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Review Article

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Current Status and Prospect of Qualitative Assessment of Antibiotics Prescriptions

Se Yoon Park [1,2,3,*], Yong Chan Kim [4,*], Raeseok Lee [5], Bongyoung Kim [6,†], Song Mi Moon [7,†], Hong Bin Kim [7], and Korea Study Group for Antimicrobial Stewardship

[1]Department of Hospital Medicine, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea
[2]Department of Biomedical Systems Informatics, Yonsei University College of Medicine, Seoul, Korea
[3]Centers for Digital Health, Yongin Severance Hospital, Yonsei University Health System, Yongin, Korea
[4]Department of Internal Medicine, Division of Infectious diseases, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea
[5]Department of Internal Medicine, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea
[6]Department of Internal Medicine, Hanyang University College of Medicine, Seoul, Korea
[7]Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea

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Corresponding Authors:
Bongyoung Kim, MD, PhD
Department of Internal Medicine, Hanyang University College of Medicine, 222-1, Wangsimni-ro, Seondong-gu, Seoul 04763, Korea.
Tel: +82-2-2290-8357
Fax: +82-2-2298-9183
Email: sobakas@hanyang.ac.kr

Song Mi Moon, MD, PhD
Department of Internal Medicine, Seoul National University Bundang Hospital, Seongnam 13620, Korea.
Tel: +82-31-787-7029
Fax: +82-31-787-4052
Email: moon7796@hanmail.net

*Se Yoon Park and Yong Chan Kim contributed equally to this study as first author.
†Bongyoung Kim and Song Mi Moon contributed equally to this study as corresponding author.

ABSTRACT

Identifying inappropriately prescribed antibiotics for infectious diseases by monitoring the quality of antibiotics use is essential for effective implementation of antibiotic stewardship. Qualitative assessment of the use of antibiotics has been conducted in some countries, including Korea, since the 2000s. The qualitative assessment generally involves an assessment of each component of the antibiotics prescription process, based on specific criteria. However, there is no standardized assessment method or cycle, and infectious diseases or antibiotics included in the assessments vary from country-to-country. According to the results reported in the United States, Europe, Australia, and Korea so far, approximately 20 - 55% of all antibiotics prescriptions are inappropriate. In this review, we describe the current progress in the quality assessment of the use of antibiotics on a global scale. Further, we highlight the future directions to improve antibiotic stewardship activities and the quality assessment of the use of antibiotics in Korea.

Keywords: Anti-Bacterial Agents; Prescriptions; Antimicrobial Stewardship; Korea

IMPORTANCE OF QUALITATIVE ASSESSMENT OF ANTIBIOTICS PRESCRIPTION

Since antibiotics were first discovered, many lives have been saved from infectious diseases owing to antibiotics treatment. However, the range of available antibiotics is narrowing given the limited number of newly developed antibiotics in contrast to the increasing number of antibiotics resistant bacteria [1, 2]. According to O'Neill's report, antibiotics resistance is expected to cause 10 million deaths worldwide in 2050, which is higher than the predicted number of deaths from cancer [3]. In addition, according to the data provided by the Centers for Disease Control and Prevention (CDC), at least 250,000 people were infected with

ORCID iDs

Se Yoon Park
https://orcid.org/0000-0002-4538-7371
Yong Chan Kim
https://orcid.org/0000-0001-5081-7906
Raeseok Lee
https://orcid.org/0000-0002-1168-3666
Bongyoung Kim
https://orcid.org/0000-0002-5029-6597
Song Mi Moon
https://orcid.org/0000-0003-1241-4895
Hong Bin Kim
https://orcid.org/0000-0001-6262-372X

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Conflict of Interest

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Clostridioides difficile in 2013, of whom 14,000 died [4]. The rise of antibiotics resistant bacteria not only increases the mortality rate but also affects the length of hospital stay and increases medical expenses [5, 6]. Accordingly, the World Health Organization declared antibiotics resistance as an important health crisis facing human life in 2014, presented a Global Action Plan in 2015, and strongly urged international cooperation for preparing countermeasures against the indiscriminate use of and resistance to antibiotics [7].

