
Continuous Quality Improvement (CQI) for Clinical Teams: A Systematic Review of Reviews

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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.

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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.

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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:

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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.

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EVIDENCE REPORT

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, particularly in settings such as individual clinics or units that may have fewer currently trained personnel to support project leadership and management, and improve the quality and efficiency of care delivery.

Continuous quality improvement (CQI) 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.^{2,3} Lean Management (Lean) – a process adapted from a 1930s manufacturing model by the Toyota Corporation that seeks to increase efficiencies and reduce waste – has subsequently been applied to a variety of medical and industrial settings and is one of the most popular CQI 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.³ 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 CQI methodology, there is uncertainty as to whether Lean is superior to other CQI frameworks, such as the Institute for Healthcare Improvement (IHI)'s Model for Change or Clinical Microsystems. There is also uncertainty as to whether certain intervention-level or health system-level factors affect the success or failure of specific CQI methodologies, such as rigorous training of staff or health system academic affiliation.

Several reviews on CQI methodologies exist; however, none identified in a preliminary literature search by the Evidence Synthesis Program (ESP) Coordinating Center currently cover all interventions, settings, and outcomes of interest. Therefore, this current review of reviews was requested by the VA Office of Systems Redesign and Improvement (SRI), which is charged with partnering with Veterans Integrated Service Networks (VISNs) in implementing the 2019 directive. This report will be used to identify effective CQI frameworks and conditions necessary for their success for dissemination and training across the VA by the SRI.

METHODS

TOPIC DEVELOPMENT

This topic was developed in response to a nomination by Vince Watts, MD, Interim Director of VA Office of System Redesign and Improvement (10E2F). Key questions were then developed with input from the topic nominator, the ESP Coordinating Center, the review team, and the technical expert panel (TEP):

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?

To be eligible for Key Question 1A, a systematic review had to explicitly focus on comparative effectiveness of multiple CQI methodologies as a stated aim. If a review commented on multiple methodologies but did not seek to compare the effectiveness of the strategies within its methods, it was included in Key Question 1B.

The review was registered in PROSPERO: CRD42021245263.

SEARCH STRATEGY

Our team, which included a medical librarian, developed and 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 03/18/2021. 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. We restricted our searches to English language publications. See Appendix A for full search strategy.

STUDY SELECTION

As multiple reviews on individual or subsets of CQI methodologies have been performed previously, this study was designed as a review of these pre-existing reviews. Three team members working independently screened all titles for relevance; any article chosen by any reviewer was included in the abstract screen. Abstracts were then reviewed in duplicate with any discrepancies resolved by group discussion. Full-text review was conducted independently by team members working in pairs, with any disagreements resolved through discussion. In order to be included, a review had to be a systematic review and include CQI as an intervention within any health care setting. An intervention was deemed to be CQI if it was either explicitly referred to as CQI or comprised of 3 essential features of CQI methods: “systematic data guided

activities”, “designing with local conditions in mind”, and “iterative development and testing.”² These strategies included Lean, Six Sigma, Lean Six Sigma, Quality Improvement Collaboratives, CQI (hereafter referred to as the ‘CQI method’ to distinguish from general CQI), Total Quality Management (TQM), Clinical Microsystems, and the Plan-Do-Check-Act (PDCA) or Plan-Do-Study-Act (PDSA) method. Thus, we rejected narrative reviews, scoping reviews, and publications that only reported components of quality improvement (QI) without a full QI framework. Specific definitions for each strategy were not included in our search strategy; rather, we allowed each systematic review to apply its own definitions and labels to the included studies. See Appendix B for the full-text review form.

DATA ABSTRACTION

Each included systematic review had data abstracted by 2 reviewers independently. Abstracted data included: CQI framework/strategy discussed, whether article described context/factors contributing to the success or failure of the framework/strategy, total number of studies included, search dates, health care condition, health care setting, and geographical region. Any discrepancies in data abstraction were resolved by group discussion.

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.

QUALITY ASSESSMENT

Each systematic review was assessed using a modified version of the Assessing the Methodological Quality of Systematic Reviews 2 (AMSTAR2) criteria.⁴ This 16-item tool was designed to assess the methodological quality of systematic reviews and meta-analysis and is considered the standard for this type of assessment. The tool includes domains such as descriptions of PICO (population, intervention, comparators, and outcomes) in both inclusion criteria and results, PROSPERO registration, use of a comprehensive and timely literature search strategy, duplicate data abstraction, and analysis of risk of bias. As some AMSTAR2 items concern meta-analysis not applicable to our set of studies, we adapted the tool for this review, resulting in a 13-item tool. The criteria in our modified tool are shown in the table below (Table 1), while the full modified tool is available in Appendix C. One item — “If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?” — was found not to be applicable in all included reviews and therefore is excluded from Tables 1 and 2.

Assessment of studies using our modified tool was 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. Reviews with a score of 7 or lower had the potential for multiple methodological flaws (given that they either did not do or did not report doing some key methodological practices), which influenced our interpretation of the completeness and rigor of their findings and conclusions. This cut-off was used in formulating certainty of evidence statements, as described below.

Table 1. Modified AMSTAR2 Questions

1.	Did the research questions and inclusion criteria for the review include a) population/setting; b) intervention; c) comparator(s); d) outcomes?
2.	Did the report of the review reference a protocol or PROSPERO registration?
3.	Did the review authors explain their selection of other study designs (non-RCTs) for inclusion in the review?
4.	Did the review authors use a comprehensive literature search strategy?
5.	Did the review authors perform study selection in duplicate?
6.	Did the review authors perform data extraction in duplicate?
7.	Did the review authors provide a list of excluded studies and/or justify the exclusions?
8.	Did the review authors describe the following components in individual included studies in adequate detail: a) populations/settings; b) interventions; c) comparators(s); d) outcomes; e) research designs?
9.	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?
10.	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?
11.	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?
12.	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

Reviews reporting results relevant to our key questions that used an established method of synthesis other than traditional systematic review methods, such as comprehensive reviews and realist reviews, were not assessed with AMSTAR2, given that AMSTAR2 was developed for systematic review and meta-analysis methods.

While quality criteria specifically for quality improvement studies have been developed, like the Quality Improvement Minimum Quality Criteria Set,⁵ they are designed for primary research articles, and as such are not appropriate for use with the systematic reviews this report discusses. Nonetheless, we did take into account the Quality Improvement Minimum Quality Criteria Set and our discussion of Key Question 2 is informed by these criteria.

DATA SYNTHESIS AND ANALYSIS

Our review is a narrative analysis. For KQ1A and KQ1B we narratively synthesized the evidence from relevant included systematic reviews based on CQI frameworks and outcomes reported. For KQ2, we conducted a template analysis using the included systematic reviews as our source material.⁶ We looked at factors affecting the success or failure of CQI frameworks according to the 5 main Consolidated Framework for Implementation Research (CFIR) domains.⁷ We used the CFIR domains as the basis for our coding structure, capturing any relevant language in the

included systematic reviews that described 1) intervention characteristics, 2) inner setting, 3) outer setting, 4) individuals involved, and/or 5) process by which implementation is accomplished.⁷

Certainty of evidence was determined by use of overall AMSTAR2 scores. We categorized evidence into low, moderate, and high certainty by the frequency with which included reviews for each key question had an AMSTAR2 score greater than or equal to 8. Key questions with fewer than 1/3 of studies having a score ≥ 8 were categorized as low certainty of evidence, those with between 1/3 and 2/3 of studies with scores ≥ 8 as moderate certainty of evidence, and those with $> 2/3$ of studies with scores ≥ 8 as high certainty of evidence.

PEER REVIEW

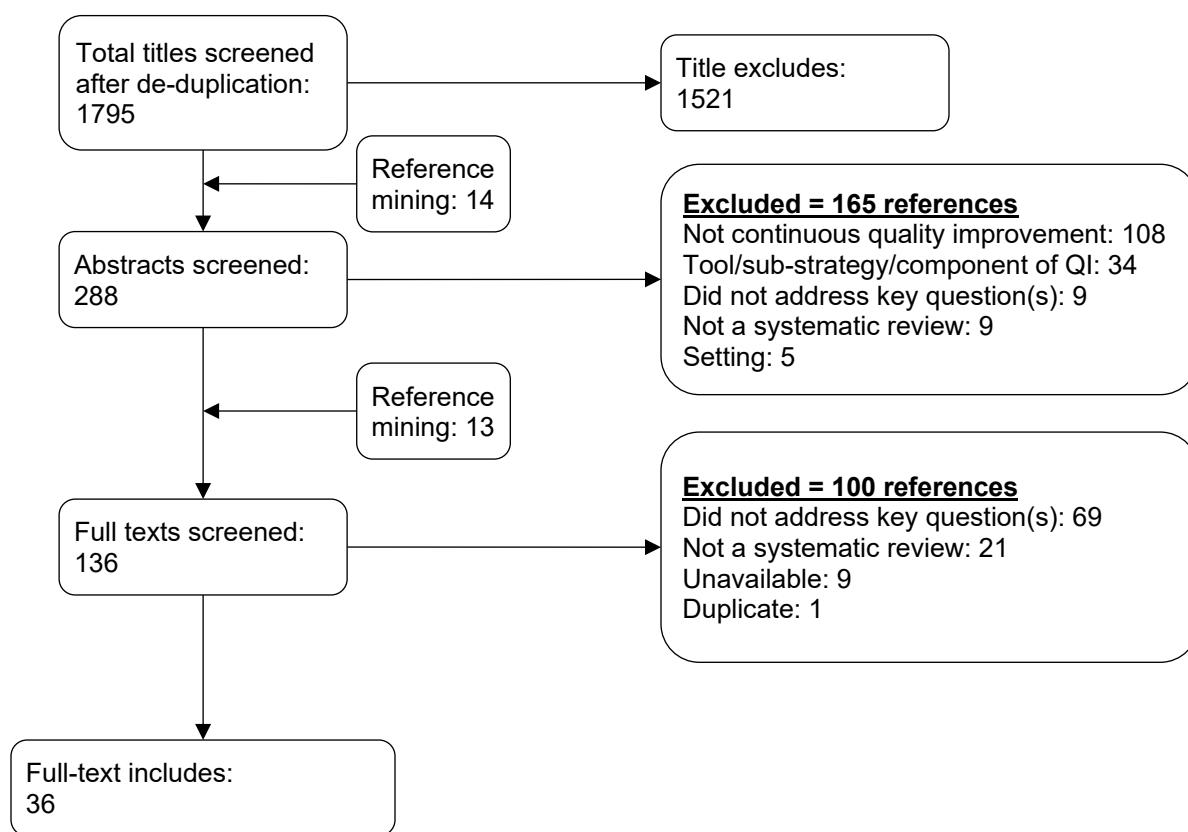
A draft version of the report was reviewed by technical experts and clinical leadership. While Technical Panel Experts are often asked to also serve as peer reviewers, we also invite experts who have not been involved with the current project to serve as peer reviewers. Reviewer comments and our responses are documented in Appendix D.

RESULTS

LITERATURE FLOW

The literature search identified 1,795 citations relevant to Key Question 1A/1B and Key Question 2 (Figure 1). After applying the inclusion and exclusion criteria to these 1,795 titles and adding 14 titles obtained from reference mining (*ie*, from citations included in previously identified literature), a total of 288 abstracts were reviewed at abstract stage. From these, a total of 165 abstracts were excluded for the following reasons: not about CQI (n=108), tool/sub-strategy/component of quality improvement (n=34), not a systematic review (n=9), and did not address key question(s) (n=9). After reference mining the cited literature in our screened full-text articles, we identified an additional 13 titles to be reviewed at the full-text stage, resulting in a total of 136 publications. From these, 100 publications were excluded for the following reasons: did not address key question(s) (n=69), not a systematic review (n=21), unavailable (n=9), and duplicate (n=1). A full list of excluded studies from the full-text review is included in Appendix F. Thirty-six studies were retained for abstraction after full-text review.

