Recommendations on routine screening pelvic examination

Canadian Task Force on Preventive Health Care adoption of the American College of Physicians guideline

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Abstract

Objective To review the 2014 American College of Physicians (ACP) guideline on the use of pelvic examinations to screen for cancer (other than cervical), pelvic inflammatory disease, or other benign gynecologic conditions to determine whether the ACP guideline on routine pelvic examinations was consistent with Canadian Task Force on Preventive Health Care (CTFPHC) standards and could be adapted or adopted.

Methods The SNAP-IT (Smooth National Adaptation and Presentation of Guidelines to Improve Thrombosis Treatment) method was used to determine whether the ACP guideline was consistent with CTFPHC standards and could be adapted or adopted.

Recommendations The CTFPHC recommends not performing a screening pelvic examination to screen for noncervical cancer, pelvic inflammatory disease, or other gynecological conditions in asymptomatic women. This is a strong recommendation with moderate-quality evidence.

Conclusion The CTFPHC adopts the recommendation on screening pelvic examination as published by the ACP in 2014.

EDITOR'S KEY POINTS

- It is increasingly recognized that adoption or adaptation of high-quality guidelines is an efficient approach to guideline development that can save resources and reduce duplication of effort. Various methods have been developed to facilitate this process in a manner that is systematic and transparent.

- After assessing the 2014 American College of Physicians guideline on the use of routine screening pelvic examinations, the Canadian Task Force on Preventive Health Care opted to adopt the American College of Physicians recommendation.

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Pelvic examinations are often performed as part of routine medical checkups to screen for cancer, pelvic inflammatory disease, or other gynecologic conditions among asymptomatic women.[1] The pelvic examination consists of inspection of the external genitalia; speculum evaluation of the vagina and cervix; bimanual palpation of the adnexa, uterus, ovaries, and bladder; and sometimes rectal or rectovaginal digital examination.[2] Pelvic examinations are distinct from the Papanicolaou test, which is used to screen for precancerous and cancerous lesions of the cervix.[3] Guidelines on screening for cervical cancer have been developed by the Canadian Task Force on Preventive Health Care (CTFPHC) and can be found at **www.canadiantaskforce.ca**.[4]

The CTFPHC identified routine pelvic screening as a priority through the annual topic prioritization process, in which we solicit input from primary care practitioners and other stakeholders (eg, family physicians, health agencies, researchers, and members of the public). It is increasingly recognized that adoption or adaptation of high-quality guidelines is an efficient approach to guideline development that can save resources and reduce duplication of effort. Methods such as ADAPTE[5] have been developed in order to facilitate this process in a manner that is systematic and transparent.

The American College of Physicians (ACP) published a guideline on the use of pelvic examinations to screen for cancer (other than cervical), pelvic inflammatory disease, or other benign gynecologic conditions in 2014.[6] The ACP recommended "against performing

screening pelvic examination in asymptomatic, nonpregnant, adult women" based on evidence that the harms of screening outweigh the benefits. The CTFPHC used the SNAP-IT (Smooth National Adaptation and Presentation of Guidelines to Improve Thrombosis Treatment[7]) method to determine whether the ACP guideline on routine pelvic examinations was consistent with CTFPHC standards and could be adapted or adopted.

METHODS

The SNAP-IT method was developed by the MAGIC (Making GRADE the Irresistible Choice) group, an international initiative seeking to improve the development and implementation of guidelines based on the GRADE (grading of recommendations, assessment, development, and evaluation) system.[8] The SNAP-IT method was developed to incorporate key features of the ADAPTE process and is a 5-step process designed to adapt guidelines using the GRADE system. The 5 steps include planning, initial assessment of the recommendations, modifications, publication, and evaluation.[7,9] The SNAP-IT system is set up to consider 1 or more recommendations for potential inclusion in a guideline statement. For the present purpose, the CTFPHC assessed only a single recommendation on pelvic screening.