The antibiotic stewardship program includes various strategies pertaining to the proper prescription of antibiotics and aims to reduce antibiotics resistance, improve patients' clinical outcomes, reduce the rate of adverse effects, and reduce medical costs [8]. According to a systematic literature review and meta-analysis, antibiotic stewardship has been confirmed to significantly reduce the incidence of *C. difficile* infection as well as infection and colonization caused by multidrug-resistant bacteria [9]. For effective antibiotic stewardship, the Infectious Diseases Society of America and Society for Healthcare Epidemiology of America recommends measuring the amount of antibiotics used to identify trends in antibiotics use at medical institutions [10]. In Korea, the Korea National Antimicrobial Use Analysis System (KONAS) monitors the antibiotics consumption at various national medical institutions [11, 12]. However, it is difficult to determine the inappropriate antibiotics use that is a target of intervention because it is challenging to accurately identify the point where inappropriate antibiotics use is taking place at medical institutions only by recording the number of antibiotics used. Therefore, to ensure effective antibiotic stewardship within medical institutions, it is essential to perform a qualitative assessment of antibiotics prescriptions to identify patterns of inappropriately prescribed antibiotics. In addition, the effectiveness of interventions involving antibiotics use can be identified if periodic qualitative assessment of antibiotics prescriptions is performed [13, 14].

According to the results of domestic and foreign studies on the qualitative assessment of antibiotics prescriptions since the 2000s, it was found that approximately 20 - 55% of all antibiotics prescriptions were inappropriate [15-18]. In a survey of domestic secondary and tertiary medical institutions, approximately 25% of all antibiotics prescriptions were found to be inappropriate, and a survey of small- and medium-sized hospitals showed that approximately 35% of all antibiotics prescriptions were inappropriate [15, 16]. Although it is difficult to directly compare the results of different countries because of the lack of globally standardized assessment methods or cycles, and infectious diseases or antibiotics included in assessment varies from country-to-country, approximately 25% of all antibiotics prescriptions in Australia and approximately 55% in the United States were presumed to be inappropriate [17, 18]. To ensure continuous and effective qualitative assessment of antibiotics prescriptions in Korea, it is necessary to examine the existing assessment methods and to establish an assessment strategy suitable for the domestic situation.

METHODS FOR QUALITATIVE ASSESSMENT OF ANTIBIOTICS PRESCRIPTIONS

Qualitative assessment of antibiotics prescriptions can be conducted by dividing it into sub-items [19, 20]. For example, the appropriate dosage and administration interval can be evaluated by referring to the patient's kidney function, weight, liver function, age, and underlying disease. In addition, depending on whether or not the result of the culture test is present, the appropriateness of antibiotics prescriptions can be evaluated by dividing

them into empirical antibiotics and definitive antibiotics prescriptions. It is also possible to evaluate whether the duration of antibiotics use is appropriate.

For the qualitative assessment of antibiotics prescriptions, several components associated with antibiotics prescriptions should be considered. One of the suggested methods is to use a set of quality indicators that are measurable elements for which sufficient evidence is present.

