ASCCP Board of Directors' Conference Call

January 17, 2023
7:00 – 8:30 PM ET

Tuesday, January 17, 2023

		Invitees: Jacob Bornstein, Patricia Cason, David Chelmow, Christine Conageski, Levi Downs, Mark Einstein, Lisa Flowers, Francisco Garcia, Michelle Khan, Lindsay Kuroki, Erin Nelson, Akiva Novetsky, Peter Schnatz, Beth Stier, and Amy Wiser		
7:00pm	7:05pm	▪ Call to Order		L. Flowers
		▪ Disclosure Statement It is my duty to remind you that the ASCCP maintains an official policy on disclosing relevant financial, professional, and other relationships with respect to participation in all ASCCP Board Meetings, Committees and Task Forces. The Society has a copy of your disclosure information on file. If your Disclosure Form identifies such relationships as defined by ASCCP, and this committee takes under consideration today a matter where that relationship would apply, such person will be asked to abstain from the discussion or vote on the related issue and not participate in the discussion for its duration		L. Flowers
7:05pm	7:10pm	▪ Consent Agenda o Approval of minutes (10/14/22)		L. Flowers
7:10pm	7:30pm	▪ President's Report		L. Flowers
7:30pm	7:40pm	▪ Treasurer's Report		F. Garcia
7:40pm	8:25pm	▪ Old Business o Enduring Guidelines Update o ListServ ▪ New Business o Strategic Planning o USPSTF – Anal Cancer o Cervical Cancer Screening in Immunocompromised - Update		 F. Garcia C. Price L. Flowers L. Flowers L. Flowers
8:25pm	8:30pm	▪ Closing Remarks o Next Board meeting: Thursday, May 4, 2023 (Houston, TX)		L. Flowers

Improving lives through the prevention and treatment of anogenital & HPV-related diseases

ASCCP Board Meeting
DoubleTree by Hilton Hotel — BWI Airport
Baltimore, MD
October 14, 2022

Summary

- Dr. Lisa Flowers highlighted two papers that will be published in January 2023—an ASCCP committee opinion on use of the adjuvant vaccine in patients undergoing CIN and a colposcopy standards update by the group led by L. Stewart Massad.
- Dr. Michelle Khan noted that membership has remained steady overall ranging from 2,100-2,300, highlighting a recent trend of declining physician members and rising APC membership. Ms. Cari Price noted that staff has implemented a new option in the past six months that allows a member to store credit card information for automatic renewal, but few members have taken advantage of this option as yet.
- Ms. Rebecca Boland reported on ASCCP financials, noting an expected $766,000 surplus at the end of the fiscal year. Given the surplus in recent years, the board discussed the possibility of pursuing special projects that may have been deferred previously due to cost concerns.
- Mr. T.J. Atkinson of Merrill Lynch discussed significant declines in the investment portfolio due to current market conditions, but noted that his firm did not recommend any changes to the investment strategy at this time.
- Dr. Francisco Garcia noted that leadership of the enduring management guidelines group has tried to improve communication and provide regular updates to stakeholders, as well as set realistic expectations. He indicated that the draft guideline from the group on dual stain won't be ready for review until the first quarter of 2023.
- The board discussed the possibility of ASCCP issuing interim statements when there is a significant lag in updating enduring guidelines. Dr. Einstein made a motion to issue two clinical practice statements on dual stain and extended genotyping limited to their use and indications. The motion passed unanimously.
- Dr. Khan offered an overview of the program for the 2023 scientific meeting, highlighting three keynote talks, two debates, and three tracks—Back to Basics, Screening and Prevention, and Management and Treatment.
- Ms. Curtis noted that the translation of the online COMP Course into Spanish is complete and task force members are currently working on voiceovers for the PowerPoint presentations. She will explore hiring a firm that does technical translation to manage ongoing edits and updates.
- Staff has engaged an attorney to review the bylaws and to update to reflect Board expectations.
- Dr. Einstein noted that he leads the SGO task force for the WHO elimination of cervical cancer initiative, and proposed that ASCCP take on screening and management as a potential project.
- Ms. Price discussed results from the 2019 management guidelines survey and the board discussed producing algorithm booklets to meet member demand.
- Dr. Akiva Novetsky discussed the launch of the president's cervical cancer roundtable and his role as chair, and Dr. Amy Wiser was nominated as the official ASCCP representative on the steering committee.
- Dr. Flowers reported on a meeting that she and Dr. Downs had with Teresa Darragh regarding the use of Pap smears at state run health clinics and discussed ways ASCCP can address leadership about the standard of care.

I CALL TO ORDER

Dr. Lisa Flowers called to order the meeting of the Board at 1:05 pm ET.

II ATTENDANCE

The following persons were present: Patty Cason, David Chelmow, Christine Conageski, Levi Downs, Mark Einstein, Lisa Flowers, Francisco Garcia, Michelle Khan, Erin Nelson, Akiva Novetsky, Peter Schnatz, and Amy Wiser

Absent: Jacob Bornstein, Lindsay Kuroki, and Elizabeth Stier

Staff: Kerry O. Curtis, Cari Price

Guests: TJ Atkinson, Keenan Becker, Rebecca Boland, Kemal Cankaya, Mark Edward, and Annette Nicolay

III DISCLOSURE STATEMENT

Dr. Flowers read the disclosure statement included in the meeting agenda.

IV APPROVAL OF MINUTES

Dr. Michelle Khan made a motion to approve the minutes from the July 19, 2022, meeting and Dr. Akiva Novetsky seconded the motion. The motion passed, with Dr. David Chelmow abstaining and all others in favor.

V PRESIDENT'S REPORT

Dr. Flowers highlighted two papers that will be published in January 2023—an ASCCP committee opinion on use of the adjuvant vaccine in patients undergoing CIN and a colposcopy standards update by the group led by L. Stewart Massad. Ms. Cari Price noted that erratum on CIN3 will be added. Dr. Flowers noted that the ECC paper from the group led by Michael Gold is still under development with an anticipated publication date in July 2023, while Dr. Khan confirmed that the LBGTQIA paper should be ready for publication in late 2022 or early 2023.

VI SECRETARY'S REPORT

Dr. Khan reviewed membership figures for 2022, noting that of the 2,163 members, approximately half are physicians while APCs (nurse/nurse practitioner/midwife) comprise the next largest group at approximately 32 percent. She noted that membership has remained steady overall ranging from 2,100-2,300, but highlighted a decline in physician members along with a rise in APC membership.

Dr. Chelmow noted a drop in membership from 2,500 in 2021. Ms. Kerry Curtis suggested the figures for 2022 were incomplete as many members are up for renewal at this time. Additionally, she indicated that efforts to adopt green practices, favoring emails and calls over mailed invoices, have been less successful and thus staff recently returned to physical mailings and expect to see membership numbers rise as a result.

Ms. Price noted that multiple automated emails are typically sent before and after a renewal date, and added that staff has more recently followed up with personal emails and calls as well. In response to a question from Dr. Khan about automatic renewals, Ms. Price noted that staff has implemented a new option in the past six months that allows a member to store credit card information for automatic renewal, but few members have taken advantage of this option as yet.

Dr. Mark Einstein noted that ASCO offers a two-year membership option at a discounted rate, and Ms. Curtis indicated that a multi-year option would be a little more difficult from an accounting standpoint per BDO, but would certainly look into again.

Dr. Flowers highlighted the convenience of automatic renewals, while Dr. Novetsky expressed a concern about security issues with stored credit card information for renewals. Ms. Rebecca Boland and Mr. Mark Edward confirmed that the information is stored and the liability is maintained by the third-party processor (PayPal) rather than ASCCP. Dr. Flowers suggested promoting the automatic renewal option more aggressively.

VII TREASURER'S REPORT

Dr. Francisco Garcia thanked Ms. Boland and the accounting team for their fiscal management. He remarked on the significant decreases in value of ASCCP's investments, reflecting the current market fluctuations, and highlighted current liabilities including $488,000 from deferred funds before asking Ms. Boland to give an overview of the society's financials.

Ms. Boland referred to the statement of financial position reflecting the 11 months ending August 31, 2022. Total revenue was $2.3 million vs $1.8 million budgeted and there was a favorable variance for expenses as well. She noted that before any unrealized losses, the operations results were very positive with a $766,000 surplus expected at the end of the fiscal year.

Dr. Einstein lauded the positive financial picture but suggested reviewing the budgeting process as under budgeting may cause the society to miss out on opportunities that may have been financially feasible. Ms. Curtis noted that the online COMP Course offered the biggest boost, generating far more revenue than expected, but Dr. Downs suggested that Dr. Einstein's concern was worth pursuing. While not suggesting a concern or error in the budgeting, Dr. Downs noted that, after three consecutive years of surplus, it may be time to consider what more ASCCP can do that's not on the table right now due to cost concerns. Dr. Chelmow highlighted the fact that the last three years were highly unusual and can't serve as a predictor of the next year. Dr. Flowers noted the opportunity of the strategic planning meeting to think about what may be possible. Dr. Garcia advocated for the society maintaining sufficient reserves to help plan for unexpected expenses, but suggested ASCCP has a fiduciary responsibility to make the best use of its resources. Dr. Chelmow agreed, provided a balance is struck to ensure a financial cushion. Dr. Peter Schnatz expressed some discomfort with the idea of raising the budget, but suggested a special project would be timely given the current financial position.

Dr. Einstein noted that the COMP Course online should be sustainable and suggested exploring additional sustainable projects while guarding against projects that might cannibalize existing revenue streams. Ms. Curtis reiterated that the past three years should not serve as an example, citing luck with the 2020 virtual meeting and the move to a virtual office. She also expressed concern about potential losses with the 2023 scientific meeting, as well as a decline in revenue from grants and investment losses. Dr. Chelmow suggested tabling further discussion until the conclusion of the financial report.

Ms. Curtis referred the board to the proposed budget which was approved by the finance committee. Dr. Einstein made a motion to approve the budget and Dr. Christine Conageski seconded. The motion passed unanimously.

Mr. T.J. Atkinson of Merrill Lynch discussed the investment portfolio. Dr. Khan noted that Hologic and Roche were not on the list of restricted companies and Dr. Einstein suggested reviewing and updating the list of companies in which the society can't invest. Ms. Curtis indicated she would work with Mr. Atkinson to update that.

Mr. Atkinson noted that performance YTD was in line with the market, with investments down 19.63%, as the performance for a 60/40 stocks/bonds asset allocation was the worst in a century. He indicated that, as investments represent long-term institutional money, Merrill Lynch does not recommend any shift in portfolio design. Mr. Atkinson indicated that the market is now adjusting and predicted a soft recession next year. He suggested losses will be made up in the long term and added that, following heightened volatility with the midterms, historically the market tends to improve after an election as uncertainty is removed. While noting that the market could continue to worsen before it ultimately rebounds, Mr. Atkinson expressed cautious optimism.

