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ORIGINAL ARTICLE

Development of quality indicators for care of chronic kidney disease in the primary care setting using electronic health data: a RAND-modified Delphi method

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Abstract

Background The prevalence of chronic kidney disease (CKD) has recently increased, and maintaining high quality of CKD care is a major factor in preventing end-stage renal disease. Here, we developed novel quality indicators for CKD care based on existing electronic health data.

Methods We used a modified RAND appropriateness method to develop quality indicators for the care of non-dialysis CKD patients, by combining expert opinion and scientific evidence. A multidisciplinary expert panel comprising six nephrologists, two primary care physicians, one diabetes specialist, and one rheumatologist assessed the appropriateness of potential indicators extracted from evidence-based clinical guidelines, in accordance with predetermined criteria. We developed novel quality indicators through a four-step process: selection of potential indicators, first questionnaire round, face-to-face meeting, and second questionnaire round.

Results Ten expert panel members evaluated 19 potential indicators in the first questionnaire round, of which 7 were modified, 12 deleted, and 4 newly added during subsequent face-to-face meetings, giving a final total of 11 indicators. Median rate of these 11 indicators in the final set was at least 7, and percentages of agreement exceeded 80 % for all but one indicator. All indicators in the final set can be measured using only existing electronic health data, without medical record review, and 9 of 11 are process indicators.

Conclusion We developed 11 quality indicators to assess quality of care for non-dialysis CKD patients. Strengths of the developed indicators are their applicability in a primary

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care setting, availability in daily practice, and emphasis on modifiable processes.

Keywords Chronic kidney disease · Quality of care · Quality indicators · RAND · Administrative claims data

Introduction

The prevalence of chronic kidney disease (CKD) has increased in developed countries with the aging of the population and increasing prevalence of diabetes mellitus and hypertension [1, 2]. Given that CKD is a relatively common, chronic disease, many patients received treatment through primary care physicians rather than nephrology specialists. Maintaining high quality of CKD care in the primary care setting has therefore become a major factor in preventing end-stage renal disease (ESRD) and its associated substantial burden on both patients and the global economy [3–5]. The first step towards improving quality of care is to assess baseline quality in a scientifically proven manner [6], and 'quality indicators' (QIs) are commonly used for such assessments [7]. However, QIs for CKD care tend to be empirical, and not developed by a scientifically appropriate approach, and few can be easily measured using available health data in daily practice, without medical record review [8].

The utility of Donabedian's framework in assessing healthcare quality is widely recognized [9]. This framework consists of three dimensions: structure, which describes characteristics of the setting where the healthcare is offered, such as facilities, equipment and human resources; process, how the care is given or received; and outcome, the effects on health status. The outcome and structure dimensions cannot be modified—the process dimension is the only modifiable factor [10]. As such, QIs associated with the process dimension are more useful than those associated with other dimensions in improving quality of care [11–14].

Here, to improve the quality of CKD care, we developed novel QIs for CKD care based on electronic health data, which can be used as a tool to bridge the gap between evidence and practice in the primary care setting. Development used a modified RAND appropriateness method [15] and was based on the predetermined criteria of applicability in a primary care setting, availability in daily practice, and close association with the modifiable process dimension.

Materials and methods

QIs are generally calculated based on two elements: the criteria to which the QI is applicable (denominator to calculate the QI), and the criteria defining appropriate treatment (numerator to calculate the QI). QI can be used to calculate either the proportion of patients who receive appropriate treatment within each facility (e.g. 40 % of patients achieved the indicator at X hospital) or the number of indicators achieved at the patient level (e.g. patient X achieved three of five indicators).

