Complete Summary

GUIDELINE TITLE

Self-collected samples for testing of oncogenic human papillomavirus: a clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Stewart DE, Johnston M, Gagliardi A, Howlett R, Barata P, Lewis N, Oliver T, Mai V, HPV Self-collection Guidelines Panel. Self-collected samples for testing of oncogenic human papillomavirus: a clinical practice guideline. Toronto (ON): Cancer Care Ontario (CCO); 2006 Apr 6. 30 p. (Evidence-based series). [70 references]

GUIDELINE STATUS

This is the current release of the guideline.

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Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

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SCOPE

DISEASE/CONDITION(S)

- Human papillomavirus infection
- Cervical cancer

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Internal Medicine
Obstetrics and Gynecology
Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To evaluate 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 deoxyribonucleic acid (DNA) testing
    - To evaluate the potential benefits and harms of self-sampling
    - To evaluate the feasiblity for women to successfully perform self-sampling
    - To evaluate whether self-sampling samples obtained by women are adequate for analysis
    - To evaluate the accuracy of self-sampling
    - To evaluate whether self-sampling is acceptable to women
    - To evaluate whether self-sampling is appealing to women
    - To evaluate whether specific characteristics of women influence preferences regarding self-sampling
    - To evaluate whether self-sampling is appropriate for women who are never or seldom screened by clinicians

TARGET POPULATION

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

INTERVENTIONS AND PRACTICES CONSIDERED

Self-sampling for human papillomavirus (HPV) testing

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of self-sampling
- Acceptability of self sampling

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The following databases were searched for relevant reports on human papillomavirus (HPV) deoxyribonucleic acid (DNA) self-testing from the years of 1985 to December 2004: MEDLINE, EMBASE, HealthSTAR, CINAHL, the Cochrane Library, Women's Studies International, Web of Science, Social Sciences Index, PsycINFO, the Campbell Library, Studies on Women and Gender Abstracts Online, Contemporary Women's Issues, the Canadian Medical Association Infobase, and the National Guideline Clearinghouse.

In addition, unpublished sources were sought through an Internet search of Google, Health Canada, the National Health Service Department of Health, the Australian Government Department of Health, the RAND Corporation, the Institute of Medicine, the World Health Organization, the Agency for Health Research and Quality, and the National Institutes of Health for relevant reports. Article bibliographies and personal files were also searched to December 2004 for evidence relevant to the guideline question.

Where sophisticated search engines were available, the literature was searched by combining disease-specific terms (cervix dysplasia/ or cervical intraepithelial neoplasia/ or cervix neoplasms/ or papillomavirus/ or papillomavirus, human/ or papillomavirus, infections/) with test-specific terms (self-collected.tw. or self-test.tw. or self-obtained.tw.) for any study design. Where limited search facilities were available, the terms (Papillomavirus AND self-collected or self-test or self-obtained or self-administered) or simply (Papillomavirus) or (HPV) were used.

Inclusion Criteria

Articles were included in the systematic review of the literature if they reported data relating to the self-collection of HPV DNA samples as they related to any of the following:

- The potential harms and benefits of self-sampling
- The feasibility of women successfully performing self-sampling
- The adequacy of self-collected samples for analysis
- The accuracy of self-sampling
- The acceptability self-sampling acceptable to women
- The appeal of self-sampling to women
- Whether specific characteristics of women influence preferences regarding self-sampling
- Whether self-sampling is appropriate for women who are never or seldom (> three years) screened by clinicians

Randomized controlled trials, case-control studies, prospective cohort studies, retrospective cohort studies, or technical reports were considered eligible for inclusion in the systematic review of the evidence. Where reports examined the subjective outcomes of appeal, perspectives, characteristics, or acceptability of self-sampling to women, the results of surveys (interviews, focus groups, questionnaires) were also deemed eligible.

Exclusion Criteria

Studies were excluded for the evidence review if they were reported in a language other than English, were reported prior to 1985, or were abstracts, letters, or editorials. Studies were also excluded if there were no data on the research methodology used to develop the report.

