Development of the Quality Improvement Minimum Quality Criteria Set (QI-MQCS): a tool for critical appraisal of quality improvement intervention publications

Susanne Hempel,1 Paul G Shekelle,1,2 Jodi L Liu,1 Margie Sherwood Danz,1,3 Robbie Foy,4 Yee-Wei Lim,5 Aneesa Motala,1 Lisa V Rubenstein1,3,6

ABSTRACT
Objective Valid, reliable critical appraisal tools advance quality improvement (QI) intervention impacts by helping stakeholders identify higher quality studies. QI approaches are diverse and differ from clinical interventions. Widely used critical appraisal instruments do not take unique QI features into account and existing QI tools (eg, Standards for QI Reporting Excellence) are intended for publication guidance rather than critical appraisal. This study developed and psychometrically tested a critical appraisal instrument, the QI Minimum Quality Criteria Set (QI-MQCS) for assessing QI-specific features of QI publications.

Methods Approaches to developing the tool and ensuring validity included a literature review, in-person and online survey expert panel input, and application to empirical examples. We investigated psychometric properties in a set of diverse QI publications (N=54) by analysing reliability measures and item endorsement rates and explored sources of disagreement between reviewers.

Results The QI-MQCS includes 16 content domains to evaluate QI intervention publications: Organisational Motivation, Intervention Rationale, Intervention Description, Organisational Characteristics, Implementation, Study Design, Comparator Description, Data Sources, Timing, Adherence/Fidelity, Health Outcomes, Organisational Readiness, Penetration/Reach, Sustainability, Spread and Limitations. Median inter-rater agreement for QI-MQCS items was κ=0.57 (83% agreement). Item statistics indicated sufficient ability to differentiate between publications (median quality criteria met 67%). Internal consistency measures indicated coherence without excessive conceptual overlap (absolute mean interitem correlation=0.19). The critical appraisal instrument is accompanied by a user manual detailing What to consider, Where to look and How to rate.

Conclusions We developed a ready-to-use, valid and reliable critical appraisal instrument applicable to healthcare QI intervention publications, but recognise scope for continuing refinement.

INTRODUCTION
Quality improvement (QI) interventions account for substantial investments by organisations aiming to improve healthcare quality, and a large volume of literature documents these efforts.1 QI research necessarily reflects work with organisational context and local environments. QI interventions tend to be complex, multi-component, often uniquely tailored to settings, and may evolve over time.1,2 Intervention details, context and information on the QI process are critical to evaluate the success of QI interventions.

To address the unique requirements of QI research, the Standards for QI Reporting Excellence (SQUIRE) group has developed detailed guidance for reporting evaluations of QI interventions.3 The reporting guideline helps authors describe QI interventions so that they can be identified as such in electronic databases. It aims
to ensure readers can understand and appraise the intervention and its evaluation by identifying for authors the details they need to report. However, tools are also needed to guide the critical appraisal of published QI studies. Critical appraisal assesses the quality of publications, informs decisions about applicability of results, and aims to identify high-quality published studies. While reporting guidelines can be aspirational and comprehensive because they are designed for future publications, critical appraisal tools must be applicable to the wide range of completed studies and concentrate on key assessment domains if they are to be useful in practice.

Researchers have frequently questioned the methodological quality of QI studies. However, tools widely used for the critical appraisal of clinical interventions, such as the Cochrane Risk of Bias tool, may not encompass the domains most relevant to QI research. The lack of a QI-specific focus can limit the ability of researchers, practitioners and policy makers to identify—and learn from—higher quality QI studies.

We have developed the QI Minimum Quality Criteria Set (QI-MQCS) to appraise the quality of QI-specific aspects of QI publications. The QI-MQCS is intended as a resource for reviewers, assisting in synthesising the vast available evidence on QI interventions, and providing a framework for critical appraisal in this complex research area. This article describes the development and evaluation of the QI-MQCS.

METHODS

Our international workgroup of QI and systematic review experts (subsequently called ‘workgroup’) followed a structured process to develop and evaluate the QI-MQCS. We used a broad and inclusive definition of QI interventions to ensure the QI-MQCS applies to a variety of efforts to change/improve the clinical structure, process and/or outcomes of care by means of an organisational or structural change.

The QI-MQCS reflects core domains developed through literature review, inputs from QI experts and stakeholders, and item development through iterative application to empirical studies. Formal reliability testing and reviewer guidance were used to enable consistent and replicable scoring. We designed the QI-MQCS items to be modest in number to ensure scoring feasibility, have strong face validity with QI stakeholders, meet psychometric standards to enable reliable assessment, avoid repeating internal validity items from study-design specific appraisal tools and applicable to a wide range of QI publications.

The following describes the development of the domains (the content the QI-MQCS aims to cover), the operationalisation as QI-MQCS items (the concrete appraisal questions and scoring criteria), the available tools and resources (the QI-MQCS form and manual) and the psychometric evaluation of the QI-MQCS.

Domain development

To ensure that the QI-MQCS represents the breadth of relevant domains, we first reviewed a wide range of existing tools. We assessed widely endorsed general and specific critical appraisal tools; reporting guidelines for QI and study design-specific guidelines; relevant frameworks such as Reach Effectiveness Adoption Implementation Maintenance; and the Medical Research Council (MRC) Guidance for Complex Interventions. Relevant resources were identified through a PubMed literature search for critical appraisal and QI; screening EQUATOR-network.com; critical appraisal resources provided by the Center for Reviews and Dissemination, the Evidence-based Practice Center programme of the Agency for Healthcare Research and Quality, the Oxford Centre for Evidence Based Medicine, the National Institute for Health and Care Excellence, and the Cochrane Effective Practice and Organisation of Care (EPOC) Review Group; and existing systematic reviews of critical appraisal and evidence level hierarchies. In addition, workgroup members assessed all 57 SQUIRE items for their relevance to a critical appraisal instrument. They rated 22 items as important or very important, for example ‘Describes the intervention and its component parts in sufficient detail that others could reproduce it’ and ‘Identifies the study design chosen for measuring impact of the intervention on primary and secondary outcomes’, but rated many other aspects of the reporting guideline as less important (eg, ‘Title states the specific aim of the intervention’, ‘Discussion relates results to other evidence’).

A consensus panel of international technical experts and key stakeholders in QI interventions, informed by the literature review and SQUIRE survey results, established the QI-MQCS domains. We elicited the input of this technical expert panel (TEP) through online surveys and in person meetings. The project aim was to establish a feasible instrument that covers core QI domains rather than compiling an exhaustive list of potentially relevant or intervention-specific elements. An overarching conclusion of the content discussions was that the QI-MQCS should address domains that complement, rather than replace, instruments addressing the internal validity of study designs.

Operationalisation

The workgroup operationalised the domains as a critical appraisal instrument. Items were iteratively developed to capture the content of the domains and to enable reliable scoring of published articles. We included a domain description (eg, ‘Rationale linking the intervention to its expected effects’), guide (eg, ‘Consider citations of theories, logic models, or existing empirical evidence that link the intervention to its expected effects’), and minimum standard for each quality criterion (‘Names or describes a rationale linking at least one central intervention component to
intended effects’). This process involved translating conceptual constructs (eg, ‘Penetration/Reach’) and phrases open to interpretation (eg, ‘Intervention and its component parts described in sufficient detail that others could reproduce it’) into practical scoring rules (‘Describes the proportion of all eligible units that actually participated’; ‘Describes at least one specific change in detail including the personnel executing the intervention’). We sought to avoid conceptual overlap, so that scoring of one domain would not influence other domain scores. We refined the criteria by applying them to empirical examples of the literature.