Figure 1: Literature Flow Chart



Quality of Included Systematic Reviews

Of the 36 included reviews, 29 reviews used traditional systematic review methodology and were assessed using the modified AMSTAR2 tool (see Table 1 for the modified AMSTAR2 questions and Appendix C for the full tool). Figure 2 presents the distribution of AMSTAR2 scores for the 29 reviews. The highest score was 11 points out of a possible 12 points, while the lowest score

was 2 points. The median and mode scores are both 5 points, a score which means that just less than half of the quality criteria were met.

Figure 2. Distribution of AMSTAR2 Quality Scores

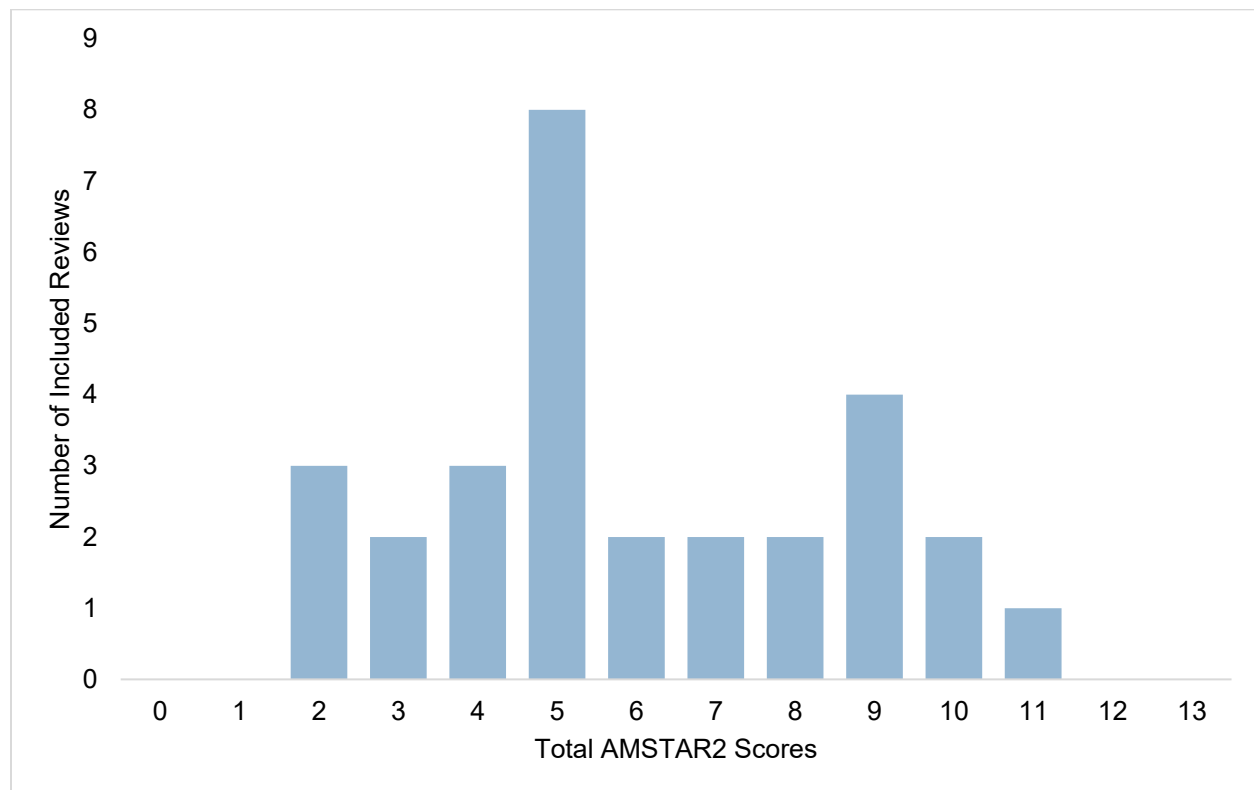


Table 2 shows the breakdown of quality ratings by criterion for each study. Whether the review included a comprehensive search strategy (Criterion 4) was the criterion the AMSTAR2-scored reviews met most frequently, with 22 reviews (76% of the 29 reviews scored by AMSTAR2) meeting this criterion. Criterion 12 was the next most frequently met criterion, which asked whether the review reported conflict of interest, and was met by 21 reviews (72% of 29 reviews with AMSTAR2 scores). All other criteria were met by less than half of the 29 AMSTAR2-scored reviews. The criterion that was met least frequently was Criterion 2, with 4 reviews (14% of 29 AMSTAR2 scored reviews) reporting on their use of a protocol or PROSPERO registration. Two criteria were composite scores with multiple sub-criteria: questions 1 and 8. These are described further below.

Table 2: Total AMSTAR2 Scores, by Criterion

Author, Year	1—Research Question / Inclusion Criteria	2—Protocol or PROSPERO	3—Explain selection of Study Design	4—Use of Search Strategy	5—Study Selection in Duplicate	6—Data Extraction in Duplicate	7—List of Excludes	8—Description of PICO-Research Design	9—Assesses Risk of Bias	10—Account for Risk of Bias in Interpretation	11—Explanation for Heterogeneity	12—Report Conflict of Interest	TOTAL SCORE
Aij, 2017 ⁸	X*			X									2
Amaratunga, 2016 ⁹	X*		X	X	X	X	X	X*				X	8
Bucci, 2016 ¹⁰	X*			X			X	X*	X				5
Côté, 2020 ¹¹	X*			X		X	X	X*	X	X	X	X	9
Dellifraire, 2010 ¹²	X*			X				X*	X	X			5
DelliFraine, 2013 ¹³	X*			X				X*			X	X	5
Dzidowska, 2020 ¹⁴	X*	X	X	X	X	X		X*			X	X	9
Glasgow, 2010 ¹⁵	X*		X	X				X*				X	5
Hill, 2020 ¹⁶	X*	X	X	X	X	X		X*	X	X	X	X	11
Hulscher, 2013 ¹⁷	X*				X	X		X*			X	X	6
Isfahani, 2019 ¹⁸	X*			X				X*				X	4
Leggat, 2015 ¹⁹	X*			X								X	3
Magalhães, 2016 ²⁰			X	X				X*					3
Mason, 2015 ²¹	X*		X	X			X	X*	X	X			7
Moraros, 2015 ²²	X*				X			X*	X			X	5
Nadeem, 2013 ²³	X*		X	X	X			X*				X	6
Nicolay, 2012 ²⁴	X*			X	X	X	X	X*	X	X	X	X	10
Nunes, 2016 ²⁵	X*			X	X		X					X	5
Powell, 2008 ¹	X*											X	2
Schouten, 2008 ²⁶	X*			X	X	X	X	X	X	X	X	X	10
Talib, 2011 ²⁷	X*							X*					2

Author, Year	1—Research Question / Inclusion Criteria	2—Protocol or PROSPERO	3—Explain selection of Study Design	4—Use of Search Strategy	5—Study Selection in Duplicate	6—Data Extraction in Duplicate	7—List of Excludes	8—Description of PICO-Research Design	9—Assesses Risk of Bias	10—Account for Risk of Bias in Interpretation	11—Explanation for Heterogeneity	12—Report Conflict of Interest	TOTAL SCORE
Taylor, 2014 ²⁸	X*			X	X	X						X	5
Tlapa, 2020 ²⁹	X*	X	X	X	X			X*	X	X			8
Trakulsunti, 2018 ³⁰	X*				X	X		X*				X	5
Tricco, 2012 ³¹	X*			X	X	X	X	X*	X		X	X	9
Wackerbarth, 2021 ³²	X*					X	X					X	4
Woodnutt, 2018 ³³	X*						X	X*	X				4
Zamboni, 2020 ³⁴	X*		X	X			X	X*	X			X	7
Zepeda-Lugo, 2020 ³⁵	X*	X	X	X	X			X*	X	X		X	9
Percent included reviews meeting criteria		14%	34%	76%	48%	38%	38%		45%	28%	28%	72%	

*Review noted as meeting this criterion; however, this criterion is only partially met, based on multiple sub-questions. See tables 3 and 4 below for detailed scoring on these 2 criteria.



The criteria for question 1, “Did the research questions and inclusion criteria for the review include a) population/setting; b) intervention; c) comparator(s); d) outcomes?”, was scored with sub-criteria for each of the 4 specific components of the question: population/setting, intervention, comparator(s), and outcomes. As such, the 29 reviews scored using AMSTAR2 could receive partial credit for up to 4 components: 2 reviews reported on all 4 sub-criteria, 13 reviews reported on 3 sub-criteria, 8 reviews reported on 2 sub-criteria, and 5 reviews reported on 1 sub-criteria. One review did not report on any sub-criteria. AMSTAR2-scored reviews most often reported population/setting and intervention in their research questions or inclusion criteria (n= 23, 79%). Comparators were reported as a part of the research questions or inclusion criteria in 5 reviews (17%).

Table 3: AMSTAR2 Scoring for Question 1 Describing Reviews Reporting Population/Setting, Intervention, Comparator(s), and/or Outcomes in the Research Questions and Inclusion Criteria

Author, Year	1A— Population/ Setting	1B— Intervention	1C— Comparator(s)	1D— Outcomes	Sub-criteria met
Côté, 2020 ¹¹	X	X	X	X	4
Hill, 2020 ¹⁶	X	X	X	X	4
Amaratunga, 2016 ⁹	X		X	X	3
Bucci, 2016 ¹⁰	X	X		X	3
Dellifraigne, 2010 ¹²	X	X		X	3
Dzidowska, 2020 ¹⁴	X	X		X	3
Hulscher, 2013 ¹⁷	X	X		X	3
Leggat, 2015 ¹⁹	X	X		X	3
Nunes, 2016 ²⁵	X	X		X	3
Schouten, 2008 ²⁶	X	X		X	3
Tlapa, 2020 ²⁹	X	X		X	3
Trakulsunti, 2018 ³⁰	X	X		X	3
Tricco, 2012 ³¹	X	X		X	3
Zepeda-Lugo, 2020 ³⁵	X	X		X	3
Zamboni, 2020 ³⁴	X	X		X	3
DelliFraine, 2013 ¹³	X	X			2
Glasgow, 2010 ¹⁵	X	X			2
Isfahani, 2019 ¹⁸	X	X			2
Mason, 2015 ²¹	X		X		2
Nicolay, 2012 ²⁴	X		X		2
Powell, 2008 ¹	X	X			2
Talib, 2011 ²⁷	X			X	2
Wackerbarth, 2021 ³²	X			X	2
Aij, 2017 ⁸		X			1
Moraros, 2015 ²²		X			1

Author, Year	1A— Population/ Setting	1B— Intervention	1C— Comparator(s)	1D— Outcomes	Sub-criteria met
Nadeem, 2013 ²³		X			1
Taylor, 2014 ²⁸		X			1
Woodnutt, 2018 ³³		X			1
Magalhães, 2016 ²⁰					0
Percent included reviews meeting this sub-criterion	79%	79%	17%	59%	

The criteria for question 8, “Did the review authors describe the following components in individual included studies in adequate detail: a) populations/settings; b) interventions; c) comparators(s); d) outcomes; e) research designs?”, was scored with sub-criteria for each of the 4 specific components of the question: population/setting, intervention, comparator(s), and outcomes. As such, the 29 reviews scored using AMSTAR2 could receive partial credit for up to 4 components: 2 reviews reported on all 5 sub-criteria, 5 reviews reported on 4 sub-criteria, 9 reviews reported on 3 sub-criteria, 5 reviews reported on 2 sub-criteria, and 2 reviews reported on 1 sub-criteria. Six reviews did not report on any sub-criteria. AMSTAR2-scored reviews most often reported population/setting (n=18, 62%) and intervention (n=14, 48%) in their research questions or inclusion criteria. Comparators were reported as a part of the research questions or inclusion criteria in 2 reviews (7%).

