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# Incorporating Stakeholder Feedback in Guidelines Development for the Management of Abnormal Cervical Cancer Screening Tests

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**Objective:** The 2019 ASCCP Risk-Based Management Consensus Guidelines present a paradigm shift from results- to risk-based management. Patient and provider factors can affect guideline adoption. We sought feedback from stakeholders to inform guideline development.

**Materials and Methods:** To solicit provider feedback, we surveyed attendees at the 2019 ASCCP annual meeting regarding readiness to adopt proposed changes and used a web-based public comment period to gauge agreement/disagreement with preliminary guidelines. We elicited patient feedback via a brief survey on preferences around proposed recommendations for treatment without biopsy. Surveys and public comment included both closed-ended and free-text items. Quantitative results were analyzed using descriptive statistics; qualitative results were analyzed using content analysis. Results were incorporated into guideline development in real time.

**Results:** Surveys indicated that 98% of providers currently evaluate their patients' past results to determine management; 88% felt formally incorporating history into management would represent an improvement in care. Most providers supported expedited treatment without biopsy: 22% currently perform expedited treatment and 60% were willing to do so. Among patients, 41% preferred expedited treatment, 32% preferred biopsy before treatment, and the remainder were undecided. Responses from the public comment period included agreement/disagreement with preliminary guidelines, reasons for disagreement, and suggestions for improvement.

**Conclusions:** Stakeholder feedback was incorporated into the development of the 2019 ASCCP Risk-Based Management Consensus Guidelines.

Proposed recommendations with less than two-thirds agreement in the public comment period were considered for revision. Findings underscore the importance of stakeholder feedback in developing guidelines that meet the needs of patients and providers.

**Key Words:** consensus guideline development, stakeholder involvement, cervical cancer screening

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Invasive cervical cancer in the adult population is prevented through screening and evaluation of abnormal screening test results to detect and treat cervical precancer. Although several organizations develop and promote cervical cancer screening guidelines and recommendations,<sup>1,2</sup> management of abnormal screening results has been guided by a series of consensus conferences hosted by the ASCCP in 2001, 2006, 2012, and the current process in 2019.<sup>3–5</sup> The 2012 guidelines were the first to introduce the concept of “equal management for equal risk” and created algorithms for short- and long-term management of abnormal screening results. However, following complex algorithms to determine the next step in management for each patient is difficult for providers,<sup>6</sup> and the rapid development and regulatory approval of new technologies, such as primary human papillomavirus (HPV) screening, necessitating interim guidance,<sup>7</sup> emphasized the need for updated management guidelines.

The 2019 ASCCP Risk-Based Consensus Management Guidelines represent a paradigm shift from recommendations that are based only on current test results to recommendations that incorporate current test results and history of cervical cancer screening tests and treatments for precancer.<sup>8</sup> The 2019 guidelines framework is designed to accommodate anticipated decreases in the risk of cervical precancer due to HPV vaccination and repeated rounds of HPV testing.<sup>9,10</sup> The 2019 guidelines are also designed to incorporate new technologies without the need for frequent interim guidance or full consensus conferences. Because the guidelines are intended to remain applicable for a decade or more, the steering committee placed great importance on incorporating feedback from stakeholders throughout the process to ensure relevance, acceptability, and increased transparency.

The Guideline Based Practice Improvement Framework by Cabana et al.<sup>11</sup> proposes that knowledge, attitudes, and external barriers must be overcome before guideline adoption. Providers may be overwhelmed with the volume of new medical information, with limited time to learn about changes in cervical cancer screening and management of abnormal results. Previous research indicates that guideline-concordant cervical cancer preventive care is more common among gynecologists (versus other primary care specialties), in part because of a higher priority placed on reproductive health, as well as fewer competing knowledge demands, such as hypertension or diabetes guidelines.<sup>12</sup> Providers may not follow guidelines if they disagree with a specific recommendation, disregard guideline-based care in general, believe that guidelines will not result in the desired patient outcome, or lack

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self-efficacy and/or motivation to implement guidelines within their practice setting.<sup>11</sup> In addition, external factors (patient or practice environment factors) affect guideline adoption/adherence.

Because patient and provider variables such as knowledge and attitudes, along with other external factors, can hinder guideline adoption if not considered, feedback from these stakeholders is imperative. Therefore, the consensus guidelines steering committee deliberately solicited key stakeholder input at various time points throughout the guideline development process. This article details the process of obtaining feedback from stakeholders via a provider survey, a patient survey, and an open public comment period, as well as the methods by which that information was considered in the development of the 2019 ASCCP Risk-Based Management Consensus Guidelines.

### METHODS

The preparatory process included soliciting participation from 19 stakeholder organizations including medical professional societies, patient advocacy groups, and federal agencies integral to cervical cancer screening and management of abnormal results.<sup>13</sup> Working groups were then created in the fall of 2018, and evidence review and development of preliminary guideline principles continued through April 2019. Between April and September 2019, feedback was collected from key stakeholders (Figure 1). We describe hereinafter the methodologic and analytic approaches at each assessment time point. All quantitative analyses were conducted in SPSS 25;  $\alpha$  levels of 0.05 were considered significant. For qualitative analyses, all responses were read in their entirety and hand coded; results were grouped thematically and analyzed using principles of content analysis.<sup>14</sup> The Boston University Institutional Review Board reviewed all study components and deemed them exempt.