Throughout the process, we held discussions with key informants and drew upon examples of empirical literature to define the domains and standards for published QI evaluations. We sought input from QI researchers, QI practitioners and systematic reviewers experienced in QI literature syntheses. We applied all suggested critical appraisal domains, reviewer guidance and scoring criteria to empirical examples of existing QI publications to establish the QI-MQCS.

### Tools and resources
We designed a form that translates the established domains into critical appraisal items with a dichotomous answer mode and scoring criteria to help reviewers decide whether a minimum quality standard is met. In addition, we adopted the Appraisal of Guidelines for Research and Evaluation structure to provide detailed guidance for QI-MQCS users. The Description defines the domain, What to Consider lists aspects relevant to the domain, Where to Look directs users to where the information is typically found in publications and How to Rate guides item scoring. The guidance provides illustrative article excerpts relevant to each domain.

### Psychometric evaluation
To test the psychometric properties of the QI-MQCS, we used a validated QI search strategy to identify an empirical sample of diverse published QI and continuous QI intervention studies indexed in PubMed. The strategy combined QI and continuous QI, QI intervention components and EPOC-eligible interventions search terms. We screened the search output to identify publications evaluating the effects of QI interventions. We applied our working definition of QI by using four broad criteria to select relevant studies: healthcare delivery organisation context; reporting data on the effectiveness, impacts or success of an intervention; reporting patient, caregiver, provider behaviour, or process of care outcomes; and interventions aiming to change how delivery of care is routinely structured. The interventions in the 54 studies included in the QI-MQCS evaluation data set focused on restructuring of departments and teams, checklists or audit and feedback to increase preventive services and performance indicators, shared medical appointments, pain management programmes, fall management and restraint prevention programmes, staff training and education restructuring, hospital care and diagnostic procedure redesigns, clinical guidelines, medication management models, incentive programmes to increase patient access, computerised registers, discharge planning, antenatal care restructuring, and telehealth.

Two reviewers agreed on the main intervention and outcome for each publication prior to quality appraisal; if publications referred to additional publications on the same study, we obtained them as well. Studies were reviewed by two independent reviewers in batches of nine and then reconciled, mirroring a systematic review process that uses independent reviewers and reviewer reconciliation to reduce reviewer errors and bias. In cases where we had to revise items to incorporate additional guidance, we discarded previous ratings. Psychometric results shown below reflect the final version of the QI-MQCS.

We analysed the answer frequency for each item (item endorsement rate: number of publications meeting the criterion in the sample) based on ratings reconciled across two reviewers. We measured two aspects of reliability: rater agreement and internal consistency. Agreement was measured through Cohen’s κ and the per cent agreement of two independent reviewers before reconciliation. We assessed internal consistency and conceptual overlap across the QI-MQCS domains through interitem correlations across the 16 assessed items, across all assessed publications, and based on reconciled reviewer ratings (correlating each item score with all other item scores to quantify the empirical associations between individual items). Finally we identified sources of disagreement for each of the assessed publications.

### RESULTS

#### QI-MQCS content
The QI-MQCS addresses the following domains: Organisational Motivation, Intervention Rationale, Intervention Description, Organisational Characteristics, Implementation, Study Design, Comparator, Data Source, Timing, Adherence/Fidelity, Health Outcomes, Organisational Readiness, Penetration/Reach, Sustainability, Spread and Limitations. Table 1 describes each domain and table 2 shows the TEP’s ratings of the importance of each domain (face validity).

Organisational Motivation assesses whether the motivational context of the organisation in which the intervention was introduced was described; for example to convey whether a given quality problem—such as shortcomings in quality of care indicators—was being addressed. Intervention Rationale assesses whether a rationale was given that suggests why the intervention may produce improvements in the outcome (empirical evidence, theories or logic models).
Table 1  Quality Improvement Minimum Quality Criteria Set (QI-MQCS) domains

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Organisational motivation</td>
<td>Organisational problem, reason or motivation for the intervention</td>
</tr>
<tr>
<td>2. Intervention rationale</td>
<td>Rationale linking the intervention to its expected effects</td>
</tr>
<tr>
<td>3. Intervention description</td>
<td>Change in organisational or provider behaviour</td>
</tr>
<tr>
<td>4. Organisational characteristics</td>
<td>Demographics or basic characteristics of the organisation</td>
</tr>
<tr>
<td>5. Implementation</td>
<td>Temporary activities used to introduce potentially enduring changes</td>
</tr>
<tr>
<td>6. Study design</td>
<td>Study design and comparator</td>
</tr>
<tr>
<td>7. Comparator</td>
<td>Information about comparator care processes</td>
</tr>
<tr>
<td>8. Data source</td>
<td>Data sources and outcome definition</td>
</tr>
<tr>
<td>9. Timing</td>
<td>Timing of intervention and evaluation</td>
</tr>
<tr>
<td>10. Adherence/fidelity</td>
<td>Adherence to the intervention</td>
</tr>
<tr>
<td>11. Health outcomes</td>
<td>Patient health-related outcomes</td>
</tr>
<tr>
<td>12. Organisational readiness</td>
<td>Barriers and facilitators to readiness</td>
</tr>
<tr>
<td>13. Penetration/reach</td>
<td>Penetration/reach of the intervention</td>
</tr>
<tr>
<td>14. Sustainability</td>
<td>Sustainability of the intervention</td>
</tr>
<tr>
<td>15. Spread</td>
<td>Ability to be spread or replicated</td>
</tr>
<tr>
<td>16. Limitations</td>
<td>Interpretation of the evaluation</td>
</tr>
</tbody>
</table>

**Intervention Description** requires a detailed description of the change in the structure or organisation of healthcare, including personnel involved. QI interventions are diverse and may address changes in care processes (eg, use of care managers) or strategies aiming to change provider behaviour (eg, electronic reminders), and the content (eg, avoiding catheter-related blood stream infections), and the means to achieve the goal (eg, audit and feedback) are often intertwined. We restricted the definition to permanent structural or organisational changes, not temporary activities aiming to develop or introduce the change. This domain had the highest rating in the assessment of the domain importance shown in table 2.

**Organisational Characteristics** assesses whether key demographics of the setting are described to provide information that enables readers to assess the generalisability to their organisation.

**Implementation** addresses temporary activities used to introduce the permanent change, for example, staff education to introduce a new care protocol. The QI-MQCS focuses here on the introduction of the intervention into clinical practice, not its development.

**Study Design** assesses whether the evaluation design to determine whether the intervention was successful was identified. Acknowledging that different questions require different study designs, the quality emphasis is on outlining the evaluation approach, not on specific designs or features (eg, randomisation).

