



Screening Pelvic Examinations in Asymptomatic Average Risk Adult Women

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PREFACE

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- develop clinical policies informed by evidence,
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
- set the direction for future research to address gaps in clinical knowledge.

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Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at nicole.floyd@va.gov.

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EXECUTIVE SUMMARY

BACKGROUND

The routine pelvic examination has been a usual part of preventive care for women for many decades. In 2008, 63.4 million pelvic examinations were performed in the United States. Many women and providers believe that the routine pelvic exam should be included in an annual comprehensive well-woman visit. The exam consists of inspection of the external genitalia, speculum examination of the vagina and cervix, bimanual examination, and sometimes rectal or rectovaginal examination. Traditionally, the examination in the asymptomatic average risk women has been used to screen for pathology through palpation, visualization, and specimen collection.

Pathology potentially detectable on the pelvic examination includes malignancies (e.g., cervical, ovarian, uterine, bladder, vaginal or vulvar); infections (e.g., Chlamydia, gonorrhea, warts, candidiasis, bacterial vaginosis); pelvic inflammatory disease (PID); or other pathology (e.g., atrophic vaginitis, cervical polyps, uterine prolapse, fibroids). In addition, pelvic examinations are often performed prior to the provision of hormonal contraception. Recent high quality evidence-based reviews and guidelines have concluded that pelvic examinations are not required for Chlamydia and gonorrhea screening or for hormonal contraception initiation and up-to-date evidence-based guidelines for cervical cancer screening are also available. However, we are unaware of any systematic reviews that have investigated the utility of the pelvic examination for the other indications.

This systematic review was undertaken to evaluate the benefits and harms of the routine screening pelvic examination in asymptomatic, average risk, non-pregnant, adult women. For cervical cancer and sexually transmitted infection (i.e., Chlamydia and gonorrhea) screening and for initiation of hormonal contraception we summarize the results of recent reviews and guidelines from major US health organizations. For all other indications, we performed and report results from a comprehensive search of the medical literature.

Summary of Recommendations for Cervical Cancer, Chlamydia, and Gonorrhea Screening and Initiation of Hormonal Contraception

According to the United States Preventive Services Task Force (USPSTF), cervical cancer screening (Pap smears) should be performed every 3 years in average risk women with a cervix who are 21 to 65 years old. Pap smears are not recommended for women under 21 regardless of sexual activity level. In women aged 30 to 65 years, the screening interval may be lengthened to 5 years when simultaneous human Papillomavirus testing is performed. Pap smears should not be performed in women over 65 years of age who have had adequate and negative prior screening and are not otherwise at high risk for cervical cancer or in women who do not have a cervix.

Pelvic examinations are not necessary prior to prescribing hormonal contraception. Only a medical history and blood pressure measurement are required to rule out contraindications.

Pelvic examinations are not required to test for Chlamydia and gonorrhea. This testing can be performed on either self-obtained vaginal swabs or urine specimens.

Key Questions

Key Question #1. How accurate is the screening pelvic exam for detection of malignancy (other than cervical), pelvic inflammatory disease (PID), or other benign gynecologic conditions?

Key Question #2. What are the benefits (reduced mortality and morbidity) and harms (overdiagnosis, over-treatment, diagnostic procedure-related) of the routine screening pelvic examination performed for the detection of malignancy, PID, or other benign gynecologic conditions?

Key Question #3. What are the examination-related harms and indirect benefits of a screening pelvic examination in asymptomatic women?

Key Question #3a. Do these harms vary by patient or provider characteristics?

METHODS

We searched MEDLINE (OVID) for articles published from 1946 through July 2013 (Appendix A). Our search was designed to identify studies of any design other than case series or case reports. We limited the search to studies involving human subjects published in the English language. To supplement our literature search, we selected nine references that we considered highly relevant to the topic and used the “Related Citations” feature of PubMed, to identify any additional abstracts. Additional articles were identified from hand-searching reference lists of existing systematic reviews and pertinent studies and from suggestions by members of the Technical Expert Panel and peer reviewers.

The full text of each article identified as potentially eligible was independently reviewed by two investigators or research associates. Study characteristics, patient characteristics, and outcomes data were abstracted from articles meeting inclusion criteria. We assessed the quality of the studies of diagnostic accuracy based on patient representativeness, quality and administration of the reference (gold standard) test, quality and administration of the index test, and data analysis. We assessed the quality of survey studies based on the population sampling method, the survey instrument, and the analysis methods used.

DATA SYNTHESIS

We compared the characteristics, methods, and findings of included studies. Pooled analyses of data were not possible due to limited reporting and heterogeneity of methods and outcomes across studies. Therefore, findings were summarized in narrative form. We identified and highlighted findings from studies involving Veterans.

PEER REVIEW

A draft version of this report was reviewed by technical experts, as well as VA clinical leadership. Reviewer comments were incorporated into this report, as appropriate, and a summary of our responses may be found in Appendix B.

RESULTS

From the primary literature search, we identified 1523 abstracts. From the “Related Citations” literature search, we identified 826 unique abstracts for a total of 2349 abstracts. We reviewed the full text of 156 references and 13 met inclusion criteria. An additional 39 references were identified by hand-searching or from suggested references.

Key Question #1. How accurate is the screening pelvic exam for detection of malignancy (other than cervical), pelvic inflammatory disease (PID), or other benign gynecologic conditions?

We identified three studies that investigated the diagnostic accuracy of the pelvic examination for detecting ovarian cancer and one for bacterial vaginosis. There were no diagnostic accuracy studies of other malignancies, PID, or any other benign gynecologic conditions in this population.

Ovarian Cancer

The 3 ovarian cancer studies enrolled a total of 5633 average risk asymptomatic women. Since not all subjects underwent the gold standard test (biopsy), sensitivity and specificity could not be calculated. One study did not identify any cases of ovarian cancer. In the other 2 studies the positive predictive value of the pelvic examination for ovarian cancer was 1.2 to 3.6%.

Bacterial Vaginosis

We identified one study of diagnostic accuracy of the pelvic examination for the detection of bacterial vaginosis that reported a sensitivity of 69% and specificity of 93%. However this study included both symptomatic and asymptomatic women and had a high prevalence of bacterial vaginosis. Furthermore, the clinical significance of this diagnosis is uncertain.

Key Question #2. What are the benefits (reduced mortality and morbidity) and harms (overdiagnosis, over-treatment, diagnostic procedure-related) of the routine screening pelvic examination performed for the detection of malignancy, PID, or other benign gynecologic conditions?

Benefits

Ovarian Cancer

We identified no studies that evaluated the mortality and morbidity benefits of the routine pelvic examination (specifically the bimanual examination) as a screening test for ovarian cancer in asymptomatic average risk women. Indeed the bimanual examination was not included as a screening modality in either of the 2 large contemporary trials of ovarian cancer screening. In the Prostate Lung Colorectal and Ovarian cancer (PLCO) study, a randomized controlled trial of over 78,000 women aged 55 to 74 years followed for a median of 12.4 years, the bimanual exam was initially included in the screening protocol but was dropped after 5 years because no cancers were detected solely by this examination. The second screening trial, the United Kingdom Collaborative Trial for Ovarian Cancer Screening (UKCTOCS), does not include pelvic examination in its screening protocol. This study of 202,638 post-menopausal women

ages 50 to 74 years is comparing no screening, screening with annual CA-125 with transvaginal ultrasound as a second-line test, or transvaginal ultrasound and is expected to report mortality results in 2015.

Other Conditions

We identified no studies investigating the benefits of the screening pelvic examination for the diagnosis of other malignancies, PID, or other benign gynecologic conditions (e.g., ovarian cysts, fibroids)

Harms

Direct harms of the pelvic examination itself (e.g., pain, discomfort, embarrassment) are discussed under Key Questions #3. We include here harms related to false reassurance, over-diagnosis, over-treatment, or diagnostic procedure-related harms that result from findings on the pelvic examination performed in asymptomatic women. We identified no studies that directly investigated any of these harms. However, one of the studies on diagnostic accuracy of the pelvic examination for detection of ovarian cancer in asymptomatic average risk women provides some indirect evidence. In this study there were 174 abnormal screening pelvic examinations in 2000 women (8.7%). These 174 women received follow-up with either a transvaginal or transabdominal ultrasound plus a serum CA-125. Based on the results of these follow-up tests, 31 women (18%) underwent either open or laparoscopic surgery which revealed ovarian cancer in 2 women (6.5%). Thus screening pelvic examination led to unnecessary surgery in 29/2000 or 1.5% of women.

Key Question #3. What are the examination-related harms and indirect benefits of a screening pelvic examination in asymptomatic women?

Examination-related Harms

We identified 15 studies that examined women's attitudes towards and/or experiences of the routine pelvic examination: 14 surveys and 1 longitudinal cohort study. These studies included more than 13,000 women. Outcomes included fear, anxiety, embarrassment, pain, discomfort, and global assessment of the pelvic examination experience. Since all the studies used different outcome measures, it was not possible to pool the data.

The percentage of respondents endorsing fear, embarrassment, or anxiety during or in advance of the pelvic examination ranged from 10 to 80% (median 34%, 7 studies, N=10,702). The percentage endorsing pain or discomfort during the pelvic exam ranged from 11 to 60% (median 35%, 8 studies, N=4,576). Women who endorsed pain or discomfort were less likely to return for another visit.

Indirect Benefits

It has been suggested that the annual pelvic examination might serve as an incentive for women to access the healthcare care system and thereby receive recommended evidence-based preventive care. Our literature search did not identify any studies that tested this hypothesis.

Key Question #3a. Do these harms vary by patient or provider characteristics?

We looked for studies investigating factors that might moderate the association between pelvic examinations and psychological harms. Patient factors include demographics and physical traits, history of sexual trauma and/or post-traumatic stress disorder, and veteran status. Provider factors include gender and specialty.

Patient Factors

Obesity

We identified only one study that reported pelvic examination-associated psychological harms in women of varying body weights. In this study, heavier women were significantly more likely than thinner women to endorse feelings of disrespect and embarrassment during a gynecology visit.

History of Sexual Violence (SV)

We identified nine studies that investigated the association between a history of SV and experience of the pelvic examination or receipt of gynecologic services. Two of four studies found significantly higher rates of pelvic examination related pain and discomfort in women with a history of SV compared to women without a history of SV. Two of three studies found a significant association between history of SV and fear, anxiety, or embarrassment during a pelvic examination. Women with a history of SV who also had a diagnosis of PTSD had significantly more distress, fear, and embarrassment than either SV+ or SV- women without PTSD.

Provider Factors

Although studies have reported patient preferences for provider characteristics (especially gender), we identified no studies that investigated the association between provider characteristics and psychological harms.

CONCLUSION AND FUTURE RESEARCH

In conclusion, there are no data supporting the effectiveness of the screening pelvic examination (including speculum and bimanual examinations) in the asymptomatic average risk woman for any indication other than periodic cervical cancer screening. The procedure causes pain, discomfort, fear, anxiety, and/or embarrassment in about a third of women and can lead to unnecessary, invasive, and potentially harmful diagnostic procedures. Conducting a pelvic examination requires additional clinician time, especially in primary care settings, and often requires the presence of a chaperone in the examination room, thus incurring resource and opportunity costs.

The most important area for future research is development and testing of strategies to reduce inappropriate use of the pelvic examination. The implementation literature suggests that passive education alone is unlikely to be effective; a variety of strategies employed at multiple levels within the healthcare system will likely be required.

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
ACS	American Cancer Society
ASCP	American Society for Clinical Pathology
ASCCP	American Society for Colposcopy and Cervical Pathology
BMI	Body mass index
CA-125	Cancer antigen-125
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
HMO	Health maintenance organization
HPV	Human Papilloma virus
NAA(T)	Nucleic acid amplification (test)
PID	Pelvic inflammatory disease
STI	Sexually transmitted infection
SV	Sexual violence
USPSTF	United States Preventive Services Task Force
UTI	Urinary tract infection
VA	Veterans Affairs
VHA	Veterans Health Administration
WHO	World Health Organization

EVIDENCE REPORT

INTRODUCTION

BACKGROUND

The routine pelvic examination has been a usual part of preventive care for women for many decades. In 2008, 63.4 million pelvic examinations were performed in the United States.¹ Many women and providers believe that the routine pelvic exam should be included in an annual comprehensive well-woman visit.² The exam consists of inspection of the external genitalia, speculum examination of the vagina and cervix, bimanual examination (placement of two fingers into the vagina with simultaneous abdominal pressure provided by the examiner's other hand), and sometimes rectal or rectovaginal examination. Traditionally, the examination in the asymptomatic average risk women has been used to screen for pathology through palpation, visualization, and specimen collection.

Pathology potentially detectable on the pelvic examination includes malignancies (e.g., cervical, ovarian, uterine, bladder, vaginal or vulvar); infections (e.g., Chlamydia, gonorrhea, warts, candidiasis, bacterial vaginosis); pelvic inflammatory disease (PID); or other pathology (e.g., atrophic vaginitis, cervical polyps, uterine prolapse, fibroids). In addition, pelvic examinations are often performed prior to the provision of hormonal contraception.

