

Discussing Cervical Cancer Screening Options: Outcomes to Guide Conversations Between Patients and Providers

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Purpose. In 2018, the US Preventive Services Task Force (USPSTF) endorsed three strategies for cervical cancer screening in women ages 30 to 65: cytology every 3 years, testing for high-risk types of human papillomavirus (hrHPV) every 5 years, and cytology plus hrHPV testing (co-testing) every 5 years. It further recommended that women discuss with health care providers which testing strategy is best for them. To inform such discussions, we used decision analysis to estimate outcomes of screening strategies recommended for women at age 30. **Methods.** We constructed a Markov decision model using estimates of the natural history of HPV and cervical neoplasia. We evaluated the three USPSTF-endorsed strategies, hrHPV testing every 3 years and no screening. Outcomes included colposcopies with biopsy, false-positive testing (a colposcopy in which no cervical intraepithelial neoplasia grade 2 or worse was found), treatments, cancers, and cancer mortality expressed per 10,000 women over a shorter-than-lifetime horizon (15-year). **Results.** All strategies resulted in substantially lower cancer and cancer death rates compared with no screening. Strategies with the lowest likelihood of cancer and cancer death generally had higher likelihood of colposcopy and false-positive testing. **Conclusions.** The screening strategies we evaluated involved tradeoffs in terms of benefits and harms. Because individual women may place different weights on these projected outcomes, the optimal choice for each woman may best be discerned through shared decision making.

Keywords

cervical cancer screening, high-risk HPV DNA testing, Pap smear, shared decision making

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Cervical cancer incidence and mortality has declined substantially in the United States due in part to widespread screening. Nonetheless, an estimated 13,800 women in the United States will be diagnosed with cervical cancer, and 4,290 women will die from the disease in 2020.¹ While screening has traditionally been based on cervical cytology (Pap tests), strategies incorporating testing for high-risk types of human papillomavirus (hrHPV) have been included in US screening guidelines for many years.

In 2015, the US Food and Drug Administration approved a stand-alone hrHPV test for cervical cancer

screening in women beginning at age 25. The Society of Gynecologic Oncologists (SGO) endorsed this strategy with a recommendation that repeat testing be no sooner than every 3 years.² In turn, the American College of Obstetricians and Gynecologists (ACOG) considered this

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new strategy an alternative to current cytology-based strategies.³ In its 2018 recommendation, the US Preventive Services Task Force (USPSTF) endorsed a stand-alone hrHPV testing strategy, but specified that testing begin at age 30, not 25, and that it be performed every 5 years.⁴ The USPSTF continued to endorse two other strategies for women ages 30 to 65: cytology alone every 3 years and cytology plus hrHPV testing (co-testing) every 5 years. In recognition of the increasing number of possible screening approaches, the USPSTF further stated that women ages 30 and older should discuss with their health care provider which testing strategy is best for them. Similarly, the ACOG stated that it is appropriate to counsel women ages 30 to 65 about all three strategies so that they can select their preferred option.⁵ A dearth of data regarding relevant outcomes anticipated with each strategy has impeded implementation of these recommendations regarding shared decision making.⁶

We previously reported cost-effectiveness analyses of various cervical cancer screening strategies over a lifetime of screening.⁷ In this study, we use decision analysis to estimate outcomes of screening strategies recommended for women at age 30, expressed per 10,000 women over a shorter-than-lifetime (15-year) horizon, similar to that used in shared decision making for breast cancer screening.⁸ Our overarching objective was to provide evidence-based information in a familiar format to guide conversations and improve shared decision making between patients and providers about various cervical cancer screening options, as recommended by the USPSTF and ACOG.⁶

Methods

Our methods have previously been described.⁷ Briefly, we constructed a type-specific HPV Markov decision model using estimates of the natural history of HPV, cervical precancerous lesions, and cancer. The model was validated using outcomes from a randomized trial of hrHPV testing compared with cytology as well as data from the Surveillance, Epidemiology and End Results (SEER) program.^{9,10}