**Comparator** assesses the control condition to which the intervention is compared, for example, routine care before the intervention was introduced. We added this item, most prominently described in the Workgroup for Intervention Development and Evaluation Research (WIDER) criteria, in response to TEP discussions and empirical evidence. Given that healthcare contexts are continually evolving, it is important to know whether the comparison group comprised current 'state-of-the-art' or

<table>
<thead>
<tr>
<th>#</th>
<th>Domain</th>
<th>Panel item</th>
<th>Mean rating*</th>
<th>% Criterion met</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Organisational motivation</td>
<td>Description of the organisational problem/reason or motivation for intervention</td>
<td>2.78</td>
<td>64</td>
</tr>
<tr>
<td>2</td>
<td>Intervention rationale</td>
<td>Description of rationale linking the intervention to expected effects</td>
<td>2.78</td>
<td>67</td>
</tr>
<tr>
<td>3</td>
<td>Intervention</td>
<td>Description of specific changes in healthcare delivery organisation/structure</td>
<td>3.00</td>
<td>93</td>
</tr>
<tr>
<td>4</td>
<td>Organisational characteristics</td>
<td>Description of organisational demographics and basic characteristics</td>
<td>2.89</td>
<td>89</td>
</tr>
<tr>
<td>5</td>
<td>Implementation</td>
<td>Description of the approach to designing and/or introducing organisational changes</td>
<td>2.89</td>
<td>92</td>
</tr>
<tr>
<td>6</td>
<td>Study design</td>
<td>Description of study design</td>
<td>2.89</td>
<td>44</td>
</tr>
<tr>
<td>7</td>
<td>Comparator</td>
<td>n/a</td>
<td>n/a</td>
<td>67</td>
</tr>
<tr>
<td>8</td>
<td>Data source</td>
<td>n/a</td>
<td>n/a</td>
<td>67</td>
</tr>
<tr>
<td>9</td>
<td>Timing</td>
<td>Description of timing (intervention components introduction and evaluation)</td>
<td>2.78</td>
<td>56</td>
</tr>
<tr>
<td>10</td>
<td>Adherence/fidelity</td>
<td>Description of intervention adherence/fidelity</td>
<td>2.78</td>
<td>47</td>
</tr>
<tr>
<td>11</td>
<td>Health outcomes</td>
<td>Description of health-related outcomes</td>
<td>2.33</td>
<td>58</td>
</tr>
<tr>
<td>12</td>
<td>Organisational readiness</td>
<td>Description of organisational readiness for the studied intervention</td>
<td>2.00</td>
<td>84</td>
</tr>
<tr>
<td>13</td>
<td>Penetration/reach</td>
<td>Description of intervention penetration/reach</td>
<td>2.56</td>
<td>85</td>
</tr>
<tr>
<td>14</td>
<td>Sustainability</td>
<td>Description of potential for intervention maintenance or sustainability</td>
<td>2.22</td>
<td>83</td>
</tr>
<tr>
<td>15</td>
<td>Spread</td>
<td>Description of ability to be spread or replicated</td>
<td>2.11</td>
<td>89</td>
</tr>
<tr>
<td>16</td>
<td>Limitations</td>
<td>Quality of the interpretation of findings</td>
<td>2.56</td>
<td>64</td>
</tr>
</tbody>
</table>

*Members (N=9) of an international TEP assessed independently whether the domain should (score=3), should maybe (score=2) or should not (score=1) be part of the Quality Improvement Minimum Quality Criteria Set (QI-MQCS). The respondents were instructed that the goal was to identify a minimum number of core domains; n/a: not applicable, the items were developed as a response to panel input.

†Percentage of publications meeting the criterion in psychometric evaluation sample (total N=54 publications, number of observations ranged from 18 to 45 as only the final item version was included in the analysis).
poor quality care. Data Source considers how data were obtained for the evaluation and whether the primary outcome was defined; conveying what exactly was measured should avoid a ‘false implicit understanding’ of terms and definitions24 and is independent from the study design selected for the evaluation.

Timing addresses the clarity of the timeline in relation to the evaluation of the intervention, for example, when a complex change was fully implemented and when evaluated, in order to determine the follow-up period. Adherence/fidelity addresses compliance with the intervention. QI interventions can be introduced with enthusiasm, but whether personnel actually adhere to them (eg, a new assessment tool) in busy routine clinical practice is another matter. Readers need to be able to judge whether any intervention failure was attributable to the intervention itself, suboptimal translation in clinical practice, or a combination of both. Any information on adherence (including the lack thereof) is acknowledged in assessing this domain.

Health Outcomes considers whether patient health outcomes are part of the evaluation. Although an intervention may result in changes in healthcare processes (eg, tests ordered), they may not necessarily improve patient outcomes. The QI-MQCS acknowledges studies that assess this crucial patient-centered question. Organisational Readiness refers to the QI culture and resources present in the organisation, which helps to assess the transferability of results. The TEP did not express strong unanimous support for including this item (table 2).

Penetration/reach assesses what proportion of eligible units participated. This domain requires a denominator; stating the number of participating sites without also reporting how many sites were initially approached or were eligible is not sufficient. Sustainability addresses whether information on the sustainability of the intervention is available; including positive evidence (eg, an extended intervention period) or acknowledgment that the intervention may be maintained only with additional resources.

Spread addresses the ability of the intervention to be spread to or replicated in other settings. The minimum quality standard is met if the potential or unsuccessful attempts at spread or positive evidence of spread (eg, large-scale rollouts) are presented. Limitation refers to disclosed limitations of the evaluation of the intervention.

Online supplementary appendix 1 shows the QI-MQCS, a ready-to-use form for critical appraisal. Online supplementary appendix 2, a user manual developed for the QI-MQCS, provides detailed information on each domain and scoring criteria, including What to consider, Where to look and How to rate.

Psychometric properties
The item endorsement rates (criterion met) ranged between 44% and 93% (table 2) with a median rate of 67% indicating that the QI-MQCS items were able to differentiate between high and low quality studies in an empirical sample of QI publications. Two items were endorsed in more than 90% of assessed QI publications (Intervention Description and Implementation).

The median inter-rater agreement between two independent reviewers across all items was $\kappa=0.52$ and 82% agreement (table 3). Coefficients ranged from $\kappa=0.09$ (Adherence/fidelity) to $\kappa=0.82$ (Sustainability) with corresponding per cent agreement values of 56% and 74%. Agreement for 81% of items was fair to good; the items Timing, Adherence/fidelity and Spread were below $\kappa=0.40$. Sources of disagreements between reviewers are documented in table 4 and encompassed omissions (ie, a reviewer overlooked reported information), the interpretation of the reported information (eg, associated with disagreements in Adherence/fidelity) and the interpretation of criteria (ie, sufficient to meet the criterion).

The mean interitem correlation across all QI-MQCS items in the empirical sample of QI publications was 0.08 (mean absolute interitem correlation 0.19) and all individual interitem correlations were below 0.67. Results indicated conceptual independence between criteria (discriminant validity); items showed some coherence but not identity of assessed domains. Correlations of 0.61 to 0.66 were found for the domains Intervention Description and Data source, Implementation and Organisational Readiness, and Data Source correlated with Penetration/Reach as well as Limitations.