Recent high quality evidence-based reviews and guidelines have concluded that pelvic examinations are not required for Chlamydia and gonorrhea screening^{3,4} or for hormonal contraception initiation⁵ and up-to-date evidence-based guidelines are also available for cervical cancer screening.⁶⁻⁸ However, we are unaware of any systematic reviews that have investigated the utility of the screening pelvic examination for detection of the other conditions in asymptomatic women.

Understanding the utility of this exam for these other conditions is important since the screening pelvic examination may cause anxiety, discomfort, and pain and may result in false positives, overdiagnosis, overtreatment, and diagnostic procedure-related harms. Moreover, fear of the exam could lead some women to avoid or postpone healthcare visits which might result in untreated sexually transmitted infections (STI), undiagnosed cervical cancer, unwanted pregnancy due to failure to obtain contraception, and/or failure to receive other preventive care such as blood pressure and cholesterol screening. Finally, conducting a pelvic examination requires additional clinician time, especially in primary care settings, and often requires the presence of a chaperone in the examination room, thus incurring resource and opportunity costs.

This systematic review was conducted to evaluate the benefits and harms of the routine screening pelvic examination in asymptomatic, average risk, non-pregnant, adult women. For cervical cancer and STI screening and for initiation of hormonal contraception we summarize the results of recent reviews and guidelines from major US healthcare organizations in the discussion section. For all other indications we performed a comprehensive search of the primary literature.

This review was nominated by the VHA Center for Health Promotion and Disease Prevention

and will be used to inform VHA Clinical Preventive Services Guidelines Statements on Screening for Cervical Cancer and Ovarian Cancer.

KEY QUESTIONS AND ANALYTIC FRAMEWORK

We developed the following key questions and an analytic framework (Figure 1) with input from a technical expert panel.

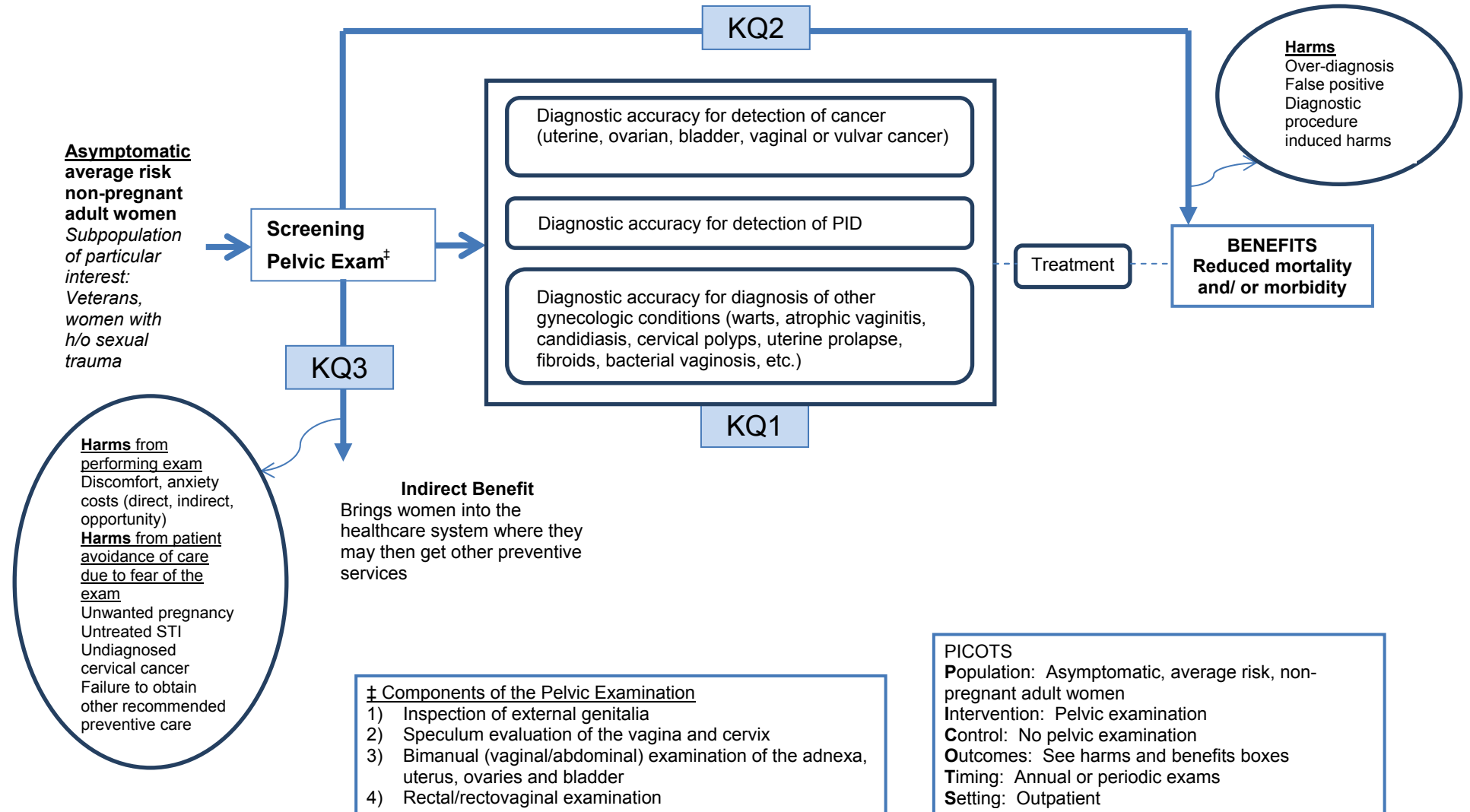
Key Question #1. How accurate is the screening pelvic exam for detection of malignancy (other than cervical), pelvic inflammatory disease (PID), or other benign gynecologic conditions?

Key Question #2. What are the benefits (reduced mortality and morbidity) and harms (overdiagnosis, over-treatment, diagnostic procedure-related) of the routine screening pelvic examination performed for the detection of malignancy (other than cervical), PID, or other gynecologic conditions?

Key Question #3. What are the examination-related harms and indirect benefits of performing a screening pelvic examination in asymptomatic women?

Key Question #3a. Do these harms vary by patient or provider characteristics?

Figure 1. Analytic Framework



METHODS

SEARCH STRATEGY

We searched MEDLINE (OVID) for articles published from 1946 through July 2013. Our search was designed to identify studies of any design other than case series or case reports. We limited the search to studies involving human subjects published in the English language. Search terms included the following Medical Subject Headings (MeSH): Gynecological Examination, Women’s Health, and Mass Screening. The full search strategy is presented in Appendix A.

To supplement our literature search, we selected nine references that we considered highly relevant to the topic (some identified in the search above, some by hand-searching). Using the “Related Citations” feature of PubMed, we identified an additional 826 English language abstracts. We also obtained additional articles from hand-searching reference lists of existing systematic reviews and pertinent studies and from suggestions by members of the Technical Expert Panel and peer reviewers.

STUDY SELECTION

Investigators and research associates trained in the critical analysis of literature assessed for relevance the abstracts of citations identified from the literature searches. We included background papers and guidelines (published within past 5 years and of high quality), clinical trials, cohort studies, or cross-sectional studies reporting diagnostic accuracy or outcomes related to the harms and benefits of pelvic examination in asymptomatic, average risk, non-pregnant women in outpatient settings. We excluded the following:

1. Studies that did not involve asymptomatic, average-risk non-pregnant adult women,
2. Studies that did not involve an outpatient screening pelvic examination for detection of malignancy, PID, or other pathology,
3. Studies that did not report harms of the pelvic exam or of avoidance of care due to fear of the pelvic exam; morbidity or mortality from pathology detectable from the pelvic exam; false positive, false negative, or over diagnosis data from the pelvic exam, and
4. Narrative reviews, opinion Papers, letters without data, case series, or case reports.

Full text reports of studies identified as potentially eligible (or indeterminate, e.g., title only) were obtained for further review using the inclusion and exclusion criteria described above. Each article was independently reviewed by two investigators or research associates. Reasons for excluding a study at full text review were noted.

DATA ABSTRACTION

Eligible studies were reviewed for outcomes of interest by investigators and research associates. Study characteristics, patient characteristics, and outcomes data were abstracted onto tables.

QUALITY ASSESSMENT

We assessed the quality of studies pertaining to key question #1 using a modification of the QUality Assessment of Studies of Diagnostic Accuracy included in Systematic reviews (QUADAS) tool.^{9,10} The eleven elements focus on patient representativeness, quality and administration of the reference (gold standard) test, quality and administration of the index test, and data analysis with each item evaluated as “yes,” “no,” or “unclear.”

For key question #3, evidence was predominantly from survey studies. There is no established instrument for evaluating the quality of survey studies. We identified the following elements as critical factors in assessing study quality.

1. Population
 - a. Is the survey population-based or was a convenience sample used?
 - b. Was the sampling structure incorporated into the analysis (e.g., weighting the analysis for oversampling)?
2. Survey instrument – Was a validated questionnaire used or were the survey questions piloted with a population similar to the population of interest?
3. Analysis of findings
 - a. Was the method for handling missing data reported and appropriate?
 - b. Were the characteristics of non-responders similar to those of responders?

Response rate was also considered although a higher response rate would be expected if a convenience sample was used. We reviewed the included studies to determine whether these factors were adequately addressed and summarized our findings.

DATA SYNTHESIS

We described and qualitatively compared the characteristics, methods, and findings of included studies. Pooled analyses of data were not possible due to limited reporting and heterogeneity of diagnostic approaches and outcomes across studies. Therefore, we summarized our findings in narrative form. We identified and highlighted findings from studies involving Veterans.

PEER REVIEW

A draft version of this report was reviewed by technical experts, as well as VA clinical leadership. Reviewer comments were addressed and our responses may be found in Appendix B.

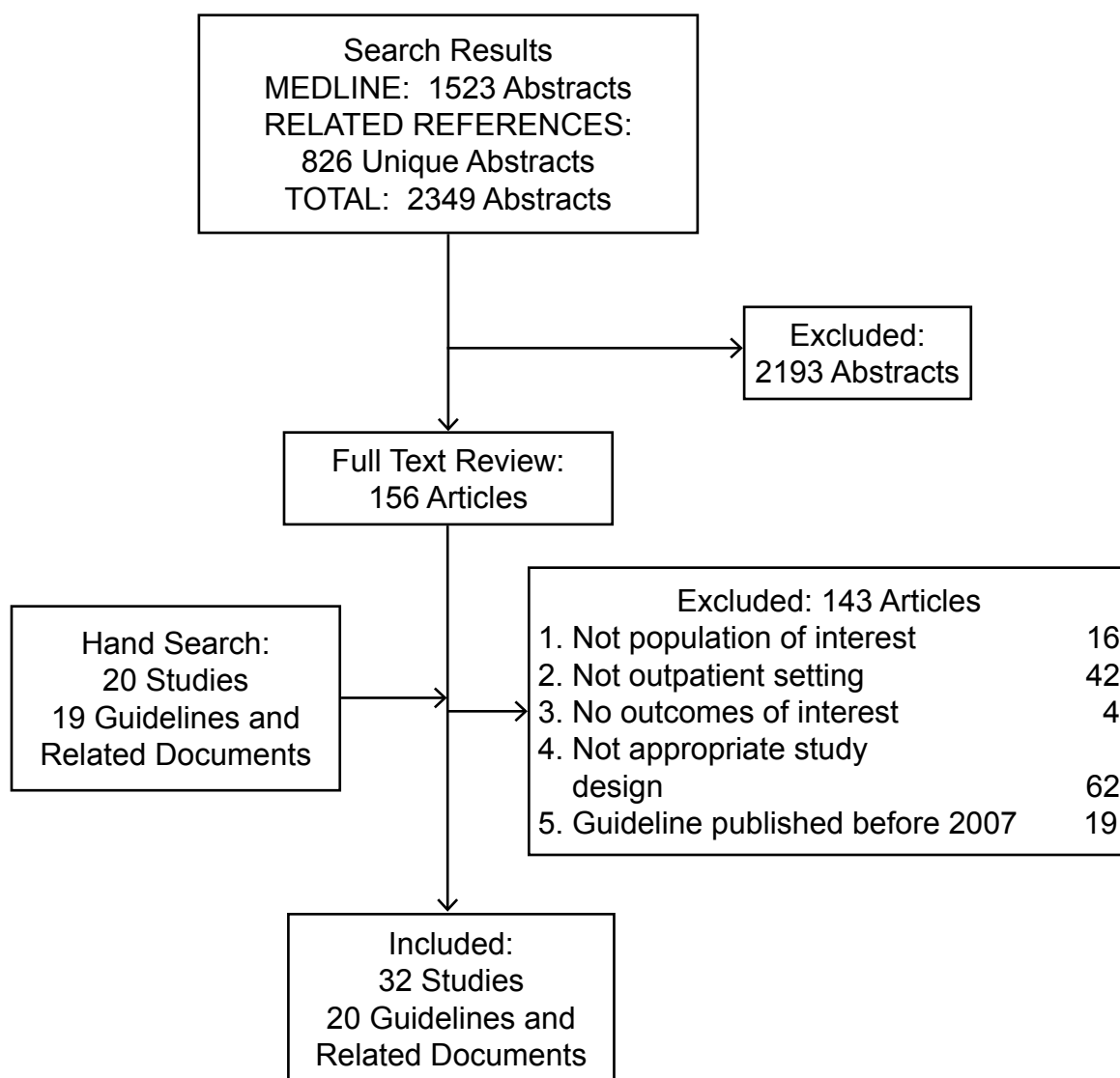
RESULTS

We identified 52 articles that met our inclusion criteria – 32 studies and 20 guidelines and related documents.