Table 4: AMSTAR2 Scoring for Question 8 Describing Reviews Reporting Population/Setting, Intervention, Comparator(s), Outcomes, and/or Research Designs in the Results

Author, Year	8A— Populations/ settings	8B— Interventions	8C— Comparators	8D— Outcomes	8E— Research Designs	Sub- criteria met
Hill, 2020 ¹⁶	X	X	X	X	X	5
Schouten, 2008 ²⁶	X	X	X	X	X	5
Bucci, 2016 ¹⁰	X	X		X	X	4
Moraros, 2015 ²²	X	X		X	X	4
Tricco, 2012 ³¹	X	X		X	X	4
Woodnutt, 2018 ³³	X	X		X	X	4
Zamboni, 2020 ³⁴	X	X		X	X	4
Amaratunga, 2016 ⁹	X			X	X	3
Dellifraigne, 2010 ¹²	X			X	X	3
Dzidowska, 2020 ¹⁴	X	X		X		3
Hulscher, 2013 ¹⁷	X	X			X	3
Mason, 2015 ²¹		X		X	X	3
Nicolay, 2012 ²⁴	X			X	X	3
Talib, 2011 ²⁷	X	X			X	3
Tlapa, 2020 ²⁹	X			X	X	3

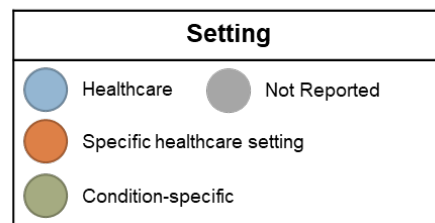
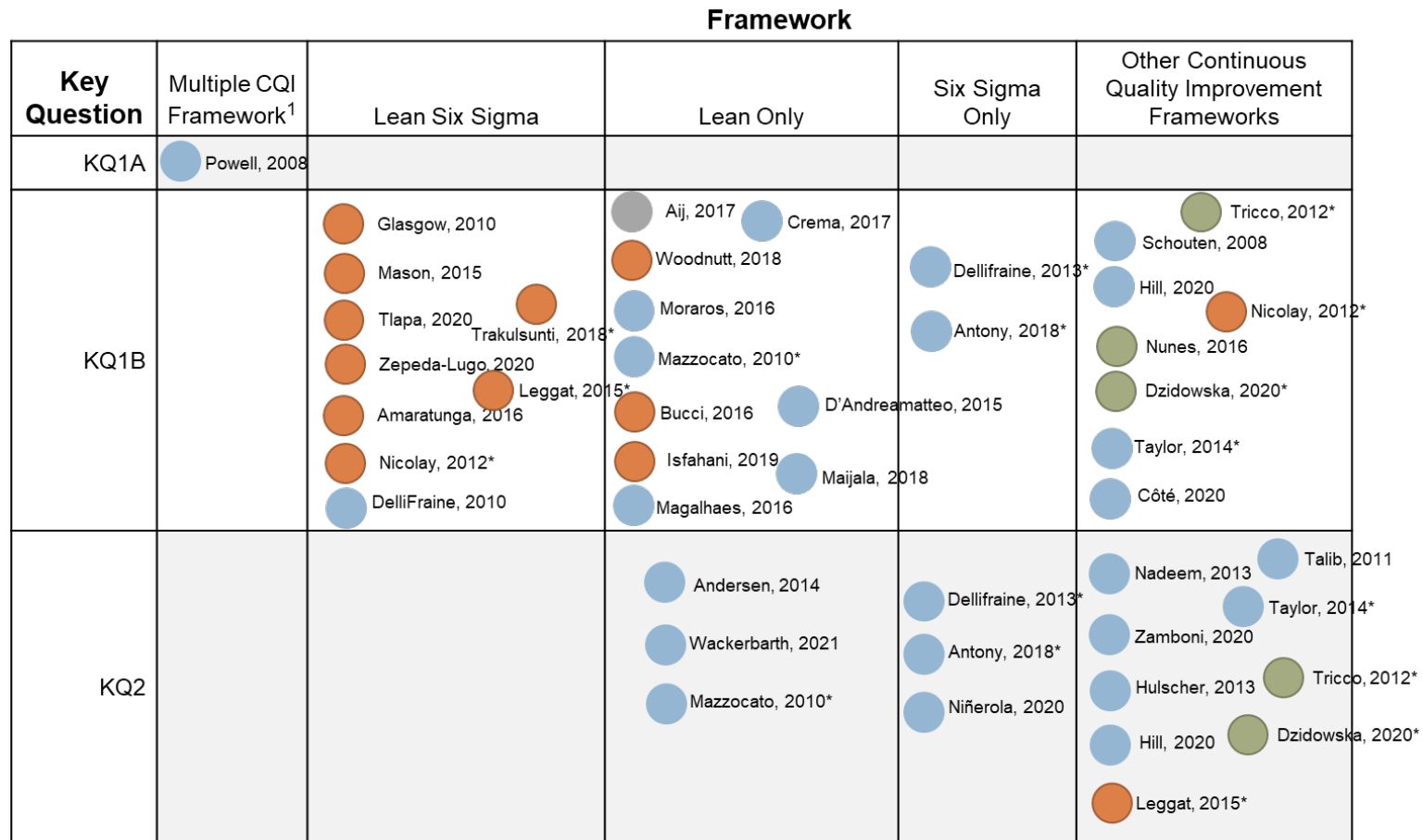
Author, Year	8A— Populations/ settings	8B— Interventions	8C— Comparators	8D— Outcomes	8E— Research Designs	Sub- criteria met
Zepeda-Lugo, 2020 ³⁵	X			X	X	3
Côté, 2020 ¹¹	X			X		2
DelliFraine, 2013 ¹³		X		X		2
Glasgow, 2010 ¹⁵	X				X	2
Isfahani, 2019 ¹⁸				X	X	2
Nadeem, 2013 ²³		X			X	2
Magalhães, 2016 ²⁰	X					1
Trakulsunti, 2018 ³⁰		X				1
Aij, 2017 ⁸						0
Leggat, 2015 ¹⁹						0
Nunes, 2016 ²⁵						0
Powell, 2008 ¹						0
Taylor, 2014 ²⁸						0
Wackerbarth, 2021 ³²						0
Percent included reviews meeting this sub-criterion	62%	48%	7%	59%	62%	

The Map of Included Reviews by Key Questions illustrates each included review, by key question, and their respective frameworks and settings (Figure 3). Reviews could appear more than once in a column if they addressed multiple Key Questions.

For Key Question 1A, there was 1 review that had described comparative effectiveness multiple CQI frameworks (*eg*, Total Quality Management, PDSA, the CQI method, *etc*) in a non-specific health care setting. For Key Question 1B, there were 9 reviews focused on Lean/Six Sigma—8 of these were in specific healthcare settings (*eg*, ambulatory & ED, radiology, *etc*) and 1 in a non-specific health care setting. Seven reviews reported Lean-only interventions for Key Question 1B, with 3 in specific health care settings (*eg*, ED, hospital) and 4 in a non-specific health care setting. Two reviews focused on Six Sigma only for Key Question 1B, both in a non-specific health care setting. Lastly, 8 reviews addressing Key Question 1B focused on other CQI frameworks (*eg*, Quality Improvement Collaboratives, Total Quality Management, clinical microsystems approach, *etc*): 4 reviews in general healthcare settings, 1 review in a hospital setting, and 3 reviews in a condition-specific setting (*eg*, kidney-disease treatment, *etc*).

Three reviews focused on Lean only in Key Question 2 were all in a non-specific health care setting. Two reviews focused on Six Sigma only, again in a non-specific health care setting. Nine studies addressing Key Question 2 focused on other CQI frameworks: 6 reviews in general health care settings, 2 reviews in a condition-specific setting (*eg*, alcohol misuse, diabetes, *etc*), and 1 review in a primary care setting. Reviews may appear more than once across Key Questions.

Figure 3. Map of Included Reviews, by Key Questions



¹CQI Method: Uses the Continuous Quality Improvement Method
 *This review appears more than once across rows.

The included systematic reviews reported on studies conducted in multiple countries, primarily in North America and Europe. The number of included studies within each review ranged from 9 studies to 295 studies (Figure 4), with search end dates from 2006 to 2019 (Figure 5).