### Table 3 Inter-rater agreement Quality Improvement Minimum Quality Criteria Set (QI-MQCS)

<table>
<thead>
<tr>
<th>#</th>
<th>Domain</th>
<th>n</th>
<th>$\kappa$ (95% CI)</th>
<th>% agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Organisational motivation</td>
<td>45</td>
<td>0.46 (0.19 to 0.73)</td>
<td>0.76</td>
</tr>
<tr>
<td>2</td>
<td>Intervention rationale</td>
<td>18</td>
<td>0.61 (0.21 to 1.00)</td>
<td>0.83</td>
</tr>
<tr>
<td>3</td>
<td>Intervention</td>
<td>27</td>
<td>0.65 (0.02 to 1.28)</td>
<td>0.96</td>
</tr>
<tr>
<td>4</td>
<td>Organisational characteristics</td>
<td>45</td>
<td>0.49 (0.17 to 0.82)</td>
<td>0.84</td>
</tr>
<tr>
<td>5</td>
<td>Implementation</td>
<td>36</td>
<td>0.62 (0.23 to 1.01)</td>
<td>0.92</td>
</tr>
<tr>
<td>6</td>
<td>Study design</td>
<td>45</td>
<td>0.73 (0.53 to 0.93)</td>
<td>0.87</td>
</tr>
<tr>
<td>7</td>
<td>Comparator description</td>
<td>54</td>
<td>0.40 (0.14 to 0.65)</td>
<td>0.72</td>
</tr>
<tr>
<td>8</td>
<td>Data source</td>
<td>18</td>
<td>0.87 (0.62 to 1.12)</td>
<td>0.94</td>
</tr>
<tr>
<td>9</td>
<td>Timing</td>
<td>54</td>
<td>0.39 (0.15 to 0.63)</td>
<td>0.70</td>
</tr>
<tr>
<td>10</td>
<td>Adherence/fidelity</td>
<td>36</td>
<td>0.09 (−0.22 to 0.40)</td>
<td>0.56</td>
</tr>
<tr>
<td>11</td>
<td>Health-related outcomes</td>
<td>45</td>
<td>0.64 (0.42 to 0.87)</td>
<td>0.82</td>
</tr>
<tr>
<td>12</td>
<td>Organisational readiness</td>
<td>45</td>
<td>0.45 (0.14 to 0.76)</td>
<td>0.82</td>
</tr>
<tr>
<td>13</td>
<td>Penetration/reach</td>
<td>27</td>
<td>0.52 (0.18 to 0.85)</td>
<td>0.81</td>
</tr>
<tr>
<td>14</td>
<td>Sustainability</td>
<td>18</td>
<td>0.82 (0.49 to 1.15)</td>
<td>0.94</td>
</tr>
<tr>
<td>15</td>
<td>Spread</td>
<td>27</td>
<td>0.13 (−0.23 to 0.48)</td>
<td>0.67</td>
</tr>
<tr>
<td>16</td>
<td>Limitations</td>
<td>45</td>
<td>0.77 (0.58 to 0.96)</td>
<td>0.89</td>
</tr>
</tbody>
</table>

$\kappa$, Cohen’s $\kappa$; $n$, Number of assessed publications.
Table 4  Sources of reviewer disagreements

<table>
<thead>
<tr>
<th>Source of disagreement</th>
<th>Source description</th>
<th>Literature examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omissions</td>
<td>Some disagreements were associated with simple reviewer mistakes, that is, one reviewer overlooking reported information</td>
<td>Several disagreements were simply due to one reviewer overlooking reported information and did not seem to follow any pattern (random errors). However, the low agreement in the Spread domain seemed to have, in parts, to do with information being ‘buried’ in the discussion section. Omission-based disagreement was also encountered repeatedly for the domain Organisational characteristics, due to information not being reported in the main manuscript text but elsewhere, for example in the author’s biography. The low agreement in the domain Adherence/fidelity was to some extent associated with publications where adherence was the main outcome or the outcome and the intervention were identical (eg, guideline implementation to improve adherence to evidence-based practices). A further example was whether reviewers considered a state-wide initiative sufficient to infer the motivation to participate for all included hospitals. Multiple site studies often do not provide information on individual facilities and studies in low-income countries may have had an initiating body that was not a healthcare delivery organisation and reviewers disagreed to which extent they extrapolated from the presented information to individual organisations. Disagreements in the Health Outcome domain were associated with the type of outcome and how systematically data were collected in order to be recognised as a health outcome/data. Identified disagreement in the domain Intervention Rationale was associated with publications where only highly selective intervention components were linked to existing empirical literature and reviewers disagreed whether the specific aspect was sufficient to meet the criterion. Disagreements in the Comparator domain were associated with the question of how much detail was considered sufficient to meet the quality criterion, for example, if only a component of the usual care was described. Disagreements also occurred when publications described a structural change without information on the uptake, for example, an installation of a comfort room for patients—but whether the room was used in clinical practice was not reported; hence reviewers had to decide whether the intervention was the installation of the room or the use of the room.</td>
</tr>
<tr>
<td>Interpretation of reported information</td>
<td>Some disagreements were associated with the interpretation of the information that was reported in the publication</td>
<td>Examples taken from validation sample (N=54 publications), rater agreement is documented in table 3. Mistakes (omissions) as well as remaining ambiguity (interpretation of reported information and interpretation of criteria) were sources of disagreement between literature reviewers. A qualitative analysis of the disagreements pointed to some systematic, rather than random, reviewer errors.</td>
</tr>
</tbody>
</table>
| Interpretation of criteria | Despite the careful, iterative development of the tool, some disagreements were associated with the interpretation of the scoring criteria. Given the large scope of interventions included in the test set, some ambiguities could not be resolved | DISCUSSION

The QI-MQCS is a critical appraisal instrument that assesses 16 expert-endorsed QI domains applicable to a wide range of QI studies. Its scoring guidance facilitates use by different raters with known psychometric properties. A structured critical appraisal instrument development process ensured feasibility, validity and reliability.

The QI-MQCS development included a comprehensive literature search to ensure content validity and iterative development of the operationalisation of domains applied to existing, published QI literature to ensure construct validity. The empirical test of the QI-MQCS shows sufficient ability to discriminate between studies, indicating that the QI-MQCS avoids items representing unattainable standards but includes items that discriminate quality across an empirical sample of publications. Furthermore, the QI-MQCS does not show excessive conceptual overlap across domains, and none of the items shows redundancy with content already captured through other items. Agreement between two independent reviewers was fair to good in a diverse sample of a complex research field.

Despite the careful, iterative development of items and scoring criteria, some domains showed limited rater agreement, such as adherence/fidelity and spread. Future work is warranted to test the reliability in a narrower set of interventions, for example, those included in typical systematic reviews, or to develop the criteria further in order to achieve better consensus. However, the QI-MQCS compared favourably to some other commonly used tools, such as the Cochrane Risk of Bias tool. Plus, few published
quality assessment tools have been tested for their psychometric properties. Reviewer disagreements may be easier to anticipate and to avoid in a more restricted sample, for example, one that is limited to a set of selected QI interventions.

QI stakeholders agree on the pressing need for better research and better literature synthesis methods. The QI-MQCS was developed to support evidence synthesis by providing a critical appraisal tool to identify high quality QI studies, for example, in the context of a systematic review. It is designed to be applicable to a wide range of QI studies. Developing critical appraisal criteria for QI publications is challenging due to the diversity of QI interventions, interdisciplinary language and study designs. Consequently, the QI-MQCS assesses, for example, whether the rationale specified for the intervention links to the study’s main outcome, without dictating which type of rationale (eg, which evidence-based intervention or theory) may be superior, given that this determination may depend on the specific interventions in this particular field of research. To ensure wide applicability, we purposefully applied the QI-MQCS to a diverse set of QI publications in the psychometric evaluation and did not limit the sample to specific clinical conditions, QI interventions, outcomes or study designs.

The QI-MQCS targets the informational value of the QI study, giving credit to publications that assess and provide information on crucial variables. Thus, for example, a publication that reports limited adherence to an intervention or describes that the spread of the intervention was unsuccessful receives credit for reporting on adherence and spread. Reviewers may want to highlight positive expressions of the domain, for example, evidence of adherence indicating that the intervention took place as outlined. In this case, the QI-MQCS can be used as a framework for a more refined assessment. The specific standards will depend on the individual field of application.

We designed the QI-MQCS to determine the minimum quality threshold of core QI domains. QI experts selected and prioritised domains in order to establish a feasible critical appraisal instrument. Furthermore, we developed detailed scoring criteria in an iterative process to ensure reliability. The assessment must rely on the information presented in the publication, and reliable scoring requires clear guidance that cannot be based on guessing or inside knowledge of individual reviewers. Nevertheless, reporting shortcomings may not necessarily indicate the absence of the process in the conduct of the study (eg, the publication’s word limits may have precluded a full description of the methods) and the psychometric evaluation distinguished only whether the domain criteria were met or not. Using the QI-MQCS and its assessment domains as a framework may allow reviewers to further differentiate study quality by creating response options for partially met criteria; by differentiating unmet criteria into ‘unclear’ and ‘low quality,’ or by defining criteria for exceptionally high quality studies. Further differentiation and moving away from the dichotomy of minimum criteria met or not may also provide a resolution for some of the described disagreements between reviewers. Additional or alternative criteria, for example criteria capturing other aspects of QI interventions building on the QI-MQCS may be important in specific research contexts.