LITERATURE FLOW

From the primary literature search, we identified 1523 abstracts. From the “Related Citations” literature search, we identified 826 unique abstracts for a total of 2349 abstracts. We excluded 2193 abstracts and reviewed the full text of 156 references. We excluded 143 articles during full text review leaving 13 eligible for inclusion. An additional 39 references were identified by hand-searching pertinent trials and related systematic reviews or were suggested by members of the Technical Expert Panel or peer reviewers. Figure 2 details the process.

Figure 2. Literature Flow



KEY QUESTION #1. How accurate is the screening pelvic examination for the detection of malignancy (other than cervical), pelvic inflammatory disease (PID), or other benign gynecologic conditions?

A diagnostic accuracy study should include an appropriate population, use a definitive gold standard test, and perform the screening and gold standard tests in all participants (p 275).¹¹ For this review, an appropriate population is defined as asymptomatic average risk women. Ovarian cancer and bacterial vaginosis were the only conditions for which we found diagnostic accuracy studies conducted in asymptomatic average risk women.

Accuracy of the Pelvic Examination for Detection of Ovarian Cancer

Assessing the diagnostic accuracy of the pelvic examination for detection of ovarian cancer is problematic because the definitive gold standard is a pathologic diagnosis of cancer made on a surgical specimen and ethical concerns arise regarding performing biopsies in people with normal physical examinations or normal follow-up imaging studies (e.g., transvaginal or trans-abdominal ultrasound). The other option, employed in the 3 studies below, is to follow all women with normal pelvic examinations to assess the subsequent incidence of cancer and assume that within a given period of time (e.g., within one year) these cancers were present but missed at the time of the pelvic examination (false negatives). Therefore, while it is reasonable to expect researchers to conduct studies to assess the true and false positive rates (and positive predictive value) of the pelvic examination (as definitive testing is clinically indicated pursuant to an abnormal pelvic exam) it is unlikely that there will be any definitive studies assessing the true and false negative rates (and negative predictive value).

We identified 3 cohort studies that investigated the value of the pelvic examination for the detection of ovarian cancer in asymptomatic average risk women (Table 1).¹²⁻¹⁴ These three studies assembled an appropriate population and used a definitive gold standard test (biopsy results) but did not perform that test in all participants. Since the gold-standard test was not performed in all patients, sensitivity and specificity cannot be calculated. We therefore report only positive predictive values.

- Grover et al. screened 2623 healthy, asymptomatic women (mean age 51 years), with pelvic examination and serum cancer antigen (CA)-125 measurement.¹² Forty women had adnexal abnormalities on pelvic examination (1.5%). All abnormalities were determined to be benign on further investigation and no cases of ovarian cancer developed in these 40 women during the 1 year follow-up. Therefore, the positive predictive value of the pelvic exam for ovarian cancer was 0%. The positive predictive value of the pelvic examination for *benign* abnormalities including dermoid cysts, endometriosis, simple cysts, cystadenoma, or fibromas was 22%.¹²
- Jacobs et al. screened 1010 healthy, asymptomatic, post-menopausal women (median age 54 years), with pelvic examination and serum CA-125 measurement.¹³ If either of these was abnormal a transabdominal ultrasound was performed within 4 weeks. If the ultrasound was normal women were followed for one year with ultrasounds and serum CA-125s every 3 months. If the ultrasound was abnormal the woman was referred to her primary care physician for further consultation. Adnexal abnormalities were present

on pelvic examination in 28 women (2.8%). In these 28 women, 1 case of ovarian cancer was diagnosed at laparotomy resulting in a positive predictive value of 3.6% for the pelvic examination alone. The addition of the CA-125 did not change the positive predictive value of the pelvic examination alone because among the 28 women with abnormal pelvic examination, the CA-125 was elevated in only the one case of ovarian cancer.¹³

- Adonakis et al. screened 2000 healthy, asymptomatic women aged 45 years or older (mean age 58.1 years), with pelvic examination and CA-125 measurement.¹⁴ If either of these was abnormal a transvaginal ultrasound was performed. If the ultrasound was normal the women were followed for one year with ultrasound and CA-125 every 3 months. Women who had an abnormal ultrasound were referred for “further management.” One hundred and seventy four women had abnormal or ambiguous pelvic examinations. In these 174 women, 2 cases of ovarian cancer were diagnosed at laparotomy resulting in a positive predictive value of 1.2% for the pelvic examination alone. The positive predictive value of an abnormal or ambiguous pelvic exam PLUS an elevated CA-125 was 2/12 (17%).¹⁴

Accuracy of the Pelvic Examination for Detection of Bacterial Vaginosis

We identified one study of bacterial vaginosis that included asymptomatic women, used a definitive gold standard test, and performed the screening and gold standard tests in all participants.¹⁵ The screening test evaluated, known as the Amsel criteria, were the following characteristics of vaginal secretions obtained by swab during the pelvic examination: thin, homogeneous consistency; pH greater than 4.5; presence of clue cells on microscopic evaluation; and release of amine odor following the addition of a base (whiff test). The presence of 3/4 of these criteria is generally considered diagnostic of bacterial vaginosis.¹⁶ The gold standard was Gram’s stain. The study was a prospective observational study of 269 women undergoing a pelvic examination at a University-based clinic in Rhode Island. Sixty seven percent of women were asymptomatic. The prevalence of bacterial vaginosis by Gram’s stain was 39%. The sensitivity and specificity of the Amsel criteria were 69% and 93% respectively.

Since this study included both symptomatic and asymptomatic women in whom the prevalence of bacterial vaginosis was higher than generally reported, the results may not be applicable to the average risk asymptomatic population that is the focus of this review.

Table 1. Prospective Cohort Studies of Diagnostic Accuracy of the Screening Pelvic Examination for Detection of Ovarian Cancer in Asymptomatic, Average-Risk Women

Author, Year Country	Reference Standard	Population	Findings	One Year Incidence of Ovarian Cancer n/N (%)	Positive Predictive Value	Harms		Study Quality (# of QUADAS Elements Met*)
						Abnormal Pelvic Exams	Laparoscopic or Open Surgery	
Adonakis 1996 ¹⁴ Greece	Surgery and histology	N=2000 Age 45 and older with no evidence of adnexal pathology Mean age: 58 years (45 to 80)	Abnormal pelvic exam: 59/2000 (3.0%) Ovarian cancer if abnormal exam: 1/59 (1.7%) Ambiguous pelvic exam: 115/2000 (5.8%) Ovarian cancer if ambiguous exam: 1/115 (0.9%)	2/2000 (0.10%)	1.2%	174	31	8
Grover 1995 ¹² Australia	Surgery	N=2623 Healthy, asymptomatic Mean age: 51 years (25 to 92)	Abnormal adnexa on pelvic exam: 40/2623 (1.5%) Ovarian disease: 9/40 (PPV=22%) (all benign) One cancer case reported at 12 month follow-up [†]	1/2623 (0.04%)	0% [‡]	40	NR	8
Jacobs 1988 ¹³ United Kingdom	Surgery and histology	N=1010 Healthy, age 45 and older, amenorrheic for >12 months Median age: 54 years (45 to 83)	Abnormal pelvic exam: 28/1010 (2.8%) Ovarian cancer if abnormal exam: 1/28 (3.6%) No additional cancer cases at 12 month follow-up	1/1010 (0.10%)	3.6%	28	NR [§]	8

NR = Not Reported

*All studies were rated identically on the 11 QUADAS elements. (Reitsma 2009)⁹ 1) Representativeness: Yes; 2) Acceptable reference standard: Yes; 3) Acceptable delay between tests: Yes; 4) Whole or random sample verification: No; 5) Same reference standard: No; 6) Reference test independent of index: Yes; 7) Index test results blinded: No; 8) Reference standard blinded: Yes; 9) Relevant clinical information available: Yes; 10) Uninterpretable results reported: Yes; 11) Withdrawals explained: Yes

[†]All women were sent a questionnaire at 1 year follow-up; the response rate was 83%

[‡]No cases of ovarian cancer were detected in women with an abnormal pelvic examination

[§]13 women with abnormal ultrasound findings were advised to consult their general practitioner for possible referral to a gynecologist

^{||}Follow-up included CA-125 and ultrasound if initial testing was abnormal or a postal questionnaire if initial testing was normal

Summary

We identified no studies of diagnostic accuracy of the pelvic examination for ovarian cancer that applied the gold standard test to all patients; thus, true sensitivity and specificity cannot be determined. However, the positive predictive value of the pelvic examination alone for the detection of ovarian cancer in asymptomatic women in the reviewed studies was low (1.2-3.6%).

We identified one study that evaluated the accuracy of the Amsel criteria for diagnosing bacterial vaginosis. The sensitivity and specificity were 69% and 93%, respectively. Since this study included both symptomatic and asymptomatic women in whom the prevalence of bacterial vaginosis was higher than generally reported, the results may not be applicable to the average risk asymptomatic population that is the focus of this review.

We identified no studies that assessed the diagnostic accuracy of the pelvic examination for PID, other gynecologic cancers, or benign conditions.

KEY QUESTION #2. What are the benefits (reduced mortality and morbidity) and harms (over-diagnosis, over-treatment, diagnostic procedure-related) of the routine screening pelvic examination performed for the detection of malignancy, PID, or other benign gynecologic conditions?

Benefits

Ovarian Cancer

We found no studies that assessed the benefits (reduced mortality or morbidity) of routine pelvic examinations for the detection of ovarian cancer in asymptomatic average risk women. Although labeled as screening studies, the three year-long cohort studies discussed under Key Question#1 were not designed to evaluate the effect of screening on ovarian cancer-related morbidity or mortality outcomes.¹²⁻¹⁴

In 2012 the USPSTF stated that there is “at least moderate certainty that harms of screening for ovarian cancer outweigh the benefits.” The screening modalities evaluated were transvaginal ultrasonography and testing for the serum tumor marker CA-125. The report comments that there are no randomized clinical trials assessing the role of the pelvic exam for cancer screening and that the pelvic examination was not a focus of its review.¹⁷ A complete discussion of screening for ovarian cancer with modalities other than the pelvic examination is included in the discussion section, below.

Other Malignancies

We found no studies that assessed the benefits of routine pelvic examinations for the detection of uterine, bladder, vaginal or vulvar cancer in asymptomatic average risk women.

PID and Other Benign Gynecologic Conditions

We found no studies that assessed the benefits of screening asymptomatic women with routine

pelvic exams for PID, fibroids, warts, atrophic vaginitis, or any other gynecological condition.

Harms

Direct harms of the pelvic examination itself (e.g., pain, discomfort, embarrassment) are discussed under Key Question #3. We include here harms related to false reassurance, over-diagnosis, over-treatment, or diagnostic procedure-related harms that result from findings on the pelvic examination performed in asymptomatic women. We identified no studies that directly investigated any of these harms. However, one of the studies on diagnostic accuracy of the pelvic examination for detection of ovarian cancer in asymptomatic average risk women provides some indirect evidence, as shown in Table 1.¹⁴ In this study there were 174 abnormal screening pelvic examinations in 2000 average risk asymptomatic women (8.7%). These 174 women received follow-up with either a transvaginal or transabdominal ultrasound plus a serum CA-125. Based on the results of these follow-up tests, 31 women (18%) underwent either open or laparoscopic surgery which revealed ovarian cancer in 2 women (6.5%). Thus screening pelvic examination led to unnecessary surgery in 29/2000 women or 1.5% of women.

Summary

We identified no studies that evaluated the benefits and harms of the routine pelvic examination as a screening test for ovarian cancer in asymptomatic average risk women. Indirect data suggest that such screening would lead to unnecessary surgery for 1.5% of women screened. We identified no studies investigating the benefits of the screening pelvic examination for the diagnosis of other malignancies, PID, or other benign gynecologic conditions.

KEY QUESTION #3. What are the examination-related harms and indirect benefits of performing a screening pelvic examination in asymptomatic women?

Harms

The pelvic examination includes insertion of a speculum and examiner fingers (for a bi-manual examination) into the vagina. Anticipating and undergoing such an examination may cause psychological harms (fear, anxiety, embarrassment, pain, discomfort).

Although physical harms (urinary tract infections and symptoms such as dysuria, and frequency) have been reported by one investigator group, these results should be interpreted with caution given substantial methodological weaknesses including inadequate control for confounding and incomplete follow-up.^{18,19} Hypothesized mechanisms include microtrauma, alteration of normal flora, or inoculation of the urinary tract with vaginal flora from insertion of the speculum and examiner fingers and use of lubricant.

