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### Authors

Sawaya, George F  
Smith-McCune, Karen K  
Gregorich, Steven E  
[et al.](#)

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## Effect of professional society recommendations on women's desire for a routine pelvic examination

George F. Sawaya, MD, Karen K. Smith-McCune, MD,PhD, Steven E. Gregorich, PhD, Michelle Moghadassi, MPH, and Miriam Kuppermann, PhD,MPH

Department of Obstetrics, Gynecology, and Reproductive Sciences (Drs Sawaya, Smith-McCune, and Kuppermann, and Ms Moghadassi), Department of Medicine (Dr Gregorich), and Center for Healthcare Value (Dr Sawaya), University of California, San Francisco, San Francisco, CA.

### Abstract

**BACKGROUND:** The American College of Physicians strongly recommends against performing pelvic examinations in asymptomatic, nonpregnant women, citing evidence of harm (false-positive testing, unnecessary surgery) and no evidence of benefit. In contrast, the American Congress of Obstetricians and Gynecologists recommends pelvic examinations in asymptomatic women beginning at age 21 years, citing expert opinion.

**OBJECTIVE:** We sought to evaluate if providing women with professional societies' conflicting statements about pelvic examinations (recommendations and rationales) would influence their desire for a routine examination.

**STUDY DESIGN:** We recruited 452 women ages 21–65 years from 2 women's clinics to participate in a 50-minute face-to-face interview about cervical cancer screening that included a 2-phase study related to pelvic examinations. In the first phase, 262 women were asked about their desire for the examination without being provided information about professional societies' recommendations. In the second phase, 190 women were randomized to review summaries of the American College of Physicians or American Congress of Obstetricians and Gynecologists statement followed by an interview.

**RESULTS:** First-phase participants served as the referent: 79% (208/262) indicated they would want a routine examination if given a choice. In the second phase, a similar percentage of women randomized to the American Congress of Obstetricians and Gynecologists summary had this desire (82%: 80/97; adjusted odds ratio, 1.37; 95% confidence interval, 0.69–2.70). Women randomized to the American College of Physicians summary, however, were less likely to indicate they would opt for an examination (39%: 36/93; adjusted odds ratio, 0.12; 95% confidence interval, 0.06–0.21). Overall, 94% (179/190) believed the potential benefits and harms should be discussed prior to the examination.

**CONCLUSION:** Providing women with a professional society's recommendation advising against routine pelvic examinations substantially reduced their desire to have one. Educational

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Corresponding author: George F. Sawaya, MD. [george.sawaya@ucsf.edu](mailto:george.sawaya@ucsf.edu).

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materials are needed to ensure women's informed preferences and values are reflected in decisions about pelvic examinations.

### Keywords

patient preferences; patient view; professional society recommendation; routine pelvic examination

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### Introduction

Pelvic examinations are commonly performed in the United States with >62 million performed in 2010.<sup>1</sup> These examinations have long provided the foundation of the annual well-woman visit.<sup>2,3</sup> In fact, obstetrician-gynecologists indicate that they would perform a routine examination in >85% of asymptomatic women of a variety of ages, believing it to be important to accommodate patients' expectations and reassure them of their health.<sup>4</sup>

Recently, the value of the routine pelvic examination has been questioned.<sup>2,3,5</sup> Most notably, the American College of Physicians (ACP) strongly recommended against routine pelvic examinations in asymptomatic, nonpregnant women in 2014.<sup>6</sup> The recommendation was based on a systematic review that found no evidence supporting the use of pelvic examination in asymptomatic, average-risk women, but did find evidence of harm.<sup>7</sup> In response to this recommendation, the American Congress of Obstetricians and Gynecologists (ACOG) acknowledged the lack of evidence of benefit, but stood by its 2012 recommendation supporting annual pelvic examinations in asymptomatic women aged 21 years, "based on expert opinion"<sup>8</sup>

An accompanying ACOG Practice Advisory further stated that the pelvic examination provides an opportunity for clinicians to recognize incontinence and sexual dysfunction, and allows gynecologists "to explain a patient's anatomy, reassure her of normalcy, and answer her specific questions thus establishing open communication between patient and physician."<sup>9</sup> In 2015, ACOG reaffirmed its recommendation and reinforced its suggestion that women discuss whether or not to have a pelvic examination with their provider before making a decision.<sup>10</sup> Thus, current recommendations by 2 influential professional societies are in direct conflict.