#### 2019 ASCCP Annual Meeting Attendee Provider Survey

Attendees of the ASCCP annual conference are typically physicians and advanced practice clinicians with a special interest in cervical cancer prevention and other issues related to the lower genital tract. To explore provider readiness to adopt risk-based guidelines, all ASCCP 2019 annual meeting attendees received an e-mail with an electronic survey link on the second day of the meeting. In addition, an information table in the meeting exhibit hall provided attendees the opportunity to complete the survey via tablets. The 31-question survey explored current practices, willingness to adopt risk-based guidelines, and demographic information. Items about practice patterns contained multiple-choice options for common practices, as well as free-text “other” options. Current use of the 2012 guidelines and the 2012 guidelines app was assessed on a 4-point Likert scale from never/rarely to always/almost always. To assess readiness to adopt recommendations for expedited treatment, defined as excisional treatment without

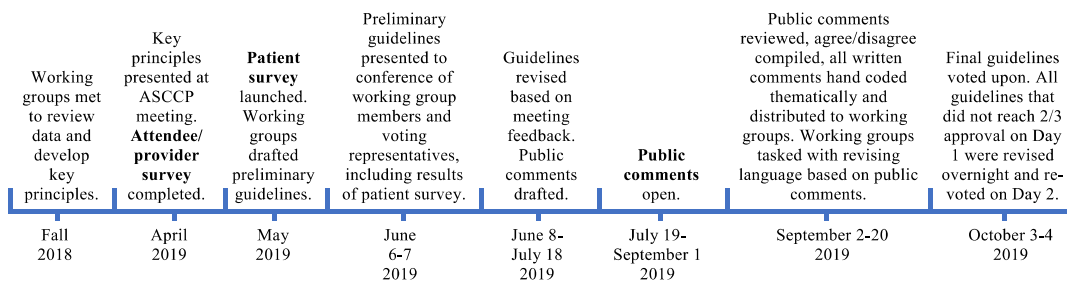
confirmatory colposcopic biopsy, attendees were asked whether they currently performed expedited treatment (yes/no), and whether or not they would be willing to adopt this practice. Surveys were anonymous and no compensation was provided. Descriptive statistics and  $\chi^2$  analyses were conducted.

#### Patient Preference Survey

To ensure that the proposed 2019 ASCCP guidelines for invasive procedures were patient centered, a survey to explore the patient perspective was designed in collaboration with Cervivor, a patient advocacy group (<https://cervivor.org/>). The survey was hosted on the Cervivor Web site in May 2019 and was promoted through organizational networks of all patient advocacy groups participating in the guidelines effort,<sup>13</sup> as well as through personal networks of respondents using respondent-driven sampling techniques.<sup>15</sup> Through a 6-item survey that included both closed- and open-ended responses, women were first asked to read a paragraph explaining precancer, its treatments, and possible adverse effects resulting from treatment (Appendix, <http://links.lww.com/LGT/A146>), then indicate their preference for either colposcopy with confirmatory biopsy or expedited treatment given a risk of greater than 75% for high-grade precancer (yes, no, not sure). Respondents were then asked to explain using free text why they would or would not prefer expedited treatment and to describe information they would like to receive from their healthcare providers to make an informed decision. Respondents also reported their age and gynecological history related to cervical cancer screening (normal results, HPV infection, previous biopsy, previous treatment, previous cancer). Qualitative themes were developed around reasons for preferring either expedited treatment or colposcopy with confirmatory biopsy. Preferred decision-making information mentioned by multiple respondents was considered important. Themes were reviewed for correctness with patient advocates. Descriptive statistics,  $\chi^2$ , and Cochran-Mantel-Haenszel analyses were conducted.

#### Open Public Comment Period

From July 19 to September 1, 2019, the working groups collected feedback on preliminary guidelines through a public comment period. Public comment was broadly publicized by the ASCCP and participating organizations via social media, e-mail blasts, newsletter blurbs, and word of mouth. Though intended for providers, the lay public could respond. Respondents were invited to read the following: (a) preliminary documents of the proposed 2019 guidelines (23 pages) and (b) portions of the 2012 guidelines recommended for inclusion in the 2019 guidelines (2 pages). After reviewing the documents, participants were asked to complete a 28-item survey to indicate their level of agreement with all preliminary recommendations; participants were asked to explain their reasons for disagreement in a free-text box after each item. The survey also included



**FIGURE 1.** The ASCCP guideline revision and stakeholder feedback timeline. This figure illustrates the timeline of consensus guideline development process highlighting time points at which stakeholder feedback was solicited and presented/incorporated into guideline development and revision.

demographic questions, practice characteristics (if applicable), and open-ended items to provide additional opinions regarding the specific guidelines or the process overall. Responses were collected anonymously or with affiliation via SurveyMonkey (which allowed only 1 response per IP address) or via e-mail to the ASCCP. Quantitative responses were summarized with descriptive statistics. Qualitative responses were reviewed separately for each public comment item. Themes were developed around reasons for disagreement with each statement, reviewed for correctness of scientific content with co-chairs of the relevant working groups and for consistency of coding with members of the research team.

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## RESULTS

### The ASCCP Meeting Survey

A total of 135 of the 383 meeting participants completed the survey (35% response rate). Providers were mostly female (79%), physicians (65%), specialized in obstetrics-gynecology (87%), practiced in urban settings (61%), and in academic medical centers (47%; Table 1). The majority (62%) screened more than 20 patients per month for cervical cancer; 30% reported performing more than 20 colposcopies per month. The overwhelming majority screened for cervical cancer using co-testing (92%); a minority used cytology (Pap test) alone (3.7%) or HPV testing alone (2.2%).