Psychological Harms (Fear, Anxiety, Embarrassment, Pain or Discomfort)

We identified 15 studies that examined women's attitudes toward and/or experiences of the routine pelvic examination; 14 surveys²⁰⁻³³ and 1 longitudinal cohort study (Table 2).³⁴ Nine were conducted in the US, two in Sweden, and one each in Jamaica, England, Scotland, and New Zealand. Median sample size was 409 (range: 40 to 7168). Generally the studies included

only women in their reproductive years. In three of the nine US studies, ethnic and racial minorities were well represented.^{27,28,34} Reported outcomes were diverse, including fear, anxiety, embarrassment, pain, discomfort and global assessment of the pelvic examination experience. Since all the studies used different outcome measures, it was not possible to pool the data. Five studies reported the association between psychological harms and self-reported adherence to return gynecologic visits or Pap smears.^{21,23,27,28,34} Three of these used multivariable analysis.^{27,28,34}

The overall quality of the studies was low. Most studies enrolled a convenience sample (i.e., women attending family planning, primary care or other clinics). Five were population based^{22-24,27,28} and three of these recruited a random sample of the population.^{22,24,28} One study developed the survey instrument based on focus group responses;²⁷ three studies reported pre-testing or piloting the instrument.^{25,28,29} Although the cohort study compared characteristics of participants who stayed in the study with those who were lost to follow-up,³⁴ none of the survey studies provided a comparison of responders and non-responders.

Table 2. Pelvic Examination-related Psychological Harms: Frequency and Impact (k=15)

Study/Date/Type	Population/Setting/N (Response Rate)	Psychological Harms			Impact on Return Visits
		Fear, Anxiety, Embarrassment	Pain, Discomfort	Global Assessment	
Osofsky, 1967 ²⁶ Survey	N=40 (RR not reported) Single clinic in US Ages 20 to 39 years	Anxiety: 32/40 (80%)			
Hesselius, 1975 ²³ Survey	N=800 (RR 88%) Population-based in Sweden Women invited to mass screening Ages 21 to 49 years	25% said “exam was not at all unpleasant”	74% said exam “not at all painful”		MVA: No Participants in screening were less likely than non-participants to endorse “unpleasantness” of the exam although it is unclear if this finding was statistically significant
Haar, 1977 ³² Survey	N=409 (RR not reported) Multiple clinics in New York Ages “under 20 to over 60” years	34% endorsed moderate or severe anxiety before a visit to the gynecologist; a similar % endorsed these same feelings about general medical check-ups.			
Petravage, 1979 ³³ Survey	N=977 (RR not reported) 14 clinics in Utah No age restrictions, median age 28.4 years		45% “felt comfortable during a pelvic examination”		
Golomb, 1983 ²⁰ Survey	N=61/70 (RR 87%) 2 clinics in Rhode Island Ages 18 or older			86% reported that pelvic examinations are “not all that bad”	
Broadmore, 1986 ³¹ Survey	N=199/250 (RR 80%) Family planning clinic in New Zealand “mostly aged 17 to 30” years		60% reported some pain or discomfort during the examination		
Wijma, 1998 ²⁴ Survey	N=531/788 (RR 67%) Population-based in Sweden Ages 25 to 49 years		Among women who were ≤19 years old at first pelvic exam, 71% reported that it was painful	75% rated the pelvic examination as ≥ 46 on a scale of 0 (very negative) to 100 (very positive)	
Yu, 1998 ³⁰ Survey	N=650 (RR not reported) Had a Pap smear (Pap +: N=523) Did not have a Pap smear (Pap -: N=127) 2 hospital-based clinics in London Ages 15 to 75 years	Pap +: 15% embarrassing Pap -: 13% embarrassed	Pap +: 11% painful Pap -: 4% painful	Pap +: 3% troublesome Pap -: 12% troublesome; 13% scared	

Study/Date/Type	Population/Setting/N (Response Rate)	Psychological Harms			Impact on Return Visits
		Fear, Anxiety, Embarrassment	Pain, Discomfort	Global Assessment	
Harper, 2001 ²¹ Telephone Survey	N=800 (RR not reported) Low-income residents of California Ages 18 to 44 years	75% endorsed fear and embarrassment			No statistical analysis done 31% said feelings of fear and embarrassment had prevented them from getting a pelvic exam at some time
Fiddes, 2003 ²⁹ Survey	N=687/1000 (RR 69%) Family planning or sexual health clinics in Scotland Age: 8% ≤ 20, 50% 21-40, 42% >40 years	10% feel anxious or distressed at the prospect of a pelvic examination		Older women and women who had been pregnant were significantly and independently less likely to “feel negative towards pelvic examination”	
Kahn, 2003 ³⁴ Cohort Study	N=490 Urban hospital in Cincinnati Ages 12 to 24 (44% < 18 years) 44% black; 24% hispanic		61% believed Pap would not be painful		MVA: yes <u>Lack of pain</u> associated with return visit (OR 1.73, 95% CI: 1.08 to 2.83) <u>Embarrassment</u> not significantly associated with return visit These outcomes did not differ by race/ethnicity.
Taylor, 2004 ²⁸ Survey	N=370/449(RR 82%) Population-based in Seattle Ages 18 to 64 years All Vietnamese-American		31% endorsed pain		MVA: yes Concern about pain and discomfort was NOT a significant barrier to Pap testing (OR 0.5, 95% CI: 0.3 to 1.1)
Hoyo, 2005 ²⁷ Survey	N=144/172 (RR 84%) Population-based, Durham, NC Ages 45 to 64 years		24% endorsed pain		MVA: yes Pain associated with Pap non-adherence (OR 4.8, 95% CI: 1.7 to 13.7)
Bourne, 2010 ²² Survey	N=7168 Population based, Jamaica Ages 15 to 49 years	Among the 57% who had never had a pelvic exam, 0.5% endorsed embarrassment as the reason		Among the 57% who had never had a pelvic exam, 1.4% said the reason was they did “not like the process” 0.1% did “not like the environment”	
Armstrong, 2012 ²⁵ Survey	N=148/635 (RR 23%) Planned Parenthood Clinic in Virginia Ages 18 to 27 years	17% endorsed fear 16% endorsed embarrassment			

RR = response rate; MVA = multivariable analysis; OR = odds ratio; CI = confidence interval

The percentage of women endorsing pain or discomfort during the pelvic exam ranged from 11 to 60% (median 35%; 8 studies, N=4576). The percentage endorsing fear, embarrassment, or anxiety ranged from 10 to 80% (median 34%; 7 studies, N=10,702). One study reported that women were more likely to report pain at their first (71%) compared to their last (33%) examination.²⁴ Similarly, another study reported that older age and previous pregnancy were both independently associated with less negative feelings towards the pelvic examination.²²

All five studies that examined the relationship between pelvic-examination pain or discomfort and return visits, reported that women who endorsed pain or discomfort were less likely to return for another visit. The three studies that used multivariable statistical analysis are described here. In the largest and most methodologically rigorous of these, Kahn et al. found that women who had not experienced pain were 73% more likely to return for another examination than those who had experienced pain (OR 1.73, 95% CI 1.08 to 2.83, N=490).³⁴ In the smallest study conducted in middle-aged African American women, the perception of pain on a Pap test was significantly associated with non-adherence to future tests (OR 4.8, 95% CI 1.7 to 13.7, N= 144).²⁷ The third study of exclusively Vietnamese American women (N=370) reported that only 55% of women who endorsed pain or discomfort had a Pap smear in the previous 3 years compared with 74% of those who did not endorse pain or discomfort (P<0.001). This association remained significant in multivariable analysis (OR and 95 % CI not reported).²⁸ One of these studies also examined the association between embarrassment and return visits and found that embarrassment was not significantly associated with likelihood of return visit.³⁴

Summary of Psychological Harms

We identified 15 studies of more than 13,000 women conducted in 6 countries that reported psychological harms. The percentage endorsing fear, embarrassment, or anxiety ranged from 10 to 80% (median 34%, 7 studies). The percentage of women endorsing pain or discomfort during the pelvic exam ranged from 11 to 60% (median 35%, 8 studies). Women who endorsed pain or discomfort were less likely to return for another visit than those who did not experience pain or discomfort.

Indirect Benefits

It has been suggested that the annual pelvic examination might serve as an incentive for women to access the healthcare care system and thereby receive recommended gynecologic services such as contraception, screening for STIs and cervical cancer and other non-gynecologic preventive care including immunizations, blood pressure, weight and cholesterol measurement, colon cancer screening, and risk factor assessment and counseling.³⁵ Our literature search did not identify any studies that tested this hypothesis. Indeed, as discussed above, fear or anxiety about the pelvic exam is associated with lower compliance with visits for Pap smears.

KEY QUESTION #3A. Do these harms vary by patient or provider characteristics?

We looked for studies investigating factors that might moderate the association between pelvic examinations and harms. Patient factors include demographics and physical traits, history of sexual trauma and/or post-traumatic stress disorder, and veteran status. Provider factors include gender and specialty. The only harms for which we found data were psychological harms

Patient Factors

Obesity

We identified one study that reported pelvic examination-associated psychological harms in women of varying body weights³⁶ and one that evaluated weight as a predictor of return visits.³⁷ The quality of both studies was low. Both enrolled a convenience sample and in one study³⁶ there was no adjustment for oversampling. One study used a survey instrument developed based on focus group data;³⁶ the other study provided no information about the development of the survey instrument.³⁷ Neither study provided information on whether non-responders were similar to responders.

A community-based study of attitudes and behavior related to gynecologic care in California surveyed 498 overweight women (response rate not reported) purposefully selected to include a high percentage of African Americans (32%).³⁶ Ages ranged from 21 to 80 years, BMI from 25 to 122 kg/m². Over 90% had health insurance. Overall, 41% reported delaying seeking healthcare because of their weight and 52% considered their weight to be a barrier to getting appropriate healthcare. BMI was an independent and significant predictor of the patient perception that weight was a “barrier to health care” and a factor in “delay of care.” Women in the highest BMI category also had a significantly lower rate of Pap test completion in the previous 2 years compared to women with lower BMIs, after controlling for age and race. Furthermore, heavier women were significantly more likely than thinner women to endorse feelings of disrespect and embarrassment during a gynecology visit.³⁶

A community-based study in Connecticut surveyed 303 women between the ages of 40 and 65 years (response rate 96%) to determine rates and predictors of screening pelvic examinations in overweight and non-overweight women.³⁷ Sixty-six percent of the respondents were classified as average weight, 20% as moderately overweight, and 14% as very overweight. Significantly fewer very overweight women (48%) reported annual pelvic examinations than average weight (68%) or moderately overweight (67%) women. The only “attitude” investigated in this study was intention to get an exam (“reluctant”, “they are routine”, and “I schedule them annually”) which was highly correlated with actual behavior.³⁷ This study did not investigate possible harms of the pelvic examination such as fear, embarrassment, anxiety, pain or discomfort.

History of Sexual Violence (Table 3)

We identified nine studies (eight with a control group), that focused on women with a history of sexual violence (SV). Two were from Europe and seven from the US. Five of the US studies were conducted in the VA, three of these at a single VA medical center.³⁸⁻⁴⁰ Outcomes included psychological harms only (k=6), self-reported utilization of gynecologic care only (k=3), or both (k=2).^{41,42} Eight of the nine studies were cross-sectional survey studies^{38-40,42-46} and one was a case-control study.⁴¹ The two studies by Weitlauf also evaluated the effect of PTSD on the pelvic examination experience.^{39,40}

Overall, the studies were of low quality. Most enrolled a convenience sample with only two being population-based and studying a random sample of the population.^{43,44} In six studies, the survey or interview tool was either validated (five studies)^{38,39,43-45} or piloted (1 study).⁴² One study reported using only complete surveys;⁴¹ no other study commented on missing data.

Characteristics of responders and non-responders were reported in one study.⁴⁰ Another study compared responders to the general clinic population.⁴⁶

In the 8 studies that included a control group, outcomes included pain and discomfort (k=4), fear, anxiety, or embarrassment (k=3), and receipt of gynecologic services (k=5). Two of the 4 studies reporting pain and discomfort found significantly higher rates in women with a history of SV compared to women without a history of SV; in the other 2 studies there was no difference. Two of the 3 studies reporting fear anxiety or embarrassment found that women with a history of SV were significantly more likely to endorse these emotions than women without a history of SV.

A survey study of 94 women (response rate 72%) from a single VA medical center, reported that women with a history of SV who also had symptoms of PTSD reported significantly more pelvic examination-related distress than women without PTSD.³⁹ A second study from the same group (N=165, response rate 55%) reported significantly higher median scores for fear, embarrassment, and distress in women who had a history of SV and a diagnosis of PTSD than in women without PTSD, irrespective of their SV history.⁴⁰ In both studies, levels of reported pain did not differ between women with and without a history of SV.

Five studies assessed receipt of gynecological services.^{41-44,46} Three were population-based,⁴²⁻⁴⁴ one enrolled primary care patients at a VA,⁴⁶ and one was a case-control study from Germany.⁴¹ The findings in these five studies were inconsistent, with two finding decreased utilization in women with a history of SV, two finding no difference, and one finding increased utilization in women with a history of SV. The methodologically strongest of these studies was the analysis of data from the Behavioral Risk Factor Surveillance System, a population-based telephone survey of a nationally representative US sample.⁴⁴ In this study of 35,048 women the prevalence of self-reported sexual violence was 15%. The percentage of women 18 or older reporting a Pap test within the prior 3 years did not differ between women with and without a history of SV (85.6% v. 84.3%, P=0.32)

Provider Factors

We identified no studies that investigated the association between provider characteristics and psychological harms.

