

Screening Pelvic Examinations in Asymptomatic, Average-Risk Adult Women: An Evidence Report for a Clinical Practice Guideline From the American College of Physicians

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Background: Pelvic examination is often included in well-woman visits even when cervical cancer screening is not required.

Purpose: To evaluate the diagnostic accuracy, benefits, and harms of pelvic examination in asymptomatic, nonpregnant, average-risk adult women. Cervical cancer screening was not included.

Data Sources: MEDLINE and Cochrane databases through January 2014 and reference lists from identified studies.

Study Selection: 52 English-language studies, 32 of which included primary data.

Data Extraction: Data were extracted on study and sample characteristics, interventions, and outcomes. Quality of the diagnostic accuracy studies was evaluated using a published instrument, and quality of the survey studies was evaluated with metrics assessing population representativeness, instrument development, and response rates.

Data Synthesis: The positive predictive value of pelvic examination for detecting ovarian cancer was less than 4% in the 2 studies

that reported this metric. No studies that investigated the morbidity or mortality benefits of screening pelvic examination for any condition were identified. The percentage of women reporting pelvic examination-related pain or discomfort ranged from 11% to 60% (median, 35%; 8 studies [$n = 4576$]). Corresponding figures for fear, embarrassment, or anxiety ranged from 10% to 80% (median, 34%; 7 studies [$n = 10\ 702$]).

Limitation: Only English-language publications were included; the evidence on diagnostic accuracy, morbidity, and mortality was scant; and the studies reporting harms were generally low quality.

Conclusion: No data supporting the use of pelvic examination in asymptomatic, average-risk women were found. Low-quality data suggest that pelvic examinations may cause pain, discomfort, fear, anxiety, or embarrassment in about 30% of women.

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Routine pelvic examination has been a regular part of preventive care in women for many decades. In 2008, 63.4 million pelvic examinations were performed in the United States (1). Many women and providers believe that routine pelvic examinations should be included in an annual comprehensive well-woman visit (2). Traditionally, the examination has been used to screen for pathologic conditions through palpation, visualization, and specimen collection and includes inspection of the external genitalia, speculum examination of the vagina and cervix, bimanual examination, and sometimes rectal or rectovaginal examination.

The consensus among major professional groups is that a pelvic examination is not required before provision of hormonal contraception (3) or to screen for chlamydia, gonorrhea, or bacterial vaginosis, all of which can be reliably detected by tests performed on self-collected vulvovaginal swabs or voided urine (for example, nucleic acid amplification for sexually transmitted infections and Gram staining for bacterial vaginosis) (4–7). Also, there is con-

sensus that screening with Papanicolaou (Pap) smears (obtained during the speculum examination of the cervix) reduces mortality from cervical cancer, and contemporary guidelines specify how often and in whom this test should be done (8, 9). Cervical cancer screening is not recommended more frequently than every 3 years or for women older than 65 years with prior negative examinations, women younger than 21 years, or women without a cervix (8). Obtaining a specimen for cervical cytologic evaluation (Pap smear) does not require and is not an indication for bimanual examination.

We are unaware, however, of any systematic reviews that have investigated the utility of the screening pelvic examination for detection of other conditions, such as non-cervical cancer, pelvic inflammatory disease, fibroids, uterine polyps, or atrophic vaginitis. Understanding the utility of this examination for these conditions is important because the screening pelvic examination may cause anxiety, discomfort, and pain and may result in false-positive results, overdiagnosis, overtreatment, false reassurance, and diagnostic procedure-related harms. Moreover, fear of the examination could lead some women to avoid or postpone health care visits, which might result in untreated sexually transmitted infections, undiagnosed cervical cancer or precursor lesions, unwanted pregnancy due to failure to obtain contraception, or failure to receive other evidence-based preventive care. Finally, conducting a pelvic examination

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requires substantial time, especially in primary care settings, and often requires the presence of a chaperone, thus incurring resource and opportunity costs.

We conducted this systematic review to evaluate the benefits and harms of routine screening pelvic examination in asymptomatic, nonpregnant adult women for indications other than sexually transmitted infection screening before provision of hormonal contraception and cervical cancer screening. The review does not address pelvic examinations for symptomatic women or women at higher-than-average risk for gynecologic cancer based on genetic testing or a personal or family history.

METHODS

The 3 objectives were to determine, for asymptomatic women at average risk, the diagnostic accuracy of the pelvic examination for detecting noncervical cancer, pelvic inflammatory disease, or other gynecologic conditions; whether routine screening pelvic examinations (not cervical cytologic examinations) reduce mortality or morbidity from any condition; and the harms and ancillary benefits of routine screening pelvic examination. A full technical report is available at www.hsrd.research.va.gov/publications/esp.