Nine quality indicators at the patient level and two quality indicators at the institution level have been suggested in the Delphi survey with a systematic literature review by van den Bosch et al., published in the Netherlands in 2015, which are considered representative examples [20]. Further, the European Driving Reinvestment in Research and Development and Responsible Antibiotic Use (DRIVE-AB) project developed 51 quality indicators for inpatients, 34 for outpatients, and 22 for emergency department patients [21-23]. In Korea, in 2019, through the consensus of 25 experts on antibiotics use, 13 quality indicators for inpatients, 7 for outpatients, and 5 for surgical antibiotics prophylaxis were suggested (**Table 1**)[24]. In Australia, a national antibiotics prescription survey is conducted every year. The results of the survey, which included the appropriateness of all antibiotics prescribed and the compliance with four quality indicators (documented indication for antibiotics use in medical records, documented review or stop date for antibiotics use, prophylactic antibiotics used for more than 24 hours after surgery, and antibiotics use compliant with national or local guidelines) developed in 2015, are presented in an annual report [17]. Through the presentation of quality indicators and feedback on the compliance rate of standard indicators, the percentage of documented indication for antibiotics use in medical records in Australia increased from 70.5% in 2013 to 84.2% in 2019 and that of prophylactic antibiotics used for more than 24 hours after surgery decreased from 41.0% in 2013 to 30.0% in 2019 [17], indicating improved quality of antibiotics prescriptions.

However, qualitative assessment of antibiotics prescriptions using quality indicators only has some limitations. Some quality indicators are difficult to be applied. For example, for infectious sites that are not suitable for culture tests, it is difficult to apply the following quality indicator: “Is a culture test performed before prescribing antibiotics?” Since the qualitative assessment using quality indicators involves the components of antibiotics prescription, there may be some differences with the results of assessment based on expert judgment [25]. Therefore, it may be useful to select individualized quality indicators according to each disease, situation, and antibiotics. The following item is an example of a

Table 1. Quality indicators for the qualitative assessment of antibiotics prescriptions in inpatient, outpatient, and emergency rooms, based on the consensus of domestic experts, that can be used in cross-sectional surveys

Antibiotics for therapeutic purposes (hospitalization/emergency room)
(1) Empirical antibiotics are prescribed according to guidelines (institutional, national, or international).
(2) If culture test results are available, appropriate antibiotics are administered according to the results.
(3) A culture test with a sample from the site suspected of infection before or immediately after administration of antibiotics is carried out for therapeutic purposes.
(4) Two or more pairs of blood culture tests are performed before administering antibiotics for therapeutic purposes.
(5) Antibiotics dose or administration interval is adjusted according to renal function.
(6) The basis and plan for prescribing antibiotics are listed in the medical record.
Antibiotics for therapeutic purposes (outpatient)
(1) Empirical antibiotics are prescribed according to guidelines (institutional, national, or international).
(2) If culture test results are available, appropriate antibiotics are administered according to the results.
(3) Antibiotics dose or administration interval is adjusted according to renal function.
Surgical prophylactic antibiotics
(1) Antibiotics for surgical prophylaxis are prescribed based on guidelines (institutional, domestic, and international).
(2) Antibiotics for surgical prophylaxis are administered within 1 h before incision at the surgical site.
(3) Antibiotics to prevent surgery are discontinued within 1 day after surgery.

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quality indicator according to a specific situation: "Antibiotics should be administered by intravenous injection in patients with sepsis." [26]. If it is difficult to measure the quality of antibiotics prescriptions using only quality indicators, expert judgment can be used. If expert judgement is being used, a method of measuring the appropriateness of antibiotics uses by categorizing them into optimal, appropriate, and inappropriate prescriptions based on certain criteria is suggested [17]. However, evaluating the various components of antibiotics prescriptions for an individual patient is a cumbersome process. Furthermore, expertise and experience in the field of infectious diseases are required to make an accurate judgment. As an alternative, one of the methods of evaluating the appropriateness of antibiotics prescriptions by minimizing the need for judgment involves the use of an algorithm for each item such that persons with relatively little expertise in the field of infectious diseases can conduct the evaluation [18, 27]. As such, there are advantages and limitations to the evaluation methods using expert judgment and those using quality indicators; hence, it is necessary to understand the evaluation method and find ways to standardize it.