Most (93%) reported always or almost always following current (2012) ASCCP guidelines for managing abnormal cytology/HPV test results; 73% via the current smartphone application (Table 1). Among those not currently using the app, most would prefer to use the guidelines via the electronic medical record (76%) or laboratory report (83%). Nearly all (98%) reported that they already evaluated their patients' past results when deciding on the next step in management; 88% felt that formally incorporating history into clinical management would represent an improvement in care. Providers were also asked their opinion on providing expedited treatment without confirmatory biopsy for patients at high risk of precancer, as this was an important proposed change to the guidelines. Among respondents, 22% reported performing expedited treatment per 2012 recommendations,<sup>5</sup> 60% did not currently perform expedited treatment but were willing to do so, and 18% reported that they would be unlikely to perform treatment without a confirmatory biopsy. Lack of provider knowledge was cited most frequently as a barrier to the adoption of new guidelines, followed by patients switching healthcare systems or lack of insurance, patient concerns, time constraints, and lack of previous screening records. A lower percentage of physicians compared with others (65% vs 85%,  $p = .03$ ) and higher percentage of obstetrician-gynecologists compared with others (73% vs 71%,  $p < .01$ ) reported use of the current ASCCP app. A lower percentage of obstetrician-gynecologists cited patient concerns as a potential barrier to guideline adoption than others (38% vs 41%,  $p = .02$ ). No other statistically significant differences were noted.

### Patient Preferences Survey

Respondents included 104 individuals, diverse in age and geographic representation (with most residing in the Midwest

and Northeast), and included women with previous abnormalities who had undergone colposcopy with biopsy (15%), excisional or ablative treatment procedures (13%), cervical cancer (15%), and those without previous abnormal cervical cancer screening (51%). After reading a detailed statement explaining cervical precancer and excisional treatments (Appendix, <http://links.lww.com/LGT/A146>), respondents were asked, "If you had a 75% risk of precancer, would you be interested in having treatment without a biopsy first?" Overall, 41% preferred expedited treatment, 32% preferred biopsy before treatment, with the remainder undecided. Nearly 70% of women 50 years and older preferred expedited treatment, compared with less than 40% among women younger than 50 years ( $p = .015$ ; Figure 2). No significant differences were noted based on previous gynecologic history ( $p = .32$ ; Table 2).

Age-related differences in preference related largely to pregnancy concerns, as summarized by this respondent: "I do not want more children (and even if I did, I am too old to have them) so if I had a pre-cancer I would want the treatment that would be the most likely to prevent a recurrence. I do not need my cervix anymore (as far as I know it's inert at my stage of life), so just take it. If I wanted more children, I would probably want a biopsy first." Prior experience with abnormal cervical cancer screening and treatment did not seem to impact patient preference consistently. Some patients with previous abnormalities or procedures strongly preferred expedited treatment: "I had CIN 3 and wish I could have avoided one of the countless biopsies and just skipped to the LEEP instead." Others wished to avoid treatments whenever possible: "Not worth risk of pain and post op[erative] issues like bleeding if did not end up being necessary. I would rather have a second procedure if biopsy results indicate it's necessary." When asked what information they would like to discuss with their providers, answers included physical, financial, and pregnancy implications as summarized by this respondent: "The cost (both physical and financial) involved with the biopsy and LEEP, a layman's terms explanation of both procedures and what they tell us, potential side effects and what is the actual increased risk of having a premature baby (5%, 10%, etc.), and does this risk increase as age of the mother at birth increases." Results from both the patient survey and ASCCP meeting provider survey were presented at the second consensus conference in June 2019 and considered when drafting preliminary guidelines for open public comment.

### Open Public Comment Period

A total of 239 individuals completed the public comment survey. Respondents were mostly physicians (64%), specializing in gynecology (60%), and in an academic practice (41%; Table 3). Participants were asked whether they agreed or disagreed with proposed guidelines and to explain reasons for disagreement. Consensus committees reviewed proportions of agreement/disagreement as well as individual comments when deciding when and how to revise preliminary guideline statements. As a two-thirds majority was required in the final voting process for approval of each recommendation,<sup>5</sup> preliminary statements with less than 67% approval were targeted for revision. Responses to key guideline statements are reported hereinafter.

Each guideline statement is represented in Figure 3 with the letters (a) through (m), corresponding to the text hereinafter. Most respondents agreed with proposed thresholds (a), (b), and (c) to return at 5, 3, and 1 years; 80%, 78%, and 84%, respectively (Figure 3 and Table 4). The proposed 5-year return threshold (a) was applied to women whose risk of developing precancer in the next 5 years was less than 0.15%, consistent with screening guidelines recommending 5-year intervals for HPV testing or co-testing.<sup>2</sup> Among those who disagreed, the majority