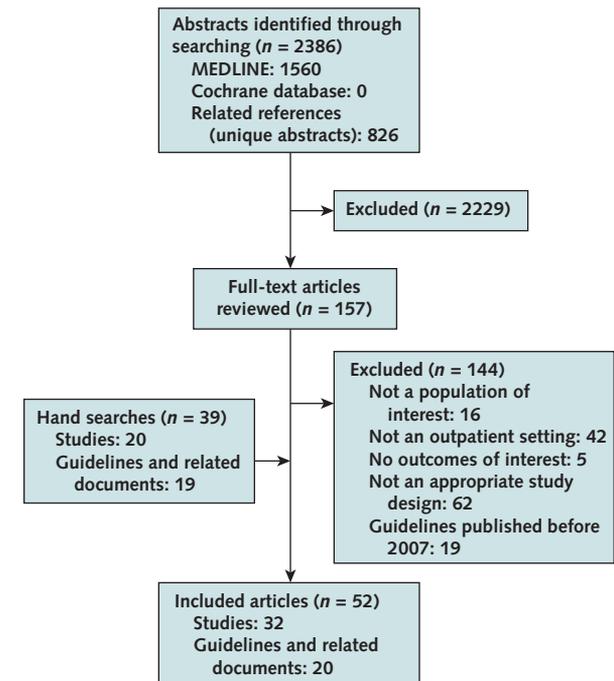
Data Sources

We searched the Ovid MEDLINE and Cochrane databases for articles published from 1946 through January 2014 to identify studies of any design other than case series or case reports. We limited the search to English-language studies involving human participants. Search terms included the following Medical Subject Headings: *gynecological examination*, *women's health*, and *mass screening*. In addition, we used the "related citations" feature of PubMed to identify an additional 826 English-language abstracts and obtained articles by hand-searching reference lists of existing systematic reviews and pertinent studies and from suggestions from our technical expert panel and peer reviewers. The full search strategy is presented in the **Appendix** (available at www.annals.org).

Study Selection

Two investigators independently evaluated each abstract to determine whether it met predefined criteria. We included background papers and guidelines (published within the past 5 years), clinical trials, cohort or case-control studies, or cross-sectional survey studies conducted in asymptomatic, nonpregnant, average-risk women seen in outpatient settings that reported outcomes of interest. These outcomes included diagnostic accuracy (sensitivity, specificity, and predictive value), morbidity or mortality from pathologic conditions detected on pelvic examination, and harms directly related to pelvic examination or indirect harms from examination findings (false reassurance, overdiagnosis, overtreatment, or diagnostic procedure-related harms). Full-text reports of studies identified as po-

Figure. Summary of evidence search and selection



tentially eligible on abstract review were independently reviewed by 2 investigators. The **Figure** shows the reasons for study exclusion at full-text review.

Data Extraction and Quality Assessment

A single investigator extracted details on study design, patient characteristics, and outcomes data onto tables. A second investigator verified the extraction. We assessed the quality of diagnostic accuracy studies using a modification of the QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool (10, 11). We assessed the quality of survey studies using a questionnaire we developed that included these domains: sampling strategy (population-based vs. convenience), incorporation of the sampling structure into the analysis, use of a validated or piloted survey instrument, appropriate method for handling missing data, comparison of responders and nonresponders, and response rates.

Data Synthesis and Analysis

We summarized our findings in narrative and tabular form, highlighting relevant characteristics of the study populations, study designs, and methodological limitations.

Role of the Funding Source

This topic was nominated by the Veterans Health Administration National Center for Health Promotion and Disease Prevention. The full evidence report was prepared by the Minneapolis Veterans Affairs Health Care System's Evidence-based Synthesis Program Center and funded by

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RESULTS

As shown in the **Figure**, we identified 2386 abstracts (all from the MEDLINE search) and performed a full-text review of 157 articles; 13 articles met the inclusion criteria. An additional 39 references were identified from other sources. Of the 52 included studies, 32 included primary data and 20 were guidelines or other reviews.

Diagnostic Accuracy of the Screening Pelvic Examination

We identified 3 studies that investigated the diagnostic accuracy of pelvic examination for detecting ovarian cancer in asymptomatic, average-risk women (12–14). We found no diagnostic accuracy studies for other types of cancer, pelvic inflammatory disease, or other benign gynecologic conditions in this population. The 3 ovarian cancer studies were high-quality cohort studies that enrolled a total of 5633 asymptomatic, average-risk women (**Appendix Table 1**, available at www.annals.org). In all 3, the reference standard test for women whose initial screening pelvic examination was abnormal included some combination of ultrasonography, measurement of serum CA-125 level, or surgical exploration. For women with a normal initial pelvic examination, the reference standard was ovarian cancer that became clinically apparent during 1 year of follow-up. One study did not identify any cases of ovarian cancer. In the other 2, the positive predictive values of the pelvic examination for ovarian cancer were 1.2% and 3.6%.