We used a modified RAND appropriateness method to develop a set of QIs for the care of non-dialysis CKD patients by combining expert opinion and scientific evidence [10]. We adopted a four-step approach to define QIs for CKD care. First, we compiled an initial set of potential indicators by conducting a literature search and examining clinical guidelines. Second, we conducted a first questionnaire round in which we asked expert panel members to rate each potential QI based on appropriateness. Third, we held a face-to-face expert panel meeting in which we asked expert panel members to discuss the appropriateness of the potential indicators based on the score in the first questionnaire round. Fourth, we conducted a second questionnaire round to compile the final set of QIs. We did not conduct data analysis using electronic health data (patient data), instead only using scores rated by our panel of experts.

Selection of potential indicators

Two nephrology specialists (S.F and M.K) reviewed the evidenced-based guideline published by the Japanese Society of Nephrology (JSN) [11] and leading international guidelines, including KDOQI [12], KDIGO [13], and European renal best practice [14]. These specialists extracted potential indicators based on the following inclusion criteria:

1. Widely applicable to a broad range of primary care settings.
2. Able to be measured without medical record review by calculation from existing electronic health data (administrative claims data and laboratory data).
3. Associated with modifiable process indicators rather than structure or outcome indicators.

First questionnaire round

Ten experts from different specialties consisting of six nephrologists (M.Y, M.N, R.K, Y.F, K.K and Y.S), two primary care physicians (T.H and S.K), one diabetes specialist (J.K), and one rheumatologist (K.S) agreed to participate in our expert panel. We sent a questionnaire by e-mail and asked them to rate each potential indicator based on appropriateness using a nine-point Likert Scale, with one indicating "definitely not appropriate" and nine indicating "definitely appropriate". Scores of ≥ 7 indicated high appropriateness.

Percentage of agreement for each indicator was defined based on the proportion of experts who rated an indicator ≥7. Potential indicators with a median score <7 and those with a percentage of agreement <80 % were allocated for discussion and modification during the subsequent expert panel meeting.

Expert panel meeting

All panel members attended the panel meeting where the results of the first questionnaire round were disclosed. The aim of this meeting was to have a face-to-face discussion about the potential indicators appraised in the first questionnaire round and to form a consensus. In this panel meeting, experts commented on the potential indicators and assessed them qualitatively. Panel members discussed the indicators according to the three important predetermined criteria as follows: first, the indicator had to be widely applicable to a broad range of primary care settings; second, it had to be measurable using existing electronic medical information; and third, it had to be associated with modifiable process indicators rather than structure or outcome indicators. Indicators deemed inappropriate according to these criteria were deleted or modified. Experts were also allowed to add new potential indicators, if necessary. New potential indicators were assessed qualitatively in the panel meeting and subsequently assessed quantitatively in the second questionnaire round.

Second questionnaire round and ranking

After the expert panel meeting, the list of all accepted, modified, and newly added potential indicators was converted into the second questionnaire and sent to panel members again by e-mail for final appraisal. In this second round, respondents were asked to rate the potential indicators in the same way as the first round. We selected indicators with a median score ≥7 and percent agreement ≥80 % as the final set of QIs for CKD care [16, 17].

Results

Extraction of potential indicators

Two nephrologists extracted 19 potential indicators for the first questionnaire round by conducting a literature search and consulting clinical guidelines between March and August 2012. Table 1 shows data sources (data required for each indicator) and criteria (definition of applicable patients and the conditions required to meet the indicator) to calculate each indicator. Fifteen of these 19 indicators were process dimension (nos. 1, 2, 4–7, 9–12, 14, and 16–19), and 14 could be measured using only administrative claims data or laboratory data (nos. 1, 2, 6–11, and 13–18).

First questionnaire round

The first questionnaire round regarding the 19 potential indicators was completed by our expert panel between September and December 2012. While the medians of all QIs were ≥7, the percentages of agreement (proportion of experts who rated ≥7) for the following five indicators were <80 %: blood pressure control, phosphorus intake guidance, phosphorus and calcium level control, screening for cardiovascular disease, and low-density lipoprotein cholesterol (LDL-C) level control (Table 2).

