REVIEW

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Revision of Quality Indicators for the Endoscopy Quality Improvement Program of the National Cancer Screening Program in Korea

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Gastroscopy and colonoscopy are widely used for the early diagnosis of stomach and colorectal cancer. The present revision integrates recent data regarding previous quality indicators and novel indicators suggested for gastroscopy and colonoscopy procedures for the National Cancer Screening Program in Korea. The new indicators, developed by the Quality Improvement Committee of the Korean Society for Gastrointestinal Endoscopy, vary in the level of supporting evidence, and most are based solely on expert opinion. Updated indicators validated by clinical research were prioritized, but were chosen by expert consensus when such studies were absent. The resultant quality indicators were graded according to the levels of consensus and recommendations. The updated indicators will provide a relevant guideline for high-quality endoscopy. The future direction of quality indicator development should include relevant outcome measures and an evidence-based approach to support proposed performance targets. Clin Endosc 2018;51:239-252

Key Words: Gastroscopy; Colonoscopy; Quality improvement; Safety; Mass screening

INTRODUCTION

Following the "First 10-year Plan for Cancer Control" screening program in Korea initiated by the government, the National Cancer Screening Program (NCSP) has been active since 1999. 1,2 Nationwide stomach cancer and colorectal cancer (CRC)

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screenings have been performed as part of the NCSP for Medical Aid recipients and National Health Insurance beneficiaries in the lower 50% income bracket.^{3,4} For stomach cancer screening, either esophagogastroduodenoscopy (EGD) or gastrointestinal series is performed biennially for adults aged 40 years or older.^{3,4} For CRC screening, fecal occult blood tests (FOBTs) are performed annually as the primary screening tool for adults aged 50 years or older, and follow-up investigation by either colonoscopy (CS) or double contrast barium enema are provided for individuals with a positive FOBT.^{5,6}

Given the variability in performance levels by endoscopists and the introduction of the NCSP, improving the quality of EGD and CS has become an important concern. Recently, many professional societies have published specific quality indicators for endoscopy procedures; however, it is difficult to adopt Western quality indicators in Korea, as these are generally country-specific. To improve the quality of endoscopy in the NCSP,



the Korean Society of Gastrointestinal Endoscopy (KSGE) developed the National Endoscopy Quality Improvement Program (NEQIP).⁷⁻⁹ The NEQIP incorporated qualifications of endoscopists and endoscopic procedures (including processes, instrument and equipment, outcome, sedation protocols, and reprocessing of endoscopes).⁷⁻⁹ Recently, revised quality indicators for EGD and CS in Western countries have included the grades of recommendation and performance targets for different quality indicators.^{10,11} It is now necessary to revise the NEQIP, as it has not been revised since 2008 and the current version does not include recent updated data relative to quality improvements for EGD and CS.

In this context, the Quality Improvement Committee of the KSGE revised the quality indicators, to be broadly applied by the NEQIP, for EGD and CS in 2017. This paper reports the statements and quality indicators for used for EGD and CS and describes the process applied for the development of these statements and quality indicators.

METHODS

Process of revision

The Quality Improvement Committee of the KSGE chose to develop a revised edition of the quality indicators for the NEQIP in March 2017 based on the previous quality indicators developed in 2008. The members of the Task Force on Revision of Quality Indicators included 14 gastroenterology professors from the university hospital, and members of the Quality Improvement Committee. At the first meeting, held on May 2017, the scope of the revision was discussed and a decision was made to focus on the NEQIP but not on general endoscopy quality indicators outside of the NCSP. After several meet-

ings and discussions by the Task Force, 29 key statements were selected using a *de novo* method or were adapted from previous quality indicators. For the adopted quality indicators, the strength of evidence supporting these quality indicators was reviewed, scrutinized, and summarized based on evidence from reports published in PubMed and EMBASE. *De novo* development was suggested from members of the Task Force based on studies published in PubMed and EMBASE. Despite new knowledge and accumulated evidence, few studies have been published, especially from Korea; therefore, many revision decisions were based on specialist's opinions owing to the lack of adequate literature to support the grading of recommendations.

Delphi process

On October 21, 2017, the draft of the revised statements and quality indicators for NEQIP was presented for a consensus meeting, which was attended by 27 gastrointestinal endoscopy specialists including members of the Task Force in Korea. To determine the level of agreement, each NEQIP statement was classified into five levels of strength of recommendation: "strongly agree", "agree", "uncertain", "disagree", or "strongly disagree" (Table 1). Each statement was accepted when ≥75% of the participants had chosen "strongly agree" or "agree"; for statements that did not reach a consensus, a second round of voting was performed following a discussion and revision of the original statements. When <75% of the participants had chosen "strongly agree" or "agree" for the revised statements on the second vote, they were deleted from this revision.

For the selected statements, the levels of recommendation were determined using an online-based voting system. Among the 27 members, 22 (81.5%) participated in this voting scheme to determine the levels of recommendation for the statement. To this end, each NEOIP statement was classified into three

Table 1. Levels of Agreement and Recommendation

Definition

Level of agreement

- A: Strongly agree with the statement and quality indicators
- B: Agree with the statement and quality indicators
- C: Uncertain of the statement and quality indicators
- D: Disagree with the statement and quality indicators
- E: Strongly disagree with the statement and quality indicators

Level of recommendation

Strong: Recommendation likely to apply to most National Cancer Screening Program endoscopy settings

Intermediate: Recommendation, best action may differ according to particular circumstances or patients in National Cancer Screening Program endoscopy settings

Weak: Recommendation, alternative approaches likely to be better under some circumstances in National Cancer Screening Program endoscopy settings

levels of strength: "strong", "intermediate", or "weak" (Table 1). Using the same rule, the level of recommendation was accepted when ≥75% of the voters had chosen "strongly agree" or "agree", whereas a second voting was planned for the revised statements when <75% of the voters had chosen "strongly agree" or "agree". However, none of the original statements proceeded to a second round of voting for the strength of the recommendations.