Benefits of the Screening Pelvic Examination

We found no studies that assessed the morbidity or mortality benefits of routine pelvic examinations for the detection of cancer (ovarian, uterine, bladder, vaginal, or vulvar) or nonmalignant conditions (pelvic inflammatory disease, fibroids, warts, atrophic vaginitis, or any other gynecologic condition) in asymptomatic, average-risk women. Although labeled as “screening studies,” the 3 diagnostic accuracy studies discussed above were not designed or powered to evaluate the effect of screening on ovarian cancer–related morbidity or mortality outcomes (12–14).

It has been suggested that an indirect benefit of the annual pelvic examination is that it prompts women to see a primary care clinician from whom they will receive recommended gynecologic and nongynecologic preventive

care (15). We did not identify any studies that tested this hypothesis.

Harms of the Screening Pelvic Examination

We categorized potential harms as either harms directly related to the pelvic examination (pain, discomfort, fear, anxiety, or embarrassment) or indirect harms resulting from findings on the examination (false reassurance, overdiagnosis, overtreatment, or diagnostic procedure–related harms). We identified no studies that specifically investigated any of these indirect harms. However, one of the studies on diagnostic accuracy of the pelvic examination for detecting ovarian cancer provides some indirect evidence, shown in **Appendix Table 1**. In this study, 174 abnormal screening pelvic examinations were in 2000 asymptomatic, average-risk women (8.7%). On the basis of follow-up test results, 31 (18%) of these women had surgery, which found ovarian cancer in 2 women (6.5% or 0.1%). Thus, screening pelvic examination led to unnecessary surgery in 1.5% (29 of 2000) of women (14).

We identified 14 surveys (16–29) and 1 cohort study (30) that examined women’s attitudes toward or experiences of pelvic examination (**Appendix Table 2**, available at www.annals.org). Median sample size was 409 (range, 40 to 7168). In 3 of 9 U.S. studies, ethnic and racial minorities were well-represented (23, 24, 30). Five studies reported the association between harms and self-reported adherence to return gynecologic visits or Pap smears (17, 19, 23, 24, 30). The overall quality of the studies was low (**Appendix Table 2**). Only 5 were population-based; the remainder enrolled convenience samples. Only 3 studies reported pretesting the survey instrument. None of the survey studies commented on the characteristics of nonrespondents.

The percentage of women reporting pain or discomfort during the pelvic examination ranged from 11% to 60% (median, 35%; 8 studies [$n = 4576$]). The percentage reporting 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%) than at their last (33%) examination (20). Similarly, another study reported that older age and previous pregnancy were independently associated with less negative feelings toward the pelvic examination (18).

All 5 studies that examined the relationship between pelvic examination–based pain or discomfort and return visits reported that women who expressed pain or discomfort were less likely to return for another visit (**Appendix Table 2**). In the largest and most methodologically rigorous of these, Kahn and colleagues (30) found that women who had not experienced pain were 73% more likely to return for another examination than were those who had experienced pain (odds ratio, 1.73 [95% CI, 1.08 to 2.83]; $n = 490$).

Two studies reported pelvic examination attitudes and experiences in overweight women. The quality of these

studies was low. A community-based study in California surveyed 498 overweight women (body mass index, 25 to 122 kg/m²) aged 21 to 80 years recruited from community settings with high proportions of English-speaking, overweight African American women (32%) (31). Although the survey was based on focus groups, it was not validated and response rates were not reported. Body mass index 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 body mass index category also had a lower rate of Pap test completion in the previous 2 years than women with a lower body mass index, after age and race were controlled for ($P < 0.02$).

A community-based study in Connecticut surveyed 303 women aged 40 to 65 years to determine rates and predictors of screening pelvic examinations in overweight and nonoverweight women (32). Neither response rates nor questionnaire development or validation procedures were reported. Twenty percent of the respondents were classified as moderately overweight and 14% as very overweight. Fewer very overweight women (48%) reported annual pelvic examinations than average-weight (68%) or moderately overweight (67%) women ($P < 0.05$). This study did not investigate harms of pelvic examination.

Nine studies (Appendix Table 3, available at www.annals.org) focused on women with a history of sexual violence: 2 from Europe and 7 from the United States. Eight were cross-sectional survey studies (33–40), and 1 was a case–control study (41). Outcomes included harms only ($n = 6$), self-reported use of gynecologic care only ($n = 3$), or both ($n = 2$). Five of the U.S. studies were conducted in a Veterans Affairs center; 3 were done at a single Veterans Affairs medical center (33–35). Two studies also evaluated the effect of posttraumatic stress disorder (PTSD) on the pelvic examination experience. Overall, the studies were low quality. Only 2 were population-based, only 1 commented on missing data, and only 1 reported comparisons between responders and nonresponders. Seven of the 9 studies validated or piloted their survey instrument.