Expert panel meeting

Following the first questionnaire round, the expert panel members attended a face-to-face panel meeting in January 2013. At this meeting, 7 of the 19 potential indicators were modified, and 12 were deleted, while 4 indicators were newly added (Table 2). Panel members discussed the appropriateness of each QI based on the predetermined criteria of applicability in a primary care setting, availability in daily practice, and close association with the modifiable process dimension.

Given that the area of "primary care" covers a rather wide area, from family physicians at small clinics to general physicians at core hospitals, our QIs developed for use in primary care settings also vary substantially. Therefore, some QIs—such as CT scans—may not be feasible for use in certain primary care settings (particularly family physicians at small clinics). However, our newly developed method allows for individual application (on a case-by-case basis) of only those QIs which are feasible for use in certain primary care settings. For example, the QI of "CT scan" is available for some primary care physicians (particularly general physicians in hospitals) who will be able to conduct CT scans in CKD patients. Our expert panel members therefore chose to include the QI of "CT scan" in the final set. In addition, expert panel members decided to include some QIs for patients with advanced CKD (eGFR <45 ml/min) who have been advised to see a nephrology specialist, as many advanced CKD patients are often incorrectly advised and instead receive treatment only from their primary care physician [18–20].

Reasons for modification or deletion are summarized in Table 3. Of the 12 deleted indicators, 4 were deleted because the percentage of agreement in the first questionnaire round was <80 % (blood pressure control, phosphorus intake guidance, phosphorus and calcium control, and screening for cardiovascular disease). The percentage of

Table 1 List of potential indicators for the first questionnaire round

No.	Indicator	Data source	Denominator to calculate the QI (criteria for applicable patients)	Numerator to calculate the QI (criteria for achievement)
1	Diagnosis of CKD	Administrative claims data Laboratory data	CKD patients with eGFR 60 ml/min or two consecutive proteinuria ≥1+	Patients labeled as having CKD-related diseases (ICD10)
2	Use of RAS inhibitors	Administrative claims data Laboratory data	CKD patients with hypertension meeting criteria A and (B or C) as follows: A, patients labeled as having hypertension in administrative claims data; B, CKD patients with diabetes mellitus (ICD10); C; CKD patients without diabetes mellitus (ICD10) but with proteinuria	Patients on RAS inhibitors
3	Blood pressure (BP) control	Administrative claims data Laboratory data Patient-reported information	CKD patients with hypertension (same as the above)	BP <130/80 mmHg and systolic BP ≥110 mmHg
4	Salt intake guidance	Administrative claims data Laboratory data Patient-reported information	CKD patients with hypertension (same as the above)	Given guidance for salt restriction in diet
5	Home blood pressure measurement	Administrative claims data Laboratory data Patient-reported information	CKD patients with hypertension (same as the above)	Given guidance for home BP measurement
6	Screening for adverse events of RAS inhibitors	Administrative claims data Laboratory data	CKD patients on RAS inhibitors with stage ≥3b, and aged ≥65 years	Measured for serum creatinine and potassium levels at least once in the past 3 months
7	Evaluation of anemia	Administrative claims data Laboratory data	CKD patients with stage ≥3a	Measured for hemoglobin levels at least once in the past year
8	Hemoglobin level control	Administrative claims data Laboratory data	CKD patients with stage ≥3 and on ESA	Hemoglobin levels between 10 and 12 g/dL
9	Use of ESA	Administrative claims data Laboratory data	CKD patients with stage ≥3a, hemoglobin <10 g/dL continuing more than 3 months and not on ESA; excluding patients with malignancy	Within 3 months of starting ESA
10	Evaluation of iron level	Administrative claims data Laboratory data	CKD patients with stage ≥3a and on ESA	Measured for iron status at least once in the past year
11	Evaluation of MBD	Administrative claims data Laboratory data	CKD patients with stage ≥3a	Measured for serum phosphate and calcium levels at least once in the past 6 months
12	Guidance of phosphorus intake	Administrative claims data Laboratory data Patient-reported information	CKD patients with stage ≥3a and serum phosphorus >4.5 mg/dL	Given guidance for phosphorus restriction in diet
13	Phosphorus and calcium level control	Administrative claims data Laboratory data	CKD patients with stage ≥3a	2.5 ≤ serum phosphorus ≤ 4.5 mg/dL, 8.4 ≤ serum calcium ≤ 10.0 mg/dL
14	Screening for cardiovascular disease	Administrative claims data Laboratory data	CKD patients with stage ≥3a and no previous history of ischemic cardiac disease	Screened for ischemic heart diseases via at least one of the following: exercise electrocardiogram, myocardial scintigraphy, coronary artery CT, or coronary angiography