Figure 4: Number of Included Studies, by Reviews

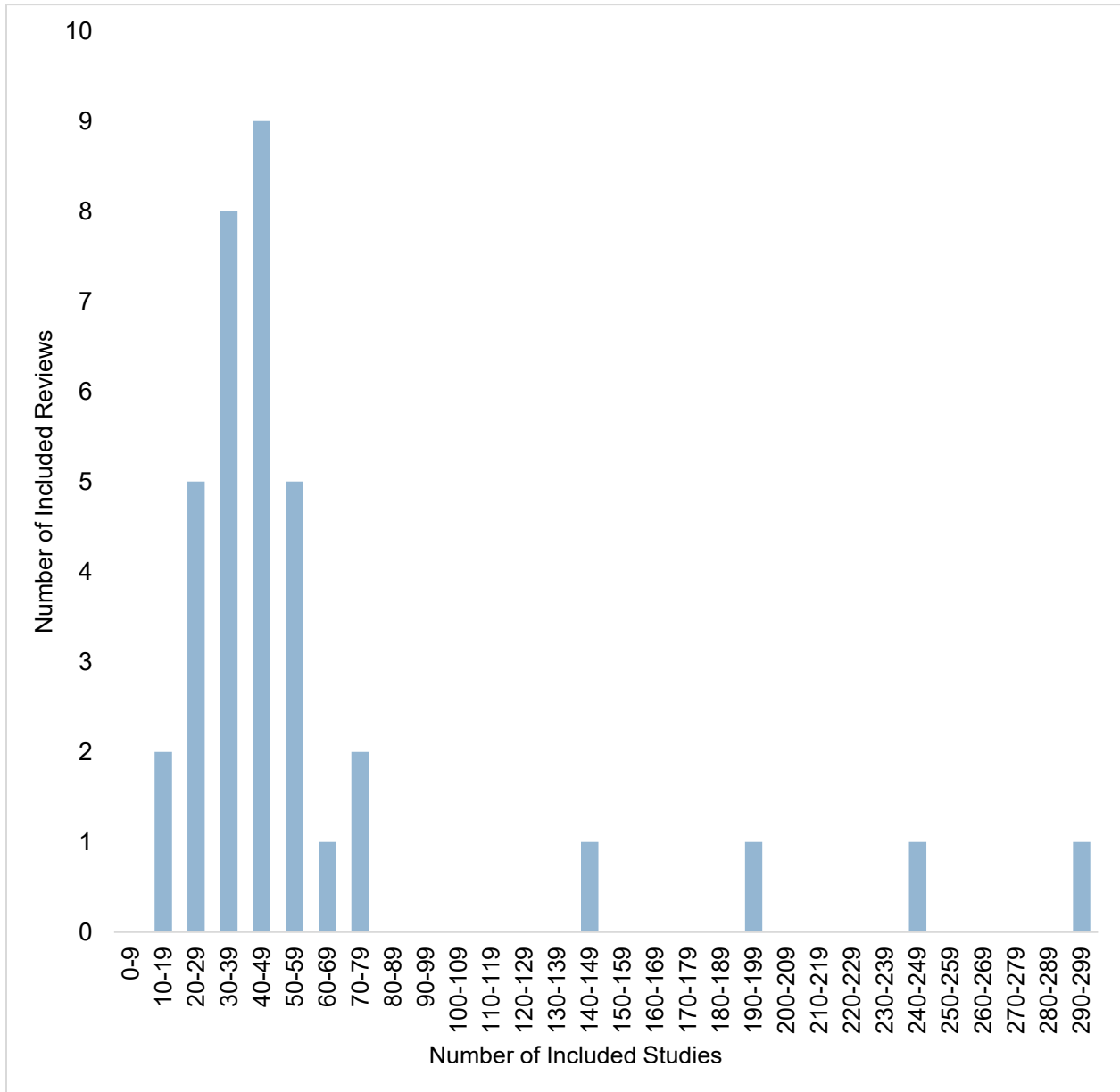
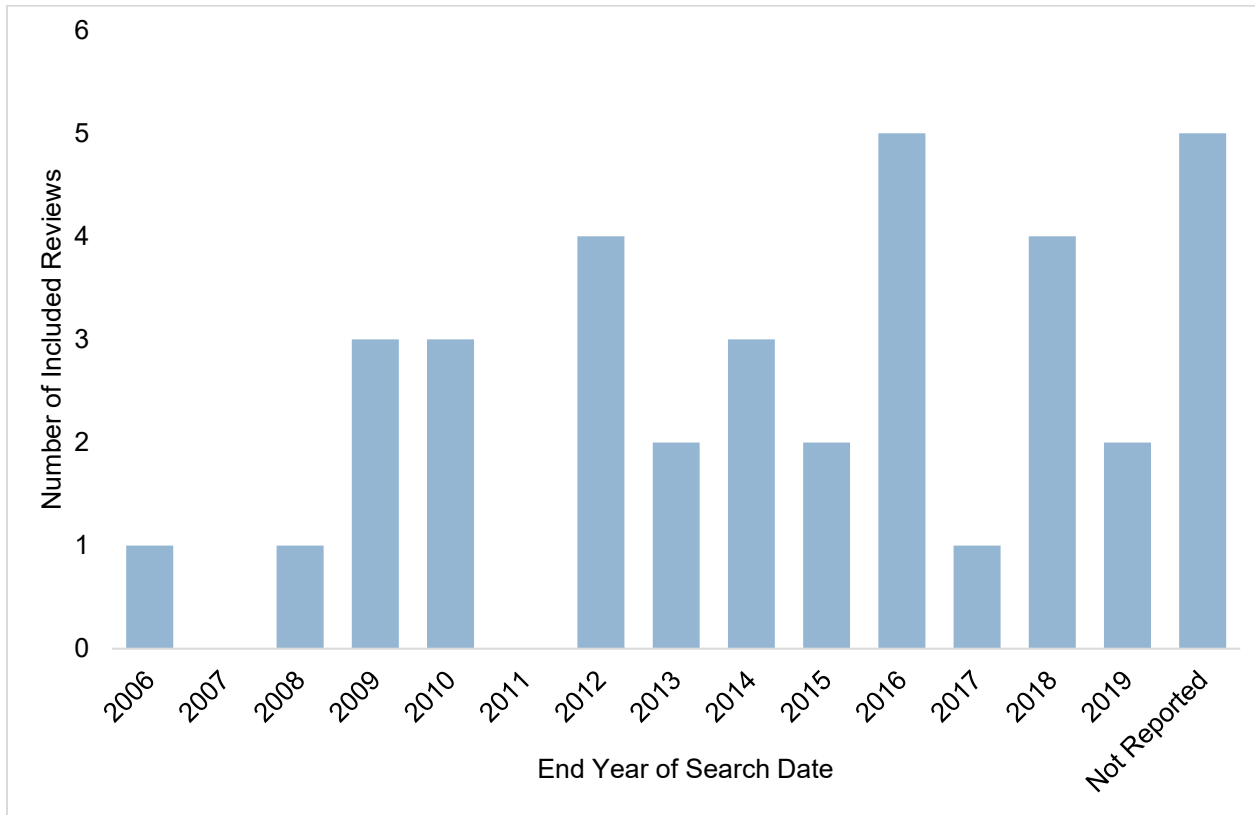


Figure 5: Number of Reviews, by End Year of Search Date



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 Points (Summary of Findings)

- Only 1 review of low certainty of evidence from 2008 directly assessed the relative effectiveness of CQI strategies, finding significant overlap in defining and implementing different approaches to CQI.
- The authors concluded that local context should dictate choice of CQI methodology, finding no evidence classifying any strategy as more or most effective.
- The authors identified 7 “necessary, but not sufficient” conditions for successful implementation of any CQI 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; availability of robust and timely data through supported information technology systems.

Detailed Findings

Comparative effectiveness of CQI frameworks

Multiple CQI frameworks

Only 1 review¹ by Powell from 2008 identified via reference mining directly assessed the relative effectiveness of a broad number of different QI strategies. In this report performed for NHS Scotland, the authors reviewed 5 organizational-level approaches for quality improvement: Total Quality Management, the CQI method, Lean and Six Sigma, business process reengineering, the IHI's rapid cycle change (Model for Improvement). The review included case-based analyses of each model, including 1 of the VA QUERI initiative in the United States. The authors note the studied approaches have been variously adopted in different health care settings, but standardization in adoption and implementation has been lacking. Specifically, they state, “there is little uniformity in nomenclature or in the content of programmes, and many organisations have used a combination of tools and approaches eclectically and variably over time”. Practically, this has meant that even when a model has been chosen for utilization across a health care system, each model “proceeds by carrying out several secondary activities” that may be outside their historical primary focus. For example, an organization implementing a Lean model may include a focus on human factors in addition to process analysis. Thus, organizations practicing different methodologies often employ the same or similar tools, and most models and organizations focus on similar measurement and data collection strategies. The end result of this evolution is that, from an outside perspective, “for all their differences – the approaches do begin to resemble each other”.

Given the variation in implementation of each model and the overlap in tools and practices, the authors' main findings identify “limited evidence available to assess how effective these

approaches are in health care”. However, they do note broad lessons may be drawn from these experiences for successful adoption of QI strategies in a variety of settings, including a set of “necessary, but not sufficient” conditions. These conditions include

- “provision of the practical and human resources to enable quality improvement;
- the active engagement of health professionals, especially doctors;
- sustained managerial focus and attention;
- the use of multi-faceted interventions;
- coordinated action at all levels of the health care system;
- substantial investment in training and development;
- and the availability of robust and timely data through supported IT systems.”

Ultimately, they conclude, “[i]mportantly, there is no one right method or approach that emerges above the others as the most effective”. They then suggest analyzing the local context prior to implementation to determine which strategy “provides the ‘best fit’ locally (however imperfect)”, which then must be applied “in a programmed and sustained way, which may include considerable adaptation of the approach to suit the local circumstances and to respond to emerging developments”.

The remainder of the reviews we identified did not assess relative effectiveness of different QI strategies. These reviews dealt with only a single strategy, like Lean or Six Sigma, or a Lean/Six Sigma hybrid strategy and do not provide evidence of differential effectiveness other than among Lean and Six Sigma.

Certainty of Evidence for Key Question 1A

This systematic review by Powell¹ received a score of 2 on our modified AMSTAR2 tool for inclusion of characteristics of methodologies in the inclusion criteria and reporting of funding source. Details such as a fully defined search strategy, article review, data abstraction, and clear reporting on the characteristics of included studies for the review were not identified. The evidence from this study was, therefore, deemed of low overall certainty.

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 Points (Summary of Findings)

- Twenty-five reviews studied at least 1 CQI framework, with 11 studying more than one. These reviews identified successful implementation of CQI frameworks in a variety of clinical settings.
- None of the 11 reviews that included more than 1 CQI strategy reached a strong conclusion that any strategy was superior to any other(s).

- Seven publications commented on sustainment of change using CQI strategies, none of which concluded that any specific methodology had definitive evidence for sustainment of change.
- None of the included reviews concluded any CQI methodology had evidence speaking to health care workers' reaction to use of that general framework, specific learning outcomes related to a CQI framework, nor identifiable behavioral changes made based on CQI training. Five studies discussed clinician/provider satisfaction as an outcome of implementation of a CQI methodology, with mixed results.

Detailed Findings

Effectiveness of CQI frameworks

Lean, Six Sigma, and/or Lean Six Sigma

Overall, 21 reviews studied the effectiveness of Lean, Six Sigma, and/or Lean Six Sigma frameworks in health care. Of these, 10 publications reviewed only Lean strategies,^{8,10,18,20,22,33,36-39} 2 only Six Sigma strategies,^{13,40} and 9 a combination of the three strategies^{9,12,15,19,21,24,29,30,35}. One review of the 3 strategies also reviewed other frameworks addressed in the 'Other CQI Frameworks' section and is discussed in both sections.²⁴ None of the reviews that assessed some combination of the QI strategies reached a strong conclusion that one strategy was superior to the others. Of the 9 reviews of a combination of the 3 strategies, 6 included a discussion of differential effectiveness.^{15,21,24,29,30,35} Of these 6 reviews, 4 explicitly stated they could not conclude 1 strategy was superior to the others,^{15,21,24,30} while the remaining two^{29,35} concluded without supporting comparative data that a combination of Lean and Six Sigma outperformed either one by itself. Several other articles addressing aspects other than effectiveness of these strategies are discussed elsewhere in this document under Key Question 2.

Each strategy has been studied in a variety of clinical settings. Collectively, these include outpatient medical and surgical clinics, emergency care settings, inpatient wards, operating theatres, radiology units, hospital and UK National Health Service trust pharmacies, and entire hospital or UK National Health Service trust systems. Often, more than 1 strategy has been used in the same general clinical setting in different locations (such as both Lean and Six Sigma used in increasing emergency department patient volume throughput, improving outpatient waiting times, or improving Methicillin-resistant *Staphylococcus aureus* [MRSA] infection rates in different studies), though they have not been directly compared in any study.

Six reviews directly commented on when to utilize 1 of the 3 strategies or improvement systems.^{15,21,24,29,30,35} Glasgow¹⁵ reviewed 47 studies and noted, "Lean and Six Sigma have been effectively applied to all components, from admission to discharge, of a patient's hospital experience." Additionally, the authors identify, "there is sufficient flexibility [in these methods] to improving quality in the acute care setting". However, given the variability in how these methods were defined, implemented, and reported across the included literature, they conclude "there is not sufficient evidence to recommend broad adoption of Lean, Six Sigma, or Lean Six Sigma".

Two reviews by the same author group looked at Lean strategies in the inpatient setting³⁵ and Lean strategies generally related to "patient flow"²⁹ across multiple settings. The former review

identified 40 studies, while the latter identified 39, with 3 overlapping studies. Both reviews found improvements in multiple outcomes with Lean strategies, including 6 of 7 outcomes in the inpatient setting and shorter length of stay and reduced outpatient waiting times in the work focusing on patient flow. Both papers suggested combining Lean and Six Sigma methodologies into Lean Six Sigma outperformed both Lean and Six Sigma, although these statements seem based on the frequency of reporting included in their review. In neither case were direct comparisons offered as evidence of the superiority of Lean Six Sigma. Specifically, Tlapa noted Lean Six Sigma “outperforms the use of only one other methodology; however, this combination tends to be composed of larger, private hospitals with more resources for quality improvement”. Zepeda-Lugo identified “25 out of 39 studies combining lean with tools and principles of the six sigma methodology, suggesting that such integration offers a more robust approach to improving speed, quality and costs, increasing customer satisfaction, and maximizing shareholder value”.

