MEETING SUMMARY

PRESIDENT'S CANCER PANEL

IMPROVING RESILIENCE AND EQUITY IN CERVICAL CANCER SCREENING: LESSONS FROM COVID-19 AND BEYOND

November 9 and 10, 2020
Virtual Meeting

This workshop was the third in the President's Cancer Panel's (the Panel) 2020–2021 series on cancer screening. The workshop brought together stakeholders from several sectors, including clinical care, healthcare systems, insurance companies, government agencies, research, and advocacy. Participants discussed barriers and opportunities related to cervical cancer screening, including those relevant to the healthcare system disruptions caused by the coronavirus disease (COVID-19) pandemic. The workshop was available to the public via live feed, and members of the public were invited to submit written comments and questions during and after the workshop. Participants were encouraged to live-Tweet at #ImprovingCancerScreening.

This meeting summary was prepared to satisfy requirements established by the Federal Advisory Committee Act. The summary provides an overview of presentations and discussions occurring as part of the workshop and does not necessarily reflect the views of Panel members.

President's Cancer Panel

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WELCOME AND INTRODUCTIONS

Dr. John Williams welcomed invited participants and other attendees, introduced the Panel members, described the history and purpose of the Panel, and provided an overview of the current Panel series of

meetings. The Panel is concerned about the long-term consequences of cancer screenings missed and delayed due to massive disruptions of the healthcare system during the COVID-19 pandemic. The pandemic has created new barriers to screening and exacerbated those that already existed. The current Panel series will explore practices and barriers present before the pandemic, implications of the pandemic on screening, and opportunities to improve the equity and resilience of cancer screening in the United States.

To assist with series planning, the Panel created the Working Group on Cancer Screening During the COVID-19 Era. Cancer type-specific planning subgroups for lung, colorectal, cervical, and breast cancers were established. These subgroups—comprising clinicians, researchers, and patient advocates—helped identify barriers, opportunities, and potential solutions in their respective areas. Several cross-cutting themes were identified across cancer types, including disparities, equity, and inclusion; telemedicine; and access and uptake issues.

Dr. Edith Mitchell introduced meeting facilitator Mr. Scott Wheeler and the Co-Chairs of the Cervical Cancer Planning Subgroup, Drs. Rebecca Perkins and Nicolas Wentzensen. Drs. Perkins and Wentzensen introduced subgroup members, as well as members of the cervical cancer stakeholder panel invited to participate in the meeting. Input received at all series meetings will be considered and inform development of recommendations to be presented in the Panel's report to the President of the United States.

CERVICAL CANCER WORKING GROUP PRESENTATION

Drs. Perkins and Wentzensen provided an overview of the opportunities to improve cervical cancer screening that were rated most highly by subcommittee and stakeholder panel members before the meeting. A noncomprehensive list of barriers and solutions related to each opportunity also was presented. Many barriers and solutions are relevant to multiple opportunities.

OPPORTUNITY 1: PRIORITIZE INCLUSION OF HUMAN PAPILLOMAVIRUS (HPV) TESTING IN SCREENING

Barriers

- Lack of access and/or insurance coverage for screening and follow-up of abnormal results
- Provider confusion over management of HPV test results
- Misperceptions about the equivalence of cytology alone and HPV testing for detection of precancer
- Requirement for systems for follow-up of positive HPV tests (e.g., triage, patient tracking) that may disadvantage smaller facilities, potentially exacerbating disparities
- Lab infrastructure changes needed to accommodate primary HPV screening
- Reimbursement often based on tests performed, which may incentivize unnecessary testing

Solutions

- Promote comprehensive insurance coverage for the continuum of screening, management, and treatment.
- Engage insurance, state, and federal partners.
- Engage organizations, like the American College of Obstetricians and Gynecologists (ACOG), American Academy of Family Physicians (AAFP), American Cancer Society (ACS), and others to educate providers about management of HPV-positive patients.
- Promote utilization of risk-based management and enduring guidelines.

