Quality Indicators for Evaluating the Health Care of Patients with Rheumatoid Arthritis: a Korean Expert Consensus

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ABSTRACT

Background: There is increasing interest in the quality of health care and considerable efforts are being made to improve it. Rheumatoid arthritis (RA) is a disease that can result in favorable outcomes when appropriate diagnosis and treatment are provided. However, several studies have shown that RA is often managed inappropriately. Therefore, the Korean College of Rheumatology aimed to develop quality indicators (QIs) to evaluate and improve the health care of patients with RA.

Methods: Preliminary QIs were derived based on the existing guidelines and QIs for RA. The final QIs were determined through two separate consensus meetings of experts. The consensus was achieved through a panel of experts who voted using the modified Delphi method.

Results: Fourteen final QIs were selected among 70 preliminary QIs. These included early referral to and regular follow-up with a rheumatologist, radiographs of the hands and feet, early initiation and maintenance of disease-modifying anti-rheumatic drug (DMARD) therapy, periodic assessment of disease activity, screening for drug safety and comorbidities,
including viral hepatitis and tuberculosis before biologic DMARD therapy, periodic laboratory testing, supplementation with folic acid, assessment of the risk for cervical spine instability before general anesthesia, patient education, and specialized nurse.  

**Conclusion:** These QIs can be used to assess and improve the quality of health care for patients with RA.

**Keywords:** Quality Indicators, Health Care; Arthritis, Rheumatoid; Quality of Health Care; Disease Management

**INTRODUCTION**

The quality of health care is defined as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” Many questions have recently been raised regarding health care quality, and various efforts are ongoing to improve the quality of health care in many countries. One such effort is the development of quality indicators (QIs) that can be used for measuring the quality of health care. These QIs can be used in the context of national policies to improve health care quality. For example, the National Health Service introduced the Quality and Outcomes Framework to link physicians’ salaries to the quality of care in the United Kingdom (UK).  

In Korea, the Quality Assessment Service has been implemented by the Health Insurance Review & Assessment Service (HIRA) since 2000. The HIRA uses QI items regarding several diseases to evaluate the quality of hospitals, and the list of diseases used for these evaluations is expanding. Quality assessment results affect the official standards of hospitals and the government’s distribution of financial resources. The current disease QIs used by the HIRA to evaluate tertiary hospitals include hypertension, diabetes, asthma, chronic obstructive pulmonary disease, pneumonia, breast cancer, gastric cancer, colon cancer, lung cancer, liver cancer, hemodialysis, coronary artery bypass grafting, acute stroke, and acute myocardial infarction. However, the HIRA has no QIs for systemic rheumatic diseases.

Rheumatoid arthritis (RA) is a chronic rheumatic disease that causes joint pain, function limitations, and joint deformities, and comorbidities involving the cardiovascular, respiratory, and ocular systems. Early diagnosis and appropriate treatment, which have been proposed by major treatment guidelines, can prevent irreversible outcomes and complications for patients with RA. However, the current practice for many patients with RA is not consistent with the current treatment guidelines. In a study conducted in the United States (US) that evaluated 1,355 patients with RA, health care quality scores were suboptimal for the domains of arthritis, comorbidities, and health care maintenance. Furthermore, a study conducted in a Canadian metropolitan area indicated that only 23% of patients with RA were treated with disease-modifying anti-rheumatic drug (DMARD) within 3 months of symptom onset.  

Recently, QIs for RA have been developed to measure and enhance the quality of RA care in several countries.
The direct evidence that is currently available is not sufficient to review and evaluate the quality of care for patients with RA in Korea. Remission or low disease activity was reportedly achieved in only 36% of Korean patients with RA. A study using the Short Form 36 Health Survey for patients with RA indicated that the mean physical and mental quality of life scores were 50 out of 100 and 54 out of 100, respectively. Patients with RA have a significantly lower employment rate than the general population (42% vs. 68%); this is mainly attributable to health-related problems. In terms of comorbidities, an annual evaluation of cardiovascular risk was performed for only 54% of patients with RA in Korea. Therefore, the Korean College of Rheumatology (KCR) has recognized the need for QIs to measure the quality of RA care and organized a task force to develop these QIs.

