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Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Abstract

Objectives: Cardiac rehabilitation is underutilized and its quality in practice is unclear. A quality indicator is a measurable element of clinical practice performance. This study aimed to propose a set of quality indicators for cardiac rehabilitation following an acute coronary event in the Japanese population and conduct a small-size practice test to confirm feasibility and applicability of the indicators in real-world clinical practice.

Design and Setting: This study used a Modified Delphi technique (the RAND/UCLA appropriateness method), a consensus method which involves an evidence review, a face-to-face multidisciplinary panel meeting and repeated anonymous rating. Evidence to be reviewed included clinical practice guidelines available in English or Japanese and existing quality indicators. Performance of each indicator was assessed retrospectively using medical records at a university hospital in Japan.

Participants: 39 patients experienced acute coronary event between January to June in 2013.

Results: In the literature review, 23 clinical practice guidelines and 16 existing indicators were identified to generate potential indicators. Through the consensus-building process, a total of 30 indicator candidates were assessed and finally 13 indicators were accepted. The practice test revealed that 74% of patients underwent cardiac rehabilitation. Median performance of process measures was 93% (interquartile range, 46-100). "Communication with the doctor who referred the patient to cardiac rehabilitation" and "Continuous participation in cardiac rehabilitation" had low performance (32% and 38%, respectively).

Conclusions: A Modified Delphi technique identified a comprehensive set of quality indicators for cardiac rehabilitation. The single-site, small-size practice test confirmed that most of the proposed indicators were measurable in real-world clinical practice. However, some clinical processes which are not

covered by national health insurance in Japan had low performance. Further studies will be needed to clarify and improve the quality of care in cardiac rehabilitation.

Abstract word count: 288/300 words

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Strengths and limitations of this study

- This is the first study to assess usage of a whole set of quality indicators for cardiac rehabilitation in the process of development.
- A guideline-based modified Delphi technique was used and medical records were reviewed as a practice test before implementing indicators in the real world clinical practice.
- The composition of our panel members may lead to a biased selection of indicators.
- The single-site, small-size practice test may limit to generalize the performance of indicators.

Introduction

Acute coronary syndrome is a leading cause of death and major social burden in the world.¹ Developments in coronary interventions, surgical procedures, pharmacological treatments and lifestyle modifications (e.g., smoking cessation) have improved prognosis, prevented recurrence and reduced mortality in patients who experience acute coronary events.^{2 3} In urban and/or suburban areas of Japan, however, the incidence of myocardial infarction and sudden cardiac death among men has increased in the past few decades.⁴

Previous studies have demonstrated the effectiveness of comprehensive cardiac rehabilitation (CR) on the survival and quality of life of patients with coronary heart disease.⁵ Yet, CR referral rates vary according to characteristics of patients, specialty units and hospitals.⁶⁻¹² Moreover, little is known about the quality of programs in real-world clinical settings.

Quality indicators are measurable elements of practice performance for which there is evidence or consensus. Process indicators, in particular, are used to express the proportion of patients who receive proper care. They can highlight and reveal quality issues, which in turn enable the formulation of solutions for improvement.¹³⁻¹⁵ The use of quality indicators has increased in Japan, particularly in cancer care settings.¹⁶

Quality indicators for cardiovascular disease prevention and CR have been developed in European countries, the United States and Canada, but not in Asia including Japan.¹⁷⁻²¹ Additionally, a practice test prior to real usage is needed when developing quality indicators.^{22 23} However, previous practice tests examined only a part of the indicator set in CR field.^{24 25}

This study aims to 1) propose quality indicators for CR following an acute coronary event (e.g., acute myocardial infarction and unstable angina), as these diseases are the most common indications for CR, 2) conduct a small-size, pilot practice test with the whole set of the proposed indicators to confirm the feasibility and applicability before using them in real world clinical

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4 practice and 3) describe a detailed process of developing quality indicators for
5 applicability to other clinical circumstances.
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10 11 12 Methods

13 14 15 Indicator Development

16 17 18 19 Overview of the Development Process

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23 This study was conducted by the task force on evidence-based
24 healthcare and clinical practice guidelines under the Ministry of Health,
25 Welfare and Labour in Japan, as a proposal of the common method to
26 develop quality indicators.
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30 A modified Delphi technique (the RAND/UCLA Appropriateness
31 Method), which has been widely used to develop healthcare quality
32 indicators, was used.²⁶ The method integrates an evidence review, a face-to-
33 face multidisciplinary panel meeting and repeated anonymous rating for
34 consensus building. This study was approved by the Ethics Committee of
35 Kyoto University Graduate School and Faculty of Medicine.
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40 41 42 Systematic Search of Evidence

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45 Kötter et al. previously reported that methods for quality indicator
46 development based on clinical guidelines are increasing and may help in the
47 efficient gathering of evidence when considering indicator candidates.²² Based
48 on this, we searched existing clinical practice guidelines available in English or
49 Japanese and quality indicators related to CR after an acute coronary event
50 developed in countries other than Japan. Specifically, we searched electronic
51 databases with the search terms "cardiovascular disease", "cardiovascular
52 system", "cardiology", "cardiac", "cardiovascular" and "rehabilitation" in August
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2011. The following databases were used: one quality indicator database (AHRQ National Quality Measures Clearinghouse); nine guideline databases (AHRQ National Guideline Clearinghouse, NICE Find Guidance, NHS Evidence, Minds, PEDro, Guidelines International Network, Australian Government National Health Medical Research Council, Canadian Medical Association and British Intercollegiate Guidelines Network); and three medical literature databases (MEDLINE, CINAHL and ICHUSHI). The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website were also reviewed for Japanese guidelines on CR. The search was limited to English or Japanese language publications from April 2006 to March 2011. Two appraisers (SO and NK) evaluated the quality of the selected guidelines with the AGREE II instrument, which is the established tool for this purpose.²⁷ For each guideline, overall assessments using AGREE II by two appraisers were averaged.

In order to generate candidate indicators, strong recommendations were extracted from each of the selected clinical practice guidelines. They were merged with existing quality indicators and applied to a structured format of the modified ACC/AHA Methodology.²⁸ One researcher (SO) assembled the candidate indicators and was supervised by two experts: TN, an epidemiologist experienced in the development of a variety of Japanese clinical practice guidelines and also the chair of the task force on evidence-based health care and clinical practice guidelines, and KU, a cardiologist familiar with CR and evidence-based medicine.

Multidisciplinary Panel

Panel members responsible for consensus development were selected from registered instructors of CR licensed by the Japanese Association of Cardiac Rehabilitation. Licensure status requires individuals to have practiced CR for at least one year, submitted ten case reports and passed an authorized examination. To assemble the multidisciplinary group, we attempted to select more than one person from each profession related to CR (cardiologists,

nurses, physical therapists, clinical laboratory technicians, registered dieticians, health fitness programmers and clinical psychologists). The sampling strategy was nonrandom selection, with recommendations by KU and approval by SO and TN. KU was a member of the committee on Japanese guidelines for CR and appointed as president of the Japan Association of Cardiac Rehabilitation in 2014. Each panel member signed a consent form for the present study.

Consensus Building

Based on the modified Delphi technique, panel members formed a consensus regarding indicator candidates in three rounds. In round 1, members individually evaluated indicator candidates using a nine-point scale postal questionnaire. In round 2, they reconvened for a one-day face-to-face meeting to discuss, revise, and individually evaluate potential candidates, and then suggest additional candidates at a later meeting. In round 3, they evaluated additional candidates with the same questionnaire as above.

Round 1

A set of documents that described the quality indicator candidates was distributed to panel members. Members were then given two weeks to individually rate each candidate with a nine-point scale questionnaire, adapted from the nine domains suggested by Spertus et al.: evidence-based, interpretable, actionable, denominator, numerator, validity, reliability, feasibility and overall assessment.²⁸

Round 2

A one-day face-to-face panel meeting was held. Panel members anonymously shared their results from round 1 and discussed each candidate indicator. The panel then revised the elements of each candidate, if all members agreed. Finally, the panel rated the revised candidates individually, using the same questionnaire from round 1. At the end of the meeting, we asked members to suggest additional indicator candidates that might be

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4 important for measuring the quality of CR services in Japan that had not been
5 examined by the panel prior to the meeting.
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8 9 Round 3

10 Additional candidates were developed from suggestions during the
11 panel meeting (round 2). A document describing the new candidates was sent
12 to panel members electronically, asking for any modifications. The candidates
13 were then revised according to the suggestions and sent to panel members
14 by mail to rate using the same questionnaire from round 1.
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20 21 Selection Criteria

22 Quality indicator candidates were adopted according to the following
23 criteria: the median individual rating during round 2 or round 3 was greater
24 than seven, and the number of panel members who gave a rating less than
25 three was two or fewer.
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33 34 Pilot Practice Test for Feasibility and Adaptability

35 36 Study Patients

37 Selected patients were those who 1) experienced an acute myocardial
38 infarction or unstable angina and 2) were admitted to Kyoto University
39 Hospital, which provides acute-to-recovery care in Japan, between January 1,
40 2013 and June 30, 2013.
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48 49 Data Collection

50 Data were collected from Kyoto University's electronic medical records
51 in January 2014. Records regarding eating habits (QI-2), coronary risk factors
52 (QI-3), psychological responses (QI-4), tobacco and alcohol (QI-5), exercise
53 capacity (QI-6), definition of the program end period (QI-8) and work and
54 leisure (QI-10) were available in the implementation planning sheets for CR
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4 per national insurance regulations. Records on education regarding the
5 importance of performance on prescription medication (QI-12) were available
6 in pharmacist instruction reports, also per national insurance regulations. SO
7 and NK assessed performance of the indicators based on each patient's
8 records. Disagreements were resolved by discussion.
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13 14 Data Analysis

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16 Patients with acute myocardial infarction and unstable angina were
17 selected consecutively during the study period from Kyoto University Hospital
18 via coronary catheterization records for measurement with the indicators.
19 Percentage scores were obtained for each indicator as follows: the number of
20 times the indicator was met / the number of subjects (excluding those with
21 obvious reasons for not implementing the process as defined by the indicator)
22 x 100. Medians of indicator scores were also computed as an overall quality
23 score of the program.
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33 34 Disclosure and update

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37 The adopted indicators were disclosed and externally reviewed at a
38 symposium during the annual meeting of the Japanese Association of Cardiac
39 Rehabilitation, of which KU was the president in July 2014. Considering
40 suggestions from external experts, an indicator regarding referral to CR was
41 updated in October 2015 based on an online panel discussion and the nine-
42 point scale assessment.
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52 53 Results

54 55 56 Quality Indicators

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4 The literature review identified 38 quality indicators from AHRQ
5 National Quality Measures Clearinghouse, of which 16 were selected
6 according to the criteria (Figure 1). Searches of guideline databases and
7 medical literature databases identified 894 articles (103 from AHRQ National
8 Guideline Clearinghouse, 121 from NICE Find Guidance, 487 from NHS
9 Evidence, two from Minds, 11 from PEDro, 25 from Guidelines International
10 Network, six from Australian Government National Health Medical Research
11 Council, nine from Canadian Medical Association, 22 from British
12 Intercollegiate Guidelines Network, 74 from MEDLINE, 24 from CINAHL and 10
13 from ICHUSHI). Seven additional guidelines were identified from Japanese
14 academic society websites. In total, 23 guidelines met our eligibility criteria.
15 The average of overall quality scores based on AGREE II was 5.0 out of a
16 possible 7 (min to max, 3.5 to 6.0). A total of 27 potential indicators were
17 included for panel assessment.

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The panel consisted of ten Japanese clinicians in CR, including two
cardiologists, two nurses, two physical therapists, one clinical laboratory
technician, one registered dietitian, one health fitness programmer and one
clinical psychologist (a member of the committee on Japanese guidelines for
CR).

Round 2 ratings accepted six candidate indicators (Figures 2 and 3).
Although a candidate regarding referral to CR from outpatient settings had
been discarded in this round, it was later accepted in the update period as a
modified indicator (QI-1, Table 1), the rating of which was a median of 8, and
min to max of 4 to 9 (Figure 3).

Of the 20 primary candidates, the panel reconstructed four indicator
candidates. The candidate "assessment and education regarding coronary risk
factors" was developed by combining the following 13 primary candidates:
"hypertension assessment", "education for patients with hypertension", "target
blood pressure goal achievement", "assessment and education regarding
blood lipids", "reassessment of blood lipids", "assessment and education
regarding physical activity habits", "intervention for physical activity habits",

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4 "reassessment of physical daily activity", "assessment of body weight",
5 "intervention for body weight control", "assessment of diabetes", "intervention
6 for diabetes" and "target HbA_{1c} goal achievement". Some panel members
7 noted that clinicians tend to deal with these issues together rather than
8 separately. As such, they agreed that combining these candidates would make
9 it easier to perform high quality measurements.
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12 The two primary candidates, "assessment of depression" and
13 "intervention for a patient suspected of having depression", gave rise to the
14 candidate indicator "assessment of psychological responses". Patients with
15 coronary disease often have psychological issues such as depression, anxiety
16 or insomnia.^{18 29} Furthermore, the panel was of the opinion that patients in
17 Japan rarely receive appropriate assessments, aside from interventions they
18 receive for CR.
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21 The candidate "assessment and education regarding tobacco and
22 alcohol" was generated by combining the following three primary candidates:
23 "assessment of tobacco use", "support of smoking cessation" and "education
24 on alcohol". The panel agreed that combining these items would improve
25 measurement quality in clinical settings, as clinicians typically deal with these
26 issues together.
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29 The primary candidate counseling to return to work was reworded as
30 "assessment and education regarding work and leisure". The panel agreed
31 that it was important for a patient requiring rehabilitation to enjoy a leisurely
32 life in addition to returning to work.
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35 In addition to the candidates discussed above, the panel suggested
36 some candidates, including "definition of program end period" and "continued
37 participation in rehabilitation program". These indicators were generated after
38 some panel members emphasized the importance of completing the CR
39 program. Given the multidisciplinary nature of the rehabilitation team, the
40 generation of another candidate ("holding a multidisciplinary conference") was
41 suggested.
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4 In the end, a total of 13 quality indicators were proposed. These
5 indicators spanned the following domains: (1) referral to CR, (2) modification
6 of coronary risk factors, (3) exercise prescription, (4) completion of CR
7 program, (5) return to social activity, (6) involvement of a multidisciplinary
8 team, (7) management of prescription medication and (8) communication with
9 other healthcare providers (Table 1).
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24 Performance in the Pilot Practice Test

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27 Of the 39 assessed patients (22 with acute myocardial infarction and 17
28 with unstable angina), 29 (74%) participated in a CR program (QI-1, Table 1).
29 The median performance, based on QI-2 to QI-13, was 93% (interquartile
30 range, 46 to 100). Indicators for which data are collected for national
31 insurance claims (QI-2, 3, 4, 5, 6, 8, 10 and 12) showed high performance
32 (median, 100%; min to max, 74 to 100), whereas others, including QI- 7, 9, 11
33 and 13, showed low performance (min to max, 32%-48%).
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43 Discussion

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46 In this study, we proposed 13 quality indicators for assessing CR in
47 patients who suffered from acute coronary syndrome in Japan. A widely used
48 consensus approach, the modified Delphi method, with a Japanese
49 multidisciplinary panel identified seven crucial domains for the quality
50 measurement. Based on results of the single-site, small-size practice test, we
51 found that most of indicators proposed were measurable in real-world clinical
52 practice and the performance for which data are collected for national
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4 insurance claims was high, whereas performance of indicators for which data
5 are recorded voluntarily was low.
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7 The structure of our proposed indicators is consistent with those
8 reported in previous studies. A few reports have been published that deal
9 with quality measures for CR in North America. ACC/AHA/AACVPR provided a
10 performance measure set that has (1) referral to CR and (2) performance in
11 the program as major parts.^{18 19} The Canadian Cardiovascular Society also
12 originally developed quality indicators on CR, and then prioritized a list of 5
13 indicators, including (1) inpatients referred to CR; (2) wait times from referral
14 to CR enrollment; (3) patient self-management education; (4) increase in
15 exercise capacity and (5) emergency response strategy.^{20 25} In the present
16 study, our set of indicators reflects the importance of referral to CR and a
17 comprehensive program. Therefore, we consider these to be essential
18 elements of quality indicators for CR.
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28 During the process of developing quality indicators, pilot practice tests
29 prior to implementation are important for determining which indicators
30 become established components because they evaluate validity, reliability and
31 feasibility.²² Some studies in other medical fields (e.g., neck tumors, diabetes,
32 pneumonia) have reported that, among accepted indicators in the
33 development process, approximately 10 to 30% were not measurable or
34 inapplicable.^{30 31} In the field of CR in the United States, Thomas et al. revealed
35 that reliability of the abstraction for the measure regarding referral was good
36 to excellent.²⁴ In addition, with respect to Canadian indicators, Grace et al.
37 assessed feasibility and concluded that the indicator assessment was
38 acceptable for the CR program.²⁵ Unlike the previous studies, our practice test
39 was small-size but included all indicators proposed. Although the
40 generalizability is limited, we found a possibility that some processes for
41 which data were not recorded per healthcare insurance regulations have low
42 performance. Since Grace et al. also reported that the information-tracking
43 process was challenging when measuring quality, that may be a common
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issue in the field of CR across countries.²⁵ Further studies will be needed to make quality measurements more appropriate and efficient.

Although panel nomination is one of the key elements of quality indicator development, many studies lack transparency in the process.²² In contrast to previous reports from the United States and Canada, our study does not stand on the initiative of any academic society, but rather is based on a project granted by the Ministry of Health, Welfare and Labour in Japan. In terms of the aim to propose a method for developing quality indicators, our study established the following explicit criteria: 1) the panel members must have an authorized license from an academic society, and 2) at least one member is selected from every relevant profession. In fact, our panel included the people concerned with the committee on the clinical practice guidelines for CR jointly developed by the relevant academic societies in Japan (i.e. Shunichi Ishihara and Shinji Sato who are respectively a member and collaborator of the committee).³²

The adaptability of each quality indicator must be reviewed before implementation because healthcare systems and social circumstances differ. This is a key element in evidence-based clinical decision-making.^{33 34} We consider, however, disclosing the explicit process of guideline-based quality indicator development, which is a time-efficient and resource-saving approach,²² will be helpful for people attempting to develop similar quality indicators in other regions or different social levels.

Conclusion

Using an explicit and integrated approach based on evidence and the consensus of a multidisciplinary panel, we proposed 13 specific indicators to measure the quality of CR for patients who experienced acute coronary events in Japan. The practice test was small-size but helpful to confirm the measurability of all indicators proposed, and found that health insurance

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4 coverage can effect on performance in related processes. Further studies will
5 be needed to clarify the reasons for this, as well as to improve the quality of
6 care in CR.
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23 Footnotes

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26 **Contributors:** SO conceived, designed and analyzed the study and drafted
27 and prepared the manuscript. NK assisted data collection and analysis and
28 manuscript preparation. NO and KU contributed to the data collection and
29 interpretation of data and manuscript preparation. TN supervised the study
30 design, administration, analysis and interpretation and gave the final approval
31 of the manuscript.
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45 accountable health care (2014-2015)".
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Table 1. Quality indicators and percentage scores for cardiac rehabilitation of inpatients with ischemic heart disease.