We evaluated a screening strategy of cytology alone every 3 years for women ages 21 to 29 followed by three different strategies for women ages 30 to 45: continued cytology alone every 3 years, hrHPV testing alone every 5 years, or cytology plus hrHPV testing (co-testing) every 5 years (Figure 1). For the cytology-alone strategy, we modeled two ways to manage those with atypical squamous cells of undetermined significance (ASC-US) results: repeat cytology in one year or immediate hrHPV triage. For any cytology results more severe than ASC-US, management was per the American Society for Colposcopy and Cervical Pathology (ASCCP) 2012 guidelines.¹¹ For the co-testing strategy, we modeled two ways to manage those with a normal cytology test and a positive hrHPV test result: repeat co-testing in one year or immediate genotyping triage. In addition, for those with ASC-US cytology and negative hrHPV test repeat co-testing was performed in 3 years. For women with other variations of cytology and hrHPV testing, management was per the ASCCP guidelines.¹¹ For the hrHPV-alone strategy, we modeled two ways to manage those with a positive hrHPV test result: genotyping triage (with cytology triage for those with negative testing for HPV types 16 or 18, as recommended by SGO²) or cytology as discussed, but not specifically recommended, by the USPSTF.⁴ Finally, because the periodicity of hrHPV testing alone in the SGO interim guidelines could be interpreted as every 3 years, we included this strategy with two ways to manage those with positive hrHPV test results as described above.

Longer-term management of abnormal test results and treatment of precancerous lesions were also based on 2012 guidelines.¹² The decision model assumed that all women adhered to screening, follow-up, and treatment. Screening test accuracy estimates were from systematic reviews. Outcomes were colposcopies, false-positive tests (a colposcopy in which no cervical intraepithelial neoplasia grade 2 or worse was found), treatments for precancerous lesions (cryosurgeries, loop excisions, cone biopsies), cancers, and cancer mortality, expressed per 10,000 women. Frequency per 10,000 women was chosen as denominator for all outcomes to provide a stable and relatable number

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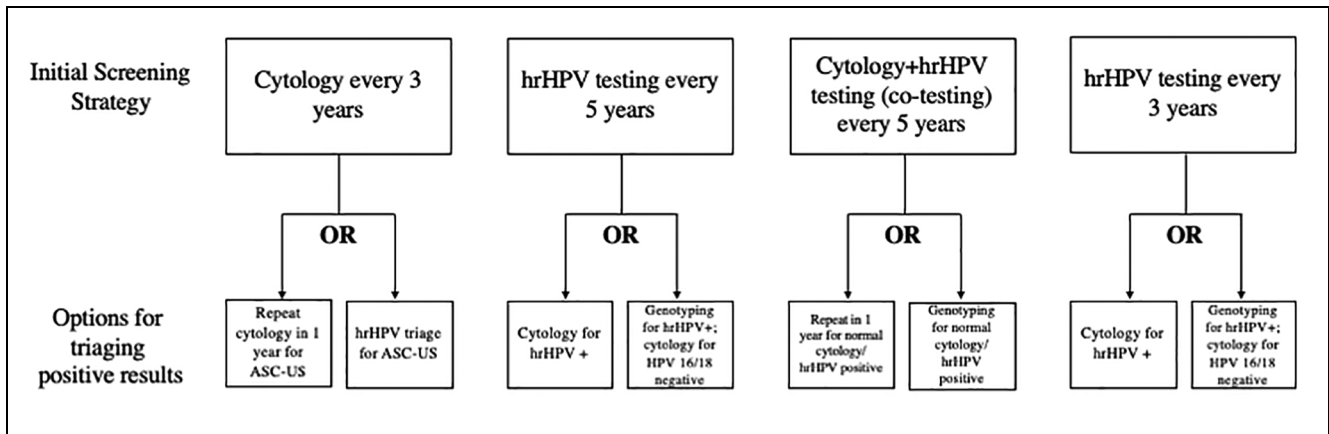


Figure 1 Primary cervical cancer screening strategies and triage options for positive test results beginning at age 30^a

^aIncludes screening with cytology alone every 3 years for women ages 21 to 29; includes outcomes for one full year after the 15-year horizon (i.e., to age 46).

ASC-US, atypical squamous cells of undetermined significance; hrHPV, high-risk human papillomavirus testing.

to enhance understanding for individuals participating in shared decision making, especially those with low numeracy skills.^{13–16}

While a shorter-than-lifetime (10-year) time horizon has been used to illustrate anticipated breast cancer screening outcomes, we used a 15-year horizon to enable us to compare directly five rounds of triennial cytology screening with three rounds of quinquennial hrHPV testing (with or without cytology). Furthermore, we chose to use a 15-year time horizon because presenting shorter-than-lifetime outcomes has proven effective in shared decision making regarding screening for other cancers¹⁷; other studies have shown that shared decision making is improved by presenting both lifetime and shorter-than-lifetime time horizons to communicate risk.^{18–20} To capture outcomes associated with the final screening test at age 45, we enumerated outcomes to the end of the 45th year.

The funding source had no role in the design and conduct of the study.