**METHODS**

**Formulation of preliminary QIs**

The task force determined 70 preliminary QIs based on a review of the existing RA-related QIs and the guidelines for RA care developed by several international and national rheumatology societies. Most preliminary QIs were associated with processes (what providers do in delivering care), and the others were associated with structures (characteristics of the healthcare system and providers). The preliminary QIs were classified according to diagnosis, treatment (planning, initiation, intensification, remission management, DMARDs, glucocorticoid and non-pharmacologic treatment), assessment, and safety.

**Consensus**

The final QIs were determined through a consensus of experts using the modified RAND/University of California at Los Angeles appropriateness method. The panel of experts comprised 15 rheumatologists with more than 10 years of clinical and scientific experience working for teaching hospitals. All of them were members of the KCR committees. The preliminary QIs were discussed and evaluated during two separate face-to-face meetings. The panel members rated the appropriateness of each preliminary QI using a scale from 1 to 9. Appropriateness was defined when the median score was between 7 and 9 without disagreement. Disagreement was defined when four or more panelist ratings were extreme (1–3 or 7–9). Before the first meeting, the preliminary QIs and the references from which they were derived were presented to the panel by e-mail. During the first meeting (December 3, 2015), 56 QIs were selected based on scientific validity and relevance. The results of the first meeting were presented to the panel by e-mail, and no modifications or additions to the QIs were made. During the second meeting (December 16, 2015), the final 14 QIs were determined based on their priority and feasibility. The final results were presented to the panel by e-mail and announced at the 36th KCR annual scientific meeting.

**Ethics statement**

The present study protocol was reviewed and approved as exempt from deliberation by the Institutional Review Board of Gachon University Gil Medical Center (approval No.: GCIRB2015-328; approval date: December 1, 2015).
RESULTS

QIs for health care of patients with RA

The final QIs and results of the expert panel ratings during the two meetings are shown in Table 1.

QI 1. Patients with suspected or diagnosed RA should be examined by a rheumatologist.

Rheumatologists specialize in the care of patients with RA. Many studies have shown that rheumatologists are better at properly diagnosing and treating RA than other physicians.\(^5,7,31\) The classification criteria for RA are usually used to determine the diagnosis; however, they are not designed for diagnosing RA. Therefore, the physician’s clinical judgment is essential for individually diagnosing each patient with suspected RA.\(^4,32\) When making treatment decisions for patients with RA, disease activity and other conditions, including structural progression and its risk factors, function, and comorbidities, must be considered. The administration of DMARDs for treating RA requires regular and careful safety monitoring.\(^3,25,28,29\) Therefore, the global recommendation for the treatment of RA is that the primary care of patients with RA should be performed by rheumatologists.\(^3,29\) This indicator does not mean that patients with suspected or diagnosed RA should be examined only by a rheumatologist; however, the management of patients with RA should be regularly and comprehensively reviewed by a rheumatologist.
QI 2. Rheumatology nurses are essential for monitoring, counseling, and educating patients with RA at outpatient rheumatology clinics.

RA is a chronic systemic disease that can affect various organs and joints and is often accompanied by comorbidities such as cardiovascular disease, diabetes, osteoporosis, and Sjögren disease. Therefore, patients may be concerned about diverse symptoms and usually use several medicines, including DMARDs. It is necessary to regularly evaluate the disease activity, physical function, and psychosocial status of the patient to ensure timely treatment decisions. Using DMARDs requires careful attention and regular monitoring for side effects and complications. It is not easy or efficient for a physician to perform all these tasks; therefore, a rheumatology nurse is necessary. Several studies have shown that a rheumatology nurse has a significant effect on the care of patients with RA. A members of a multidisciplinary team, they have a specialized role in the education and management of patients with RA. They can obtain or assist with measurements of disease activity as well as take charge of instructions regarding the administration and storage of DMARDs. Additionally, they can be counselors and communicators for patients, thereby helping patients understand the disease and participate in treatment decisions.