Dr. Chelmow asked if ASCCP had been cushioned against loss given its long-term conservative approach. Mr. Atkinson stated that while a conservative strategy typically helps, the recent unprecedented aggressive rate raises by the Federal Reserve obliviate the cushion. He did suggest one change of strategy—investing some cash in a CD ladder. In response to a question from Dr. Einstein, Mr. Atkinson confirmed that a 60/40 split remains a conservative strategy. Dr. Amy Wiser asked for clarity on the term soft recension and Mr. Atkinson explained this would entail a further market downturn of 5-10%.

VIII OLD BUSINESS

a. Enduring Management Guidelines Updates

Dr. Garcia noted that while he is not an ASCCP representative in the enduring guidelines group, he does serve as part of the leadership group with Rebecca Perkins and Nicolas Wentzensen. Following critiques he brought to table, leadership has tried to improve communication and provide regular updates to stakeholders, as well as set realistic expectations. He highlighted challenges the group has faced, including COVID-related staffing issues, a contractor not producing the yield expected, and the complexity of the analysis given the many permutations of different HPV types. He noted that while other datasets have been incorporated, the Kaiser Permanente data weighs heavily due to the size and scope of the data source. While an additional dataset from Mississippi will be incorporated into this process in November and December, the group doesn't anticipate this will significantly change things numerically. He noted that the draft won't be ready for review until the first quarter of 2023.

In response to a question from Dr. Einstein, Dr. Garcia indicated that a percentage of the dataset from New Mexico with dual stain will be included and suggested that when all the datasets are brought together, the group will have an incredibly powerful tool that reflects the diversity of the heterogeneous nature of this country.

Dr. Einstein asked if the committee will entertain a different approach if there is limited data for other new technologies. Dr. Garcia assumed so, but suggested the path forward is as yet undefined. Dr. Einstein noted that clinicians need guidance and suggested that ASCCP can put out clinical alerts, without advocating, to alert clinicians to what is available, noting precedence for this approach with Cervista.

Dr. Downs noted that, while the group will likely move more swiftly going forward as originally expected, he asked if there is a need for intermediate guidance when the enduring guidelines process moves slowly. Dr. Chelmow suggested either a reasonable interim guidance process or a change to the process for enduring guidelines. Dr. Downs asked if there is a way ASCCP could offer guidance under the tent of the enduring guideline committee. Dr. Chelmow suggested ASCCP offer its own statement and ask others to sign on. Dr. Garcia cautioned against issuing an interim statement when a definitive statement with subtle differences may be issued within a short span. He also noted that ASCCP stopped issuing interim guidance purposely as it required significant staff and volunteer work. Dr. Chelmow agreed that, with a short time frame of three months, forgoing interim guidance makes sense, but noted that a two-year gap is a problem.

Dr. Downs iterated that the opportunity at the moment is with methylation. Dr. Schnatz suggested a notification on when guidelines are coming along with a preview of what to expect when they are issued. Again citing the example of Cervista, Dr. Einstein noted that a concise statement was issued discussing approval and data but not offering guidance. Dr. Flowers agreed that a statement of methylation may be possible.

Dr. Novetsky cautioned against undermining the enduring guidelines with statements that may conflict with those and asked if an interim statement could come from the enduring guidelines group rather than from ASCCP. While acknowledging Dr. Garcia's statement about staffing challenges, he expressed concern that too many statements make the enduring guidelines less relevant.

Dr. Khan opined that interim guidance on methylation shouldn't come out until it is FDA-approved, while Dr. Einstein said the company is filing for approval soon.

Dr. Chelmow offered his opinion that interim guidance comes from the ASCCP to ensure the enduring guidelines preserve its identity as adhering to a rigorous scientific process, noting that a statement would be watered down with opinion-based thoughts. Dr. Novetsky acknowledged that point, but highlighted the years-long lag time between major releases and a concern that the process is too "perfect." Dr. Flowers asked about a middle ground where ASCCP can consider a statement when guidance is not forthcoming in a timely manner.

Dr. Einstein put forward a motion to issue two clinical practice statements on both dual stain and extended genotyping for two FDA-approved tests that talk exclusively about the available data, with references. Dr. Chelmow cautioned that ASCCP should be careful not to appear to be appeasing funders and suggested the statement include a mention that enduring guidelines on these technologies are pending. Dr. Khan seconded the motion. The motion passed unanimously.

Dr. Chelmow iterated the importance of clarifying and standardizing the types of documents issued and the formats for these document types and Dr. Schnatz agreed. Ms. Curtis confirmed that the Practice Committee will be tasked with producing draft statements.

Dr. Downs asked Dr. Garcia whether or not he represents ASCCP in the enduring guidelines process. Dr. Garcia clarified that the official ASCCP representatives are Warner Huh and Richard Guido. He serves as an advocate for the enduring guidelines process, just as others on the leadership team do. Dr. Downs acknowledged the value of this approach but noted concern that this doesn't address previous board concerns with establishing ASCCP's value as a stakeholder in the process. Dr. Garcia suggested that, in response to concerns, the enduring guidelines team has improved its communication and transparency to organization partners.

b. Annual Meeting Update

Dr. Khan referred the board to the draft program, noting the three tracks for the 2023 meeting: Back to Basics, Screening and Prevention, and Management and Treatment. She highlighted the three keynote speakers—Philip Castle (NCI) discussing the landscape of cervical cancer screening globally, Vicar Sahasrabuddhe (NCI) discussing US-based programs targeting underserved populations, and Joel Palefsky discussing the ANCHOR study, as well as other notable sessions. Dr. Khan also noted the new abstract deadline set for November 10.

c. COMP Course Online—Spanish Translation

Ms. Curtis noted that an eight-person workgroup, including Drs. Garcia and Flowers, completed translation of the online COMP Course into Spanish and are currently working on voiceovers for the PowerPoint presentations..

Dr. Garcia indicated that the quality of translations has varied from presentation to presentation and the inconsistencies have slowed down the process. As the guardian of overall quality, Dr. Garcia continues his work to review the content to ensure a faithful reproduction of English language quality. He also suggested that a lower price point would reach a larger audience.

Ms. Curtis highlighted the challenge of ongoing edits and updates and the need for continued translation support. Dr. Garcia agreed on the need and suggested hiring a firm that does technical translation to ensure uniformity and consistency. Given the possibility of translation of the course to Portuguese, Ms. Curtis suggested finding a firm that can manage multiple languages.

Ms. Patty Cason thanked Dr. Garcia for managing this huge undertaking and agreed on the need to engage technical translation professionals. Dr. Einstein noted that online courses offer the opportunity for audience response and asked if interactive elements could be added. Dr. Novetsky suggested the online course, as a revenue source, is a good place to invest and such improvements would also be a one-time expenditure.

IX NEW BUSINESS

a. Board Commitment/Bylaws Review

Dr. Flowers explained that both expectations for board members and the bylaws are under review. Ms. Curtis confirmed that staff will employ an attorney to do a full overview of the bylaws and that she and Ms. Price will make any necessary updates and ensure the bylaws match the board manual.

b. WHO Initiative

Dr. Einstein discussed the WHO initiative on the elimination of cervical cancer, noting the number of professional organizations interested in collaborating toward the stated goals and working to improve access for all. Dr. Einstein stated that he leads the SGO task force on the initiative and is working with sister organizations on a five-year plan. SGO, he noted, will focus on treatment domestically and internationally, including minimal acceptable standards of treatment.

Dr. Einstein proposed that ASCCP take on screening and management as a potential project. He highlighted specific deliverables SGO identified (e.g. white papers, lobbying, updated online education platforms) and suggested ASCCP task committees with outlining their own and offered the idea of an ASCCP task force. Dr. Khan agreed and suggested targeting populations that aren't getting screened and vaccinated, perhaps using more feasible goalposts (e.g. Healthy People 2030) Dr. Einstein suggested ASCCP focus on deliverables for management, possibly partnering with SGO. Dr. Flowers agreed that this would align with the mission.

Dr. Einstein noted the need for administrative support and asked about reaching out to corporate partners for possible sponsorship of these activities, and Ms. Curtis cautioned against cutting into what these partners already contribute toward the annual meeting. Dr. Einstein suggested that the development committee discuss this and suggested a possible part-time person for administrative support, noting that both SGO and IGCS have taken this approach. While this is an expense, he noted that it is also an opportunity for development and sponsorship. Dr. Flowers suggested a discussion on the topic at the next Executive Committee meeting.

c. 2019 Management Guidelines Survey

Ms. Price noted that staff receives numerous requests for algorithm booklets and thus conducted a survey to discern whether disparities in access to technology might be behind these requests. She highlighted the fact that 10% of respondents still use the 2012 guidelines as well as the number of comments referring to the need for algorithm booklets, for varied reasons. Ms. Price noted the responses to question 3 that revealed a large number of clinicians do not use technology (e.g. cell phone or laptop)

in the exam room. Additionally, she highlighted survey responses and comments on the complicated guidelines that require expert opinion or refer to the use of clinical judgment as a point of contention, a complaint mirrored in comments received by staff.

While Dr. Einstein lamented the lack of education among clinicians, Dr. Novetsky suggested that the task of educating the thousands of providers who do screening is unrealistic. Rather, he suggested the need for a system similar to the BIRAD system used with mammograms, as the current complexity of the guidelines remains a challenge for many providers. He also acknowledged that the steps have gotten progressively more challenging with each iteration of the guidelines, with an increasing number of articles, pages, and tables for each.

Dr. Downs suggested readdressing the charge of ASCCP's mission, noting that ASCCP has issued increasingly complex guidelines without adding innovation to how we educate. He suggested ASCCP has a responsibility to take leadership in figuring out how to innovate so the guidelines can be implemented correctly. Dr. Schnatz suggested a hybrid model for the guidelines, taking algorithms from the app and creating booklets for the most common scenarios while also directing to the app. Ms. Curtis agreed that ASCCP needs to be open to meeting this need, despite the cost. Dr. Garcia suggested the issue is fundamentally about communication more than quality of the guidelines and agreed with the need for innovative strategies, suggesting the possible need for consultants to bridge communication barriers. Dr. Chelmow noted that, in addition to the communication gap, there is a technology gap that could be solved by an EMR connection.

Dr. Erin Nelson agreed that algorithms would be valued by members, noting that she typically forgoes a phone or laptop in the exam room as she feels it interferes with patient communication. She also noted issues of access, pointing out that she is unable to use the desktop version due poor WiFi at her clinic. Dr. Chelmow acknowledged that requirement to submit a verification code on the website to access the application presents an additional barrier to use the web version efficiently in clinic.

Dr. Einstein highlighted the fact that unrestricted web access wouldn't remove the demand for algorithms and suggested addressing HPV primary screening in an algorithm. While Dr. Khan highlighted the fact that not everyone has access to primary screening, Dr. Garcia suggested this could help move the practice culture to a primary screening platform. Dr. Einstein suggested as a printed product, these algorithms could be a revenue source.