Table 3. History of Sexual Violence (SV) as a Predictor of the Pelvic Examination Experience and Receipt of Pap Smears (k=9)

Study/Year/Design	Population/Setting	Predictors	Outcomes	Findings
Lee, 2007 ³⁸ In-person survey, no control group	N=31/46 (Response Rate 67%) SV+ female veterans VA clinic	PTSD	Anticipated PE-related distress	No association between PTSD symptom severity and anticipated PE-related distress
Weitlauf, 2008 ³⁹ Survey (immediately after routine PE)	N=68/94 (Response Rate 72%) Female veterans 77% SV+ 22% PTSD 18 to 65 years VA clinic	SV PTSD (current)	Distress Pain Both measured on Likert scales, 0-10	<u>Distress (median)</u> SV+ 4.27 SV- 0 P=0.03 <u>Pain (median)</u> SV+ 2.5 SV- 0 P=0.04 SV+ women with PTSD had significantly increased distress (but not pain) compared to women without PTSD (either SV+ or SV-) (P=0.02)
Weitlauf, 2010 ⁴⁰ Survey	N=90/165 (Response Rate 55%) SV-, no PTSD: 17 SV+, no PTSD: 48 SV+ and PTSD: 22 Female veterans 18 to 65 years VA clinic	SV PTSD (current)	Fear Embarrassment Distress Pain Each measured on Likert scales	Median scores for fear, embarrassment, and distress were significantly higher in the SV+ plus PTSD group than the SV-, no PTSD group (Ps <0.005) and the SV+ no PTSD group (Ps <0.001)
Hilden, 2003 ⁴⁵ Mailed Survey (1 week following PE)	N=808/1,011 (Response Rate 80%) 165 SV+ Age ≥18 years Denmark University hospital clinic	SV	Discomfort	On multivariate analysis, SV+ women were significantly more likely to report discomfort than SV- women (OR 1.85, 95% CI: 1.19 to 2.87)
Robohm, 1997 ⁴² Mailed survey	N=74 (Response Rate: NR) SV+ 44 SV- 30 population-based, small mid-western US city	SV	Distress Physical pain, discomfort Receipt of gynecological care Embarrassment, shame, fear	<u>Distress</u> : significantly higher in SV+ than SV- (P<0.01) <u>Physical pain or discomfort</u> : no significant difference SV+ significantly less likely to <u>seek regular gyn care</u> (P<0.05) All 3 significantly higher in SV+ than SV- (P<0.05, 0.01, 0.05, respectively)
Leeners, 2007 ⁴¹ Case-control, Mailed survey	N=255 (Response Rate: NR) SV+ 85 SV- 170 Germany	SV	% endorsing assumption "that a visit to the GYN would cause an important psychological strain" Receipt of gynecologic services	SV+ 37.7 SV- 3.5 P<0.0001 No significant difference in self-reported receipt of GYN services

Study/Year/Design	Population/Setting	Predictors	Outcomes	Findings
Farley, 2002 ⁴³ Mailed survey	N= 364/1,314 w/ Pap test in prior 2 yrs; 372/2897 without (Response Rate 17%) Age 21 to 64 years SV+ 26% HMO in California	SV	Receipt of Pap test in past 2 years	On multivariate analysis, SV was associated with a significantly lower odds of Pap smear receipt in past 2 years (OR 0.56, 95% CI: 0.34 to 0.91)
Lang, 2003 ⁴⁶ Mailed survey	N=221/419 (Response Rate 56%) Mean age 46.6 SV+ 96 SV- 122 Primary care clinic at San Diego VA	SV	Mean number of Pap tests in past 5 years	SV+ 4.5 (SD 2.5) SV- 3.8 (SD 2.0) P<0.05
Watson-Johnson, 2012 ⁴⁴ Telephone survey (Behavioral Risk Factor Surveillance System)	N=35,048 women (Response Rate: NA) SV+ 5,404 SV- 29,644 US population based	SV	% of women age ≥ 18 with Pap test within prior 3 yrs	SV+ 85.6 (SE 1.2) SV- 84.3 (SE 0.5) P=0.32

NR = not reported; PTSD = post traumatic stress disorder; PE = pelvic examination; SV = sexual violence; VA = Veterans Affairs; OR = odds ratio; CI = confidence interval; SD = standard deviation; HMO = health maintenance organization

Summary

Women who are very overweight may be less likely than other women to get Pap tests, possibly due to feelings of embarrassment (2 studies).

We identified nine studies that investigated the association between a history of sexual violence (SV) and experience of the pelvic examination or receipt of gynecologic services. Two of four studies found significantly higher rates of pelvic examination related pain and discomfort in SV+ women compared to SV- women. Two of three studies found a significant association between history of SV and fear, anxiety, or embarrassment during a pelvic examination. Among the five studies reporting receipt of gynecologic services, two found increased utilization, two found decreased utilization, and one (the methodologically strongest) found no difference in utilization between women with and without a history of SV. Women with a history of SV who also have a diagnosis of PTSD have significantly more distress, fear, and embarrassment than either SV+ or SV- women without PTSD (2 studies).

SUMMARY AND DISCUSSION

INTRODUCTION

This systematic review was conducted to evaluate the benefits and harms of the routine screening pelvic examination in asymptomatic average risk non-pregnant adult women. Our primary conclusion is that there are no data indicating that the performance of the routine pelvic examination in asymptomatic average risk women reduces morbidity or mortality from any condition other than cervical cancer. For cervical cancer the recommended examination is visual inspection of the cervix and cervical swabs for cancer and HPV. Nevertheless pelvic examinations in asymptomatic women are often performed even when cervical cancer screening is not required. Commonly cited indications are to screen for ovarian cancer, prior to prescribing hormonal contraception, to detect sexually transmitted infections or other pathology, or simply as part of the well-woman exam.^{2,47}

In this review we summarize the results of recent reviews and guidelines from major US health organizations for cervical cancer and sexually transmitted infections (i.e., Chlamydia and gonorrhea) screening and for initiation of hormonal contraception. For all other indications we performed and report results from a comprehensive search of the medical literature.

CERVICAL CANCER SCREENING

During the speculum examination, cervical swabs for human Papillomavirus infection and for cervical cancer (Pap smears) may be obtained. According to the United States Preventive Services Task Force (USPSTF), Pap smears should be performed every 3 years in average risk women with a cervix who are 21 to 65 years old; or every 5 years in women age 30 to 65 years if co-testing for human Papillomavirus testing is performed (Grade A Recommendation, i.e., USPSTF recommends the service; high certainty that the net benefit is substantial). Average risk is defined as absence of personal history of cervical cancer or high-grade precancerous cervical lesion, *in utero exposure* to diethylstilbestrol, or immunocompromised status.⁶

Pap smears should not be performed in the following circumstances (all Grade D recommendations, i.e. USPSTF recommends against the service; moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits): women under 21 years of age, even if sexually active; women over 65 years of age who have had adequate and negative prior screening and are not otherwise at high risk for cervical cancer; women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (cervical intraepithelial neoplasia, grade 2 or 3) or cervical cancer.⁶

Similar recommendations have been issued by the Centers for Disease Control and Prevention, American College of Obstetricians and Gynecologists (ACOG), the American Cancer Society (ACS), the American Society for Clinical Pathology (ASCP), and the American Society for Colposcopy and Cervical Pathology (ASCCP).^{7,8,48}

SCREENING FOR CHLAMYDIA AND GONORRHEA

Chlamydia and gonorrhea are common sexually transmitted infections (STIs) that are often asymptomatic. These infections can cause serious complications in women including PID, infertility, and increased risk of ectopic pregnancy. Clinical trials have demonstrated that screening of high risk populations for Chlamydia reduces incidence of PID^{49,50} and many professional organizations, and the USPSTF, endorse such screening for all sexually active, non-pregnant women 24 years of age or younger and older women at increased risk.^{3,51-53} Sexually active pregnant or non-pregnant women of any age who are at increased risk should be screened for gonorrhea.⁵³ The USPSTF is currently in the process of updating its recommendations for screening for gonorrhea and Chlamydia (<http://www.uspreventiveservicestaskforce.org/uspstf/uspschlm.htm#update>).

Although screening for Chlamydia and gonorrhea traditionally required a speculum examination to obtain endocervical samples, newer assays achieve high diagnostic accuracy with self-obtained specimens. For Chlamydia, nucleic acid amplification tests (NAATs) perform well (i.e., high specificity and sensitivity) on either self-collected vaginal swabs or urine⁵⁴ and are endorsed by the USPSTF.^{3,55} For gonorrhea, NAA testing of self-collected vulvovaginal swabs is equivalent to NAA testing of clinician obtained endocervical samples;⁵⁶ this test may not have adequate sensitivity for gonorrhea detection when performed on urine samples.⁵⁵

Studies have shown that women of all ages, of varying education levels, and of diverse ethnic and racial groups are easily able to self-collect vaginal samples. Furthermore, these self-obtained samples are comparable to those obtained by clinicians and, most importantly, women prefer this to the more invasive speculum examination.⁵⁷⁻⁵⁹ Reflecting the widespread acceptance of this non-invasive screening strategy for sexually transmitted infections, ACOG recently issued an opinion stating that “NAA testing on urine samples or vaginal swab specimens is now an acceptable form of screening for gonorrhea and chlamydial infection.”²

Current screening recommendations for Chlamydia and gonorrhea as well as for other sexually transmitted infections diagnosed by blood tests (human immunodeficiency virus, syphilis, and hepatitis B) are shown in Appendix C.

PRIOR TO INITIATING HORMONAL CONTRACEPTION

In the mid 1990’s several professional organizations, including the World Health Organization and ACOG, published recommendations stating that routine pelvic examinations were not required prior to prescribing hormonal contraception for healthy asymptomatic women (summarized in Stewart, 2001).⁵ These women require only a medical history and a blood pressure measurement to rule out contraindications to birth control pills.⁵ Nevertheless, according to a recent survey of obstetrician-gynecologists and primary care providers in the US, about a third require a pelvic examination prior to provision of oral contraceptives.⁶⁰ Other, somewhat older data indicate that fewer than 5% of practicing obstetrician-gynecologists in the US would fill a prescription for hormonal contraception unless a woman was up-to-date on cervical cancer screening.⁶¹ Requiring a pelvic examination prior to prescribing hormonal contraception may cause women, especially teen age women, to avoid or delay obtaining contraception due to fear of the exam,^{21,25} thus increasing their risk of unwanted pregnancy.

OVARIAN CANCER

We identified no studies that evaluated the mortality and morbidity benefits of the routine pelvic examination (specifically the bimanual examination) as a screening test for ovarian cancer in asymptomatic average risk women. Even under ideal circumstances (i.e., examination under anesthesia by an experienced gynecologist) and in a population with a high pre-test probability of disease (i.e., women undergoing gynecologic surgery), the bimanual examination has a sensitivity of only 28% and a positive predictive value of 64% for detection of adnexal masses.⁶²

The bimanual examination was not included as a screening modality in either of the 2 large contemporary trials of ovarian cancer screening. In the Prostate Lung Colorectal and Ovarian cancer (PLCO) study, a randomized controlled trial of over 78,000 women aged 55 to 74 years followed for a median of 12.4 years, the bimanual exam was initially included in the screening protocol but was dropped after 5 years because no cancers were detected solely by this examination.⁶³ The second screening trial, the United Kingdom Collaborative Trial for Ovarian Cancer Screening (UKCTOCS), does not include pelvic examination in its screening protocol. This study of 202,638 post-menopausal women ages 50 to 74 years is comparing no screening, screening with annual CA-125 with transvaginal ultrasound as a second-line test, or transvaginal ultrasound and is expected to report mortality results in 2015.⁶⁴

Results from the PLCO screening trial were disappointing. The screening tests included serum CA-125 (offered annually for 6 years) and transvaginal ultrasonography (offered annually for 4 years). Despite an increase in ovarian cancer detection rates in the screened group, mortality from ovarian cancer was not reduced.⁶³ If these 2 tests, which have greater diagnostic accuracy than the bimanual examination, are not associated with decreased mortality from ovarian cancer, it is difficult to make the case that the less specific and sensitive bimanual examination should be used for ovarian cancer screening.