For the purpose of the ACP guideline, a pelvic examination was defined as a speculum or bimanual examination, not including the Pap test for screening for cervical cancer. The guideline focused on average risk, asymptomatic, nonpregnant adult women. The ACP used a modified GRADE system (they excluded the very-low-quality evidence category and allowed for an insufficient evidence category) to rate the quality of evidence and strength of the recommendation statement.[10]

As a preliminary step, 4 Public Health Agency of Canada scientific staff assessed the guideline according to the AGREE II (Appraisal of Guidelines Research and Evaluation) criteria[11] to determine whether the guideline was of high enough quality for further consideration. The CTFPHC considers a guideline to be high quality and eligible for further consideration if it scores at least 60% in the AGREE II domains of scope and purpose, rigour of development, and editorial independence.[12] The ACP guideline received scores of 97%, 91%, and 88% on those domains, respectively.

A CTFPHC workgroup was then established. Members of the CTFPHC workgroup, which included 3 current CTFPHC members, then reviewed the guideline and supporting documentation using the SNAP-IT method to determine whether the recommendation could be considered for adoption as a CTFPHC pelvic screening guideline or whether it required adaptation to the local context. This involved determining the

Box 1. Steps in the SNAP-IT process

Step 1: Planning (1 mo)

- Establish editorial committee: CTFPHC workgroup established according to CTFPHC processes
- Define consensus and leadership process: CTFPHC processes were followed
- Select broad subject areas for adaptation: CTFPHC topic prioritization process identified routine pelvic examination as number 8 in its top 10 list for 2014 and number 4 in the top 10 list from the College of Family Physicians of Canada
- Search and retrieve current and trustworthy parent guidelines: The following sites were searched for guidelines on pelvic screening examination and ovarian screening: Guidelines International Network, NICE, National Guideline Clearinghouse, US Preventive Services Task Force, and CMA Infobase. Five guidelines were identified; however, only the ACP guideline discussed the role of the pelvic examination, which was the topic of interest
- Prescreen ACP guideline: ACP guideline was prescreened according to CTFPHC criteria (guideline must be based on a systematic review of the evidence, and the review must be readily available and must use an evidence grading system (GRADE preferred), have at least 1 family doctor on the author list, be focused on a primary care audience, and be produced by a non-specialist group*
- Assess eligibility for further consideration: ACP guideline was assessed with AGREE II by 4 reviewers to ensure it met the criteria for high-quality guidance*
- Procure licensing agreement with guideline developers to potentially endorse or adapt

Step 2: Initial assessment of the recommendations (3 mo)

- Record financial and intellectual conflicts of interest according to CTFPHC procedures: Disclosures can be found at **www.canadiantaskforce.ca/about-us/competing-interests**
- Assess recommendations: Individual assessment by workgroup members of the need to modify, exclude, or develop de novo recommendations according to SNAP-IT taxonomy; 2 of 5 workgroup members highlighted a potential change to quality of evidence (from moderate to low). After discussion the group agreed that the moderate rating of evidence was appropriate. Decision by workgroup to adopt the guideline as is

Step 3: Modifications (1 mo)

- Perform a systematic search for new literature: The search identified 52 unique citations; none met the inclusion criteria of the guideline or provided additional data on the effectiveness of screening with pelvic examination or its diagnostic properties related to the outcomes of interest
- Write draft recommendations
- Review and seek approval by full CTFPHC
- Submit final draft for peer review

Step 4: Publication

Step 5: Evaluation and planning for the future

ACP—American College of Physicians; AGREE—Appraisal of Guidelines Research and Evaluation; CMA—Canadian Medical Association; CTFPHC—Canadian Task Force on Preventive Health Care; GRADE—grading of recommendations, assessment, development, and evaluation; NICE—National Institute for Health and Care Excellence; SNAP-IT—Smooth National Adaptation and Presentation of Guidelines to Improve Thrombosis Treatment.

*Added to the SNAP-IT process.

SNAP-IT process adapted from Kristiansen et al.[7]

degree to which the workgroup members agreed that the guideline and the supporting evidence were consistent with CTFPHC standards.