QI 3. Patients with suspected RA should be examined by a rheumatologist as soon as possible.

It is well-known that the early diagnosis and treatment of RA improves outcomes. Therefore, patients with suspected RA should consult with or be referred to a rheumatologist during the early stage of disease. Early referral to a rheumatologist enables a quick diagnosis and DMARD treatment. According to the date of the Korean Observational Study Network for Arthritis, the average diagnostic delay is 20 months, which is approximately 3–5 times longer than it is in western countries. The UK National Institute for Health and Care Excellence (NICE) guidelines recommend that individuals with suspected persistent synovitis of the hands or feet should be referred to a rheumatology service within 3 days of presentation and assessed by a rheumatology service within 3 weeks of referral.

QI 4. Radiographs should be performed during the early stage of disease for patients with persistent synovitis of the hands or feet.

RA is a chronic inflammatory arthritis that mainly affects the small joints of the hands and feet. Radiography is a basic and simple imaging tool used to evaluate the bones and joints, assess possible structural damage to the joints, and diagnose RA in patients with persistent synovitis. When patients have persistent synovitis of the hands or feet and are suspected of having RA, radiographs of the hands and feet should be obtained during the early stage of disease.

QI 5. Patients with RA should be treated with DMARDs.

DMARDs are the main medications for patients with RA to ameliorate disease activity and prevent joint deformity. They are classified as conventional synthetic DMARDs (csDMARDs), biologic DMARDs (bDMARDs), and targeted synthetic DMARDs (tsDMARDs). All patients with active RA should be treated with DMARDs. At the population level, however, DMARD use is reportedly low and inconsistent. Fewer than half of the RA cohort received DMARDs over the course of 5 years. The nationwide prevalence of patients with RA treated with DMARDs is reportedly 0.26–0.27% according to the Korean National Health Insurance claims data. However, it is necessary to actively use the DMARDs in patients with RA.
QI 6. Therapy including DMARDs should be started immediately after the diagnosis of RA.

It has been reported that only 23% of patients with RA received DMARDs within 3 months of symptom onset in Toronto, Canada. Earlier initiation of DMARD therapy for patients with RA improves the prevention of joint destruction, thereby improving the quality of life. Therefore, the administration of DMARDs immediately after the diagnosis of RA is strongly recommended.3,25,28,29

QI 7. Disease activity, comorbidities, and drug safety should be considered when starting bDMARD therapy.

bDMARDs are genetically engineered proteins that target specific parts of the immune system and are administered subcutaneously or intravenously. The bDMARDs used to treat RA in Korea include tumor necrosis factor (TNF) inhibitors, interleukin-6 receptor blockers, B-cell depleting agents, and T-cell co-stimulation inhibitors. If the disease activity of patients with RA is not well-controlled by csDMARDs, bDMARDs are usually administered.3,25,28,29,35 However, they have several potential adverse effects, such as increasing the risk of infection, including reactivation of tuberculosis and exacerbation of hepatitis B virus (HBV) and hepatitis C virus (HCV).36,37 Because of concerns regarding cancer, these drugs require caution when patients have a history of malignancy.37 Some bDMARDs may be deleterious to vital organ function. For example, TNF inhibitors should be avoided in patients with heart failure.25,37 Therefore, before starting bDMARD therapy, it is necessary to consider not only disease activity, but also comorbidities and safety concerns, including active or hidden infections, vital organ disease, and history of malignancy.

QI 8. Patients diagnosed with RA should be educated about the nature and course of their disease, treatment, and self-management.

Patients should receive appropriate information about their disease and treatment. RA is not a disease with high prevalence, its pathogenesis is unclear, and various medications are used to treat it. This disease is unfamiliar to the public in Korea. Although a large amount of information regarding RA is available on the Internet, most of it are not of good quality. All patients with RA should be provided with standardized education regarding the nature and course of the disease and its treatment.29 This will help to improve their understanding of the disease and promote their participation in treatment decisions, thereby improving treatment outcomes. Moreover, self-management training may help patients manage their own illnesses in daily life.