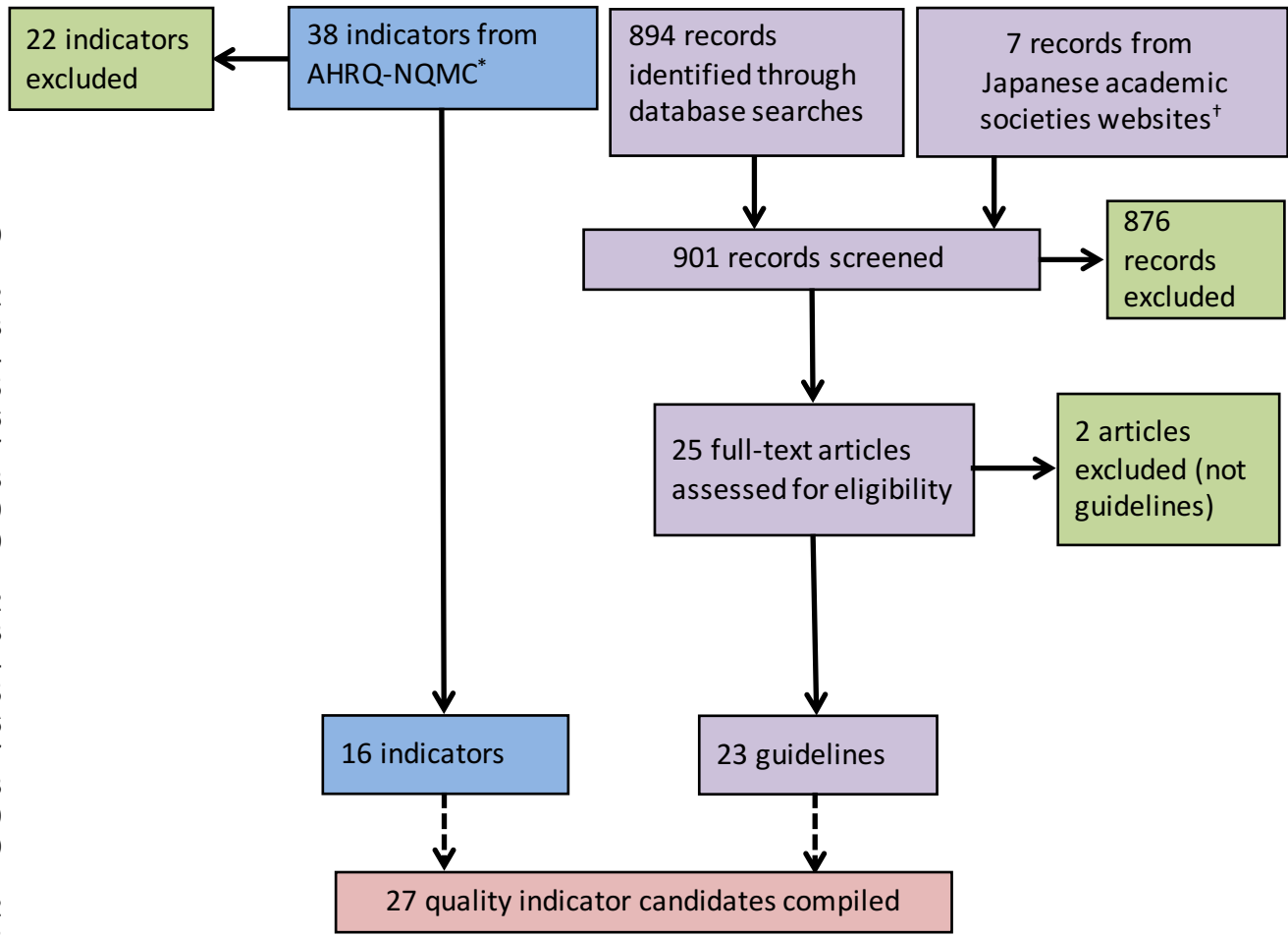
Domains	Indicators	Numerator/	Performance,
		Denominator	%
Domain 1. Referral to cardiac rehabilitation	QI-1. Referral to cardiac rehabilitation	29/39	74
	QI-2. Assessment and education regarding eating habits	29/29	100
Domain 2. Modification of coronary risk factors	QI-3. Assessment and education regarding coronary risk factors	29/29	100
	QI-4. Assessment of psychological responses	28/29	97
	QI-5. Assessment and education regarding tobacco and alcohol	29/29	100
Domain 3. Exercise therapy	QI-6. Prescribed exercise based on assessment of exercise capacity	20/27	74
	QI-7. Reassessment of exercise capacity	11/24	46
Domain 4. Completion of cardiac rehabilitation program	QI-8. Definition of the program end period	29/29	100

	QI-9. Continued participation in rehabilitation program	8/21	38
Domain 5. Return to social activity	QI-10. Assessment and education regarding work and leisure	29/29	100
Domain 6. Involvement of multidisciplinary team	QI-11. Holding a multidisciplinary conference	14/29	48
Domain 7. Management of prescription medication	QI-12. Education on the importance of adherence to prescription medication	26/29	90
Domain 8. Communication with other healthcare providers	QI-13. Communication with a doctor who referred the patient to cardiac rehabilitation	8/25	32

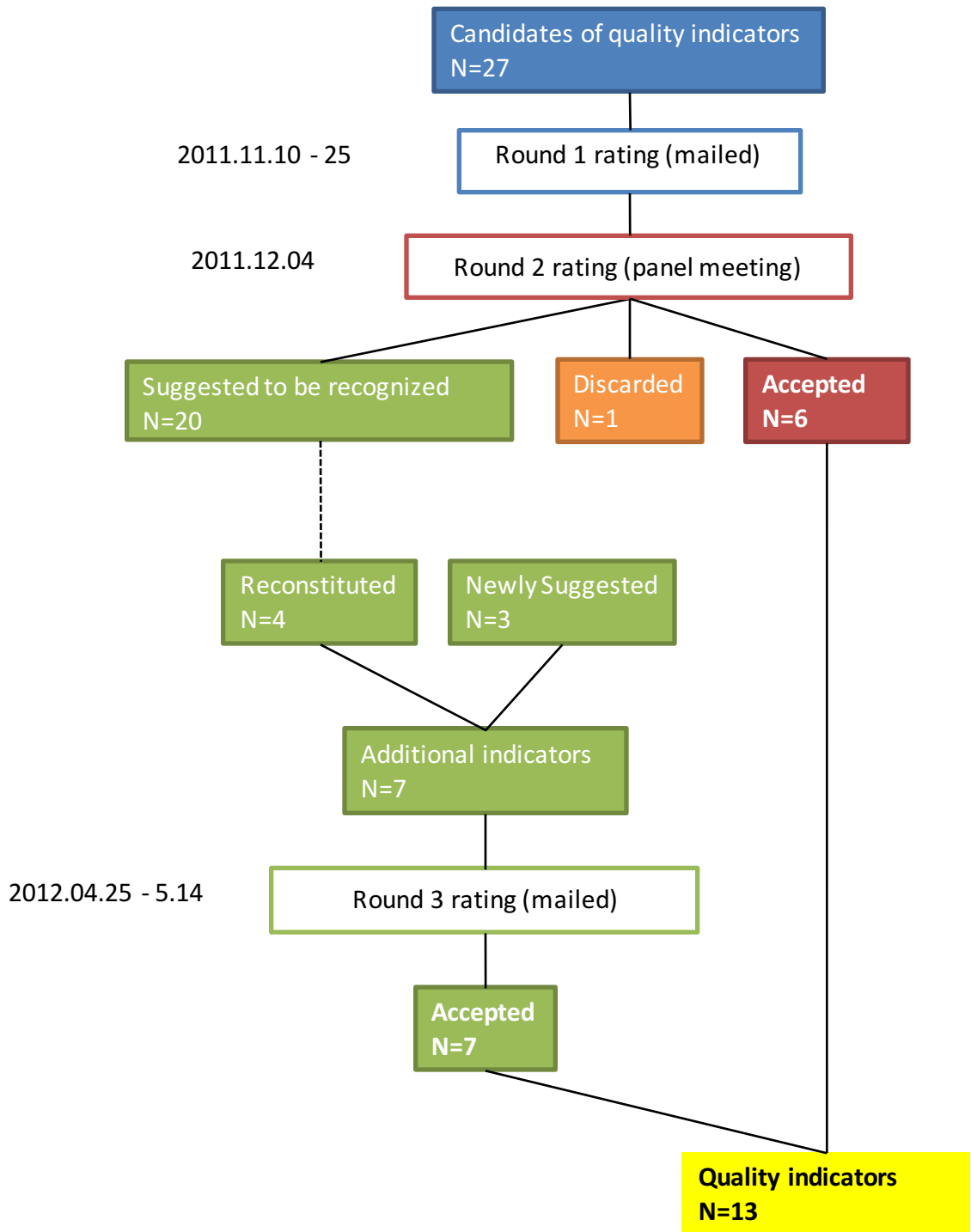
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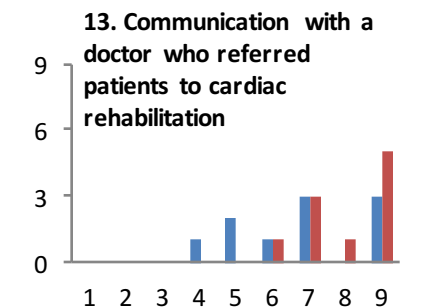
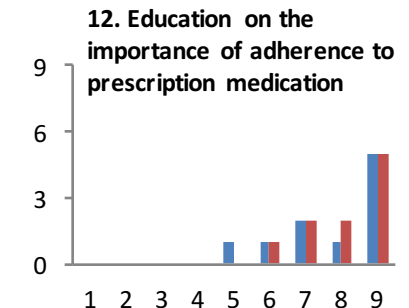
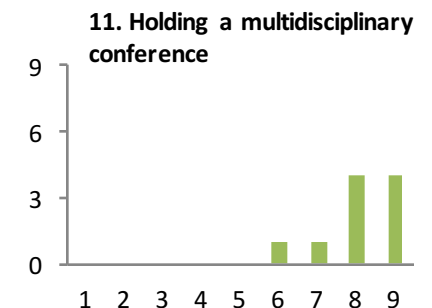
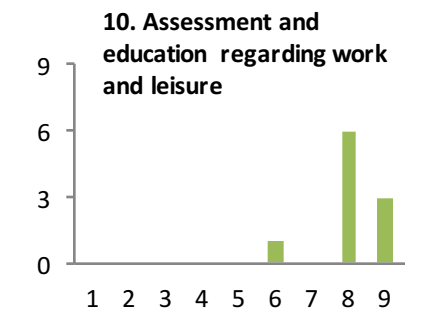
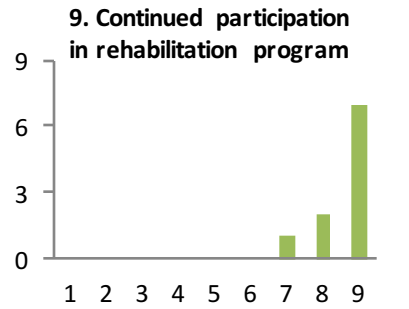
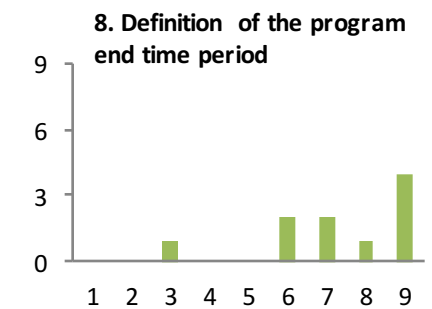
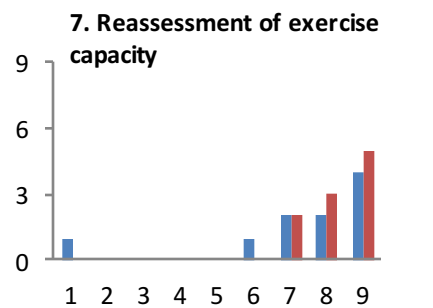
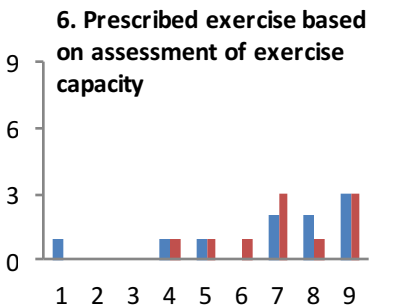
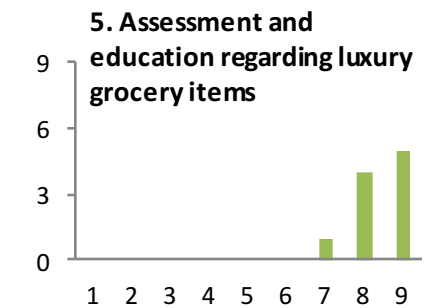
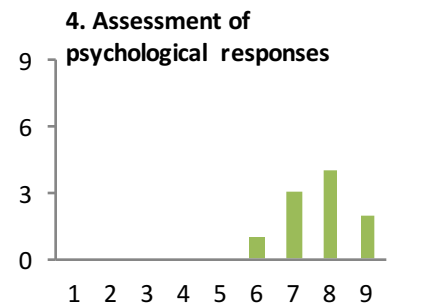
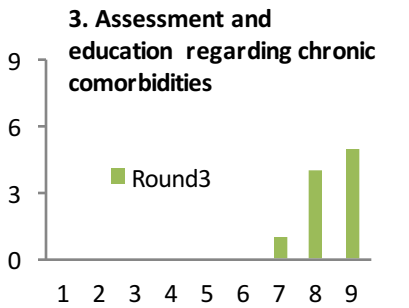
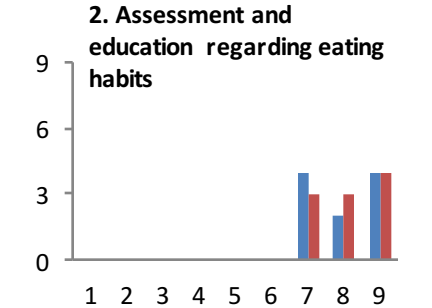
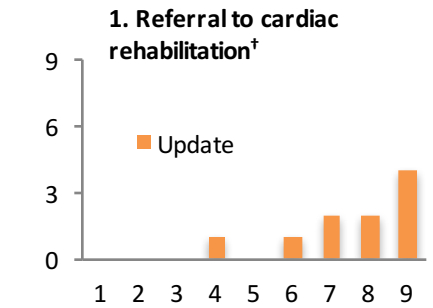
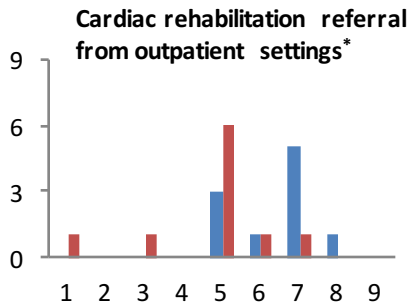
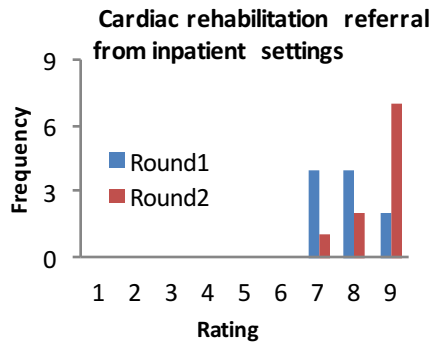
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Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Abstract

Objectives: Cardiac rehabilitation is underutilized and its quality in practice is unclear. A quality indicator is a measurable element of clinical practice performance. This study aimed to propose a set of quality indicators for cardiac rehabilitation following an acute coronary event in the Japanese population and conduct a small-size practice test to confirm feasibility and applicability of the indicators in real-world clinical practice.

Design and Setting: This study used a Modified Delphi technique (the RAND/UCLA appropriateness method), a consensus method which involves an evidence review, a face-to-face multidisciplinary panel meeting and repeated anonymous rating. Evidence to be reviewed included clinical practice guidelines available in English or Japanese and existing quality indicators. Performance of each indicator was assessed retrospectively using medical records at a university hospital in Japan.

Participants: Ten professionals in cardiac rehabilitation for the consensus panel.

Results: In the literature review, 23 clinical practice guidelines and 16 existing indicators were identified to generate potential indicators. Through the consensus-building process, a total of 30 indicators were assessed and finally 13 indicators were accepted. The practice test (n = 39) revealed that 74% of patients underwent cardiac rehabilitation. Median performance of process measures was 93% (interquartile range, 46-100). "Communication with the doctor who referred the patient to cardiac rehabilitation" and "Continuous participation in cardiac rehabilitation" had low performance (32% and 38%, respectively).

Conclusions: A Modified Delphi technique identified a comprehensive set of quality indicators for cardiac rehabilitation. The single-site, small-size practice test confirmed that most of the proposed indicators were measurable in real-world clinical practice. However, some clinical processes which are not

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covered by national health insurance in Japan had low performance. Further studies will be needed to clarify and improve the quality of care in cardiac rehabilitation.

Abstract word count: 287/300 words

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Strengths and limitations of this study

- This is the first study to assess usage of a whole set of quality indicators for cardiac rehabilitation in the process of development.
- A guideline-based modified Delphi technique was used and medical records were reviewed as a practice test before implementing indicators in the real world clinical practice.
- The composition of our panel members may lead to a biased selection of indicators.
- The single-site, small-size practice test may limit to generalize the performance of indicators.

Introduction

Acute coronary syndrome is a leading cause of death and major social burden in the world.¹ Developments in coronary interventions, surgical procedures, pharmacological treatments and lifestyle modifications (e.g., smoking cessation) have improved prognosis, prevented recurrence and reduced mortality in patients who experience acute coronary events.²⁻³ In urban and/or suburban areas of Japan, however, the incidence of myocardial infarction and sudden cardiac death among men has increased in the past few decades.⁴

Previous studies have demonstrated the effectiveness of comprehensive cardiac rehabilitation (CR) on the survival and quality of life of patients with coronary heart disease.⁵ Yet, CR referral rates vary according to characteristics of patients, specialty units and hospitals.⁶⁻¹² Moreover, little is known about the quality of programs in real-world clinical settings.

Quality indicators are measurable elements of practice performance for which there is evidence or consensus. Process indicators, in particular, are used to express the proportion of patients who receive proper care. They can highlight and reveal quality issues, which in turn enable the formulation of solutions for improvement.¹³⁻¹⁵ The use of quality indicators has increased in Japan, particularly in cancer care settings.¹⁶

Quality indicators for cardiovascular disease prevention and CR have been developed in European countries, the United States and Canada, but not in Asia including Japan.¹⁷⁻²¹ Additionally, a practice test prior to real usage is needed when developing quality indicators.²²⁻²³ However, previous practice tests examined only a part of the indicator set in CR field.²⁴⁻²⁵

This study aims to 1) propose quality indicators for CR following an acute coronary event (e.g., acute myocardial infarction and unstable angina), as these diseases are the most common indications for CR, 2) conduct a small-size, pilot practice test with the whole set of the proposed indicators to confirm the feasibility and applicability before using them in real world clinical

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4 practice and 3) describe a detailed process of developing quality indicators for
5 applicability to other clinical circumstances.
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10 11 12 Methods

13 14 15 Indicator Development

16 17 18 Overview of the Development Process

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21 This study was conducted by the task force on evidence-based
22 healthcare and clinical practice guidelines under the Ministry of Health,
23 Welfare and Labour in Japan. The aim was to propose the common method
24 to develop quality indicators.
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29 A modified Delphi technique (the RAND/UCLA Appropriateness
30 Method), which has been widely used to develop healthcare quality
31 indicators, was used.²⁶ The method integrates an evidence review, a face-to-
32 face multidisciplinary panel meeting and repeated anonymous rating for
33 consensus building. This study was approved by the Ethics Committee of
34 Kyoto University Graduate School and Faculty of Medicine.
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40 41 42 Systematic Search of Evidence

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44 Kötter et al. previously reported that methods for quality indicator
45 development based on clinical guidelines are increasing and may help in the
46 efficient gathering of evidence when considering indicators.²² Based on this,
47 we searched existing clinical practice guidelines available in English or
48 Japanese and quality indicators related to CR after an acute coronary event
49 developed in countries other than Japan. Specifically, we searched electronic
50 databases with the search terms "cardiovascular disease", "cardiovascular
51 system", "cardiology", "cardiac", "cardiovascular" and "rehabilitation" in August
52 2011. The following databases were used: one quality indicator database
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4 (AHRQ National Quality Measures Clearinghouse); nine guideline databases
5 (AHRQ National Guideline Clearinghouse, NICE Find Guidance, NHS Evidence,
6 Minds, PEDro, Guidelines International Network, Australian Government
7 National Health Medical Research Council, Canadian Medical Association and
8 British Intercollegiate Guidelines Network); and three medical literature
9 databases (MEDLINE, CINAHL and ICHUSHI). The Japanese Association of
10 Cardiac Rehabilitation website and the Japanese Circulation Society website
11 were also reviewed for Japanese guidelines on CR. The search was limited to
12 English or Japanese language. In 2011, we searched literature published from
13 April 2006 to March 2011, because clinical guidelines are generally outdated
14 after five years.^{27 28} Two appraisers (SO and NK) evaluated the quality of the
15 selected guidelines with the AGREE II instrument, which is the established tool
16 for this purpose.²⁹ For each guideline, overall assessments using AGREE II by
17 two appraisers were averaged.