**TABLE 1.** The ASCCP Meeting Provider Characteristics and Key Responses (*n* = 135)

Provider characteristics		<i>n</i>	%
Age	30–39	19	14.84
	40–49	34	26.56
	50–59	39	30.47
	60+	36	28.13
Sex	Female	101	78.91
Training	MD/DO	87	67.97
	NP/CNM	37	28.91
	Other	4	3.13
Specialty	OB/GYN	111	86.72
	Family medicine	11	8.59
	Other	6	4.69
Type of practice <sup>a</sup>	Academic medical center	63	46.67
	Hospital-based practice	20	14.81
	Private practice	38	28.15
	Federally qualified health center/community health center	26	19.25
	Other	7	5.19
Practice setting	Urban	78	61.42
	Suburban	35	27.56
	Rural	14	11.02
On average, how many colposcopies do you do per month?	0–1	10	8.06
	2–5	30	24.19
	6–10	21	16.94
	11–20	26	20.97
	>20	37	29.84
On average, how many patients per month do you screen for cervical cancer (cytology/Pap and/or HPV tests)?	<10	22	17.60
	11–20	25	20.00
	>20	78	62.40
<b>Key Provider Responses</b>		<b><i>n</i></b>	<b>%</b>
In your current practice, for women 30 y and older, what test do you screen with? <sup>b</sup>	Cytology (Pap test) alone	5	3.70
	Cytology (Pap test)/HPV co-testing	124	91.85
	HPV testing alone	3	2.22
	N/A	3	2.22
If you have HPV testing, does the HPV test you use give you partial genotyping results (i.e., HPV 16, 18, 45)?	Yes	101	79.53
	No		
If you use HPV-based screening (e.g., age-appropriate co-testing or primary HPV testing) when did this start in your practice?	0–5 y ago	28	22.40
	5–10 y ago	64	51.20
	>10 y ago	33	26.40
How often do you follow the current (2012) ASCCP consensus guidelines to manage abnormal cytology (Pap test)/HPV test results?	Always/almost always	126	93.33
	Sometimes	5	3.70
	N/A	4	2.96
Do you use the current ASCCP app for managing abnormal results?	Yes	98	72.59
	No		
For those who do not use the ASCCP app, would you be more likely to use it if it were incorporated into the electronic medical record?	Yes	25	75.76
	No		
For those who do not use the ASCCP app, would you be more likely to use it if it were incorporated as a risk score and/or recommendation attached to the patient's laboratory result?	Yes	29	85.29
	No		
Do you currently look at a patient's past cytology (Pap test), HPV test, and/or colposcopy results when deciding on how to manage a current abnormal result?	Yes	131	98.50
	No		
Do you think incorporating patients' history into the recommendation for their current management will be an improvement over the current guidelines?	Yes	119	88.15
	No		

Continued next page



TABLE 1. (Continued)

Key Provider Responses		n	%
New guidelines are likely to recommend treatment without colposcopic biopsy for patients at high risk of CIN 2/3. Which of the following statements is most true for you?	Already doing see-and-treat for appropriate patients	29	22.31
	Currently perform colposcopy on everyone, but willing to adopt this change for appropriate patients	78	60.00
	Unlikely to perform treatment without a confirmatory biopsy on any patient	23	17.69
Obstacles to adoption of a new ASCCP guidelines	Lack of provider knowledge	102	29.47
	Patients switching healthcare systems or lack of insurance	89	25.72
	Patient concerns	48	13.87
	Inadequate time for visits or to enter data	46	13.29
	Lack of patient data	33	22.60
	Fear of being sued	28	8.09

<sup>a</sup>Total does not equal 100%—respondents could select multiple responses.

<sup>b</sup>3 of 5 respondents using cytology only used HPV testing to reflex atypical squamous cells of undetermined significance atypical squamous cells of undetermined significance results.

CNM indicates Certified Nurse Midwife; DO, Doctor of Osteopathic Medicine; MD, Doctor of Medicine; NP, nurse practitioner; OB/GYN, Obstetrics/Gynecology.

preferred shorter management intervals and expressed confusion around recommended screening intervals. Reasons for preferring management follow-up intervals less than 5 years included concerns about false-negative results and poor adherence. (Table 4 for representative quotes.) The proposed 3-year return threshold (b) was applied to women whose risk of developing precancer in the next 5 years was between 0.15% and 0.55%, consistent with screening guidelines recommending 3-year intervals after a negative Pap test without an HPV test.<sup>2</sup> Among those who disagreed with the 3-year threshold, some wanted a shorter interval, whereas others preferred a longer interval. A 1-year follow-up interval (c) was proposed for patients whose risk was higher than recommended for a 3-year return and lower than the risk recommended for colposcopy. Comments were generally supportive but emphasized the need for high-quality provider and patient education to avoid patient confusion. Nearly all (93%) respondents agreed with the 4% or greater threshold to send patients to colposcopy (d). Regarding general responses to all proposed thresholds, some indicated agreement

with proposed intervals only if co-testing was used. Because agreement exceeded 67% for all proposed statements related to return intervals of 5, 3, or 1 year or referral to colposcopy, no changes were made to these statements before the voting conference.