The final level of agreement and recommendations were indicated as a percentage value below the statement and quality indicators in respective tables. The statements and quality indicators were classified into six domains.

Statements and quality indicators

Statements and quality indicators were classified into six domains: workforce, process, facilities and equipment, outcome, reprocessing, and sedation. Among the potential 32 statements and 38 quality indicators that were proposed, a consensus agreement was reached for 29 statements and 34 quality indicators after discarding three statements and four quality indicators. The discarded statement and quality indicators were 'examination time for EGD, 'documentation of complications of CS, and 'adenoma detection rate over 40%'. All the participants agreed on the importance of these discarded quality indicators, but they postponed their acceptance as they were considered too premature to be accepted as quality indicators for the NEQIP in Korea. Finally, a total of 29 statements (Tables 2 and 3) and 34 quality indicators (Tables 4 and 5) were accepted for this revision of the NEQIP. All statements and quality indicators were described by tagging EGD, CS, or EGD/CS at the end of the sentence, respectively.

Domain: workforce

The domain for the workforce is composed of four statements (Table 2) and six quality indicators (Table 4). An endoscopist who performs EGD and CS should be an expert with the following skills: (1) the ability to perform reasonable, safe, and efficient endoscopy; (2) the ability to accurately describe and interpret endoscopic findings; (3) the ability to recognize and minimize the risk factors of endoscopy and to take appropriate action in the event of endoscopy-related complications; (4) the ability to clearly understand and provide an appropriate endoscopic diagnosis and recommended treatment for the requested exam; (5) the ability to understand the principles involved in sedative endoscopy and to conduct clinical evaluation and monitoring during sedative endoscopy; and (6) the ability to identify the importance of the reprocessing of endoscopes and to educate and perform endoscopic cleansing and reprocessing. In order to perform high-quality gastrointestinal endoscopy, an endoscopist must have the ability to diagnose and treat disease with endoscopy. In addition, they must have received supervised training for the advisement and management of gastrointestinal disease and cooperate with other specialists and assistant personnel as a part of a medical team. It is difficult to achieve an optimal level of competence in endoscopy training within a short time. Quality guidelines for gastric cancer screening define "a specialized endoscopist for EGD" as "a specialist who has undergone supervised EGD training of at least one year or more," and "specialized endoscopists for CS" as "a specialist who has undergone supervised CS training in more than 150 cases over at least one year or more." In this revision, the levels of agreement and recommendation were very high for the statement regarding endoscopist qualifications and continuing medical education.

There is insufficient evidence regarding the adequate duration of and methods for gastrointestinal endoscopy training. In general, supervised gastrointestinal endoscopy training is recommended for at least one year in Korea. With regard to the optimal volume of supervised EGD procedures, 1,000 cases are recommended by both the KSGE and the Japan Gastroenterological Endoscopy Society, but only 130 cases are recommended by the American Society for Gastrointestinal Endoscopy (ASGE).¹² Although an endoscopy specialist is not required to perform EGD screening for gastric cancer in Japan, the Japan Gastroenterological Endoscopy Society recommends at least 5 years of clinical experience and at least 1,000 cases of EGD experience for endoscopy specialists, while the Japanese Association for Cancer Detection and Diagnosis requires over three years of clinical experience, experience in over 1,000 EGD procedures, and experience with over 15 cases of gastric cancer detection for endoscopy specialists. In the Quality Guidelines for Gastric Cancer Screening, 12 which were revised in 2017, it is recommended that the EGD for the NCSP should ideally be performed by an endoscopist who has undergone at least one year of supervised endoscopy or by an endoscopist with experience in at least 500 cases of EGD as the minimum qualifications.¹²

For CS training, at least 1 year of supervised CS training is recommended by both the KSGE and the Korean Society of Coloproctology.¹³ With regard to the volume of optimal supervised CS training, 140 and 150 cases are recommended by the ASGE and KSGE, respectively.^{14,15} In the revised Quality Guidelines for CRC Screening,¹³ CS for the NCSP should be performed by a specialist with at least one year of supervised CS training comprising over 150 cases or an endoscopist who has performed at least 300 or more successful CS procedures as a minimum qualification. The European Society of Gastrointestinal Endoscopy recommends a minimum number of CSs to be performed annually.¹⁶ The National Health Service Bowel Cancer Screening Programme of the United Kingdom and the Spanish Society of Gastrointestinal Endoscopy recom-



Table 2. Final Statements and Their Level of Agreement for Esophagogastroduodenoscopy and Colonoscopy in the National Cancer Screening Program: Workforce, Process, Facilities and Equipment, and Outcome

Statements

Workforce

An experienced endoscopist with sufficient training in EGD should perform EGD. (EGD)

[Level of agreement: strongly agree 95.2%, agree 4.8%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

An experienced endoscopist with sufficient training in colonoscopy should perform colonoscopy. (CS)