Little is known about women's attitudes and beliefs about these examinations. We recently reported the first phase of this study in which we interviewed 262 women about their perceptions of the examination; about half of women did not know the examination's purpose, although many believed it to be of value, especially in reassuring them of their health.<sup>11</sup> Here, we report the second phase of the interview study focused on understanding whether professional societies' conflicting statements (recommendation and rationale) would influence women's desires to have the examination. To address this question, we randomly assigned women to review summaries of either the ACP or the ACOG statements followed by a series of attitudinal questions.

## Materials and Methods

This study was imbedded in a larger study of patient preferences regarding cervical cancer screening. The traditional coupling of cervical cancer screening with pelvic examinations allowed us an opportunity to explore women's attitudes and beliefs about the examination. From September 2014 through June 2016, we recruited women from 2 women's health clinics at an academic medical center (University of California, San Francisco) and an innercity clinic (Zuckerberg San Francisco General Hospital and Trauma Center) to participate in a 50-minute face-to-face interview during which a demographics questionnaire and series of preference elicitation exercises were completed. Eligible women were aged 21–65 years and spoke either English or Spanish. Written consent was obtained and participants were compensated with a \$50 gift card. Both the University of California, San Francisco Committee on Human Research and the Zuckerberg San Francisco General Hospital Institutional Review Board approved the study.

To prepare participants for answering questions about cervical cancer screening, we showed them an illustration of a woman in dorsal lithotomy position undergoing a pelvic examination, specifically a speculum examination with collection of cervical specimens. At the end of the preference elicitations, we provided participants with an illustration of a bimanual examination and asked about their prior experiences with, and attitudes and beliefs about, this examination.

The portion of the study focused on pelvic examinations was performed in 2 phases. In the first phase (September 2014 through October 2015), we sought to describe women's understanding of the examination's purpose and its perceived value within a sample of participants who were not exposed to summary statements describing professional societies' recommendations regarding the examination; these results were recently reported.<sup>11</sup> We focused the second phase on evaluating the effect of professional societies' statements on participants' desire to undergo the examination. The randomized second phase of the study took place from October 2015 through June 2016.

Because neither professional society had materials regarding this examination designed specifically for patients, we wrote plain-language summaries through an iterative process to assure accuracy. Study interviewers and research associates of other study teams further reviewed the summaries to insure readability at a low literacy level and clarity (Table 1). Randomization was performed by the research assistant using the computerized Research Electronic Data Capture System and was stratified by interview language (English or Spanish) and by recruitment site.

Each participant was given the assigned summary to read on her own in either English or Spanish. The research assistant was present to answer any questions in the participant's chosen language and provide clarifications if necessary. In both the first and second phases, the research assistant asked: "Given a choice, would you want to have this examination even if you were having no problems?" and "Do you think this examination helps establish open communication between you and your health care provider?" In phase 2 alone, the research assistant asked 3 additional questions regarding other advantages of the examination cited by

ACOG in the practice advisory: “Do you think this examination would prompt you to talk to your provider about problems with urine leakage that you would otherwise not discuss?”; “Do you think this examination would prompt you to talk to your provider about sexual problems that you would otherwise not discuss?”; and “Do you think this examination would prompt you to talk to your provider about concerns about your anatomy that you would otherwise not discuss?” Finally, the research assistant asked “Do you believe that women with no health problems should discuss the potential benefits and harms of this examination with their provider before deciding to have one?” The response options for all questions were “yes”; “no”; and “don’t know.”

