



Consensus-based guideline of the Korean Society of Gynecologic Oncology for high-risk human papillomavirus testing in cervical cancer screening

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High-risk human papillomavirus (hrHPV) is an important cause of cervical cancer. hrHPV testing has emerged as an effective screening modality to address the limitations of cytology-based screening. However, in Korea, the absence of standardized clinical guidance has resulted in variability in practice. This consensus-based clinical practice guideline was developed by a multidisciplinary expert committee under the Korean Society of Gynecologic Oncology and includes specialists in gynecologic oncology, pathology, laboratory medicine, and public health. Relevant domestic and international evidence was systematically reviewed and perspectives from diverse clinical settings were incorporated through four public hearings. The final recommendations were established through expert consensus. These guidelines present four key recommendations. First, hrHPV testing may be considered for women aged ≥ 25 years, with a screening interval of 3 to < 5 years. Second, screening assays should differentiate between HPV genotypes 16 and 18 while detecting other high-risk types, and tests with established clinical validity are recommended. Third, hrHPV testing should be performed in appropriately equipped settings, following standardized procedures for specimen handling and reporting, with clear documentation of HPV 16/18 status in positive cases. Fourth, the testing should operate under rigorous internal and external quality control systems to ensure reliability and consistency. These guidelines aim to promote consistent and evidence-based implementation of hrHPV testing for cervical cancer screening in Korea, supporting early detection and prevention.

Keywords: Uterine cervical neoplasms; Cancer screening; Human papillomavirus DNA tests; Clinical practice guideline

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Introduction

Cervical cancer is a major malignancy affecting women worldwide. Persistent infection with high-risk human papillomavirus (hrHPV) is recognized as a cause of cervical carcinogenesis [1]. Most cervical cancers and cervical intraepithelial neoplasia (CIN) are closely associated with hrHPV infection, and HPV genotypes 16 and 18 account for more than 70% of cervical cancer cases globally, representing the most oncogenic high-risk types [2].

In Korea, cervical cancer screening has been conducted through the National Cancer Screening Program using cervical cytology at 2-year intervals for women aged 20 years or older, contributing to reductions in cervical cancer incidence and mortality [3]. However, cervical cytology has inherent limitations, including a relatively high false-negative rate and substantial variability in test performance depending on examiner expertise and testing conditions [4,5]. Consequently, there is continued demand for alternative screening methods that can complement or overcome the limitations of cytology-based screening methods.

Against this background, hrHPV testing, which directly detects the etiological agent of cervical cancer, has emerged as a promising alternative screening modality. By detecting HPV DNA or mRNA in cervical specimens, hrHPV testing enables the identification of both infection status and viral genotypes, and has demonstrated higher sensitivity for detecting high-grade lesions (CIN2 or worse) than cytology alone [4-8].

Based on this evidence, several international organizations and countries, including the World Health Organization (WHO), have adopted hrHPV testing as the primary screening method, or in combination with cytology for cervical cancer screening [9-11]. In particular, the WHO recommends DNA-based hrHPV testing as a primary screening test as part of its global strategy for the elimination of cervical cancer [9].

Currently, a wide range of hrHPV assays approved by the Ministry of Food and Drug Safety is used in clinical practice in Korea [12-15]. However, regulatory approval is primarily based on analytical performance and comparative data on the clinical validity of different assays are limited. Consequently, substantial variation exists in the application of hrHPV testing across institutions and clinicians, potentially compromising consistency in cervical cancer screening and clinical decision-making.

In response to these challenges, the Korean Society of

Gynecologic Oncology has comprehensively reviewed existing domestic and international cervical cancer screening guidelines and the latest available evidence. Through multidisciplinary committee deliberations involving experts in gynecology, pathology, laboratory medicine, and public health, as well as four public hearings, clinical practice guidelines for hrHPV testing tailored to the Korean clinical context were developed. This guideline aims to provide a standardized framework to support the rational and consistent implementation of hrHPV testing for cervical cancer screening in Korea.

Methods

1. Scope and purpose of the guideline

This clinical practice guideline aims to provide standardized guidance for the use of hrHPV testing for cervical cancer screening in Korea, with an emphasis on key clinical decisions related to target population selection, screening intervals, testing methods, test performance and interpretation, and quality assurance.

The target population for this guideline comprises asymptomatic adult women undergoing cervical cancer screening. It is not intended for diagnostic or therapeutic testing in women with symptoms or those who have already been diagnosed with cervical cancer or high-grade CIN. In addition, this guideline does not address policy- or system-level issues, such as the policy justification for incorporating hrHPV testing into the National Cancer Screening Program, cost-effectiveness analyses, comparative performance of different testing platforms, or the implementation of self-sampling strategies.

