. In December 2019, the Deputy Under Secretary for Health issued a directive outlining the deployment of a new VA-wide program for systems redesign and improvement. As part of this directive, Lean was designated as the primary process improvement methodology to be utilized across the VA.

Despite designation as the preferred continuous quality improvement methodology, there is uncertainty as to whether Lean is superior to other continuous quality improvement strategies, such as Clinical Microsystems or the Institute for Healthcare Improvement (IHI)’s Model for Change. There is also uncertainty as to whether certain intervention-level or health system-level factors affect the success or failure of specific methodologies, such as rigorous training of staff or health system academic affiliation.

Several reviews on continuous quality improvement methodologies exist; however, none identified in a preliminary literature search by the Evidence Synthesis Program (ESP) Coordinating Center currently cover all continuous quality improvement frameworks, settings, and outcomes of interest. Therefore, this current review of reviews was requested by the VA Office of Systems Redesign and Improvement (SRI), which addresses the following Key Questions:

Key Question 1A: What is the comparative effectiveness of implementing continuous quality improvement frameworks in terms of health care workers’ reaction, learning, behavior change, results, and sustainment of change?

Key Question 1B: What is the effectiveness of implementing a continuous quality improvement framework in terms of health care workers’ reaction, learning, behavior change, results, and sustainment of change?

Key Question 2: What factors (including intervention characteristics, inner setting, outer setting, individuals involved, and process by which implementation is accomplished) contribute to the success or failure of these continuous quality improvement frameworks?
METHODS

We developed and followed a standard protocol for this review in collaboration with operational partners and a Technical Expert Panel (PROSPERO registration number CRD42021245263).

Data Sources and Searches

We conducted broad systematic review searches using terms relating to “quality improvement” or “continuous quality improvement” or “system redesign” in 4 databases: PubMed, CINAHL, DARE, and Cochrane. Search dates for PubMed are from 01/01/2010 through 03/18/21. Search dates for CINAHL and Cochrane are from 01/01/2010 through 03/30/2021. Search dates for DARE are from 01/01/2010 to 03/31/2015.

Study Selection

Four team members working independently screened the titles of retrieved citations. Full-text review was conducted in duplicate by teams of 2, with any disagreements resolved through discussion.

Data Abstraction and Quality Assessment

Data extraction was completed in duplicate. All discrepancies were resolved with full-group discussion. We abstracted data on the following: continuous quality improvement framework/strategy discussed, whether the article described context/factors contributing to the success or failure of the framework/strategy, total number of studies included, search dates, health care condition, healthcare setting, and geographical region.

Each systematic review was assessed using a modified version of the Assessing the Methodological Quality of Systematic Reviews 2 (AMSTAR2) criteria. This 16-item tool was designed to assess the methodological quality of systematic reviews. As some AMSTAR2 items concern meta-analysis, we adapted the tool for this review, resulting in a 13-item tool. Assessment of studies using our modified tool was also completed in duplicate, with discrepancies resolved with group discussion. No study was excluded from analysis based on AMSTAR2 score; however, we chose a score of greater than or equal to 8 to represent higher-quality systematic reviews. Studies reporting results relevant to our key questions utilizing an established method of synthesis other than traditional systematic review methods were not assessed with our modified AMSTAR2 tool.

We used the Consolidated Framework for Implementation Research (CFIR) to guide abstraction and synthesis of Key Question 2 around the following domains: intervention characteristics, inner setting, outer setting, individuals involved, and process by which implementation is accomplished. All studies discussed in Key Question 2 were assessed for inclusion in duplicate, with discrepancies resolved with group discussion.

Data Synthesis and Analysis

Our review is a narrative analysis.
RESULTS

Results of Literature Search

We identified 1,795 potentially relevant citations, of which 274 were included at the abstract screening level. A total of 136 publications were reviewed at the full-text stage, and 36 publications were identified at full-text review as meeting initial inclusion criteria. The systematic reviews reported on studies conducted in multiple countries, primarily in North America and Europe. Of the 36 included reviews, 29 reviews were assessed using the modified AMSTAR2 tool. Scores on the AMSTAR2 tool ranged from a high of 11 points, out of a possible 12 points, to a low of 2 points. The median and mode scores on the modified tool were both 5.

Summary of Results for Key Questions

Key Question 1A: What is the comparative effectiveness of implementing continuous quality improvement frameworks in terms of health care workers’ reaction, learning, behavior change, results, and sustainment of change?

We assessed the literature for evidence regarding the comparative effectiveness of different continuous quality improvement strategies. We were only able to identify a single review,1 with an AMSTAR2 rating of 2, that met inclusion criteria. This review is over a decade old and found no evidence that any single continuous quality improvement strategy was more effective than others. Instead, the authors found there was significant overlap in defining and implementing different approaches to quality improvement, concluding that the local context should guide which continuous quality improvement framework is ultimately implemented. The authors did identify 7 “necessary, but not sufficient” conditions for successful implementation of any continuous quality improvement strategy: provision of the practical and human resources to enable quality improvement; active engagement of health professionals, especially doctors; sustained managerial focus and attention; use of multi-faceted interventions; coordinated action at all levels of the health care system; substantial investment in training and development; and availability of robust and timely data through supported information technology systems.

Key Question 1B: What is the effectiveness of implementing a continuous quality improvement framework in terms of health care workers’ reaction, learning, behavior change, results, and sustainment of change?