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29 In order to generate indicators to be evaluated in a subsequent
30 consensus panel, clinical practices which were strongly recommended in the
31 selected guidelines were extracted. They were merged with existing quality
32 indicators and applied to a structured format of the modified ACC/AHA
33 Methodology.³⁰ One researcher (SO) assembled the indicators and was
34 supervised by two experts: TN, an epidemiologist experienced in the
35 development of a variety of Japanese clinical practice guidelines and also the
36 chair of the task force on evidence-based health care and clinical practice
37 guidelines, and KU, a cardiologist familiar with CR and evidence-based
38 medicine.

48 Multidisciplinary Panel

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50 Panel members responsible for consensus development were selected
51 from registered instructors of CR licensed by the Japanese Association of
52 Cardiac Rehabilitation. Licensure status requires individuals to have practiced
53 CR for at least one year, submitted ten case reports and passed an authorized
54 examination. To assemble the multidisciplinary group, we attempted to select
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4 more than one person from each profession related to CR (cardiologists,
5 nurses, physical therapists, clinical laboratory technicians, registered dieticians,
6 health fitness programmers and clinical psychologists). The sampling strategy
7 was nonrandom selection, with recommendations by KU and approval by SO
8 and TN. KU was a member of the committee on Japanese guidelines for CR
9 and appointed as president of the Japan Association of Cardiac Rehabilitation
10 in 2014. Each panel member signed a consent form for the present study.
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18 Consensus Building

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20 Based on the modified Delphi technique, panel members formed a
21 consensus regarding indicators in three rounds. In round 1, members
22 individually evaluated indicators using a nine-point scale postal questionnaire.
23 In round 2, they reconvened for a one-day face-to-face meeting to discuss,
24 revise, and individually evaluate potential indicators, and then suggest
25 additional ones at a later meeting. In round 3, they evaluated additional
26 indicators with the same questionnaire as above.
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34 Round 1

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36 A set of documents that described the quality indicators was
37 distributed to panel members. Members were then given two weeks to
38 individually rate each indicator with a nine-point scale questionnaire, adapted
39 from the nine domains suggested by Spertus et al.: evidence-based,
40 interpretable, actionable, denominator, numerator, validity, reliability, feasibility
41 and overall assessment.³⁰
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48 Round 2

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50 A one-day face-to-face panel meeting was held. Panel members
51 anonymously shared their results from round 1 and discussed each indicator.
52 When the panel members felt necessity, they revised the elements of each
53 potential indicator considering member's suggestion. Any disagreements were
54 resolved through discussion. Finally, the panel rated the revised indicators
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4 individually, using the same questionnaire from round 1. At the end of the
5 meeting, we asked members to suggest additional indicators that might be
6 important for measuring the quality of CR services in Japan that had not been
7 examined by the panel prior to the meeting.
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10 11 12 Round 3

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14 Additional indicators were developed from suggestions during the
15 panel meeting (round 2). A document describing the new indicators was sent
16 to panel members electronically, asking for any modifications. The indicators
17 were then revised according to the suggestions and sent to panel members
18 by mail to rate using the same questionnaire from round 1.
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24 25 Selection Criteria

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27 Quality indicators were adopted according to the following criteria: the
28 median individual rating during round 2 or round 3 was greater than seven,
29 and the number of panel members who gave a rating less than three was two
30 or fewer.
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37 38 Pilot Practice Test for Feasibility and Adaptability

39 40 Study Patients

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42 Selected patients were those who 1) experienced an acute myocardial
43 infarction or unstable angina and 2) were admitted to Kyoto University
44 Hospital, which provides acute-to-recovery care in Japan, between January 1,
45 2013 and June 30, 2013.
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50 51 Data Collection

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53 Data were collected from Kyoto University's electronic medical records
54 in January 2014. Records regarding eating habits (QI-2), coronary risk factors
55 (QI-3), psychological responses (QI-4), tobacco and alcohol (QI-5), exercise
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4 capacity (QI-6), definition of the program end period (QI-8) and work and
5 leisure (QI-10) were available in the implementation planning sheets for CR
6 per national insurance regulations. Especially with regard to QI-2, as routine in
7 the hospital, professionals assessed a suitable period for every patient in view
8 of one's clinical situation and recorded it in the planning sheet. Records on
9 education regarding the importance of performance on prescription
10 medication (QI-12) were available in pharmacist instruction reports, also per
11 national insurance regulations. SO and NK assessed performance of the
12 indicators based on each patient's records. Disagreements were resolved by
13 discussion.
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22 Data Analysis

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25 Patients with acute myocardial infarction and unstable angina were
26 selected consecutively during the study period from Kyoto University Hospital
27 via coronary catheterization records for measurement with the indicators.
28 Percentage scores were obtained for each indicator as follows: the number of
29 times the indicator was met / the number of subjects (excluding those with
30 obvious reasons for not implementing the process as defined by the indicator)
31 x 100. Medians of indicator scores were also computed as an overall quality
32 score of the program.
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43 Disclosure and update

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45 The adopted indicators were disclosed and externally reviewed at a
46 symposium during the annual meeting of the Japanese Association of Cardiac
47 Rehabilitation, of which KU was the president in July 2014. Considering
48 suggestions from external experts, an indicator regarding referral to CR was
49 updated in October 2015 based on an online panel discussion and the nine-
50 point scale assessment.
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Results

Quality Indicators

The literature review identified 38 quality indicators from AHRQ National Quality Measures Clearinghouse, of which 16 were selected according to the criteria (Figure 1). Searches of guideline databases and medical literature databases identified 894 articles (103 from AHRQ National Guideline Clearinghouse, 121 from NICE Find Guidance, 487 from NHS Evidence, two from Minds, 11 from PEDro, 25 from Guidelines International Network, six from Australian Government National Health Medical Research Council, nine from Canadian Medical Association, 22 from British Intercollegiate Guidelines Network, 74 from MEDLINE, 24 from CINAHL and 10 from ICHUSHI). Seven additional guidelines were identified from Japanese academic society websites. In total, 23 guidelines met our eligibility criteria. The average of overall quality scores based on AGREE II was 5.0 out of a possible 7 (min to max, 3.5 to 6.0). A total of 27 potential indicators created from above-mentioned 16 existing indicators and 23 guidelines were included for panel assessment.

The panel consisted of ten Japanese clinicians in CR, including two cardiologists, two nurses, two physical therapists, one clinical laboratory technician, one registered dietitian, one health fitness programmer and one clinical psychologist (a member of the committee on Japanese guidelines for CR).

Round 2 ratings accepted six indicators (Figures 2 and 3). Although a indicator regarding referral to CR from outpatient settings had been discarded in this round, it was later accepted in the update period as a modified indicator (QI-1, Table 1), the rating of which was a median of 8, and min to max of 4 to 9 (Figure 3).

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4 Of the 20 primary indicators, the panel reconstructed four indicators.
5 The indicator "assessment and education regarding coronary risk factors" was
6 developed by combining the following 13 primary indicators: "hypertension
7 assessment", "education for patients with hypertension", "target blood
8 pressure goal achievement", "assessment and education regarding blood
9 lipids", "reassessment of blood lipids", "assessment and education regarding
10 physical activity habits", "intervention for physical activity habits",
11 "reassessment of physical daily activity", "assessment of body weight",
12 "intervention for body weight control", "assessment of diabetes", "intervention
13 for diabetes" and "target HbA_{1c} goal achievement". Some panel members
14 noted that clinicians tend to deal with these issues together rather than
15 separately. As such, they agreed that combining these indicators would make
16 it easier to perform high quality measurements.
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18 The two primary indicators, "assessment of depression" and
19 "intervention for a patient suspected of having depression", gave rise to the
20 indicator "assessment of psychological responses". Patients with coronary
21 disease often have psychological issues such as depression, anxiety or
22 insomnia.^{18 31} Furthermore, the panel was of the opinion that patients in Japan
23 rarely receive appropriate assessments, aside from interventions they receive
24 for CR.
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26 The indicator "assessment and education regarding tobacco and
27 alcohol" was generated by combining the following three primary indicators:
28 "assessment of tobacco use", "support of smoking cessation" and "education
29 on alcohol". The panel agreed that combining these items would improve
30 measurement quality in clinical settings, as clinicians typically deal with these
31 issues together.
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33 The primary indicator counseling to return to work was reworded as
34 "assessment and education regarding work and leisure". The panel agreed
35 that it was important for a patient requiring rehabilitation to enjoy a leisurely
36 life in addition to returning to work.
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4 In addition to the indicators discussed above, the panel suggested
5 some indicators, including "definition of program end period" and "continued
6 participation in rehabilitation program". These indicators were generated after
7 some panel members emphasized the importance of completing the CR
8 program. Given the multidisciplinary nature of the rehabilitation team, the
9 generation of another indicator ("holding a multidisciplinary conference") was
10 suggested.
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16 In the end, a total of 13 quality indicators were proposed. These
17 indicators spanned the following domains: (1) referral to CR, (2) modification
18 of coronary risk factors, (3) exercise prescription, (4) completion of CR
19 program, (5) return to social activity, (6) involvement of a multidisciplinary
20 team, (7) management of prescription medication and (8) communication with
21 other healthcare providers (Table 1).
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37 Performance in the Pilot Practice Test

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40 Of the 39 assessed patients (22 with acute myocardial infarction and 17
41 with unstable angina), 29 (74%) participated in a CR program (QI-1, Table 1).
42 The median performance, based on QI-2 to QI-13, was 93% (interquartile
43 range, 46 to 100). Indicators for which data are collected for national
44 insurance claims (QI-2, 3, 4, 5, 6, 8, 10 and 12) showed high performance
45 (median, 100%; min to max, 74 to 100), whereas others, including QI- 7, 9, 11
46 and 13, showed low performance (min to max, 32%-48%).
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55 Discussion

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4 In this study, we proposed 13 quality indicators for assessing CR in
5 patients who suffered from acute coronary syndrome in Japan. A widely used
6 consensus approach, the modified Delphi method, with a Japanese
7 multidisciplinary panel identified seven crucial domains for the quality
8 measurement. Based on results of the single-site, small-size practice test, we
9 found that most of indicators proposed were measurable in real-world clinical
10 practice and the performance for which data are collected for national
11 insurance claims was high, whereas performance of indicators for which data
12 are recorded voluntarily was low.
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20 The structure of our proposed indicators is consistent with those
21 reported in previous studies. A few reports have been published that deal
22 with quality measures for CR in North America. ACC/AHA/AACVPR provided a
23 performance measure set that has (1) referral to CR and (2) performance in
24 the program as major parts.^{18 19} The Canadian Cardiovascular Society also
25 originally developed quality indicators on CR, and then prioritized a list of 5
26 indicators, including (1) inpatients referred to CR; (2) wait times from referral
27 to CR enrollment; (3) patient self-management education; (4) increase in
28 exercise capacity and (5) emergency response strategy.^{20 25} In the present
29 study, our set of indicators reflects the importance of referral to CR and a
30 comprehensive program. Therefore, we consider these to be essential
31 elements of quality indicators for CR. Additionally, our study includes a
32 measurement for the completion of cardiac rehabilitation, which is common
33 with measure set of the US. It is because completion of the prescribed course
34 of the program is a key to promoting patients' life-long behavior change and
35 physiologic adaptations from regular exercise.¹⁸
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48 During the process of developing quality indicators, pilot practice tests
49 prior to implementation are important for determining which indicators
50 become established components because they evaluate validity, reliability and
51 feasibility.²² Some studies in other medical fields (e.g., neck tumors, diabetes,
52 pneumonia) have reported that, among accepted indicators in the
53 development process, approximately 10 to 30% were not measurable or
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4 inapplicable.^{32 33} In the field of CR in the United States, Thomas et al. revealed
5 that reliability of the abstraction for the measure regarding referral was good
6 to excellent.²⁴ In addition, with respect to Canadian indicators, Grace et al.
7 assessed feasibility and concluded that the indicator assessment was
8 acceptable for the CR program.²⁵ Unlike the previous studies, our practice test
9 was small-size but included all indicators proposed. Although the
10 generalizability is limited, we found a possibility that some processes for
11 which data were not recorded per healthcare insurance regulations have low
12 performance. Since Grace et al. also reported that the information-tracking
13 process was challenging when measuring quality, that may be a common
14 issue in the field of CR across countries.²⁵ Further studies will be needed to
15 make quality measurements more appropriate and efficient.

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25 Although panel nomination is one of the key elements of quality
26 indicator development, many studies lack transparency in the process.²² In
27 contrast to previous reports from the United States and Canada, our study
28 does not stand on the initiative of any academic society, but rather is based
29 on a project granted by the Ministry of Health, Welfare and Labour in Japan.
30 In terms of the aim to propose a method for developing quality indicators,
31 our study established the following explicit criteria: 1) the panel members
32 must have an authorized license from an academic society, and 2) at least one
33 member is selected from every relevant profession. In fact, our panel included
34 the people concerned with the committee on the clinical practice guidelines
35 for CR jointly developed by the relevant academic societies in Japan (i.e.
36 Shunichi Ishihara and Shinji Sato who are respectively a member and
37 collaborator of the committee).³⁴

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48 The adaptability of each quality indicator must be reviewed before
49 implementation because healthcare systems and social circumstances differ.
50 This is a key element in evidence-based clinical decision-making.^{35 36} We
51 consider, however, disclosing the explicit process of guideline-based quality
52 indicator development, which is a time-efficient and resource-saving
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4 approach,²² will be helpful for people attempting to develop similar quality
5 indicators in other regions or different social levels.
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10 Conclusion

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14 Using an explicit and integrated approach based on evidence and the
15 consensus of a multidisciplinary panel, we proposed 13 specific indicators to
16 measure the quality of CR for patients who experienced acute coronary events
17 in Japan. The practice test was small-size but helpful to confirm the
18 measurability of all indicators proposed, and found that health insurance
19 coverage can effect on performance in related processes. Further studies will
20 be needed to clarify the reasons for this, as well as to improve the quality of
21 care in CR.
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27 American Physical Therapy Association, Canadian Association of Cardiac
28 Rehabilitation, European Association for Cardiovascular Prevention and
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39 the American Physical Therapy Association, the Canadian Association of
40 Cardiac Rehabilitation, the Clinical Exercise Physiology Association, the
41 European Association for Cardiovascular Prevention and Rehabilitation,
42 the Inter-American Heart Foundation, the National Association of
43 Clinical Nurse Specialists, the Preventive Cardiovascular Nurses
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18 Footnotes

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20
21 **Contributors:** SO conceived, designed and analyzed the study and drafted
22 and prepared the manuscript. NK assisted data collection and analysis and
23 manuscript preparation. NO and KU contributed to the data collection and
24 interpretation of data and manuscript preparation. TN supervised the study
25 design, administration, analysis and interpretation and gave the final approval
26 of the manuscript.
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39 accountable health care (2014-2015)".
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47 **Competing interests:** We have read and understood BMJ policy on
48 declaration of interests and declare that we have no competing interests.
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52 **Data sharing statement:** No additional data are available.
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Table 1. Quality indicators and percentage scores for cardiac rehabilitation of inpatients with ischemic heart disease.

Domains	Indicators	Numerator/	Performance,
		Denominator	%
Domain 1. Referral to cardiac rehabilitation	QI-1. Referral to cardiac rehabilitation	29/39	74
	QI-2. Assessment and education regarding eating habits	29/29	100
Domain 2. Modification of coronary risk factors	QI-3. Assessment and education regarding coronary risk factors	29/29	100
	QI-4. Assessment of psychological responses	28/29	97
	QI-5. Assessment and education regarding tobacco and alcohol	29/29	100
Domain 3. Exercise therapy	QI-6. Prescribed exercise based on assessment of exercise capacity	20/27	74
	QI-7. Reassessment of exercise capacity	11/24	46
Domain 4. Completion of cardiac rehabilitation program	QI-8. Definition of the program end period	29/29	100

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	QI-9. Continued participation in rehabilitation program	8/21	38
Domain 5. Return to social activity	QI-10. Assessment and education regarding work and leisure	29/29	100
Domain 6. Involvement of multidisciplinary team	QI-11. Holding a multidisciplinary conference	14/29	48
Domain 7. Management of prescription medication	QI-12. Education on the importance of adherence to prescription medication	26/29	90
Domain 8. Communication with other healthcare providers	QI-13. Communication with a doctor who referred the patient to cardiac rehabilitation	8/25	32

For peer review only

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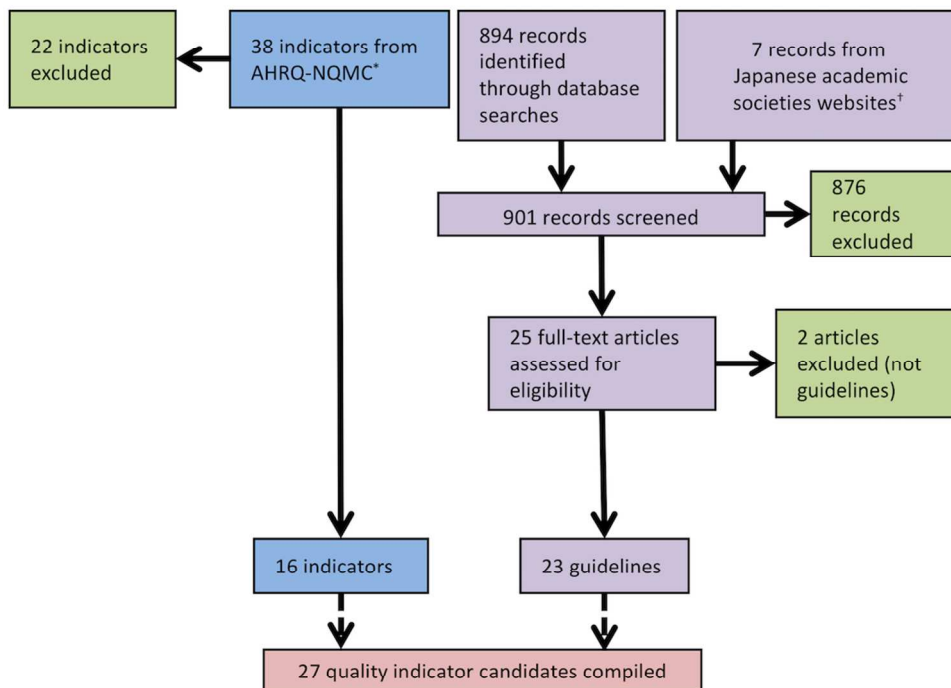


Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

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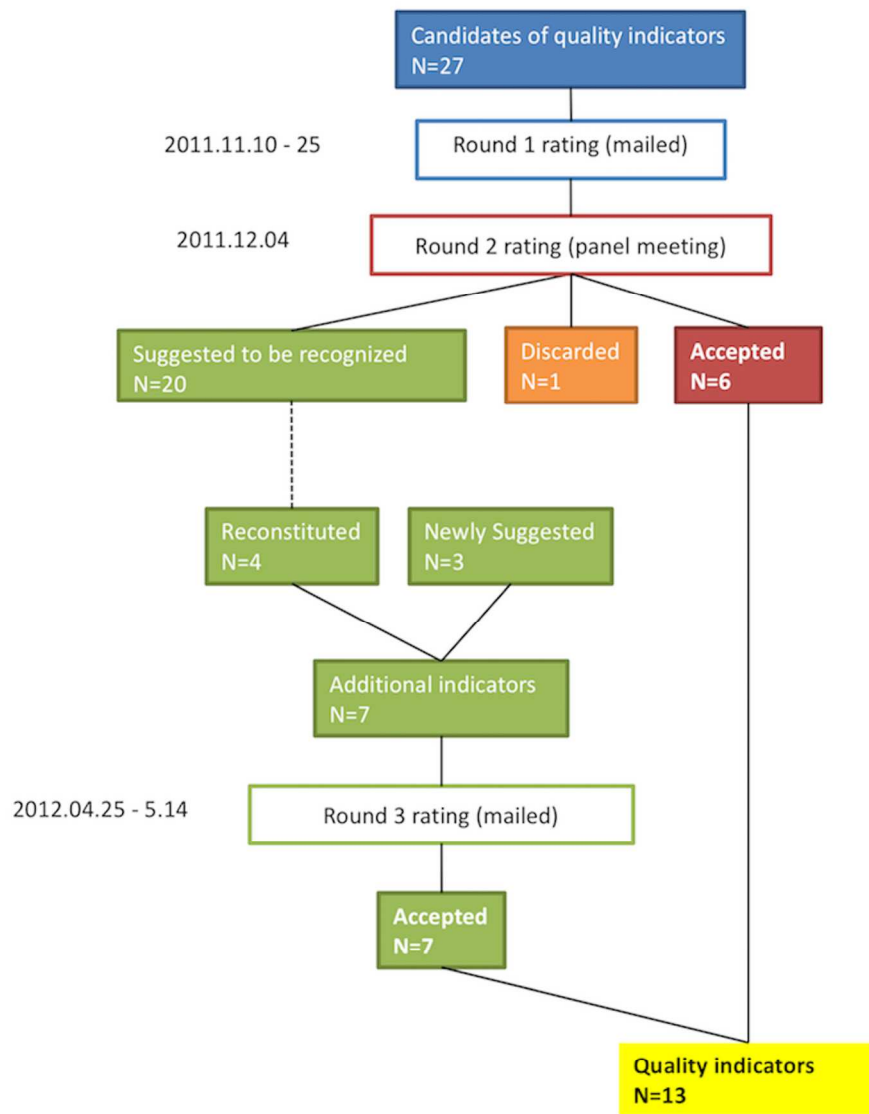


Figure 2. Flow chart of quality indicator selection

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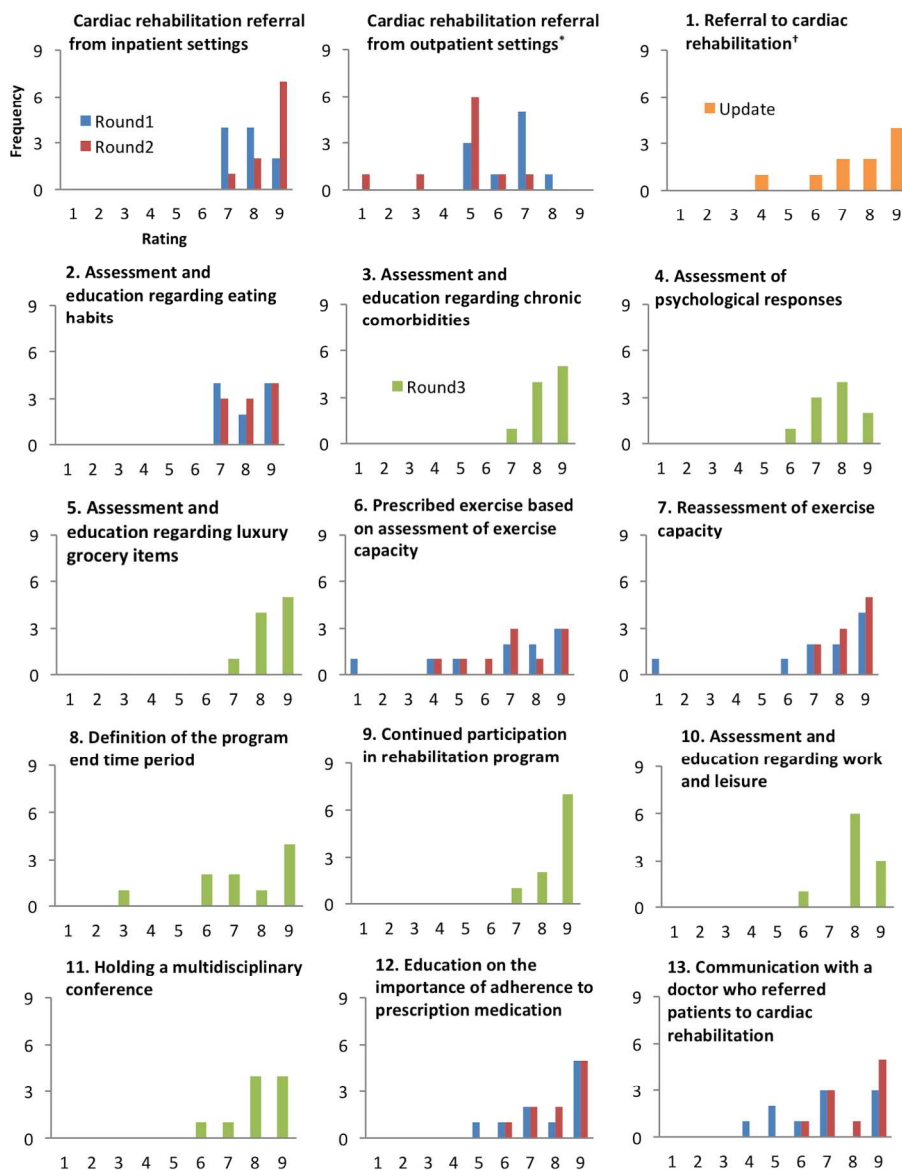


Figure 3. Rating distribution of candidate indicators
 The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.

*This candidate indicator did not gain consensus and was discarded in Round 2.

†This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

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BMJ Open

Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Abstract

Objectives: Cardiac rehabilitation is underutilized and its quality in practice is unclear. A quality indicator is a measurable element of clinical practice performance. This study aimed to propose a set of quality indicators for cardiac rehabilitation following an acute coronary event in the Japanese population and conduct a small-size practice test to confirm feasibility and applicability of the indicators in real-world clinical practice.

Design and Setting: This study used a Modified Delphi technique (the RAND/UCLA appropriateness method), a consensus method which involves an evidence review, a face-to-face multidisciplinary panel meeting and repeated anonymous rating. Evidence to be reviewed included clinical practice guidelines available in English or Japanese and existing quality indicators. Performance of each indicator was assessed retrospectively using medical records at a university hospital in Japan.

Participants: Ten professionals in cardiac rehabilitation for the consensus panel.

Results: In the literature review, 23 clinical practice guidelines and 16 existing indicators were identified to generate potential indicators. Through the consensus-building process, a total of 30 indicators were assessed and finally 13 indicators were accepted. The practice test (n = 39) revealed that 74% of patients underwent cardiac rehabilitation. Median performance of process measures was 93% (interquartile range, 46-100). "Communication with the doctor who referred the patient to cardiac rehabilitation" and "Continuous participation in cardiac rehabilitation" had low performance (32% and 38%, respectively).

Conclusions: A Modified Delphi technique identified a comprehensive set of quality indicators for cardiac rehabilitation. The single-site, small-size practice test confirmed that most of the proposed indicators were measurable in real-world clinical practice. However, some clinical processes which are not

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4 covered by national health insurance in Japan had low performance. Further
5 studies will be needed to clarify and improve the quality of care in cardiac
6 rehabilitation.
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For peer review only

Strengths and limitations of this study

- This is the first study to assess usage of a whole set of quality indicators for cardiac rehabilitation in the process of development.
- A guideline-based modified Delphi technique was used and medical records were reviewed as a practice test before implementing indicators in the real world clinical practice.
- The composition of our panel members may lead to a biased selection of indicators.
- The single-site, small-size practice test may limit to generalize the performance of indicators.

Introduction

Acute coronary syndrome is a leading cause of death and major social burden in the world.¹ Developments in coronary interventions, surgical procedures, pharmacological treatments and lifestyle modifications (e.g., smoking cessation) have improved prognosis, prevented recurrence and reduced mortality in patients who experience acute coronary events.^{2 3} In urban and/or suburban areas of Japan, however, the incidence of myocardial infarction and sudden cardiac death among men has increased in the past few decades.⁴

Previous studies have demonstrated the effectiveness of comprehensive cardiac rehabilitation (CR) on the survival and quality of life of patients with coronary heart disease.⁵ Yet, CR referral rates vary according to characteristics of patients, specialty units and hospitals.⁶⁻¹² Moreover, little is known about the quality of programs in real-world clinical settings.

Quality indicators are measurable elements of practice performance for which there is evidence or consensus. Process indicators, in particular, are used to express the proportion of patients who receive proper care. They can highlight and reveal quality issues, which in turn enable the formulation of solutions for improvement.¹³⁻¹⁵ The use of quality indicators has increased in Japan, particularly in cancer care settings.¹⁶

Quality indicators for cardiovascular disease prevention and CR have been developed in European countries, the United States and Canada, but not in Asia including Japan.¹⁷⁻²¹ Additionally, a practice test prior to real usage is needed when developing quality indicators.^{22 23} However, previous practice tests examined only a part of the indicator set in CR field.^{24 25}

This study aims to 1) propose quality indicators for CR following an acute coronary event (e.g., acute myocardial infarction and unstable angina), as these diseases are the most common indications for CR, 2) conduct a small-size, pilot practice test with the whole set of the proposed indicators to confirm the feasibility and applicability before using them in real world clinical

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4 practice and 3) describe a detailed process of developing quality indicators for
5 applicability to other clinical circumstances.
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13 14 15 Indicator Development

16 17 18 Overview of the Development Process

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21 This study was conducted by the task force on evidence-based
22 healthcare and clinical practice guidelines under the Ministry of Health,
23 Welfare and Labour in Japan. The aim was to propose the common method
24 to develop quality indicators.
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29 A modified Delphi technique (the RAND/UCLA Appropriateness
30 Method), which has been widely used to develop healthcare quality
31 indicators, was used.²⁶ The method integrates an evidence review, a face-to-
32 face multidisciplinary panel meeting and repeated anonymous rating for
33 consensus building. This study was approved by the Ethics Committee of
34 Kyoto University Graduate School and Faculty of Medicine.
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40 41 42 Systematic Search of Evidence

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44 Kötter et al. previously reported that methods for quality indicator
45 development based on clinical guidelines are increasing and may help in the
46 efficient gathering of evidence when considering indicators.²² Based on this,
47 we searched existing clinical practice guidelines available in English or
48 Japanese and quality indicators related to CR after an acute coronary event
49 developed in countries other than Japan. Specifically, we searched electronic
50 databases with the search terms "cardiovascular disease", "cardiovascular
51 system", "cardiology", "cardiac", "cardiovascular" and "rehabilitation" in August
52 2011. The following databases were used: one quality indicator database
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4 (AHRQ National Quality Measures Clearinghouse); nine guideline databases
5 (AHRQ National Guideline Clearinghouse, NICE Find Guidance, NHS Evidence,
6 Minds, PEDro, Guidelines International Network, Australian Government
7 National Health Medical Research Council, Canadian Medical Association and
8 British Intercollegiate Guidelines Network); and three medical literature
9 databases (MEDLINE, CINAHL and ICHUSHI). The Japanese Association of
10 Cardiac Rehabilitation website and the Japanese Circulation Society website
11 were also reviewed for Japanese guidelines on CR. The search was limited to
12 English or Japanese language. In 2011, we searched literature published from
13 April 2006 to March 2011, because clinical guidelines are generally outdated
14 after five years.^{27 28} Two appraisers (SO and NK) evaluated the quality of the
15 selected guidelines with the AGREE II instrument, which is the established tool
16 for this purpose.²⁹ For each guideline, overall assessments using AGREE II by
17 two appraisers were averaged.

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29 In order to generate indicators to be evaluated in a subsequent
30 consensus panel, clinical practices which were strongly recommended in the
31 selected guidelines were extracted. They were merged with existing quality
32 indicators and applied to a structured format of the modified ACC/AHA
33 Methodology.³⁰ One researcher (SO) assembled the indicators and was
34 supervised by two experts: TN, an epidemiologist experienced in the
35 development of a variety of Japanese clinical practice guidelines and also the
36 chair of the task force on evidence-based health care and clinical practice
37 guidelines, and KU, a cardiologist familiar with CR and evidence-based
38 medicine.

48 Multidisciplinary Panel

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50 Panel members responsible for consensus development were selected
51 from registered instructors of CR licensed by the Japanese Association of
52 Cardiac Rehabilitation. Licensure status requires individuals to have practiced
53 CR for at least one year, submitted ten case reports and passed an authorized
54 examination. To assemble the multidisciplinary group, we attempted to select
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4 more than one person from each profession related to CR (cardiologists,
5 nurses, physical therapists, clinical laboratory technicians, registered dieticians,
6 health fitness programmers and clinical psychologists). The sampling strategy
7 was nonrandom selection, with recommendations by KU and approval by SO
8 and TN. KU was a member of the committee on Japanese guidelines for CR
9 and appointed as president of the Japan Association of Cardiac Rehabilitation
10 in 2014. Each panel member signed a consent form for the present study.
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17 18 Consensus Building

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20 Based on the modified Delphi technique, panel members formed a
21 consensus regarding indicators in three rounds. In round 1, members
22 individually evaluated indicators using a nine-point scale postal questionnaire.
23 In round 2, they reconvened for a one-day face-to-face meeting to discuss,
24 revise, and individually evaluate potential indicators, and then suggest
25 additional ones at a later meeting. In round 3, they evaluated additional
26 indicators with the same questionnaire as above.
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34 Round 1

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36 A set of documents that described the quality indicators was
37 distributed to panel members. Members were then given two weeks to
38 individually rate each indicator with a nine-point scale questionnaire, adapted
39 from the nine domains suggested by Spertus et al.: evidence-based,
40 interpretable, actionable, denominator, numerator, validity, reliability, feasibility
41 and overall assessment.³⁰
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48 Round 2

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50 A one-day face-to-face panel meeting was held. Panel members
51 anonymously shared their results from round 1 and discussed each indicator.
52 When the panel members felt necessity, they revised the elements of each
53 potential indicator considering member's suggestion. Any disagreements were
54 resolved through discussion. Finally, the panel rated the revised indicators
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4 individually, using the same questionnaire from round 1. At the end of the
5 meeting, we asked members to suggest additional indicators that might be
6 important for measuring the quality of CR services in Japan that had not been
7 examined by the panel prior to the meeting.
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10 11 12 Round 3

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14 Additional indicators were developed from suggestions during the
15 panel meeting (round 2). A document describing the new indicators was sent
16 to panel members electronically, asking for any modifications. The indicators
17 were then revised according to the suggestions and sent to panel members
18 by mail to rate using the same questionnaire from round 1.
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24 25 Selection Criteria

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27 Quality indicators were adopted according to the following criteria: the
28 median individual rating during round 2 or round 3 was greater than seven,
29 and the number of panel members who gave a rating less than three was two
30 or fewer.
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37 38 Pilot Practice Test for Feasibility and Adaptability

39 40 Study Patients

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42 Selected patients were those who 1) experienced an acute myocardial
43 infarction or unstable angina and 2) were admitted to Kyoto University
44 Hospital, which provides acute-to-recovery care in Japan, between January 1,
45 2013 and June 30, 2013. Based on the Ethical Guidelines for Epidemiological
46 Research established by the Ministry of Education, Culture, Sports, Science
47 and Technology and Ministry of Health, Labour and Welfare in Japan, we
48 prepared a protocol mentioning that the investigators disclose requisite
49 information on the study and, consequently, the protocol was approved by
50 the university ethics committee.
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Data Collection

Data were collected from Kyoto University's electronic medical records in January 2014. Records regarding eating habits (QI-2), coronary risk factors (QI-3), psychological responses (QI-4), tobacco and alcohol (QI-5), exercise capacity (QI-6), definition of the program end period (QI-8) and work and leisure (QI-10) were available in the implementation planning sheets for CR per national insurance regulations. Especially with regard to QI-2, as routine in the hospital, professionals assessed a suitable period for every patient in view of one's clinical situation and recorded it in the planning sheet. Records on education regarding the importance of performance on prescription medication (QI-12) were available in pharmacist instruction reports, also per national insurance regulations. SO and NK assessed performance of the indicators based on each patient's records. Disagreements were resolved by discussion.

Data Analysis

Patients with acute myocardial infarction and unstable angina were selected consecutively during the study period from Kyoto University Hospital via coronary catheterization records for measurement with the indicators. Percentage scores were obtained for each indicator as follows: the number of times the indicator was met / the number of subjects (excluding those with obvious reasons for not implementing the process as defined by the indicator) x 100. Medians of indicator scores were also computed as an overall quality score of the program.

Disclosure and update

The adopted indicators were disclosed and externally reviewed at a symposium during the annual meeting of the Japanese Association of Cardiac

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4 Rehabilitation, of which KU was the president in July 2014. Considering
5 suggestions from external experts, an indicator regarding referral to CR was
6 updated in October 2015 based on an online panel discussion and the nine-
7 point scale assessment.
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11 Results

12 Quality Indicators

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22 The literature review identified 38 quality indicators from AHRQ
23 National Quality Measures Clearinghouse, of which 16 were selected
24 according to the criteria (Figure 1). Searches of guideline databases and
25 medical literature databases identified 894 articles (103 from AHRQ National
26 Guideline Clearinghouse, 121 from NICE Find Guidance, 487 from NHS
27 Evidence, two from Minds, 11 from PEDro, 25 from Guidelines International
28 Network, six from Australian Government National Health Medical Research
29 Council, nine from Canadian Medical Association, 22 from British
30 Intercollegiate Guidelines Network, 74 from MEDLINE, 24 from CINAHL and 10
31 from ICHUSHI). Seven additional guidelines were identified from Japanese
32 academic society websites. In total, 23 guidelines met our eligibility criteria.
33 The average of overall quality scores based on AGREE II was 5.0 out of a
34 possible 7 (min to max, 3.5 to 6.0). A total of 27 potential indicators created
35 from above-mentioned 16 existing indicators and 23 guidelines were included
36 for panel assessment.³¹⁻⁵³
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49 The panel consisted of ten Japanese clinicians in CR, including two
50 cardiologists, two nurses, two physical therapists, one clinical laboratory
51 technician, one registered dietitian, one health fitness programmer and one
52 clinical psychologist (a member of the committee on Japanese guidelines for
53 CR).
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4 Round 2 ratings accepted six indicators (Figures 2 and 3). Although a
5 indicator regarding referral to CR from outpatient settings had been discarded
6 in this round, it was later accepted in the update period as a modified
7 indicator (QI-1, Table 1), the rating of which was a median of 8, and min to
8 max of 4 to 9 (Figure 3).
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12 Of the 20 primary indicators, the panel reconstructed four indicators.
13 The indicator "assessment and education regarding coronary risk factors" was
14 developed by combining the following 13 primary indicators: "hypertension
15 assessment", "education for patients with hypertension", "target blood
16 pressure goal achievement", "assessment and education regarding blood
17 lipids", "reassessment of blood lipids", "assessment and education regarding
18 physical activity habits", "intervention for physical activity habits",
19 "reassessment of physical daily activity", "assessment of body weight",
20 "intervention for body weight control", "assessment of diabetes", "intervention
21 for diabetes" and "target HbA_{1c} goal achievement". Some panel members
22 noted that clinicians tend to deal with these issues together rather than
23 separately. As such, they agreed that combining these indicators would make
24 it easier to perform high quality measurements.
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27 The two primary indicators, "assessment of depression" and
28 "intervention for a patient suspected of having depression", gave rise to the
29 indicator "assessment of psychological responses". Patients with coronary
30 disease often have psychological issues such as depression, anxiety or
31 insomnia.^{18 54} Furthermore, the panel was of the opinion that patients in Japan
32 rarely receive appropriate assessments, aside from interventions they receive
33 for CR.
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36 The indicator "assessment and education regarding tobacco and
37 alcohol" was generated by combining the following three primary indicators:
38 "assessment of tobacco use", "support of smoking cessation" and "education
39 on alcohol". The panel agreed that combining these items would improve
40 measurement quality in clinical settings, as clinicians typically deal with these
41 issues together.
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4 The primary indicator counseling to return to work was reworded as
5 "assessment and education regarding work and leisure". The panel agreed
6 that it was important for a patient requiring rehabilitation to enjoy a leisurely
7 life in addition to returning to work.
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11 In addition to the indicators discussed above, the panel suggested
12 some indicators, including "definition of program end period" and "continued
13 participation in rehabilitation program". These indicators were generated after
14 some panel members emphasized the importance of completing the CR
15 program. Given the multidisciplinary nature of the rehabilitation team, the
16 generation of another indicator ("holding a multidisciplinary conference") was
17 suggested.
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21 In the end, a total of 13 quality indicators were proposed. These
22 indicators spanned the following domains: (1) referral to CR, (2) modification
23 of coronary risk factors, (3) exercise prescription, (4) completion of CR
24 program, (5) return to social activity, (6) involvement of a multidisciplinary
25 team, (7) management of prescription medication and (8) communication with
26 other healthcare providers (Table 1).
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37 Performance in the Pilot Practice Test