This guideline is primarily intended for healthcare professionals who perform and interpret hrHPV testing in clinical practice and was developed to serve as a practical reference for the rational application of hrHPV testing within the cervical cancer screening system in Korea.

2. Organization of the clinical practice guideline committee

This clinical practice guideline was developed under the auspices of the Korean Society of Gynecologic Oncology. Guideline development began in April 2023 within the Cancer Prevention Committee of the Society and was subsequently transferred to the Clinical Practice Guideline Committee in

2025, where clinical recommendations for hrHPV testing were finalized. To reflect perspectives from disciplines directly involved in cervical cancer screening and clinical application of hrHPV testing, a multidisciplinary expert committee was convened during the guideline development process.

The committee included specialists in gynecological oncology, pathology, laboratory medicine, public health, and preventive medicine. In particular, an expert consultation from the Korean Society of Pathologists and the Korean Society for Laboratory Medicine was incorporated throughout the guideline development process to ensure technical expertise in test performance and interpretation of results. Each participating professional society provided specialized input for the selection of hrHPV testing methods, interpretation of test results, laboratory operations, and quality assurance. This multidisciplinary collaboration formed a critical foundation for ensuring both the clinical applicability and reliability of the testing processes addressed in this guideline.

3. Evidence review and development of recommendations

The guideline development committee reviewed the existing domestic and international cervical cancer screening guidelines and key studies to formulate key questions related to the clinical application of hrHPV testing. The evidence review process included a comprehensive assessment of the WHO strategy for cervical cancer elimination, recommendations for hrHPV testing, screening guidelines issued by major countries and professional societies, and relevant studies on hrHPV testing conducted in Korea.

Based on this review, the committee identified four core domains to be addressed in these guidelines: target population and screening interval, selection of testing methods, test performance and result reporting, and quality assurance. Within each domain, recommendations were developed by focusing on key issues repeatedly encountered in clinical practice.

4. Public hearings and consensus process

This clinical practice guideline was developed not only through a review of the available evidence but also through a structured process designed to adequately reflect feasibility and acceptability in real-world clinical practice, including four public hearings and internal committee deliberations. Public hearings were planned and conducted to facilitate a step-

wise discussion of key issues related to the clinical application of hrHPV testing and to gather input from a broad range of professional disciplines.

The first public hearing was held on March 27, 2024 and focused on reviewing the status of HPV testing in Korea and identifying the minimum requirements for HPV testing as a cervical cancer screening tool (Fig. 1). Multidisciplinary experts in gynecology, pathology, laboratory medicine, and cancer control, along with representatives from related industries participated in this meeting. Key discussion topics included the target age and screening interval for HPV testing, quality assurance, testing platforms and genotyping strategies, standardization of test result reporting, and the potential implementation of self-sampling approaches.

The second public hearing was held on April 27, 2024 and involved more detailed discussions centered on a draft version of the clinical guideline for HPV testing that incorporated feedback from the first public hearing (Fig. 2). Presentations and discussions addressed the target population and timing of HPV testing, clinical application of different testing methods, comparative sensitivity and specificity among assays, and cost-effectiveness of HPV testing.

Subsequently, parallel evaluations of quality assurance and assay stability for HPV testing as well as a cost-effectiveness analysis of HPV testing were conducted. With respect to quality assurance, the committee reviewed the current landscape of HPV assays and testing institutions in Korea, internal and external quality control systems, regulatory approval standards of the Ministry of Food and Drug Safety, and existing quality management programs operated by the Korean Society of Pathologists and Korean Society for Laboratory Medicine.

During the third and fourth rounds of deliberation, an in-depth review and revision of the draft guideline were conducted under the leadership of the Clinical Practice Guideline Committee of the Korean Society of Gynecologic Oncology. The wording, strength of the recommendations, and scope of application were carefully reviewed at the third Gynecologic Cancer Prevention Committee meeting held on October 7, 2024 (Fig. 3). Following an internal review within the society, the guideline was finalized after external consultation with the Korean Society of Pathologists and Korean Society for Laboratory Medicine.

All recommendations were ultimately determined by the consensus of a multidisciplinary expert panel of the Korean



Fig. 1. The first public hearing for the development of the clinical practice guideline on high-risk HPV testing for cervical cancer screening in Korea. HPV, human papillomavirus.



Fig. 2. The second public hearing for the development of the clinical practice guideline on high-risk HPV testing for cervical cancer screening in Korea. HPV, human papillomavirus.