Table 1 continued

No.	Indicator	Data source	Denominator to calculate the QI (criteria for applicable patients)	Numerator to calculate the QI (criteria for achievement)
15	LDL-cholesterol level control	Administrative claims data Laboratory data	CKD patients with stage ≥3a and LDL-cholesterol measured	LDL-cholesterol <120 mg/dL
16	Prevention of contrast induced nephropathy	Administrative claims data Laboratory data	CKD patients stage ≥3b and having contrast CT scan	Hydration in contrast CT scan
17	No routine use of NSAIDs	Administrative claims data Laboratory data	CKD patients with stage ≥3b	No routine use of NSAIDs (less than 14 days of prescription in a month)
18	Nutritional guidance	Administrative claims data Laboratory data	CKD patients with stage ≥3a	Given nutritional guidance in diet
19	Therapeutic option for ESRD	Administrative claims data Laboratory data Patient-reported information	CKD patients stage ≥3b	Given guidance on selection of the therapeutic option for ESRD

CKD chronic kidney disease, *eGFR* estimated glomerular filtration rate, *ICD 10* International classification of diseases, 10th revision, *RAS* renin–angiotensin system, *ESA* erythropoiesis-stimulating agent, *MBD* mineral and bone disorder, *CT* computed tomography scan, *LDL* low-density lipoprotein, *NSAIDs* non-steroidal anti-inflammatory drugs, *ESRD* end-stage renal disease

agreement for LDL-C level control was also <80 %, but this was modified and retained for ongoing discussion because of its clinical relevance. The other eight indicators were deleted during qualitative assessment in the meeting due to a dearth of data or lack of evidence for the indicator, despite having percentages of agreement ≥80 % (salt intake guidance, home blood pressure management, hemoglobin level control, erythropoiesis-stimulating agent usage, evaluation of anemia, MBD and iron level, and guidance on selection of the therapeutic option for ESRD). Evaluations of anemia, MBD and iron level were deleted due to a lack of consensus on appropriate follow-up periods.

Regarding the QI "no routine use of NSAIDs", our expert panel members decided to exclude CKD patients with rheumatoid arthritis, as these patients tend to have complex clinical conditions hampering use of this indicator. However, the panel did decide to include osteoarthritis patients, as osteoarthritis is common and the National Health Service (NHS) guidelines suggested that pharmacological management be limited to short-term symptomatic relief of pain and stiffness.

Second questionnaire round, final set of selected QIs

After the expert panel meeting, the second questionnaire round was completed between January and March 2013. Results are shown in Table 2. The median rates for all indicators were ≥7 and the percentages of agreement were ≥80 %, except for LDL/non-HDL cholesterol control. Although inclusion of LDL/non-HDL cholesterol control remained controversial even after the second questionnaire round, panel members elected to retain this QI in the final set on the grounds that it should be discussed in future investigations about the association between QIs and clinical outcomes. The final set of 11 QIs is shown in Table 4.