A standard template was completed by each member of the workgroup* on which they independently evaluated the ACP recommendation and assessed whether it met CTFPHC standards, and, if so, if it should be adopted or adapted. To determine adoption versus adaptation, members considered if the recommendation could stand as it was (adoption) or whether it would need modification and if so how and why (adaptation). Adaptation could include changes to reflect local context (owing to identified new population, intervention, comparator, or outcomes). In cases of disagreement with a recommendation, the SNAP-IT method asks for explicit documentation of the components of a recommendation and the underlying evidence for areas of disagreement. In addition to excluding the recommendation from consideration, reviewers are able to suggest an alternative recommendation. A detailed description of the adaptation process appears in **Box 1**.[7]

In addition to using the SNAP-IT method to assess the compatibility of the ACP guideline with CTFPHC standards, we updated the database searches conducted by the ACP for the systematic review that was used to develop the guideline. This was done to determine if there was any new evidence published since the ACP guideline that would require reconsideration of the recommendation. The search was updated, using the same search strategy as the original review,[2] from the last date of the ACP search in January 1, 2014 through to May 15, 2015.

RECOMMENDATIONS

All workgroup members and subsequently the entire CTFPHC unanimously agreed that the recommendation could be adopted without adaptation and that the ACP evidence grading was consistent with how the CTFPHC grades evidence for its guidelines.

Thus, the CTFPHC has adopted the ACP recommendation[6] against performing a screening pelvic examination in asymptomatic, nonpregnant, adult women (**Box 2**).

Summary of evidence

The ACP guideline was based on an evidence review conducted by the Department of Veteran Affairs.[2] It examined the literature on the accuracy, benefits, and harms of screening pelvic examinations. The potential benefits of screening that were evaluated included

*The standard template is available at **www.cfp.ca.** Go to the full text of the article online and click on **CFPlus** in the menu at the top right-hand side of the page.

Box 2. Summary of the recommendation

Recommendations are presented for the use of a screening pelvic examination (speculum or bimanual examination) in asymptomatic women. Pregnant women are excluded from this recommendation

The Canadian Task Force on Preventive Health Care recommends not performing a screening pelvic examination to screen for noncervical cancer, pelvic inflammatory disease, or other gynecological conditions

This is a strong recommendation with moderate-quality evidence

Box 3. Summary of evidence

As described in the ACP guideline statement,[6] high-quality evidence from 3 prospective cohort studies[13-15] (more details about GRADE evidence gradings can be found at **www.gradeworkinggroup.org**) found that the diagnostic accuracy of the pelvic screening examination was low for detecting ovarian cancer (positive predictive value < 4%) for asymptomatic women. The Prostate Lung Colorectal and Ovarian Cancer Trial included pelvic screening for the first 5 years of the trial, but when no cancers were identified as a result of this intervention, the pelvic screen was dropped from the trial.[16] No studies were found that examined the diagnostic properties for detecting other types of cancers, pelvic inflammatory disease, or other benign conditions[2,17] in asymptomatic women

No studies were identified that examined the mortality or morbidity benefits of pelvic screening in reducing the risk of ovarian cancer, other cancers, pelvic inflammatory disease, or other benign gynecologic conditions[2,17]

Low-quality evidence of harms, based on 14 surveys[18-31] and 1 cohort study,[32] examined women's experiences with the pelvic examination. Approximately one-third of women (median 34%) reported fear, embarrassment, or anxiety associated with the pelvic examination, and 35% reported pain or discomfort.[2,16] Those who experienced pain were less likely to return for additional visits.[2,17] There were no studies that reported on the harms of false reassurance, overdiagnosis, or overtreatment, or on diagnostic procedure–related harms. However, 1 high-quality prospective cohort study[15] found that, as a result of follow-up procedures from pelvic screening, 1.5% of women who were screened experienced unnecessary surgery (open or laparoscopic)[2]

The update to the ACP database search identified 52 unique citations, including the ACP guideline and their accompanying systematic review. No studies provided additional information about the effectiveness of screening with pelvic examination on the outcomes of interest or on its diagnostic properties

ACP—American College of Physicians; GRADE—grading of recommendations, assessment, development, and evaluation.

decreased mortality and morbidity. Potential harms of screening that were considered included overdiagnosis, overtreatment, or other harms related to diagnostic procedures. The evidence is summarized in **Box 3**.[2,6,13-32]

The ACP made a strong recommendation based on its judgment that the likely harms from routine pelvic examinations outweighed any benefits.[6] Given the absence of evidence of benefit and the potential for harm, the CTFPHC agrees that the recommendation should be a strong recommendation against screening pelvic examinations. This means that we recommend that providers do not offer this service to asymptomatic women. Just as with the ACP recommendation, patients' preferences and values, as well as resource use, were not considered in adopting this guideline.