Dr. Wiser outlined her efforts to educate primary care providers about the app, speaking at meetings for AAFP and the American College of Physicians. The survey, she noted, is telling and clearly shows the barriers. Ms. Patty Cason advised that the educational needs are far deeper than the current guidelines, as her experience educating providers has revealed that many clinicians don't know the basics, particularly those in family practice. As such, the app is just the tip of the iceberg. While the printed algorithms are a good, concrete solution, she noted, there are other issues at play, including practice settings, how are people coding, insurance-related guidance, etc. Ms. Cason suggested the issue is with healthcare in the US rather than the guidelines, and while ASCCP can't resolve that issue, it does need to be aware of it and mitigate it.

Dr. Novetsky suggested the survey lacks key demographic data (e.g. age, location) that can guide targeted interventions and advocated for free distribution of algorithms that could also serve to advertise the app. He also offered the suggestion for a speaker's bureau that could provide community hospitals with grand round speakers, and Ms. Curtis suggested discussing the idea at the strategic planning session.

Ms. Cason added that the biggest problem from the app is the guidance to "use clinical judgment" and asked if the app could get more granular about those answers. Dr. Downs noted prior discussion on publishing these types of answers in the journal and suggested ASCCP begin publishing documents that address areas where the app defers to "expert opinion." Dr. Einstein suggested adding dual stain and

intermediate risk to the algorithms, given the survey results. Dr. Novetsky added a suggestion to publish in the *JLGTD*.

d. NRTCC

Dr. Novetsky noted the president's cervical cancer roundtable will launch on Monday, October 24, at the White House with FLOTUS as a guest speaker. The effort, based on the cancer moonshot, covers prevention, screening, treatment, and management, with a focus on equity. There are three chairs, including a standing representative from ACS—Debbie Saslow, currently. Dr. Novetsky indicated that he is also a chair along with Deborah Arrindell. He noted the goal to assemble a steering committee comprising a diverse population and providers representing diverse populations. The inaugural steering committee members include Camile Claire, Bethany Berry, Brittany Davidson, Tamika Felder, Francisco Garcia, Electra Paskett, Rebecca Perkins, Mark Schiffman, Susan Vadaparampil, Claudia Werner, and Amy Wiser.

Dr. Novetsky stated that the committee will have their first talks around the time of the event with the initial goal of setting priorities, such as approval and adoption of self-screening and accessibility of end-of-life care. He noted interest in exploring a partnership with the WHO on shared goals and indicated that the committee website will launch next week. He indicated that he is open to input from members of the board for the committee and while he is happy to represent the society he welcomes other representation from ASCCP.

Dr. Chelmow asked if there was a conflict to represent an organization while serving as a tri-chair. Dr. Novetsky noted that while there would be conflict if he was involved in any decision about ASCCP sponsoring the initiative, ACS will be the backbone of the committee, providing full funding for two years. Dr. Garcia recommended that Dr. Wiser serve as ASCCP's official representative on the committee, and Dr. Wiser accepted.

Dr. Novetsky shared the draft mission statement of the committee: "*Organizations from across the cancer continuum working collaboratively and centering our work in health equity to focus on the elimination of cervical cancer by improving prevention, screening, and treatment. We aim to reduce barriers to care, eliminate disparities, reduce harms, and promote new technologies*."

e. DES—SGO Collaboration

Dr. Chelmow noted that ASCCP and SGO were approached by ACOG to offer guidance for DES patients. As SGO declined to participate, Dr. Chelmow advised ASCCP take on the project as it is under ASCCP's purview. With no data to review, Dr. Chelmow noted, the guidance will largely comprise expert opinion and the resulting paper should be a draw to the journal. Ms. Price noted that a draft from the practice committee was submitted on October 14.

f. Use of Pap Smear for CC Screening (Pap vs. Liquid)

Dr. Flowers reported on a meeting that she and Dr. Downs had with Teresa Darragh, where Dr. Darragh discussed the fact that many allied health providers in state-run health clinics still use Pap smears rather than a liquid-based process, let alone primary screening. While Drs. Flowers and Downs discussed whether it would be helpful for ASCCP to assist with communication and education around this issue, Dr. Darragh suggested that the issue would be addressed with the guidelines related to primary screening, and thus, there would be no utility in a special statement or recommendation on Pap vs liquid from ASCCP.

In response to a question about barriers from Ms. Cason, Dr. Flowers noted that Medicaid was cited as a barrier. Dr. Garcia acknowledged artificial regulatory and payment barriers, noting that one-third of women in public center clinics in New Mexico are screened with cytology only. Ms. Cason suggested that while there may be barriers from a payment perspective, the issue may be a perception of barriers and asked if a statement addressing payers (e.g. Medicaid, BCCP) could address miscommunication. Dr. Chelmow noted that ASCCP has issued a statement endorsing cytology, HPV primary, and co-testing, and

thus cautioned against contradicting any previous statement. Dr. Garcia suggested ASCCP can appropriately say that the world is moving towards primary HPV screening and that organizations should be moving that direction, and Ms. Cason agreed that HPV-based screening is not a contentious issue. Dr. Chelmow acknowledged room to address the use of smears without contradicting ASCCP's statement.

Dr. Garcia asked about the purpose of the statement, and Dr. Flowers affirmed that the goal was to address the leadership about the standard of care. Dr. Einstein asked about including cervical pathologists and Dr. Flowers noted that Dr. Darragh thought that the new updates should be focused on that group. Dr. Garcia suggested the messaging focus on the move to primary screening rather a move from dry to wet, as the end goal is a transition to primary HPV screening. Dr. Flowers suggested both messages were a priority but felt that Dr. Darragh made a good case since we're moving towards primary screening.

g. HIV Paper—Update

Dr. Flowers noted some discrepancies between the CDC website on HIV management and screening and the information on the app. Dr. Flowers indicated that she spoke with Rebecca Perkins regarding updating the guidelines and app to match content from CDC. She noted a group of experts in the field will draft a one- to two-page paper in support of the data and asked anyone interested to contact her.

X CLOSING REMARKS

The next board meeting will take place via conference call on January 17, 2023 at 7:00 pm ET.

XI ADJOURNMENT

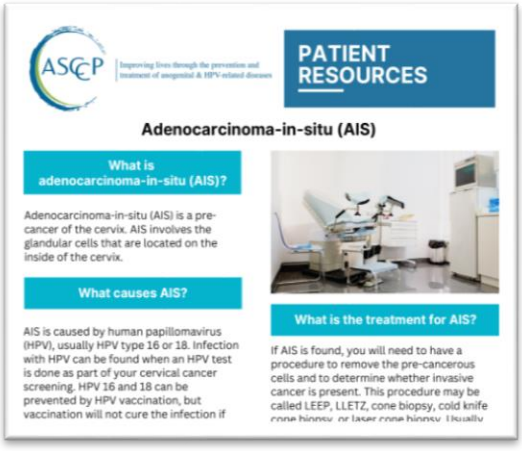
The meeting was adjourned at 4:15 pm ET.

ASCCP Staff Project Update - January 2023

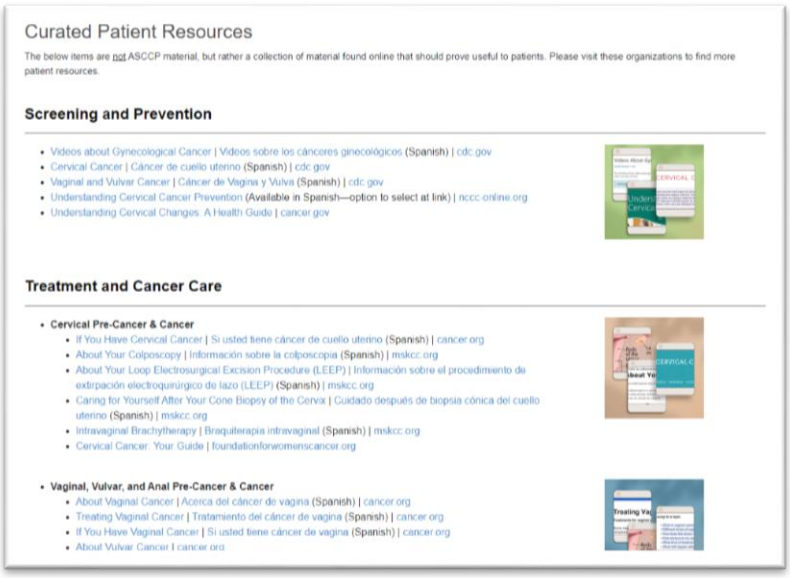
This report features many of the staff projects since the last Board Meeting.

- Membership - Dues
    - Working with IT to improve the auto dues payment system that was launched last year.
    - Launched new electronic invoices via email to pair with current marketing renewal emails. Working to retain Jan 2022 - Dec 2022 expired memberships.
        - Membership Assistant will be analyzing the success of this project, and staff will determine if the cost of mailed invoices are worthwhile, or if this low-cost alternative is enough to improve membership retention.
        - Between 1-4-23 and 1-13-23, new members and renewals increased membership by 80 members
    - Working with IT on (2) new membership dues enhancements estimated to launch 1st quarter 2023
        - Updates to the membership workflow, opening orders when membership expires and not expiring that order, adding “save for later” rather than delete.
        - Updating the pop-up to “join to save on registration” so it will work not just for new members, but also for lapsed members. Discounted registration ALWAYS drives our largest new membership and membership renewal, so this will be an important driver.

- Membership - Benefits
    - Working with IT for updated member profiles. This will allow us to add custom fields (such as pronouns) as well as improve reporting capabilities. Project started in September 2022, but due to the complexities of our database and complicated membership structure, we’ve had to send it back for improvements several times. We’re hoping for a Q1 or Q2 2023.
    - Updated Patient Documents for a streamlined look



- Sourced patient resources (CDC, ACS, etc), and added to page: www.asccp.org/patient-resources



Curated Patient Resources

The below items are not ASCCP material, but rather a collection of material found online that should prove useful to patients. Please visit these organizations to find more patient resources.