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40 Of the 39 assessed patients (22 with acute myocardial infarction and 17
41 with unstable angina), 29 (74%) participated in a CR program (QI-1, Table 1).
42 The median performance, based on QI-2 to QI-13, was 93% (interquartile
43 range, 46 to 100). Indicators for which data are collected for national
44 insurance claims (QI-2, 3, 4, 5, 6, 8, 10 and 12) showed high performance
45 (median, 100%; min to max, 74 to 100), whereas others, including QI- 7, 9, 11
46 and 13, showed low performance (min to max, 32%-48%).
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55 Discussion

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4 In this study, we proposed 13 quality indicators for assessing CR in
5 patients who suffered from acute coronary syndrome in Japan. A widely used
6 consensus approach, the modified Delphi method, with a Japanese
7 multidisciplinary panel identified seven crucial domains for the quality
8 measurement. Based on results of the single-site, small-size practice test, we
9 found that most of indicators proposed were measurable in real-world clinical
10 practice and the performance for which data are collected for national
11 insurance claims was high, whereas performance of indicators for which data
12 are recorded voluntarily was low.
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20 The structure of our proposed indicators is consistent with those
21 reported in previous studies. A few reports have been published that deal
22 with quality measures for CR in North America. ACC/AHA/AACVPR provided a
23 performance measure set that has (1) referral to CR and (2) performance in
24 the program as major parts.^{18 19} The Canadian Cardiovascular Society also
25 originally developed quality indicators on CR, and then prioritized a list of 5
26 indicators, including (1) inpatients referred to CR; (2) wait times from referral
27 to CR enrollment; (3) patient self-management education; (4) increase in
28 exercise capacity and (5) emergency response strategy.^{20 25} In the present
29 study, our set of indicators reflects the importance of referral to CR and a
30 comprehensive program. Therefore, we consider these to be essential
31 elements of quality indicators for CR. Additionally, our study includes a
32 measurement for the completion of cardiac rehabilitation, which is common
33 with measure set of the US. It is because completion of the prescribed course
34 of the program is a key to promoting patients' life-long behavior change and
35 physiologic adaptations from regular exercise.¹⁸
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48 During the process of developing quality indicators, pilot practice tests
49 prior to implementation are important for determining which indicators
50 become established components because they evaluate validity, reliability and
51 feasibility.²² Some studies in other medical fields (e.g., neck tumors, diabetes,
52 pneumonia) have reported that, among accepted indicators in the
53 development process, approximately 10 to 30% were not measurable or
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4 inapplicable.^{55 56} In the field of CR in the United States, Thomas et al. revealed
5 that reliability of the abstraction for the measure regarding referral was good
6 to excellent.²⁴ In addition, with respect to Canadian indicators, Grace et al.
7 assessed feasibility and concluded that the indicator assessment was
8 acceptable for the CR program.²⁵ Unlike the previous studies, our practice test
9 was small-size but included all indicators proposed. Although the
10 generalizability is limited, we found a possibility that some processes for
11 which data were not recorded per healthcare insurance regulations have low
12 performance. Therefore, the result suggests that incentive such as insurance
13 coverage can improve performance in clinical practice and recording the
14 process. Since Grace et al. also reported that the information-tracking process
15 was challenging when measuring quality, that may be a common issue in the
16 field of CR across countries.²⁵ Further studies will be needed to make quality
17 measurements more appropriate and efficient.

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Although panel nomination is one of the key elements of quality indicator development, many studies lack transparency in the process.²² To increase transparency, our study established the following explicit criteria: 1) the panel members must have an authorized license from an academic society, 2) at least one member is selected from every relevant profession, and 3) the panel involves some members who have experiences of CR guideline development. Finally, our panel included the people concerned with the committee on the clinical practice guidelines for CR jointly developed by the relevant academic societies in Japan (i.e. Shunichi Ishihara and Shinji Sato who are respectively a member and collaborator of the committee).⁵⁷

In contrast to previous reports from the United States and Canada, our study did not directly stand on the initiative of any academic society. However, there were opportunities for authorized experts of CR to express his or her views into the present quality indicators.

The adaptability of each quality indicator must be reviewed before implementation because healthcare systems and social circumstances differ. This is a key element in evidence-based clinical decision-making.^{58 59} We

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4 consider, however, disclosing the explicit process of guideline-based quality
5 indicator development, which is a time-efficient and resource-saving
6 approach,²² will be helpful for people attempting to develop similar quality
7 indicators in other regions or different social levels.
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11 12 13 14 Conclusion

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17 Using an explicit and integrated approach based on evidence and the
18 consensus of a multidisciplinary panel, we proposed 13 specific indicators to
19 measure the quality of CR for patients who experienced acute coronary events
20 in Japan. The practice test was small-size but helpful to confirm the
21 measurability of all indicators proposed, and suggested that incentive such as
22 insurance coverage can improve performance in clinical practice and
23 recording the process. Further studies will be needed to clarify the reasons for
24 this, as well as to improve the quality of care in CR.
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45 n collaboration with the American College of Emergency Physicians, the
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47 ety of Thoracic Surgeons endorsed by the American Association of Card
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47 Footnotes

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49
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51 and prepared the manuscript. NK assisted data collection and analysis and
52 manuscript preparation. NO and KU contributed to the data collection and
53 interpretation of data and manuscript preparation. TN supervised the study
54
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4 design, administration, analysis and interpretation and gave the final approval
5 of the manuscript.
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8
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14 "Research on the subjects of clinical practice guidelines to realize socially
15 accountable health care (2014-2015)".
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19 **Competing interests:** We have read and understood BMJ policy on
20 declaration of interests and declare that we have no competing interests.
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Table 1. Quality indicators and percentage scores for cardiac rehabilitation of inpatients with ischemic heart disease.

Domains	Indicators	Numerator/	Performance,
		Denominator	%
Domain 1. Referral to cardiac rehabilitation	QI-1. Referral to cardiac rehabilitation	29/39	74
	QI-2. Assessment and education regarding eating habits	29/29	100
Domain 2. Modification of coronary risk factors	QI-3. Assessment and education regarding coronary risk factors	29/29	100
	QI-4. Assessment of psychological responses	28/29	97
	QI-5. Assessment and education regarding tobacco and alcohol	29/29	100
Domain 3. Exercise therapy	QI-6. Prescribed exercise based on assessment of exercise capacity	20/27	74
	QI-7. Reassessment of exercise capacity	11/24	46
Domain 4. Completion of cardiac rehabilitation program	QI-8. Definition of the program end period	29/29	100

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	QI-9. Continued participation in rehabilitation program	8/21	38
Domain 5. Return to social activity	QI-10. Assessment and education regarding work and leisure	29/29	100
Domain 6. Involvement of multidisciplinary team	QI-11. Holding a multidisciplinary conference	14/29	48
Domain 7. Management of prescription medication	QI-12. Education on the importance of adherence to prescription medication	26/29	90
Domain 8. Communication with other healthcare providers	QI-13. Communication with a doctor who referred the patient to cardiac rehabilitation	8/25	32

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Figure legends

Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

Figure 2. Flow chart of quality indicator selection

Figure 3. Rating distribution of candidate indicators

The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.

*This candidate indicator did not gain consensus and was discarded in Round 2.

†This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

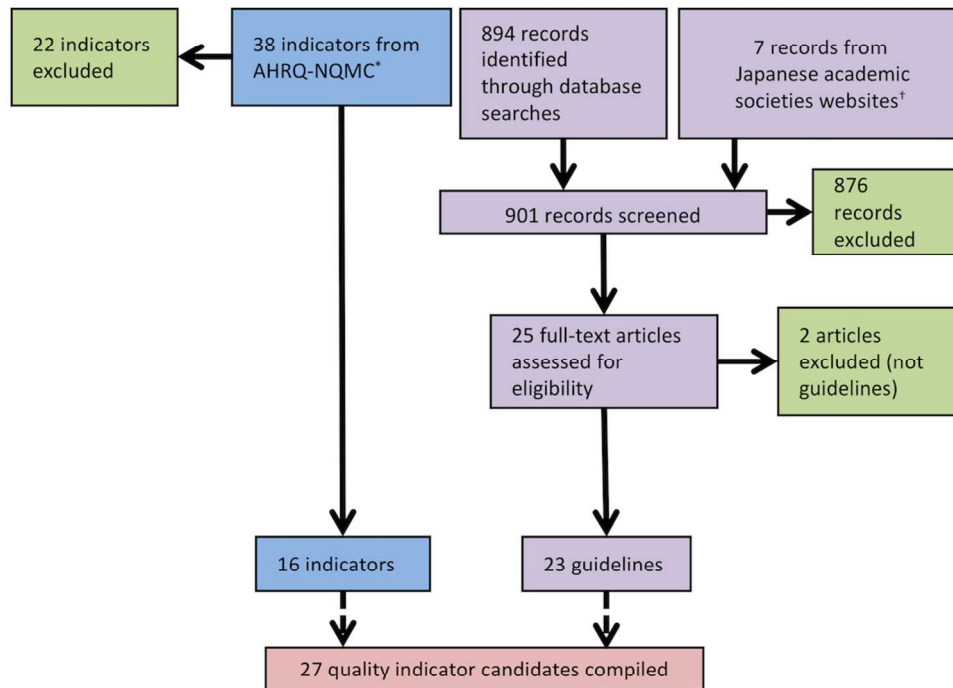


Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

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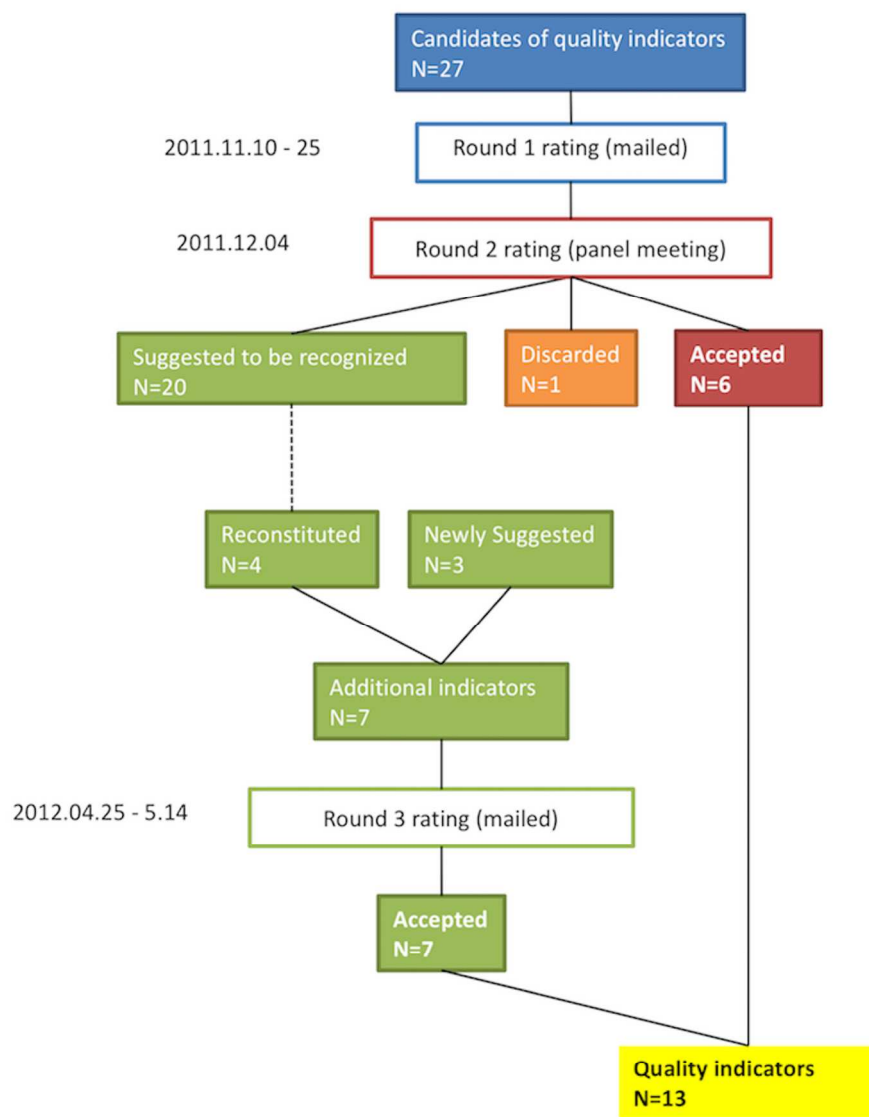


Figure 2. Flow chart of quality indicator selection

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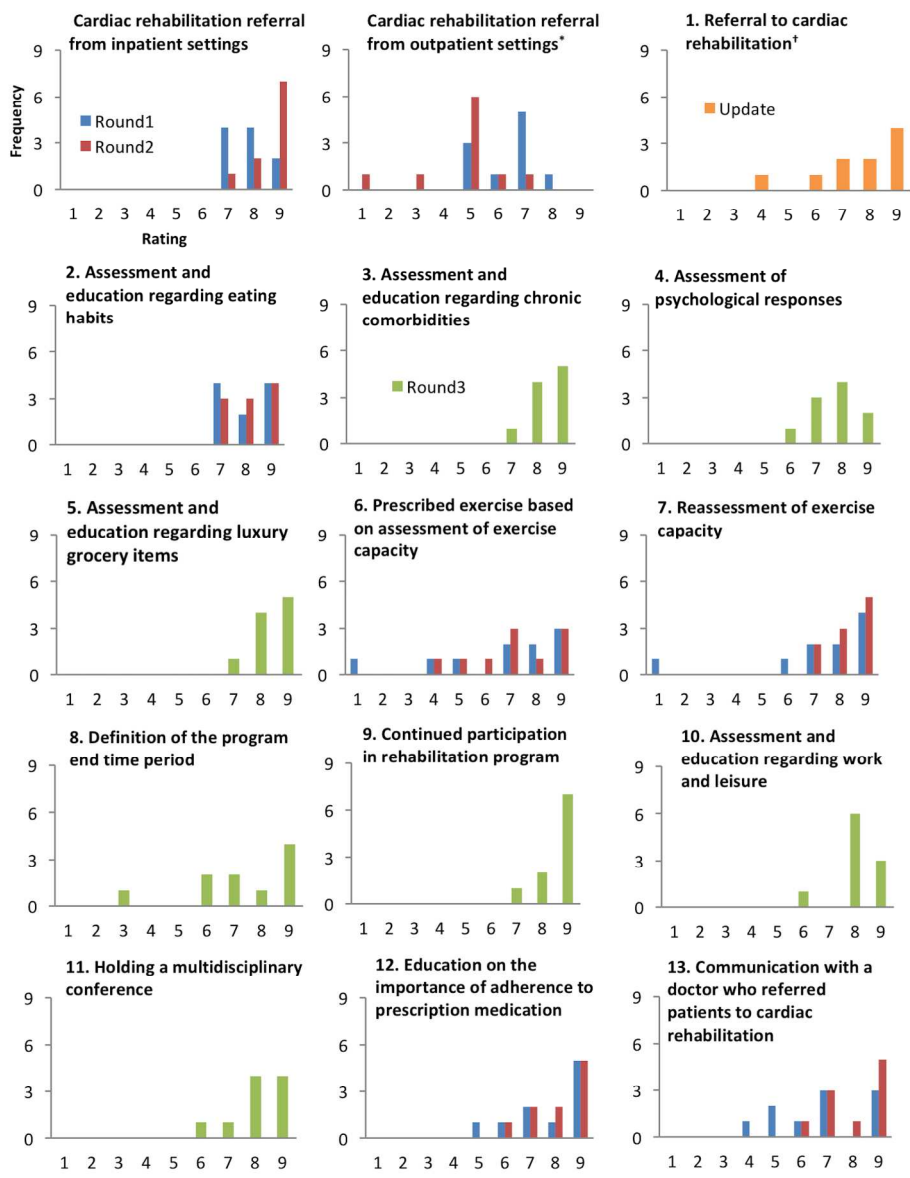


Figure 3. Rating distribution of candidate indicators
 The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.

*This candidate indicator did not gain consensus and was discarded in Round 2.

†This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

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Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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Abstract

Objectives: Cardiac rehabilitation is underutilized and its quality in practice is unclear. A quality indicator is a measurable element of clinical practice performance. This study aimed to propose a set of quality indicators for cardiac rehabilitation following an acute coronary event in the Japanese population and conduct a small-size practice test to confirm feasibility and applicability of the indicators in real-world clinical practice.

Design and Setting: This study used a Modified Delphi technique (the RAND/UCLA appropriateness method), a consensus method which involves an evidence review, a face-to-face multidisciplinary panel meeting and repeated anonymous rating. Evidence to be reviewed included clinical practice guidelines available in English or Japanese and existing quality indicators. Performance of each indicator was assessed retrospectively using medical records at a university hospital in Japan.

Participants: Ten professionals in cardiac rehabilitation for the consensus panel.

Results: In the literature review, 23 clinical practice guidelines and 16 existing indicators were identified to generate potential indicators. Through the consensus-building process, a total of 30 indicators were assessed and finally 13 indicators were accepted. The practice test (n = 39) revealed that 74% of patients underwent cardiac rehabilitation. Median performance of process measures was 93% (interquartile range, 46-100). "Communication with the doctor who referred the patient to cardiac rehabilitation" and "Continuous participation in cardiac rehabilitation" had low performance (32% and 38%, respectively).

Conclusions: A Modified Delphi technique identified a comprehensive set of quality indicators for cardiac rehabilitation. The single-site, small-size practice test confirmed that most of the proposed indicators were measurable in real-world clinical practice. However, some clinical processes which are not

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3 covered by national health insurance in Japan had low performance. Further
4 studies will be needed to clarify and improve the quality of care in cardiac
5 rehabilitation.
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11 **Abstract word count:** 287/300 words
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Strengths and limitations of this study

- This is the first study to assess utility of a whole set of quality indicators for cardiac rehabilitation that were established with the RAND/UCLA Appropriateness Method.
- A guideline-based modified Delphi technique was used and medical records were reviewed as a practice test before implementing indicators in the real world clinical practice.
- The composition of our panel members may lead to a biased selection of indicators.
- The single-site, small-size practice test may limit to generalize the performance of indicators.

Introduction

Acute coronary syndrome is a leading cause of death and major social burden in the world.¹ Developments in coronary interventions, surgical procedures, pharmacological treatments and lifestyle modifications (e.g., smoking cessation) have improved prognosis, prevented recurrence and reduced mortality in patients who experience acute coronary events.^{2 3} In urban and/or suburban areas of Japan, however, the incidence of myocardial infarction and sudden cardiac death among men has increased in the past few decades.⁴

Previous studies have demonstrated the effectiveness of comprehensive cardiac rehabilitation (CR) on the survival and quality of life of patients with coronary heart disease.⁵ Yet, CR referral rates vary according to characteristics of patients, specialty units and hospitals.⁶⁻¹² Moreover, little is known about the quality of programs in real-world clinical settings.