[Level of agreement: strongly agree 96.0%, agree 4.0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

An endoscopist who performs endoscopies is required to receive continuous endoscopy education. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Endoscopy nursing staff is required to receive training for endoscopy quality improvement. (EGD/CS)

[Level of agreement: strongly agree 91.3%, agree 8.7%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 81.8%, intermediate 18.2%, weak 0%]

Process

Clinicians should verify the overall condition of the patient before EGD. (EGD)

[Level of agreement: strongly agree 95.8%, agree 4.2%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Clinicians should verify the fasting state, general health status, previous medical history, current medication history including anti-platelets or anticoagulants (antithrombotics), and quality of bowel preparation before colonoscopy. (CS)

[Level of agreement: strongly agree 95.7%, agree 4.4%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Clinicians should provide bowel preparation education to examinees before colonoscopy. (CS)

[Level of agreement: strongly agree 95.7%, agree 4.4%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Clinicians should provide a sufficient explanation of the procedure and obtain informed consent before colonoscopy. (CS)

[Level of agreement: strongly agree 95.8%, agree 4.2%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

All of the standard imaging sites of EGD should be clearly photographed and stored as image records. (EGD)

[Level of agreement: strongly agree 91.3%, agree 8.7%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]

All of the standard imaging sites of colonoscopy should be clearly photographed and stored as image records. (CS)

[Level of agreement: strongly agree 91.3%, agree 8.7%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 81.8%, intermediate 18.2%, weak 0%]

Average withdrawal time in negative-result colonoscopies should be measured and should not be ≥6 min. (CS)

[Level of agreement: strongly agree 70.8%, agree 29.2%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 72.7%, intermediate 27.3%, weak 0%]

After EGD, the clinician should instruct the examinee as to the post-procedure precautions and how to obtain exam results. (EGD)

[Level of agreement: strongly agree 91.3%, agree 8.7%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 81.8%, intermediate 18.2%, weak 0%]

After colonoscopy, the clinician should instruct the examinee as to the post-procedure precautions and how to obtain exam results. (CS)

[Level of agreement: strongly agree 95.8%, agree 4.2%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]

The tissue sample obtained during endoscopy should be managed properly according to specific protocols. (EGD/CS)

[Level of agreement: strongly agree 91.7%, agree 8.3%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

Table 2. Continued

Statements

Facilities and equipment

The endoscopy unit should be an independent facility from the outpatient clinic. (EGD/CS)

 $[Level\ of\ agreement:\ strongly\ agree\ 92.3\%,\ agree\ 3.9\%,\ uncertain\ 3.9\%,\ disagree\ 0\%,\ strongly\ disagree\ 0\%]$

[Level of recommendation: strong 77.3%, intermediate 22.7%, weak 0%]

Clinicians should be prepared for complications and emergency situations during endoscopy. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Outcome

Endoscopy reports should be recorded with high accuracy. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Pathologic findings identified during endoscopy should be precisely described. (EGD/CS)

[Level of agreement: strongly agree 95.8%, agree 4.2%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 95.5%, intermediate 4.5%, weak 0%]

Helicobacter pylori infection should be assessed in patients diagnosed with peptic ulcers. (EGD)

[Level of agreement: strongly agree 78.3%, agree 21.7%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 63.6%, intermediate 36.4%, weak 0%]

Bowel preparation should be adequate for a thorough colonoscopy. (CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

EGD, esophagogastroduodenoscopy; CS, colonoscopy.

mend at least 150 and 200 annual CSs each year for their respective national CRC screening programs.¹⁷ Therefore, 50 cases (i.e., at least 150 cases over three years) of CS annually in Korea seems to be the minimum requirement. The strength of recommendation for the annual EGD and CS volume was intermediate with a 31.8% and 40.9% consensus, respectively.

It is well known that high-quality gastrointestinal endoscopy should be performed despite the variability in detection rates and performance by endoscopists. Yalamarthi et al. 18 reported that 6.6% of 305 patients diagnosed with gastric cancers had undergone a minimum of one EGD within the previous three years and one year, respectively. Among those patients with a definitively missed diagnosis (7.2%), endoscopist errors accounted for the majority of failures (73%). Ren et al.19 showed that 23 (22.2%) of 103 cases of early gastric cancer/high-grade intraepithelial neoplasia had been missed on previous EGD. According to the population-based study using the NCSP database (from 2002 to 2005) by Choi et al.,20 the sensitivity of EGD screening to detect gastric cancer was only 69.0% (95% confidence interval, 66.3%-71.8%). Moreover, 2,415 gastric cancers were detected by EGD screening, and 1,083 interval cancers were detected within one year of a negative EGD screening result (rate, 1.17/1,000). Cha et al.8 reported that endoscopist

specialization is important for high-quality endoscopy in Korea, as NEQIP scores were significantly higher in the endoscopy units where endoscopy subspecialists performed the endoscopies than in those where endoscopy subspecialists did not perform them. Yamazato et al.21 showed that 2 years of supervised endoscopy training facilitates detection of early gastric cancer by 5-fold. More studies were performed in CS given the variable detection rate among different colonoscopists. In the analysis of the results of 10,034 colonoscopies performed by nine colonoscopists between 1999 and 2004, a 2.7-fold difference was reported in the adenoma detection rate of the colonoscopists.²² For sessile serrated adenoma, the detection rate varied by 7.3-18.0-fold. 23,24 In addition, the complete resection rate of detected polyps showed a 3.5-fold difference among colonoscopists.²⁵ Therefore, the qualifications and experience of the endoscopists performing EGD and CS for the NCSP are essential for a superior endoscopy.