Screening and Prevention

- Videos about Gynecological Cancer | Videos sobre los cánceres ginecológicos (Spanish) | cdc.gov
- Cervical Cancer | Cáncer de cuello uterino (Spanish) | cdc.gov
- Vaginal and Vulvar Cancer | Cáncer de Vagina y Vulva (Spanish) | cdc.gov
- Understanding Cervical Cancer Prevention (Available in Spanish—option to select at link) | nccc-online.org
- Understanding Cervical Changes: A Health Guide | cancer.gov

Treatment and Cancer Care

- **Cervical Pre-Cancer & Cancer**
  - If You Have Cervical Cancer | Si usted tiene cáncer de cuello uterino (Spanish) | cancer.org
  - About Your Colposcopy | Información sobre la colposcopia (Spanish) | mskcc.org
  - About Your Loop Electrosurgical Excision Procedure (LEEP) | Información sobre el procedimiento de extirpación electroquirúrgico de lazo (LEEP) (Spanish) | mskcc.org
  - Caring for Yourself After Your Cone Biopsy of the Cervix | Cuidado después de biopsia cónica del cuello uterino (Spanish) | mskcc.org
  - Intravaginal Brachytherapy | Braquiterapia intravaginal (Spanish) | mskcc.org
  - Cervical Cancer: Your Guide | foundationforwomenscancer.org
- **Vaginal, Vulvar, and Anal Pre-Cancer & Cancer**
  - About Vaginal Cancer | Acerca del cáncer de vagina (Spanish) | cancer.org
  - Treating Vaginal Cancer | Tratamiento del cáncer de vagina (Spanish) | cancer.org
  - If You Have Vaginal Cancer | Si usted tiene cáncer de vagina (Spanish) | cancer.org
  - About Vulvar Cancer | cancer.org

- Social Media
  - Exchanged emails with consultant Heather Mansfield. She can provide a white paper report, but her brief recommendations included:
    - Social media in turmoil – organic reach is approximately 2% and advertising results/data is questionable. 2023 recommendation is to return to the basics – prioritize website/SEO/Google Ads and email marketing/growing your list to secure/retain members and secure attendees in 2023.
    - If doing social, focus on Facebook and LinkedIn only. Remove Twitter and Instagram profiles. Not the right target for our programs.
  - Staff has continued working to boost social trying new tactics – posting videos, trying LinkedIn long-form posts.
  - Have transitioned one of our part-time employees to a social media only focus to build this effort.

- Programs / Projects
  - Consultant hired to review/translate Spanish Comp Slides - target 1st Quarter completion of translation, with target 2nd Quarter completion of voiceovers.
  - Staff launched another successful Comprehensive Colposcopy Course with 203 attendees and 4 exhibitors, as well as putting an additional 161 attendees through the online course Oct – Dec.

    - Education, Membership, and Practice Committee met in December with renewed focus on Cases of the Month, Practice Pearls, and suggested improvements for the Advisor.
    - Papers
        - ECC Paper #1 published. Finalizing endorsements
        - In progress: ECC, DES

    - Journal:
        - Marketing for new reviewers with 45 responses. Dr. Bornstein chose 40.
        - Scheduled with J&J for a project to clean up the reviewer database.
        - Working through an overhaul of the Journal website – updating materials, graphics, and links.
        - Finalizing Journal affiliate contracts

- Scientific Meeting
    - All preliminary work complete and 2,500 draft programs mailed. Website updated with program, bios, photos. COIs checked.
    - Working on: abstracts, trainee research award, staffing and room assignments, travel.
    - Researched a list of over 100 potential exhibitors and have started with exhibit outreach. Have commitments from 10 exhibitors, 2 satellite symposia, and 2 additional sponsorships.

- Governance / Big Picture
    - Working with consultant to improve Board Handbook and build a Board Training process.
    - Working with consultant to develop a Financial Reserves Policy.
    - Working with consultant to update Bylaws.
    - Cyber Security Insurance Policy purchased.
    - Finalized Strategic Planning budget, timeline, and champions for Board Review.

ASCCP Financial Statements
Treasurer's Report to Board
January 11, 2023

- ***Financial report is for the 2 months ended November 30, 2022. This is a draft, internally prepared report and is subject to change***

- Total cash is $1,523,165 and includes the following:
  Operating account - $301,840
  Short-term investments Merrill Lynch - $1,221,325

- Merrill Lynch long term investments are $5.16 million. Investment reflects a $836,000 decrease over November 30, 2021, which reflects the fact that the market has been mostly down since early in 2022.

- Total assets are $6.91 million reflecting a $537,000 decrease over the prior fiscal year at this time. The primary decreases are due to the prior year.

- Current liabilities total $578,000 and consist primarily of $207,500 of deferred registrations, deferred dues and exhibit income relating to future meetings. Deferred registrations and exhibit payments are recognized as income after each course is completed. Deferred Dues are recognized ratably over the membership period.

- Total Revenue from Operations for the two months ended November 30, 2022, is $298,500 vs $306,000 budgeted. Unrealized gains on the portfolio were $505,000 as of November 30, 2022.
  Expenses for that same period are $330,000 vs $341,000 budgeted. There was deficit of revenue in excess of expenses from operations for the two-month period of $31,500. These deficits are before the unrealized gains on the portfolio as mentioned above.

Francisco Garcia, Treasurer

ASCCP			
Statement of Activities - Budget vs. Actual			
For the Two Months Ended November 30, 2022			
	YTD		
	Actual	Budget	Variance
Revenue			
4013.2 Mobile App	36,487	20,000	16,487
Meetings			
4000.1 Exhibit Income	7,700	4,600	3,100
4000.4 Registration Income	211,225	198,333	12,892
4000.5 Symposium Income	-	-	-
Total Meetings	**218,925**	**202,933**	**15,992**
Membership			
4010.1 Dues Income	51,347	60,000	(8,653)
Education			
4011.1 CMP Income	270	300	(30)
4011.2 Resident Educ Exam	525	500	25
Total Education	**795**	**800**	**(5)**
Journal			
4012.2 Journal Royalty	75	4,779	(4,704)
40340 Journal - Subscription - Emrts & Res	995	1,083	(88)
Total Journal	**1,070**	**5,862**	**(4,792)**
Total Membership	**53,212**	**66,662**	**(13,450)**
Other			
40345 Other Income	-	-	-
40470 Realized Gains/Losses	(17,888)	-	(17,888)
89001 Investment Fees	(6,513)	-	(6,513)
89002 Foreign Taxes (investments)	(13)	-	(13)
90000 Interest and Dividends	14,365	16,667	(2,302)
Total Other	**(10,050)**	**16,667**	**(26,716)**
Total Income	**298,574**	**306,262**	**(7,688)**
Expenses			
80105 Accreditation	6,350	6,000	350
80490 Audio Visual/Internet	29,783	32,000	(2,217)
80500 Meeting Supplies	-	500	(500)
81650 Food and Beverage	75,381	70,000	5,381
81730 Gratuities	46	-	46
81850 Honorarium	9,500	10,000	(500)
83670 Travel & Lodging			
81020 Board Travel & Lodging	4,162	5,000	(838)
83671 Staff Travel & Lodging	678	3,000	(2,322)
83680 Speaker/Member Travel & Lodging	5,341	8,500	(3,159)
Total 83670 Travel & Lodging	**10,182**	**16,500**	**(6,318)**
Journal Expenses			

	YTD		
	Actual	Budget	Variance
82120 Journal Subscriptions	22,782	16,667	6,115
82121 Journal Editor's Stipend	-	7,200	(7,200)
Total Journal Expenses	**22,782**	**23,867**	**(1,085)**
Operating Expenses			
81400 Depreciation Expense	-	-	-
81901 IFCPC Dues	8,202	11,000	(2,798)
Total 81900 IFCPC Expenses	**8,202**	**11,000**	**(2,798)**
82000 Insurance	9,206	8,617	590
82100 Gifts and Awards	115	83	31
82135 Licenses and Permits	-	-	-
82150 Dues & Subscriptions	5,687	3,500	2,187
82752 Miscellaneous/Other Expense	21	-	21
82800 Office Supplies	25	833	(809)
82850 Office Services	997	1,130	(133)
82975 Payroll Expenses			
83185 Pension Contributions	1,742	7,375	(5,633)
83695 Payroll Taxes	2,991	6,641	(3,650)
83696 Health	11,672	14,310	(2,638)
83697 Salaries	68,828	75,917	(7,089)
83950 Tuition/Training Expense	-	833	(833)
Total 82975 Payroll Expenses	**85,233**	**105,076**	**(19,843)**
83000 Postage & Freight	4,891	3,200	1,691
83300 Printing & Reproduction	-	1,000	(1,000)
83304 President - Program Expense	-	-	-
83339 Professional Fees			
83338 Consulting	30,119	14,583	15,536
83340 Accounting	14,676	15,000	(324)
83344 Legal	341	1,667	(1,325)
Total 83339 Professional Fees	**45,136**	**31,250**	**13,886**
83350 Storage	3,193	1,233	1,960
83700 Telephone & Cable	111	-	111
84200 Web Site Maintenance	7,020	6,000	1,020
89000 Bank, Credit Card and Payroll Fees	6,259	6,667	(407)
Total Operating Expenses	**176,096**	**179,589**	**(3,493)**
Web Hosting	-	-	-
Temporary Help	-	-	-
Total Expenses	**330,120**	**338,456**	**(8,336)**
Net Operating Revenue	**(31,545)**	**(32,194)**	**649**
Net Revenue(Expenses) in Excess of Expenses(Revenue)	**(31,545)**	**(32,194)**	**649**

ASCCP
BVA San Diego CC 2022
For the Two Months Ended November 30, 2022

	Total		
	Actual	Budget	Variance
Income			
Meetings			
4000.1 Exhibit Income	7,700	4,600	3,100
4000.4 Registration Income	214,410	190,000	24,410
Total Income	**222,110**	**194,600**	**27,510**
Expenses			
80500 Meeting Supplies	-	500	(500)
81650 Food and Beverage	70,390	70,000	390
81730 Gratuities	36	-	36
83670 Travel & Lodging			
81020 Board Travel & Lodging	156	-	156
83671 Staff Travel & Lodging	1,164	3,000	(1,836)
83680 Speaker/Member Travel & Lodging	2,923	8,500	(5,577)
Total 83670 Travel & Lodging	**4,242**	**11,500**	**(7,258)**
Meeting Expenses			
80490 Audio Visual/Internet	29,837	32,000	(2,163)
81850 Honorarium	9,500	10,000	(500)
Total Meeting Expenses	**39,337**	**42,000**	**(2,663)**
Operating Expenses			
81511 Equipment Expense	-	-	-
82000 Insurance	-	-	-
83000 Postage & Freight	4,891	2,700	2,191
83300 Printing & Reproduction		1,000	(1,000)
83339 Professional Fees			
83338 Consulting	9,500	7,500	2,000
Total 83339 Professional Fees	**9,500**	**7,500**	**2,000**
Total Expenses	**128,396**	**135,200**	**(6,804)**
Net	**93,714**	**59,400**	**34,314**

ASCCP
BVA Membership
For the Two Months Ended November 30, 2022

	YTD		
	Actual	**Budget**	**Variance**
Income			
Membership			
4010.1 Dues Income	40,564	47,400	(6,836)
Education			
4011.1 CMP Income	270	300	(30)
4011.2 Resident Educ Exam	525	500	25
Total Income	**41,359**	**48,200**	**(6,841)**
Expenses			
Total Expenses	**-**	**-**	**-**
Net	**41,359**	**48,200**	**(6,841)**