In the 8 studies of sexual violence that included a control group, outcomes included pain or discomfort in 4 (34–36, 39); fear, anxiety, distress, or embarrassment in 3 (33–35); and receipt of gynecologic services in 5 (36–39, 41). Two of the 4 studies reporting pain and discomfort found significantly higher rates in women with a history of sexual violence than women without such history (34, 39); the other 2 studies found no difference (35, 36). Two of the 3 studies reporting fear, anxiety, distress, or embarrassment found that women with a history of sexual violence were significantly more likely to report these emotions than women without such history (34, 35).

A survey study of 94 women from a single Veterans Affairs medical center reported that women with a history

of sexual violence who also had symptoms of PTSD reported more pelvic examination–related distress ($P = 0.03$) and higher pain ratings ($P = 0.04$) than women without PTSD (34). A second study from the same group ($n = 165$; response rate 55%) reported higher median scores for fear, embarrassment, and distress in women who had a history of sexual violence and a diagnosis of PTSD than in women without PTSD, regardless of their history of sexual violence ($P < 0.005$). This study found no significant differences in pain (35).

Five studies assessed receipt of gynecologic services (37, 38, 40, 41). Two reported decreased utilization of gynecologic services in women with a history of sexual violence, 2 found no difference, and 1 found increased use in women with a history of sexual violence. The largest and methodologically strongest of these studies, a population-based telephone survey of a representative sample of more than 35 000 women in the United States, found no significant difference in the percentage of women with and without a history of sexual violence who reported having a Pap test in the past 3 years (85.6% vs. 84.3%; $P = 0.32$) (38).

DISCUSSION

We conducted this systematic review to evaluate the benefits and harms of routine screening pelvic examination in asymptomatic, nonpregnant adult women who are not at increased risk for gynecologic cancer. We did not include conditions for which strong evidence and consensus exist (that is, cervical cancer screening, which requires a speculum examination, and screening before hormonal contraception initiation or screening for chlamydia, gonorrhea, or bacterial vaginosis, which do not). Our primary conclusion is that no data support the use of routine pelvic examination (excluding cervical cytologic examination) for reducing the morbidity or mortality of any condition (Table). Furthermore, limited evidence suggests that screening pelvic examinations may be associated with pain, discomfort, fear, anxiety, or embarrassment in about one third of women and can lead to unnecessary, invasive, and potentially harmful diagnostic procedures.

We identified no studies evaluating the mortality and morbidity benefits of bimanual examination to screen for ovarian cancer in asymptomatic, average-risk women, and most major professional and governmental groups recommend against such screening (42–45). The examination was not included in either of the 2 large contemporary ovarian cancer screening trials. In the PLCO (Prostate, Lung, Colorectal, and Ovarian) cancer screening study, a randomized, controlled trial of more than 78 000 women followed for a median of 12.4 years, bimanual examination was initially included in the screening protocol but was dropped after 5 years because no malignancies were detected solely by this examination (46). The screening tests used were serum CA-125 and transvaginal ultrasonogra-

Table. Summary of Screening Pelvic Examination Review

Outcome	Studies	Women Included, <i>n</i>	Findings
Diagnostic accuracy of pelvic examination	3 cohort studies (ovarian cancer)	5633 (3 studies) 0	Ovarian cancer: positive predictive value of 0% (no cases identified) to 3.6%* Other conditions: no evidence
Benefits of pelvic examination for detection of malignant or benign conditions	None	0	Reduced morbidity: no evidence Reduced mortality: no evidence Increased attainment of other preventive care: no evidence
Direct harms (pain, discomfort, fear, anxiety, or embarrassment)	14 survey studies; 1 cohort study	Pain or discomfort: 4576 (8 studies) Fear, embarrassment, or anxiety: 10 702 (7 studies)	Reported pain or discomfort: 35% (median); range, 11% to 60% Reported fear, embarrassment, or anxiety: 34% (median); range, 10% to 80%
Indirect harms (false reassurance, overdiagnosis, overtreatment, or diagnostic procedure–related harms)	None	0	Indirect evidence from 1 cohort study (<i>n</i> = 2000) found that screening pelvic examination led to unnecessary surgery in 1.5% of women

* Reference standard test was some combination of ultrasonography, CA-125 testing, or surgical exploration if pelvic examination was abnormal or ambiguous and 1-y follow-up if pelvic examination was normal.

phy. Despite an increase in ovarian cancer detection rates in the screened group, death from ovarian cancer was not reduced. The second screening trial, UKCTOCS (United Kingdom Collaborative Trial for Ovarian Cancer Screening), does not include the bimanual examination. This study of 202 638 postmenopausal women is comparing no screening, screening with annual CA-125 and transvaginal ultrasonography as a second-line test, and transvaginal ultrasonography; it is expected to report mortality results in 2015 (47).