Discussion

Here, using a RAND-modified Delphi method, we developed a set of QIs to assess the quality of care for non-dialysis CKD patients. The final set of 11 indicators was obtained through discussion between ten experts in four steps: selection of potential indicators from clinical guidelines, a primary questionnaire round to evaluate the appropriateness of potential indicators, and a face-to-face expert panel meeting with subsequent secondary questionnaire to achieve final consensus. Our indicators focus on the three important criteria of applicability in a primary care setting, availability in daily practice, and emphasis on the process dimension. All 11 indicators in the final set can

Table 2 Assigned scores during the first and second questionnaire rounds

Quality indicators	Round 1		Meeting decision	Round 2		Final decision
	Median rate	% Agreement		Median rate	% Agreement	
#1. Diagnosis of CKD	8.5	90	Modified	9	100	Selected
#2. Use of RAS inhibitors	8	90	Modified	8	90	Selected
#3. Blood pressure control	7.5	70	Deleted	–	–	–
#4. Salt intake guidance	8	80	Deleted	–	–	–
#5. Home blood pressure measurement	8	90	Deleted	–	–	–
#6. Screening for adverse events of RAS inhibitors	9	90	Modified	9	100	Selected
#7. Evaluation of anemia	8	80	Deleted	–	–	–
#8. Hemoglobin level control	8	100	Deleted	–	–	–
#9. Use of ESA	8	80	Deleted	–	–	–
#10. Evaluation of iron level	8	80	Deleted	–	–	–
#11. Evaluation of MBD	8.5	80	Deleted	–	–	–
#12. Phosphorus intake guidance	8	70	Deleted	–	–	–
#13. Phosphorus and calcium level control	7.5	70	Deleted	–	–	–
#14. Screening for cardiovascular disease	7	70	Deleted	–	–	–
#15. LDL-cholesterol level control	8	70	Modified	7	60	To be discussed
#16. Prevention of contrast induced nephropathy	8	100	Modified	8.5	100	Selected
#17. No routine use of NSAIDs	8.5	90	Modified	7.5	80	Selected
#18. Nutritional guidance	8	90	Modified	8	90	Selected
#19. Therapeutic option for ESRD	7.5	80	Deleted	–	–	–
#20. Screening for CKD	–	–	Added	9	100	Selected
#21. Glycemic control	–	–	Added	7.5	90	Selected
#22. No use of biguanide	–	–	Added	9	100	Selected
#23. Urine test	–	–	Added	8	90	Selected

CKD chronic kidney disease, *RAS* renin–angiotensin system, *ESA* erythropoiesis-stimulating agent, *MBD* mineral and bone disorder, *LDL* low-density lipoprotein, *NSAIDs* non-steroidal anti-inflammatory drugs, *ESRD* end-stage renal disease

be measured using only existing electronic health information of administrative claims data and laboratory data without medical record review. Of the 11 indicators, 9 are process indicators which can be regarded as modifiable factors. Establishing these QIs is the first step in the quality improvement project for CKD care funded by the Ministry of Education, Science and Technology in Japan.

QIs must meet several requirements to ensure physicians' receptivity and permeate daily practice [15]. First, indicators should be developed on the basis of scientific evidence, as in the present study, wherein we referenced evidence-based clinical guidelines [11]. We next plan to evaluate the impact of these QIs on clinical outcomes (incidence of ESRD and change in estimated glomerular filtration rate) using a national administrative claims database and annual health check-up data. Second, indicators should focus on practices widely used in a primary care setting. Our present panel involved experts from a number of fields involved in CKD care, not only nephrology, as the increasing prevalence of CKD makes it clear that input from a wide range of specialists is needed to establish useful indicators [18, 21]. Given that many CKD patients are treated in a primary care setting, QIs available with primary care may be useful in improving the quality of CKD care in this population. Third, the quality indicator should show sufficient variation between patients or facilities; in other words, if all (or no) patients meet an indicator, then it is too easy (or too difficult) to achieve and cannot be used to improve quality.