Results

Table 1 shows the estimated outcomes for each overarching strategy and its respective triage methods. As expected, all strategies resulted in substantially lower cancer and cancer death rates compared with no screening. Per 10,000 women, cytology every 3 years generally had the lowest number of colposcopies (range 15,643–17,188, depending on triage strategy) and false-positive tests (range 9,444–11,025) and the highest number of

cancers (range 13–16) and cancer deaths (range 6–8); hrHPV testing every 3 years generally had the highest number of colposcopies (range 20,726–23,474) and false-positive tests (range 15,398–17,755); and the lowest number of cancers (range 11–12) and cancer deaths (range 5–6).

Discussion

Our study is specifically responsive to the recommendations by the USPSTF and ACOG that clinicians discuss various cervical cancer screening strategies with women to decide which strategy is best for them. The screening strategies we evaluated involved tradeoffs in terms of benefits and harms. Specifically, women who place a higher value on screening benefits and are less concerned about harms may prefer hrHPV testing every 3 years beginning at age 30, a strategy currently endorsed by SGO and ACOG, but not by the USPSTF. Those placing a higher value on avoidance of invasive procedures and false-positive testing may prefer cytology every 3 years, especially if they consider the cancer risks conferred by each strategy to be similar. Because individual women may place different weights on these projected outcomes, the optimal choice for each woman may best be discerned through shared decision making. Other women may not want to participate in shared decision making, instead preferring to rely on the recommendation of their clinician.

In context, our findings may play an important role in helping women decide on a cervical cancer screening strategy concordant with their values. It has been shown

Table 1 Estimated Cervical Cancer Screening Outcomes per 10,000 Women by Various Screening Strategies, 15-Year Time Horizon Beginning at Age 30 Years^a

Screening Strategy	Screening and Surveillance Outcomes ^b			Cervical Cancer Outcomes ^b	
	Colposcopies with Biopsy	False-Positive Tests ^c	Treatments ^d	Cancers	Cancer Deaths
No screening	NA	NA	N/A	147	65
Cytology every 3 years					
Repeat cytology in 1 year for ASC-US	15,643	9,444	3,902	16	8
hrHPV triage for ASC-US	17,188	11,025	3,730	13	6
hrHPV testing every 5 years					
Cytology triage for hrHPV positive	16,939	11,944	4,212	15	7
Genotyping triage for hrHPV positive; cytology for HPV16/18 negative	18,942	13,632	4,239	14	7
Cytology plus hrHPV testing (co-testing) every 5 years					
Repeat in 1 year for normal cytology/hrHPV positive	21,135	15,585	4,933	13	6
Genotyping for normal cytology/hrHPV positive	22,546	16,867	4,941	13	6
hrHPV testing every 3 years^e					
Cytology triage for hrHPV positive	20,726	15,398	4,826	12	6
Genotyping triage for hrHPV positive; cytology for HPV16/18 negative	23,474	17,755	4,852	11	5

ASC-US, atypical squamous cells of undetermined significance; hrHPV, high-risk human papillomavirus testing.

^aIncludes screening with cytology alone every 3 years for women aged 21 to 29 years. Includes outcomes for one full year after the 15-year horizon (i.e., age 46 years).

^bEstimates reflect best summary estimates based on the available data; true estimates likely fall within a broad interval around each value.

^cA colposcopy in which no cervical intraepithelial neoplasia grade 2 or worse was found.

^dFor precancerous lesions: cryosurgeries, loop excisions, cone biopsies.

^eEndorsed by the American College of Obstetricians and Gynecologists and Society for Gynecologic Oncology but not the US Preventive Services Task Force.

in previous studies that women generally prefer cytology-based screening or cytology plus hrHPV testing rather than hrHPV testing alone.²¹ Our parent study found that a normal cytologic test result conferred a higher mean utility for women compared with a negative hrHPV test alone.⁷ In addition, other studies have found that women prefer shorter time intervals for cervical cancer screening rather than longer intervals.^{21–23} Given the outcomes presented in our study, women can make decisions based on forecasted benefits and harms related to cervical cancer screening strategies they personally prefer and decide what frequency of screening would allow them to feel secure that the risk of cervical cancer is minimal while balancing the harms of possible false-positive tests and treatments. Of note, the relatively high number of false-positive test results we estimated for some strategies can be explained by the low prevalence of the disease being sought (CIN2+, prevalence of ~1%), the specificity of screening tests used and the frequency in which they are applied. Furthermore, we used separate accuracy estimates for tests applied in the surveillance and posttreatment settings in which specificity was lower.^{24–26} In sum, screening

strategies that used tests with the lowest specificity and that were applied more frequently had higher cumulative numbers of false-positive tests over a 15-year horizon (e.g., hrHPV testing every 3 years).