We identified no studies evaluating mortality or morbidity outcomes of the screening pelvic examination for diagnosing other types of cancer or other benign gynecologic conditions, including pelvic inflammatory disease. Pelvic inflammatory disease often presents with vague or minimal symptoms (48) and, if untreated, can lead to infertility, ectopic pregnancy, or chronic pelvic pain (49–52). The Centers for Disease Control and Prevention state that “the optimal treatment regimen and long-term outcome of early treatment of women with asymptomatic or subclinical pelvic inflammatory disease are unknown” and recommends treatment only when a woman with some symptoms (for example, lower abdominal or pelvic pain) has physical examination findings (for example, cervical motion or uterine and adnexal tenderness) suggestive of pelvic inflammatory disease (53). Symptom questionnaires are available to help determine which patients require bimanual examination for diagnosis of pelvic inflammatory disease (54).

We identified no studies that specifically investigated overdiagnosis, overtreatment, false reassurance, 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 pelvic examinations led to unnecessary surgery in 1.5% of women screened (14), which exposed them to risk for major surgical complications that may be as high as 15% (46).

Other harms include distress in anticipation of, and during, the pelvic examination. We identified 15 studies that examined these outcomes. Overall, this literature had substantial methodological weaknesses, including unrepresentative populations, low response rates, and inadequately validated survey instruments. About one third of respondents reported fear, embarrassment, anxiety, pain, or discomfort during, or before, the pelvic examination. Women who reported pain or discomfort were less likely to return for another visit than those who did not. Although our review focused on adult women, several groups have reported that younger women are more likely than older women to experience pelvic examination–associated embarrassment and pain (25, 26). Other data suggest that fear of the examination may lead women, especially teenagers, to delay or avoid obtaining oral contraceptives (5, 55).

Some investigators have hypothesized that victims of sexual violence may be more likely than others to experience harms from the pelvic examination and less likely to get regular Pap smears (34, 35). The 9 studies addressing this issue reported mixed results, although the largest and methodologically strongest of these studies found no statistically significant difference in the percentage of women with and without a history of sexual violence who reported having a Pap smear in the past 3 years (38).

This review focused on the morbidity and mortality benefits of pelvic examination in asymptomatic women; however, there may be other benefits. For example, pelvic examinations might be an incentive for women to access health care and thereby receive recommended gynecologic services, such as contraception, screening for sexually transmitted infections and cervical cancer, and other evidence-based nongynecologic preventive care (15). Another possible benefit might be that the examination provides a context in which women are more willing to raise sensitive issues, such as incontinence or sexual dysfunction. Our literature search did not identify any studies that empirically evaluated any of these possible benefits.

Despite the limited indications for pelvic examinations, providers continue to perform it for many reasons, including screening for ovarian cancer, before prescribing hormonal contraception, to diagnose sexually transmitted infections, or as part of the well-woman visit (1, 56, 57). The American College of Obstetricians and Gynecologists recommends annual routine pelvic examinations while acknowledging that “this recommendation is based on expert opinion” (2). In a survey of 1250 U.S. physicians, most primary care providers indicated that they perform pelvic examinations “as part of a well-woman exam” (1, 56). In a clinical-vignette survey study of 521 obstetrician-gynecologists, more than 95% indicated that they would perform bimanual examination in asymptomatic women even if they are not due for a Pap test (57).

Studies indicate that many providers perform pelvic examinations to obtain Pap tests for women in whom the test is not indicated (58). A recent study showed that adherence of primary care providers 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 (59). This overuse was recently highlighted by the American Board of Internal Medicine Foundation’s Choosing Wisely Campaign (60).

Conducting a pelvic examination incurs substantial costs. Medicare “National Payment Amount” values for 2013 were \$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.aspx). The estimated total annual cost of preventive gynecologic examinations and associated laboratory and radiologic services in the United States is \$2.6 billion (61). About a third of this total (\$850 million) is spent on unnecessary cervical cancer screening in women younger than 21 years (62) and an indeterminate additional percentage on other unnecessary pelvic examinations. Such examinations may also incur opportunity costs, including the time required for the examination and its preparation (a patient disrobing and putting on a gown, a clinician finding a chaperone, or a chaperone taking time away from other duties).

This review has several limitations. First, we included only English-language publications. Second, few studies addressed the diagnostic accuracy or the morbidity or mortality benefits of the pelvic examination in asymptomatic women. Third, the studies reporting harms were generally low quality; did not exclusively focus on asymptomatic nonpregnant women; and may, because of selective reporting, represent an overestimate of the frequency of these harms.