Similarly, the Nicolay²⁴ and Mason²¹ reviews had some overlapping authors and shared 10 references for Lean, Six Sigma, and Lean Six Sigma involving the operating theatre. In the later work,²¹ Mason also included additional 11 Lean, Six Sigma, and Lean Six Sigma works from surgical outpatient clinics and wards, while Nicolay also reviewed other methodologies such as the CQI method and PDCA in the operating room that are discussed later in this report. The Mason review identified a “role for Lean and Six Sigma QI methodologies within surgery, with significant improvements demonstrated across a variety of outcomes within the pre-operative, operative and in-patient settings”. These outcomes included outpatient clinic efficiency, operating room turnaround time, use of prophylactic perioperative antibiotics, glycemic control postoperatively while hospitalized, and nosocomial infections. Nicolay further detailed, “these methodologies have been applied successfully to many different aspects of care, but in particular those that are repetitive and can be standardized”. Mason highlighted the flexibility of both methods to meet “unique challenges in a particular place at a particular time”. In both reviews, the authors were unable to make recommendations favoring 1 strategy over the others, with Mason concluding, “This review is unable to make formal recommendations on the use of Lean and Six Sigma methodologies in improving specified outcomes in surgical practice” and Nicolay, “it is not possible to make evidence-based recommendations for different indications, as different studies implemented different aspects of various methodologies to varying extents, and in different contexts”.

Trakulsunti³⁰ et al identified 24 articles across the 3 methodologies focused on reducing medication errors. In this review, 22 Lean and 22 Six Sigma tools were “used across the medication process including prescribing, transcribing, dispensing and administration”. The tools were generally reported to be successful, with their results determining “Lean, Six Sigma and Lean Six Sigma implementation can reduce errors in the medication delivery process”. In specifying tools by framework, the authors conclude that “very few studies use pure Lean, Six Sigma and Lean Six Sigma to reduce medication errors”. Similar to Tlapa²⁹ and Zepeda-Lugo,³⁵ Trakulsunti suggests, “the integration of Lean and Six Sigma may lead to better results”, specifically as “practitioners can use tools from both philosophies”. However, this statement was not based on comparative data, as they note, “the current literature does not provide a Lean, Six Sigma or Lean Six Sigma road map for practitioners to follow in order to reduce medication errors in their hospitals”.

Three other publications^{9,12,19} reviewed more than 1 of the 3 methodologies but did not comment on utilizing one approach over another. Amaratunga⁹ reviewed 23 articles across the 3

methodologies involving Radiology modalities and units. The authors identified 7 different themes to which the strategies had been applied, including wait times, patient volumes, costs, and satisfaction and found “benefits can be derived through the application of Lean and Six Sigma methodologies within the field of radiology”. In their appraisal, however, they determined the evidence was insufficient to determine the overall effectiveness of the methodologies, “consequently preventing one from recommending their widespread implementation” when considering possible upfront costs relative to other methodologies such as audit-and-feedback. Dellifraime¹² reviewed 34 articles across different health care settings, with 26 following a Six Sigma strategy and 20 included in a later review¹³ on just Six Sigma methodologies. In this review, the individual strategy often was not identified during specific discussion points, making it difficult to draw detailed conclusions. However, the authors note, “the level of evidence supporting a positive relationship between the use of [Six Sigma and Lean] and performance improvement was weak” and therefore the limited evidence may only identify explicit potential applications. Finally, Leggatt¹⁹ reviewed multiple strategies for process redesign in health care across 41 articles, including Lean and Six Sigma. The authors included 4 reviews, including those from Dellifraime¹² and Nicolay.²⁴ Of the 41 articles, 17 correlated practice changes with outcomes, although the structure of the article prevents identification of specific strategies for the stated improved outcomes.

Lean only

The 10 publications of only Lean strategies reviewed implementation in emergency settings,^{10,18} general health care settings,^{20,22,36,38,39} and within the UK National Health Service.³³ Two additional reviews did not report setting.^{8,37} Four publications were not appropriate for use of the AMSTAR2 tool,³⁶⁻³⁹ and none of the other 6 publications had AMSTAR2 ratings ≥ 8 .

The first of the 2 reviews of the effectiveness of Lean in emergency settings by Bucci¹⁰ identified 9 studies on patient flow and found specific improvements reported on outcomes that included increased patient volumes, decreased rates of length of stay and patients who left without being seen, cost reduction, and patient satisfaction. The Lean strategies adopted across these 9 studies were not standardized, though “[a]most all studies considered showed that Lean interventions contributed to the EDs performance improvement”. Importantly, no study included by Bucci expanded their patient flow efforts to other health care settings, such as primary care, that have direct or indirect effects on emergency care volumes or access. The second review by Isfahani¹⁸ was a descriptive overview of the literature and identified 26 articles documenting 23 studies. Very little was stated regarding effectiveness of Lean strategies, though the authors did identify an average duration of intervention of 10 months as reported across 16 of those studies.

Five publications reviewed the effectiveness of Lean in any health care setting, with 3 finding positive results in general categories of care, such as “productivity” and “clinical quality”.^{20,38,39} In the most recent of these articles, Magalhaes²⁰ identified 47 articles but did not provide specific examples or citations of improvement. Instead, the authors noted multiple general areas in which improvements have been documented, such as waiting times and improved teamwork. Similarly, Mazzocato³⁸ reviewed 33 articles and commented on effectiveness in general improvement categories such as “time-savings” and “several quality aspects including reduction in errors or mistakes” in their results with individual citations provided. Most of Mazzocato’s work focused on a realist review of contextual aspects related to 4 change mechanisms more appropriately discussed under Key Question 2.

D'Andreamatteo³⁹ and Moraros²² attempted to discuss Lean strategies in any health care setting at a more systemic level, with the former identifying 243 articles, more than 90% of which were noted to be from the acute care setting. The authors identified 7 studies addressing a systemic organizational Lean approach, stating, “[w]hen Lean was implemented within a plan of actions aimed to improve the whole organization performance, the organizations appeared to become more process-oriented, reduce costs and increase quality”. However, as relatively few articles reviewed Lean at a high level, they also commented on studies with narrower scopes, finding “similar [positive] results were achieved with projects implemented in a single ward, in other specific units or addressing only one organizational process”. Moraros,²² on the other hand, identified 22 articles, 4 of which considered health outcomes, 3 a combination of health and process outcomes, and 15 process outcomes only. In reviewing the health outcomes, only 1 of the 4 studies found a statistically significant result. This finding was on reduced MRSA infection incidence, with another 1 of the 4 studies finding a null result on the same outcome, and the other 2 studies finding null results on adverse events and 30-day mortality. Similarly, only 2 studies on patient visits and surgical consults out of the 15 process outcome studies identified a statistically significant positive effect of Lean implementation. The overall conclusion by the authors was “[w]hile some may strongly believe that Lean interventions lead to quality improvements in healthcare, the evidence to date simply does not support this claim. It is far more likely that Lean is but one of many strategies that might or might not have an impact on healthcare delivery”.

Woodnutt³³ reviewed Lean processes across the UK National Health Service, finding 12 articles with different methodologies, including 1 systematic review. Lean adoption differed between the studies, with 22 different outcomes measured. The most commonly studied outcome was waiting times, which had 5 positive results and 3 null results across 8 studies. In reviewing the literature across time, the authors noted a general “evolution from pragmatic (quasi-scientific and experiential) research to more academic and scientific designs”. However, even in the UK National Health Service, the authors identified different definitions of value in Lean that may influence different implementation strategies and that there is “no blueprint to guide the introduction of QI in complex organisations”. As such, they conclude “Lean has ostensible value but it is difficult to draw a conclusion on efficacy or sustainability”.

Six Sigma only

The 2 publications of only Six Sigma strategies both reviewed implementation across multiple health care settings.^{13,40} The Antony⁴⁰ study focuses mainly on success factors and challenges with Six Sigma, although it briefly reviews outcomes for which some effectiveness has been shown. These outcomes include 16 sub-categories, including the 5 most frequently reported of patient satisfaction, process speed (reduction of process cycle time), revenue enhancement, cost savings, and defect reduction. They conclude, “the most common benefits of Six Sigma implementation in healthcare are improvement in patient safety, improvement in process speed (i.e. increased productivity) and revenue enhancement (i.e. bottom-line savings).” Dellifraigne¹³ narrowed their earlier work from 2010¹² to only Six Sigma methodologies, including 20 studies from the earlier work and an additional 35 works for inclusion. Of the 55 total articles, only 30 identified each of the Define, Measure, Analyze, Improve, and Control (DMAIC) steps in full and only 16 reported a sigma level achieved. Most often, the ‘Control’ step was not included (20 of the 25 studies that did not report all steps). The studies included multiple outcomes, such as medication administration errors, operating room throughput, pain management, hospital hand hygiene, falls, ventilator-associated pneumonia, cost savings, and patient safety. Most articles

noted some improvement, though only 7 included statistical comparisons. The authors note, “articles that focused more narrowly on more targeted areas were able to present stronger in-depth evidence that Six Sigma can improve processes of care” and that a greater number of more narrowly focused studies reported statistical testing and/or sigma level achieved. They conclude, “the level of evidence supporting a positive relationship between the use of Six Sigma and statistically significant improvement in quality was weak.” Additionally, the authors note the difficulty in achieving Six Sigma levels of standardization, as having no more than 1 defect per 3.4 million opportunities “may not be realistic or applicable to many QI issues faced by health care organizations”. Even with these concerns, however, the authors state, “Six Sigma is a good tool to identify the key procedures or problems in the process of care.”

Other CQI frameworks

In addition to the reviews focused on the use of Lean and/or Six Sigma strategies in health care, we also identified a number of reviews on other topics: 1 review on the “evidence for the impact of quality improvement collaboratives”²⁶; 3 reviews on the effectiveness of the CQI method, 1 of which was the CQI method “for developing professional practice and improving health care outcomes”,¹⁶ another 1 of which was the use of the CQI method “in nephrology”,²⁵ and the third of which was the role of the CQI method “to improve practice, detection and treatment of unhealthy alcohol use in primary health care”¹⁴; 1 review on the use of PDSA “to improve quality in health care”²⁸; 1 review about the Clinical Microsystems (CMS) approach¹¹; and 2 reviews that included many different QI strategies in specific clinical situations, 1 of which was the management of diabetes,³¹ and other of which was about “surgical healthcare” (also discussed in the ‘Lean, Six Sigma, and/or Lean Six Sigma’ section for their results studying those frameworks).²⁴ We discuss these only briefly, as none had head-to-head comparisons of QI approaches and almost all had included either Lean or Six Sigma as part of their eligibility criteria.

These last 2 publications^{24,31} reviewed all identified QI articles meeting eligibility criteria within their respective clinical foci. In the review by Tricco and colleagues on diabetes (search end date of 2010), 142 original studies (including 48 cluster randomized trials) were included.³¹ Studies were characterized by the components of the intervention used, such as audit-and-feedback, clinician education, clinician reminders, etcetera. The CQI method was 1 such component, for which 4 studies were included. A meta-analysis and meta-regression analysis found that almost all QI components were effective at improving outcomes such as reduction in hemoglobin A1c and reduction in LDL, etcetera. However, only 1 of the CQI method studies entered into the meta-analysis, and none entered into the meta-regression analysis, meaning conclusions about use of the CQI method were not possible. The review of QI strategies in “surgical healthcare”²⁴ (search end date of 2010) included 4 original studies using PDSA, 3 studies using statistical process control, 9 studies using the CQI method, 5 studies using Total Quality Management, 5 studies using Six Sigma, 4 studies using Lean, and 1 study using Lean Six Sigma; however, there were no head-to-head studies comparing different QI methods. All studies improved some aspect of surgical health care (such as infection control, operating room turnaround time, or use of pre-operative beta-blockade, *etc*).