STATUS OF QUALITATIVE ASSESSMENT OF ANTIBIOTICS PRESCRIPTIONS IN COUNTRIES OUTSIDE OF KOREA

Qualitative assessment of antibiotics prescriptions began in the 2000s, mainly in Europe, the United States, and Australia. Qualitative assessments are conducted in an independent manner in these continents, and they have developed their own systems. In Europe, the European Surveillance of Antimicrobial Consumption-Network (ESCA-Net) conducted a study on antibiotics usage and qualitative assessment of antibiotics prescriptions [28-31]. Specifically, the proportions of indications for the use of antibiotics in medical records, of surgical prophylactic antibiotics used for more than 24 h [28-30], of antibiotics prescriptions according to the guidelines [28, 30], and of antibiotics in inappropriate combination prescriptions, such as redundant antibiotics coverage in anaerobic antibiotics [30] were evaluated. In the Netherlands, a qualitative assessment was conducted in 2011 and 2012 with 1,890 inpatients in 22 hospitals using 11 quality indicators selected through a systematic literature review and Delphi survey [32]. An institution in Spain also conducted a qualitative assessment using the same quality indicators developed in the Netherlands [33].

In Australia, data on qualitative assessment are recorded through the National Antimicrobial Prescribing Survey (NAPS), run by the National Center for Antimicrobial Stewardship, a multidisciplinary team at the Melbourne Doherty Institute. The NAPS is subdivided into Hospital NAPS, Surgical NAPS, and Aged Care NAPS, and a qualitative assessment of antibiotics prescriptions is performed for each module. The Hospital NAPS, which was first launched in 2010, is a simple offline survey in which individual institutions identify and benchmark antibiotics use patterns of similar institutions to improve their use of antibiotics. In 2013, the method of collecting data was changed to online collection, and the Aged Care NAPS, Quality Improvement NAPS, and Surgical NAPS were added. The hospitals included in the Hospital NAPS can check each institution's results of qualitative assessment of antibiotics prescriptions online and filter and compare the results of other institutions according to the region where the medical institution is located, degree of access to the medical institution, operating entity of the medical institution, and size of the hospital [17].

In the United States, a CDC-led analysis of antibiotics usage and qualitative assessment of antibiotics prescription at medical institutions have been conducted [34]. Qualitative

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assessment of antibiotics prescribed for pediatric patients was conducted by the Sharing Antimicrobial Reports for Pediatric Stewardship Collaborative [35]. In 2009, a pilot study investigating the prevalence of healthcare-associated infections was conducted to analyze the improvements required in antibiotics prescriptions; at that time, 110 of 296 cases (37.2%) needed improvement [36]. In 2011, a qualitative assessment of antibiotics prescriptions at acute care hospitals in 10 states in the United States was conducted, and the surveillance was conducted by purpose of antibiotics prescription and classified as prescriptions for community-acquired infections or healthcare-associated infections [37]. Afterward, in 2015, a qualitative assessment was performed for hospitalized patients who were diagnosed with community-acquired pneumonia or urinary tract infection and for those who received fluoroquinolone or intravenous vancomycin. In the 2015 CDC survey, instead of using specific quality indicators or conducting evaluations using expert judgment, a case report form called Antimicrobial Quality Assessment (AQUA) and algorithm developed for qualitative assessment of antibiotics prescriptions were used in the evaluation process [18]. The case report form included information on the patient's underlying disease, possible healthcare-associated infection, antibiotics allergy, disease severity, infection during hospitalization, culture test results, and prescribed antibiotics [18]. Clinical information was collected through a retrospective review of medical records in hospitals participating in the survey. The collected information was analyzed using the developed algorithm for qualitative assessment of antibiotics prescriptions, and the appropriateness of the antibiotics prescriptions for each patient was evaluated by dividing them into supported and unsupported categories [18].