Agreement was lower for proposed thresholds for expedited treatment. Sixty-four percent of respondents agreed with recommendations that expedited treatment should be an option for patients with cervical intraepithelial neoplasia grade 3 or higher (CIN 3+) risks between 25% and 49% (e), and 61% of respondents agreed with recommendations to preferentially perform expedited treatment instead of biopsy for CIN 3+ risks exceeding 50% (f). Note that CIN3+ risks of 50% correspond with CIN2+ risks of approximately 75%. As CIN2 is the clinical threshold for recommending treatment, the patient survey used CIN2+ risks to assess patient agreement with this proposed threshold. Reasons for disagreement included believing that the risk threshold should be higher that expedited treatment or colposcopy with biopsy should be equally acceptable options, concern for infringing on patient autonomy, and concern about logistical

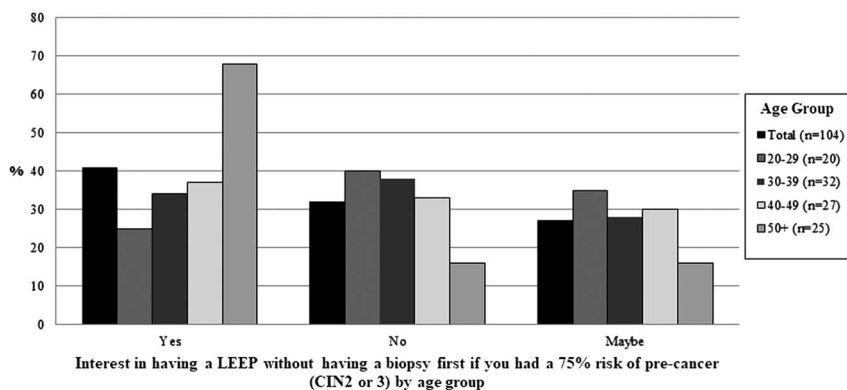


FIGURE 2. Patient survey precancer treatment preference by age group (n = 104). This figure illustrates patients' desire for expedited treatment based on age. Women 50 years and older were more likely to prefer expedited treatment than younger women (p = .015).

**TABLE 2.** Patient Survey Precancer Treatment Preference by Gynecological History ( $n = 104$ )

	Total $n$ (%)	HPV infection	LEEP	Biopsy	Cervical cancer	None
Age group						
20–29	20 (19.23)	—	2 (15.38)	1 (6.25)	—	17 (32.08)
30–39	32 (30.77)	4 (66.67)	5 (38.46)	6 (37.50)	5 (31.25)	12 (22.64)
40–49	27 (25.96)	1 (16.67)	4 (30.77)	4 (25)	5 (31.25)	13 (24.53)
50–59	11 (10.58)	—	1 (7.69)	2 (12.50)	2 (12.50)	6 (11.32)
60+	14 (13.46)	1 (16.67)	1 (7.69)	3 (18.75)	4 (25)	5 (9.43)
If you had a 75% risk of precancer (CIN 2 or 3), would you be interested in having a LEEP without having a biopsy first?						
Yes	43 (41.35)	3 (50)	5 (38.46)	5 (31.25)	9 (56.25)	21 (39.62)
No	33 (31.73)	2 (33.33)	7 (53.85)	7 (43.75)	4 (25)	13 (24.53)
Maybe	28 (26.92)	1 (16.67)	1 (7.69)	4 (25)	3 (18.75)	19 (35.85)

barriers, such as insurance coverage or difficulties implementing expedited treatment in clinical practice. Additional concerns included a desire to nuance the expedited treatment recommendation

**TABLE 3.** The ASCCP Risk-Based Management Consensus Public Comment Period Participant Demographics ( $n = 242$ )

Item	Response	$n$	%
Participant role/expertise	Clinician on behalf of self	168	71.19
	Clinician on behalf of professional society or organization	24	10.17
	Pathologist on behalf of self	17	7.20
Participant training	Other <sup>a</sup>	27	11.44
	MD	146	64.32
	Advanced practice professional <sup>b</sup>	63	27.75
Participant specialty	Other <sup>c</sup>	18	7.93
	Gynecology	137	60.35
	Internal medicine	2	0.88
	Family medicine	37	16.30
Participant practice type <sup>d</sup>	Other	51	22.47
	Academic	90	41.47
	Community	30	13.82
	Hospital	46	21.20
	Private Practice	46	21.20
	Clinic	15	6.91
	Federally qualified health clinic	9	4.15
	Public health	9	4.15
	Government/military	5	2.30
	Residency faculty	3	1.38
	College health	4	1.84
Nonprofit	2	0.92	
Other	11	5.07	

<sup>a</sup>Responses collapsed include: “pathologist on behalf of professional society or organization,” “consumer or patient on behalf of self/advocacy organization,” “policymaker,” “researcher,” and “other.”

<sup>b</sup>Includes NP ( $n = 40$ ), nurse midwife ( $n = 18$ ), and “other” ( $n = 18$ ).

<sup>c</sup>Includes MD/PhD ( $n = 2$ ), DO ( $n = 4$ ), physician assistant ( $n = 2$ ), RN/BSN ( $n = 2$ ), cytotechnologist ( $n = 2$ ), other ( $n = 5$ ). DO indicates Doctor of Osteopathic Medicine; NP, nurse practitioner.