The QI-MQCS was explicitly designed to complement, not to replace, critical appraisal instruments focusing on the internal validity of study designs. Other tools that may be helpful to reviewers are the EPOC group criteria for randomised controlled trials, controlled trials and controlled before-after studies; the quality criteria for programme evaluations, and a published critical appraisal instrument for Plan-Do-Study-Act QI. Fan et al provide a hierarchy of methodological strength to evaluate a body of evidence for QI interventions.

The QI-MQCS facilitates access to the vast available literature on QI interventions by identifying high quality studies, for example in the context of a systematic review aiming to synthesise the available evidence for specific interventions or outcomes, and provides a framework for critical appraisal in this complex research area. It is accompanied by a ready-to-use standardised quality assessment form and a detailed user manual. However, we have deliberately titled the tool V1.0, expecting that its use will lead to further refinement and improvements.

**CONCLUSIONS**

We developed a ready-to-use, valid and reliable critical appraisal instrument applicable to a wide range of healthcare QI intervention evaluation publications, but recognise scope for continuing refinement.

**Author affiliations**

1RAND Corporation, Santa Monica, California, USA
2Veterans Affairs West Los Angeles Medical Center, Los Angeles, California, USA
3Veterans Affairs Greater Los Angeles, North Hills, California, USA
4University of Leeds, Leeds Institute of Health Sciences, Leeds, UK
5National University of Singapore, Saw Swee Hock School of Public Health, Singapore
6University of California, Department of Medicine, Los Angeles, California, USA

**Acknowledgements** The authors thank the members of the international expert panel that guided the selection of the domains: David Atkins, Department of Veterans Affairs; Frank Davidoff, Institute for Healthcare Improvement; Martin Eccles, Newcastle University Institute of Health and Society; Robert Lloyd, Institute for Healthcare Improvement; Vin McLoughlin, The Health Foundation; Shirley Moore, Case Western Reserve University; Drummond Rennie, University of California, San Francisco; Susanne Salem-Schatz, Independent Consultant; David P Stevens, Dartmouth Institute; Edward H Wagner, Group Health Center for Health Studies; Brian Mittman,

Department of Veterans Affairs; and Greg Ogrinc, Dartmouth Institute. The authors thank Sean O’Neill, Denise Dougherty, Judy Sangl and Larry Kleinman for valuable contributions to the workgroup, Roberta Shanman for the literature searches, Jeremy Miles and Martika Suttorp for assistance with the statistical analysis, Breanne Johnsen for project assistance and Sydne Newberry for editorial assistance.

Contributors SH is the guarantor of the work and had full access to the data. LVR and PGS obtained funding; SH, JL, MSD, MA, RF and Y-WL contributed to the data acquisition; JL and SH to the data analysis; LVR, SH, PGS, JL, Y-WL and RF to the interpretation of the data. SH drafted the manuscript, all authors provided critical revisions and approved the final version of the manuscript.

Funding The project was funded by a grant from the Robert Wood Johnson (RWJ) Foundation (ID 65113), the Veterans Affairs (VA) Greater Los Angeles Healthcare System, the RAND Corporation, and the Agency for Healthcare Research and Quality (AHRQ). The funding agencies had no role in the study design, collection, analysis and interpretation of the data; the writing and the decision to submit the manuscript for publication. The findings and conclusions are those of the authors; the content of the manuscript should not be construed as the official position of the RWJ Foundation, the Department of Veteran Affairs, the RAND Corporation, or AHRQ.

Competing interests None declared.

Ethics approval The study was reviewed by the Human Subject Protection Committee (HSPC) of the RAND Corporation and determined to be exempt (ID 2009-0071).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The raw data can be obtained from the authors.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

REFERENCES


BMJ Qual Saf, first published as 10.1136/bmjqs-2014-003151 on 26 August 2015. Downloaded from http://qualitysafety.bmj.com/ on February 27, 2022 by guest. Protected by copyright.
Research and reporting methodology


APPENDIX 1 – QI-MQCS FORM
**Quality Improvement Minimum Quality Criteria Set (QI-MQCS) – Version 1.0**

ID: __________ Author, year: ___________________________ Reviewer: __________

Intervention: ___________________________ Outcome: ___________________________

<table>
<thead>
<tr>
<th>Domain</th>
<th>Minimum standard</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Organizational Motivation: Organizational problem, reason, or motivation for the intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider quality of care problems; organizational problems; regulations, legal constraints, and external financial incentives at the target organization; or organizational motivation.</td>
<td>Names or describes at least one motivation for the organization’s participation in the intervention</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>2. Intervention Rationale: Rationale linking the intervention to its expected effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider citations of theories, logic models, or existing empirical evidence that links the intervention to its expected effects.</td>
<td>Names or describes a rationale linking at least one central intervention component to intended effects</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>3. Intervention Description: Change in organizational or provider behavior</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider the presented details that describe the change in the delivery of care, provider behavior, or structure of the organization needed to replicate the evaluated intervention including the involved key personnel.</td>
<td>Describes at least one specific change in detail including the personnel executing the intervention</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>4. Organizational Characteristics: Demographics or basic characteristics of the organization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider environment (e.g., urban/rural, academic/non-academic), type of care (e.g., primary care), size of the organization, patient mix, staff mix, or reimbursement type.</td>
<td>Reports at least two organizational characteristics</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>5. Implementation: Temporary activities used to introduce potentially enduring changes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider types of staff involved, activities or methods used such as pilot testing or Plan-Do-Study-Act (PDSA) cycles, staff education, and involvement of stakeholders in introducing the intervention.</td>
<td>Names at least one approach used to introduce the intervention</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>6. Study Design: Study design and comparator</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider the type of evaluation (e.g., post-only, pre-post, time series, parallel control group, randomized groups; same participants assessed multiple times or different samples) / how the authors evaluated whether the intervention worked</td>
<td>Names the study design</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>7. Comparator: Information about comparator care processes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider details about the control group or the status quo without the intervention (even if there was no formal control group / data), e.g., the existing standard of care / routine care / before the intervention was introduced, or care processes used in the control group.</td>
<td>Describes at least one key care process</td>
<td>Not met Met</td>
</tr>
<tr>
<td><strong>8. Data Source: Data source and outcome definition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Consider the data sources (e.g., routine hospital data, data collected by the study investigator), the data collection method (e.g., survey, interview, objective/subjective measurement) and the outcome of interest is defined (e.g., definition of a reportable patient fall).</td>
<td>Describes the data source and defines the outcome of interest</td>
<td>Not met Met</td>
</tr>
</tbody>
</table>
- Consider the clarity of the timeline of the intervention, e.g., when introduced, when fully implemented, when evaluated relative to the intervention implementation status, and a clear indication of whether baseline data (defined as before the intervention was introduced) was present.
- **Not met**

### 10. Adherence / Fidelity: Adherence to the intervention
- Consider reporting of compliance with the intervention for the duration of the study, fidelity data on intervention use, or described mechanisms that ensures compliance (e.g., provider reminder integrated in electronic health record that cannot be skipped).
- **Not met**

### 11. Health Outcomes: Patient health-related outcomes
- Consider patient and non-professional care-giver health-related outcomes (including e.g., quality of life), but exclude satisfaction, provider-behavior (e.g., number of diagnostic tests ordered, knowledge) and process improvements.
- **Not met**