- Conduct patient and provider education.
- Harmonize screening guidelines.
- Develop evidence on best practices.
- Engage quality improvement departments to build capacity to implement systems interventions and practice facilitation to follow-up on positive HPV tests.
- Integrate electronic health records (EHRs), lab results, and guidelines.
- Develop patient health record and reminder systems.
- Encourage commercial and academic laboratories to implement primary HPV testing with reflex triage if not already available.
- Develop quality assurance and control metrics.
- Reimburse primary care visits for health maintenance, independent of tests done.
- Use telemedicine to determine need for in-person preventive services.

OPPORTUNITY 2: USING TECHNOLOGY TO IMPROVE SCREENING, MANAGEMENT, AND COMMUNICATION WITH PATIENTS

Barriers

- Lack of EHR and laboratory system integration with screening and management guidelines
- Lack of health information technology (HIT) standardization
- Reliance on technology that may increase health disparities due to Internet and smartphone and/or computer requirements
- Limited patient knowledge of how to use technology (telehealth, online portals, etc.)
- Lack of patient-facing education related to new guidelines
- Limited patient access to guidelines (currently posted on app or website for providers)

Solutions

- Encourage EHR companies and laboratories to provide clinical decision support.
- Create HIT standards for clinical decision support around cervical cancer prevention.
- Create platform-neutral add-on software.
- Provide materials in paper format.
- Encourage adoption of health technology.
- Engage healthcare systems.
- Encourage and incentivize use of patient portals.
- Promote patient access to and use of personal health information.
- Create simple platforms with educational materials.
- Engage patient advocate organizations and media to destigmatize HPV infection and encourage screening.
- Optimize searchability of reliable patient education sources.
- Develop additional options to access guidelines, including open-access models.

OPPORTUNITY 3: RISK-BASED APPROACH TO SCREENING AND MANAGEMENT

Barriers

- Lack of provider and patient familiarity with new screening and management recommendations
- Lack of integration of EHR and laboratory systems with screening and management guidelines
- Inadequate access and insurance coverage for screening and follow-up of abnormal results
- Patients' lack of perception of their own risk
- Provider confusion over how to manage HPV test results
- Lack of patient-facing education related to new guidelines
- Limited access to platforms to access guidelines (currently posted on app or website for providers)
- Reimbursement often based on tests performed, which may incentivize unnecessary testing
- Stigma of HPV infection

Solutions

- Engage organizations (e.g., AAFP, ACOG, ACS, American Society for Colposcopy and Cervical Pathology [ASCCP]) to educate providers and create technical assistance and toolkits.
- Promote utilization of risk-based management and enduring guidelines.
- Work with the Centers for Disease Control and Prevention (CDC) and patient advocacy organizations on patient education.
- Encourage EHR companies and laboratories to include clinical decision support.
- Promote comprehensive insurance coverage for the continuum of screening, management, and treatment.
- Engage insurance, state, and federal partners.
- Engage patient advocacy organizations and media to destigmatize infection and encourage screening.
- Optimize searchability of reliable patient education sources.
- Develop additional options to access guidelines, including open-access models.
- Reimburse primary care visits for health maintenance, independent of tests done.
- Use telemedicine to determine the need for in-person preventive services.

OPPORTUNITY 4: HPV SELF-SAMPLING TO INCREASE ACCESS FOR UNDERSERVED POPULATIONS

Barriers

- Need for infrastructure and process for sample collection (mail vs. in clinic)
- Need for regulatory approval and clinical endorsement for use
- Resistance from clinicians and patients about moving away from pelvic exams
- Lack of access and/or insurance coverage for screening and follow-up of abnormal results
- Requirement for systems for follow-up of positive HPV tests (e.g., triage, patient tracking) that may disadvantage smaller facilities, potentially exacerbating disparities
- Lab infrastructure changes needed to accommodate primary HPV screening
- Provider confusion over management of HPV test results

- Reimbursement often based on tests performed, which may incentivize unnecessary testing
- Patient concerns around stigma of HPV infection and HPV testing as first-line screening