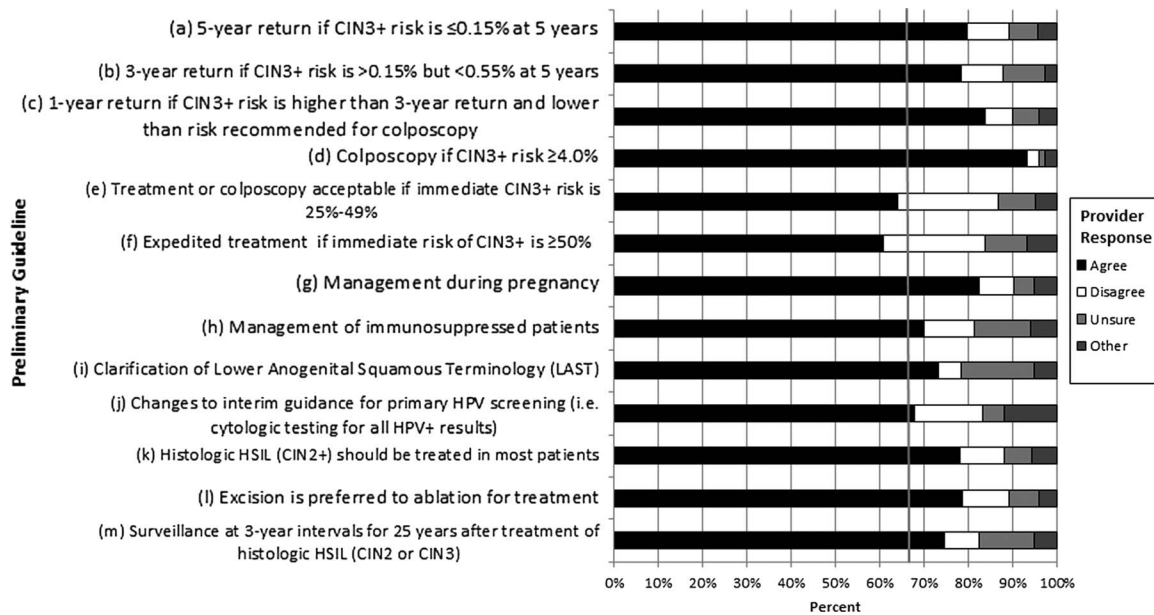
<sup>d</sup>Total does not equal 100%—respondents could select multiple responses.

to avoid overtreatment of young women and those desiring future fertility, and preferring to always perform colposcopy to influence the choice of management. The consensus committee considered these public comments, and the final recommendations reflected their revisions by raising the preferred treatment threshold to a 60% immediate risk of CIN 3+, indicating the need for shared decision-making for individuals 25 years and older who desired future fertility, and specifying that expedited treatment recommendations do not apply to those younger than 25.<sup>13</sup>

Most respondents (82%) agreed with recommendations for management of abnormal results during pregnancy (g). Disagreements were divided between desiring fewer and more interventions during pregnancy; comments also expressed a need to clarify the intervals at which colposcopy should be repeated. Most respondents (70%) agreed with recommendations for management of immunosuppressed patients (h). Comments focused on the desire to manage HPV-negative results less aggressively, to classify degrees of immunosuppression, and the need to clarify age-related recommendations. Because agreement exceeded 67% for the proposed statements, wording was clarified but no substantive revisions were made before voting.

Two recommendations related to laboratory management of cervical screening and biopsy results. The proposed statement (i) to increase the clarity of the Lower Anogenital Squamous Testing (LAST) recommendations for reporting histopathology of squamous lesions of the lower anogenital tract by including the corresponding CIN 2 or CIN 3 equivalent in parentheses when reporting histologic high-grade squamous intraepithelial lesion (HSIL) was supported by 73% of respondents. The primary concern was the lack of reproducibility of CIN 2 diagnoses, making this difficult to implement in practice. The second laboratory-focused proposed statement recommended changes to interim guidance for primary HPV screening, specifically cytologic testing for all positive HPV results, to replace previous interim guidance, which recommended reflex cervical cytology only for non-16/18 HPV types (j). Most (71%) respondents agreed with this statement.

Agreement was high for other statements related to precancer treatment and follow-up. Most (78%) respondents agreed that histologic HSIL (CIN 2+) should be the threshold for providing treatment for most patients (k), and 79% agreed that excisional treatment modalities (e.g., LEEP) should be preferred to ablative treatments (e.g., cryotherapy) for treating precancer in the United States (l). After treatment for precancer, long-term surveillance at



**FIGURE 3.** Agreement with the ASCCP risk-based management consensus guidelines during public comment period ( $n = 242$ ). This figure illustrates percent agreement with preliminary guidelines statements as expressed during the open public comment period. The gray line represents two-thirds agreement, which was the threshold used to consider revision of preliminary guidelines before presentation at the final voting conference.

3-year intervals is now recommended for at least 25 years and may continue as long as patient remains in good health (m); 74% agreed with this recommendation. As agreement exceeded 67% for all of these statements, no substantive changes were made before voting.

### DISCUSSION

Organizations may take different approaches to including stakeholder feedback when revising clinical practice guidelines. For example, the United States Preventive Services Task Force<sup>16</sup> indicates that stakeholder feedback consists of both engagement with the public and engagement with liaisons and partners.<sup>17,18</sup> At the outset of this guidelines revision process, the ASCCP leadership committed to: “broad stakeholder representation in setting the consensus risk thresholds.”<sup>19</sup> Participation of multiple stakeholder organizations and the use of an open public comment period aligns with the United States Preventive Services Task Force process for soliciting and using stakeholder feedback.<sup>17,18</sup> Results from the open public comment period provided critical quantitative (% agree/disagree) and qualitative (commentary on each proposed guideline) information useful to the guideline development process. Proposed guidelines that did not meet two-thirds agreement in the open public comment period were revised, and additional comments noted areas requiring clarification. The patient preference survey was helpful in determining the acceptability of expedited treatment and ultimately contributed to the final guidelines using a higher threshold for expedited treatment and including statements about shared decision-making. Taken together, these results underscore the importance of patient and provider feedback for developing guidelines that are relevant to clinical practice.

