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Evidence-based Series: Section 1

Self-collected Samples for Testing of Oncogenic Human Papillomavirus: A Clinical Practice Guideline

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Questions

What is the role of self-sampling for human papillomavirus (HPV) testing as an alternative to cervical cancer screening by clinicians (i.e., Pap test)? Specifically, for HPV DNA testing,

- What are the potential benefits and harms of self-sampling?
- Is it feasible for women to successfully perform self-sampling?
- With self-sampling, are samples obtained by women adequate for analysis?
- What is the accuracy of self-sampling?
- Is self-sampling acceptable to women?
- Is self-sampling appealing to women?
- Do specific characteristics of women influence preferences regarding self-sampling?
- Is self-sampling appropriate for women who are never or seldom screened by clinicians?

Background

High-risk (oncogenic) types of HPV are a necessary, but not sufficient, cause of cervical cancer. Based on this strong causal relationship, if equivocal cell changes are identified with a Pap test, it is important to find out if the cell changes are due to the presence of high-risk HPV. The most efficient way to determine if there is cause for concern is to test for oncogenic HPV. Cells collected from the cervix can be tested for the presence of one or more of the high-risk HPV types that are associated with cervical dysplasia and cancer. If the HPV test is positive, the risk is higher that abnormal cells may progress to more severe changes or that there is underlying pathology, either of which could result in cervical cancer. Therefore, it is important to detect HPV as cell changes caused by high-risk HPV can lead to cancer. Finding and treating HPV-related tissue changes is a way to prevent cancer.

Target Population

The target population for this guideline is women in Ontario for whom cervical cancer screening is recommended with an emphasis on those who are never or seldom (> three years) screened

by clinicians. Pap testing performed by clinicians is accepted as an effective screening test for reducing mortality from cervical cancer and is the current standard practice in Ontario. The self-collection of HPV samples may offer an acceptable alternative to Pap testing by clinicians especially for women who are never or seldom screened.

Recommendations

- There is insufficient evidence to recommend for or against self-sampling for HPV testing as an alternative to cervical cancer screening by clinicians. Further research is needed to provide evidence that will allow a decision to be made about using self-sampling to increase screening rates, especially in women who are never or seldom screened.

Key Evidence

- *What are the potential benefits and harms of self-sampling?*
In theory, this method offers benefits to women with no access to a health care provider, who are uncomfortable with physical examination, or whose values prohibit an examination by a male physician. No studies evaluated the impact of self-sampling for HPV testing on participation rates in cervical screening, early detection of cervical cancer, survival, or quality of life. Data on harms from HPV self-testing is limited and largely restricted to assessment of false-negative and false-positive rates.
- *Is it feasible for women to successfully perform self-sampling?*
Women in many countries, across a range of ages, were successful in collecting samples for HPV testing using a variety of self-collection techniques (e.g., swabs, brushes, tampons, lavage, and pads).
- *With self-sampling, are samples obtained by women adequate for analysis?*
The quality of the patient samples was as good as the clinician samples, with more than 95% of samples yielding HPV testing results.
- *What is the accuracy of self-sampling?*
Evidence on the accuracy of self-sampling for HPV testing was available from 14 studies, but interpretation is hampered by incomplete colposcopy data from women with negative HPV tests. A wide range of sensitivity and specificity values were observed among both patient- and clinician-collected samples, but the sensitivity of self-collection methods appeared to be slightly lower than that for samples collected by clinicians. Eleven of 19 studies found reasonable agreement ($\kappa > 0.6$) between the HPV test results from self- and physician-collected samples.
- *Is self-sampling acceptable to women?*
The majority of women were willing to perform self-sampling, did not find it difficult or painful, and preferred self-sampling to physician sampling.
- *Is self-sampling appealing to women?*
One study reported that women were more comfortable and less embarrassed with self-sampling than with physician sampling but wanted assurance that self-collection of HPV samples would not make them ineligible for physician visits for other concerns.
- *Do specific characteristics of women influence preferences regarding self-sampling?*
There is little evidence about which women are interested in, or willing to perform, self-sampling.
- *Is self-sampling appropriate for women who are never or seldom screened by clinicians?*
Findings from one study suggested that written self-sampling instructions might be hard to follow for women with limited education; however, among that group of women, their requests for graphics or practice sessions in the clinic were seen as possible solutions to aid sample collection.

Future Research

Further research is needed to inform a policy regarding the use of HPV self-sampling. Ideally, research in the randomized setting would compare primary outcomes for women by the type of screening schedule: HPV self-sampling versus the standard practice of cervical cancer screening by clinicians. This type of trial however is not likely to occur given the known efficacy of established cervical cancer screening programs. At a minimum, well-conducted studies producing accurate estimates of sensitivity and specificity, and studies testing intermediate outcomes such as method of collection, women's preferences, participation rates, referral rates, detection of abnormalities, and cancer detection rates would be needed to develop a policy regarding the use of HPV self-sampling.

In particular, future studies should examine the accuracy of self-collection for HPV testing in a cohort of women already undergoing primary screening, as that would be most relevant to the potential use of self-collection in Ontario. Future studies should also move beyond evaluating HPV testing as an isolated test and should include data on accessibility and adherence to follow-up and treatment after HPV results are obtained.

More studies are needed that specifically target women for whom screening is recommended but who have never or seldom had cervical cancer screening. Women of low literacy, women of specific cultural groups, and women living in poverty have been identified as populations who are less likely to be screened. To increase understanding about the procedure of self-sampling, a combination of graphic, verbal, and written instructions should be developed.

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