Fig. 3. The third public hearing for the development of the clinical practice guideline on high-risk HPV testing for cervical cancer screening in Korea. HPV, human papillomavirus.



Fig. 4. The fourth public hearing for the development of the clinical practice guideline on high-risk HPV testing for cervical cancer screening in Korea. HPV, human papillomavirus.

Society of Gynecologic Oncology, considering the clinical validity and healthcare environment in Korea (Fig. 4).

Recommendation

Recommendation 1. Target population and screening interval for hrHPV testing

hrHPV testing may be considered as a screening method for the early detection of cervical cancer in women aged 25 years or older. When hrHPV testing is used for screening, a screening interval of 3 to <5 years is recommended.

The hrHPV testing has demonstrated higher sensitivity than cervical cytology for the detection of high-grade CIN, allowing the identification of more women with high-grade lesions [4-8]. According to the WHO guidelines, hrHPV testing is the preferred screening method over visual inspection with acetic acid and cervical cytology (Pap smear) [9]. For cervical cancer screening, hrHPV testing is recommended for adult women aged 25 years or older, with a screening interval of 3 to <5 years [10-19]. In women younger than 20 years, routine screening is not recommended because of the very high prevalence of HPV infection, high rates of spontaneous viral clearance, and extremely low incidence of invasive cervical cancer; however, hrHPV testing may be performed when cervical cancer or precancerous lesions are clinically suspected [16-21].

According to the 2021 Clinical Practice Guidelines for cervical cancer screening published by the Korean Society of Gynecologic Oncology, hrHPV testing may be considered a screening option for women aged 25 years or older, with a recommended screening interval of 3 to <5 years [22]. However, before adopting hrHPV testing as a primary screening modality, careful consideration is required regarding the selection of appropriate assays and determination of the starting age and screening interval. A reassessment is warranted after obtaining sufficient domestic evidence of comparative effectiveness and cost-effectiveness in the Korean population has been accumulated.

hrHPV testing in women with abnormal cervical cytology findings, rather than for routine screening purposes, should follow the recommendations outlined in the 2021 Korean Society of Gynecologic Oncology guidelines for cervical cancer screening [22].

Recommendation 2. Selection of hrHPV testing methods

hrHPV tests used for cervical cancer screening should be capable of differentiating HPV genotypes 16 and 18 and detecting the presence of other high-risk HPV types. Tests with established clinical validity should be preferentially selected.

HPV genotypes 16 and 18 are strongly associated with the development of cervical cancer and provide critical information for risk stratification and decisions regarding follow-up and management after screening. Accordingly, through public hearings and expert discussions, the differentiation of HPV genotypes 16 and 18 was agreed upon as the minimum requirement for hrHPV assays used for screening purposes. The Korean Society of Pathologists and Korean Society for Laboratory Medicine recommend hrHPV assays that have been officially approved by the Ministry of Food and Drug Safety for use as primary screening tests in Korea.

Although various hrHPV assays are currently used in clinical practice in Korea, there is considerable variability in test performance and the level of supporting clinical evidence. To ensure the reliability of cervical cancer screening, this guideline emphasizes the preferential use of hrHPV assays with demonstrated clinical validity. While domestic evidence remains limited, data from the clinical effectiveness of human papillomavirus testing for cervical cancer screening in Korea report published by the National Evidence-Based Healthcare Collaborating Agency in 2019 may serve as a reference. In addition, future domestic studies evaluating the clinical validity of hrHPV testing methods should be incorporated as supporting evidence as they become available [12].

Recommendation 3. Performance of hrHPV testing and result reporting

hrHPV testing should be performed by gynecologic specialists or physicians at screening facilities using clinically validated hrHPV assays in appropriately equipped clinical settings. After specimen collection, proper storage is essential; because storage requirements may vary according to the testing technology used, manufacturers' instructions for specimen handling and storage should be carefully followed. The hrHPV test results should be reported as negative, positive, or invalid. In cases with positive results, the presence of HPV genotypes 16 and/or 18 should, at a minimum, be documented in the test report.

The accuracy of hrHPV testing is influenced by all stages of

the testing process, including specimen collection, storage, and analysis. Therefore, standardized testing environments and performance by trained personnel are essential. Specimen storage conditions differ across testing platforms and products and strict adherence to assay-specific handling instructions is critical to ensure reliable test results.