However, several challenges face the implementation of QIs in daily practice [22]. For example, most QIs require medical record review, which can be too labor intensive for daily use. As such, the two criteria of "immediacy" and "low burden" are important for ensuring continuous implementation of QIs in quality improvement. We believe we have met these criteria, as all 11 of the QIs we

Table 3 Modified and deleted indicators and reasons for modification and deletion

Indicators	Status	Reasons for modification or deletion
#1. Diagnosis of CKD	Modified	The criteria of "two consecutive urine test of proteinuria ≥1+" was modified to "proteinuria ≥1+ at least once" from the perspective of data accessibilities
#2. Use of RAS inhibitors	Modified	Patients labeled as having hyperkalemia were additionally excluded from applicable patients, as practitioners are likely to hesitate to prescribe RAS inhibitors in such patients due to adverse events from hyperkalemia
#3. Blood pressure control	Deleted	% Agreement <80 %
#4. Salt intake guidance	Deleted	Measuring whether or not patients receive guidance on salt intake is difficult
#5. Home blood pressure measurement	Deleted	Whether or not CKD patients with hypertension should measure blood pressure at home is controversial
#6. Screening for adverse events of RAS inhibitors	Modified	The cut-off value of eGFR changed from 60 to 45 mL/min/1.73 m^2, as patients with severe CKD stage are applicable to this indicator
#7. Evaluation of anemia	Deleted	Little evidence is available on appropriate follow-up periods
#8. Hemoglobin level control	Deleted	Its effectiveness on mortality or end-stage renal disease has not been established yet
#9. Use of ESA	Deleted	It is too specific a therapy for a primary care physician
#10. Evaluation of iron level	Deleted	It is too specific a therapy for a primary care physician. There are few evidences about appropriate follow-up periods
#11. Evaluation of MBD	Deleted	It is too specific therapy for primary care physician. Too little evidence is available on appropriate follow-up periods
#12. Phosphorus intake guidance	Deleted	% Agreement <80 %
#13. Control of phosphorus and calcium	Deleted	% Agreement <80 %
#14. Screening for cardiovascular disease	Deleted	% Agreement <80 %
#15. LDL-cholesterol level control	Modified	Wording was revised to "non-HDL-cholesterol" because LDL-cholesterol can be calculated in only fasting cases and non-HDL-cholesterol is often used in non-fasting cases
#16. Prevention of contrast induced nephropathy	Modified	Patients with congestive heart failure were excluded from applicable patients in lighypertension of little evidence as to whether or not hydration is effective in those patients
#17. No routine use of NSAIDs	Modified	Patients with rheumatoid arthritis were excluded from applicable patients as they may need routine NSAIDs to relieve pain
#18. Nutritional guidance	Modified	The follow-up period necessary for definition of the indicator was defined as 6 months
#19. Therapeutic option for ESRD	Deleted	The stage from which CKD patients should be given guidance on therapeutic options for ESRD remains controversial, hampering detailed assessment of how guidance is given

CKD chronic kidney disease, *RAS* renin–angiotensin system, *ESA* erythropoiesis-stimulating agent, *MBD* mineral and bone disorder, *LDL* low-density lipoprotein, *NSAIDs* non-steroidal anti-inflammatory drugs, *ESRD* end-stage renal disease

developed can be measured using existing electronic health data without medical record review. We also developed a semi-automatic calculation algorithm to provide immediate feedback on the results of QIs.

Secondary use of administrative claims data for clinical research and quality assessment is becoming increasingly common [23–25]. Quality improvement projects using administrative claims data have been ongoing since the 1990s worldwide [26], and the Agency for Healthcare Research and Quality (AHRQ) developed QIs based on administrative data [27, 28]. Nevertheless, despite the potential to derive meaningful knowledge for both clinical and health policy issues by measuring quality of care using administrative claims data, relatively few quality improvement projects have taken advantage of these data in Japan. If administrative claims data can be linked to other clinical data, such as laboratory data and annual health check-up data, quality of care can be assessed with greater precision by a scientific approach. A future goal of our quality improvement project is to implement a system we developed to link administrative claims data to laboratory data for clinical research.