Endoscopists must continuously receive endoscopic education to maintain endoscopic performance skills and be updated on the clinical aspects of gastrointestinal diseases at an optimal level to provide the best care. ²⁶ The ASGE also suggests that continuous medical education (CME) for endoscopy be undertaken to maintain the endoscopists' qualifications. ²⁷ In



Table 3. Final Statements and Their Level of Agreement for Esophagogastroduodenoscopy and Colonoscopy in the National Cancer Screening Program: Reprocessing and Sedation

Statements

Reprocessing

Endoscopy reprocessing and disinfection guidelines approved by the Endoscopy Professional Association should be available in each endoscopy unit. (EGD/CS)

[Level of agreement: strongly agree 94.1%, agree 5.9%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]

Endoscopic reprocessing procedures should be performed as directed by established protocols and guidelines. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Endoscopic accessories that pass through the mucosa, such as biopsy forceps or incision instruments, must be sterilized. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

Personnel performing endoscopic reprocessing and disinfection should wear personal protective equipment. (EGD/CS)

[Level of agreement: strongly agree 72.7%, agree 22.7%, uncertain 4.6%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 54.6%, intermediate 45.4%, weak 0%]

Endoscopic reprocessing equipment and storage methods should be appropriate as directed by guidelines. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

Endoscopists and reprocessing workers should complete endoscopic reprocessing education programs approved by the Endoscopy Professional Association. (EGD/CS)

[Level of agreement: strongly agree 95.0%, agree 5.0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

Sedation

Pre-sedation history, risk assessment, and sedation-specific informed consent should be obtained for sedative endoscopy. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 8.7%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 100%, intermediate 0%, weak 0%]

During sedative endoscopy, the patient's vital signs should be monitored and documented. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

Patients should be monitored with discharge assessment scales after sedative endoscopy. (EGD/CS)

[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

EGD, esophagogastroduodenoscopy; CS, colonoscopy.

the revised Quality Guidelines for Gastric Cancer and CRC Screening, ^{12,13} at least 12 hours of CME over a three-year cycle is encouraged by attending courses aimed at endoscopic quality improvement and endoscopic reprocessing and disinfection, as well as academics and lectures. The ASGE Quality Management Committee recommends that endoscopy nursing staff should be regularly trained and educated to fulfill the responsibilities and maintain proficiency.²⁸ The Revised Quality Guidelines for Gastric Cancer and CRC Screening^{12,13} also suggest that endoscopy nursing staff should receive CME on endoscopic

management. In this revision, however, the strength of recommendation for the CME of endoscopy nurse staff in a three-year cycle was intermediate according to many votes; therefore, this gap should be considered.

Domain: process

The process domain is composed of 10 statements (Table 2) and nine quality indicators (Table 4). The use of a pre-procedure assessment worksheet is recommended to perform adequate and precise endoscopy. Both the ASGE and American

 Table 4. Final Quality Indicators and Their Level of Agreement for Esophagogastroduodenoscopy and Colonoscopy in the National Cancer Screening Program:

 Workforce, Process, Facilities and Equipment, and Outcome

Quality indicators
Workforce
Is the EGD for the NCSP performed by specialists with at least one year of supervised endoscopy training or endoscopists with experience of at least 500 or more EGD procedures? (EGD)
□ Specialists with at least one year of supervised endoscopy training
□ Endoscopist with experience of at least 500 or more EGDs
□ Endoscopist without one year of supervised endoscopy training or experience of less than 500 EGDs
[Level of agreement: strongly agree 61.9%, agree 38.1%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 77.3%, intermediate 22.7%, weak 0%]
Is the colonoscopy of the NCSP performed by a specialist with at least one year of supervised colonoscopy training in more than 150 cases or an endoscopist with experience of at least 300 or more successful colonoscopies? (CS)
\Box Specialist with one year of supervised colonoscopy training with over 150 cases
\Box Endoscopist with experience of 300 or more successful colonoscopies
□ Endoscopist without one year of supervised endoscopy training or experience of less than 300 successful colonoscopies
[Level of agreement: strongly agree 66.7%, agree 33.3%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 77.3%, intermediate 22.7%, weak 0%]
Did the endoscopist perform at least 300 EGDs during the 3-year 'National Endoscopy Quality Improvement Program'? (EGD)
□ Yes □ No
[Level of agreement: strongly agree 13.6%, agree 50.0%, uncertain 36.4%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 59.1%, intermediate 31.8%, weak 9.1%]
Did the endoscopist perform at least 150 colonoscopies during the 3-year 'National Endoscopy Quality Improvement Program'? (CS)
□ Yes □ No
[Level of agreement: strongly agree 37.5%, agree 54.2%, uncertain 4.2%, disagree 4.2%, strongly disagree 0%]
[Level of recommendation: strong 54.6%, intermediate 40.9%, weak 4.5%]
Did the endoscopist the complete at least 12 hours of endoscopy-related education courses during the 3-year 'National Endoscopy Quality Improvement Program'? (EGD/CS)
□ Yes □ No
How many hours of endoscopy-related education courses did the endoscopist attend over the past 3 years? (EGD/CS) () Hours
[Level of agreement: strongly agree 36.7%, agree 33.3%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 81.8%, intermediate 18.2%, weak 0%]
How often did endoscopic nursing staff participate in training for endoscopy quality improvement over the past 3 years? (EGD/CS)
□ More than 3 times □ More than 1 time □ None
[Level of agreement: strongly agree 66.7%, agree 33.3%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 54.6%, intermediate 40.9%, weak 4.5%]
Process
Does the clinician verify the fasting state, general health status, past medical history, and medication history including anti-platelets or anticoagulants (antithrombotics) using a pre-procedure checklist before endoscopy? (EGD/CS)
□ Yes □ No
[Level of agreement: strongly agree 96.0%, agree 4.0%, uncertain 36.4%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]
Does the clinician educate examinees on bowel preparation and provide colonoscopy information before examination? (CS)
\square Yes \square No
[Level of agreement: strongly agree 54.6%, agree 31.8%, uncertain 9.1%, disagree 4.6%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]