The 3 reviews focused on the CQI method^{14,16,25} found mixed results. In the review about “improving health care outcomes”¹⁶ (search end date of 2019), 28 RCTs were identified that assessed the effectiveness of the CQI method. Over half did not report statistically significant

improvements on clinical, patient, or other outcomes. In the review focused on the CQI method “to improve practice, detection, and treatment of unhealthy alcohol use”¹⁴ (search end date of 2018), 56 publications met eligibility criteria, and more than 90% of these reported some improvement. However, only 5 studies reported clinical outcomes, and of these none reported statistically significant differences. The third review, about use of the CQI method “in nephrology”²⁵ (search end date of 2014), identified 76 studies meeting eligibility criteria. Only 1 included study was a randomized trial, and it found better blood pressure control among dialysis patients in the intervention group. All 3 reviews concluded more and better-conducted research of the CQI method was needed. Although not the same as the CQI method, the use of PDSA is common to many general CQI frameworks, and so we include here a discussion of the review focused on PDSA.²⁸ This review (search end date of 2012) identified 73 articles meeting eligibility criteria. The review reported details about the design, execution, and reporting of the studies (such as the country of origin, clinical focus, how many studies used iterative cycles, *etc*), but it did not report any data on effectiveness. This review concluded that better reporting was needed.

The last 2 non-Lean, non-Six Sigma reviews were about Quality Improvement Collaboratives²⁶ and “the CMS approach”.¹¹ The review of Quality Improvement Collaboratives (search end date of 2006) identified 72 studies meeting eligibility criteria, of which 12 publications (describing 9 studies) found “moderate positive effects”, with 7 studies reporting some statistically significant effects on outcomes and 2 finding no significant effect. The review of CMS¹¹ (search end date of 2018) identified 35 studies that could be of any research design (including case studies and cross-sectional studies) which contained in the title or abstract of the article “keywords related to clinical microsystems” and could concern any health care provider on any clinical topic. The authors stated that “all the included studies underlined the positive aspects regarding the achievement of the targeted objectives, namely a higher quality of care and of better patient safety”.

Sustainment of Change in CQI Frameworks

No publication included in our review concluded that any specific methodology had definitive evidence for sustainment of change. Several, in fact, specifically noted the literature is lacking on this aspect of QI in their analyses.^{10,13,15,33,35,39,40} Only 1 review calculated an average duration of study implementation, finding an average of 10 months reported across 16 of 26 studies on Lean management in emergency settings,¹⁸ while another stated only 15% of 39 studies reported a follow-up duration greater than 1 year.³⁵ Another review suggested reporting data for at least 2 years post-implementation would be “necessary to determine whether process changes are accepted and become part of the permanent culture”.¹⁵

Health Care Workers’ Reaction, Learning, and Behavior Change to CQI Frameworks

No publication included in this review concluded that any specific methodology had evidence speaking to health care workers’ reaction to that general framework in perceptions of the usefulness of the CQI training. Additionally, no study commented on specific learning outcomes related to any CQI framework nor tested participant knowledge or skill acquisition with tools such as the Quality Improvement Knowledge Application Tool. Furthermore, no study analyzed whether staff made specific behavioral changes based on training. Several reviews included

provider/clinician satisfaction as a possible outcome,^{9,20,22,38,39} although these outcomes may represent staff working in locations with implemented CQI strategies, rather than those who received training as part of each study. In studies reporting results for employee satisfaction outcomes, Moraros²² concluded implementation of Lean had “a negative association” with worker satisfaction, while 3 other studies drew the opposite conclusion.^{20,38,39}

Certainty of Evidence for Key Question 1B

Of the 25 studies speaking to Key Question 1B, 22 were rated using the modified AMSTAR2.^{9-16,18-22,24-26,28-31,33,35} The AMSTAR2 scores for these 22 reviews ranged from 3 to 11 points, with a mean of 6.5. Nine^{9,11,14,16,24,26,29,31,35} of these 22 studies had a modified AMSTAR2 score of 8 points or higher. None of the articles with higher AMSTAR2 ratings had supported conclusions widely diverging from the rest of the articles. Therefore, we conclude there is moderate certainty of evidence that CQI frameworks may be successfully implemented in a variety of clinical settings.

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?

Key Points (Summary of Findings)

- Twenty reviews studied at least 1 CFIR factor related to success or failure of CQI frameworks. Fifteen discussed intervention characteristics, 6 discussed individuals involved, and 10 discussed inner setting.
- No reviews compared the success or failure of different CQI strategies based on intervention characteristics, characteristics of individuals, or inner setting. Instead, the majority of studies listed aspects of some or each of these 3 CFIR categories deemed important for implementation of that methodology with little to no supporting evidence or discussion of the influence of the category on ultimate project success or failure.
- No publication included in this review discussed whether either outer setting or specific processes during implementation of a CQI framework contributed to either the success or failure of implementation for any framework.

Detailed Findings

Factors contributing to success or failure of CQI frameworks

We looked at factors affecting the success or failure of CQI according to the 5 main Consolidated Framework for Implementation Research (CFIR) domains⁷. Of these, we found relevant data on intervention characteristics, characteristics of individuals, and inner setting. However, no studies compared the success or failure of different frameworks based on intervention characteristics, characteristics of individuals, or inner setting. Additionally, no studies discussed whether either the outer setting or specific processes during implementation of a CQI framework contributed to either the success or failure of implementation of any methodology.

Overall, few studies addressed intervention characteristics, characteristics of individuals, or inner setting in detail. Rather, the majority of studies listed aspects of some or each of these categories deemed important with little to no supporting evidence or discussion of the influence of the category on ultimate project success or failure. When discussed, the factors were often paired with an example of how the aspect in question might be helpful.

Intervention Characteristics Contributing to Success or Failure of CQI Frameworks

Multiple CQI frameworks

In all, 15 reviews^{13,14,16,17,19,23,27,28,31,32,34,38,40-42} mentioned intervention characteristics contributing to either the success or failure of CQI frameworks. These articles reviewed Lean^{32,38,42} and Six Sigma frameworks,^{13,40,41} Total Quality Management,²⁷ the CQI method,^{14,31} Quality Improvement Collaboratives,^{17,23,34} PDCA,²⁸ or multiple strategies.^{16,19}

Three reviews specifically discussed characteristics of Lean strategies in terms of success or failure. Two only superficially analyzed these characteristics, however. Andersen⁴² identified 23 facilitators associated with successful Lean interventions, including administrative support, IT systems, physicians, and teamwork. None of the 23 facilitators were specifically discussed in terms of how they might be best fostered or included within a Lean framework, and many of the 23 factors might be considered related to inner setting (such as IT systems and administrative support). Wackerbarth³² defined Lean interventions as having 8 specific steps, of which articles in their review documented an average of 2.77 steps. The authors felt adhering to more of these steps would likely increase overall project success; however, their categorizations of these steps and tools within them were unvalidated.

Mazzocato³⁸ performed a realist review of Lean studies and identified several common characteristics across various studies, but did not specify how these common characteristics serve to facilitate or hinder quality improvement work. They also identified 4 general components of Lean that led to different mechanisms of improvement: “methods to understand processes in order to identify and analyse problems; methods to organise more effective and/or efficient processes; methods to improve error detection, relay information to problem solvers, and prevent errors from causing harm; [and] methods to manage change and solve problems with a scientific approach”. The authors then gave some general examples of how these mechanisms may lead to success. Using tools to understand a process as in the first component creates shared understanding, for example, which “helps members of different professions to communicate and see how their roles and their work relate to the bigger picture”. Detecting errors and sharing data on their occurrence with leaders quickly as in the third component leads to clarity for those in different roles and “makes workarounds or a lack of routines more noticeable and enables stakeholders to promptly address deviations”. Finally, creating a team-based and collaborative approach for problem-solving can “strengthen the belief among staff that errors are preventable and change a culture of blame into one of safety and continual improvement”.

As noted in the Key Question 1 discussion, DelliFraine¹³ found that “articles that focused more narrowly on more targeted areas were able to present stronger in-depth evidence that Six Sigma can improve processes of care”, specifically examples around operating room or ED throughput and turnaround time. Additionally, they identified which DMAIC stages each article included,

finding many did not mention ‘Control’, although the presence or absence of discussing ‘Control’ within their reviewed articles was not correlated with success nor failure in their discussion. Antony⁴⁰ identified 19 challenges and 16 success factors for Six Sigma methodologies in the literature, discussing that 8 challenges account for 80% of the total reported: “availability of data, cultural issues, resistance to change, sustainability of results, insufficient resources, inadequate knowledge of Six Sigma, complexity of current practice and lack of leadership commitment”. Five authors specifically noted availability of quality data as being the single greatest challenge faced. Similarly, 7 success factors accounted for 80% of the total reported: “understanding of Six Sigma tools and techniques, management involvement and commitment, communication, organization infrastructure and culture, training, patient focus and cultural change”. No evidence was available for ways to foster success factors or avoid challenges.

In their Table 2, Talib²⁷ reviewed the included articles for 8 best practices they identified in Total Quality Management: top-management commitment, teamwork and participation, process management, customer focus and satisfaction, resource management, organization behavior and culture, continuous improvement, and training and education. Although 4 managerial implications of this work are listed in the discussion, none of these implications provided specific guidance on designing a Total Quality Management intervention.

Quality Improvement Collaboratives were explored in 3 studies.^{17,23,34} Nadeem²³ reviewed both quasi-experimental and randomized studies of 3 different named models, the IHI Breakthrough Series, Chronic care model, and Vermont Oxford Network, as well as an “other model” category. Their Table 2 details the presence or absence of 13 components within each study, and they state more recent collaboratives more often reported on the Breakthrough Series model. Furthermore, they found, “[f]ormal pre-collaborative preparation was rarely reported and was described in only five studies” and “[o]n average, each study implemented an average of six or seven Quality Improvement Collaboratives components.” All 20 studies reported in-person learning sessions, three-quarters reported use of PDSA cycles and new data collection, and 14 reported use of multidisciplinary QI teams. Very few details were shared about the way these components were delivered, however, preventing comment on aspects related to ultimate success or failure. Both Zamboni³⁴ and Hulscher¹⁷ list some characteristics of their studied interventions within their reviews, but focused more on setting and individuals as noted below. Hulscher¹⁷ did include a brief section on “the collaborative process”, finding no specific evidence for success based on the “intensity of intervention” nor “exchange and sharing information”. A very small sample of studies found positive influence from “being on preconference calls” and “timeliness of submission of reports”.

Both reviews including the CQI method focused on narrower clinical problems than otherwise represented in our systematic review. Tricco³¹ included the CQI method as an analyzed strategy while using HbA1c data to provide the only statistical evidence related to specific intervention characteristics leading to success. However, this work focused more on individual QI tools than a specific framework. Specifically, the authors note, “HbA1c was further lowered when the QI strategy included team changes (0.33%), case management (0.21%), promotion of self-management (0.21%), clinician education (0.19%), patient education (0.16%), facilitated relay (0.12%), an electronic patient registry (0.08%), and patient reminders (0.02%)”. Furthermore, “[d]ecreases in HbA1c of more than 0.5% were noted for four QI strategies (team changes, case management, patients’ education, and promotion of self-management) in trials enrolling patients

with HbA1c greater than 8.0%, and one QI strategy (facilitated relay) in trials enrolling patients with HbA1c of 8.0% or less”. Finally, “[a]ll QI strategies were associated with significant changes in HbA1c, except for clinician education” and “[w]e noted greater improvements in HbA1c control for QI strategies targeting health systems and patients”. Dzikowska¹⁴ reported the 3 CQI method elements described by Rubenstein² of 1) using “systematic data guided activities” to identify problems and achieve improvement, 2) “designing with local conditions in mind”, and 3) using an “iterative development and testing process” in their review. They found any of the elements in 22 and all 3 elements in 12 of their 56 reports. Additionally, they determined studies with all 3 elements “had implementation and follow-up durations above the median; utilised multifaceted designs; targeted both practice and health system levels; [and] improved screening and brief intervention [for unhealthy alcohol use]” relative to studies without all 3 CQI method elements.