Clinical considerations

While not recommended for screening asymptomatic women, pelvic examination is appropriate in other clinical situations, such as diagnosing gynecologic conditions when women present with symptoms or for follow-up of a previously diagnosed condition.

Conclusion

The CTFPHC adopts the recommendation on screening pelvic examination as published by the ACP in 2014.[6]

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Editorial independence

While the Public Health Agency of Canada funds the Canadian Task Force on Preventive Health Care, the views of the funding body have not influenced the content of the guideline; competing interests have been recorded and addressed.

Competing interests

None of the Canadian Task Force on Preventive Health Care members has any relevant financial conflicts of interest to disclose. Full disclosures are available from **www.canadiantaskforce.ca/about-us/competing-interests**.

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References

1. Society of Obstetricians and Gynaecologists of Canada. *My first pelvic exam*. Ottawa, ON: Society of Obstetricians and Gynaecologists of Canada. Available from: **http://sogc.org/publications/my-first-pelvic-exam**. Accessed 2015 May 5.
2. Bloomfield H, Olson A, Cantor A, Greer N, MacDonald R, Rutks I, et al. *Screening pelvic examinations in asymptomatic average risk adult women. Veterans Affairs Evidence-based Synthesis Program Project #09-009*. Washington, DC: Department of Veterans Affairs; 2013.
3. Canadian Cancer Society [website]. *Pap test.* Toronto, ON: Canadian Cancer Society; 2015. Available from: **www.cancer.ca/en/cancer-information/diagnosis-and-treatment/tests-and-procedures/pap-test/?region=on**. Accessed 2015 May 5.
4. Canadian Task Force on Preventive Health Care. *Screening for cervical cancer.* Calgary, AB: University of Calgary; 2013. Available from: **http://canadiantaskforce.ca/ctfphc-guidelines/2013-cervical-cancer**. Accessed 2016 Feb 3.
5. ADAPTE Collaboration. *Guideline adaptation: a resource toolkit. Version 2.0*. Perthshire, Scot: Guidelines International Network; 2011. Available from: **www.g-i-n.net/document-store/adapte-resource-toolkit-guideline-adaptation-version-2/view?searchterm=adapte**. Accessed 2011 Aug 17.
6. Qaseem A, Humphrey LL, Harris R, Starkey M, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Screening pelvic examination in adult women: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2014;161(1):67-72.
7. Kristiansen A, Brandt L, Agoritsas T, Akl EA, Berge E, Bondi J, et al. Adaptation of trustworthy guidelines developed using the GRADE methodology: a novel five-step process. *Chest* 2014;146(3):727-34.
8. MAGIC. *MAGICapp* [mobile app]. Oslo, Nor: MAGIC; 2014. Available from: **www.magicproject.org**. Accessed May 5, 2015.
9. Kristiansen A, Brandt L, Agoritsas T, Akl EA, Berge E, Flem Jacobsen A, et al. Applying new strategies for the national adaptation, updating, and dissemination of trustworthy guidelines: results from the Norwegian adaptation of the antithrombotic therapy and the prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest* 2014;146(3):735-61.
10. Qaseem A, Snow V, Owens DK, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. *Ann Intern Med* 2010;153(3):194-9.
11. AGREE Next Steps Consortium. *AGREE II instrument (manual)*. AGREE Research Trust; 2013. Available from: **www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manual-and-23-item-Instrument_2009_UPDATE_2013.pdf**. Accessed 2014 Jan 17.