Solutions

- Evaluate self-sampling barriers and solutions.
- Evaluate whether the colon cancer screening model (fecal immunochemical test [FIT] testing) is applicable.
- Conduct large demonstration projects.
- Engage regulatory agencies.
- Engage professional medical associations to communicate with members.
- De-implement routine pelvic exams.
- Expand screening to providers who do not perform pelvic exams.
- Promote comprehensive insurance coverage for the continuum of screening, management, and treatment.
- Engage insurance, state, and federal partners.
- Engage quality improvement departments to build capacity to implement systems interventions and practice facilitation to follow-up on positive HPV tests.
- Integrate EHRs, lab results, and guidelines.
- Develop patient health record and reminder systems.
- Encourage commercial and academic laboratories to implement primary HPV testing with reflex triage if not already available.
- Develop quality assurance and control metrics.
- Engage organizations (e.g., ACOG, AAFP, ACS) to educate providers about management of HPV-positive patients.
- Promote utilization of risk-based management and enduring guidelines.
- Reimburse primary care visits for health maintenance, independent of tests done.
- Use telemedicine to determine the need for in-person preventive services.
- Encourage patient advocacy organizations and media to destigmatize HPV infection and educate about and encourage screening.

OPPORTUNITY 5: REDUCE SARS-COV-2 INFECTION RISK IN CLINICAL SETTINGS

Barriers

- Patient and provider anxiety about going into a clinical setting
- Patients' perceptions of risks of cancer vs. SARS-CoV-2 in clinical settings
- Limited screening access as cervical cancer and SARS-CoV-2 risk are often both high in the same communities
- Shifting availability of in-person screening depending on the local infection burden and financial repercussions of the pandemic to health systems
- Patient and provider confusion about COVID-19 risk and meaning of testing results
- Cost and availability of using rapid testing of SARS-CoV-2 in outpatient clinic settings

- Limited patient knowledge of how to use technology (telehealth, online portals, etc.)
- Shifting priorities for personnel and supplies

Solutions

- Demonstrate safety of personal protective equipment (PPE), distancing, and ventilation protocols.
- Educate patients.
- Implement SARS-CoV-2 testing in diverse populations.
- Strengthen call and recall systems to ensure follow-up.
- Ensure adequate PPE availability.
- Develop evidence-based guidelines for safely performing cancer prevention services.

CERVICAL CANCER SCREENING IMPROVEMENT OPPORTUNITIES

A mind map was used to visually organize and present barriers and potential solutions identified prior to the meeting. Mr. Wheeler facilitated discussion on each of the five opportunity areas. Stakeholders elaborated on previously identified barriers and solutions and offered new suggestions for ways to improve cervical cancer screening. Input was recorded in real time through updates to the mind map. Participants were urged to think about what screening barriers have been exacerbated during the COVID-19 pandemic and how changes created by the pandemic may provide opportunities to enhance cancer screening in the long term. They also were encouraged to think about the feasibility and potential impact of the potential recommendations being discussed, as well as what stakeholders or organizations would be responsible for implementing the recommendations.

PRIORITIZE INCLUSION OF HPV TESTING IN SCREENING

Insurance Coverage for and Access to Screening and Follow-Up

- People who have a cervix but do not identify as women also need to be screened for cervical cancer. Insurance coverage should be based on anatomy, not gender identity. Blue Cross Blue Shield has removed gender identity checks from claims review processes to ensure that coverage is not denied based on an apparent gender mismatch. Other payors may need to reconfigure their systems to avoid inappropriately denying claims.
- Cost estimates of expanding insurance coverage of abnormal screening results follow-up should be generated to inform discussion on this issue. Estimates should address state and local levels of coverage.
- If coverage without cost-sharing were extended to follow-up and diagnosis after an abnormal cervical cancer screening test, it also would need to be extended to cover the same services for other cancer types and chronic conditions (e.g., diabetes). This would be costly for payors, which would likely result in increased premiums. In theory, self-insured employers could create riders that would cover services for specific cancers or diseases, but this type of arrangement would not be feasible for fully insured plans. There also are tax implications of selectively removing cost-sharing for some services but not others; this would need to be explored.
- Consideration must be given to whether and how all cervical cancer screening tests—including HPV tests done via self-sampling—are covered by insurance. It is also important to have tracking systems that encompass all test types.
- The U.S. Preventive Services Task Force (USPSTF) recommends primary HPV testing, so it is covered as a preventive service under the Affordable Care Act (ACA).