In addition, women may take other considerations into account in choosing a strategy, one of which may be anticipated out-of-pocket expenses. Our prior cost-effectiveness analysis that included indirect costs such as patient travel, waiting, and examination suggested that cytology-based strategies were the most cost-effective from a societal perspective.⁷ Beyond the outcomes presented here, other harms that are difficult to quantify should be communicated: including the frequency of screening strategy itself and the psychological impact of a positive initial test that requires further management.²⁷

Clinicians may use our findings to form their opinions about which strategy best balances benefits and harms. In addition, we hope that our findings will foster deeper discussions between clinicians and patients regarding the possible outcomes of different screening strategies and help patients engage in informed, shared decisions about which strategy would work best for them. Finally, these

outcomes could be used by a clinician to advocate for change in the local practice if it adheres to a single approach or if only one approach is offered by their healthcare system.²⁸

Our outcomes are similar in rank ordering to those reported in our prior analyses⁷ and in a decision analysis commissioned by the USPSTF,²⁹ both projected over a lifetime of screening. Our analysis is unique in that we provide outcomes from two strategies endorsed in current guidelines but not included in the USPSTF modeling (cytology with repeat cytology in one year for ASC-US and cytology plus hrHPV testing with genotyping triage for normal cytology/hrHPV positivity).

Our study has strengths and limitations. While we modeled current management of abnormal test results with high fidelity, management guidelines continue to evolve. We assumed 100% adherence to allow for meaningful comparisons between strategies, but if adherence differs by strategy, screening outcomes will be different than the modeled estimates. In addition, it is unclear whether the interim strategy of hrHPV testing every 3 years will continue to be endorsed by either ACOG or SGO. We also assumed cytology alone for screening ages 21 to 29 and evaluated outcomes beginning at age 30 for the various strategies. To minimize complexity, we did not evaluate outcomes of switching to another strategy among women screened with various strategies up to an age greater than 30. Thus, our results are most clearly applicable to those at age 30 when informed decision making about choosing a screening strategy is recommended. Also, the screening modalities presented are limited to those endorsed by ACOG, the USPSTF, SGO, and the American Cancer Society. We did not evaluate self-collection with hrHPV testing because it is not specifically endorsed by any of these major US guideline groups. The USPSTF states that self-collection may increase screening rates among populations where they are currently low but that rigorous comparative studies are needed to test this hypothesis.

While HPV vaccination, approved by the FDA in 2006, has begun to decrease prevalence of HPV type 16/18-related cancers and precancerous lesions,³⁰ current ACOG and USPSTF guidelines recommend that screening be the same for HPV vaccinated and unvaccinated women. Thus, our model does not account for the effect of HPV vaccination on screening outcomes. Also, while our findings are focused on US guidelines, we used test accuracy estimates derived from non-US sources. Thus, our findings may be relevant to settings outside of the United States that employ cytology and hrHPV testing at various ages. Finally, our estimates reflect best

summary estimates based on the available data; true estimates likely fall within a broad interval around each value.

While informing women of the expected outcomes of various cervical cancer screening strategies may facilitate informed shared decision making, it continues to be critical to understand how, and when, to implement such a process.³¹ A recent commentary expressed concern that having a too-low threshold to recommend shared decision making in guidelines might undermine their credibility and usefulness and perhaps even reduce their value in patient care.¹⁴ The outcomes forecasted in our study may be perceived as showing relatively small differences in terms of benefits (cervical cancer-related outcomes) and relatively large differences in harms (additional colposcopies, false-positive tests, and precancer treatments) between the various screening options. In addition, the utilities we measured previously were higher for false-positive testing than for cancer,⁷ thereby strengthening the case for integrating patient preferences into the choice of screening strategy at age 30. Furthermore, our previous study suggested that screening with cytology alone every 3 years provides an optimal balance of benefits, harms, and costs from a societal perspective; all other screening options were dominated, meaning that they provided less health benefit (measured as quality-adjusted life-years) at greater costs.⁷ Whether dominated screening strategies should be included as a choice in shared decision making deserves further discussion as low-value options could potential mislead users rather than guide them.¹⁴


If shared decision making is widely deemed necessary and useful for cervical cancer screening, future guidelines should include explicit disclosure and explanation for why low-value options should be included. Carefully crafted decision aids could be used to communicate cancer-related outcomes.^{17,32,33} These high-quality decision tools would need to use outcomes such as those included in this study and be adaptable to individual patients, health care providers, and health systems.

Authors' Note

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Supplemental Material

Supplementary material for this article is available on the *Medical Decision Making Policy & Practice* website at <https://journals.sagepub.com/home/mpp>.

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