Quality indicators are measurable elements of practice performance for which there is evidence or consensus. Process indicators, in particular, are used to express the proportion of patients who receive proper care. They can highlight and reveal quality issues, which in turn enable the formulation of solutions for improvement.¹³⁻¹⁵ The use of quality indicators has increased in Japan, particularly in cancer care settings.¹⁶

Quality indicators for cardiovascular disease prevention and CR have been developed in European countries, the United States and Canada, but not in Asia including Japan.¹⁷⁻²¹ Additionally, a practice test prior to real usage is needed when developing quality indicators.^{22 23} However, previous practice tests examined only a part of the indicator set in CR field.^{24 25}

This study aims to 1) propose quality indicators for CR following an acute coronary event (e.g., acute myocardial infarction and unstable angina), as these diseases are the most common indications for CR, 2) conduct a small-size, pilot practice test with the whole set of the proposed indicators to confirm the feasibility and applicability before using them in real world clinical

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4 practice and 3) describe a detailed process of developing quality indicators for
5 applicability to other clinical circumstances.
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10 11 12 Methods

13 14 15 Indicator Development

16 17 18 Overview of the Development Process

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21 This study was conducted by the task force on evidence-based
22 healthcare and clinical practice guidelines under the Ministry of Health,
23 Welfare and Labour in Japan. The aim was to propose the common method
24 to develop quality indicators.
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29 A modified Delphi technique (the RAND/UCLA Appropriateness
30 Method), which has been widely used to develop healthcare quality
31 indicators, was used.²⁶ The method integrates an evidence review, a face-to-
32 face multidisciplinary panel meeting and repeated anonymous rating for
33 consensus building. This study was approved by the Ethics Committee of
34 Kyoto University Graduate School and Faculty of Medicine.
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40 41 42 Systematic Search of Evidence

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44 Kötter et al. previously reported that methods for quality indicator
45 development based on clinical guidelines are increasing and may help in the
46 efficient gathering of evidence when considering indicators.²² Based on this,
47 we searched existing clinical practice guidelines available in English or
48 Japanese and quality indicators related to CR after an acute coronary event
49 developed in countries other than Japan. Specifically, we searched electronic
50 databases with the search terms "cardiovascular disease", "cardiovascular
51 system", "cardiology", "cardiac", "cardiovascular" and "rehabilitation" in August
52 2011. The following databases were used: one quality indicator database
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4 (AHRQ National Quality Measures Clearinghouse); nine guideline databases
5 (AHRQ National Guideline Clearinghouse, NICE Find Guidance, NHS Evidence,
6 Minds, PEDro, Guidelines International Network, Australian Government
7 National Health Medical Research Council, Canadian Medical Association and
8 British Intercollegiate Guidelines Network); and three medical literature
9 databases (MEDLINE, CINAHL and ICHUSHI). The Japanese Association of
10 Cardiac Rehabilitation website and the Japanese Circulation Society website
11 were also reviewed for Japanese guidelines on CR. The search was limited to
12 English or Japanese language. In 2011, we searched literature published from
13 April 2006 to March 2011, because clinical guidelines are generally outdated
14 after five years.^{27 28} Two appraisers (SO and NK) evaluated the quality of the
15 selected guidelines with the AGREE II instrument, which is the established tool
16 for this purpose.²⁹ For each guideline, overall assessments using AGREE II by
17 two appraisers were averaged.

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29 In order to generate indicators to be evaluated in a subsequent
30 consensus panel, clinical practices which were strongly recommended in the
31 selected guidelines were extracted. They were merged with existing quality
32 indicators and applied to a structured format of the modified ACC/AHA
33 Methodology.³⁰ One researcher (SO) assembled the indicators and was
34 supervised by two experts: TN, an epidemiologist experienced in the
35 development of a variety of Japanese clinical practice guidelines and also the
36 chair of the task force on evidence-based health care and clinical practice
37 guidelines, and KU, a cardiologist familiar with CR and evidence-based
38 medicine.

48 49 Multidisciplinary Panel

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51 Panel members responsible for consensus development were selected
52 from registered instructors of CR licensed by the Japanese Association of
53 Cardiac Rehabilitation. Licensure status requires individuals to have practiced
54 CR for at least one year, submitted ten case reports and passed an authorized
55 examination. To assemble the multidisciplinary group, we attempted to select
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4 more than one person from each profession related to CR (cardiologists,
5 nurses, physical therapists, clinical laboratory technicians, registered dieticians,
6 health fitness programmers and clinical psychologists). The sampling strategy
7 was nonrandom selection aiming to seek participants who would be
8 informative, with recommendations by KU and approval by SO and TN. KU
9 was a member of the committee on Japanese guidelines for CR and
10 appointed as president of the Japan Association of Cardiac Rehabilitation in
11 2014. Each panel member signed a consent form for the present study.
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20 Consensus Building

21 Based on the modified Delphi technique, panel members formed a
22 consensus regarding indicators in three rounds. In round 1, members
23 individually evaluated indicators using a nine-point scale postal questionnaire.
24 In round 2, they reconvened for a one-day face-to-face meeting to discuss,
25 revise, and individually evaluate potential indicators, and then suggest
26 additional ones at a later meeting. In round 3, they discussed additional
27 indicators by email instead of a face-to-face meeting and evaluated them with
28 the same postal questionnaire as above.
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38 Round 1

39 A set of documents that described the quality indicators was
40 distributed to panel members. Members were then given two weeks to
41 individually rate each indicator with a nine-point scale questionnaire, adapted
42 from the nine domains suggested by Spertus et al.: evidence-based,
43 interpretable, actionable, denominator, numerator, validity, reliability, feasibility
44 and overall assessment.³⁰
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51 Round 2

52 A one-day face-to-face panel meeting was held. Panel members
53 anonymously shared their results from round 1 and discussed each indicator.
54 When the panel members felt necessity, they revised the elements of each
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4 potential indicator considering member's suggestion. Any disagreements were
5 resolved through discussion. Finally, the panel rated the revised indicators
6 individually, using the same questionnaire from round 1. At the end of the
7 meeting, we asked members to suggest additional indicators that might be
8 important for measuring the quality of CR services in Japan that had not been
9 examined by the panel prior to the meeting.
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14 15 16 Round 3

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18 Additional indicators were developed from suggestions during the
19 panel meeting (round 2). A document describing the new indicators was sent
20 to panel members electronically, asking for any modifications. The indicators
21 were then revised according to the suggestions and sent to panel members
22 by mail to rate using the same questionnaire from round 1.
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28 29 Selection Criteria

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31 Quality indicators were adopted according to the following criteria: the
32 median individual rating during round 2 or round 3 was greater than seven,
33 and the number of panel members who gave a rating less than three was two
34 or fewer.
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40 41 Pilot Practice Test for Feasibility and Adaptability

42 43 Study Patients

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45 Selected patients were those who 1) experienced an acute myocardial
46 infarction or unstable angina and 2) were admitted to Kyoto University
47 Hospital, which provides acute-to-recovery care in Japan, between January 1,
48 2013 and June 30, 2013. Based on the Ethical Guidelines for Epidemiological
49 Research established by the Ministry of Education, Culture, Sports, Science
50 and Technology and Ministry of Health, Labour and Welfare in Japan, we
51 prepared a protocol mentioning that the investigators disclose requisite
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4 information on the study and, consequently, the protocol was approved by
5 the university ethics committee.
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8 9 Data Collection

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11 Data were collected from Kyoto University's electronic medical records
12 in January 2014. Records regarding eating habits (QI-2), coronary risk factors
13 (QI-3), psychological responses (QI-4), tobacco and alcohol (QI-5), exercise
14 capacity (QI-6), definition of the program end period (QI-8) and work and
15 leisure (QI-10) were available in the implementation planning sheets for CR
16 per national insurance regulations. Especially with regard to QI-2, as routine in
17 the hospital, professionals assessed a suitable period for every patient in view
18 of one's clinical situation and recorded it in the planning sheet. Records on
19 education regarding the importance of adherence to prescription medication
20 (QI-12) were available in pharmacist instruction reports, also per national
21 insurance regulations. SO and NK assessed performance of the indicators
22 based on each patient's records. Disagreements were resolved by discussion.
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34 Data Analysis

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36 Patients with acute myocardial infarction and unstable angina were
37 selected consecutively during the study period from Kyoto University Hospital
38 via coronary catheterization records for measurement with the indicators.
39 Percentage scores were obtained for each indicator as follows: the number of
40 times the indicator was met / the number of subjects (excluding those with
41 obvious reasons for not implementing the process as defined by the indicator)
42 x 100. Medians of indicator scores were also computed as an overall quality
43 score of the program.
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53 Disclosure and update

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4 The adopted indicators were disclosed and externally reviewed at a
5 symposium during the annual meeting of the Japanese Association of Cardiac
6 Rehabilitation, of which KU was the president in July 2014. Considering
7 suggestions from external experts, an indicator regarding referral to CR was
8 updated in October 2015 based on an online panel discussion and the nine-
9 point scale assessment.
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20 21 22 23 Quality Indicators

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26 The literature review identified 38 quality indicators from AHRQ
27 National Quality Measures Clearinghouse, of which 16 were selected
28 according to the criteria (Figure 1). Searches of guideline databases and
29 medical literature databases identified 894 articles (103 from AHRQ National
30 Guideline Clearinghouse, 121 from NICE Find Guidance, 487 from NHS
31 Evidence, two from Minds, 11 from PEDro, 25 from Guidelines International
32 Network, six from Australian Government National Health Medical Research
33 Council, nine from Canadian Medical Association, 22 from British
34 Intercollegiate Guidelines Network, 74 from MEDLINE, 24 from CINAHL and 10
35 from ICHUSHI). Seven additional guidelines were identified from Japanese
36 academic society websites. In total, 23 guidelines met our eligibility criteria.
37 The average of overall quality scores based on AGREE II was 5.0 out of a
38 possible 7 (min to max, 3.5 to 6.0). A total of 27 potential indicators created
39 from above-mentioned 16 existing indicators and 23 guidelines were included
40 for panel assessment.³¹⁻⁵³
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53 The panel consisted of ten Japanese clinicians in CR, including two
54 cardiologists, two nurses, two physical therapists, one clinical laboratory
55 technician, one registered dietitian, one health fitness programmer and one
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4 clinical psychologist (a member of the committee on Japanese guidelines for
5 CR).
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7 Round 2 ratings accepted six indicators (Figures 2 and 3). Although a
8 indicator regarding referral to CR from outpatient settings had been discarded
9 in this round, it was later accepted in the update period as a modified
10 indicator (QI-1, Table 1), the rating of which was a median of 8, and min to
11 max of 4 to 9 (Figure 3).
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16 The panel had a debate about the arrangement of indicators regarding
17 coronary risk factors. The members understood importance of assessment and
18 education for each risk factor. However, at the same time, they concerned
19 measurement burden in clinical practice due to a lot of indicators. They
20 considered that practitioners, generally in Japan, assess coronary risk factors
21 comprehensively and arrange education programs for individual patients.
22 Finally, the indicators were grouped as follows: 1) chronic disease as coronary
23 risk factors and the preventive behavior, 2) consumption of luxury items which
24 increases coronary risk, such as tobacco and alcohol and 3) psychological
25 responses.
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34 Of the 20 primary indicators, the panel reconstructed four indicators.
35 The indicator "assessment and education regarding coronary risk factors" was
36 developed by combining the following 13 primary indicators: "hypertension
37 assessment", "education for patients with hypertension", "target blood
38 pressure goal achievement", "assessment and education regarding blood
39 lipids", "reassessment of blood lipids", "assessment and education regarding
40 physical activity habits", "intervention for physical activity habits",
41 "reassessment of physical daily activity", "assessment of body weight",
42 "intervention for body weight control", "assessment of diabetes", "intervention
43 for diabetes" and "target HbA_{1c} goal achievement". Some panel members
44 noted that clinicians tend to deal with these issues together rather than
45 separately. As such, they agreed that combining these indicators would make
46 it easier to perform high quality measurements.
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4 The two primary indicators, "assessment of depression" and
5 "intervention for a patient suspected of having depression", gave rise to the
6 indicator "assessment of psychological responses". Patients with coronary
7 disease often have psychological issues such as depression, anxiety or
8 insomnia.^{18 54} Furthermore, the panel was of the opinion that patients in Japan
9 rarely receive appropriate assessments, aside from interventions they receive
10 for CR.
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16 The indicator "assessment and education regarding tobacco and
17 alcohol" was generated by combining the following three primary indicators:
18 "assessment of tobacco use", "support of smoking cessation" and "education
19 on alcohol". The panel agreed that combining these items would improve
20 measurement quality in clinical settings, as clinicians typically deal with these
21 issues together.
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27 The primary indicator counseling to return to work was reworded as
28 "assessment and education regarding work and leisure". The panel agreed
29 that it was important for a patient requiring rehabilitation to enjoy leisure
30 activities, in addition to returning to work.
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34 In addition to the indicators discussed above, the panel suggested
35 some indicators, including "definition of program end period" and "continued
36 participation in rehabilitation program". These indicators were generated after
37 some panel members emphasized the importance of completing the CR
38 program. Given the multidisciplinary nature of the rehabilitation team, the
39 generation of another indicator ("holding a multidisciplinary conference") was
40 suggested.
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46 In the end, a total of 13 quality indicators were proposed. These
47 indicators spanned the following domains: (1) referral to CR, (2) modification
48 of coronary risk factors, (3) exercise prescription, (4) completion of CR
49 program, (5) return to social activity, (6) involvement of a multidisciplinary
50 team, (7) management of prescription medication and (8) communication with
51 other healthcare providers (Table 1).
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Performance in the Pilot Practice Test

Of the 39 assessed patients (22 with acute myocardial infarction and 17 with unstable angina), 29 (74%) participated in a CR program (QI-1, Table 1). The median performance, based on QI-2 to QI-13, was 93% (interquartile range, 46 to 100). Indicators for which data are collected for national insurance claims (QI-2, 3, 4, 5, 6, 8, 10 and 12) showed high performance (median, 100%; min to max, 74 to 100), whereas others, including QI- 7, 9, 11 and 13, showed low performance (min to max, 32%-48%).

Discussion

In this study, we proposed 13 quality indicators for assessing CR in patients who suffered from acute coronary syndrome in Japan. A widely used consensus approach, the modified Delphi method, with a Japanese multidisciplinary panel identified seven crucial domains for the quality measurement. Based on results of the single-site, small-size practice test, we found that most of indicators proposed were measurable in real-world clinical practice and the performance for which data are collected for national insurance claims was high, whereas performance of indicators for which data are recorded voluntarily was low.

The structure of our proposed indicators is consistent with those reported in previous studies. A few reports have been published that deal with quality measures for CR in North America. ACC/AHA/AACVPR provided a performance measure set that has (1) referral to CR and (2) performance in the program as major parts.^{18 19} The Canadian Cardiovascular Society also originally developed quality indicators on CR, and then prioritized a list of 5 indicators, including (1) inpatients referred to CR; (2) wait times from referral to CR enrollment; (3) patient self-management education; (4) increase in exercise capacity and (5) emergency response strategy.^{20 25} In the present

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4 study, our set of indicators reflects the importance of referral to CR and a
5 comprehensive program. Therefore, we consider these to be essential
6 elements of quality indicators for CR. Additionally, our study includes a
7 measurement for the completion of cardiac rehabilitation, which is common
8 with measure set of the US. It is because completion of the prescribed course
9 of the program is a key to promoting patients' life-long behavior change and
10 physiologic adaptations from regular exercise.¹⁸

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16 During the process of developing quality indicators, pilot practice tests
17 prior to implementation are important for determining which indicators
18 become established components because they evaluate validity, reliability and
19 feasibility.²² Some studies in other medical fields (e.g., neck tumors, diabetes,
20 pneumonia) have reported that, among accepted indicators in the
21 development process, approximately 10 to 30% were not measurable or
22 inapplicable.^{55 56} In the field of CR in the United States, Thomas et al. revealed
23 that reliability of the abstraction for the measure regarding referral was good
24 to excellent.²⁴ In addition, with respect to Canadian indicators, Grace et al.
25 assessed feasibility and concluded that the indicator assessment was
26 acceptable for the CR program.²⁵ Unlike the previous studies, our practice test
27 was small-size but included all indicators proposed. Although the
28 generalizability is limited, we found a possibility that some processes for
29 which data were not recorded per healthcare insurance regulations have low
30 performance. Therefore, the result suggests that incentive such as insurance
31 coverage can improve performance in clinical practice and recording the
32 process. Since Grace et al. also reported that the information-tracking process
33 was challenging when measuring quality, that may be a common issue in the
34 field of CR across countries.²⁵ Further studies will be needed to make quality
35 measurements more appropriate and efficient.

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52 Although panel nomination is one of the key elements of quality
53 indicator development, many studies lack transparency in the process.²² To
54 increase transparency, our study established the following explicit criteria: 1)
55 the panel members must have an authorized license from an academic

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3 society, 2) at least one member is selected from every relevant profession,
4 and 3) the panel involves some members who have experiences of CR
5 guideline development. Finally, our panel included the people concerned with
6 the committee on the clinical practice guidelines for CR jointly developed by
7 the relevant academic societies in Japan (i.e. Shunichi Ishihara and Shinji Sato
8 who are respectively a member and collaborator of the committee).⁵⁷

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14 In contrast to previous reports from the United States and Canada, our
15 study did not directly stand on the initiative of any academic society. However,
16 there were opportunities for authorized experts of CR to express his or her
17 views into the present quality indicators.

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21 The adaptability of each quality indicator must be reviewed before
22 implementation because healthcare systems and social circumstances differ.
23 This is a key element in evidence-based clinical decision-making.^{58 59} We
24 consider, however, disclosing the explicit process of guideline-based quality
25 indicator development, which is a time-efficient and resource-saving
26 approach,²² will be helpful for people attempting to develop similar quality
27 indicators in other regions or different social levels.
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37 Conclusion

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40 Using an explicit and integrated approach based on evidence and the
41 consensus of a multidisciplinary panel, we proposed 13 specific indicators to
42 measure the quality of CR for patients who experienced acute coronary events
43 in Japan. The practice test was small-size but helpful to confirm the
44 measurability of all indicators proposed, and suggested that incentive such as
45 insurance coverage can improve performance in clinical practice and
46 recording the process. Further studies will be needed to clarify the reasons for
47 this, as well as to improve the quality of care in CR.
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Footnotes

Contributors: SO conceived, designed and analyzed the study and drafted and prepared the manuscript. NK assisted data collection and analysis and manuscript preparation. NO and KU contributed to the data collection and interpretation of data and manuscript preparation. TN supervised the study design, administration, analysis and interpretation and gave the final approval of the manuscript.

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Competing interests: We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Data sharing statement: No additional data are available.

Table 1. Quality indicators and percentage scores for cardiac rehabilitation of inpatients with ischemic heart disease.

Domains	Indicators	Numerator/	Performance,
		Denominator	%
Domain 1. Referral to cardiac rehabilitation	QI-1. Referral to cardiac rehabilitation	29/39	74
	QI-2. Assessment and education regarding eating habits	29/29	100
Domain 2. Modification of coronary risk factors	QI-3. Assessment and education regarding coronary risk factors	29/29	100
	QI-4. Assessment of psychological responses	28/29	97
	QI-5. Assessment and education regarding tobacco and alcohol	29/29	100
Domain 3. Exercise therapy	QI-6. Prescribed exercise based on assessment of exercise capacity	20/27	74
	QI-7. Reassessment of exercise capacity	11/24	46
Domain 4. Completion of cardiac rehabilitation program	QI-8. Definition of the program end period	29/29	100

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	QI-9. Continued participation in rehabilitation program	8/21	38
Domain 5. Return to social activity	QI-10. Assessment and education regarding work and leisure	29/29	100
Domain 6. Involvement of multidisciplinary team	QI-11. Holding a multidisciplinary conference	14/29	48
Domain 7. Management of prescription medication	QI-12. Education on the importance of adherence to prescription medication	26/29	90
Domain 8. Communication with other healthcare providers	QI-13. Communication with a doctor who referred the patient to cardiac rehabilitation	8/25	32

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Figure legends

Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

Figure 2. Flow chart of quality indicator selection

Figure 3. Rating distribution of candidate indicators

The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.

*This candidate indicator did not gain consensus and was discarded in Round 2.