Despite its widespread use in clinical practice, data supporting the use of the pelvic examination in asymptomatic women not at increased risk for gynecologic cancer are scant. Cervical cancer screening, which was not included in this review, should be performed at intervals recommended by evidence-based guidelines for specific groups of women

defined by age, presence of a cervix, and prior Pap test results (3, 4). Low-quality data suggest that pelvic examinations may cause pain, discomfort, fear, anxiety, or embarrassment in about 30% of women. An important area for future research is the development and testing of strategies to reduce the high rate of inappropriate use of the pelvic examination.

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AD LIBITUM

The Hollow Man

The hollow men have nothing on you.
 You were hollow before you died. How long
 Before they called me?

I count your ribs, count the seconds, listening.
 You're empty now, no noise to hear. "The virus"
 You called it, but in truth it felt like love, felt like
 A friend you'd found at the bottom of the glass.

The horror, the horror; well, Mistah Kurtz
 Had the same problem, I suppose; and he dead, too.
 Did someone have to tell his children?

"Thank you," she says. Thank you for telling me
 That my daddy is dead in a Northern city.
 "I'm his third daughter." Order, connection, family.
 All lost to you when you went hollow. I wonder
 Did you miss it? Last week, when a space in your brain
 Suddenly filled with blood, was it your body
 Weeping, finally, for what your soul never found?

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APPENDIX: SEARCH STRATEGY

Database: Ovid MEDLINE (1946 to July 2013)

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

Study, Year (Reference)	Country	Reference Standard	Population	Findings, n/N (%)	Incidence of Ovarian Cancer After 1 Year, n/N (%)	PPV, %	Abnormal or Ambiguous Pelvic Examination, n	Laparoscopic or Open Surgery, n	QUADAS Elements of Study Quality Met, n*
Adonakis et al, 1996 (14)	Greece	Surgery and histology	2000 women Aged ≥ 45 y with no evidence of adnexal pathology Mean age: 58 y (range, 45–80 y)	Abnormal pelvic examination: 59/2000 (3.0) Ovarian cancer: 1/59 (1.7) Ambiguous pelvic examination: 115/2000 (5.8) Ovarian cancer: 1/115 (0.9)	2/2000 (0.10)	1.2	174	31	8
Grover and Quinn, 1995 (12)	Australia	Surgery	2623 women Healthy and asymptomatic Mean age: 51 y (range, 25–92 y)	Abnormal adnexa on pelvic examination: 40/2623 (1.5) Ovarian disease: 9/40 (PPV, 22; all benign) One cancer case reported at 12-mo follow-up†	1/2623 (0.04)	0‡	40	NR	8
Jacobs et al, 1988 (13)	United Kingdom	Surgery and histology	1010 women Healthy, aged ≥ 45 y and amenorrheic for >12 mo Median age: 54 y (range, 45–83 y)	Abnormal pelvic examination: 28/1010 (2.8) Ovarian cancer: 1/28 (3.6) No additional cancer cases at 12-mo follow-up§	1/1010 (0.10)	3.6	28	NR	8

NR = not reported; PPV = positive predictive value; QUADAS = Quality Assessment of Diagnostic Accuracy Studies.

* All studies were rated identically on the 11 QUADAS elements (10).

† 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.

§ Follow-up included CA-125 and ultrasonography if initial testing was abnormal or a postal questionnaire if initial testing was normal.

|| Thirteen women with abnormal ultrasonographic findings were advised to consult their general practitioner for possible referral to a gynecologist.

Appendix Table 2. Pelvic Examination–Related Harms and the Effect on Return Visits