ASCCP
BVA - Journal
For the Two Months Ended November 30, 2022

	YTD		
	Actual	Budget	Variance
Income			
Membership			
4010.1 Dues Income	10,783	12,600	(1,817)
Journal			
4012.1 Journal Editorial Grant - Publ	-	-	-
4012.2 Journal Royalty	75	4,779	(4,704)
40340 Journal - Subscription - Emrts & Res	995	1,083	(88)
Total Journal	**1,070**	**5,862**	**(4,792)**
Total Income	**11,852**	**18,462**	**(6,609)**
Expenses			
Journal Expenses			
82120 Journal Subscriptions	22,782	16,667	6,115
82121 Journal Editor's Stipend	-	7,200	(7,200)
83338 Consulting	-	1,667	(1,667)
Total Expenses	**22,782**	**25,533**	**(2,751)**
Net	**(10,930)**	**(7,071)**	**(3,858)**

ASCCP
BVA All Committees
For the Two Months Ended November 30, 2022

	YTD		
	Actual	Budget	Variance
Income			
Total Income	**-**	**-**	**-**
Expenses			
83680 Speaker/Member Travel & Lodging	2,062	-	2,062
82150 Dues & Subscriptions	5,090	3,500	1,590
82100 Gifts and Awards	-	-	-
82752 Miscellaneous/Other Expense	-	-	-
83000 Postage & Freight	-	-	-
83339 Professional Fees			
83338 Consulting	180	-	180
Web Hosting	-	-	-
Total Operating Expenses	**7,332**	**3,500**	**3,832**
Total Expenses	**7,332**	**3,500**	**3,832**
Net	**(7,332)**	**(3,500)**	**(3,832)**

ASCCP
Statement of Activities - Committees
For the Two Months Ended November 30, 2022

	Humanitarian	Practice	Total Committees
Total Income	**-**	**-**	**-**
Expenses			
83680 Speaker/Member Travel & Lodging	2,062	-	2,062
82150 Dues & Subscriptions	-	5,090	5,090
83339 Professional Fees			
83338 Consulting	180	-	180
Total Expenses	**2,242**	**5,090**	**7,332**
Net	**(2,242)**	**(5,090)**	**(7,332)**

ASCCP
BVA - G&A
For the Two Months Ended November 30, 2022

	YTD		
	Actual	Budget	Variance
Income			
4013.2 Mobile App	36,487	20,000	16,487
Other			
40470 Realized Gains/Losses	(17,888)	-	(17,888)
40475 Unrealized Invest. Gain (Loss)	504,925	-	504,925
89001 Investment Fees	(6,513)	-	(6,513)
89002 Foreign Taxes (investments)	(13)	-	(13)
90000 Interest and Dividends	14,365	16,667	(2,302)
Total Income	**531,362**	**36,667**	**494,696**
Expenses			
80105 Accreditation	6,350	6,000	350
81650 Food and Beverage	83	-	83
81400 Depreciation Expense	-	3,333	(3,333)
81901 IFCPC Dues	8,202	11,000	(2,798)
82000 Insurance	9,206	8,617	590
82100 Gifts and Awards	115	83	31
82150 Dues & Subscriptions	597	-	597
82800 Office Supplies	25	833	(809)
82850 Office Services	997	1,130	(133)
82975 Payroll Expenses			
83185 Pension Contributions	1,742	7,375	(5,633)
83695 Payroll Taxes	2,991	6,641	(3,650)
83696 Health	11,672	14,310	(2,638)
83697 Salaries	68,828	75,917	(7,089)
83950 Tuition/Training Expense	-	833	(833)
Total 82975 Payroll Expenses	**85,233**	**105,076**	**(19,843)**
83000 Postage & Freight	-	500	(500)
83339 Professional Fees			
83338 Consulting	12,439	5,417	7,022
83340 Accounting	14,676	15,000	(324)
83344 Legal	341	1,667	(1,325)
Total 83339 Professional Fees	**27,456**	**22,083**	**5,373**
83350 Storage	3,193	1,233	1,960
83700 Telephone & Cable	111	-	111
84200 Web Site Maintenance	7,020	6,000	1,020
89000 Bank, Credit Card and Payroll Fees	6,259	6,667	(407)
Total Operating Expenses	**148,414**	**166,556**	**(18,142)**
Total Expenses	**154,847**	**172,556**	**(17,709)**
Net Income	**376,515**	**(135,889)**	**512,405**

Letter to the Editor: 2019 ASCCP Risk-based Management Consensus Guidelines: updates through 2022

Running title: Updates to 2019 ASCCP Risk-based Management Consensus Guidelines

Authors: Rebecca B. Perkins, MD,* Richard L. Guido, MD,* Philip E. Castle, PhD, David Chelmow, MD, Mark H. Einstein, MD, Francisco Garcia, MD, Warner K. Huh, MD, Jane J. Kim, PhD, Anna-Barbara Moscicki, MD, Ritu Nayar, MD, Mona Saraiya, MD, George Sawaya, MD, Nicolas Wentzensen, MD, and Mark Schiffman, MD, for the 2019 ASCCP Risk-Based Management Consensus Guidelines Committee

*Both authors contributed equally to the development of this manuscript and are co-first authors

From

Boston University School of Medicine/ Boston Medical Center, Boston, MA; University of Pittsburgh/ Magee-Women's Hospital, Pittsburgh, PA; Albert Einstein College of Medicine, New York, NY; Virginia Commonwealth University School of Medicine, Richmond, VA; Rutgers, New Jersey Medical School, Newark, NJ; Pima County Health & Community Services, Tucson, AZ; UAB School of Medicine, Birmingham, AL; Harvard T.H. Chan School of Public Health Boston, MA; University of California, Los Angeles, CA; Northwestern University, Feinberg School of Medicine-Northwestern Memorial Hospital, Chicago, IL; Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Atlanta, GA; University of California, San Francisco; San Francisco, California; Division of Cancer Epidemiology and Genetics and Division of Cancer Prevention, National Cancer Institute, Bethesda, MD; Division of Cancer Prevention, National Cancer Institute, Bethesda, MD

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Conflict of interest:

The following listed authors have no conflicts of interest to disclose: Drs. Perkins, Wentzensen, Schiffman, Chelmow, Garcia, Kim, Nayar, Saraiya, and Sawaya.

The following listed authors have conflicts of interest:

- Dr. Moscicki: Merck and GSK, Advisory Board member
- Dr. Guido: Inovio Pharmaceuticals DSMB, ASCCP Consultant
- Dr. Huh: Inovio Pharmaceuticals DSMB
- Dr. Castle has received HPV tests and assays at a reduced or no cost from Roche, Becton Dickinson, Arbor Vita Corporation, and Cepheid for research.

Commented [RP1]: Please check your affiliation and conflicts and update as needed. Thank you!

Commented [RP2]: Please update COI

- Dr. Einstein has advised companies and participated in educational activities, but does not receive any honoraria or payments for these activities, In some cases, his employer, Rutgers, receives payment for his time for these activities from Papivax, Cynvec, Merck, Hologic, and PDS biotechnologies. He has been the overall PI or local PI for clinical trials from Johnson&Johnson, Pfizer, Iovance, and Inovio. Funding for these activities is for the research related costs of the trials.

Disclaimer: The conclusions, findings, and opinions expressed by authors contributing to this journal do not necessarily reflect the official position of the U.S. Department of Health and Human Services, the Public Health Service, the Centers for Disease Control and Prevention, or the National Cancer Institute.

Word and Figure/Table Counts:

Précis: The 2019 guidelines were designed to be continuously updated. This letter summarizes updates through 2022.

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Dear Dr. Bornstein,

This Letter to the Editor includes updates to the 2019 ASCCP Risk-based Management Consensus Guidelines (hereafter abbreviated as 2019 guidelines).[1] This update summarizes all changes and corrections through 2022, and is expected to be the final update of the 2019 guidelines linked to the original paper.[1] Future updates, including guidelines for use of new technologies and updated recommendations related to new risk estimates for established technologies will be developed by the Enduring Consensus Cervical Cancer Screening and Management Guidelines (hereafter abbreviated Enduring Guidelines).[2] The Enduring Guidelines process is an extension of the 2019 guidelines consensus process, and represents a consensus group representing 20 national organizations, nearly all of which participated in the 2019 guidelines process. Enduring Guidelines updates will be disseminated through full guidelines papers.[3]

Since the publication of the 2019 guidelines, two types of updates have been required: updates that change recommendations, and updates related to wording errors or minor clarifications. Updates that involve a change in recommendations or a new recommendation were put to a formal vote of the original 2019 committee, which required a 2/3 majority to pass. Minor wording clarifications and typographical errors were corrected and reviewed by co-authors, but not formally voted upon. Between 2020-2021, one recommendation change and one minor clarification were published as Letters to the Editor and/or Errata that are linked to the original 2019 guidelines paper.[4,5] This Letter to the Editor summarizes all voted recommendation updates (one previously published, two new) and also addresses several cumulative minor clarifications and corrections.

2019 Guideline updates that change recommendations (with formal votes)

1) Endorsement of the 2021 Opportunistic Infections Guidelines: The 2019 guidelines endorsed the 2018 "Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV" that were current at the time of publication.[6] The opportunistic infections guidelines were subsequently updated in 2021.[7] The updated opportunistic infections guidelines recommend beginning cervical cancer screening at age 21 years, a change from prior guidelines that recommended initiating screening 1 year after sexual debut. The 2019 guidelines committee voted in October 2022 to officially endorse the new guidelines.

2) Clarification to wording for patients undergoing observation of CIN2:

The wording has been updated to clarify that both HPV testing alone and co-testing are acceptable for patients undergoing observation of CIN2. The revised wording is below:

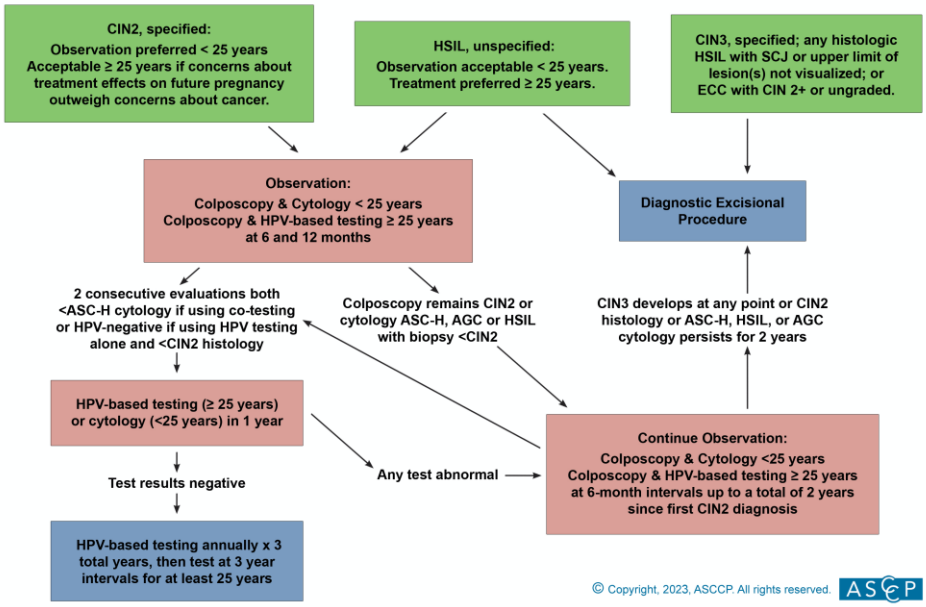
Guideline: For patients with a diagnosis of histologic HSIL (CIN 2) whose concerns about the effects of treatment on a future pregnancy outweigh their concerns about cancer, either observation or treatment is acceptable provided the squamocolumnar junction is visible and CIN 2+ or ungraded CIN is not identified on endocervical sampling (CII) (see Figure 8). If the histologic HSIL cannot be specified as CIN 2, treatment is preferred, but observation is acceptable (CIII). For patients 25 years or older, observation includes colposcopy and HPV-based testing at 6-month intervals for up to 2 years (See Section K.1 for management age of younger than 25 years). If during surveillance, all evaluations demonstrate less than CIN 2 histology and either less than ASC-H cytology if using co-testing or HPV-negative if using HPV testing alone on 2 successive occasions, 6 months apart, subsequent surveillance should occur at 1 year after the second evaluation and use HPV-based testing. If negative on 3 consecutive

Commented [FG3]: I think its unclear here which guidelines you are talk ing about here. I think you mean our guidelines here but it is unfortunate that opportunistic inf is also referred to as guidelines.