Standardized reporting of hrHPV test results is necessary because test reports directly affect clinical decision making and patient counseling. Accordingly, this guideline recommends a clear categorization of results as negative, positive, or invalid, with mandatory reporting of HPV 16/18 genotype status in positive cases. Recent epidemiologic data from Korea indicate an increasing prevalence of high-risk HPV types, such as HPV 53, 58, and 52, relative to HPV 16/18, along with a decline in HPV 16/18 prevalence associated with the widespread uptake of prophylactic HPV vaccination [13-15]. Because the clinical implications of hrHPV test results may vary depending on the genotype distribution and clinical context, positivity for high-risk HPV types other than HPV 16/18 may also be clinically significant. Therefore, information regarding the presence of additional oncogenic HPV types should be provided when feasible, particularly for infections with highly carcinogenic genotypes. However, because the range of detectable high-risk HPV types differs among assays owing to technical variability, further discussions among clinicians, laboratory specialists, and relevant professional societies are required to establish standardized reporting formats for non-16/18 high-risk HPV genotypes.

Recommendation 4. Quality assurance of hrHPV testing

Quality assurance in hrHPV testing should be rigorously implemented through both internal and external quality control programs, with performance evaluation conducted for both testing instruments and reagents. At present, quality management and proficiency testing for hrHPV assays are performed by individual supervising institutions; however, further discussion among clinicians and relevant stakeholders involved in hrHPV testing is required to establish a more standardized quality assurance framework.

Comprehensive laboratory-level quality management is essential to ensure the reliability and reproducibility of hrHPV testing. In Korea, internal and external quality control programs operate under the auspices of the Korean Society of Pathologists and Korean Society for Laboratory Medicine,

which play critical roles in maintaining the quality of hrHPV testing. This guideline reflects the expert consensus that the application of existing quality assurance systems to hrHPV testing is appropriate and desirable.

Nevertheless, because variations currently exist in quality management practices and specific criteria across supervising institutions, the development of unified quality assurance standards through collaboration among clinicians, laboratory specialists, and relevant professional societies is warranted. Establishing standardized quality assurance systems is expected to contribute to the long-term consistency and reliability of hrHPV testing as a screening tool for cervical cancer. A Korean summary of the guideline is provided in the Supplementary Material 1.

Conclusion

This clinical practice guideline represents a consensus-based recommendation for the clinical application of hrHPV testing in cervical cancer screening in Korea, and was developed based on a comprehensive review of existing evidence and multidisciplinary expert agreement. In particular, as the clinical utility of hrHPV testing is increasingly being established internationally, these guidelines are meaningful in that they propose practical standards that are applicable in real-world clinical practice while reflecting the specific characteristics of the Korean healthcare environment and testing systems.

In Korea, cervical cytology has been implemented for an extended period of time through the National Cancer Screening Program, resulting in a screening system with relatively high accessibility and clinical acceptability. In contrast, hrHPV testing is characterized by heterogeneity in testing methods and platforms, as well as substantial interinstitutional variation in result reporting and quality management practices. Under these circumstances, the introduction of unstandardized hrHPV testing as a screening modality may lead to clinical confusion rather than improved screening performance.

Reflecting these domestic realities, this guideline focuses on clearly defining the minimum requirements for the clinical application of hrHPV testing. The designation of HPV genotypes 16 and 18 differentiation as a core requirement for screening assays, emphasis on standardized result reporting, and recommendation to utilize existing society-led quality assurance systems were deliberate decisions aimed at ensuring

both feasibility and reliability within the current Korean testing environment.

A key feature of this guideline is that it was developed through a consensus-based process that included not only an evidence review but also four public hearings and extensive multidisciplinary expert discussions. Through this process, this guideline sought to avoid bias toward any single specialty or institution and to produce recommendations that are applicable in routine clinical practice.

Nevertheless, because these guidelines are based on currently available domestic evidence and the existing health-care environment, ongoing revision is necessary as additional evidence on hrHPV testing accumulates or as policy changes occur within the National Cancer Screening Program. Further studies are required to address the effectiveness of hrHPV testing as a standalone primary screening method, feasibility of self-sampling strategies, and cost-effectiveness of hrHPV-based screening in the Korean context. Advances in HPV vaccination and HPV-based screening strategies continue to improve the prevention and early detection of HPV-related diseases, highlighting the need for further research [23].

In summary, this clinical practice guideline acknowledges the clinical potential of hrHPV testing while proposing minimum standards to ensure its safe and consistent implementation within the cervical cancer screening system in Korea. This guideline is expected to serve as practical reference points for the continued evolution of national cervical cancer screening strategies.

Conflict of interest

The authors have no conflict of interest to declare.

Ethical approval

This study did not involve human participants, clinical specimens, or animal experiments; therefore, it did not require approval from the institutional review board.

Patient consent

This study does not include individual patient data or identifiable

information. Therefore, informed consent from patients was not required.

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