Our primary outcome was the response to the question regarding desire to have a pelvic examination. Responses in the nonrandomized first phase served as the comparator. We used  $\chi^2$  tests to evaluate differences in demographic and medical history characteristics among the 3 groups and if present ( $P < .05$ ), included these variables in multivariable logistic regression models. The outcome referent category combined “no” and “don’t know” responses. Univariate and multivariate odds ratios (OR) and 95% confidence intervals (CI) are reported ( $P < .05$  significant, 2-sided). The number needed to treat was calculated as the inverse of the absolute risk difference between the randomized groups. For responses to the questions unique to the second phase regarding incontinence, sexual problems, and concerns about anatomy, we report only univariate outcomes because there were no significant demographic or health history differences between the randomized groups. Our planned sample size of a total of 450 for both phases of the study was based on precision of preference score estimates; we performed no formal power or sample size analyses for hypotheses related to pelvic examinations.

## Results

A total of 452 women completed interviews: 262 in the first phase and 190 in the second phase. In the second phase, 93 women were randomized to review the summarized ACP statement, and 97 were randomized to review the summarized ACOG statement. Participants were racially and ethnically diverse (57% nonwhite); most were educated and of reproductive age. Compared with participants in the first phase, those in second phase had attained a higher educational level, reported a higher income, and were less likely to be interviewed in Spanish (Table 2). Demographic and medical history characteristics were similar between participants randomized to the 2 groups. About 90% of all participants reported having a previous bimanual pelvic examination.

In response to the question “Given a choice, would you want to have this examination even if you were having no problems?” 79% (208/262) of participants in the first phase responded “yes,” a similar percentage to those randomized in the second phase to the ACOG summary (82%: 80/97; adjusted OR, 1.37; 95% CI, 0.69–2.70) (Table 3). Those randomized to the ACP summary, however, were less likely to answer “yes” (39%: 36/93; adjusted OR, 0.12; 95% CI, 0.06–0.21). The absolute risk difference was 44%, corresponding to a number needed to treat of 2.3. In response to the question about the examination helping to establish open communication with the health care provider, 62% in the first phase responded “yes”; reviewing either the ACP or the ACOG summary had no significant effect on “yes”

responses (53% and 63%, respectively). OR were adjusted for the following characteristics as defined in Table 2: randomization group, age, race/ethnicity, education level, income, ever birth, ever Pap test, ever bimanual pelvic exam, and language.

Compared with women randomized to ACOG summary, fewer viewing the ACP summary believed that the examination provided an opportunity to discuss urinary leakage (37% vs 53%; OR, 0.52; 95% CI, 0.29–0.93), sexual problems (39% vs 54%; OR, 0.56; 95% CI, 0.31–0.99), and concerns about anatomy (44% vs 61%; OR, 0.51; 95% CI, 0.28–0.90). Nearly all (94%, 179/190) participants regardless of randomization group believed that the potential benefits and harms should be discussed prior to the examination.

## Comment

We found that providing women with a professional society's recommendation advising against routine pelvic examinations significantly reduced their desire to have one. The effect was large in both relative and absolute terms. Women viewing the ACP summary were 88% less likely to desire the examination compared with those viewing the ACOG summary; for every 2–3 women provided the ACP recommendation, 1 would opt out of the examination. Our study is one of the few in women's health to assess the effect of an educational intervention about the benefits and harms of a clinical preventive service on participants' intended behaviors.

Our findings suggest that reviewing the ACP recommendation had the independent effect of making women substantially less likely to want the examination (39%), compared to women who were not exposed to a summary from any professional society in the first phase (79%) and compared to women randomized to review the ACOG summary in the second phase (82%). Our findings also support the opinions expressed in the June 2014 ACOG Practice Advisory that the examination affords an opportunity for women to discuss problems that they would otherwise not discuss: urinary incontinence, sexual dysfunction, and concerns about anatomy.<sup>9</sup> However, whereas most participants who reviewed the ACOG summary agreed that the examination would prompt them to talk about these problems that they would otherwise not discuss, women reviewing the ACP summary were less likely to believe that the examination offered these potential benefits, suggesting that knowing the examination is not recommended tempers the perception of benefit.