Commented [RP4]: Note, this is the revised text that we voted on

annual surveillance tests, proceed to long-term surveillance (Section J.3). If CIN 2 remains present for a 2-year period, treatment is recommended (CII).

Figure 8: Management of CIN2 at age <25 years or for those concerned about the effects of treatment on future pregnancy



3) Updated Guidelines Addressing Patient Scenarios Not Initially Addressed in the 2019 Guidelines: Additional guidance was developed to address scenarios for which the 2019 Guidelines did not initially provide management recommendations. This guidance was voted on in July 2021 and previously published.[4] To summarize, this guidance (1) outlined management guidelines for cytology results without HPV testing among individuals aged 25 years and older, and (2) clarified management when prior guidelines had not been followed:[4]

(1) Guideline for individuals aged 25 and older screened with cytology alone: For individuals aged 25 years or older screened with cytology alone, the 2012 guidelines should be followed. In

the 2012 guidelines, colposcopy is recommended for low-grade squamous intraepithelial lesion (LSIL) or more severe cytologic interpretation.[8]

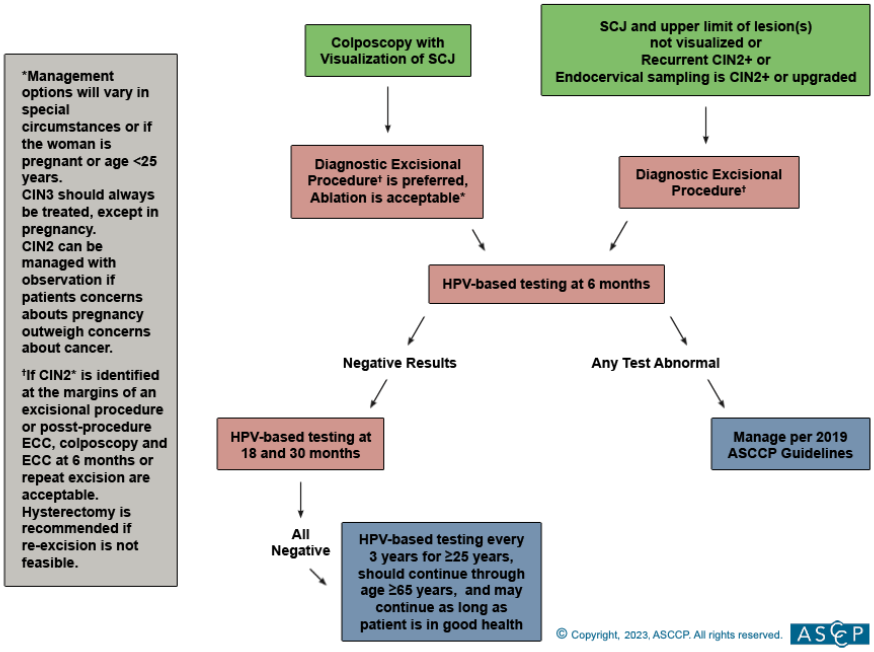
(2) Guideline for cases in which colposcopy was previously recommended but not completed: In cases in which a colposcopy was previously recommended but not completed, the recommendation is for colposcopy if the prior result was high-grade cytology [atypical squamous cells cannot exclude a high-grade squamous intraepithelial lesion (ASC-H) atypical glandular cells (AGC), or high grade squamous intraepithelial lesion (HSIL)]. If the prior cytology result was not high-grade, and the patient undergoes repeat testing with HPV testing or co-testing instead of colposcopy: (a) colposcopy is recommended if the result on repeat testing indicates a second consecutive HPV-positive result and/or persistent cytologic abnormality (atypical squamous cells of uncertain significance, ASC-US, or more severe); (b) repeat HPV testing or co-testing in 1 year is acceptable if the result on repeat testing is HPV negative or co-test negative.

2019 Guideline updates that relate to typographical errors or wording clarifications (formal votes not conducted)

1) Correction to Figure 7 clarifying that a total of 3 negative HPV-based tests are needed after treatment to return to a 3-year testing interval: Figure 7 was updated to match the information included in Table 5b of Egemen *et al*[9] and the text of the guidelines paper which reads: "In patients treated for histologic or cytologic HSIL, after the initial HPV-based test at 6 months, annual HPV or cotesting is preferred until 3 consecutive negative tests have been obtained (AII)."[1] Risk estimates for the 2019 guidelines indicate that, following excisional treatment for histologic HSIL/ CIN2-3, three consecutive negative HPV tests or co-tests are needed at 1-year

intervals to identify a group of patients at sufficiently low risk that they can safely return to 3-year testing interval. The 2019 guidelines recommend that the first test occur 6 months following the excisional procedure. Figure 7 erroneously recommended an HPV test or co-test at 6 months followed by 3 consecutive annual HPV or co-tests (a total of 4 consecutive negative tests). This has been corrected to recommend the first HPV test or co-test at 6 months followed by additional HPV or co-tests at 18 months and 30 months. The Figure has also been modified to clarify that follow up should continue at 3-year intervals for a minimum of 25 years and through at least age 65 years, and may continue for as long as the patient is in good health.

Figure 7: Management of Histologic HSIL (CIN2 or CIN3 or Not Further Specified)*



Summary of prior correction to Figure 2 Legend published October 2020[5]

The Legend for Figure 2 was updated to clarify the algorithm for management after a minimally abnormal screening test result followed by a colposcopy at which high-grade histology was not found.[5] First, repeat HPV-based testing (HPV testing or co-testing) at 1 year is recommended to guide additional management. If this HPV test or co-test is negative, return in 3 years is recommended. If HPV testing is negative but cytology (in the case of co-testing) is ASCUS or LSIL, return in 1 year is recommended. If HPV testing is positive and/or cytology is ASC-H or higher, repeat colposcopy is recommended.

Commented [FG5]: Consider this clarification

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2. NCI. Enduring Consensus Cervical Cancer Screening and Management Guidelines. Accessed October 10, 2022. https://dceg.cancer.gov/research/cancer-types/cervix/enduring-guidelines

3. Egemen D, Perkins RB, Clarke MA, et al. Risk-Based Cervical Consensus Guidelines: Methods to Determine Management if Less Than 5 Years of Data Are Available. *J Low Genit Tract Dis*. 2022;26(3):195-201. doi:10.1097/LGT.0000000000000685

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9. Egemen D, Cheung LC, Chen X, et al. Risk Estimates Supporting the 2019 ASCCP Risk-Based Management Consensus Guidelines. *J Low Genit Tract Dis*. 2020;24(2):132-143. doi:10.1097/LGT.0000000000000529

Lead the Field

Promote research and be the clear voice in developing and disseminating evidence-based best practices

Strategic Objective	Task	Due Date	Committee	Notes	Cost	
Continue developing and implementing guidelines	Define categories for guidelines, white papers, etc. (guidelines, statements (expert opinions), alerts (time sensitive)	4/24	Practice Committee	Draft policy started		
	Develop a process to identify topics for guidelines/products	4/24	Practice Committee	Will be part of the final guidelines policy		
	Participate in other organizations' guideline development process while endorsing and/or adopting other organizations' guidelines	4/24	Practice Committee	Policy already done; will revisit and incorporate into one policy; our guideines and participating in others		
	Develop structure for continuous update and review	4/24	Practice Committee	Will be outlined in the policy; suggestion is every (3) years unless something comes up before then; list on website with published date	$ 100,000.00	(1) additonal staff for entire Lead the Field
Serve as the communication channel in the dissemination and implementation of methods, guidelines, and best practices	Develop consumer facing tools to explain guidelines, best practices, and other tools: online courses, algorithms, web resources, social media, video/visual/demo	10/24	Special Task Force	Create Social Media Task Force - send out call for volunteers Create attractive Patient page - link out to ACS, ASHA - post their stuff on social media; hire outside experts	$ 75,000.00	Possible grant
	Develop collaborations with trainee facing organizations (CREOG, APGO, etc) and cross link with SM	4/25	Staff	KC to research APGO opps; consider mid-career orgs also; (IANS/ISSVD) - consider (3) tracks at 2025AM/San Diego; ASCCP, IANS and ISSVD	$ -	
	Engage with patient/consumer-oriented organizations and cross link with SM	10/24	Staff	Survivor; ASHA - offer free booth at Annual; repurpose 2017 presentation by Alegra Woodard; research Tamika (IPV mtg)	$ 5,000.00	
	Investigate and improve implementation advocacy considerations (what gets paid for)	10/24	Special Task Force/Consultant	Partner with ACOG - create a task force/assign ASCCP liaison	$ -	If partnership with ACOG doesn't pan out, consultant will run 100k
Be known as the "home" where people bring research in order to increase researcher engagement	Continue scientific sessions at meeting	4/23	PDs		$ -	
	Implementation science around guidelines	4/24	Practice/PDs/Staff	Partner with ACOG	$ -	
	Identify ways in which the society can highlight science from other researchers	4/24	Practice/PDs/Staff	Collaborations with other societies - will continue to highlight their research "Top Articles" session at SM - include JLGTD and top articles in the field	$ -	
High	1 year to 18 months					
Medium	24-36 months			Projected Cost	$ 180,000.00	
Low	Start thinking about it in 3 year plan					
Majority of cost for this goal is staff time						
				Projected Total Costs:	**$ 585,000.00**	

Member Support

Continue to develop educational opportunities and other resources that provide value to our members