Guidelines to manage abnormal cervical cancer screening tests function only to the extent to which they are accepted by patients and applied correctly by a diverse array of primary care providers and colposcopists. National provider surveys indicate that

only a minority of providers properly use HPV testing and adhere to cervical cancer screening guidelines for extended screening intervals.<sup>20–26</sup> As most guidelines take over a decade to incorporate into practice, understanding providers' and patients' needs and concerns are important to develop guidelines that are acceptable and feasible to incorporate into clinical practice.

The process of soliciting and incorporating feedback is not without challenges. The survey administered to 2019 ASCCP annual meeting attendees was inherently biased as attendees may be different than those who do not attend professional meetings. In addition, respondents may represent those with the greatest interest or strongest opinions. The sample size of the patient survey was small, the survey was provided only in English, we lacked statistical power to link past patient experience with current preference, and response rate cannot be estimated because the survey was shared via social networks. Patient responses could also have been affected by their understanding of the scenarios presented. The large number of qualitative responses from the public comment period presented challenges in terms of collating data and determining a focus for presentation of results. Although the public comment period solicited feedback from a broader audience, the sample may still not represent the “typical” provider who manages abnormal screening results. Of note, the guidelines are intended for use in the United States; stakeholders in other countries may hold different views.

Overall, the process of incorporating provider, patient, and public feedback has enhanced the final 2019 ASCCP Risk-Based Management Consensus Guidelines. This report may serve to motivate other professional organizations to consider and directly elicit feedback from key stakeholders and incorporate their findings in real time during the guideline development process. In addition, this publication may encourage greater participation by front-line providers to ensure that their perspectives are incorporated into the clinical practice guidelines they use to manage patients. Feedback from patients helped determine the acceptability and practicality of expedited

**TABLE 4.** Summary of Themes and Corresponding Representative Public Comments

Proposed guideline	Agree	Themes and representative quotes	Comments, n
(a) Patients should return in 5 years if their 5-year risk of CIN 3+ is <0.15%	80%	<p><b>Concern about false-negative previous screens</b>            “5-year follow up for a single negative HPV test result doesn't seem to take into account the possibility of lab error or assay inaccuracy. An undetected HPV infection can progress to significant disease in 5 years; 3-year follow-up after a negative HPV result (in the absence of other results) would reduce this risk.”</p> <p><b>Concern about poor compliance</b>            “This places the onus on the patient when the system doesn't have an effective and consistent program for ensuring that [5-year] recommendations are followed.”</p>	20
(b) Patients should return in 3 years if their 5-year risk of CIN 3+ is between 0.15% and 0.55%	78%	<p><b>Shorter interval</b>            “A more graduated return to 3-year testing would be advisable. Suggest 1-year repeat, and then if normal, then repeat in 3 years.”</p> <p><b>Longer interval</b>            “The European studies show that every 5 years is sufficient in this risk range. Going to every 3 years creates confusion and makes the guidelines messy once again.”</p>	19
(c) Patients should return in 1 year if their risk of CIN 3+ is higher than a 3-year return and lower than the risk recommended for colposcopy	84%	<p><b>Communication suggestion</b>            “This is difficult, medically repeat in a year is appropriate BUT too many women and primary care providers in the US today still think of ‘repeat in 1 year’ as normal. If the low-grade squamous intraepithelial lesion Pap with a prior neg[ative] HPV adds up to repeat in 1 year on the App and she [the patient] is told “repeat in 1 year” by her primary care doctor, she absolutely will not realize the true situation. She will think everything is normal. Many will not be diligent about repeating in 1 year. I would prefer that the abnormal Pap that falls short of requiring colpo[scopy] still comes to see me even if all I do is counsel her...but that is not practical, I know. Maybe if the recommendation, instead of simply stating repeat in a year, includes a blurb [a statement] like ‘the patient should be told screening results are not normal, modifiable risk factors must be addressed, and she should be told to return in 1 year for repeat testing because of her increased risk of dysplasia.’”</p>	32
(d) Patients should undergo colposcopy if their immediate risk of CIN 3+ is $\geq$ 4%	93%	<i>No substantive comments; majority were statements of agreement.</i>	15
(e) Expedited treatment or colposcopy is acceptable if the immediate CIN 3+ risk is 25%–49%	64%	<p><b>Nuance the expedited treatment recommendations to avoid overtreatment/harm</b>            “It will depend on [the scenario]: 1) If you are not sure if the patient will come back for the treatment, I agree with see-and-treat 2) If the colposcopic impression is different from the cytology, we should perform the biopsy otherwise we may have overtreatment, [e]specially in young women without children.”</p> <p><b>Prefer colposcopy to influence management</b>            “As a colposcopist, I prefer my colposcopic and histological confirmation, to evaluate the type of lesion, the extent, the invasion in the endocervical canal and the type of excision to be performed by performing the colposcopy.”</p>	73

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TABLE 4. (Continued)