QI 9. RA disease activity should be regularly assessed using standardized methods.

The treat-to-target strategy for controlling disease activity is now of the essence in RA treatment paradigms. Treatment should be intensified until the target, which is remission or low disease activity, is reached. To ensure that the target has been reached and to adjust the treatment accordingly, it is necessary to regularly measure disease activity. It has been recommended that RA disease activity be measured at least once every three months.25 Several standardized instruments are available to measure RA disease activity, including the disease activity score 28, simplified disease activity index, clinical disease activity index, patient activity scale (PAS), PAS-II, and routine assessment of patient index data 3.38
QI 10. Pretreatment and periodic investigations should be performed to monitor drug toxicities and manage adverse drug-related reactions in patients treated with DMARDs.

Monitoring for drug toxicity is essential to ensure the safety of patients with RA. DMARDs are immune-modulatory or suppressant, and they are potentially toxic to vital organs. DMARDs are used solely or in combination in patients with RA who may have several comorbidities; therefore, particular attention to DMARD toxicity is needed. Before DMARD therapy is initiated, it is necessary to conduct a basic laboratory examination and obtain radiographs to determine whether there are any abnormalities in the functions of the major organs, such as the lung, liver, and kidney. Periodic assessments are important to monitor any adverse effects related to DMARD use. Pretreatment investigations before DMARD therapy usually include complete blood count, liver function and renal function tests, viral hepatitis serology test, and chest radiography. Laboratory monitoring intervals and items have been proposed for each DMARD drug. For example, it is suggested that for patients receiving methotrexate (MTX), their complete blood counts, serum liver transaminase levels, and serum creatinine levels should be assessed every 2–4 weeks during the initial 3 months of MTX treatment, every 8–12 weeks during the next 3 months, and every 12 weeks thereafter.

QI 11. Patients treated with MTX should use folic acid supplements.

Weekly low-dose MTX is an anchor drug for treating RA and is relatively safe. However, low-dose MTX can cause side effects in many organs, such as gastrointestinal symptoms (nausea, vomiting, abdominal pain), mucositis, liver function abnormalities, bone marrow suppression, and alopecia. Folic acid supplementation has been shown to reduce these side effects in patients with RA receiving MTX. Therefore, it is recommended that patients with RA using MTX should also use folic acid supplements.

QI 12. Patients with RA initiating bDMARD therapy should be screened for HBV and HCV.

HBV and HCV are global public health problems. The overall prevalence of HBsAg has been reported to be 3.5%; it is especially high in Asian regions than in the US and Europe. The World Health Organization (WHO) estimated that in 2015, 1% of the global population had HCV. bDMARDs, including B-cell depleting agents, TNF inhibitors, and others, pose a moderate or high risk for immunosuppression and a risk for viral reactivation. These drugs can reactivate the virus, leading to liver failure and death for HBV-infected patients with RA. HBV reactivation can be prevented by appropriate antiviral therapy before administering bDMARDs. Antiviral treatment is recommended for patients with RA with latent HBV (hepatitis B surface antigen or anti-hepatitis core antibody positivity) as well as active HBV. Highly effective treatments for HCV are now available, and it is suggested that HCV eradication should be attempted before treatment with bDMARDs for all infected patients with RA. Therefore, screening for HBV and HCV before starting bDMARD therapy is recommended.
QI 13. Patients with RA initiating bDMARD therapy should be screened for active or latent tuberculosis. If tuberculosis is identified, it should be treated with an appropriate anti-tuberculosis regimen before initiating bDMARD therapy.