Strategic Objective	Task	Due Date	Committee	Notes	Cost	
Expand content and resources to provide relevance and value to our members	Develop a train the trainer course that includes soft science training which will lead to partnership and diversity of science. (i.e. implicit bias)	10/23	Education Committee	Create mini-course using other material on Implicit Bias/Racial Disparities Free slides with Notes for members or anyone who enrolls in the course	$ -	Use current LMS and current recordings; staff time
	Expand the educational systemic structure in order to cover smaller areas for education and offer consultation for treatment questions and management *Break up comp course	4/24	Education Committee	Mini Courses at AM/Online and other meetings (i.e. PA Association, SGNO, NPWH) Work to build the Clinical Practice Listserv and VIP involvement for Q&A	$ 25,000.00	Editing costs/recording
	Compile annually the top articles (task force; summary) - present at annual meeting and website *Task force to develop a summary for presentation during the AM	4/24	PDs	AM2024 session (Top Articles for JLGTD and/or anywhere in the field	$ -	Refer to Lead the Field
	Develop a mentorship program modeled after SGO/SASGOG with a focus on programs that ASCCP is nurturing *Meet the professors lunch *Meet attendees at AM with follow up	4/24	Staff/PDs	CP - research SGO and SASGOG programs; At AM2023 - network reception	$ 30,000.00	F&B cost
	Investigate the feasibility and utility of a social media campaign through the use of a consultant *Consultant hired would be prohibited from submitting proposal for consideration for potential social media campaign	10/24		Cost estimate needed to hire consultant.	$ 50,000.00	consultant
Create additional engagement opportunities	Develop train the trainer program (i.e. mini programs) - apply for grant (regional)	4/24	Education Committee	already mentioned previously	$ -	Refer above
	Reinvent the resident program	1/24	Education Committee	Working on residents page	$ -	
	Train the trainer - Develop a "simulation how to" program	10/24	Education Committee	Film the COMP Course for Online Access	$ 75,000.00	Try to film at course; otherwise special filming
	Develop a task force for engagement by bringing in trainee and other voices	4/24	Membership Committee	Add 2-3 trainees to membership committee - discuss their thoughts	$ -	
Conduct and analysis of the ASCCP annual meeting in order to understand the "science" of how to run a meeting, what venues are optimal, and the best modalities of delivery	Engage a consultant to conduct a strategic review of the annual meeting *Determine return on investment of any changes recommended prior to implementation in order to minimize the impact on staff resources while identifying opportunities for efficiencies *Develop an ad-hoc task force to work with the consultant	6/24	PDs/Staff	Purchase PCMA Trend Report Survey; Need data on about format preference/trend; no adhoc committee is necessary; KC/CP can review the report/trends and determine ROI; Outline cost differences between in-person/online, etc Survey membership on their wants/needs/challenges (format, pricing, frequency, length of meeting, content priorities - hands on, science, networking, etc)	$ 5,000.00	Cost of reports; Recommend staff purchase and analyze reports; initially no consultant needed; recommedation for AM2025

	Develop focus groups at the annual meeting and structured interviews in order to inform its future direction (consultant-led)	4/24	Consultant	Meet the Professors at Networking Reception - APC table; new members table, GYN Onc table (no nurses breakfast); estimate for outside consultant to run focus groups	$ 50,000.00	estimate for consultant for AM2024
	Develop QR codes at the end of each presentation	4/23		CP will create for AM2023	$ -	
Understand members' needs in order to continuously improve and increase relevance and value	Develop a membership survey	10/23	Membership Committee	Create a quarterly Membership survey so that data may be discussed at the quarterly Board meetings; Suggest no more than 5-10 questions to be discussed/developed with the membership committee	$ -	
	Ensure awareness of patient handouts	1/23	Staff	Staff will include in marketing/promotion plan	$ -	already begun
	Translate patient handouts into other languages	1/25	Consultant	low bearing fruit - but will get cost estimate for translation company and/or see if other patient groups already provide and link to them	$ 25,000.00	Spanish to start
	Education on newest guidelines (handouts, lectures, flipcharts)	1/25	Education Committee	Repurpose content into mini-course Webinars	$ 15,000.00	
	Investigate the feasibility of conducting an annual member needs study	10/23	Membership Committee	Quarterly Member survey will address this; intensive/long surveys were done in the past with little yield	$ -	See above
High	1 year to 18 months			Projected Cost	$ 275,000.00	
Medium	24-36 months					
Low	Start thinking about it in 3 year plan					

Champion Equity

Promote accessible and equitable care

Strategic Objective	Tasks	Due Date	Committee	Notes	Cost	
Develop additional ASCCP resources that promote accessible and equitable care	Expand patient and provider materials (either patient facing or provider to patient facing) on management including colposcopy, HPV, genotyping (including intermediate risk), new tech (i.e., dual stain), treatments and clinical trials	10/24	Practice/Special Task Force	Similar to other tabs: expand current provider resources (Pearls, papers, etc), and create patient webpage and social media posts.	$ -	
	Discuss simplified algorithm booklets	4/24	Special Task Force	Develop a task force to create some simplified algorithm booklet options: HPV Primary Screening or possibly Management w/o Past History	$ 15,000.00	
	Consider the development of 'free' webinars for providers for new developments in management (i.e. deliver a community talk on dual stain for free or offer as a free webinar on website)	10/24	Education Committee	Offer free short 5 minute non-CME sessions as recorded on-demand video of the most vital info. Keep the 30-60 minute CME webinars as free for members, affordable for non-members.	$ 25,000.00	
Develop partnerships and initiate community outreach	Expand reach of the society's patient resources and materials to a broad group of providers. Expand access of community providers to ASCCP experts with regards to management	1/25	Practice Committee	In connection with building the patient resources pages of the website linking to patient materials on other sites, network with our collaborative partners to link back to anything management related.	$ -	
	Consider the feasibility and any risk issues of providing access to the society's listserv and patient resources for everyone	1/25	Practice Committee	The patient resources will be open to all. The listserv is a vital member benefit, and due to the nature of it, should remain members-only.	$ -	
	Improving relationships with advocacy	4/25	PDs/Staff	Working with advocacy groups for: tables at the SM, speakers at the SM, additional patient resources.	$ 15,000.00	
	Consider broadening board membership with patient focus in mind (i.e. representative from advocacy)	4/25	Staff	KC to colllaborate with ASHA and possibly invite to ASCCP Board Mtg	$ 2,500.00	possible travel
	Patient survey/direct engagement from engaged patients who work with advocacy	4/25	Staff	Work with ASHA; discuss grant funding and collaboration	$ -	
	Consider developing a half-day for patients at a meeting	4/26	Membership/Staff	Membership Committee and Staff to research how this is being done at other organization meetings.	$ -	No idea on cost
	Develop ASCCP partnership with the WHO Cervical Cancer Elimination Initiative	4/23	Practice Committee	Recruit more junior volunteers for current committees; incorporate WHO initiative in respective committees - i.e. Pearls, white papers, educational initiatives		already begun

	Deliverable considerations for screening / management both domestically and internationally	4/25	Practice Committee	Rolliing out deliverables in conjunction with WHO Initiative	$ -	unknown
High	1 year to 18 months			Projected Cost	$ 57,500.00	
Medium	24-36 months					
Low	Start thinking about it in 3 year plan					

Expand Membership

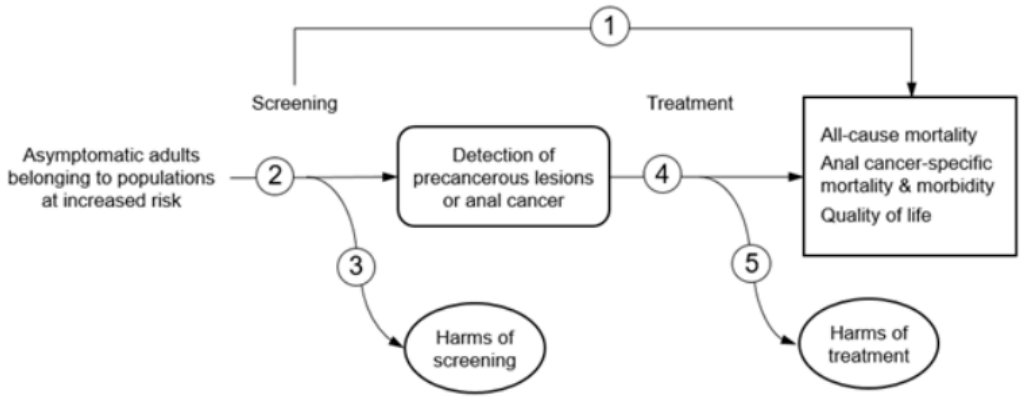
Diversify Membership and increase member engagement

Strategic Objective	Tasks	Due Date	Committee	Notes	Cost	
Develop a targeted outreach effort to increase membership and engagement	Develop targeted outreach to pathologists and residents by *Attending Meetings *Exhibiting at ACP Meetings *Conducting outreach to Program Directors	10/24	Membership Committee	Volunteers reach out personally about speaking opportunities with affilated societies/organizations; Membership committee to suggest local exhibiting opportunities (DC area)	$ 10,000.00	recruit local volunteers and/or invited speakers
	Demonstrate ASCCP mobile application at meetings	4/25	Membership Committee	ASCCP has a standard slide template that can be shared with volunteers; marketing campaign as well as submitting abstracts for meetings	$ 10,000.00	travel costs
	Provide a discounted rate for those who sign up within the first few months of moving into an attending role	10/24	Membership Committee	Offer a Junior Membership for transitioning from Trainee to Full Membership	$ 25,000.00	AMS Costs
	Develop a presence at AAFP targeting family medicine fellowships in women's health	10/24	Membership Committee	Research local AAFP chapter speaking ops; exhibiting opps	$ 10,000.00	travel costs
	Exhibit at NPWH and PA conferences	10/23	Membership Committee	ASCCP will have a Mini Comp Course at the PA meeting. Discuss thoughtful collaboartive efforts with NPWH	$ 5,000.00	
	Develop free virtual networking events with a talk by MD's, APC's, trainees, and fellows	10/24	Membership/Education Committee	30 minute virtual "How to grow your career in this field" and "meet the experts" sessions. Networking sessions being implemented at the SM starting 2023	$ 10,000.00	2x/year
Expand Benefits and Resources	Develop different tracks within the annual meeting (partial and not throughout the meeting)	4/25	PDs/Staff	Consideration for 2024; consideration for IAN/ISSVD track for 2025	$ -	unknown
Increase volunteer engagement in order to develop the next generation of leaders	Design informational sessions at the annual meeting	4/24	PDs/Staff		$ -	
	Develop a slide on volunteering at the end of the session	4/23		will include in break slides in AM2023	$ 2,500.00	graphic design
	Develop an ad-hoc task force to evaluate available volunteers and new opportunities for committees and engagement	10/24	Staff	Staff is working to develop additional Task Forces and volunteer opportunities based on the strategic plan. Will refer to ASAE for short-term volunteer opportunities.	$ -	unknown
High	1 year to 18 months			Projected Cost	$ 72,500.00	
Medium	24-36 months					
Low	Start thinking about it in 3 year plan					

U.S. Preventive Services Task Force (USPSTF)
Anal Cancer Screening Draft Research Plan
Response to public comment solicitation provided on behalf of the American Society of Colposcopy and Cervical Pathology (ASCCP)

Draft based on January 10, 2023 committee discussion

Proposed Analytic Framework



Please select one of these options.