Study, Year (Reference)	Study Design	Population and Setting	Harms		Global Assessment	Multivariable Analysis	Effect on Return Visits	Study Quality*	
			Fear, Anxiety, or Embarrassment	Pain or Discomfort				Population	Survey Instrument
Osofsky, 1967 (22)	Survey	40 women RR (NR); single clinic in the United States; aged 20 to 39 y	32 of 40 (80%) reported anxiety	–	–	–	–	Low	High
Hesselius et al, 1975 (19)	Survey (population-based)	800 women (88% RR); women invited to mass screening in Sweden; aged 21 to 49 y	25% said "exam was not at all unpleasant"	74% said examination "not at all painful"	–	No	Participants in screening were less likely than nonparticipants to report "unpleasantness" associated with the examination, although it is unclear if this finding was statistically significant	High	Low
Haar et al, 1977 (28)	Survey	409 women RR (NR); multiple clinics in New York; "ages under 20 to over 60 y"	34% reported moderate or severe anxiety before a visit to the gynecologist; a similar percentage reported these same feelings about general medical check-ups	–	–	–	–	Low	Medium
Petravage et al, 1979 (29)	Survey	977 women RR (NR); 14 clinics in Utah with no age restrictions; median age: 28.4 y	–	45% "felt comfortable during a pelvic examination"	–	–	–	Low	Low
Golomb, 1983 (16)	Survey	61 of 70 women (87% RR); 2 clinics in Rhode Island; aged ≥ 18 y	–	–	86% reported that pelvic examinations are "not all that bad"	–	–	Low	Low
Broadmore et al, 1986 (27)	Survey	199 of 250 women (80% RR); family planning clinic in New Zealand; "mostly aged 17 to 30"	–	60% reported some pain or discomfort during the examination	–	–	–	Medium	Low
Wijma et al, 1998 (20)	Survey (population-based)	531 of 788 women (67% RR); Sweden; aged 25 to 49 y	–	Among women who were aged ≤ 19 y at first pelvic examination, 71% reported that it was painful	75% rated the pelvic examination as ≥ 46 on a scale of 0 (very negative) to 100 (very positive)	–	–	High	Medium
Yu and Rymmer, 1998 (26)	Survey	650 women (Pap+; 523; Pap–; 127) RR (NR); 2 hospital-based clinics in London; aged 15 to 75 y	Reported embarrassment: Pap+; 15% Pap–; 13%	Reported pain: Pap+; 11% Pap–; 4%	Troublesome: Pap+; 3% Pap–; 12% Scared: Pap–; 13%	–	–	Medium	Low
Harper et al, 2001 (17)	Survey (telephone)	800 women RR (NR); low-income residents of California; aged 18 to 44 y	75% reported fear and embarrassment	–	–	No statistical analysis done	31% said feelings of fear and embarrassment had prevented them from getting a pelvic examination at some time	Medium	Low
Fiddes et al, 2003 (25)	Survey	687 of 1000 women (69% RR); family planning or sexual health clinics in Scotland; ≥ 20 (8%); aged 21 to 40 (50%); aged >40 y	10% felt anxious or distressed at the prospect of having a pelvic examination	–	Older women and women who had been pregnant were significantly and independently less likely to "feel negative towards pelvic examination"	–	–	Low	High
Kahn et al, 2003 (30)	Cohort	490 women (44% black; 24% Hispanic); urban hospital in Cincinnati, Ohio; aged 12 to 24 y (44% aged ≤ 18 y)	–	61% believed Pap smear would not be painful	–	Yes	Lack of pain associated with return visit (OR, 1.73 [95% CI, 1.08 to 2.83]) Embarrassment not significantly associated with return visit These outcomes did not differ by race/ethnicity	Medium	Low

Continued on following page

Appendix Table 2—Continued

Study, Year (Reference)	Study Design	Population and Setting	Harms			Global Assessment	Multivariable Analysis	Effect on Return Visits		Study Quality*	
			Fear, Anxiety, or Embarrassment	Pain or Discomfort	Pain or Discomfort			Population	Survey Instrument	Analysis	
Taylor et al, 2004 (24)	Survey (population-based)	370 of 449 women (82% RR), Seattle; aged 18 to 64 y (all Vietnamese American)	—	31% reported pain	—	—	Yes	Concern about pain and discomfort was not a significant barrier to having a Pap smear (OR, 0.5 [CI, 0.3 to 1.1])	High	Medium	
Hoyo et al, 2005 (23)	Survey (population-based)	144 of 172 women (84% RR), Durham, North Carolina; aged 45 to 64 y	—	24% reported pain	—	—	Yes	Pain associated with Pap smear nonadherence (OR, 4.8 [CI, 1.7 to 13.7])	High	Low	
Boume et al, 2010 (18)	Survey (population-based)	7168 women; Jamaica; aged 15 to 49 y	Among the 57% who had a pelvic examination, 0.5% reported embarrassment as the reason	—	Among the 57% who had never had a pelvic examination, 1.4% said the reason was that they did "not like the process" and 0.1% did "not like the environment"	—	—	—	High	Low	
Armstrong et al, 2012 (21)	Survey	148 of 635 women (23% RR), Planned Parenthood clinic in Virginia; aged 18 to 27 y	17% reported fear; 16% reported embarrassment	—	—	—	—	—	Medium	High	

NR = not reported; OR = odds ratio; Pap = Papanicolaou; Pap+ = had a Pap smear; Pap- = did not have a Pap smear; RR = response rate.

* Population (sampling strategy and incorporation of sampling structure into the analysis), survey instrument (use of a validated or piloted survey instrument), and analysis (appropriate method for handling missing data, comparison of responders and nonresponders, and RR) were individually rated as high, medium, or low quality.