It is estimated that approximately 25% of the worldwide population has *Mycobacterium tuberculosis*. The WHO stated that in 2018, 10 million individuals contracted tuberculosis and 1.5 million died. The rates of tuberculosis are intermediate to high throughout Asia. Patients with active infection, including tuberculosis, should not use bDMARDs because of their potent immunosuppressive effect. Additionally, TNF has an important role in the formation of granulomas; therefore, the use of TNF inhibitors may trigger the activation of latent tuberculosis. Non-TNF inhibitor bDMARDs can also induce the activation of latent tuberculosis to variable degrees. Therefore, appropriate screening for tuberculosis is necessary before patients with RA can start bDMARD therapy. If patients have active or latent tuberculosis, they should receive appropriate treatment before initiating bDMARD therapy.

QI 14. Before patients with RA undergo surgery with general anesthesia, the risk of atlantoaxial instability (AAI) should be assessed and managed.

Patients with RA have a high prevalence of AAI, and approximately 50% of them are asymptomatic. Forced movements of the neck during intubation for general anesthesia may cause compression of the brainstem and quadriplegia in patients with AAI. The risk of AAI can usually be detected using radiography of the cervical spine before surgery. Airway intubation for patients with AAI should be performed by experts in an appropriate way.

DISCUSSION

Although there have been advances in the diagnosis and treatment of RA over the course of the past few decades, health care quality for patients with RA is still suboptimal. Several QIs have been developed based on scientific evidence and expert opinions to assess and improve the quality of RA care. In 2004, with financial support from the Arthritis Foundation, a formal set of 27 QIs for RA care based on a comprehensive literature review and expert panel scores was published in the US. These QIs included the following items: time to referral; history and physical examination; regular follow-up; radiographs of the hands and feet; radiographs of the cervical spine; DMARDs; folic acid supplementation; osteoporosis prophylaxis; glucocorticoids; exercise; assistive devices; surgery; baseline and follow-up laboratory studies; liver toxicity with MTX; informing patients about risks; reproductive issues; and vaccines. In 2006, the American College of Rheumatology (ACR) developed a starter set of RA QIs that incorporate previous QIs. The ACR and the National Committee for Quality Assurance as well as the Physician Consortium for Performance Improvement convened by the American Medical Association collaborate to develop six RA QIs based on the ACR 2008 recommendations for RA for the Physician Quality Reporting System (which is a voluntary quality reporting program of the Centers for Medicare and Medicaid Services). They included tuberculosis screening, periodic assessment of disease activity, functional status assessment, assessment and classification of disease prognosis, glucocorticoid management, and DMARD therapy. In 2014, the ACR developed electronic QIs relying on computer algorithms to extract data from electronic health records, disease activity assessments, functional status assessments, DMARD therapy, and tuberculosis screening before biologic therapy or certain new synthetic DMARDs. These four QIs have been endorsed by the National Quality Forum,
which is a national organization in the US that was established in 1999 to ensure patient protections and healthcare quality through measurements and public reporting.

Interest in the quality of RA care that began in the US has spread to other countries. In 2009, 18 QIs that specifically monitor the disease course of RA to evaluate the quality of daily practice were developed in The Netherlands. The NICE in the UK released quality standards for RA in 2013. During the same year, patient-centered standards and healthcare QIs for RA in Europe were published by the European Musculoskeletal Conditions Surveillance and Information Network, which is supported by the European Union and European League Against Rheumatism. In Canada, 11 QIs regarding cardiovascular disease care for patients with RA were developed using an online process created by an international expert panel.

To our knowledge, there have been no publications regarding RA QIs developed in Asia. Asian countries have varied medical systems and cultures that are different from those in western countries. Because public concern regarding rheumatic diseases as a major health issue is increasing in Asia, it is important to improve the healthcare quality of rheumatic disease care. The establishment of quality standards and/or QIs for rheumatic disease is an essential step in improving the quality of care. When using the QIs, it can be noted whether there are any gaps between the current practice and quality standards. Furthermore, differences among practitioners, hospitals and/or regions would be revealed. These findings can help the community and government recognize the need to make efforts to improve care for patients with rheumatic diseases. They can also be a basic tool used to assess current practices and appropriately allocate medical resources, thereby allowing medical societies and health professionals to improve the quality of care and provide efficient quality management of medical services.