A systematic review commissioned by the Agency for Healthcare Research and Quality reiterated a lack of evidence of benefit and better characterized harms of screening pelvic examinations, at least in the context of ovarian palpation; abnormal results can be expected in 1.2–8.7% of those screened, leading to surgical exploration in up to 36% of those with positive testing.<sup>12</sup> A recommendation by the US Preventive Services Task Force (USPSTF) that followed the review concluded that current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations.<sup>13</sup> The USPSTF believes that statements of insufficient evidence should prompt clinicians to explain to patients the uncertainty about the balance of benefits and harms if the service is offered.<sup>14</sup> At the time of publication of the USPSTF draft review (and during the randomized portion of our study), the June 2014 ACOG Practice Advisory was withdrawn and replaced with a new advisory

focused on reiterating the clearest indication for pelvic examinations (in symptomatic women vs asymptomatic women) and pointing out the limited number of disease conditions addressed by the new review (ovarian cancer, bacterial vaginosis, genital herpes, trichomoniasis).<sup>15</sup> Thus, ACOG currently has no stated position about what the possible benefits are, or might be, and no harms of the examination are mentioned.

The strengths of our study include its enrollment of a relatively large sociodemographically diverse group of women and its randomized design. Our success in enrolling a large number of nonwhite women, however, may limit the generalizability to other populations. We were limited by a lack of materials from these professional societies specifically designed for patients regarding pelvic examinations; we had to rely on plain-language summaries produced by our team. Although the interviewer was immediately available to provide clarifications, it is possible that some women may not have understood the written summary. Ideally, we would have randomized participants into 3 groups (no summary, ACP summary, or ACOG summary) but the opportunistic nature of our study did not allow this design. The nonrandomized group was drawn from the same clinics and in close temporal proximity to the randomized groups, thus we believe the comparison regarding responses to desire for a pelvic examination to be valid. In addition, we performed logistic regression analyses controlling for potential demographic confounders and found no significant difference in primary outcome response between the nonrandomized first phase group and the ACOG group. Because the 2 phases of our study were performed sequentially, however, temporal effects may have influenced our results. Finally, although the pelvic examination has traditionally been defined as a speculum examination and bimanual examination, we did not describe inspection of external genitalia, which can also be considered part of the examination. Nevertheless, we believe that the materials we provided our participants captured the essence of the procedure that most women would identify as a pelvic examination.

It is notable that nearly 40% of women viewing the negative ACP recommendation still wanted a routine examination, perhaps reflecting long-held beliefs about its value. More research is needed to better understand factors that influence such preferences with an overarching goal of identifying ways to improve the care delivered at the time of a well-woman visit. In addition, it would be useful to have better methods to uncover potential problems during medical history taking, including a more specific review of systems focused on urinary incontinence and sexual dysfunction. Finally, it is important to emphasize that this discussion concerns the stand-alone value of the pelvic examinations outside of current screening recommendations for cervical cancer and sexually transmissible infections, both of which may require a pelvic examination.