Appendix Table 3. History of SV as a Predictor of the Pelvic Examination Experience and Receipt of Pap Smears

Study, Year (Reference)	Study Design	Population and Setting	Predictors	Outcomes	Findings	Study Quality*		
						Population	Survey Instrument Analysis	
Lee et al., 2007 (33)	In-person survey with no control group	31 of 46 female veterans (SV+) (67% RR); VA clinic	PTSD	Anticipated pelvic examination-related distress	No association between PTSD symptom severity and anticipated pelvic examination-related distress	Low	High	Low
Weitlauf et al., 2008 (34)	Survey (immediately after routine pelvic examination)	68 of 94 female veterans (77% SV+ and 22% had PTSD) (72% RR); VA clinic; aged 18 to 65 y	SV, PTSD (current)	Distress or pain, both measured on Likert scales from 0 to 10	Distress (median): SV+: 4.27 SV-: 0 P = 0.03 Pain (median): SV+: 2.5 SV-: 0 P = 0.04 SV+ women with PTSD had significantly increased distress (but not pain) compared with women without PTSD (SV+ or SV-) (P = 0.02)	Low	High	Low
Weitlauf et al., 2010 (35)	Survey	90 of 165 female veterans (SV-, no PTSD: 17; SV+, no PTSD: 48; SV+ and PTSD: 22) (55% RR); VA clinic; aged 18 to 65 y	SV, PTSD (current)	Fear, embarrassment, distress, or pain, each measured on Likert scales from 0 to 10	Median scores for fear, embarrassment, and distress were significantly higher in the SV+ with PTSD group than the SV- with no PTSD group (P < 0.005) and the SV+ with no PTSD group (P < 0.001)	Low	Low	Medium
Hilden et al., 2003 (39)	Mailed survey (1 wk after pelvic examination)	808 of 1011 women (165 SV+) (80% RR); university hospital clinic in Denmark; aged ≥18 y	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])	Low	High	Low
Robohm and Bittenheim, 1996 (36)	Mailed survey (population-based)	74 women (SV+, 44; SV-, 30) RR (NR); small midwestern U.S. city; age NR	SV	Distress; physical pain or discomfort; received gynecologic care; or embarrassment, shame, or fear	Distress: significantly higher in SV+ than SV- women (P < 0.01) Physical pain or discomfort: no significant difference SV+ women significantly less likely to seek regular gynecologic care (P < 0.05) Embarrassment, shame, and fear: significantly higher in SV+ than SV- women (P values were <0.05, 0.01, and 0.05, respectively)	Low	High	Low
Leeners et al., 2007 (41)	Case-control, mailed survey	255 women (SV+, 85; SV-, 170) RR (NR); Germany; mean age: 38.4 y for SV+ and 38.9 y for SV-	SV	% reporting assumption "that a visit to the GYN would cause an important psychological strain," participants had receipt of gynecologic services	SV+: 37.7 SV-: 3.5 P < 0.001 No significant difference in self-reported receipt of gynecologic services	Low	Low	Medium
Farley et al., 2002 (37)	Mailed survey	364 of 1314 women with and 372 of 2897 without a Pap smear in the past 2 y (SV+, 26%) (17% RR); HMO in California; aged 21 to 64 y	SV	Received Pap smear in past 2 y	On multivariate analysis, SV was associated with a significantly lower odds of having a Pap smear in the past 2 y (OR, 0.56 [CI, 0.34 to 0.91])	Medium	High	Low

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Appendix Table 3—Continued

Study, Year (Reference)	Study Design	Population and Setting	Predictors	Outcomes	Findings	Study Quality*		
						Population	Survey Instrument	Analysis
Lang et al, 2003 (40)	Mailed survey	221 of 419 women (SV+, 96; SV-, 122) (56% RR); primary care VA clinic in San Diego; mean age, 46.6 y	SV	Mean number of Pap smears in past 5 y	SV+: 4.5 (SD, 2.5) SV-: 3.8 (SD, 2.0) P < 0.05	Medium	Medium	Medium
Watson-Johnson et al, 2012 (38)	Telephone survey (Behavioral Risk Factor Surveillance System; population-based)	35 048 women (SV+, 5404; SV-, 29 644) RR (NA); United States; age NR	SV	% of women aged ≥18 y who had a Pap smear in the past 3 y	SV+: 85.6 (±1.2 SE) SV-: 84.3 (±0.5 SE) P = 0.32	High	High	Low

GYN = gynecologist; NA = not applicable; NR = not reported; OR = odds ratio; PTSD = posttraumatic stress disorder; Pap = Papanicolaou; SV = sexual violence; SV+ = experienced sexual violence; SV- = did not experience sexual violence; VA = veterans affairs.

* Population (sampling strategy and incorporation of sampling structure into the analysis), survey instrument (use of a validated or piloted survey instrument), and analysis (appropriate method for handling missing data, comparison of responders and nonresponders, and RR) were individually rated as high, medium, or low quality.