RA is a chronic complex disease that has a major impact on multiple organs and overall health. The diagnosis of RA is usually a clinical judgment by experts (i.e., rheumatologists), and management requires a multidisciplinary approach centered on medicinal therapy. There is no single measure available to quantify the quality of care. Therefore, QIs for RA have been developed to assess different facets of caring for patients with RA. We developed 14 QIs for RA care based on an expert consensus and a review of QIs and treatment recommendations published previously. The preliminary QIs suggested by the task force were screened by an expert panel during two meetings. During the first meeting, their scientific validity and relevance were discussed. During the second meeting, the priority and feasibility were discussed. We finalized QIs based on the following: human resources (specialized nurse); diagnosis (early referral to and regular follow-up with a rheumatologist, radiographs of the hands and feet); treatment (early initiation and maintenance of DMARD therapy); disease monitoring (periodic assessment of disease activity); safety (screening for drug safety and comorbidities, including viral hepatitis and tuberculosis, before bDMARD therapy, periodic laboratory testing, supplementation with folic acid, risk assessment of cervical spine instability before general anesthesia); and patient education. Measurement methods for our QIs are suggested in Supplementary Table 1.

Our QIs do not address tsDMARDs such as tofacitinib and baricitinib because they were not launched in Korea at the beginning of QI development. tsDMARDs are often used to treat active RA using the same strategy as that used for bDMARDs. Therefore, QI 12 and QI 13 regarding bDMARD therapy are applicable to patients treated with tsDMARDs.

Glucocorticoids are often used to treat RA because they quickly improve symptoms; however, they have some risks. The use of glucocorticoids increases the risks of cardiovascular disease,
hyperglycemia, osteoporosis, and infection. Therefore, the lowest dose should be used for the shortest time possible, and they should not be used as monotherapy.\textsuperscript{3,25,28,29} The proper use of glucocorticoids is a potential QI for RA care. Seven items relevant to the use of glucocorticoids were included in our preliminary QIs. All of these QIs were rated as appropriate during the first meeting; however, during the second meeting, they were excluded because of their lower priority and feasibility. When evaluating the suitability of glucocorticoid therapy, the dose, duration of use, and disease activity should be considered. Therefore, it is difficult to establish proper glucocorticoid use as a criterion for evaluating the quality of RA care.

QIs are usually categorized into three domains: structure, which reflects the attributes of the providers and system; process, which involves practicable targets and adhering to clinical guidelines or quality standards; and outcome, which are the end results of care and are often considered the most meaningful.\textsuperscript{49} Ideal quality measurements have all three relevant domains. Our QIs are related only to structure and process; they do not include outcome indicators such as disease activity and disability. Quality assessments of chronic diseases such as RA often focus on the process. Outcomes of RA usually require years to manifest and are influenced by factors not related to the quality of clinical care.\textsuperscript{50} We excluded some outcome indicators because it is not feasible to find the data regarding the outcomes of patients with RA.

A limitation of the present QIs may be that only rheumatologists participated in their development. Therefore, our QIs may represent mainly the views of rheumatologists, who are the primary physicians caring for patients with RA. Patients’ views and preferences might have been underestimated because they were not involved in the development of these QIs.

In conclusion, a set of 14 QIs with multi-faceted clinical relevance were developed based on scientific validity, priority, and feasibility to assess the quality of care for patients with RA. Quality measurements obtained using these QIs can be used in the context of national health policies as well as clinical practice to improve the quality of care for patients with the rheumatic disease.

- The QIs used to measure the quality of care for patients with RA were developed based on scientific validity, priority, and feasibility by experts in Korea.
- The QIs included multiple aspects of RA care such as human resources, diagnosis, treatment, disease monitoring, safety, and patient education.
- The QIs can be used to assess and improve the quality of care for patients with RA.

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Supplementary Table 1
Measurement methods of QIs

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