The PDCA strategy was reviewed by Taylor,²⁸ with PDCA intervention principles defined as iterative cycles, prediction-based test of change, small-scale testing, use of data over time, and documentation. Although more than 45 of their 73 identified articles reported many of these characteristics, only 2 articles reported all of them. Only 7 articles reported data over time and only 4 documented any predictions. PDSA was the most frequent strategy reviewed by Hill,¹⁶ with 19 of the 28 studies using some variant of the model. In their review, the authors noted that “[i]mportant characteristics of approaches to CQI were infrequently reported” across the various frameworks, including the frequency and total number of team meetings, duration of these meetings, and training type and duration. Finally, Leggatt¹⁹ identified 20 examples where the “process redesign programme included the injection of resources (financial, physical and human)” but did not state further if there was evidence as to timing or type of additional resources that best led to success.

Characteristics of Individuals Contributing to Success or Failure of CQI Frameworks

Multiple CQI frameworks

Six articles^{10,15-17,23,42} mentioned the individuals involved in the CQI frameworks in their reviews. These articles reviewed Lean^{10,15,30,42} and Six Sigma,^{15,30} Quality Improvement Collaboratives,^{17,23} or multiple strategies¹⁶.

Bucci¹⁰ generally noted in their review of 9 studies on Lean in ED flow that “the staff involved was generally comprised of not only clinicians and nurses, but also by assistants and engineers”, and “[i]n almost all the studies a quality improvement facilitator, often a Lean consultant, led the team”. They included 2 comments regarding personnel and success or failure: in 1 study, “best results were obtained when Lean intervention was owned by the frontline workers who worked in the ED and the commitment of the leadership was principally involved sustaining the improvement”. Additionally, they found, “[w]hen both leadership commitment and frontline workers” involvement were missing, “lack of improvement or even a worsening in LOS [length of stay] and patient satisfaction were observed.” Andersen⁴² lists personnel in an “Application” section, specifically “collaborating and multiskilled teams” and “physicians and management”. These teams and members are mentioned to “facilitate local applications of Lean” and “encourage change”, respectively. Glasgow¹⁵ stated that few details regarding team members were available in the 47 articles reviewed, with only 8 specifically mentioning that physicians

were directly involved in the project. They do mention that “[t]eams are typically multidisciplinary, including representatives from most groups that provide any direct patient care potentially impacted by the QI project”. Trakulsunti³⁰ found only 5 of their included studies on medication errors “mentioned project team members, without explaining the criteria to select such members and their responsibilities”.

The other methodologies reviewed included similar information about participants. Nadeem²³ found that Quality Improvement Collaboratives began with an in-person learning session “attended by the multidisciplinary quality improvement teams (QI teams) and led by Quality Improvement Collaborative expert faculty”. Follow-up was typically done with a combination of in-person learning sessions and phone meetings, both of which involved multiple sites. These multidisciplinary teams were named as such within their analysis, but the authors found the individual studies “did not always specify whether [the multidisciplinary teams] represented a range of positions within the organization’s hierarchy”. Additionally, these studies usually did not “describe the team members’ roles within the organization”. Finally, “[n]ine studies reported that the organization’s leadership was involved in the Quality Improvement Collaboratives, but it was unclear whether the organizational leadership was included on the QI team or was engaged through other means.” Only 6 total studies “reported that the QI team members trained additional staff in the organization.” Hulscher¹⁷ included some analysis of nursing engagement; however, this seemed more related to the inner setting of the Quality Improvement Collaboratives studied rather than nursing staff inclusion in the intervention team. Hill¹⁶ very generally documented whether or not included studies utilized multidisciplinary teams, finding “[m]ulti-disciplinary teams were used in 19 RCTs, with 8 RCTs not adequately describing membership of their teams. One RCT explicitly stated that they did not use an multi-disciplinary team approach.”

Setting and Process Characteristics Contributing to Success or Failure of CQI Frameworks

Multiple CQI frameworks

Ten articles^{11,17,19,30,31,34,38-40,42} discussed the inner setting of CQI frameworks. These articles reviewed Lean^{30,38,39,42} and Six Sigma frameworks,^{30,40} the CQI method,³¹ Quality Improvement Collaboratives,^{17,34} the CMS Approach,¹¹ or multiple strategies.¹⁹

Four groups^{30,39,40,42} named some inner setting aspects in their sections on facilitators and challenges for Lean and/or Six Sigma strategies, while 1 reviewing Lean Six Sigma and other strategies¹⁹ and 1 reviewing the CMS approach¹¹ also listed similar facilitators. Across these 6 papers, the general inner setting areas mentioned included IT systems, administrative support, staff engagement, organizational knowledge, physicians, knowledge of the methodology, training, management/leadership involvement, teamwork, and cultural issues. None of these papers, however, discussed how these facilitators could be cultivated within or across organizations or provided strong evidence of their influence on overall success or failure.

A few authors provided more discussion and context of inner setting. Mazzocato³⁸ found “similar methods were used in different settings to address problems and that they yielded concrete and easily implementable suggestions”. This finding suggests that systems have “either the existence of similar needs (eg, reduce excessive inventory, delays and waiting times) irrespective of setting” and that there may be “flexibility of the lean methods”. Notably, an organization’s

general approach and frontline/managerial structure matters, although no specific guidance on how to construct these theories and hierarchy were provided — “A team-based (collaborative) approach for systematic problem solving reinforces the understanding and values which can transform an error into a learning opportunity. When problem resolution required authority and information beyond that of the front-line staff, stable structures involving managers were effective”. Trakulsunti,³⁰ on the other hand, reviewed use of Lean and Six Sigma in medication errors and identified “lack of top management support and availability of data” as 2 of the biggest challenges to successful implementation of either strategy. The authors also identified 7 success factors — “understanding of Lean Six Sigma tools and techniques and its philosophy, top management support, training, staff engagement, leadership capability, appropriate team formation, or implementation infrastructure and cultural change” — without further specifying how they might be cultivated.

Non-Lean, non-Six Sigma strategies generally provided more in-depth analysis of inner setting. Tricco³¹ looked at specific strategies that were shown to statistically significantly improve HbA1c, some of which are facets of inner setting. The strategies included team changes, which were defined as changes to the structure or organization of the primary health care team such as adding a team member or multidisciplinary group, creation of patient registries, and case management. Unlike many other reviews, Zamboni³⁴ commented directly on inner setting and outcomes, finding “no conclusive evidence that facility size, voluntary or compulsory participation in the Quality Improvement Collaboratives programme, and baseline performance influence Quality Improvement Collaboratives outcomes”. They also found inconclusive evidence for the positive impact of “health facility readiness”, which included various factors such as health information systems and senior level commitment mentioned above. Mixed evidence was found for project-specific factors of external support and functionality of quality improvement teams. Hulscher¹⁷ examined 2 Quality Improvement Collaboratives papers discussing “engagement of nurses”, finding “four comparisons showed positive effects and seven comparisons showed no relationship”. Additionally, they looked at 3 papers invoking “previous quality-improvement experience” and found no relationship to success. Finally, they listed “Essential Features” similar to the 3 Lean Six Sigma studies on facilitators and barriers, finding mixed results or no effects on success in 4 papers examining “organisational readiness and commitment”, 6 on “leadership support”, 4 on “team climate”, 2 on “shared vision”, and 2 on alignment of goals. Three of their papers were performed across VA facilities on adverse drug events, patient safety, and falls, respectively. Two papers on VA Quality Improvement Collaboratives work showed, specifically, that “‘frontline staff support’ did not influence success”.

Certainty of Evidence for Key Question 2

Of the 20 studies included in the analysis for Key Question 2, 15 were rated using the modified AMSTAR2.^{10,11,13-17,19,23,27,28,30-32,34} The AMSTAR2 scores for these 15 reviews ranged from 3 to 11 points; 4^{11,14,16,31} of these studies 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 CQI methodology.

SUMMARY AND DISCUSSION

We sought to identify effective CQI interventions (Key Question 1) and conditions necessary for their success (Key Question 2) in a review of reviews.

Our systematic review of reviews is innovative in that it used a rigorous search and review methodology to include a breadth of systematic reviews on each of these Key Questions. Additionally, we evaluated the certainty of evidence for each Key Question using a modification of the AMSTAR2 tool for systematic reviews. No included reviews specifically addressed care of Veterans as a study objective nor were any conducted fully in VA settings, although several individual articles within the included systematic reviews were based at VA.

SUMMARY OF EVIDENCE BY KEY QUESTION

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 CQI strategies. However, we were only able to identify a single study¹ with an AMSTAR2 rating of 2 that met inclusion criteria. This study is over a decade old and found no evidence that any single CQI strategy was more effective than others. Instead, the authors concluded that local context should guide which framework is ultimately implemented.

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 study comparing the effectiveness of different CQI strategies, we then turned to assess 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 CQI 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 OR and ED, multiple different strategies have been used in different geographic locations. Several studies had AMSTAR2 ratings of at least 8; however, studies with higher AMSTAR2 scores did not draw more specific conclusions than studies with lower scores.

Similarly, none of the 7 reviews discussing sustainment of change identified a superior strategy. Additionally, no study directly commented on health care workers' reactions in being involved as part of CQI framework implementation, what health care workers learned or retained as part of CQI training, nor behavior changes noted after implementation of a CQI strategy.

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 CFIR factors. Ultimately, 20 reviews studied at least 1 CFIR factor; however, none compared the success or failure of different CQI strategies based on intervention characteristics, characteristics of individuals, or inner setting. Instead, the majority of studies listed aspects of some or each of these 3 CFIR categories deemed important for implementation of that CQI methodology with little to no supporting evidence. No study included in this review discussed whether either outer setting or specific processes during implementation of a CQI framework contributed to either the success or failure of implementation for any framework.

LIMITATIONS

Our review has a number of strengths, including a protocol-driven design, a comprehensive search, and careful quality assessment. Both our review and the literature, however, have limitations. Our review was limited to English-language publications, but the likelihood of identifying relevant data unavailable from English-language sources is low. Identified studies, with 1 exception, did not discuss comparative effectiveness, and none compared different methodologies for the other outcomes of interest. The single study explicitly discussing comparative effectiveness was identified via reference mining given its age. We chose to include this article, despite not making our publication date cut-off, as it was the only study we identified directly address the first Key Question. Similarly, one limitation of the review of reviews approach is an inability to closely align the inclusion criteria or scopes of the individual systematic reviews. Other limitations are detailed below.

Publication Bias

Multiple included systematic reviews noted the possibility of publication bias across the quality improvement methodologies, with positive results greatly outnumbering null or negative findings. Given our focus on systematic reviews for this study, quantitative publication bias analysis was not appropriate.

Quality of Included Reviews

We were also limited by the existing literature. We utilized a modified version of the AMSTAR2 tool for articles deemed appropriate for its use, finding 9 of 29 studies for which we were able to use the tool had a score of at least 8. These nine studies did not differ substantially in their conclusions from other articles included with lower AMSTAR2 scores. These low ratings on the AMSTAR2 tool leads us to conclude the overall certainty of evidence related to these reviews is low to moderate.