### 12. Organizational Readiness: Barriers and facilitators to readiness
- Consider reported QI resources and culture (e.g., existing QI committee, leadership commitment, prior QI experience, staff attitudes, and education and decision support resources) and results of barriers and facilitator assessments.
- **Not met**

### 13. Penetration / Reach: Penetration / reach of the intervention
- Consider the number of units or sites participating in the intervention compared to the available / eligible units (e.g., the number of participating sites without knowing how many sites were initially approached / were eligible is not sufficient).
- **Not met**

### 14. Sustainability: Sustainability of the intervention
- Consider discussions of sustainability, reference to organizational resources (e.g., costs and necessary commitments) and policy changes needed to sustain the intervention after withdrawal of study personnel and research resources, evidence of enduring changes (e.g. automated electronic reminders), or an extended duration of the intervention period as evidence of sustainability.
- **Not met**

### 15. Spread: Ability to be spread or replicated
- Consider evidence of spread or failure to spread and large rollouts; available resources such as a toolkits, how-to manuals, protocols, or booklets that describe the intervention in detail and could facilitate spread and replication; or discussions of spread potential.
- **Not met**

### 16. Limitations: Interpretation of the evaluation
- Consider whether the interpretation of the reported findings takes the study design (e.g., the lack of comparator) or other evaluation limitations into account; refers to the presented data (not future research / developments or intervention limitations)
- **Not met**

**Note:** QI: Quality improvement. The intervention and the outcome of interest need to be determined before scoring.
QUALITY IMPROVEMENT MINIMUM QUALITY CRITERIA SET
(QI-MQCS) – VERSION 1.0
USER MANUAL

Overview
The purpose of the Quality Improvement Minimum Quality Criteria Set (QI-MQCS) is to assist in the assessment of quality improvement intervention evaluations in healthcare reported in scientific literature. The QI-MQCS domains were selected by a stakeholder panel informed by literature and represent core aspects important to quality improvement. The QI-MQCS tool builds upon methods that identify and classify quality improvement and continuous quality improvement publications. 1-4

The 16 domains have been operationalized and psychometrically tested to allow a reliable and valid assessment. The QI-MQCS provides concrete scoring guidance and states minimum standards for each item to differentiate whether criteria have been met. The tool was developed to be applicable to a broad range of quality improvement intervention evaluations in healthcare. The QI-MQCS domains provide a framework to structure the assessment. The tool was designed and tested using a dichotomous answer mode (criterion met versus not). However, the framework can be used to differentiate the critical appraisal further, e.g., to distinguish partially met criteria; for this purpose, literature reviewers have to define the minimum standard of the additional answer mode.

Prior to rating a publication, reviewers should agree on the intervention and the primary outcome of interest described in the publication. The following sections are provided in this manual: the domain Title, a short Description of the domain, What to Consider, Where to Look, and How to Rate for each domain of the QI-MQCS. Where to Look directs users to where the information is typically found, but contains suggestions rather than an exclusive list of possible sections. Publications reporting on quality improvement intervention evaluations, patient health outcomes, and potentially enduring organizational changes were used in the design and validation of the QI-MQCS and example article excerpts relevant to each domain are provided.

References

2
DOMAIN 1. ORGANIZATIONAL MOTIVATION

Description
Organizational problem, reason, or motivation for the intervention

What to Consider
Consider quality of care problems, organizational problems, regulations, legal constraints, and external financial incentives at the target organization; or organizational motivation.

Where to Look
Examine the introduction and background paragraphs. This information may be referred to in the description of purpose, objectives, or scope.

How to Rate
Minimum standard: Names or describes at least one reason or motivation for the organization’s participation in the intervention

Examples
- “At Jefferson Medical College, clinical efficiency and bed availability are important priorities to the Department of Medicine (DOM). To this end, in 2002, a multidisciplinary program was designed; this initiative was led by the DOM…”
  
  *Feldman et al. 2006. The physician-hospital team: a successful approach to improving care in a large academic medical center.* This publication meets the minimum standard because the priorities of the Department of Medicine are one reason for the organization’s participation in the intervention.

- “The rationale to improve medication management in response to current national fiscal, clinical, and external quality measures and evolution of this process in the agency is detailed.”

  *Atkinson et al. 2005. Integration of a medication management model into outcome-based quality improvement: a pilot program in a rural proprietary home healthcare agency.* This publication meets the minimum standard because the organization’s participation was in response to national fiscal, clinical, and external quality measures.
DOMAIN 2. INTERVENTION RATIONALE

Description
Rationale linking the intervention to its expected effects

What to Consider
Consider citations of theories, logic models, or existing empirical evidence that links the intervention to its expected effects.

Where to Look
Examine the opening paragraphs and introduction. Examples of commonly labeled sections include background, introduction, and literature review.

How to Rate
*Minimum standard:* Names or describes a rationale linking at least one central intervention component to intended effects

Examples
- “Use of a fast track for less urgent patients (CTAS 4/5) has been shown to improve the ED flow and reduce the rate of patients who leave without being seen by a physician (LWBS) [4,10].”
  *Al Darrab et al. 2006. How does fast track affect quality of care in the emergency department?* This publication meets the minimum standard because references to empirical evidence supporting the intervention are given.
- “A review of case management worldwide has revealed a median case fatality rate of ~25%, with rates in some hospitals as high as 50% [2]. Many of these deaths are avoidable and are due to outdated procedures and protocols, and unfamiliarity with modern practices of management. Centres that improved their treatment of malnutrition have successfully reduced the death rate to <10% [3,4]. This suggests the need to motivate health practitioners to review current practices in the management of severely malnourished children in paediatric wards, and to adopt practices that will improve the quality of care.”
  *Puoane et al. 2004. Improving the hospital management of malnourished children by participatory research.* This publication meets the minimum standard because references to empirical evidence supporting the intervention are given.
DOMAIN 3. INTERVENTION DESCRIPTION

Description
Change in organizational or provider behavior

What to Consider
Consider the presented details that describe the change in the delivery of care, provider behavior, or structure of the organization needed to replicate the evaluated intervention including the involved key personnel.

Where to Look
Examine the title and abstract first. This information may also be found in the introduction or methods sections.

How to Rate
Minimum standard: Describes at least one specific change in detail including the personnel executing the intervention

Examples
• “We implemented a medical emergency team (MET) in our free-standing children’s hospital…. The MET was defined as experienced clinicians dispatched to evaluate and triage patients who were perceived as having a declining clinical status…. This team would arrive within 15 mins after activation. MET functions included assessment, stabilization if necessary, and triage of general care floor patients to the most appropriate unit in the hospital.”
  Brilli et al. 2007. Implementation of a medical emergency team in a large pediatric teaching hospital prevents respiratory and cardiopulmonary arrests outside the intensive care unit. This publication meets the minimum standard because the MET intervention and the personnel involved were described.
• “…an integrated program of task-shifting among providers. Appropriate health care responsibilities have been transferred from physicians to mid-level clinicians (e.g., nurses and clinical officers) and from nurses to community health workers…. The task-shifting model requires the transfer of specific clinical responsibilities to other providers who can be trained for the task (Figure 1).”
  Morris et al. 2009. Use of task-shifting to rapidly scale-up HIV treatment services: experiences from Lusaka, Zambia. This publication meets the minimum standard because the task-shifting intervention and the personnel involved were described.
DOMAIN 4. ORGANIZATIONAL CHARACTERISTICS

Description
Demographics or basic characteristics of the organization

What to Consider
Consider environment (e.g., urban/rural, academic/non-academic), type of care (e.g., primary care), size of the organization, patient mix, staff mix, or reimbursement type.