NUMBER OF SOURCE DOCUMENTS

A total of 25 studies published in 31 papers between 1992 and 2004 were reviewed.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data on the design of each study were extracted and tabulated, and the methodologic quality of each study assessed using published criteria. Based on that first examination of the literature, a data extraction form was created, and one reviewer extracted data from each of the eligible articles. A second reviewer checked the extracted data against the primary study reports and discrepancies were discussed with the first reviewer to achieve consensus. Where outcomes of interest were not reported but source data was, the reviewers calculated sensitivity, specificity, positive predictive value, and negative predictive value (using the Predictive Value Calculator available on the Web at http://www.azzopardi.freeserve.co.uk/easycalc/Additions/predict.htm) or Cohen's kappa (using a statistical calculator available on the Web at http://www.niwa.co.nz /services/statistical/).

Data were not pooled across studies because of important heterogeneity among studies in design, population, technique, timing of self-sampling, and outcome measures.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This systematic review was developed by the Human Papillomavirus (HPV) Self-collection Guidelines Panel as a collaborative effort between the Cancer Care Ontario (CCO) Screening Guidelines Steering Committee and the CCO Program in Evidence-based Care (PEBC). Evidence was selected and reviewed by six members of the HPV Self-collection Guidelines Panel and methodologists. The six panel members interpreted the evidence, formulated recommendations, and contributed to writing the guideline report. The panel included behavioural scientists, methodologists, a gynecologic oncologist, a policy analyst, and, from Cancer Care Ontario, the Manager of the Ontario Cervical Screening Program and the Acting Vice-President of Preventive Oncology.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

External Review

Practitioner feedback was obtained through a mailed survey of 178 practitioner sin Ontario. The survey consisted of items evaluating the methods, results, and interpretive summary. Written comments were invited. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The Human Papillomavirus (HPV) Self-collection Guidelines Panel reviewed the results of the survey.

Report Approval Panel

The evidence was circulated to three reviewers, the two members of the Report Approval Panel and the Guidelines Coordinator of the Program in Evidence-Based Care (PEBC). Feedback provided by the Panel and the Coordinator is summarized in the original guideline document. The feedback was reviewed by the HPV Self-collection Guidelines Panel, and modifications were made to the series in response.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

There is insufficient evidence to recommend for or against self-sampling for human papillomavirus (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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by prospective, observational studies.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

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 human papillomavirus (HPV) testing on participation rates in cervical screening, early detection of cervical cancer, survival, or quality of life.

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 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.

POTENTIAL HARMS

What are the potential benefits and harms of self-sampling?

Data on harms from human papillomavirus (HPV) self-testing is limited and largely restricted to assessment of false-negative and false-positive rates.

QUALIFYING STATEMENTS

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Care has been taken in the preparation of the information contained in this document. Nonetheless, any person seeking to apply or consult the practice guideline is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding their content or use or application and disclaims any for their application or use in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr 6

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

HPV Self-collection Guidelines Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

For a current list of past and present members, please see the Cancer Care Ontario Web site.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Prior to embarking on guideline development, members of the panel disclosed information on potential conflict of interest. No conflicts were declared. There is a relationship between the guideline panel and the Ontario Human Papillomavirus (HPV) Pilot Study, which is funded by the Ontario Women's Health Council. Two panel members are affiliated with the Ontario Women's Health Council, and six panel members are investigators or members of the steering committee for the pilot study. The pilot study's primary objectives are to determine: i) how reflex HPV testing [by clinicians] in patients with atypical squamous cells of undetermined significance (ASCUS) influences colposcopy rates and compliance with colposcopy compared with usual screening care, ii) the information needs of practitioners and women related to the topic of HPV and its use as a reflex test following a Pap test abnormality (ASCUS) and iii) the barriers and facilitators related to physician and patient acceptance of the new follow-up protocol. As a secondary objective, the pilot study is examining the acceptability of self-collection of samples for HPV testing. To this end, the study plan included a systematic review on self-collection and several focus groups with women across Ontario.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Self-collected samples for testing of oncogenic human papillomavirus: a clinical practice guideline summary. Toronto (ON): Cancer Care Ontario (CCO), 2006 Apr. Various p. Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.
- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 21, 2006. The information was verified by the guideline developer on August 23, 2006.

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Date Modified: 9/22/2008