†This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

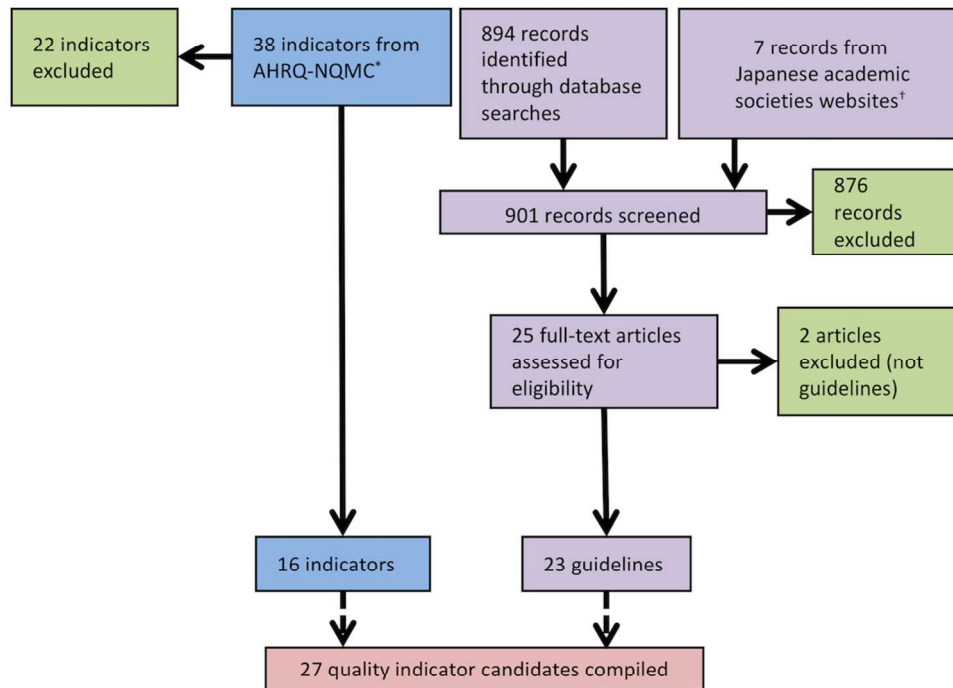


Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

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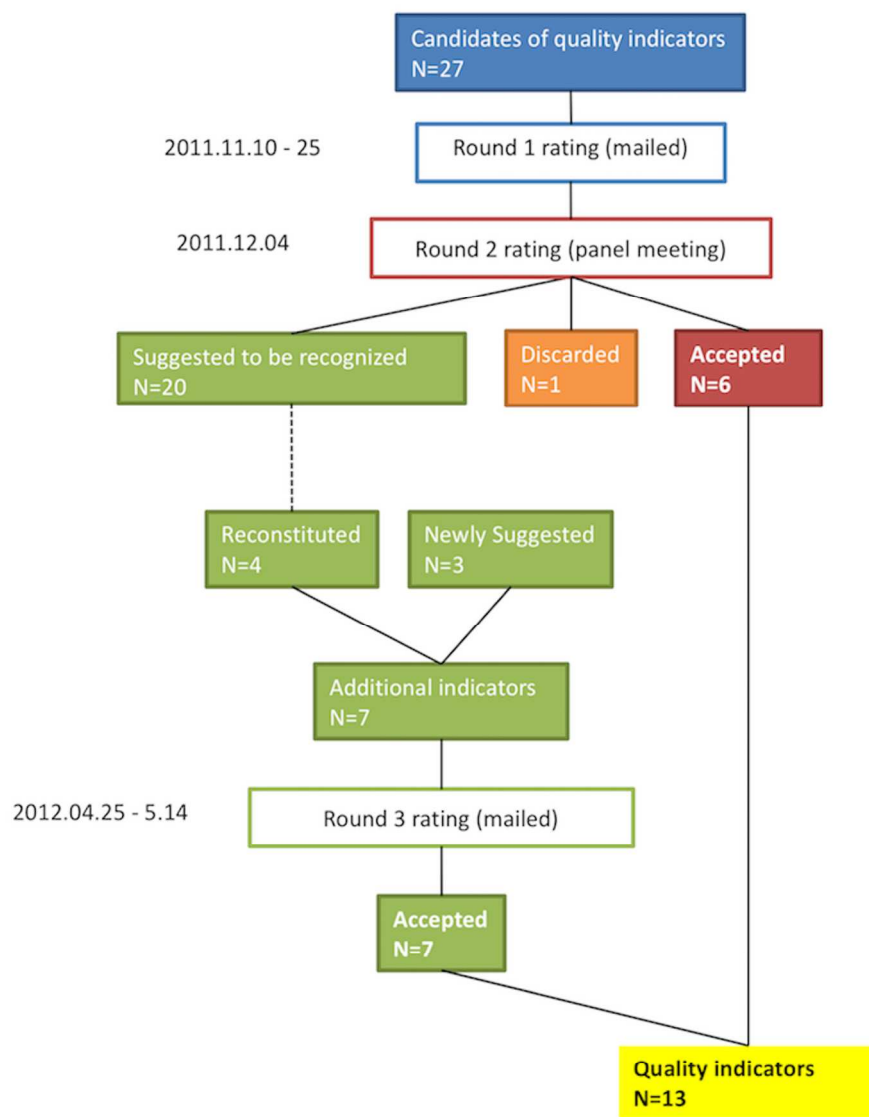


Figure 2. Flow chart of quality indicator selection

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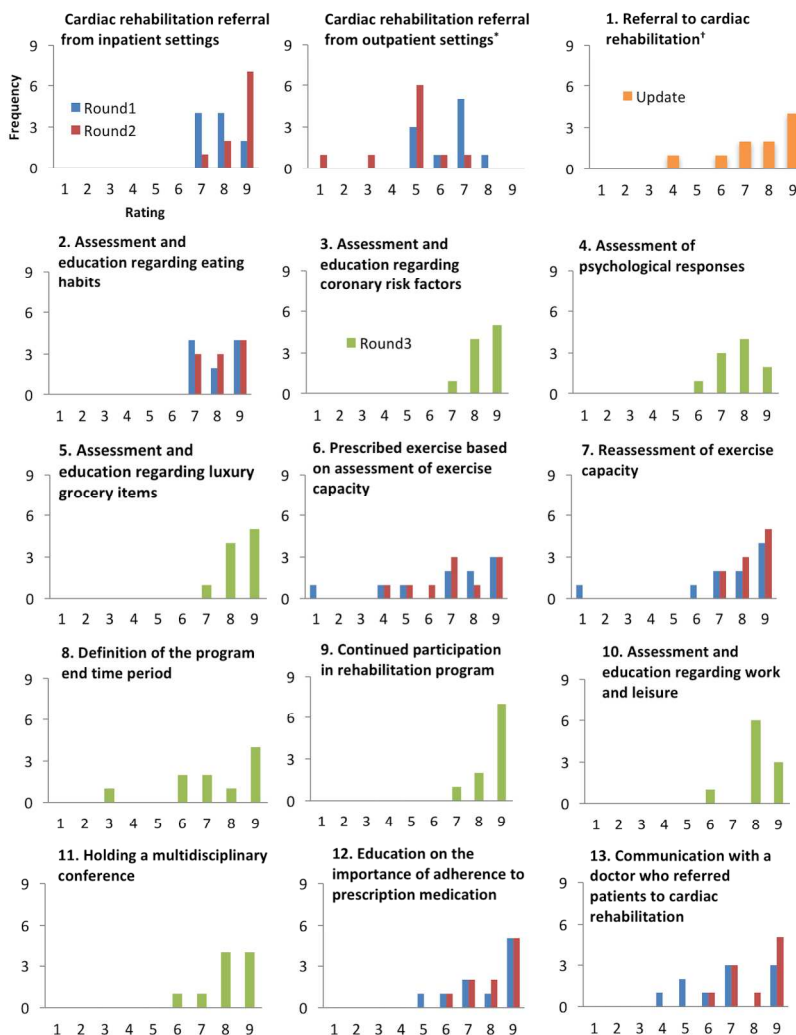


Figure 3. Rating distribution of candidate indicators
 The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.

*This candidate indicator did not gain consensus and was discarded in Round 2.

†This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

299x399mm (300 x 300 DPI)

BMJ Open

Proposal of Quality Indicators for Cardiac Rehabilitation After Acute Coronary Syndrome in Japan: a Modified Delphi Method and Practice Test

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5 Proposal of Quality Indicators for Cardiac
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8 Rehabilitation After Acute Coronary Syndrome in
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11 Japan: a Modified Delphi Method and Practice Test
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41 **Word count:** 3,354/4,000 words (without the reference list)
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Abstract

Objectives: Cardiac rehabilitation is underutilized and its quality in practice is unclear. A quality indicator is a measurable element of clinical practice performance. This study aimed to propose a set of quality indicators for cardiac rehabilitation following an acute coronary event in the Japanese population and conduct a small-size practice test to confirm feasibility and applicability of the indicators in real-world clinical practice.

Design and Setting: This study used a Modified Delphi technique (the RAND/UCLA appropriateness method), a consensus method which involves an evidence review, a face-to-face multidisciplinary panel meeting and repeated anonymous rating. Evidence to be reviewed included clinical practice guidelines available in English or Japanese and existing quality indicators. Performance of each indicator was assessed retrospectively using medical records at a university hospital in Japan.

Participants: Ten professionals in cardiac rehabilitation for the consensus panel.

Results: In the literature review, 23 clinical practice guidelines and 16 existing indicators were identified to generate potential indicators. Through the consensus-building process, a total of 30 indicators were assessed and finally 13 indicators were accepted. The practice test (n = 39) revealed that 74% of patients underwent cardiac rehabilitation. Median performance of process measures was 93% (interquartile range, 46-100). "Communication with the doctor who referred the patient to cardiac rehabilitation" and "Continuous participation in cardiac rehabilitation" had low performance (32% and 38%, respectively).

Conclusions: A Modified Delphi technique identified a comprehensive set of quality indicators for cardiac rehabilitation. The single-site, small-size practice test confirmed that most of the proposed indicators were measurable in real-world clinical practice. However, some clinical processes which are not

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covered by national health insurance in Japan had low performance. Further studies will be needed to clarify and improve the quality of care in cardiac rehabilitation.

Abstract word count: 287/300 words

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Strengths and limitations of this study

- This is the first study to assess utility of a whole set of quality indicators for cardiac rehabilitation that were established with the RAND/UCLA Appropriateness Method.
- A guideline-based modified Delphi technique was used and medical records were reviewed as a practice test before implementing indicators in the real world clinical practice.
- The composition of our panel members may lead to a biased selection of indicators.
- The single-site, small-size practice test may limit to generalize the performance of indicators.

Introduction

Acute coronary syndrome is a leading cause of death and a major social burden in the world.¹ Developments in coronary interventions, surgical procedures, pharmacological treatments and lifestyle modifications (e.g., smoking cessation) have improved prognosis, prevented recurrence and reduced mortality in patients who experience acute coronary events.²⁻³ In urban and/or suburban areas of Japan, however, the incidence of myocardial infarction and sudden cardiac death among men has increased in the past few decades, although the trend in rural areas is unclear.⁴⁻⁶

Previous studies have demonstrated the effectiveness of comprehensive cardiac rehabilitation (CR) on the survival and quality of life of patients with coronary heart disease.⁷ Yet, CR referral rates vary according to characteristics of patients, specialty units and hospitals.⁸⁻¹⁴ Moreover, little is known about the quality of programs in real-world clinical settings.

Quality indicators are measurable elements of practice performance for which there is evidence or consensus. Process indicators, in particular, are used to express the proportion of patients who receive appropriate care. They can highlight and reveal quality issues, which in turn enable the formulation of solutions for improvement.¹⁵⁻¹⁷ The use of quality indicators has increased in Japan, particularly in cancer care settings.¹⁸

Quality indicators for cardiovascular disease prevention and CR have been developed in European countries, the United States and Canada, but not in Asia including Japan.¹⁹⁻²³ Additionally, a practice test prior to real usage is needed when developing quality indicators.²⁴⁻²⁵ However, previous practice tests examined only a part of the indicator set in CR field.²⁶⁻²⁷

This study aims to 1) propose quality indicators for CR following an acute coronary event (e.g., acute myocardial infarction and unstable angina), as these diseases are the most common indications for CR, 2) conduct a small-size, pilot practice test with the whole set of the proposed indicators to confirm the feasibility and applicability before using them in real world clinical

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4 practice and 3) describe a detailed process of developing quality indicators for
5 applicability to other clinical circumstances.
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10 11 12 Methods

13 14 15 Indicator Development

16 17 18 Overview of the Development Process

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21 This study was conducted by the task force on evidence-based
22 healthcare and clinical practice guidelines under the Ministry of Health,
23 Welfare and Labour in Japan. The aim was to propose the common method
24 to develop quality indicators.
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29 A modified Delphi technique (the RAND/UCLA Appropriateness
30 Method), which has been widely used to develop healthcare quality
31 indicators, was used.²⁸ The method integrates an evidence review, a face-to-
32 face multidisciplinary panel meeting and repeated anonymous rating for
33 consensus building. This study was approved by the Ethics Committee of
34 Kyoto University Graduate School and Faculty of Medicine.
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40 41 42 Systematic Search of Evidence

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44 Kötter et al. previously reported that methods for quality indicator
45 development based on clinical guidelines are increasing and may help in the
46 efficient gathering of evidence when considering indicators.²⁴ Based on this,
47 we searched existing clinical practice guidelines available in English or
48 Japanese and quality indicators related to CR after an acute coronary event
49 developed in countries other than Japan. Specifically, we searched electronic
50 databases with the search terms "cardiovascular disease", "cardiovascular
51 system", "cardiology", "cardiac", "cardiovascular" and "rehabilitation" in August
52 2011. The following databases were used: one quality indicator database
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4 (AHRQ National Quality Measures Clearinghouse); nine guideline databases
5 (AHRQ National Guideline Clearinghouse, NICE Find Guidance, NHS Evidence,
6 Minds, PEDro, Guidelines International Network, Australian Government
7 National Health Medical Research Council, Canadian Medical Association and
8 British Intercollegiate Guidelines Network); and three medical literature
9 databases (MEDLINE, CINAHL and ICHUSHI). The Japanese Association of
10 Cardiac Rehabilitation website and the Japanese Circulation Society website
11 were also reviewed for Japanese guidelines on CR. The search was limited to
12 English or Japanese language. In 2011, we searched literature published from
13 April 2006 to March 2011, because clinical guidelines are generally outdated
14 after five years.^{29 30} Two appraisers (SO and NK) evaluated the quality of the
15 selected guidelines with the AGREE II instrument, which is the established tool
16 for this purpose.³¹ For each guideline, overall assessments using AGREE II by
17 two appraisers were averaged.

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29 In order to generate indicators to be evaluated in a subsequent
30 consensus panel, clinical practices which were strongly recommended in the
31 selected guidelines were extracted. They were merged with existing quality
32 indicators and applied to a structured format of the modified ACC/AHA
33 Methodology.³² One researcher (SO) assembled the indicators and was
34 supervised by two experts: TN, an epidemiologist experienced in the
35 development of a variety of Japanese clinical practice guidelines and also the
36 chair of the task force on evidence-based health care and clinical practice
37 guidelines, and KU, a cardiologist familiar with CR and evidence-based
38 medicine.

48 Multidisciplinary Panel

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50 Panel members responsible for consensus development were selected
51 from registered instructors of CR licensed by the Japanese Association of
52 Cardiac Rehabilitation. Licensure status requires individuals to have practiced
53 CR for at least one year, submitted ten case reports and passed an authorized
54 examination. To assemble the multidisciplinary group, we attempted to select
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4 more than one person from each profession related to CR (cardiologists,
5 nurses, physical therapists, clinical laboratory technicians, registered dieticians,
6 health fitness programmers and clinical psychologists). The sampling strategy
7 was nonrandom selection aiming to seek participants who would be
8 informative, with recommendations by KU and approval by SO and TN. KU
9 was a member of the committee on Japanese guidelines for CR and
10 appointed as president of the Japan Association of Cardiac Rehabilitation in
11 2014. Each panel member signed a consent form for the present study. The
12 indicator development part of this study was approved by the Kyoto
13 University Graduate School and Faculty of Medicine, Ethics Committee.
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23 Consensus Building

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25 Based on the modified Delphi technique, panel members formed a
26 consensus regarding indicators in three rounds. In round 1, members
27 individually evaluated indicators using a nine-point scale postal questionnaire.
28 In round 2, they reconvened for a one-day face-to-face meeting to discuss,
29 revise, and individually evaluate potential indicators, and then suggest
30 additional ones at a later meeting. In round 3, they discussed additional
31 indicators by email instead of a face-to-face meeting and evaluated them with
32 the same postal questionnaire as above.
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41 Round 1

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43 A set of documents that described the quality indicators was
44 distributed to ten panel members. Members were then given two weeks to
45 individually rate each indicator with a nine-point scale questionnaire, adapted
46 from the nine domains suggested by Spertus et al.: evidence-based,
47 interpretable, actionable, denominator, numerator, validity, reliability, feasibility
48 and overall assessment.³² We planned more than once reminder with email or
49 telephone for non-responders.
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57 Round 2

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4 A one-day face-to-face panel meeting was held. Panel members
5 anonymously shared their results from round 1 and discussed each indicator.
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7 When the panel members felt the necessity, they revised the elements of each
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9 potential indicator considering member's suggestion. Any disagreements were
10
11 resolved through discussion. Finally, the panel rated the revised indicators
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13 individually, using the same questionnaire from round 1. At the end of the
14
15 meeting, we asked members to suggest additional indicators that might be
16
17 important for measuring the quality of CR services in Japan that had not been
18
19 examined by the panel prior to the meeting.
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21 Round 3

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23 Additional indicators were developed from suggestions during the
24
25 panel meeting (round 2). A document describing the new indicators was sent
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27 to panel members electronically, asking for any modifications. The indicators
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29 were then revised according to the suggestions and sent to panel members
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31 by mail to rate using the same questionnaire from round 1.
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33 Selection Criteria

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36 Quality indicators were adopted according to the following criteria: the
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38 median individual rating during round 2 or round 3 was greater than seven,
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40 and the number of panel members who gave a rating less than three was two
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42 or fewer.
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46 Pilot Practice Test for Feasibility and Adaptability

47 Study Patients

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50 Selected patients were those who 1) experienced an acute myocardial
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52 infarction or unstable angina and 2) were admitted to Kyoto University
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54 Hospital, which provides acute-to-recovery care in Japan, between January 1,
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56 2013 and June 30, 2013. Based on the Ethical Guidelines for Epidemiological
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4 Research established by the Ministry of Education, Culture, Sports, Science
5 and Technology and Ministry of Health, Labour and Welfare in Japan, we
6 prepared a protocol mentioning that the investigators disclose requisite
7 information on the study and, consequently, the protocol for the practice test
8 was approved by the university ethics committee.
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13 14 Data Collection

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16 Data were collected from Kyoto University's electronic medical records
17 in January 2014. Records regarding eating habits (QI-2), coronary risk factors
18 (QI-3), psychological responses (QI-4), tobacco and alcohol (QI-5), exercise
19 capacity (QI-6), definition of the program end period (QI-8) and work and
20 leisure (QI-10) were available in the implementation planning sheets for CR
21 per national insurance regulations. Especially with regard to QI-2, as routine in
22 the hospital, professionals assessed a suitable period for every patient in view
23 of their clinical situation and recorded it in the planning sheet. Records on
24 education regarding the importance of adherence to prescription medication
25 (QI-12) were available in pharmacist instruction reports, also per national
26 insurance regulations. SO and NK assessed performance of the indicators
27 based on each patient's records. Disagreements were resolved by discussion.
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39 40 Data Analysis

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42 Patients with acute myocardial infarction and unstable angina were
43 selected consecutively during the study period from Kyoto University Hospital
44 via coronary catheterization records for measurement with the indicators.
45 Percentage scores were obtained for each indicator as follows: the number of
46 times the indicator was met / the number of subjects (excluding those with
47 obvious reasons for not implementing the process as defined by the indicator)
48 x 100. Medians of indicator scores were also computed as an overall quality
49 score of the program.
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Disclosure and update

The adopted indicators were disclosed and externally reviewed at a symposium during the annual meeting of the Japanese Association of Cardiac Rehabilitation, of which KU was the president in July 2014. Considering suggestions from external experts, an indicator regarding referral to CR was updated in October 2015 based on an online panel discussion and the nine-point scale assessment.