Where to Look
Examine the introduction, design, and methods sections. Examples of commonly labeled sections include background, research design, methods, setting, population, and participants.

How to Rate
Minimum standard: Reports at least two organizational characteristics

Examples
- “The Sutherland Hospital is a district hospital serving The Sutherland Shire, a metropolitan area of Sydney. It has a population of approximately 220,000, which is predominantly Anglo-Saxon in ethnic origin. The Emergency Department (ED) provides emergency services for 30,000 new patients per annum. Of these 6500 presentations are between the ages of 0 and 16 years. There have been 913 paediatric asthma presentations between January 1999 and December 2001.”
  Studdert et al. 2005. Introduction of standardised emergency department paediatric asthma clinical guidelines into a general metropolitan hospital. This publication meets the minimum standard because the environment (metropolitan area), number of patient served is an indicator of the size of the organization, and patient mix are provided.
- “Implementation of a medical emergency team in a large pediatric teaching hospital…”
  Brilli et al. 2007. Implementation of a medical emergency team in a large pediatric teaching hospital prevents respiratory and cardiopulmonary arrests outside the intensive care unit. This publication meets the minimum standard because the size of the organization (large), patient type (pediatric), and the context (teaching hospital) are described.
DOMAIN 5. IMPLEMENTATION

Description
Temporary activities used to introduce potentially enduring organizational / structural changes

What to Consider
Consider types of staff involved, activities or methods used such as pilot testing or Plan-Do-Study-Act (PDSA) cycles, staff education, and involvement of stakeholders in introducing the intervention.

Where to Look
Examine the design and methods sections.

How to Rate
Minimum standard: Names at least one approach used to introduce the intervention

Examples
• “Unexpected health needs were identified during the piloting of the project…”
  Harrison et al. 2006. Valuing people: health visiting and people with learning disabilities. This publication meets the minimum standard because piloting was used to introduce the intervention.
• “We advocate a comprehensive, three-pronged approach to task-shifting that comprises training, on-site clinical mentoring, and continuous quality assurance.”
  Morris et al. 2009. Use of task-shifting to rapidly scale-up HIV treatment services: experiences from Lusaka, Zambia. This publication meets the minimum standard because it describes approaches (training, mentoring) to introduce the intervention.
DOMAIN 6. STUDY DESIGN

Description
Study design and comparator

What to Consider
Consider the type of evaluation (e.g., post-only, pre-post, time series, historic or parallel control group, randomized groups; same participants assessed multiple times or different samples) / how the authors evaluated whether the intervention worked.

Where to Look
Examine the title, abstract, introduction, and methods sections.

How to Rate
Minimum standard: Names the study design

Examples
- “A before-after intervention comparison analysis was completed…”
  Al Darrab et al. 2006. How does fast track affect quality of care in the emergency department? This publication meets the minimum standard because the design was reported (before-after comparison).
- “Study design: Quasi-experimental with concurrent, but non-randomised controls…”
  Kirsh et al. 2007. Shared medical appointments based on the chronic care model: a quality improvement project to address the challenges of patients with diabetes with high cardiovascular risk. This publication meets the minimum standard because the study design was reported (quasi-experiment).
DOMAIN 7. COMPARATOR

Description
Information about the comparator care processes

What to Consider
Consider details about the control group or the status quo without the intervention (even if there was no formal control group / data), e.g., the existing standard of care / routine care / before the intervention was introduced, or care processes used in the control group.

Where to Look
Examine the introduction and discussion sections.

How to Rate
Minimum standard: Describes at least one key care process

Examples
• “Prior to the introduction of our RRT <rapid response team>, no specific system was in place for emergent triage, assessment, and expedited treatment of off-unit patients, outpatients, and visitors.”
  King et al. 2006. Establishing a rapid response team (RRT) in an academic hospital: one year’s experience. This publication meets the minimum standard because the status quo prior to the intervention is described.
• “This was a randomized controlled trial examining the combination of audit with feedback and benchmarking, academic detailing, practice facilitation, and IT [information technology] support compared with feedback and benchmarking alone on implementation of wellness visits, recall and reminder systems, and standing orders in primary care practices (Figure 1).”
  Mold et al. 2008. Implementation of evidence-based preventive services delivery processes in primary care: an Oklahoma physicians resource/research network (OKPRN) study. This publication meets the minimum standard because the care processes in the comparison group (feedback and benchmarking alone) are described.
DOMAIN 8. DATA SOURCE

Description
Data sources and outcome definition

What to Consider
Consider the data sources (e.g., routine hospital data, data collected by the study investigator), the data collection method (e.g., survey, interview, objective/subjective measurement), and the definition of the outcome of interest (e.g., definition of a reportable patient fall).

Where to Look
Examine the design and methods sections.

How to Rate
Minimum standard: Describes the data source and defines the outcome of interest

Examples
• “A respiratory reference group at Sydney Children’s Hospital collected and collated data relating to paediatric asthma management across SESAHS.”
  Studdert et al. 2005. Introduction of standardised emergency department paediatric asthma clinical guidelines into a general metropolitan hospital. This publication meets the minimum standard because data collection and the personnel involved was described.
• “As shown in Figure 2 (page 29), mean patient satisfaction scores related to pain (as measured on our standard patient satisfaction survey administered by mail following discharge*)…”
  Paice et al. 2006. Creating organizational change through the pain resource nurse program. This publication meets the minimum standard because the data collection method (survey) was described.
DOMAIN 9. TIMING

Description
Timing of intervention and evaluation

What to Consider
Consider the clarity of the timeline of the intervention, e.g., when introduced, when fully implemented, when evaluated relative to the intervention implementation status, and a clear indication of whether baseline data (defined as before the intervention was introduced) was present.

Where to Look
Examine the methods, results, tables, and figures.

How to Rate
Minimum standard: Describes the timing of the intervention and evaluation to determine the presence of baseline data and the follow-up period after all intervention components were fully implemented.

Examples
- “...St. John’s, in collaboration with its surgeons, set aside an operating room as a trial project in November 2002....After approximately three months of segmenting this room as an “add-on” room, the data were reassessed....the number of surgical cases increased by 5.1 percent.”  
  Henderson et al. 2003. A case study of successful patient flow methods: St. John’s Hospital. This publication meets the minimum standard because the baseline and follow-up periods can be determined.
- “The preintervention period was between January 1, 2004, and August 31, 2005, and the postintervention period, defined for identical time duration and seasonality, was between January 1, 2006, and August 31, 2007. Staff education and rapid response team program rollout occurred from September 1 to December 31, 2005, and patient data from this period was excluded.”  [Note: pre-intervention data provided in a table.]  
  Chan et al. 2008. Hospital-wide code rates and mortality before and after implementation of a rapid response team. This publication meets the minimum standard because the timing of the pre- and post-periods and rollout are described.
DOMAIN 10. ADHERENCE / FIDELITY

Description
Adherence to the intervention

What to Consider
Consider reporting of compliance with the intervention for the duration of the study, fidelity data on intervention use, or described mechanisms that ensures compliance (e.g., provider reminder integrated in electronic health record that cannot be skipped).

Where to Look
Examine the results section and tables.

How to Rate
Minimum standard: Reports fidelity information for at least one intervention component, or describes evidence of adherence or a mechanism ensuring compliance to the intervention.