Table 4. Continued

Quality indicators

S
Does the endoscopist obtain written informed consent for the risks and benefits associated with colonoscopy? (CS)
□ Yes □ No
[Level of agreement: strongly agree 91.3%, agree 8.7%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]
Does the endoscopist photograph and record at least 8 clear standard EGD images? (EGD)
□ Excellent □ Fair □ Poor
[Level of agreement: strongly agree 73.9%, agree 21.7%, uncertain 4.4%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]
Does the endoscopist photograph and record at least 8 clear standard colonoscopy images including the maximal insertion site (e.g., the cecum)? (CS)
□ Excellent □ Fair □ Poor
[Level of agreement: strongly agree 77.3%, agree 22.7%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]
Does the endoscopist maintain an average withdrawal time of \geq 6 min in negative-result colonoscopies in order to inspect the colon mucosa sufficiently? (CS)
\square Yes \square No
[Level of agreement: strongly agree 87.5%, agree 12.5%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 77.3%, intermediate 22.7%, weak 0%]
Does the clinician instruct the examinee as to the precautions and how to check the results after EGD? (EGD)
\Box Yes \Box No
[Level of agreement: strongly agree 85.7%, agree 14.3%, uncertain 4.4%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 81.8%, intermediate 18.9%, weak 0%]
Does the clinician instruct the examinee as to the post-procedure precautions and how to obtain examination results after colonoscopy? (CS)
□ Yes □ No
[Level of agreement: strongly agree 91.7%, agree 8.3%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 81.8%, intermediate 18.9%, weak 0%]
Does the clinician label the tissue sample obtained during endoscopy? (EGD/CS)
□ Yes □ No
[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]
Facilities and equipment
Is the endoscopy unit separate from the outpatient clinic? (EGD/CS)
□ Excellent □ Fair □ Poor
[Level of agreement: strongly agree 92.3%, agree 3.9%, uncertain 3.9%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]
Are endoscopic treatment devices (① injection catheter, ② hemoclips) and resuscitation equipment available for the management of adverse events during endoscopy? (EGD/CS)
□ Yes □ No
[Level of agreement: strongly agree 84.0%, agree 16.0%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

Table 4. Continued

Quality indicators

Outcome

Does the EGD report include all of the following items? (EGD) (1) date of examination; (2) patient information: name, sex and age; (3) name of endoscopist; (4) medications; (5) diagnosis; (6) findings; (7) biopsy details; and (8) complications, if any.

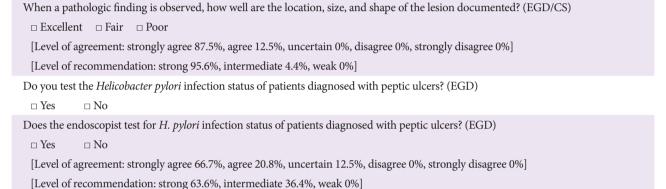
[Level of agreement: strongly agree 95.8%, agree 4.2%, uncertain 0%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 95.5%, intermediate 4.5%, weak 0%]

Does the colonoscopy report include all of the following items? (CS) (1) date of examination; (2) patient information: name, sex, and age; (3) name of endoscopist; (4) medications; (5) diagnosis; (6) findings; (7) biopsy details; and (8) quality of bowel preparation (or maximum insertion site); (9) cecal intubation, (10) withdrawal time; and (11) complications, if any.

[Level of agreement: strongly agree 66.7%, agree 25.0%, uncertain 8.3%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 77.3%, intermediate 18.2%, weak 4.5%]



Is the proportion of patients who achieved adequate bowel preparation higher than 85%?

□ Yes □ No

[Level of agreement: strongly agree 41.7%, agree 54.2%, uncertain 4.2%, disagree 0%, strongly disagree 0%]

[Level of recommendation: strong 40.9%, intermediate 59.1%, weak 0%]

EGD, esophagogastroduodenoscopy; NCSP, National Cancer Screening Program; CS, colonoscopy.