In the absence of evidence, most major professional and government groups recommend against screening for ovarian cancer in asymptomatic average risk women.^{65,66} For example, the Australian National Breast and Ovarian Cancer Centre stated there is no evidence that supports any form of screening for ovarian cancer, including the pelvic examination.⁶⁷ A joint statement from ACOG and the Society of Gynecologic Oncologists states that there is “no effective strategy for ovarian cancer screening”.⁶⁸ The American Cancer Society states that there is “no proven effective screening strategy for the early detection of ovarian cancer” and does not recommend screening asymptomatic women at average risk.⁶⁹ In 2012, the United States Preventive Services Task Force (p 903) noted that “no randomized trial has assessed the role of the bimanual pelvic examination for cancer screening.”¹⁷ Further, it concluded that there is “at least moderate certainty that harms of screening for ovarian cancer [with transvaginal ultrasonography and serum tumor marker CA-125] outweigh the benefits”.¹⁷ Nevertheless, recent data indicate that about a third of US physicians continue to order these tests to screen for ovarian cancer.⁶⁵

PELVIC INFLAMMATORY DISEASE

We identified no studies investigating the benefits of the screening pelvic examination for the diagnosis of pelvic inflammatory disease. PID is a condition often presenting with vague

or minimal symptoms⁷⁰ which if left untreated can lead to infertility, ectopic pregnancy, or chronic pelvic pain.⁷¹⁻⁷⁴ Nevertheless, the Centers for Disease Control and Prevention states that “the optimal treatment regimen and long-term outcome of early treatment of women with asymptomatic or subclinical PID are unknown” and recommends treatment only when a woman with some symptoms (e.g., lower abdominal or pelvic pain) has physical exam findings (e.g., cervical motion, uterine or adnexal tenderness) suggestive of PID.⁷⁵ Symptom questionnaires are available to help determine which patients require a bi-manual examination for diagnosis of PID.⁷⁶

BACTERIAL VAGINOSIS

We identified one study of bacterial vaginosis that included both symptomatic and asymptomatic women (N=269, 67% asymptomatic), used a definitive gold standard test (Gram’s stain), and performed the screening and gold standard tests in all participants.¹⁵ The screening test evaluated, known as the Amsel criteria, are characteristics of vaginal secretions obtained by swab during the pelvic examination.¹⁶ The prevalence of bacterial vaginosis (39%) was higher than usually reported. The sensitivity and specificity of the Amsel criteria were 69% and 93% respectively and were not reported separately for the subgroup of asymptomatic women.

Since this study included both symptomatic and asymptomatic women in whom the prevalence of bacterial vaginosis was high, the results may not be applicable to the average risk asymptomatic population that is the focus of this review. Furthermore the clinical significance of a diagnosis of bacterial vaginosis in asymptomatic women is unclear; many of these cases may represent overdiagnosis.⁷⁷

OTHER CONDITIONS

We identified no studies investigating the benefits of the screening pelvic examination for the diagnosis of other malignancies or other benign gynecologic conditions. Although several studies have documented a 2-4% prevalence of pelvic-examination-detected abnormalities in asymptomatic women, these studies did not determine if detection in the asymptomatic phase had any impact on patient outcomes.^{78,79}

PELVIC EXAMINATION-RELATED HARMS

We identified no studies that specifically investigated over-diagnosis, over-treatment, or diagnostic procedure-related harms resulting from findings on the pelvic examination performed in asymptomatic women. However data from one of the older screening studies indicated that screening pelvic examinations led to unnecessary surgery in 1.5% of women screened,¹⁴ exposing them to a major surgical complication risk that may be as high as 15%.⁶³

Other harms include psychological distress in anticipation of, and during, the pelvic examination. In the 15 studies (N>13,000) that examined these outcomes, the percentage of respondents endorsing fear, embarrassment, or anxiety during or in advance of the pelvic examination ranged from 10 to 80% (median 34%, 7 studies, N=10,702). The percentage endorsing pain or discomfort during the pelvic exam ranged from 11 to 60% (median 35%, 8 studies, N=4,576).

Women who endorsed pain or discomfort were less likely to return for another visit than those who did not experience pain or discomfort.

It has been hypothesized that women who have been victims of sexual violence (SV) are more likely to experience psychological harms from the pelvic examination. Our review however indicates that the data are mixed. Pain and discomfort were significantly more common in SV + compared to SV- women in only 2 of 4 studies^{39,45} and 2 of 3 studies found a significant association between history of SV and fear, anxiety, or embarrassment.^{40,42} Post traumatic stress disorder was evaluated as a co-variate in 2 controlled studies and was found to be significantly associated with pelvic examination-related fear, embarrassment, and distress, independent of SV history.^{39,40}

Although our review focused on adult women it is worth noting that several groups have reported that younger women (e.g., age \leq 25 years) are more likely than older women to experience pelvic examination-associated embarrassment and pain.^{29,30}

Finally, it has been suggested that the opportunity for an annual pelvic examination might serve as an incentive for women to access the healthcare care system and thereby receive recommended gynecologic services such as contraception, screening for sexually transmitted infections and cervical cancer, and other non-gynecologic preventive care including immunizations, blood pressure, weight and cholesterol measurement, colon cancer screening, and risk factor assessment and counseling.³⁵ Our literature search did not identify any studies that tested this hypothesis. Indeed, as discussed above, fear or anxiety about the pelvic exam is associated with reduced compliance with visits for Pap smears.

PROVIDER ATTITUDES, BELIEFS AND PRACTICES

As documented in this report, the evidence does not support performance of the routine pelvic examination in asymptomatic women to screen for any condition other than cervical cancer. Nevertheless providers continue to perform this exam for a variety of reasons including prior to prescribing hormonal contraception, to diagnose sexually transmitted infections, or to screen for benign conditions or malignancies other than cervical cancer. A recent study, for example, reported that 33% of providers (obstetric-gynecology and family physicians and advanced practice nurses) said that they *always* and 44% said they *usually* require a pelvic exam prior to prescribing oral contraceptives.⁶⁰

In addition, many providers perform the examination to obtain Pap tests for women in whom the test is not indicated (e.g., those who have had a hysterectomy for benign conditions or are younger than 21 years of age⁸⁰ or at more frequent intervals than recommended (Perkins 2013). A recent study showed that primary care provider adherence to recommended screening intervals for cervical cancer screening was poor, with 67 to 94% of respondents stating they would perform subsequent screening sooner than recommended by contemporary guidelines.⁸¹ This overuse was recently high-lighted by the American Board of Internal Medicine Foundation's Choosing Wisely Campaign.⁸⁰

Finally, many providers continue to include a pelvic examination as part of the well woman visit. Indeed, ACOG recommends annual routine pelvic examinations while acknowledging (p 422)

that “this recommendation is based on expert opinion.”² In a survey study of 1250 physicians in the US, 54% of internists, 90% of family practitioners and 98 % of obstetrician-gynecologists indicated that they perform pelvic examinations “as part of a well-woman exam.”^{1,82} In a clinical-vignette survey study of 521 obstetrician-gynecologists, over 95% indicated that they would perform a bimanual examination in asymptomatic women not due for a Pap test.⁴⁷

Reasons for performing routine pelvic examinations include clinician preference, legal concerns, financial incentives and reimbursement, and the influence of medical training.^{2,35,82} In a small (n=27) study of US general practitioners, clinicians cited “patient reassurance, documenting the norm, ‘because I was taught to,’ for legal reasons, and for completeness” as a few of the reasons they continue the exam annually.³⁵ In a recent survey of 521 US obstetrician-gynecologists, performing a routine pelvic examination was considered very important for adherence to standard medical practice (45% of respondents), patient reassurance (49%), detection of ovarian cancer (47%), and identification of benign conditions (54-59%). The authors of this study concluded that more provider education is required, particularly with regard to ovarian cancer screening.⁴⁷

CONCLUSIONS AND FUTURE DIRECTIONS

There are no data indicating that the performance of the routine pelvic examination in asymptomatic average risk women reduces morbidity or mortality from any condition other than cervical cancer. For cervical cancer screening, the pelvic examination only needs to include visual inspection of the cervix and collection of a cervical specimen for Pap testing and, if indicated, for human papillomavirus testing. A bimanual examination is not indicated for cervical cancer screening. Although the pelvic examination may detect abnormalities in about 2-4% of asymptomatic women, the vast majority of these conditions are of minimal clinical importance.^{78,79,83}

Harms of the screening pelvic examination include unnecessary laparoscopies or laparotomies performed because of abnormalities detected on the speculum or bimanual examination. This occurs at a rate of about 1.5% and may expose these women to a 15% risk of one or more major surgical complications. Other harms of the examination include fear, embarrassment, or anxiety (in 10 to 80%, median 34%) and pain or discomfort (in 11 to 60%, median 35%). Victims of sexual violence may be more likely than other women to experience pelvic examination-related distress, fear and embarrassment. Women who endorse pain or discomfort are less likely to return for another visit than those who don’t. We did not identify any studies that evaluated possible indirect benefits of the pelvic examination (e.g., as an incentive to women to seek healthcare).

Conducting a pelvic examination incurs substantial costs. It has been estimated that the total annual cost of preventive gynecologic exams and associated laboratory and radiologic services in the US is \$2.6 billion.⁸⁴ Medicare “National Payment Amount” values for 2013 are \$38.11 for a screening pelvic examination and \$45.93 for collection of a Pap smear specimen (www.cma.gov/apps/physician-fee-schedule/overview/asp). It is likely that a substantial percentage of the annual cost represents unnecessary care, given that a majority of clinicians report performing routine pelvic examinations in asymptomatic women even if they are not due for a Pap smear and a substantial proportion report doing Pap smears more often than recommended.

Unnecessary pelvic examinations incur opportunity costs as well, including the time required for the examination and its preparation (patient disrobing and putting on a gown, clinician finding a chaperone, chaperone taking time away from other duties).

In conclusion, we found no data supporting the use of the screening pelvic examination (including speculum and bimanual examinations) in the asymptomatic average risk woman for any indication other than periodic cervical cancer screening. The procedure causes pain, discomfort, fear, anxiety and/or embarrassment in about a third of women. It is time and resource intensive, and can lead to unnecessary, invasive, and potentially harmful diagnostic procedures.⁸⁵ The most important area for future research is development and testing of strategies to reduce the high rate of inappropriate use of the pelvic examination.⁸⁶ Because the implementation literature suggests that passive education alone is unlikely to be effective⁸⁷ a variety of strategies employed at multiple levels within the healthcare system will likely be required.⁸⁸

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APPENDIX A. SEARCH STRATEGIES

Database: Ovid MEDLINE(R) <1946 to July 2013>

Search Strategy:

-
- 1 (pelvic exam\$ or gynaecol\$ exam\$).mp. or exp Gynecological Examination/
 - 2 pelvi\$.mp. or exp Pelvis/
 - 3 palpation.mp. or exp Palpation/
 - 4 or/1-3
 - 5 women\$ health.mp. or exp Women's Health/
 - 6 exp Female/
 - 7 5 or 6
 - 8 (asymptom\$ or routin\$ or screen\$ or mandat\$).mp. or exp Mass Screening/
 - 9 4 and 7 and 8
 - 10 ovar\$ cancer.mp. or exp Ovarian Neoplasms/
 - 11 exp Uterine Cervical Neoplasms/ or uter\$ cancer.mp.
 - 12 adnexa uteri.mp. or exp Adnexa Uteri/
 - 13 vagin\$ smear\$.mp.
 - 14 vagin\$ disease\$.mp. or exp Vaginal Diseases/
 - 15 contracept\$.mp. or exp Contraception/
 - 16 contraceptives.mp. or exp Contraceptive Agents/
 - 17 chlamydia.mp. or exp Chlamydia Infections/ or exp Chlamydia/
 - 18 std.mp. or exp Sexually Transmitted Diseases/
 - 19 or/10-18
 - 20 9 and 19
 - 21 limit 20 to English language
 - 22 limit 21 to humans
 - 23 case report.mp. or exp Case Reports/
 - 24 case series.mp.
 - 25 23 or 24
 - 26 22 not 25
 - 27 prostate.mp. or exp Prostate/
 - 28 26 not 27

APPENDIX B. PEER REVIEW COMMENTS AND AUTHOR RESPONSES

REVIEWER COMMENT	RESPONSE
1. Are the objectives, scope, and methods for this review clearly described?	
Yes	None required (NR)
Yes. Very clear. The analytic framework seems somewhat atypical since KQ1 often pertains to the most direct evidence of screening benefit (indicated by KQ2 in the current plan).	NR
Yes. I think that the objectives and methods are clearly described. I do have two minor comments that might help further clarify the objectives: 1. I wonder if, in the Executive Summary, there can be a “Bottom Line” statement right after the Introduction so that readers will be able to quickly surmise the clinical implications of the review 2. I think in Key question 1, it might be helpful to highlight that the review seeks to assess the accuracy for detection of malignancies other than cervical cancer.	Thank you. The suggestions have been incorporated in the final version of the review.
Yes. The methods and scope are well described.	NR
Yes	NR
Yes The analytic framework is well described and complete. (Minor point: For KQ3 reword as “Harms from receiving exam” instead of from performing exam) The methods for assessing the risk of bias or quality of studies for KQs other than KQ1 are not given, and it seems that studies of all quality levels are included (more on this below). Some presentation of the methods with regard to study quality for all key questions should be included.	The studies were primarily survey studies. There is no established method for evaluating the quality of survey studies so we identified key elements of survey research and report on whether the included studies addressed those key elements. More detail is provided in the Methods section.
2. Is there any indication of bias in our synthesis of the evidence?	
No	NR
No	NR
No. I think the methods are solid. However, in the review of the potential psychological harms associated with pelvic exams, the authors state that the studies could not be pooled but then report median values across the studies. It’s unclear how they obtained these median values.	The median is a descriptive statistic – the middle value of the values reported for a particular outcome. For example, 7 studies reported percentage endorsing fear etc. The middle value of those 7 percentages was 34%.
No	NR
No	NR
While there is not an indication of author bias in the synthesis, the report does in places draw conclusions based on studies with a high risk of bias. In some cases, it seems more correct to say that there is not sufficient evidence to draw a conclusion rather than making a statement of findings. For example, with regard to provider race and pelvic exam experiences, one study from 1973 with an n=163 is the basis for suggesting that patients seeing black providers experience more pain and discomfort than those seeing a white provider. I would hesitate to even hint at this with the evidence from that Paper – the study was conducted at one clinic and patients saw a limited number of providers – even if 20 different providers were seen, and half of these were black and half were white (I suspect it was far less), the experiences of these women speak to the examination practices of very few practitioners (trained more than 50 years ago, using speculums from 40 years ago). That the results can be generalized at all is suspect, given that clustering of patients by provider probably was not accounted for, and that they would relate to the experiences of women in the current era seems highly unlikely. (I recommend dropping that study from your review as not relevant.)	