Having found only a single review comparing the effectiveness of different continuous quality improvement strategies, we then assessed the 25 reviews that studied at least 1 framework for evidence of effectiveness for a variety of outcomes. None of the 11 reviews that examined more than 1 methodology reached a conclusion that any strategy was superior to the others in terms of results. However, many frameworks have been successfully implemented in a variety of clinical settings. In some clinical settings, such as in the operating room (OR) and emergency department (ED), multiple different strategies have been used in different geographic locations. Nine of the 22 reviews for which an AMSTAR2 rating was calculated had a modified AMSTAR2 rating of at least 8; however, reviews with higher AMSTAR2 scores did not draw more specific conclusions regarding Key Question 1B outcomes than reviews with lower scores.
Similarly, none of the 7 reviews discussing sustainment of change identified a superior strategy. Additionally, no review directly commented on health care workers’ reactions in being involved as part of continuous quality improvement framework implementation, what health care workers learned or retained as part of continuous quality improvement training, nor any health care worker behavior changes noted after implementation of a continuous quality improvement strategy. Five reviews discussed clinician/provider satisfaction as an outcome of implementation of a continuous quality improvement methodology, with mixed results. It is unclear from these 5 reviews whether the clinicians/providers in whom satisfaction was studied were part of the implementation teams or were frontline workers affected by the implementation.

**Key Question 2: What factors (including intervention, inner setting, outer setting, individuals involved, and process by which implementation is accomplished) contribute to the success or failure of these continuous quality improvement frameworks?**

We then assessed the literature for evidence regarding success or failure factors associated with Consolidated Framework for Implementation Research (CFIR) factors. Ultimately, 20 reviews studied at least 1 of 3 CFIR factors: intervention characteristics (n=15), characteristics of individuals (n=6), and/or inner setting (n=10). None of these 20 reviews compared the success or failure of different continuous quality improvement strategies based on any of these 3 factors, however. Instead, the majority of reviews listed aspects of some or each of these 3 CFIR categories that the authors deemed important for implementation of the studied strategy, with little to no supporting evidence. No publication included in this review discussed whether either outer setting or specific processes during implementation of a continuous quality improvement framework contributed to either the success or failure of implementation for any framework. Four of these 15 reviews for which an AMSTAR2 rating was calculated had a modified AMSTAR2 score of 8 points or higher. However, as none of the conclusions related to the CFIR topics were supported by comparative data, we conclude there is low certainty of evidence for specific intervention characteristics, individuals to be involved, or inner setting aspects leading to success in implementing a continuous quality improvement methodology.

**DISCUSSION**

**Applicability of Findings to the VA Population**

The vast majority of reviews within these reviews were conducted in Organisation for Economic Co-operation and Development countries, which are a group of 38 countries with mature economies and, often, well-financed healthcare systems. Additionally, some individual studies within these reviews were performed with Veteran populations, both of which improve applicability to VA.

**Research Gaps/Future Research**

In brief, comparative research of different continuous quality improvement strategies is needed both in US populations and with Veterans. Additionally, improved reporting of ongoing work would improve the evidence base regarding implementation of continuous quality improvement frameworks. Pursuing such initiatives across large health systems such as the VA has the potential to improve health care for millions of patients.
Conclusions

Prior systematic reviews of continuous quality improvement strategies have not, with 1 exception, compared the effectiveness of different methodologies. Instead, many published reviews have shown success for 1 or more methodologies within specific contexts. However, these findings are likely subject to significant publication bias from the constituent studies, as it is probable unsuccessful quality improvement work is less likely to receive publication, making the overall certainty of evidence low. Few data are available regarding sustainment of changes made through continuous quality improvement and no systematic reviews we identified discussed health care workers’ reactions, learning, or behavior changes related to participating in continuous quality improvement. Similarly, no systematic reviews compared the success or failure of different continuous quality improvement frameworks based on intervention characteristics, characteristics of individuals, or inner setting. Furthermore, no studies discussed whether either the outer setting or specific processes during implementation of a continuous quality improvement framework contributed to either the success or failure of implementation of any methodology. Few systematic reviews included in this review of reviews had high ratings on a modified AMSTAR2 tool, leading us to conclude the overall certainty of evidence related to these topics is low to moderate. Thus, evidence gaps remain regarding whether any continuous quality improvement strategy is superior to others and how any methodology should be implemented at large scale within the VA context.

ABBREVIATIONS TABLE

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<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>CFIR</td>
<td>Consolidated Framework for Implementation Research</td>
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<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<td>CQI</td>
<td>Continuous Quality Improvement</td>
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<td>DMAIC</td>
<td>Define, Measure, Analyze, Improve, and Control</td>
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<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
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<td>MRSA</td>
<td>Methicillin-resistant Staphylococcus aureus</td>
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<td>PDCA</td>
<td>Plan-Do-Check-Act</td>
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<tr>
<td>PDSA</td>
<td>Plan-Do-Study-Act</td>
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<tr>
<td>QI</td>
<td>Quality Improvement</td>
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<td>RCT</td>
<td>Randomized Control Trial</td>
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<td>SRI</td>
<td>VA Office of Systems Redesign and Improvement</td>
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<td>TEP</td>
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<td>VA QUERI</td>
<td>VA Quality Enhancement Research Initiative</td>
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<td>VA</td>
<td>Department of Veterans Affairs</td>
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<td>VISN</td>
<td>Veterans Integrated Service Network</td>
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