An important characteristic of our QI development was our clear focus on process indicators. Of the 11 indictors, 9 are categorized as process indicators in Donabedian's framework. While previous studies have not distinguished clearly between the process and outcome categories, process indicators are potentially modifiable and can be efficient markers for quality improvement. Process-focused QIs are crucial for improving quality of treatment and bridging the gap between evidence and practice [6, 29].

Table 4 Final set of quality indicators

Quality indicators		Data sources	Dimension	Denominator to calculate the QI (criteria for applicable patients)	Numerator to calculate the QI (criteria for achievement)
1	Diagnosis of CKD	Administrative claims data Laboratory data	Process	CKD patients with eGFR <60 ml/min or proteinuria ≥1+ at least once	Patients labeled with CKD-related diseases (ICD10)
2	Use of RAS inhibitors	Administrative claims data Laboratory data	Process	CKD patients with hypertension who satisfied criteria of A and (B or C) A: patients labeled with hypertension (ICD10) B: CKD patients labeled with diabetes (ICD10) C: non-DM CKD patients with proteinuria Patients labeled with hyperkalemia are excluded	Patients on RAS inhibitors
3	Screening for adverse events of RAS inhibitors	Administrative claims data Laboratory data	Process	CKD patients on RAS inhibitor with eGFR <60 ml/min and age ≥65 years	Measurement of serum creatinine (or cystatin) and potassium levels at least once during 3 months
4	Control of LDL/non HDL cholesterol level	Administrative claims data Laboratory data	Outcome	CKD patients with eGFR <60 ml/min	LDL-cholesterol <120 mg/dL or non HDL cholesterol <150 mg/dL
5	Prevention of contrast induced nephropathy	Administrative claims data Laboratory data	Process	CKD patients with eGFR <45 ml/min receiving contrast CT scan Patients labeled with congestive heart failure are excluded	Hydration before contrast CT scan
6	No routine use of NSAIDs	Administrative claims data Laboratory data	Process	CKD patients with eGFR <45 ml/min Patients labeled with rheumatoid arthritis are excluded	No routine use of NSAIDs Routine use are defined as NSAIDs prescription ≥14 days during the latest 1 month
7	Nutritional guidance	Administrative claims data Laboratory data	Process	CKD patients with eGFR <45 ml/min who visit clinics for over a year	Given nutritional guidance in diet during the latest 1 year
8	Screening for CKD	Administrative claims data Laboratory data	Process	Patients who satisfied criteria of A or B A: patients labeled with hypertension or hyperlipidemia or diabetes (ICD10) B: patients aged ≥65 years	Screened by serum creatinine level or urine test during the latest 1 year
9	Glycemic control	Administrative claims data Laboratory data	Outcome	Diabetic CKD patients with eGFR <60 ml/min and HbA1c measured Patients labeled with hypoglycemia are excluded	Patients with HbA1c <7.0 %
10	No use of biguanide	Administrative claims data Laboratory data	Process	Diabetic CKD patients with eGFR <45 ml/min	Patients without biguanide
11	Urine test	Administrative claims data Laboratory data	Process	CKD patients with eGFR <60 ml/min who visit clinics for over a year	Patients receiving urine tests including qualitative screening or sediment test ≥4 times in the latest 1 year

CKD chronic kidney disease, *eGFR* estimated glomerular filtration rate, *ICD 10* International classification of diseases, 10th revision, *RAS* renin–angiotensin system, *LDL* low-density lipoprotein, *HDL* high-density lipoprotein, *CT* computed tomography scan, *NSAIDs* non-steroidal anti-inflammatory drugs

Some organizations have also developed their own sets of QIs for CKD patients. As mentioned before, the AHRQ developed patient safety indicators (PSIs), which are a set of QIs reflecting patient safety [28]. However, these PSIs are outcome indicators, providing information on short-term adverse events of hypoglycemia, hyperkalemia, and overdose of selected medications [30]. In contrast, our developed QIs are process indicators, which are associated with long-term outcomes of incidence of end-stage renal disease. The National Institute for Health and Care Excellence (NICE) indicators for CKD patients include CKD stage, use of renin–angiotensin system (RAS) inhibitors, blood pressure control, and urine protein: creatinine test findings [31]. However, most of these indicators require medical record review, whereas our indicators do not.