REVIEWER COMMENT	RESPONSE
<p>More broadly, the report would benefit from more careful accounting of the merits of the evidence from the studies identified and some summary of the strength of the evidence for conclusions drawn. A summary table evaluating the strength of evidence and conclusions for each KQ would be helpful. Where there no study quality criteria used to exclude studies? For example – one included study for psychological harms is from 1967 and has an n=40 and no response rate reported. This seems no better than a case report, and yet it is included. In fact, this study serves as the high end of the range of estimates for psychological harms – a misleading range perhaps. Another study, Robohm, is a mailed survey of 74 women with no response rate reported that has arguably little to offer in terms of generalizable accurate estimates</p>	<p>Thank you. The suggestions have been incorporated in the final version of the review. Specifically, we have provided an assessment of the quality of the survey studies (as noted above). We did not exclude studies based on study quality.</p>
<p>3. Are there any <u>published</u> or <u>unpublished</u> studies that we may have overlooked?</p>	
<p>No</p>	<p>NR</p>
<p>The Mayo Clinic physical exam studies from the 1970s included pelvic exams and may be useful.</p>	<p>Thank you for the suggestion.</p>
<p>No. The review seems to have been comprehensive.</p>	<p>NR</p>
<p>Not to my knowledge.</p>	<p>NR</p>
<p>Yes. I've attached several studies about receipt of clinical preventive services, including Pap smears, by BMI. 1. <i>Prev Med</i>. 2012 May;54(5):302-5. doi: 10.1016/j.ypmed.2012.02.010. Epub 2012 Feb 25. Prospective association between body mass index and receipt of preventive services: results from the Central Pennsylvania Women's Health Study (CePAWHS). Kraschnewski JL, McCall-Hosenfeld JS, Weisman CS. 2. <i>Am J Prev Med</i>. 2011 Nov;41(5):465-72. doi: 10.1016/j.amepre.2011.07.020. Preventive care in relation to obesity: an analysis of a large, national survey. Littman AJ, Koepsell TD, Forsberg CW, Boyko EJ, Yancy WS Jr. 3. <i>Obesity (Silver Spring)</i>. 2010 Sep;18(9):1827-35. doi: 10.1038/oby.2010.40. Epub 2010 Mar 4. Obesity and receipt of clinical preventive services in veterans. Yancy WS Jr, McDuffie JR, Stechuchak KM, Olsen MK, Oddone EZ, Kinsinger LS, Datta SK, Fisher DA, Krause KM, Østbye T.</p>	<p>Thank you for the suggested references. We reviewed all these articles and they did not meet inclusion criteria.</p>
<p>This recently published article was not overlooked, but gives some additional information that might be useful to the report, particularly provider concerns about extended gynecologic screening intervals. Perkins RB, Anderson BL, Sheinfeld Gorin S, Schulkin JA. Challenges in cervical cancer prevention: a survey of U.S. Obstetrician-gynecologists. <i>Am J Prev Med</i>. 2013 Aug;45(2):175-81. doi: 10.1016/j.amepre.2013.03.019.</p>	<p>Included</p>
<p>4. Please write any additional suggestions or comments below. If applicable, please indicate the page and line numbers from the draft report.</p>	
<p>Looks great. No additional comments or corrections.</p>	<p>Thank you.</p>
<p>Lines were not numbered, so referral is to page and paragraph. - Page 3: KQ2. About 85% respondents in the Henderson survey reported bimanual exams as being “very important or important” to identify benign ovarian processes (eg, cysts). From a clinical perspective, providers might believe this will avoid subsequent ovarian torsion (a surgical emergency); this reasoning is articulated in the commentary to the 2011 Stormo article but is not specifically stated in the current study. The document should at least describe benign lesions specifically as an “other gynecologic condition”. - Page 3: KQ2, benefits, ovarian cancer, the second paragraph (“There are likely...”) This paragraph is about harms and seems misplaced in the benefits section.</p>	

REVIEWER COMMENT	RESPONSE
<ul style="list-style-type: none"> - Page 8: “S” is missing from ASCCP acronym. - Page 13: Figure 2 is empty. - Page 14: The last sentence seems incorrect. The addition of CA-125 seems to increase the PPV of the exam: if a ‘positive test’ were defined as both a positive pelvic exam and a positive CA-125, the PPV would be 100%. That is, the only woman with a positive pelvic exam and a positive CA-125 was the one woman identified as having ovarian cancer. The confidence limit is certainly wide. - Page 17: The statement from ACS (Smith, 2011, mid-page) perhaps should be “asymptomatic ovarian cancer” not “symptomatic.” - Page 18: The potential benefit of screening for BV is not articulated in the document. Is it to prompt treatment to avert future PID? - Pages 24, 25, 26, 29, etc.: The small-case “k” is used where traditionally an “n” is used to denote sample size (or in this case the number of studies). This is confusing. - Page 29: Paragraph on specialty. Here, a study is described as “the Schmittiel study” but the document does not use that style elsewhere (instead referring to studies by parenthetical reference and year rather than by first-author name). - Page 31: Sometimes the C in ACOG is “College” (page 31) and other times “Congress” (page 6) - Page 31: Schwartz et al showed that cervical cancer screening has limited provision of contraception; consider citing here (Contraception 72 (2005) 179– 181). - Page 37: The ACOG Bulletin on well woman exams also articulates reasons for doing the exam: “Concerns, such as individual risk factors, patient expectations, or medical–legal concerns may influence the decision to perform an internal pelvic examination or clinical breast examination.” Consider citing this bulletin in addition to Stormo and Stewart. - Page 37: Conclusion, first paragraph, last line. As indicated earlier, the Buys study included BME but no cancer found above and beyond those found by U/S or CA-125 (so dropped). By extension, the results of the trial could support a conclusion no effect of BME on ovarian cancer mortality. - Page 37: Conclusion. The first sentences of the first and third paragraphs are nearly identical. - Page 37: Conclusion. The last two sentences are important (and likely true) but seem out of scope for an evidence report. The authors seem to making judgments about the adequacy of evidence about both benefits and harms of screening pelvic exams, although the report states a striking lack of any evidence for any outcome. The authors further suggest that the net benefit is zero or in the direction of harm, thereby justifying a focus on practice change. This is all (very) likely true, but seems to be a conclusion that readers/interpreters of the report should make. 	<p>Thank you. These suggestions have been incorporated in the final version. Specifically, suggested references have been reviewed and included if relevant to the scope of the review. We have corrected the typographical errors and verified any confusing statements in the review.</p>
<p>Other relatively minor comments:</p> <ol style="list-style-type: none"> 1. I found the report to be unnecessarily repetitive. I wonder if the final summary by question. I thought that the conclusion paragraphs succinctly summarized the findings already discussed in the main body. 2. As clinicians may use this document to inform their screening practices for both Chlamydia and cervical cancer screening, I wonder if it would be worthwhile to highlight in the executive summary that Paps should not be done in women < 21 years regardless of sexual activity and that Chlamydia screening should be performed in all sexually active women <25 – especially since these practices are commonly not followed. 3. I wonder if BV detection should even be included since most experts do not even recommend treating in asymptomatic, non-pregnant women (treatment in pregnant women, I believe, is controversial – a point worth potentially mentioning). If it is included, perhaps a discussion of the harms of detection should include the fact that treatment does not lead to improved outcomes, and may be associated with increased incidence of yeast infection (harms related to overdiagnosis or overtreatment). The authors mention this on p.32 in the summary but I think this should be discussed earlier on. 	

REVIEWER COMMENT	RESPONSE
<p>4. Since there are relatively few documented harms (or benefits), I think that KQ 2 and 3 could be combined. That is, what are the harms and benefits. Then KQ3a could just be the 3rd main question. This will, of course, require some edits to the conceptual/analytic framework.</p> <p>5. Conclusion, page 5: I think it is worth mentioning that pelvic exams can also reduce likelihood for returning for future Pap smears which do have proven benefit.</p> <p>6. Consider including the 2nd paragraph of the evidence report introduction in the executive summary intro.</p> <p>7. The patient characteristics discussed all impact initial screening, not harms associated with screening. I think this could be more clearly stated – essentially that studies do not really assess association between demographic factors and harms of screening but rather focus on likelihood of undergoing screening.</p> <p>8. The 2 paragraphs on page 32 regarding detection belong under question 1 (accuracy of diagnosis) and I think should also be placed within the main text, not the summary section.</p>	<p>Thank you. The suggestions have been incorporated in the final version of the review. Specifically, we have attempted to reduce the repetitiveness. for Item #3, we decided to include BV for completeness. For item #4, we considered this suggestion but decided to follow the original plan. We agreed with the suggestions in items 6 and 7 and have made changes to the review.</p>
<p>General comments—This is a good review and will be very important clinically. Please see comments below. I have gone through this carefully as I know it is likely to be published and may guide guideline development. It is an important topic.</p> <p>1. I think you can develop the logic better that if TVUS has not been shown to be beneficial, given the PE’s lower sensitivity/specificity (if this is true—I believe it is but maybe no data) that it is highly unlikely that a less sensitive and less specific test would be beneficial.</p> <p>2. I don’t understand the reason for separating harms as done in KQ 2 and 3. Also, I suggest you keep the same order—benefits/harms in KQ2 and 3 so it is easier to follow</p> <p><i>Executive Summary</i> Line comments/edits: Page 1 28—Do you mean “adequate and negative”? 42-45—I believe psychosocial distress, deferral of care, avoidance of care are also harms. Page 2 10—Update search. P3 4—? for “identifying ovarian cancer”? 5—of rather than or? 9-13—Is surgery the “gold standard”? Did any studies compare pelvic exam to transvaginal us? What about PLCO? Be clear that the PPV pertains to diagnosing ovarian cancer. 16-21—Clarify the gold standard for dx BV 34—Isn’t stating “this test has poor dx accuracy” one of the topics of the review? 35—State how many studies contribute to the statement “screeninglead to unnecc...surger 1.5%” P4 2-3—I thought there were no screening trials? 24-33—During topic development, I recall that one of Carolyn Westhoffs comments in her review/editorial dealing with this topic was that the exam has been shown to deter women from seeking birth control. Did you find evidence about this? Also, reduced Pap testing is an important negative finding/harm. What was the effect size? 38-42—How many studies? <i>Introduction</i> P8 8— “adequate and negative”? 27—Is the correct acronym for the amer soc of clin path listed? 36—Ref TF also</p>	<p>Thank you. We have incorporated many of these suggestions in the final review (one exception- we kept the 2 harms section separate.</p> <p>PLCO is discussed in the discussion section; we changed the language to make sure it was clear that PPV pertains to diagnosis of ovarian cancer. We identified only 1 study that compared the pelvic exam to TVUS in asymptomatic women. This study concluded that about 20% of pelvic examinations differed from TVUS findings.</p> <p>We clarified that the gold standard for diagnosis of BV is the Amsel criteria.</p> <p>We clarified that there are no screening trials of pelvic exam Information about deterring women from further healthcare Is included in text - too complicated for the executive summary</p> <p>We have modified the statement about systematic review quality in the body of the report and in the executive summary. We did not assess the quality of the existing systematic reviews.</p> <p>Regarding use of a biopsy as a gold standard: We stand by our selection of biopsy as the “gold standard” for cancer detection whereby the diagnostic accuracy of the pelvic examination should be measured. This is consistent with the assessment of other cancer screening tests such as the digital rectal examination for prostate cancer and mammography for breast cancer. We understand that no studies have</p>