X - I agree with it; I have no comments
Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about the Analytic Framework?
No comment.

Proposed Key Question 1

Does screening for anal cancer in high-risk persons change all-cause mortality, anal cancer–specific mortality or morbidity, or quality of life?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Key Question 1?

We suggest that this key question include the term “anal high-grade squamous intraepithelial lesions (HSIL)” since the screening process includes an effort to detect both anal HSIL and cancer. We also suggest that this question include morbidity related to anal HSIL treatment and management.

As screening is considered, please note the lack of adequate workforce to implement wide-scale screening, therefore priority should be given to high-risk populations. Additionally, it should be noted that gynecologists serve as primary care clinicians for individuals with risk factors for anal cancer, i.e. lower genital tract HSIL and cancer and the recommendations should consider adequate workforce training.

Proposed Key Question 2

What is the accuracy of screening tests for anal cancer?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Key Question 2?

Comments:

As noted for KQ1, we suggest that this key question also include reports on the accuracy of screening tests for both anal HSIL and for anal cancer. Additionally, please explore what is the accuracy of screening tests in the general population vs the accuracy of screening tests in high-risk populations, as well as accuracy during active surveillance (post-treatment), given that the test characteristics change in different populations.

Proposed Key Question 3

What are the harms associated with screening for anal cancer?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Key Question 3?

Comments: As noted for KQ1 and KQ2, we suggest that this key question also include reports on harms associated with screening for both anal HSIL and for anal cancer. Additionally, please explore harms based on age to balance risk/harms for the younger populations weighed against benefits. Quality of life, including sexual side effects, should also be explored.

Proposed Key Question 4

What is the effectiveness of treatment of anal intraepithelial neoplasia and early-stage (Stage I), localized anal cancer?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Key Question 4?

We suggest exploring the effectiveness of different types of treatments - excision vs ablation vs. topical - for different diagnoses (HSIL, SISCCA, etc).

Additionally, we suggest that the researchers revise this question to limit considerations of the effectiveness of treatment of anal intraepithelial neoplasia to anal HSIL, since that is the lesion that can be treated to reduce the incidence of anal cancer.

While it is reasonable for the researchers to focus on the effectiveness of treatment for the earliest cancers, we also suggest that considerations of the effectiveness of treatment anal cancer be expanded to include the entire range of stages of anal cancer.

It is unclear if the researchers intend to group anal HSIL with superficially invasive squamous cell carcinoma of the anus, or SISCCA, as defined by the Lower Anogenital Squamous Terminology Standardization Project, or LAST) (1), and its treatment approach, which may be limited to local excision, but the data on the effectiveness of this approach for anal cancer treatment are still in progress (e.g., protocol AMC-092/ NCT02437851 and the PLATO trial's Anal Cancer Trial 3 cohort / ISRCTN88455282). Stage 1 anal cancer as defined by the American Joint Commission on Cancer (AJCC) includes both SISCCA and small tumors with more extensive depth and spread (2), the latter of which are generally managed with standard treatment approach for later stages of anal cancer (chemoradiotherapy).

(1) Darragh TM, Colgan TJ, Cox JT, Heller DS, Henry MR, Luff RD, McCalmont T, et al. "The Lower Anogenital Squamous Terminology Standardization Project for HPV-Associated Lesions: Background and Consensus Recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology." Archives of Pathology & Laboratory Medicine 136, no. 10 (October 1, 2012): 1266–97. https://doi.org/10.5858/arpa.LGT200570.

(2) American Joint Committee on Cancer. Anus. In: AJCC Cancer Staging Manual. 8th ed. New York, NY: Springer; 2017: 275.

Proposed Key Question 5

What are the harms associated with treatment of anal intraepithelial neoplasia, high-grade squamous intraepithelial lesions, and early-stage (Stage I), localized anal cancer?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Key Question 5?

Our comments on KQ4 regarding consideration specifically of treatment of anal HSIL, and on treatment of the entire range of stages of anal cancer should also be considered for KQ5. Additionally, similar to KQ4, we suggest harms be stratified based on different types of treatment (excision vs ablation vs topical) for different diagnoses (HSIL, SISCCA, etc), as well as the role age may play a role on harms. Quality of life challenges, such as sexual side effects, need to be included or recommended for future research.

Proposed Contextual Question 1

Does screening for anal cancer in high-risk persons change the incidence of anal cancer and the distribution of cancer types and stages (i.e., stage shift)?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Contextual Question 1?

We recommend including screening for anal HSIL be added to screening for anal cancer in this context. It is unclear what the researchers are referring to with respect to change in the distribution of cancer types. We recommend that the question be focused solely on the stages of anal squamous cell carcinoma.

Proposed Contextual Question 2

What is the magnitude of change in all-cause and anal cancer–specific mortality that results from a specified change in anal cancer incidence (and change in distribution of anal cancer stages [i.e., stage shift]) after screening?

Please select one of these options.
X - I agree with it; I have no comments
Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Contextual Question 2?

No comment.

Proposed Contextual Question 3

What risk assessment tools are available for use in primary care to identify adults at increased risk for anal cancer?

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about Contextual Question 3?

We recommend that consideration of the risk assessment tools reflect the populations at highest risk of anal cancer, as described by Clifford et al. These include HIV-positive men who have sex with men older than 35, older HIV positive men and women, women with other gynecologic cancers, and solid organ transplant recipients (1).

As mentioned in KQ1, we recommend it be noted that gynecologists serve as primary care clinicians for individuals with risk factors for anal cancer, i.e. lower genital tract HSIL/cancer given they are trained in colposcopic appearance of anogenital intraepithelial neoplasia.

(1) Clifford, GM, Georges D, Shiels MS, Engels EA, Albuquerque A, Poynten IM, de Pokomandy A, Easson AM, and Stier EA. “A Meta-Analysis of Anal Cancer Incidence by Risk Group: Toward a Unified Anal Cancer Risk Scale.” International Journal of Cancer 148, no. 1 (2021): 38–47.

Proposed Approach to Assessing Health Equity and Variation in Evidence Across Populations

To the extent possible, we plan to describe the population, screening, and intervention characteristics of the included studies. Data on population characteristics will help us explore the degree to which the findings are representative of persons at risk for anal cancer as well as investigate potential differences in benefit and harms by different population groups. These groups include, but are not limited to, categorizations by age; racial, ethnic, and cultural identity; behavioral risk factors; and chronic health conditions.

Please select one of these options.
I agree with it; I have no comments
X - Generally, I agree with it; see comments below
I have concerns; see comments below
I do not wish to give comments on this question

Do you have any comments about the Approach to Assessing Health Equity and Variation in Evidence Across Populations?

We recommend adding categorizations for gender, sexual minority status, and socioeconomic status, as well as including the groups at high risk of anal cancer as described by Clifford et. al (1).

(1) Clifford, GM, Georges D, Shiels MS, Engels EA, Albuquerque A, Poynten IM, de Pokomandy A, Easson AM, and Stier EA. “A Meta-Analysis of Anal Cancer Incidence by Risk Group: Toward a Unified Anal Cancer Risk Scale.” International Journal of Cancer 148, no. 1 (2021): 38–47.

Proposed Research Approach

The Proposed Research Approach identifies the study characteristics and criteria that the Evidence-based Practice Center will use to search for publications and to determine whether identified studies should be included or excluded from the Evidence Review. Criteria are overarching as well as specific to each of the key questions.

Populations

For KQ 1, 3, inclusions of persons with HPV-related cancers and precursors should be moved from the excluded category to the included category, as standard programs for cervical cancer screening do not evaluate patients for the risk of anal HSIL or anal cancer.

KQ2: Suggest using the term "HSIL" instead of AIN.

KQ 4, 5: Suggest using the term "HSIL" instead of AIN, and extending the staging of cancers to include the entire range.

Screening

KQ 1, 3: We recommend using the term "cytology" instead of “Pap test".

KQ 2: The researchers should consider including dual staining (p16 and ki67 immunocytochemical staining), and partial/extended HPV genotyping.

Comparisons

KQ 1, 3. Usual care is no screening; the comparison group should be a screened group. Now that ANCHOR has shown that treatment of anal HSIL is effective in reducing the incidence of anal cancer, we believe that assessment of comparative effectiveness of different treatments may be of value.

KQ2- We do not understand what is meant by "biopsy" in this context.

Outcomes

KQ 2. We recommend including the screening test characteristics of the other tests suggested under the “screening” heading above.

KQ 3. We believe that a false-positive result is essentially the same as "over diagnosis". We recommend clarifying what is considered overdiagnosis.

Study designs

In absence of RCT, we would recommend using data generated from the ANCHOR trial and the following publications listed below. As other studies looking at high-risk populations are published, based on the rigor of the studies, data produced by those studies should be considered.

(1) Burkhalter JE at al. Initial Development and Content Validation of a Health-Related Symptom Index for Persons either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions. Group. Value Health. 2018;21:984- 992.

(2) Atkinson TM et al. Reliability and between-group stability of a health-related quality of life symptom index for persons with anal high-grade squamous intraepithelial lesions: an AIDS Malignancy Consortium Study (AMC-A03). 2019; 28:1265-1269.

(3) Atkinson TM et al. Linguistic validation of the Spanish version of the Anal Cancer High-Grade squamous intraepithelial lesions outcomes Research Health-Related Symptom Index (A-HRSI): AMC-A04. J Patient Rep Outcomes. 2022 Oct 11;6(1):108.

(4) Palefsky JM, Lee JY, Jay N, Goldstone SE, Darragh TM, Dunlevy HA, Rosa-Cunha I, et al. “Treatment of Anal HighGrade Squamous Intraepithelial Lesions to Prevent Anal Cancer.” New England Journal of Medicine 386, no. 24 (June 16, 2022): 2273–82. https://doi.org/10.1056/NEJMoa2201048

Contact Information

You may provide such information if you are willing to be contacted if we have questions about your comments. This information will only be used by USPSTF and will never be shared with third parties. The USPSTF does not provide individual responses to comments. Please review our Privacy Policy.

Contact Information (Protocol chair contact information listed)
Kerry O. Curtis, CEO as liaison to the ASCCP Board of Directors and the ASCCP Executive Committee

Lisa Flowers MD, President of ASCCP

Please select the category that you identify with best

Clinician on behalf of self
Consumer or Patient
Member of advocacy organization
Member of health care organization
Member of professional society or organization
Policymaker Researcher
Other: On behalf of the American Society of Colposcopy and Cervical Pathology (ASCCP)