Society of Anesthesiologists (ASA) recommend verifying past medical history and general conditions of the patient before the endoscopy procedure to confirm health status. The patient's medical history should be checked for adverse reactions to sedatives, drug allergies, drug-drug interactions, and concurrent medications.²⁸⁻³⁰ In the case of CS, education and written instructions for adequate bowel preparation should be provided before CS, as poor bowel preparation may lead to the postponement of CS or need for additional bowel preparation. 31,32 The risk of bleeding induced by the use of antithrombotic agents is minimal for diagnostic endoscopy, but it is important to verify their use before the procedure, as the risk of bleeding increases with therapeutic endoscopy. For patients taking anti-thrombotic agents, their underlying disease and risk of thromboembolism by temporary cessation of antithrombotics should be considered. Since CS is often followed by polypectomy, discontinuation of antithrombotic agents may further complicate CS.²⁹ An endoscopy must be preceded by the provision of informed consent, which should include the type of the endoscopic procedure, risk of bleeding, perforation, infection, and sedation-related adverse events. 11,32-34 Owing to the higher risks of bleeding and perforation, informed consent is mandatory, particularly for CS over EGD. 11,34 Fasting is recommended for endoscopy, and ASA guidelines recommend verifying a fasting time of 2 hours for water, 6 hours for milk and light meals, and 8 hours or more for fatty foods. 55 However, fasting time should be individualized based on the patient's health status and diet, as longer fasting may be necessary in those with specific conditions, such as gastroparesis or achalasia. 36

Photo-documentation should be performed after careful inspection of the EGD. For EGD procedures, at least eight images should be taken, and complementary images should certainly be taken in the case of a pathologic lesion. The order in which standard images are taken will differ for each endoscopist, and it is important for the endoscopist to take images according to his or her routine so as not to miss any region. The European Society of Gastrointestinal Endoscopy recommends photo-documentation of at least 10 representative images of each of the



Table 5. Final Quality Indicators and Their Level of Agreement for Esophagogastroduodenoscopy and Colonoscopy in National Cancer Screening Program: Reprocessing and Sedation

Quality indicators
Reprocessing
Does the Endoscopy unit have 'Endoscopy reprocessing and disinfection protocols' approved by the Endoscopy Professional Association? (EGD/CS)
□ Yes □ No
[Level of agreement: strongly agree 95.2%, agree 4.8%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]
Are the endoscopic reprocessing procedures performed properly as directed by specific protocols? (EGD/CS)
□ Excellent □ Fair □ poor
[Level of agreement: strongly agree 95.7%, agree 4.4%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 100%, intermediate 0%, weak 0%]
Are high-level disinfectants used during endoscopy reprocessing? (EGD/CS)
□ Yes □ No
[Level of agreement: strongly agree 100%, agree 0%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 95.5%, intermediate 4.5%, weak 0%]
Do reprocessing personnel follow the disinfectant procedures during endoscopy reprocessing? (EGD/CS)
☐ Check both the disinfectant instructions and protocols regarding disinfectant management
☐ Check only disinfectant instructions
☐ Check only procedures of disinfectant management
[Level of agreement: strongly agree 90.5%, agree 9.5%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 86.4%, intermediate 13.6%, weak 0%]
Are the endoscopic accessories that pass through the mucosa, such as biopsy forceps or incision instruments, disposable or sterilized for reuse in the case of reusable products? (EGD/CS)
\Box Yes \Box No
[Level of agreement: strongly agree 90.5%, agree 9.5%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 100%, intermediate 0%, weak 0%]
Do reprocessing personnel wear personal protective equipment? (EGD/CS)
\Box Yes \Box No
[Level of agreement: strongly agree 80.0%, agree 20.0%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 50.0%, intermediate 50.0%, weak 0%]
Is there an appropriate reprocessing area separate from the endoscopy examination room? (EGD/CS)
□ Excellent □ Fair □ Poor
Is there an appropriate reprocessing room separate from the endoscopy unit? (EGD/CS)
□ Excellent □ Fair □ Poor
[Level of agreement: strongly agree 90.0%, agree 10.0%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 72.3%, intermediate 22.7%, weak 0%]
Are endoscopes kept in a dedicated endoscope storage cabinet where the tip of endoscope does not touch the bottom surface of the storage cabinet? (EGD/CS)
□ Excellent □ Fair □ Poor
[Level of agreement: strongly agree 85.0%, agree 15.0%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]
Do endoscopists and reprocessing personnel complete endoscopic reprocessing education programs approved by the Endoscopy Professional Association? (EGD/CS)
□ Excellent □ Fair □ Poor
[Level of agreement: strongly agree 83.3%, agree 16.7%, uncertain 0%, disagree 0%, strongly disagree 0%]
[Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%]

Table 5. Continued

Quality indicators

Sedation

Does the clinician document the pre-sedation history and risk assessment and obtain sedation-specific informed consent separately?

| Excellent | Fair | Poor |
| [Level of agreement: strongly agree 95.0%, agree 5.0%, uncertain 0%, disagree 0%, strongly disagree 0%] |
| [Level of recommendation: strong 95.5%, intermediate 4.5%, weak 0%] |
| Does the clinician monitor and record patient status (oxygen saturation, blood pressure, pulse rate), type and dose of sedatives, and adverse events during sedative endoscopy? (EGD/CS) |
| Yes | No |
| [Level of agreement: strongly agree 89.5%, agree 10.5%, uncertain 0%, disagree 0%, strongly disagree 0%] |
| [Level of recommendation: strong 90.9%, intermediate 9.1%, weak 0%] |
| Does the clinician monitor patients using a standardized discharge scoring system after sedative endoscopy? (EGD/CS) |
| Yes | No |
| [Level of agreement: strongly agree 95.0%, agree 5.0%, uncertain 0%, disagree 0%, strongly disagree 0%]

EGD, esophagogastroduodenoscopy; CS, colonoscopy.