REVIEWER COMMENT	RESPONSE
<p>P9 25-27—Isn't this statement a result? <i>Methods</i> P11 22—High quality? Assessed how <i>Results</i> P14 11-18—I am struggling with how you are defining gold standard. I have never seen biopsy considered the gold standard for evaluating a screening test. The gold standard in screening typically is: follow-up time, a better study (imaging, in this case ? TVUS) or perhaps surgery that looks at both ovaries in this case. Were there no studies comparing the pelvic exam to TVUS? Sure would be easy to do this if it hasn't been done! 25— "benign abnormalities" such as???? Do any of the studies in this section provide any data on what happens to the women with no pelvic abnormalities on exam over the next years of fu? How many of these pts develop ovarian cancer? I am guessing this info is not provided. P16 14—Clarify what the gold standard is ? is there a reason to identify BV in asymptomatic, non-preg women? P18—Some mention of false reassurance in this section on harms would be good. I am sure there are no studies but the importance of it remains (and is plausible) P19 I am struggling with how harms in this section differs from harms in KQ2. Also, keep same order as in KQ2. 6-12—I think this is an overview. Aren't lines 10-12 results? P23 7-9—Comment—Perhaps because of the inclusion of the pelvic exam??? 18-22—Did any of the studies evaluate likelihood of return visits based on embarrassment/fear of the exam? P24 38-40—What does "k" mean? I am assuming it is the "n" P25 9-18—Is the thought process here that because overwt women have less intention to get an exam there is more distress caused by it? 20-27—Why does compliance matter? Can you connect this with your review? I don't see this as a review of compliance with exams. Is the point that you are making that because disabled people are as compliant as non-disabled that there is no difference in how they perceive the exam? I am not sure of the point of this paragraph 44—Survey? Prevalence studies? P26 27-33—Can you connect the logic here a little more clearly?</p>	<p>been designed to accurately assess the diagnostic accuracy of the pelvic examination against a biopsy gold standard. None of the studies have biopsied a representative cohort of women regardless of pelvic examination findings; nor have they followed women for a sufficient period of time to determine if interval cancers plausibly missed by a pelvic examination but present at that time arise. Thus the negative predictive value and the false and true negative value of the pelvic examination is not known. We also do not believe that other screening tests, such as TVUS, or CA-125 should be used as a gold standard because similar issues arise. No studies have biopsied women with normal TVUS or CA-125 results. The screening trial while, while providing sufficient follow-up to assess for development of ovarian cancer and ovarian cancer death is unlikely to provide sufficient information to allow these studies to be considered "gold standard". At best we could make some comments on the operating characteristics of pelvic examination versus other tests sometimes used to assess for ovarian cancer.</p> <p>In the ovarian cancer studies, patients were followed for 1 year.</p> <p>There is some uncertainty around the value of identifying BV so we decided to leave it in the report.</p> <p>We have clarified the harms sections.</p> <p>We have added information on the likelihood of return visits.</p> <p>"k" is used to indicate the number of studies; "n" indicates the number of patients</p> <p>We have removed this comment.</p> <p>We have removed this paragraph.</p> <p>We have modified the text to clarify these statements.</p>

REVIEWER COMMENT	RESPONSE
<p><i>Discussion</i> In general, I think a stronger discussion in the more conventional/article type format would be better. If you feel the need to summarize, I think you would do it with bullet points or a separate section titled summary. As it is, it seems more like you are just repeating the results. I know this is going to be published somewhere so I think this is a really important part of the document. Also, somewhere, I would talk about the cost/charges of the exam and opportunity costs. Also, I think more discussion of absence of benefit with evidence of harm (again, where is the avoiding the exam, missing birth control stuff that Carolyn Westhoff talks about) is warranted. I think an article such as this will get lots of attention so anything you can do to develop the discussion will be good. P31 27—? For identifying other abnormalities such as.... P32 35-38—Does ACS have data to support the statement that the sensitivity and specificity of the exam are “poor”? I agree with this based on my fund of knowledge but am interested in where they get this data. I am assuming it is presumptive based on your review of not finding this info. P33 1-9—2 things in this paragraph. The first is as mentioned above, I think you can develop the logic much more strongly that if TVUS doesn’t work that it is highly unlikely that the pelvic exam would work. The second is, in lines 7-9 you hint about sensitivity. Was there no info on sensitivity and spec from PLCO? P34 15—I would reword this to say, “to the best of our knowledge, this is the first systematic review to include and evaluation of the harms of the</p>	<p>The discussion was re-written and now includes a section on costs.</p> <p>This is correct.</p> <p>One screening study is still underway. From PLCO there was no information for pelvic exam, only for TVUS and CA-125.</p> <p>We have modified this sentence.</p>
<p>Page 8 (top line): Please correct the name of the nominating office to “the VHA National Center for Health Promotion and Disease Prevention” Page 8 (middle of page): The abbreviations for American Society for Clinical Pathology and American Society for Colposcopy and Cervical Pathology should be, respectively, ASCP and ASCCP. Page 8 (next to last paragraph): would include reference for USPSTF recommendation Page 31 (first paragraph): Consider noting that the pelvic examination for cervical cancer screening needs to include only the speculum portion of the exam; inspection of the external genitalia and the bimanual portion of the exam are not indicated for cervical cancer screening. Page 33 (last paragraph): add “s” to Centers (for Disease Control and Prevention)</p>	<p>Thank you. All these comments are addressed in the final version.</p>

REVIEWER COMMENT	RESPONSE
<p>This important and timely review of the evidence for routine pelvic examination is well scoped and includes a broad literature dating back more than 60 years. The authors have included important contextual issues in the review.</p> <p>1. In the introduction, page 7 line 32, the suggestion that “fear of the exam” seems a bit overstated without any evidence to cite. Perhaps it is better to say simply that discomfort with the internal examination might result in avoidance. As currently written, the introduction reads as though the reviewers may have some a priori assumptions going into the evidence review. Alternatively, consider citing references suggesting that women might avoid health care because of the pelvic exam.</p> <p>2. The Singh study of 2000 asymptomatic women and the outcomes of pelvic examination could be further highlighted in the discussion, as it is important evidence of “yield” from routine assessment above and beyond what would be found with swab and urine samples.</p> <p>3. Greater importance and space should be given to the decision to drop the pelvic examination arm from the PLCO trial. This should lead the discussion of the results on page 32 (line 27). The information provided by the PLCO trial is somewhat buried, when it can be read as strong evidence that the pelvic exam does more harm than good with respect to this outcome. Even the ultrasound and CA125 arms were not found sufficiently sensitive and specific for detecting ovarian cancer, and pelvic examination performed even more poorly – so much so that it was dropped from the trial. Instead of discussing this important evidence to begin, you state that the guidelines of professional organizations were made “in the absence of evidence” – in fact, the evidence of no benefit from the PLCO trial drives many of these guidelines, I believe. Based on my own research, screening for ovarian cancer is a main reason physicians conduct the pelvic exam – since this is such a strong motivation for screening, a more detailed discussion of these large trials should be given.</p> <p>When discussing the Specificity and Sensitivity of PE for BV, it would be helpful to point out in the discussion what the low sensitivity (69%) means pragmatically – relative to other screening tests, does this one have merit based on these values (especially when considering they are based on a population where nearly 1/3 were symptomatic).</p> <p>4. The Fiddes 2003 study highlights the importance of age and parity for women’s experiences of the pelvic exam – you may want to discuss possible life stage differences in pelvic exam experiences in addition to the other subgroups you consider. Is more discussion, for example, of adolescents’ experiences versus adult women possible?</p> <p>5. It is not clear whether the provider gender preference data reviewed is relevant to the KQs as scoped. Reporting on these preferences might make sense in the discussion on improving the pelvic examination experience. Given the absence of harms or benefits data related to provider gender, I do not think it does in discussion of the KQ results. Minor points: You should be able to find the RR for the BRFSS Survey online – it is listed as NR in your table (Watson-Johnson 2012).</p> <p>Page 8, line 36 – Consider adding the ages at which yearly screening is recommended to highlight the very life stage specific relevance of this issue.</p> <p>Page 8, line 40 – Better to cite the primary studies rather than the Westhoff article – hers is a very pointed argument review article. Since you are conducting an SER, it should be founded in original research.</p> <p>Page 34, line 7-8 – It is confusing that you say one study but then cite 2 studies. Where the estimates you cite there derived from both?</p> <p>Page 36, line 9 – I do not think that is a direct quote from our Paper – you can probably remove the quotes. Consider citing our more nuanced conclusions.</p>	<p>Thank you. We have modified the introduction and discussion sections as noted. We have clarified the information about the sensitivity and specificity of PE for BV.</p> <p>We have added information about age to the discussion although the focus of our literature search was on adult women so we can only comment on studies that stratified outcome reporting by age.</p> <p>We have removed the provider gender preference data as suggested. For the BRFSS Survey data, the response rates varied by state as noted in Watson-Johnson 2012. We calculated a weighted average response rate for the 11 states and 1 territory administering the SV module: 52.2%. However, since the analysis in the Watson-Johnson Paper is based on 88.2% of respondents and we focus on the women respondents, an exact response rate cannot be determined. We have added ages at which yearly screening is recommended.</p> <p>Thank you. We have modified the statement that was in quotes..</p>

REVIEWER COMMENT	RESPONSE
<p>For KQ#3 (harms) see Westhoff C and Clark C, BJOG 1992;99:329-332, Benign ovarian cysts in England and Wales and in the U.S. This international comparison provides indirect evidence that increased routine pelvic exams in the U.S. lead to an increased rate of surgery for asymptomatic ovarian cysts, without any benefit (such as downstaging of ovarian cancer diagnosis). Possibly relevant as a harm.</p>	<p>Thank you for the suggested reference. We have added this reference to the report.</p>
<p>5. Please provide any recommendations on how this report can be revised to more directly address or assist implementation needs.</p>	
<p>See above; clearly discern that this applies to bimanual exam, not Paps</p>	
<p>No comment</p>	
<p>Please see text edits/line edits/comments/addendum.</p>	
<p>You might consider discussing some of the clinical communication challenges that could emerge – our survey of clinicians found that they believe many of their patients expect the exam and are reassured by it. This may in fact be the case, especially for women who have become accustomed to the usual practice. Providers may need guidance, tools, and support to communicate the reasons for a major change in practice – otherwise the patients may feel underserved, and clinicians may not adopt new practices due to the negative perceptions it could breed. Perhaps the report should acknowledge the communication needs/challenges as well as the need for research in this area. There are also important implications for women’s health care delivery patterns with a change in the annual gynecologic exam practice – women would not necessarily see ob/gyns as frequently. The paragraph on improving the pelvic examination experience seems a little out of place in its current placement in the text. It seems outside of the scope of the review, but if to be included, it might go into a section on clinical issues late in the discussion – not in the section discussing implications of the review findings.</p>	<p>Thank you. We incorporated these suggestions in the final version. The paragraph on improving the pelvic examination experience has been omitted.</p>

APPENDIX C. USPSTF RECOMMENDATIONS FOR SCREENING FOR SEXUALLY TRANSMITTED INFECTIONS IN WOMEN

STI, Year ^a	Population	Recommendation	Timing of Intervention	Method of Screening	Grade ^b
Chlamydia, 2007 ⁵¹	Sexually active, non-pregnant women age ≤ 24 and older women at increased risk	Perform Screening	Not specified	NAAT	A
	Pregnant women age ≤ 24 and older pregnant women at increased risk	Perform screening	First prenatal visit	NAAT	B
	Women age ≥ 25 whether or not they are pregnant who are at increased risk	Do not perform screening			C
Gonorrhea, 2005 ⁵³	Sexually active women (pregnant and non-pregnant) at increased risk	Perform screening	<i>Pregnant:</i> First prenatal visit and, if applicable, during third trimester <i>Non-pregnant:</i> Not specified	Vaginal culture OR NAAT OR Nucleic acid hybridization testing	B
	Woman at low risk	Do not perform screening			D
	Pregnant women not at increased risk	Insufficient evidence for or against screening			I
Hepatitis B, 2004 ⁹⁰	General asymptomatic population	Do not perform screening			D
Hepatitis B, 2009 ⁹¹	Pregnant women	Perform screening	First prenatal visit	HBsAg testing	A
Herpes Simplex Virus, 2005 ⁸⁹	Asymptomatic pregnant women	Do not perform screening			D
	Asymptomatic adolescents and adults	Do not perform screening			D
Human Immunodeficiency Virus, 2013 ⁹²	Persons ages 15-65 years; younger and older adults at increased risk	Perform screening	One time screening of all persons and possibly annually (highest risk) or every 3-5 years (increased risk)	Repeatedly reactive immunoassay followed by Western blot or immunofluorescent assay OR rapid testing followed by conventional testing	A
	Pregnant women, including those who present in labor who are untreated and whose HIV status is unknown	Perform screening	During pregnancy, including women who present in labor	Repeatedly reactive immunoassay followed by Western blot or immunofluorescent assay OR rapid testing followed by conventional testing	A
Syphilis, 2004 ⁹³	Persons at increased risk	Perform Screening	Not specified	VDRL or RPR followed by FTA-ABS or TP-PA	A
Syphilis, 2009 ⁹³	Pregnant women	Perform Screening	During Pregnancy	VDRL or RPR followed by FTA-ABS or TP-PA	A
Syphilis, 2004 ⁹³	Persons not at increased risk	Do not perform screening			D

^aYear of USPSTF recommendation. At the time of publication, many of these recommendations are being updated; ^bGrade of USPSTF recommendation

USPSTF = United States Preventive Services Task Force; NAAT = nucleic acid amplification testing; VDRL = venereal disease research laboratory; FTA-ABS = fluorescent treponemal antibody absorption test; TP-PA = treponema pallidum particle agglutination assay; RPR = rapid plasma regain; HBsAg = Hepatitis B surface antigen