At present, 3 high-profile guideline groups have 3 differing opinions: the ACP strongly recommends against performing a routine pelvic examination, the USPSTF believes the evidence to be insufficient to make a recommendation for or against the examination, and ACOG recommends it be offered as part of shared decision making. Similarly, ACOG Well-Woman Task Force in 2015 reiterated that the decision to perform a speculum and bimanual examination in asymptomatic women be a shared one between patients and providers, implying a discussion of benefits and harms.<sup>10</sup> Our finding that women's desires for a

routine pelvic examination may be highly influenced by information available from professional societies suggests that educational materials are needed to ensure women's informed preference and values are reflected in decisions about having this examination.<sup>16</sup>

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Salient points of original statements by professional societies regarding recommendations for pelvic examinations and plain-language summaries

TABLE 1

ACP	ACOG
<p><b>Salient points of original statements</b></p>	
<p>Recommendation: ACP recommends against performing screening pelvic examination in asymptomatic, nonpregnant, adult women (strong recommendation, moderate-quality evidence).</p>	<p>Recommendation: “Annual pelvic examination of patients 21 years of age or older is recommended.”</p>
<p>Benefits of screening: None identified; “...there is indirect evidence that pelvic examination (as distinct from cervical cancer screening) in asymptomatic, adult women does not reduce morbidity or mortality rates.”</p>	<p>“At this time, this recommendation is based on expert opinion, and limitations of the internal pelvic examination should be recognized.”</p> <p>ACOG “guidelines recommend that a pelvic examination be performed on an annual basis in all patients aged 21 years and older. No evidence supports or refutes the annual pelvic examination or speculum and bimanual examination for the asymptomatic, low-risk patient. An annual pelvic examination seems logical, but also lacks data to support a specific time frame or frequency of such examinations. The decision whether or not to perform a complete pelvic examination at the time of the periodic health examination for the asymptomatic patient should be a shared decision after a discussion between the patient and her health care provider.”</p>
<p>Harms of screening: Unnecessary laparoscopies or laparotomies, fear, embarrassment, anxiety, pain or discomfort, avoidance of necessary care; “Many false positive findings are associated with pelvic examination, with attendant psychological and physical harms, as well as harms associated with the examination itself.</p>	
<p>Harms of pelvic examination include unnecessary laparoscopies or laparotomies, fear, anxiety, embarrassment, pain, and discomfort.”</p>	
<p>“The current evidence shows that harms outweigh any demonstrated benefits associated with the screening pelvic examination.”</p>	
<p>Plain-language summaries used in this study</p>	
<p>Many providers follow recommendations of a group called the American College of Physicians. In 2014, the College looked at research about doing pelvic examinations in women <b>with no health problems.</b></p> <p>For these women:</p> <ul style="list-style-type: none"> <li>• The College found no scientific evidence that pelvic examinations improve health.</li> <li>• The College found some evidence of harm, including “false-alarms” that lead to further testing and occasionally lead to unnecessary surgery.</li> <li>• The College concluded that pelvic examinations are more</li> <li>• The College <b>strongly recommends against doing pelvic examinations</b> in women with no health problems.</li> </ul>	<p>Many providers follow recommendations of a group called the American College of Obstetricians and Gynecologists. In 2012, the College made recommendations about doing pelvic examinations in women <b>with no health problems.</b></p> <p>For these women:</p> <ul style="list-style-type: none"> <li>• The College said there is no scientific evidence that such women should have annual pelvic examination.</li> <li>• The College also said there is no scientific evidence that such women should NOT have annual pelvic examination.</li> <li>• The College believes that each woman should discuss whether or not to have pelvic examination with her provider before harmful than beneficial, deciding to have one.</li> <li>• Based on expert opinion, the College <b>recommends doing annual pelvic examinations</b> in women with no health problems.</li> </ul>

ACOG, American Congress of Obstetricians and Gynecologists; ACP, American College of Physicians.