12. Canadian Task Force on Preventive Health Care [website]. *Overview—appraisal process*. Calgary, AB: University of Calgary; 2015. Available from: **http://canadiantaskforce.ca/appraised-guidelines/overview**. Accessed 2015 Mar 9.
13. Grover SR, Quinn MA. Is there any value in bimanual pelvic examination as a screening test. *Med J Aust* 1995;162(8):408-10.
14. Jacobs I, Stabile I, Bridges J, Kemsley P, Reynolds C, Grudzinskas J, et al. Multimodal approach to screening for ovarian cancer. *Lancet* 1988;1(8580):268-71.
15. Adonakis GL, Paraskevaidis E, Tsiga S, Seferiadis K, Lolis DE. A combined approach for the early detection of ovarian cancer in asymptomatic women. *Eur J Obstet Gynecol Reprod Biol* 1996;65(2):221-5.
16. Buys SS, Partridge E, Black A, Johnson CC, Lamerato L, Isaacs C, et al. Effect of screening on ovarian cancer mortality: the prostate, lung, colorectal and ovarian (PLCO) cancer screening randomized controlled trial. *JAMA* 2011;305(22):2295-303.
17. Bloomfield HE, Olson A, Greer N, Cantor A, MacDonald R, Rutks I, et al. Screening pelvic examinations in asymptomatic, average-risk adult women: an evidence report for a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2014;161(1):46-53.
18. Golomb D. Attitudes toward pelvic examinations in two primary care settings. *R I Med J* 1983;66(7):281-4.
19. Harper C, Balistreri E, Boggess J, Leon K, Darney P. Provision of hormonal contraceptives without a mandatory pelvic examination: the first stop demonstration project. *Fam Plann Perspect* 2001;33(1):13-8.
20. Bourne PA, Charles CA, Francis CG, South-Bourne N, Peters R. Perception, attitude and practices of women towards pelvic examination and Pap smear in Jamaica. *N Am J Med Sci* 2010;2(10):478-86.
21. Hesselius I, Lisper HO, Nordstrom A, Anshelm-Olson B, Odlund B. Comparison between participants and non-participants at a gynaecological mass screening. *Scand J Soc Med* 1975;3(3):129-38.
22. Wijma B, Gullberg M, Kjessler B. Attitudes towards pelvic examination in a random sample of Swedish women. *Acta Obstet Gynecol Scand* 1998;77(4):422-8.
23. Armstrong L, Zabel E, Beydoun HA. Evaluation of the usefulness of the 'hormones with optional pelvic exam' programme offered at a family planning clinic. *Eur J Contracept Reprod Health Care* 2012;17(4):307-13.
24. Osofsky HJ. Women's reactions to pelvic examination. *Obstet Gynecol* 1967;30(1):146-51.
25. Hoyo C, Yarnall KS, Skinner CS, Moorman PG, Sellers D, Reid L. Pain predicts non-adherence to Pap smear screening among middle-aged African American women. *Prev Med* 2005;41(2):439-45.
26. Taylor VM, Yasui Y, Burke N, Nguyen T, Acorda E, Thai H, et al. Pap testing adherence among Vietnamese American women. *Cancer Epidemiol Biomarkers Prev* 2004;13(4):613-9.
27. Fiddes P, Scott A, Fletcher J, Glasier A. Attitudes towards pelvic examination and chaperones: a questionnaire survey of patients and providers. *Contraception* 2003;67(4):313-7.
28. Yu CK, Rymer J. Women's attitudes to and awareness of smear testing and cervical cancer. *Br J Fam Plann* 1998;23(4):127-33.
29. Broadmore J, Carr-Gregg M, Hutton JD. Vaginal examinations: women's experiences and preferences. *N Z Med J* 1986;99(794):8-10.
30. Haar E, Halitsky V, Stricker G. Patients' attitudes toward gynecologic examination and to gynecologists. *Med Care* 1977;15(9):787-95.
31. Petravage JB, Reynolds LJ, Gardner HJ, Reading JC. Attitudes of women toward the gynecologic examination. *J Fam Pract* 1979;9(6):1039-45.
32. Kahn JA, Goodman E, Huang B, Slap GB, Emans SJ. Predictors of Papanicolaou smear return in a hospital-based adolescent and young adult clinic. *Obstet Gynecol* 2003;101(3):490-9.