- CDC screening programs for cervical cancer should be expanded to address the unmet need. These programs reach a small proportion of the eligible population, although patients in some states may be covered under ACA Medicaid expansions. Inadequate communication may contribute to the incomplete reach of these programs, but it is not the major barrier. Systems are needed to determine what screening-eligible populations are not being screened; this will require coordination among programs and healthcare systems within a state.
- CDC screening programs primarily cover people at or below the poverty level; this does not address the needs of those who may be underinsured. Insurance copayments may be prohibitively high, even for people with ACA healthcare plans.
- Partnerships with professional societies such as ASCCP, ACOG, and the Society of Gynecologic Oncology (SGO) could help improve the efficiency and effectiveness of CDC screening programs. Partnerships with organizations representing vulnerable population groups (e.g., racial/ethnic minority groups, LGBTQ, homeless, migratory and seasonal agricultural workers) could help with community engagement.
- Systems are needed to ensure patients with abnormal screening tests and/or cancer diagnoses are connected to the appropriate treatment and specialty care providers.
- New approaches will be needed to address insurance coverage if the ACA is overturned.
- Medical groups could organize programs like the College of American Pathologists (CAP) Foundation See, Test & Treat program, which provides same-day screening and follow-up services for breast and cervical cancer. This type of program is helpful for women who must travel long distances to obtain care.
- A case-control study of women with and without cervical cancer found a large proportion of women—particularly Hispanic women—who had had tubal ligations were not screened for cervical cancer because they stopped receiving reproductive services.
- Primary care providers play a critical role in cervical cancer screening in many rural areas. In these settings, screening often is done via Pap smear.

Screening Guidelines

- Efforts must be made to effectively communicate with providers about guidelines for screening and management of screening results.
- It is challenging for providers to keep up with frequent guideline changes.
- It would be helpful if patients and providers could access all guidelines in a single location.
- Screening programs would benefit from harmonization of screening guidelines. ACS, USPSTF, and ACOG should work together to create unified guidelines. Lack of alignment is confusing for providers and can foster mistrust among patients.
- Different organizations update guidelines on different schedules, so different guidelines may not be based on the same body of data. Organizations also have different cultures and priorities, which can result in differences in guidelines even when the same data are reviewed. For example, different organizations may weight relative benefits and harms differently. Organizations should release clear statements about why their guidelines are different.
- ACOG, ACS, and USPSTF attempted to harmonize their breast cancer screening guidelines but were unsuccessful. It may be easier to achieve consensus for cervical cancer screening guidelines because the differences are relatively minor.
- Guideline organizations should do a better job communicating common messages to the media rather than focusing on differences.

- The benefits of screening would be realized if providers adhered to any one of the three main cervical cancer screening guidelines.
- Guidelines might become more closely aligned if guideline developers were open to updating guidelines when important new data become available rather than adhering to a strict schedule (e.g., 5 years).

Management of HPV Test Results

- Providers need guidance on how to manage HPV test results. It would be helpful if management guidelines were integrated into EHR systems so they would appear automatically when providers need them. However, it has been difficult to work with EHR developers to do this. Addressing barriers—possibly with a national mandate—would be helpful.
- Ideally, algorithms would automatically generate personalized recommendations for each patient. This already is being done, to some extent, with bone density test results. One participant suggested that artificial intelligence (AI) may be useful to accomplish this, but another noted that the appropriate guidelines can be determined without AI.
- Embedding guidelines within EHRs would allow tracking and targeted education of providers not complying with the guidelines.
- ASCCP has a management guidelines app, but there is a cost to use it. It would be helpful to make this resource available for free. The guidelines are available for free on the ASCCP website, but providers, particularly trainees, are more likely to use an app.
- A potential alternative to embedding guidelines within EHRs would be to include links to external resources, such as ASCCP. However, requiring providers to enter information into an external resource is inefficient and prone to error.
- CDC is creating interoperable modules that will provide cervical cancer screening and management guidelines. It is hoped that the effort will result in creation of quality measures for disease management; current metrics address only screening.