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TABLE 2

Characteristics of study participants, N = 452

Characteristic	First phase Not randomized, n = 262		Second phase Randomized, n = 190		P <sup>a</sup>
	n (%)	n (%)	ACP summary n = 93	ACOG summary n = 97	
Age, y					.75
21–44	201 (77)	69 (74)	71 (73)		
45–65	61 (23)	24 (26)	26 (27)		
Race/ethnicity					.20
White	109(42)	40 (43)	45 (46)		
Black	35 (13)	13(14)	11 (11)		
Asian/Pacific Islander	36 (14)	19(20)	15 (16)		
Latina/Hispanic	48 (18)	13(14)	8(8)		
Mixed/other	34 (13)	8(9)	18(19)		
Highest education level achieved					<.001
Less than high school	25 (10)	3(3)	3(3)		
High school graduate, some college or vocational school	90 (34)	17(19)	23 (24)		
College graduate	73 (28)	44 (47)	36(37)		
Professional degree	74 (28)	29(31)	35 (36)		
Annual income, \$					.03
<50,000	111 (46)	24 (27)	32 (34)		
50,000–100,000	55 (23)	29 (32)	21 (22)		

Characteristic	First phase Not randomized, n = 262		Second phase Randomized, n = 190		P <sup>a</sup>
	n (%)	n (%)	n (%)	n (%)	
100,001–200,000	48 (20)	21 (23)	23 (25)		
>200,000	27 (11)	16(18)	18(19)		
Ever given birth	132 (50)	39 (42)	45 (46)		0.36
Ever had Pap test	259 (99)	92 (99)	96 (100)		0.58
Ever had bimanual pelvic examination	235 (90)	84 (90)	88 (91)		0.22
Interviewed in Spanish	23 (9)	1 (1)	3(3)		0.01

ACOG, American Congress of Obstetricians and Gynecologists; ACP, American College of Physicians

<sup>a</sup> P from  $\chi^2$  tests evaluating differences among all 3 groups. No significant differences were noted between 2 randomized groups.

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**TABLE 3**

Effect of professional society statement summaries on women’s attitudes and beliefs about routine pelvic examinations

Question	Yes N (%)	No or don't know N (%)	Univariable OR (95% CI)	Multivariable <sup>a</sup> OR (95% CI)
Given choice, would you want to have this examination even if you were having no problems?				
No guideline (first phase)	208 (79)	54 (21)	Reference	Reference
ACP	36 (39)	57 (61)	0.16 (0.10–0.27)	0.12 (0.06–0.21)
ACOG	80 (82)	17 (18)	1.22 (0.67–2.23)	1.37 (0.69–2.70)
Do you think this examination helps establish open communication between you and your health care provider?				
No guideline (first phase)	163 (62)	99 (38)	Reference	Reference
ACP	48 (53)	43 (47)	0.68 (0.42–1.10)	0.70 (0.41–1.20)
ACOG	61 (63)	36 (37)	1.03 (0.64–1.67)	1.09 (0.63–1.86)
Do you think this examination would prompt you to talk to your provider about problems with urine leakage that you would otherwise not discuss?				
ACP	34 (37)	59 (63)	0.52 (0.29–0.93)	
ACOG	51 (53)	46 (47)	Reference	
Do you think this examination would prompt you to talk to your provider about sexual problems that you would otherwise not discuss?				
ACP	36 (39)	56 (61)	0.56 (0.31–0.99)	
ACOG	52 (54)	45 (46)	Reference	
Do you think this examination would prompt you to talk to your provider about concerns about your anatomy that you would otherwise not discuss?				
ACP	41 (44)	52 (56)	0.51 (0.28–0.90)	
ACOG	59 (61)	38 (39)	Reference	
Do you believe that women with no health problems should discuss potential benefits and harms of this examination with their provider before deciding to have one?				
ACP	89 (96)	4 (4)	1.73 (0.49–6.12)	
ACOG	90 (93)	7 (7)	Reference	

ACOG, American Congress of Obstetricians and Gynecologists; ACP, American College of Physicians; CI, confidence interval; OR, odds ratio.

<sup>a</sup> Adjusted for randomization group, age, race/ethnicity, education level, income, ever birth, ever Pap test, ever bimanual pelvic exam, and language. Multivariable analyses were not performed for final 4 questions because there were no differences in characteristics between randomized groups

Sawaya et al. Society recommendations and routine pelvic examinations. Am J Obstet Gynecol 2017.