[Level of recommendation: strong 83.4%, intermediate 13.6%, weak 0%]

following anatomical landmarks: the duodenum, major ampulla, antrum, angulus, fundus in inversion, greater curvature of the proximal body, greater curvature of the distal body, squamocolumnar junction, upper esophagus, and lower esophagus.³⁷ For CS, it is essential to take photographs of the maximal insertion site including the cecum. Cecal intubation is defined as passage of the colonoscope into a proximal part of the ileocecal valve, such that the entire cecal caput, including the medial side of the cecum between the ileocecal valve and appendiceal orifice, is visible. 11,38 When it is not clear whether the cecum has been entered, visualization of the ileocecal valve or intubation of the terminal ileum is necessary.^{36,39} It is important to maintain an optimal cecal intubation rate, since low cecal intubation rates have been associated with a high incidence of proximal interval cancer. The withdrawal time should be measured for all CS procedures, and the mean withdrawal time should be kept to at least 6 minutes for negative CS. 11,36,38,39 Sufficient observation time is required for careful inspection of the CS, and a longer withdrawal time is associated with an increased adenoma detection rate. Therefore, an average withdrawal time of ≥6 minutes is recommended during CS. As various uncomfortable symptoms and complications, such as bleeding or perforation, may occur after endoscopy, it is beneficial to provide a description of possible complications, coping methods, and contact information in writing after CS. In addition, when a biopsy is performed during endoscopy, patients should be guided to check the biopsy results through an outpatient clinic. 11,39 In this revision, the level of agreement and recommendation for this domain was very high; however, considering an intermediate recommendation of 22.7% for a ≥6 minutes withdrawal time,

further efforts to increase the recommendation level may be necessary.

Domain: facilities and equipment

The domain concerning facilities and equipment comprised two statements (Table 2) and two quality indicators (Table 4). Unexpected complications may occur during endoscopy, and acute bleeding may be controlled by epinephrine injection, electrocoagulation, or endoscopic clipping. 40,41 An endoscopic treatment device is particularly necessary to reduce hospitalization or transfusion for acute bleeding occurring during colonoscopic polypectomy. In addition, a cardiopulmonary resuscitation kit including an endotracheal tube should be available to handle emergency situations that may occur in patients with poor general conditions or during sedative endoscopy. 11,38 In the revision for the facilities and equipment domain, a 22.7% intermediate recommendation was observed for the separation of the endoscopy unit from the outpatient clinic, which may be due to the fact that most primary clinics divide these spaces using curtains or partitions.

Domain: outcome

The domain concerning outcome consists of four statements (Table 2) and five quality indicators (Table 4). As the quality of the gastrointestinal endoscopy is closely associated with the quality of the endoscopy report, accurate endoscopy reporting is one of the main goals of the NEQIP.³⁷ The endoscopy report helps to exchange information about endoscopic findings, treatment, clinical recommendations, adverse effects, and test results.^{11,42,43} In order to monitor the occurrence of complications



associated with endoscopy, it is necessary to record the occurrence of complications in the endoscopy report. With regard to the CS, it is essential to report the bowel preparation quality, cecal intubation, and withdrawal time to monitor the main quality indicators of CS. 42,43 Since Helicobacter pylori infection is the most common cause of peptic ulcer and successful eradication of H. pylori significantly reduces recurrence of peptic ulcers, 44 the ASGE has recommended that H. pylori infection should be tested for all patients with peptic ulcers. 45 When the bowel preparation of CS is poor, the examination may be postponed or an additional bowel preparation may be necessary, which may result in inconvenience and added medical expenses for the examinee. The ASGE recommends that the frequency of adequate bowel preparation during outpatient screening CS should be over 85%. 11 Adequate bowel preparation can be defined according to the following scores: Boston Bowel Preparation Scale ≥6, Ottawa Scale ≤7, or Aronchick Scale ≥ fair.¹¹

In this revision, the levels of agreement and recommendation for the outcome domain were relatively high. Nonetheless, the strength of recommendation for the statement and quality indicators for *H. pylori* infection testing in cases of peptic ulcer were each 36.4%; therefore, it is necessary to establish a more specific definition of peptic ulcer. For example, a discussion as to whether *H. pylori* infection status should be assessed for peptic ulcers that are indistinguishable from scarring ulcers or erosions is warranted. Even though the levels of agreement and recommendation for the statements regarding the confirmation of an adequate bowel preparation were high, the quality indicators for the 85% adequate bowel preparation received a 59.1% intermediate recommendation; therefore, further study is needed to determine the optimal level of adequate bowel preparation.

Domain: reprocessing of endoscopes

The domain of reprocessing is composed of six statements (Table 3) and nine quality indicators (Table 5). Recently, public and health authorities have been increasingly interested in proper and safe endoscopy and endoscope reprocessing methods. For proper endoscope reprocessing, disinfection, and storage, optimal guidelines should be established and reprocessing should be performed accordingly in each endoscopy unit. 46-48 Endoscope reprocessing is classified as manual disinfection or as disinfection by an automatic reprocessor and consists of six steps: pre-cleaning, cleaning, disinfection, rinsing, drying, and storage. In 2017, an amendment to the "Guidelines for the use and disinfection of medical devices" was issued (Ministry of Health and Welfare notification No. 2017-1010) as follows: "Medicines or quasi-drugs reported to or approved by the Food and Drug Administration should be subjected to sterilization and disinfection, and the manufacturer's instructions for each prod-