Shift to HPV Testing

- The views of clinical organizations (e.g., ACOG) and public health organizations may differ with respect to cervical cancer screening tests. HPV testing—and self-sampling in particular—can be viewed as disruptive to current clinical practice built around annual exams. This may affect how clinicians view the shift to HPV testing.
- Guideline makers should promote the best possible medicine for cervical cancer screening. The evidence indicates primary HPV testing is the best approach, with follow-up as needed via cytology or dual staining. However, many clinicians do not feel comfortable doing only an HPV test for the initial screen. Clinicians tend to follow the guidelines of provider organizations. ACOG has not endorsed primary HPV testing and promotes co-testing, so many providers believe co-testing is superior to primary HPV testing.
- ACS guidelines state that primary HPV testing is preferred for cervical cancer screening but acknowledge that it will take time for providers and infrastructure to transition to this approach. Incentives are needed to speed this transition.
- It is important to communicate the safety and effectiveness of primary HPV testing to providers.
- Some providers may be unsure what to do if a patient's screening history is unknown. Based on the evidence available, patients who have a negative or unknown history of abnormal screening results should be screened using primary HPV testing. If the initial HPV test is positive, it should be followed by partial HPV typing and cytology or dual stain.

- Many women perceive the shift from Pap smears to HPV testing as diminishing the quality of women's healthcare. The recommended later start age and longer screening intervals contribute to this. Some women think the shift is a cost-saving measure. There should be messaging to clarify that HPV testing represents an improvement in screening and that annual pelvic exams and provider appointments can continue. A reduction in screening does not mean a reduction in reproductive healthcare. It also may help to point out that there have been increases in services in some areas (e.g., lower starting age for colorectal cancer screening).
- There is concern that some patients—particularly those who are screened by providers other than gynecologists—will forgo annual provider visits if they do not have a Pap smear every year. This may result in lower rates of recommended screening for and/or poor management of other diseases, including other cancers.
- Efforts should be made to increase health literacy to help patients understand recommendations.

Self-Sampling

- In the COVID-19 era, self-sampling provides opportunity to be screened for cervical cancer without attending an in-person appointment. It also provides flexibility and autonomy to the person being screened. It will increase access among people who currently are not being screened, which has potential to reduce cervical cancer rates.
- Global data suggest that self-sampling is safe and effective. The U.S. Food and Drug Administration (FDA) is considering the evidence in support of self-sampling.
- Data indicate that samples collected by patients are just as reliable for HPV testing as those collected by clinicians.
- Primary care providers could provide patients with self-sampling kits for HPV testing and manage the results.

Systems

- Patients should have digital access to all their cancer screening records. Ideally, EHRs and data systems would be interoperable, which would allow sharing and compiling of patient data; however, widespread interoperability has not yet been achieved. In the meantime, it may be helpful for patients to be able to compile and store their records themselves.
- Efforts should be made to ensure patients can effectively engage with patient portals. There may be health literacy considerations.
- There must be a clinician charged with interpretation of HPV test results, including tests done using samples collected by patients outside the clinical setting.
- Patients are more likely to be lost to follow-up or managed incorrectly in the absence of strong reminder-recall systems. This is true for all types of cancer screening. Automated reminders would ease provider burden.

Lab Infrastructure

- There are concerns about barriers to laboratory adoption of HPV testing platforms; however, laboratories generally purchase platforms to support tests providers want to order. Infrastructure will adapt to meet provider demand. This supports the need to promote provider acceptance and use of primary HPV testing. Improved provider education—including of community providers—may be needed.
- Laboratories need time to transition to primary HPV testing. The most recent ACS guidelines for cervical cancer screening recommend that providers and systems begin this transition.

- In some cases, laboratories may bundle HPV and cytology testing, which promotes co-testing. Some HPV testing platforms are intended only for use in the context of co-testing; they are not FDA-approved for primary testing.

Disincentives for Overscreening

- Annual Pap smears continue to be covered by insurance despite not being recommended, which incentivizes overscreening. Providers are reimbursed at a lower rate for explaining to a patient why she does not need to be screened, even if that conversation takes more time. Reimbursement should be structured to incentivize appropriate screening, and providers should be compensated for the time they spend reviewing patient records and conferring with patients about screening even if a screening test is not administered.