Reasons for the low AMSTAR2 scores of identified studies may include underlying issues with study design and implementation in the primary QI literature, as well as with study reporting. Most QI initiatives are designed and implemented in pragmatic clinical or operational settings, which may limit overall study quality for inclusion into a systematic review. Even when sufficient elements are included in QI projects, however, the elements may not be fully explained in subsequent manuscripts. Such issues may then be compounded in performing and reporting systematic reviews. In general, fewer than 40% of our included systematic reviews reported the following: specific comparators as an inclusion criteria (19%); PROSPERO registration (15%); explanation for inclusion of non-randomized controlled trial methodologies within the review (37%); duplicate data extraction (37%); justifications in a list or figure for exclusion of studies

(37%); results of comparators found in individual trials (4%); review for risk of bias of included studies (26%); and discussion of heterogeneity found (26%).

Applicability of Findings to the VA Population

Several studies included work done within VA as part of their larger reviews. Additionally, most reviews focused on studies performed in Organisation for Economic Co-operation and Development countries, which generally have well-funded health care systems and which improves applicability to VA. The only review mentioning comparative effectiveness was conducted in the United Kingdom and included reflections on the VA QUERI program. Across included reviews, there were limited data on intervention and setting characteristics to compare to the overall VA population. However, the findings presented here likely have applicability to any large health care system seeking to implement a multi-site improvement methodology.

Within VA, there are several ongoing initiatives that use CQI methodologies or frameworks with CQI elements, such as the Evidence-Based Quality Improvement (EBQI) Training Hub and The Learn. Engage. Act. Process. (LEAP) Program, in addition to the focus on Lean in systems redesign. These current efforts may not be represented universally in the published literature, nor were any of these initiatives specifically identified in the systematic reviews that comprised this review of reviews, limiting our ability to discuss comparisons with other strategies. However, these initiatives may provide opportunities for future comparative evaluations of CQI methods.

RESEARCH GAPS/FUTURE RESEARCH

This comprehensive review of the literature identified several gaps in the current evidence that warrant future investigation, even across studies with higher AMSTAR2 ratings. The most notable of these gaps is a lack of comparative studies analyzing multiple CQI methodologies within health care settings. Although such comparative examples may be identifiable in other fields, such as manufacturing, the complexity of healthcare processes, the differences in outcomes pertaining to health, and the variability in local contexts for implementation of QI methodologies within health care warrants creation of such studies. As noted above, current VA efforts from resources such as the EBQI or LEAP programs may provide opportunities to promote such comparative investigations. An alternative approach would be to attempt meta-analysis of multiple CQI methodologies with narrow questions in specific settings from the existing primary literature, such as waiting times in emergency departments. However, given the limitations of the systematic reviews in our review of reviews, such an initiative would likely require sharing and re-analysis of the primary data from the original studies.

The overall evidence base would be improved if future reported individual QI studies more closely adhered to SQUIRE 2.0 reporting standards.^{5,43} Similarly, future systematic reviews of these works would be stronger by considering the AMSTAR2 categories we found to be often lacking, such as specifying comparators as an inclusion criteria and sharing the results of comparators from individual trials, PROSPERO registration, and explicitly discussing risk of bias.

CONCLUSIONS

Prior systematic reviews of CQI strategies have, with 1 exception, not 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, making the overall certainty of evidence low. Additionally, few data are available regarding sustainment of changes made through CQI and no systematic reviews we identified discussed health care workers' reactions, learning, or behavior changes related to participating in CQI. Similarly, no systematic reviews compared the success or failure of different CQI 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 CQI 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 CQI strategy is superior to others or how any such methodology should be implemented at large scale within the VA context. Future work should emphasize comparative designs for CQI methodologies. Available resources at VA may help facilitate such work in the future.

REFERENCES

1. Powell A, Rushmer R, Davies H. A systematic review of quality improvement models in health care. *NHS Quality Improvement Scotland*. 2008.
2. Rubenstein L, Khodyakov D, Hempel S, et al. How can we recognize continuous quality improvement? *Int J Qual Health Care*. 2014;26(1):6-15.
3. Hill JE, Stephani AM, Sapple P, Clegg AJ. The effectiveness of continuous quality improvement for developing professional practice and improving health care outcomes: a systematic review. *Implement Sci*. 2020;15(1):23.
4. Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*. 2017;358:j4008.
5. Rubenstein LV, Hempel, S., Liu, J.L., Danz, M.J., Foy, R., Lim, Y.W., Motala, A. and Shekelle, P.G. The Minimum Quality Criteria Set (QI-MQCS) for critical appraisal: advancing the science of quality improvement. *Implementation Science: IS*. 2015;10:A19.
6. King N. Template analysis. 1998.
7. Damschroder LJ, Aron, D.C., Keith, R.E. et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*. 2009;4(50).
8. Aij KH, Teunissen M. Lean leadership attributes: a systematic review of the literature. *J Health Organ Manag*. 2017;31(7-8):713-729.
9. Amaratunga T, Dobranowski J. Systematic Review of the Application of Lean and Six Sigma Quality Improvement Methodologies in Radiology. *J Am Coll Radiol*. 2016;13(9):1088-1095.e1087.
10. Bucci S, de Belvis AG, Marventano S, et al. Emergency Department crowding and hospital bed shortage: is Lean a smart answer? A systematic review. *Eur Rev Med Pharmacol Sci*. 2016;20(20):4209-4219.
11. Côté A, Beogo I, Abasse KS, Laberge M, Dogba MJ, Dallaire C. The clinical microsystems approach: Does it really work? A systematic review of organizational theories of health care practices. *J Am Pharm Assoc (2003)*. 2020;60(6):e388-e410.
12. DelliFraine JL, Langabeer JR, II, Nembhard IM. Assessing the evidence of Six Sigma and Lean in the health care industry. *Qual Manag Health Care*. 2010;19(3):211-225.
13. DelliFraine JL, Zheng W, McCaughey D, Langabeer Ii JR, Erwin C. The Use of Six Sigma in Health Care Management: Are We Using It to Its Full Potential? *Qual Manag Health Care*. 2013;22(3):210-223.
14. Dzidowska M, Lee KSK, Wylie C, et al. A systematic review of approaches to improve practice, detection and treatment of unhealthy alcohol use in primary health care: a role for continuous quality improvement. *BMC Fam Pract*. 2020;21(1):33.
15. Glasgow JM, Scott-Caziewell JR, Kaboli PJ. Guiding inpatient quality improvement: a systematic review of Lean and Six Sigma. *Jt Comm J Qual Patient Saf*. 2010;36(12):533-540.
16. Hill JE, Stephani A-M, Sapple P, Clegg AJ. The effectiveness of continuous quality improvement for developing professional practice and improving health care outcomes: a systematic review. *Implement Sci*. 2020;15(1):23.
17. Hulscher MEJL, Schouten LMT, Grol RPTM, Buchan H. Determinants of success of quality improvement collaboratives: what does the literature show? *BMJ Qual Saf*. 2013;22(1):19-31.

18. Mousavi Isfahani H, Tourani S, Seyedin H. Features and Results of Conducted Studies Using a Lean Management Approach in Emergency Department in Hospital: A Systematic Review. *Bull Emerg Trauma*. 2019;7(1):9-20.
19. Leggat SG, Bartram T, Stanton P, Bamber GJ, Sohal AS. Have process redesign methods, such as Lean, been successful in changing care delivery in hospitals? A systematic review. *Public Money & Management*. 2015;35(2):161-168.
20. Pestana Magalhães AL, Erdmann AL, Lima da Silva E, Guedes dos Santos JL. Lean thinking in health and nursing: an integrative literature review. *Revista Latino-Americana de Enfermagem (RLAE)*. 2016;24:1-13.
21. Mason SE, Nicolay CR, Darzi A. The use of Lean and Six Sigma methodologies in surgery: a systematic review. *Surgeon*. 2015;13(2):91-100.
22. Moraros J, Lemstra M, Nwankwo C. Lean interventions in healthcare: do they actually work? A systematic literature review. *Int J Qual Health Care*. 2016;28(2):150-165.
23. Nadeem E, Olin SS, Hill LC, Hoagwood KE, Horwitz SM. Understanding the components of quality improvement collaboratives: a systematic literature review. *Milbank Q*. 2013;91(2):354-394.
24. Nicolay CR, Purkayastha S, Greenhalgh A, et al. Systematic review of the application of quality improvement methodologies from the manufacturing industry to surgical healthcare. *Br J Surg*. 2012;99(3):324-335.
25. Nunes JW, Seagull FJ, Rao P, Segal JH, Mani NS, Heung M. Continuous quality improvement in nephrology: a systematic review. *BMC Nephrol*. 2016;17(1):190.
26. Schouten LM, Hulscher ME, van Everdingen JJ, Huijsman R, Grol RP. Evidence for the impact of quality improvement collaboratives: systematic review. *BMJ*. 2008;336(7659):1491-1494.
27. Talib F, Rahman Z, Azam M. Best practices of total quality management implementation in health care settings. *Health Mark Q*. 2011;28(3):232-252.
28. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. *BMJ Qual Saf*. 2014;23(4):290-298.
29. Tlapa D, Zepeda-Lugo CA, Tortorella GL, et al. Effects of Lean Healthcare on Patient Flow: A Systematic Review. *Value Health*. 2020;23(2):260-273.
30. Trakulsunti Y, Antony J, Ghadge A, Gupta S. Reducing medication errors using LSS methodology: A systematic literature review and key findings. *Total Quality Management and Business Excellence*. 2018:1-19.
31. Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis. *Lancet*. 2012;379(9833):2252-2261.
32. Wackerbarth SB, Bishop SS, Aroh AC. Lean in Healthcare: Time for Evolution or Revolution? *Journal for Healthcare Quality: Promoting Excellence in Healthcare*. 2021;43(1):32-38.
33. Woodnutt S. Is Lean sustainable in today's NHS hospitals? A systematic literature review using the meta-narrative and integrative methods. *Int J Qual Health Care*. 2018;30(8):578-586.
34. Zamboni K, Baker U, Tyagi M, Schellenberg J, Hill Z, Hanson C. How and under what circumstances do quality improvement collaboratives lead to better outcomes? A systematic review. *Implement Sci*. 2020;15(1):27.

35. Zepeda-Lugo C, Tlapa D, Baez-Lopez Y, et al. Assessing the Impact of Lean Healthcare on Inpatient Care: A Systematic Review. *Int J Environ Res Public Health*. 2020;17(15).
36. Crema M, Verbano C. Lean Management to support Choosing Wisely in healthcare: the first evidence from a systematic literature review. *Int J Qual Health Care*. 2017;29(7):889-895.
37. Maijala R, Eloranta S, Reunanen T, Ikonen TS. SUCCESSFUL IMPLEMENTATION OF LEAN AS A MANAGERIAL PRINCIPLE IN HEALTH CARE: A CONCEPTUAL ANALYSIS FROM SYSTEMATIC LITERATURE REVIEW. *Int J Technol Assess Health Care*. 2018;34(2):134-146.
38. Mazzocato P, Savage C, Brommels M, Aronsson H, Thor J. Lean thinking in healthcare: a realist review of the literature. *Qual Saf Health Care*. 2010;19(5):376-382.
39. D'Andreamatteo A, Ianni L, Lega F, Sargiacomo M. Lean in healthcare: A comprehensive review. *Health Policy*. 2015;119(9):1197-1209.
40. Antony J, Palsuk P, Gupta S, Mishra D, Barach P. Six Sigma in healthcare: a systematic review of the literature. *International Journal of Quality & Reliability Management*. 2018.
41. Niñerola A, Sánchez-Rebull M-V, Hernández-Lara A-B. Quality improvement in healthcare: Six Sigma systematic review. *Health Policy*. 2020;124(4):438-445.
42. Andersen H, Røvik KA, Ingebrigtsen T. Lean thinking in hospitals: is there a cure for the absence of evidence? A systematic review of reviews. *BMJ Open*. 2014;4(1):e003873.
43. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf*. 2016;25(12):986-992.