The global point prevalence study (PPS), designed by the University of Antwerp in Belgium, targets acute care hospitals worldwide. Participating institutions voluntarily collect clinical information related to antibiotics use and conduct a qualitative assessment of antibiotics prescriptions. The PPS provides the results of qualitative assessment of antibiotics use at institutions within a given country as well as at institutions in the same continent, making it possible to objectively analyze the status of antibiotics prescriptions at individual hospitals and annual antibiotics usage at the participating institutions, additionally providing data to confirm the trends in the qualitative assessment results [27]. Furthermore, antibiotics prescription prevalence and antibiotics use patterns by the disease are also presented. In China, since 2020, the medical information database has been used to evaluate the quality of antibiotics prescriptions according to the International Classification of Diseases (ICD)-10 code [38-40]. The evaluation results are classified and presented as (1) appropriate (tier 1 diagnosis), (2) potentially appropriate (tier 2 but not tier 1), (3) inappropriate (tier 3), and (4) not linked to diagnosis [39].

CURRENT STATUS OF ANTIBIOTICS QUALITATIVE ASSESSMENT IN KOREA

In Korea, qualitative assessment of antibiotics prescriptions has been performed sporadically in some institutions since the early 2000s [15, 16, 41-44]. In 2003, qualitative assessment of the use of intravenous ciprofloxacin was conducted at eight domestic hospitals, and during 2006 - 2008, qualitative assessment of the use of antibiotics for surgical prophylaxis was conducted at six hospitals [41, 42].

Qualitative assessment of nationwide antibiotics prescriptions has been conducted every year as part of the Korea Disease Control and Prevention Agency's policy on research service

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projects since 2018, and 20 hospitals participated in the first-year quality assessment based on expert judgment, which targeted all antibiotics prescribed on a specific day [15]. In 2019, after having expanded the target institutions to 74 hospitals nationwide, some of the antibiotics prescribed on a specific day were selected through random sampling and a qualitative assessment of those antibiotics based on expert judgment was performed. In 2020, a qualitative assessment of antibiotics prescribed for urinary tract infections was conducted at 26 hospitals, and in 2022, a qualitative assessment of antibiotics prescribed for the treatment of bacteremia was conducted (**Table 2**). Through these studies, it was confirmed that approximately 26 - 27% of the total antibiotics use at domestic hospitals was inappropriate [15]. In addition, in 2021, a qualitative assessment of antibiotics was conducted for 10 small- and medium-sized hospitals with less than 400 beds across the country. From the survey, it was confirmed that 34.2% of the antibiotics prescribed for inpatients at acute care small- and medium-sized hospitals and 36.7% of antibiotics prescribed to inpatients at long-term care hospitals were inappropriate [16].

Through these investigations, it was possible to identify infectious diseases for which antibiotics are mainly prescribed and the frequently prescribed antibiotics, and detailed analyses of situations involving inappropriate prescriptions of antibiotics (by prescription purpose, by infectious diseases by type of antibiotics, and others) were performed. However, there is still no effective strategy to promote standardized antibiotic stewardship activities at individual medical institutions based on the results of the qualitative assessment of antibiotics prescriptions.

Meanwhile, the evaluation of the appropriateness of reimbursement for drug prescribed in Korean hospital began in 2001, led by the Health Insurance Review and Assessment Service (HIRA). Antibiotics prescription rates for acute upper respiratory infections were demonstrated in 2006, and evaluation of the appropriate use of prophylactic antibiotics before and after surgery was introduced as an item for medical institutions evaluation standard in 2007. Monitoring antibiotics prescription rates for acute lower respiratory infections, excluding pneumonia and chronic lower respiratory disease, was newly conducted in 2019. The results of monitoring are announced on the website of the HIRA, and each health care institution can also identify the results through written report or electronic notification. With a series of implementations led by HIRA, the antibiotics prescription rates for acute upper respiratory tract infections and the prophylactic antibiotics use of surgery improved [42, 45]. Moreover, these implementations had a positive effect on an increasing