Results

Quality Indicators

The literature review identified 38 quality indicators from AHRQ National Quality Measures Clearinghouse, of which 16 were selected according to the criteria (Figure 1). Searches of guideline databases and medical literature databases identified 894 articles (103 from AHRQ National Guideline Clearinghouse, 121 from NICE Find Guidance, 487 from NHS Evidence, 2 from Minds, 11 from PEDro, 25 from Guidelines International Network, 6 from Australian Government National Health Medical Research Council, 9 from Canadian Medical Association, 22 from British Intercollegiate Guidelines Network, 74 from MEDLINE, 24 from CINAHL and 10 from ICHUSHI). 7 additional guidelines were identified from Japanese academic society websites. In total, 23 guidelines met our eligibility criteria. The average of overall quality scores based on AGREE II was 5.0 out of a possible 7 (min to max, 3.5 to 6.0). A total of 27 potential indicators created from above-mentioned 16 existing indicators and 23 guidelines were included for panel assessment.³³⁻⁵⁵

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4 Ten Japanese clinicians in CR were invited to the panel, including two
5 cardiologists, two nurses, two physical therapists, one clinical laboratory
6 technician, one registered dietitian, one health fitness programmer and one
7 clinical psychologist (a member of the committee on Japanese guidelines for
8 CR). Finally, all of them participated to the consensus development process.
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12 Round 2 ratings accepted six indicators (Figures 2 and 3). Although a
13 indicator regarding referral to CR from outpatient settings had been discarded
14 in this round, it was later accepted in the update period as a modified
15 indicator (QI-1, Table 1), the rating of which was a median of 8, and min to
16 max of 4 to 9 (Figure 3).
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20 The panel had a debate about the arrangement of indicators regarding
21 coronary risk factors. The members understood importance of assessment and
22 education for each risk factor. However, at the same time, they concerned
23 measurement burden in clinical practice due to a lot of indicators. They
24 considered that practitioners, generally in Japan, assess coronary risk factors
25 comprehensively and arrange education programs for individual patients.
26 Finally, the indicators were grouped as follows: 1) chronic disease as coronary
27 risk factors and the preventive behavior, 2) consumption of non-essential
28 grocery items which increases coronary risk, such as tobacco and alcohol and
29 3) psychological responses.
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34 Of the 20 primary indicators, the panel reconstructed four indicators.
35 The indicator "assessment and education regarding coronary risk factors" was
36 developed by combining the following 13 primary indicators: "hypertension
37 assessment", "education for patients with hypertension", "target blood
38 pressure goal achievement", "assessment and education regarding blood
39 lipids", "reassessment of blood lipids", "assessment and education regarding
40 physical activity habits", "intervention for physical activity habits",
41 "reassessment of physical daily activity", "assessment of body weight",
42 "intervention for body weight control", "assessment of diabetes", "intervention
43 for diabetes" and "target HbA_{1c} goal achievement". Some panel members
44 noted that clinicians tend to deal with these issues together rather than
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4 separately. As such, they agreed that combining these indicators would make
5 it easier to perform high quality measurements. The panel agreed that you
6 judge to be met the criteria when there is a record regarding assessment and
7 education on at least one of the coronary risk factor above mentioned or a
8 record that a patient have none of the risks.
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12 The two primary indicators, "assessment of depression" and
13 "intervention for a patient suspected of having depression", gave rise to the
14 indicator "assessment of psychological responses". Patients with coronary
15 disease often have psychological issues such as depression, anxiety or
16 insomnia.^{20 56} Furthermore, the panel was of the opinion that patients in Japan
17 rarely receive appropriate assessments, aside from interventions they receive
18 for CR.
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21 The indicator "assessment and education regarding tobacco and
22 alcohol" was generated by combining the following three primary indicators:
23 "assessment of tobacco use", "support of smoking cessation" and "education
24 on alcohol". The panel agreed that combining these items would improve
25 measurement quality in clinical settings, as clinicians typically deal with these
26 issues together. The panel agreed that you judge to be met the criteria when
27 there is a record regarding assessment of tobacco and alcohol use and
28 education on them if it is necessary.
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31 The primary indicator counseling to return to work was reworded as
32 "assessment and education regarding work and leisure". The panel agreed
33 that it was important for a patient requiring rehabilitation to enjoy leisure
34 activities, in addition to returning to work.
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37 In addition to the indicators discussed above, the panel suggested
38 some indicators, including "definition of program end period" and "continued
39 participation in rehabilitation program". These indicators were generated after
40 some panel members emphasized the importance of completing the CR
41 program. Given the multidisciplinary nature of the rehabilitation team, the
42 generation of another indicator ("holding a multidisciplinary conference") was
43 suggested.
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4 In the end, a total of 13 quality indicators were proposed. These
5 indicators spanned the following domains: (1) referral to CR, (2) modification
6 of coronary risk factors, (3) exercise prescription, (4) completion of CR
7 program, (5) return to social activity, (6) involvement of a multidisciplinary
8 team, (7) management of prescription medication and (8) communication with
9 other healthcare providers (Table 1).
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14 Performance in the Pilot Practice Test

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20 Of the 39 assessed patients (22 with acute myocardial infarction and 17
21 with unstable angina), 29 (74%) participated in a CR program (QI-1, Table 1).
22 The median performance, based on QI-2 to QI-13, was 93% (interquartile
23 range, 46 to 100). Indicators for which data are collected for national
24 insurance claims (QI-2, 3, 4, 5, 6, 8, 10 and 12) showed high performance
25 (median, 100%; min to max, 74 to 100), whereas others, including QI- 7, 9, 11
26 and 13, showed low performance (min to max, 32%-48%).
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36 Discussion

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39 In this study, we proposed 13 quality indicators for assessing CR in
40 patients who suffered from acute coronary syndrome in Japan. A widely used
41 consensus approach, the modified Delphi method, with a Japanese
42 multidisciplinary panel identified seven crucial domains for the quality
43 measurement. Based on results of the single-site, small-size practice test, we
44 found that most of indicators proposed were measurable in real-world clinical
45 practice and the performance for which data are collected for national
46 insurance claims was high, whereas performance of indicators for which data
47 are recorded voluntarily was low.
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55 The structure of our proposed indicators is consistent with those
56 reported in previous studies. A few reports have been published that deal
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4 with quality measures for CR in North America. ACC/AHA/AACVPR provided a
5 performance measure set that has (1) referral to CR and (2) performance in
6 the program as major parts.^{20 21} The Canadian Cardiovascular Society also
7 originally developed quality indicators on CR, and then prioritized a list of 5
8 indicators, including (1) inpatients referred to CR; (2) wait times from referral
9 to CR enrollment; (3) patient self-management education; (4) increase in
10 exercise capacity and (5) emergency response strategy.^{22 27} In the present
11 study, our set of indicators reflects the importance of referral to CR and a
12 comprehensive program. Therefore, we consider these to be essential
13 elements of quality indicators for CR. Additionally, our study includes a
14 measurement for the completion of cardiac rehabilitation, which is common
15 with measure set of the US. It is because completion of the prescribed course
16 of the program is a key to promoting patients' life-long behavior change and
17 physiologic adaptations from regular exercise.²⁰

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During the process of developing quality indicators, pilot practice tests prior to implementation are important for determining which indicators become established components because they evaluate validity, reliability and feasibility.²⁴ Some studies in other medical fields (e.g., neck tumors, diabetes, pneumonia) have reported that, among accepted indicators in the development process, approximately 10 to 30% were not measurable or inapplicable.^{57 58} In the field of CR in the United States, Thomas et al. revealed that reliability of the abstraction for the measure regarding referral was good to excellent.²⁶ In addition, with respect to Canadian indicators, Grace et al. assessed feasibility and concluded that the indicator assessment was acceptable for the CR program.²⁷ Unlike the previous studies, our practice test was small-size but included all indicators proposed. Although the generalizability is limited, we found a possibility that some processes for which data were not recorded per healthcare insurance regulations have low performance. Therefore, the result suggests that incentives such as insurance coverage can improve performance in clinical practice and recording the process. Since Grace et al. also reported that the information-tracking process

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4 was challenging when measuring quality, that may be a common issue in the
5 field of CR across countries.²⁷ Further studies will be needed to make quality
6 measurements more appropriate and efficient.
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9 Although panel nomination is one of the key elements of quality
10 indicator development, many studies lack transparency in the process.²⁴ To
11 increase transparency, our study established the following explicit criteria: 1)
12 the panel members must have an authorized license from an academic society,
13 2) at least one member is selected from every relevant profession, and 3) the
14 panel involves some members who have experiences of CR guideline
15 development. Finally, our panel included the people concerned with the
16 committee on the clinical practice guidelines for CR jointly developed by the
17 relevant academic societies in Japan (i.e. Shunichi Ishihara and Shinji Sato who
18 are respectively a member and collaborator of the committee).⁵⁹
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21 In contrast to previous reports from the United States and Canada, our
22 study did not directly stand on the initiative of any academic society. However,
23 there were opportunities for authorized experts of CR to express his or her
24 views into the present quality indicators.
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27 The adaptability of each quality indicator must be reviewed before
28 implementation because healthcare systems and social circumstances differ.
29 This is a key element in evidence-based clinical decision-making.^{60 61} We
30 consider, however, disclosing the explicit process of guideline-based quality
31 indicator development, which is a time-efficient and resource-saving
32 approach,²⁴ will be helpful for people attempting to develop similar quality
33 indicators in other regions or different social levels.
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49 Conclusion

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51 Using an explicit and integrated approach based on evidence and the
52 consensus of a multidisciplinary panel, we proposed 13 specific indicators to
53 measure the quality of CR for patients who experienced acute coronary events
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4 in Japan. The practice test was small-size but helpful to confirm the
5 measurability of all indicators proposed, and suggested that incentives such
6 as insurance coverage can improve performance in clinical practice and
7 recording the process. Further studies will be needed to clarify the reasons for
8 this, as well as to improve the quality of care in CR.
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5 ce-based medicine and patient choice. *ACP J Club* 2002;**136**(2):A11-4.
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33 Footnotes

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35
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38 manuscript preparation. NO and KU contributed to the data collection and
39 interpretation of data and manuscript preparation. TN supervised the study
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41 of the manuscript.
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4 "Research on the subjects of clinical practice guidelines to realize socially
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Table 1. Quality indicators and percentage scores for cardiac rehabilitation of inpatients with ischemic heart disease.

Domains	Indicators	Numerator/ Denominator	Performance, %
Domain 1. Referral to cardiac rehabilitation	QI-1. Referral to cardiac rehabilitation	29/39	74
	QI-2. Assessment and education regarding eating habits	29/29	100
Domain 2. Modification of coronary risk factors	QI-3. Assessment and education regarding coronary risk factors	29/29	100
	QI-4. Assessment of psychological responses	28/29	97
	QI-5. Assessment and education regarding tobacco and alcohol	29/29	100
Domain 3. Exercise therapy	QI-6. Prescribed exercise based on assessment of exercise capacity	20/27	74
	QI-7. Reassessment of exercise capacity	11/24	46
Domain 4. Completion of cardiac rehabilitation	QI-8. Definition of the program end period	29/29	100
program			

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3		QI-9. Continued participation in rehabilitation program	8/21	38
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5	Domain 5. Return to social activity	QI-10. Assessment and education regarding work and leisure	29/29	100
6				
7				
8	Domain 6. Involvement of multidisciplinary team	QI-11. Holding a multidisciplinary conference	14/29	48
9				
10				
11	Domain 7. Management of prescription medication	QI-12. Education on the importance of adherence to prescription medication	26/29	90
12				
13				
14	Domain 8. Communication with other healthcare	QI-13. Communication with a doctor who referred the patient to cardiac		
15			8/25	32
16	providers	rehabilitation		
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Figure legends

Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

Figure 2. Flow chart of quality indicator selection

Figure 3. Rating distribution of candidate indicators

The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.

*This candidate indicator did not gain consensus and was discarded in Round 2.

†This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

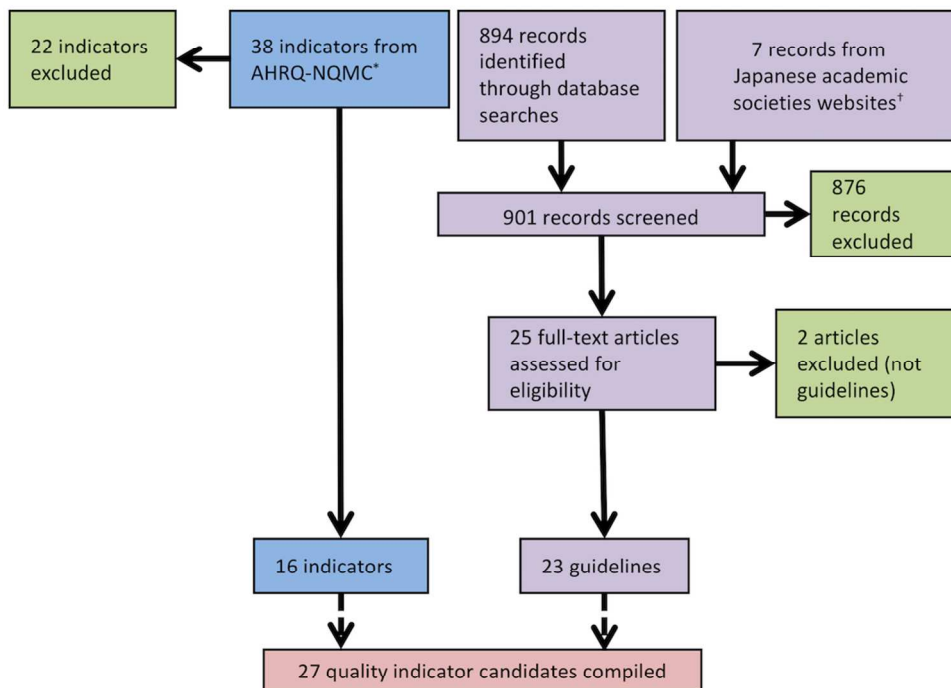


Figure 1. Flow chart of the literature search

*Agency for Healthcare Research and Quality National Quality Measures Clearinghouse

†The Japanese Association of Cardiac Rehabilitation website and the Japanese Circulation Society website

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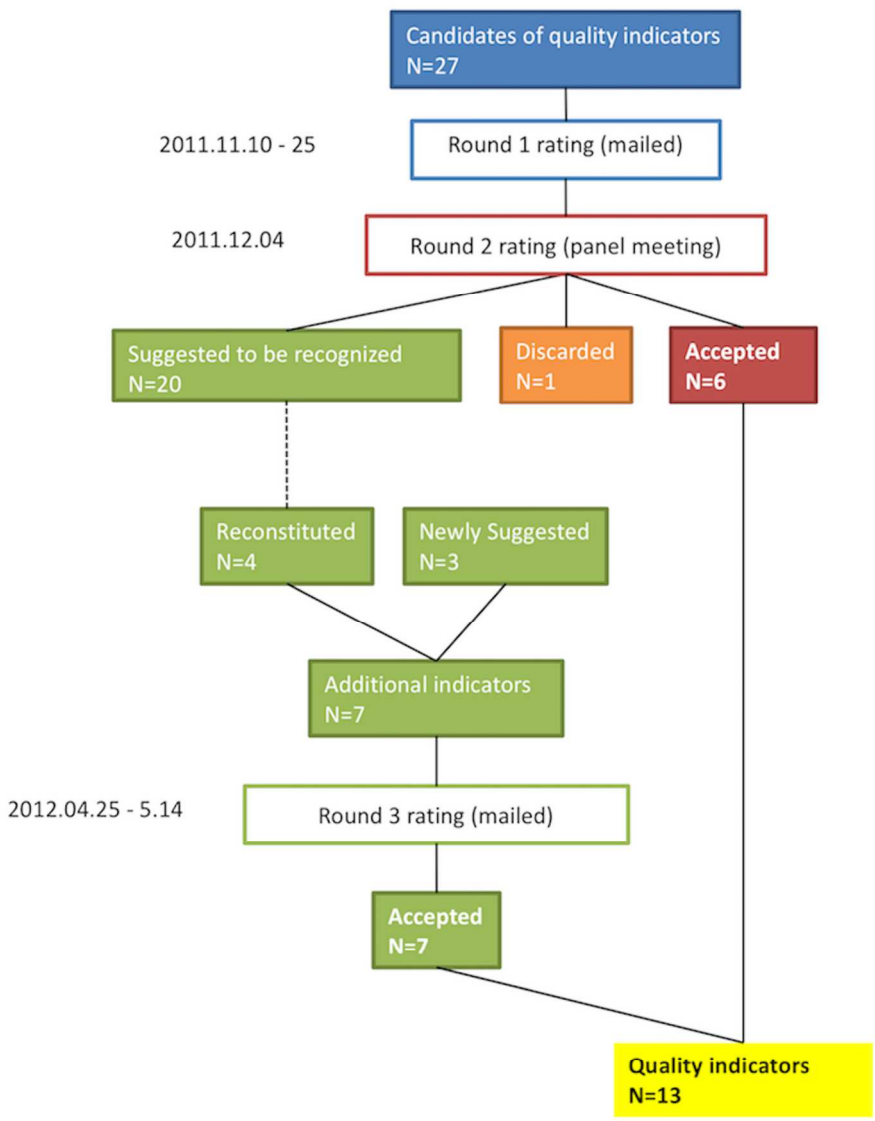


Figure 2. Flow chart of quality indicator selection

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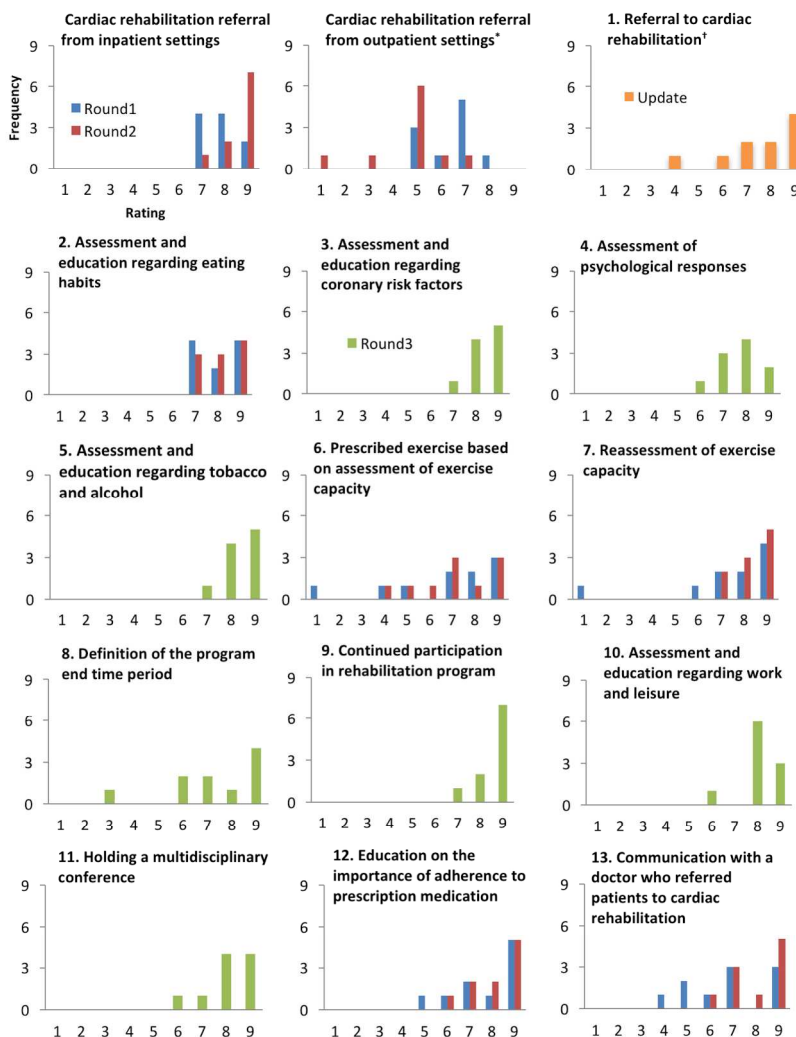


Figure 3. Rating distribution of candidate indicators!! † The X-axis indicates individual indicator evaluation by the panel (1: disagree, 9: agree). The Y-axis indicates the number of panel members who scored the indicator.!! † *This candidate indicator did not gain consensus and was discarded in Round 2.!! † †This was an updated indicator that includes referral from outpatient settings as well as inpatient settings.

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