Several limitations of the present study were not mentioned. First, we did not conduct a systematic review of the literature to select potential indicators in the first step of our study. However, we did select potential indicators in accordance with well-established clinical guidelines which integrated the best available evidence [11–14]. Second, while our panel involved experts from a number of fields, we developed quality indicators only from the perspective of medical doctors and did not involve other health professionals. In the next stage of the quality improvement project, we will evaluate the quality of CKD care from the perspective of other health professionals involved in caring for these patients, such as nurses and pharmacists. Third, we have not yet conducted practice testing to confirm the operational validity of our QIs using electronic health data. These tests will be conducted in a future study, before implementation of our QIs in a real-world setting. However, we did confirm that all necessary variables for our QIs were included in electronic health data (claims data and laboratory data) in Japan and Taiwan, where we plan to conduct practice tests. Because our QIs can be evaluated using standardized electronic health data without medical record review, we can confirm the measurability of our developed QIs by checking the list of variables included in the electronic health data, which contains both claim data and laboratory data. In addition, a previous systematic review reported that practice testing was not always conducted in QI development studies (2/42 studies planned to conduct practice tests, while 21/42 studies did not mention practice testing at all) [32]. Fourth, we developed our QIs based on the Japanese clinical guidelines of 2009, but a revised version of the guidelines was published in 2013 (only in Japanese) [33]. However, we confirmed that our QIs remain consistent with these revised guidelines, and so we do not believe this revision influenced the utility of our QIs in any meaningful way. Fifth, our definition of CKD differs slightly from the international definition. In many epidemiological studies, the definition of CKD is simplified to a degree and adapted to make use of the available data [34, 35]. Had we used the original criterion of 'positive results on two consecutive urine tests', we would not have been able to evaluate the quality of CKD care until patients had visited clinics/hospitals at least twice and undergone a second urine test. Our expert panel members discussed this point in the meeting and select a modified simple definition of CKD to meet the criterion of 'availability in daily practice'. In accordance with the guidelines outlined in the RAND-modified Delphi method, we abided by decisions made by the expert panel members.

In conclusion, we used the RAND-modified Delphi method to develop 11 QIs for assessing quality of care for non-dialysis CKD patients. Strengths of our QIs include their applicability in a primary care setting, availability in daily practice, and emphasis on the modifiable process dimension. Our indicators can be measured using only existing electronic health information without medical record review. Establishment of these QIs is the first step in the quality improvement project for CKD care in Japan.

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Compliance with ethical standards

Conflict of interest Consultancies: Shingo Fukuma (Kyowa Hakko Kirin), Motoko Yanagita (Astellas), Shunichi Fukuhara (Kyowa Hakko Kirin), Masaomi Nangaku (Kyowa Hakko Kirin, Taisho, GSK, Tanabe-Mitsubishi, Takeda, Astellas, JT), Yugo Shibagaki (Asteras Pharma), Honoraria: Masaomi Nangaku (Kyowa Hakko Kirin, Daiichi-Sankyo, MSD, AstraZeneca, Alexion, GSK, Tanabe-Mitsubishi, Taisho, Chugai, Takeda, Astellas, JT, Bayer, Medical Review), Yugo Shibagaki (Novartis Pharma, Otsuka Pharmaceuticals, Kyowa Hakko Kirin). Sayaka Shimizu, Kakuya Niihata, Ken-ei Sada, Tsuguru Hatta, Ritsuko Katafuchi, Yoshihiro Fujita, Junji Koizumi, Shunzo Koizumi and Kenjiro Kimura have declared no competing interest.

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