Table 2. Qualitative assessment of antibiotics prescriptions in Korea

Study year	Study institutions	Target antibodies	Study contents
2003	8 university hospitals [41]	Ciprofloxacin	Surgical prophylactic antibiotics, therapeutic antibiotics
2007	6 university hospitals [42]	Surgical prophylactic antibiotics	5 types of surgeries—gastrectomy, joint surgery (hip arthroplasty, knee arthroplasty), hysterectomy, craniotomy, spine surgery
2014	1 university hospital [43]	Surgical prophylactic antibiotics	11 types of surgeries designated by the Health Insurance Review and Assessment Service—gastrectomy, colorectal resection, laparoscopic cholecystectomy, hip arthroplasty, knee arthroplasty, hysterectomy, cesarean section, heart surgery, craniotomy, prostatectomy, glaucoma surgery
2015	1 university hospital [44]	All antibiotics	Asymptomatic bacteriuria
2018	20 secondary and tertiary medical institutions [15]	All antibiotics[a]	Therapeutic, surgical prophylactic, medical prophylactic antibiotics
2019	74 secondary and tertiary medical institutions	All antibiotics	Therapeutic, surgical prophylactic, medical prophylactic antibiotics
2019	10 small- and medium-sized hospitals [16]	All antibiotics	Therapeutic, surgical prophylactic, other antibiotics
2020	24 secondary and tertiary medical institutions and 2 long-term care hospitals	All antibiotics	Asymptomatic bacteriuria, lower urinary tract infection, upper urinary tract infection (complicated/non-complicated)
2022	27 secondary and tertiary medical institutions	All antibiotics	Bacteremia

[a]Excluding topical antibiotics, antivirals, and anti-tuberculosis drug.

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interest in improving the quality of antibiotics prescriptions for healthcare workers in Korean medical institutions. However, there are some limitations in the evaluation of the appropriateness of reimbursement for drug prescribed in Korean hospital. First of all, since the results of the evaluation affect the degree of medical insurance payment and are reflected in the evaluation of hospital accreditation, some medical institutions input distorted diagnoses in favor of the evaluation. In addition, since the collection and submission of evaluation data related to the prophylactic antibiotics use of surgery were performed by healthcare workers in individual medical institutions, it can be a burden, especially for medical institutions that lack manpower.

CHALLENGES IN THE QUALITATIVE ASSESSMENT OF ANTIBIOTICS PRESCRIPTIONS IN KOREA

Qualitative assessments of antibiotics prescriptions have been performed in various countries by using their own methods, and the number of target institutions are increasing in each country. Hence, it is difficult to evaluate which method is appropriate with a clear advantage, as each method has advantages and disadvantages.

To perform a qualitative assessment of antibiotics prescriptions in connection with antibiotic stewardship activities, it is necessary to secure sufficient manpower and institutional support [46, 47]. In Korea, the number of active infectious diseases specialists per 100,000 people in 2019 was only 0.47, *i.e.*, 0.26 per 100 beds, and compared with the criterion suggested in Europe of 1.21 infectious diseases specialists/clinical microbiology specialists/infection control physicians per 100 beds at institutions that conduct basic activities for antibiotic stewardship and infection control, the figure is rather inadequate [48]. According to a survey conducted in Korea, due to limited resources, the work of infectious diseases specialists is mainly focused on patient care, and very limited time is available for antibiotic stewardship or infection control [49].

To overcome these limitations, it is necessary to consider the following points: (1) policy support to increase the number of infectious diseases specialists, (2) diversification of manpower that can perform qualitative assessment of antibiotics prescriptions, as observed in the United States [18], and (3) development of a standardized method for qualitative assessment. Effort of government for financial and manpower support, like the United States and Australia, is also essential to ensure that qualitative assessment of antibiotics prescriptions can be established in the long term. As shown in Chinese studies, qualitative assessment of antibiotics prescriptions based on a specific diagnosis may be applied to some institutions [39, 40]. Considering the current situation and limited resources in Korean hospitals, a practical strategy for the selection of target institutions and antibiotics is needed. For developing specific methods of qualitative assessment of antibiotics prescriptions, the measures that can be implemented to achieve present and long-term goals should be suggested through discussions with infectious diseases experts and government officials.

SUPPLEMENTARY MATERIAL

Guideline Korean version

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