uct should be followed." Currently, the high-level disinfectants listed in the "Guidelines for the use and disinfection of medical devices" specified by the Ministry of Health and Welfare include glutaraldehyde, ortho-phthalaldehyde, peracetic acid, hydrogen peroxide, hypochlorite (produced by electrolysis at the site of use), and a material data safety sheet must be available for identification of the disinfectants and their ingredients. 12,13 Since hypochlorite, a type of electrochemical water disinfectant, is easily inactivated, water electrolysis equipment should be equipped at the site of use. It can only be recognized as a high-level disinfectant if it is used immediately after the production of hypochlorite in the field. As endoscope accessories have numerous small gaps and leaks that can be easily infiltrated by the patient's blood or mucus, insufficient disinfection or reuse of a disposable device is vulnerable to transmission of infection. 46,47 Therefore, cleansing, disinfecting, and sterilizing an accessory device, which can cause infection transmission, is as important as reprocessing the endoscope. As high-level disinfectants may cause irritation of the eyes, skin, and respiratory system, workers who perform endoscopic reprocessing and disinfection should wear personal protective equipment, such as protective masks, gowns, and rubber gloves, and a ventilation system is required in the reprocessing room. 46,47 Recently, the continuous training, education, and surveillance of workers who perform endoscopic reprocessing and disinfection have been emphasized around the world, including in the United States and Japan.

However, it is difficult to evaluate the appropriate level of endoscopic reprocessing training for all workers in an actual clinical practice setting. Therefore, over 50% of endoscopists and reprocessing personnel are required to complete endoscopic reprocessing education programs to participate in the NCSP in Korea. 12,13 The endoscopic reprocessing education program requires the participation of experts in the endoscope disinfection field, and the education program must include hands-on courses for reprocessing workers as well as lectures. It is recommended that the endoscopy unit should be divided into a clean zone and a contaminated zone and that the endoscopy unit should be separate from the reprocessing room since the completely sterilized endoscope may be re-contaminated during storage. 46,47 Even in the reprocessing room, it is necessary to separate the clean area from the contaminated area so that the contaminated and clean endoscopes are not in close proximity. In this revision of the domain of reprocessing, the level of agreement and strength of recommendations for reprocessing were generally high. However, the level of recommendation for the statement and quality indicators regarding the wearing of personal protective equipment by workers was deemed of intermediate strength by 45.4% and 50.0% of respondents, respectively, which indicates that further education and clear definitions of personal protective equipment are necessary.

Domain: sedation

The domain of sedation is composed of three statements (Table 3) and three quality indicators (Table 5). Drug-related risk assessment should be performed and documented before sedative endoscopy to decrease the risk of adverse events and to devise a sedation plan. The pre-sedation evaluation involves mainly the ASA physical status classification system and Mallampati classification. 36,49,50 During sedative endoscopy, oxygen saturation, pulse rate, and blood pressure should be monitored to assess the condition of the examinee and check for cardiopulmonary adverse events induced by sedation. It is recommended that oxygen saturation be monitored continuously and pulse and blood pressure at 5 minute intervals. 11,36,38 Each endoscopy unit should have written discharge criteria that allow the examinees to exit the endoscopy unit after sedative endoscopy, and whether the examinees exited according to predetermined discharge criteria should be documented. 11,36,38 For example, the discharge criteria provided by the KSGE includes the following questions: (1) Are the vital signs stable?; (2) Is there any respiratory distress?; (3) Is it possible to walk without assistance?; (4) Is communication possible?; (5) Are there any abnormal symptoms such as nausea or vomiting?; and (6) Is the patient able to drink beverages without assistance? The levels of agreement and strength of recommendation for the sedation domain were generally high for the revised statement and the quality indicators.

CONCLUSIONS

Considering that many endoscopy units perform both EGD and CS in accordance with the NCSP, statements and quality indicators were not described separately for EGD and CS procedures. In this revision, the level of evidence for quality indicators was suggested by binary description of the statement and quality indicator, and the level of agreement and strength of recommendation were presented. However, a limitation of this revision was that optimal performance targets for each quality indicator were not established, since the performance level of each endoscopist may vary and suitable evidence regarding performance measures in the literature was lacking. Given that the outcome measure is the most important objective in the NEQIP, the introduction of many quality indicators of outcome measure was considered. Nevertheless, another limitation of this revision was that the outcome indicators were difficult to introduce due to the lack of consensus even among experts. Since the adenoma detection rate and detection rates of gastric cancer or CRC, which are the representative outcome measures, are longitudinal measures that are derived by analyzing long-term data, it is likely that a registry system is preferable to on-site evaluation. Data relative to adverse events and complications are likely to be missed, even if they are introduced as outcome indicators; thus, further deliberation as to how to evaluate the patient's experience and safety profile is necessary. The NEQIP is processed by document evaluation and on-site evaluation within the activity of the NCSP; however, as this revision did not focus on quality indicators optimized for document evaluation, further study is needed in that specific area. It is also important to establish a research environment that can actively investigate quality issues relative to the NCSP, since it is more appropriate to develop quality indicators based on scientific evidence rather than expert opinion for greater objectivity.

Notice

Ongoing revisions are not an absolute standard in clinical practice. Medical practice for individual patients should be determined by the attending physician considering the overall condition and situation of each patient. This revision should not be used for the purposes of restricting the medical practice of clinicians as a standard for health insurance review, or for formulating legal judgment as to the medical management of a specific patient.

Conflicts of Interest -

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