Proposed guideline	Agree	Themes and representative quotes	Comments, <i>n</i>
(f) Patients should have expedited treatment if their immediate risk of CIN 3+ is $\geq 50\%$	61%	<p><b>Raise the threshold level</b></p> <p>1) “50% is a point estimate, or absolute value. Might be better to recommend based on lower bound of 95% CI [confidence interval] being 50% or higher.”</p> <p>2) “I think 50% is low for see-and-treat. I'd like to see it closer to 70%.”</p> <p><b>Expedited treatment should be optional</b></p> <p>“This means that half of patients are treated without need. I would say both acceptable. I recognize that in cases with negative biopsy it can be difficult to define what to do in order to improve risk stratification. Anyway, starting with a biopsy and if negative at least reviewing the cytology (these are women with HSIL cytology) seems to me a reasonable alternative.”</p> <p><b>Patient autonomy</b></p> <p>“If this guideline is going to be made, I think it should be very clearly stated that immediate treatment is chosen ONLY after a discussion with the patient of R/B/A [Risks/Benefits/Alternatives]. It is not appropriate in medicine today for providers to be making these decisions for the patient. Patient-centered medicine has many benefits, one being the empowerment of women to make the best decisions for themselves.”</p> <p><b>Logistics</b></p> <p>“Difficult to do in practice and may cause insurance problems.”</p>	90
(g) Management of abnormal results during pregnancy	82%	<p><b>Do Less</b></p> <p>“Do not continue to do colposcopy on a pregnant woman—natural history shows that this does not move progress to invasion within the time span of a pregnancy. Never repeat biopsy during pregnancy... there is NO rush.”</p> <p><b>Do more</b></p> <p>“Since number of biopsies at each colposcopy in pregnancy is limited, I favor repeat biopsy(s) during a repeat colposcopy (every 12–20 wks) if the lesion appears the same or worse. A second biopsy at the second colposcopy will increase the chance of finding CIN 3 or cancer, and will not cause additional morbidity. Hence an additional biopsy with the second colposcopy will increase the sensitivity of the diagnostic exam just as multiple biopsies do in the nonpregnant state.”</p>	38
(h) Recommendation to follow CDC guidelines for opportunistic infections in immunosuppressed patients	70%	<p><b>HPV negative results should be managed less aggressively</b></p> <p>“Why ASCUS<sup>c</sup>, HPV negative when the whole concern is that the person is immunocompromised (i.e., at higher risk of persistent HPV infection).”</p> <p><b>Degrees of immunosuppression</b></p> <p>“‘Immunocompromised [patients]’ is vague and clinically, I have a difficult time with this. HIV+ and on chemo, or posttransplant is clearly immunocompromised, but what about lupus or other dx [diagnosis] [associated] with immunocompromise? If HPV neg[ative] and less than 25 y, colpo[scopy] seems extreme—how about co-test in a year?”</p>	43

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TABLE 4. (Continued)

Proposed guideline	Agree	Themes and representative quotes	Comments, n
(i) Proposed clarification to the LAST statement	73%	<b>Distinguishing CIN 2 from CIN 3 is not reproducible</b> “The first statement is great when used correctly. However, there is a misconception that p16 [an immunohistochemical marker] can help to differentiate CIN 1 and CIN 2. The best way to differentiate CIN 1 and CIN 2 is based solely on morphologic H&E [hematoxylin and eosin stain] and experienced gynecologic pathologists are often much better at this. It would be nice to add the following statement: “When a pathologist is considering CIN 1 vs CIN 2, do not use p16 to adjudicate in this scenario. It would be best to consult other experienced pathologists for consensus. When consensus cannot be reached, a diagnosis of CIN 1–CIN 2 with a comment regarding its ambiguity should be considered.” For the second statement, I would add “young patients” to the sentence (e.g., “it is strongly recommended to qualify an HSIL result by –CIN 2 or –CIN 3 in young patients”). Reproducibility of CIN 2 is terrible and that was the whole point of LAST. When a pathologist report HSIL (CIN 2/CIN 3), it typically means the pathologist prefers a LEEP rather than observation. Since CIN 2 can be monitored in young patients, this diagnosis should only be used in that population.”	44
(k) Histologic HSIL (CIN 2+) should be treated in most patients	78%	<b>CIN 2 alone does not justify treatment</b> “The diagnosis of CIN 2 is not enough for performing an excisional treatment. We need information about p16 or more parameters.”	20
(l) Excision is preferred to ablation for treatment	79%	<b>Insufficient rationale for preferring excision to ablation</b> “The basis for preferring excision over ablation is unclear. The elements of interest in making such a designation include consideration of benefits, harms and costs, some of which are challenging due to lack of high-quality evidence.” <b>Ablation should be discouraged because it is less effective</b> “Ablation does not confer any advantage with regard to decreased risk of preterm delivery. Ablative depth is highly variable and the expertise of providers is diminishing yearly. I am unclear as to why this is offered.” <b>Ablation should be an option</b> “Individualized. Where you are sure you have a confined lesion that is completely CIN 2, one can treat that differently than an extensive CIN 3. Age of patient always makes a difference. Reproduction desires frequently affect decision-making.”	42
General comment mentioned frequently, not related to a specific threshold		<b>Cotesting preferred for all scenarios</b> “[I do] not [agree with recommendations] when HPV testing is used as a standalone test (personal experience of few invasive cancers even in young patients).”	<sup>b</sup>

<sup>a</sup>Note that quotes are not included for the following statements due to comments being largely about clarification of statement and need to cite literature justifying recommendations: (j) Changes to interim guidance for primary HPV screening (i.e., cytologic testing for all HPV+ results); (m) Surveillance at 3-year intervals for 25 years after treatment of histologic HSIL (CIN 2 or CIN 3).

<sup>b</sup>Comments related to co-testing were not counted as respondents frequently repeated their comments in responses to multiple questions.

<sup>c</sup>ASCUS indicates atypical squamous cells of undetermined significance.

treatment. Feedback from providers about proposed guidelines enhances our understanding of how 2019 guidelines will be accepted and implemented in their practices.

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