Examples
• “Attachment rate of educational reminder messages was close to 100%, or was 100%, in departments in which messages were attached electronically; was 100% in departments in which messages were attached by hand; and around 40% in that in which an operator pressed a key to add the message.”
  Eccles et al. 2001. Effect of audit and feedback, and reminder messages on primary care radiology referrals: a randomised trial. This publication meets the minimum standard because fidelity data is provided.
• “Moreover, of the 188 codes in the rapid response team postintervention period, 20 occurred in non-ICU patients who had documented acute physiological decline within 12 hours of the code (10.6%), but where the rapid response team was not activated (potential rapid response team underuse accounting for 16 deaths).”
  Chan et al. 2008. Hospital-wide code rates and mortality before and after implementation of a rapid response team. This publication meets the minimum standard quality because fidelity data is provided.
DOMAIN 11. HEALTH OUTCOMES

Description
Patient health-related outcomes

What to Consider
Consider patient and non-professional care-giver health-related outcomes (including e.g., quality of life), but exclude satisfaction, provider-behavior (e.g., number of diagnostic tests ordered, knowledge) and process improvements.

Where to Look
Examine the results section, tables, and figures.

How to Rate
Minimum standard: Reports data on at least one health-related outcome

Examples
- “Over the 4-year period since the HQSR <Hospital Quality Service and Recognition> program was first implemented in 2001, the average risk-adjusted complication rate declined by approximately 2 percentage points in both surgical and obstetrical categories. Weighted average risk-adjusted complication rates and the associated 95% confidence intervals are presented in Figures 2 and 3.”
  Berthiaume et al. 2006. Aligning financial incentives with quality of care in the hospital setting. This publication meets the minimum standard because complication rates are reported.
- “An unexpected but significant result of the test of change was the dramatic decrease in nosocomial infections on the unit. The rates decreased gradually over the first five months and then held at zero for three months.”
  Stefancyk et al. 2009. High-use supplies at the bedside. This publication meets the minimum standard because infection rates are reported.
DOMAIN 12. ORGANIZATIONAL READINESS

Description
Barriers and facilitators to readiness

What to Consider
Consider reported QI resources and culture (e.g., QI committee, leadership commitment, prior QI experience, staff attitudes, and education and decision support resources) and results of barriers and facilitator assessments.

Where to Look
Examine the introduction and discussion sections.

How to Rate
Minimum standard: Reports at least one organizational-level barrier or facilitator

Examples
- “In February 2000 an Asthma forum was held in South Eastern Sydney Area Health Service (SESAHS). This forum identified a lack of coordinated paediatric asthma services, and acknowledged a need for improved asthma services. An Asthma advisory group was established with representatives from St George Hospital, Sydney Children’s Hospital, Randwick, The Sutherland Hospital, community based health professionals and allied health professionals.”
  Studdert et al. 2005. Introduction of standardised emergency department paediatric asthma clinical guidelines into a general metropolitan hospital. This publication meets the minimum standard because the organizational interest in the topic (an advisory group was established) was reported.
- “Inadequate knowledge and lack of resources were the most common perceived barriers…. The role of external facilitators was important to the process.”
  Puoane et al. 2004. Improving the hospital management of malnourished children by participatory research. This publication meets the minimum standard because perceived barriers and facilitators were assessed.
DOMAIN 13. PENETRATION / REACH

Description
Penetration / reach of the intervention

What to Consider
Consider the number of units or sites participating in the intervention compared to the available / eligible units (e.g. the number of participating sites without knowing how many sites were initially approached / were eligible is not sufficient).

Where to Look
Examine the results and discussion sections.

How to Rate
Minimum standard: Provides information on the proportion of all eligible units who actually participated

Examples
• “Of the 94 eligible practices in the network, 24 (25%) agreed to participate in this project.”
  Mold et al. 2008. Implementation of evidence-based preventive services delivery processes in primary care: an Oklahoma physicians resource/research network (OKPRN) study. This publication meets the minimum standard because the proportion of eligible practices is reported.
• “Hospital-wide code rates and mortality before and after implementation of a rapid response team.”
  Chan et al. 2008. Hospital-wide code rates and mortality before and after implementation of a rapid response team. This publication meets the minimum standard because the penetration is hospital-wide.
DOMAIN 14. SUSTAINABILITY

Description
Sustainability of the intervention

What to Consider
Consider discussions of sustainability, reference to organizational resources (e.g., costs and necessary commitments) and policy changes needed to sustain the intervention after withdrawal of study personnel and research resources, evidence of enduring changes (e.g. automated electronic reminders), or an extended duration of the intervention period as evidence of sustainability.

Where to Look
Examine the discussion and limitations sections.

How to Rate
Minimum standard: Describes the sustainability or the potential for sustainability

Examples
• “We are currently developing appropriate monitoring strategies to ensure that lessons in basic clinical practices and HIV medical management are properly disseminated. This is a critical component to the sustainability of such a program, particularly as it rolls out into semi-urban and rural sites.”
  Morris et al. 2009. Use of task-shifting to rapidly scale-up HIV treatment services: experiences from Lusaka, Zambia. This publication meets the minimum standard because the sustainability potential is described; the minimum standard for study quality is not met because evidence of sustainability is not provided.
• “Over the 4-year period since the HQSR <Hospital Quality Service and Recognition> program was first implemented in 2001, the average risk-adjusted complication rate declined by approximately 2 percentage points in both surgical and obstetrical categories.”
  Berthiaume et al. 2006. Aligning financial incentives with quality of care in the hospital setting. This publication meets the minimum standard because evidence of sustainability is provided (4-year program).
DOMAIN 15. SPREAD

Description
Ability to be spread or replicated

What to Consider
Consider evidence of spread or failure to spread and large rollouts; available resources such as a toolkits, how-to manuals, protocols, or booklets that describe the intervention in detail and could facilitate spread and replication; or discussions of spread potential.

Where to Look
Examine the discussion and limitations sections.

How to Rate
Minimum standard: Describes the potential for spread, existing tools for spread, or spread attempts / large-scale rollout

Examples
- “The lack of correlation of improvements with baseline practice characteristics might suggest that the multicomponent intervention can be effective across a range of practices and clinicians.”
  Mold et al. 2008. Implementation of evidence-based preventive services delivery processes in primary care: an Oklahoma physicians resource/research network (OKPRN) study. This publication meets the minimum standard because the potential for spread is described.
- “Following the experience in these two hospitals, the process has been scaled-up within the province and staff at a further 23 hospitals have been trained…. They use a detailed training guide [14].”
  Puoane et al. 2004. Improving the hospital management of malnourished children by participatory research. This publication meets the minimum standard because spread and successful scale-up to 23 hospitals are described.


DOMAIN 16. LIMITATIONS

Description
Interpretation of the evaluation

What to Consider
Consider whether the interpretation of the reported findings in the abstract / summary and/or the discussion section takes the study design (e.g., the lack of a comparator) or other evaluation limitations into account; refers to the presented data (not future research / developments or intervention limitations)

Where to Look
Examine the discussion and limitations sections.

How to Rate
Minimum standard: Reports at least one limitation of the design / evaluation

Examples
- “There are several limitations of this that may confound our findings. A number of other pain initiatives… were in place during this time frame, so that their relative contribution to the changes in pain prevalence and satisfaction cannot be determined…. Second, one of the measures used to establish efficacy of the PRN <Pain Resource Nurse> program relies on patients’ memories of whether a doctor or nurse asked them about their pain.”

  Paice et al. 2006. Creating organizational change through the pain resource nurse program. This publication meets the minimum standard because limitations of the study design and measurement are reported.

- “There are 4 major important limitations of the present report. First, there was no comparison group, and it is not possible to be certain that the improvements noted among the 66 practices were due to the study interventions and not merely to secular changes occurring for other reasons.”

  Ornstein et al. 2009. Improving diabetes care through a multicomponent quality improvement model in a practice-based research network. This publication meets the minimum standard because limitations of the evaluation are reported.