HPV SELF-SAMPLING TO INCREASE ACCESS FOR UNDERSERVED POPULATIONS

Challenges and Potential Benefits

- HPV self-sampling requires infrastructure and a process for sample collection. All of the potential solutions proposed before the meeting—evaluating barriers and solutions, evaluating the applicability of the colorectal cancer screening model, and creating large demonstration projects—will be important for addressing this barrier.
- The primary goal of self-sampling is to extend access to screening for patients who otherwise would not be screened. This may include people who are uncomfortable receiving a speculum exam, such as those who have experienced trauma or those who have disabilities. Self-sampling is particularly relevant during a pandemic when it is preferable to minimize patient-provider contact.
- Numbers of cervical cancer cases and deaths have changed little since 2007. The goal of the National Cancer Institute (NCI) Last Mile Initiative is to find ways to further reduce the burden of cervical cancer. One factor is that there are some people who are not being screened. Self-sampling may help make screening accessible to people less likely to be screened in the traditional medical setting.
- A study from the 1990s found that emergency room screening identified disease but patients were unlikely to receive follow-up care. The same factors that reduce the likelihood that people will be screened tend to also keep them from pursuing follow-up care. This lesson may be relevant for self-sampling.

Learning from Colorectal Cancer

- Efforts to transition from colonoscopy to FIT largely have been unsuccessful. Adoption of FIT has been relatively low. Promotion of HPV self-sampling may be more successful if it builds on relationships between patients and gynecologic providers, particularly if the relationship with gynecologic services is maintained.

Demonstration Projects

- NCI and ACS co-sponsored the Breast Cancer Detection Demonstration Project. It may be helpful to develop a similar demonstration project for cervical cancer. It would be good to involve organizations in addition to NCI and ACS.
- The Last Mile Initiative has funding and a plan to evaluate self-sampling with the goal of determining whether European data are applicable to the United States. Both NCI and FDA are involved. In order to move forward, companies with approved primary HPV tests must be willing to participate. This requires interaction with and approval by FDA.
- Demonstration tests are needed to evaluate implementation and uptake in different populations.

Provider Role in Self-Sampling

- Professional societies should be engaged to build support for the idea and process of self-sampling.
- In the United States, self-sampling for HPV testing would require a provider prescription; there will not be direct-to-consumer promotion.
- Self-sampling kits for HPV testing could be distributed via mail or made available at a provider's office. One benefit would be to allow providers who do not conduct pelvic exams (e.g., internal medicine, family practice) to oversee cervical cancer screening. Expanding the types of providers who provide cervical cancer screening is particularly important for sexual and gender minorities (e.g., transgender men) or women outside of reproductive ages who may not see a gynecologist.
- Facilitating cervical cancer screening in the primary care setting would allow cervical cancer to be addressed at the same time as other cancer screening tests.
- Self-sampling could support a "flipped classroom" model for well-woman appointments. Patients could complete their testing before the visit, allowing more time during the visit for discussion.
- Self-sampling could allow well-women visits to be conducted via telemedicine.

Outreach, Education, and Navigation

- Changes in cervical cancer screening guidelines over the past 5 to 7 years have confused many patients. Many patients do not understand the difference between a Pap smear and an HPV test. Many also do not know that HPV causes cervical cancer.
- Educational materials at different literacy levels must be created. There should be printed educational materials in addition to digital resources. Some patients prefer printed materials or do not have consistent Internet access.
- Many people access health information on line. Public health campaigns should have a strong and inclusive presence on platforms that people use to access information (e.g., Instagram, Facebook). It is not sufficient to post information on organizational or agency websites. A campaign in Washington, DC found that advertising on the Metro and at movie theaters was an effective way to reach underserved communities. Churches and faith communities also can be important partners. The Balm of Gilead has worked with many black churches in the South on cervical cancer prevention.
- It is important to engage key influencers, particularly in communities that experience disparities.
- Providers also are a trusted source of information, so it is important that they understand the science around HPV and HPV testing.
- The Roundtable model used for lung cancer, colorectal cancer, and HPV vaccination could be helpful for developing and delivering central messaging related to cervical cancer. Messages developed through a Roundtable could be disseminated through advocacy organizations. Roundtables also provide economy of scale. Many key stakeholders for cervical cancer screening already participate on the National HPV Vaccination Roundtable.
- Messaging on cervical cancer screening and HPV testing could be shared with the community through NCI-designated cancer center community engagement programs. This type of outreach could be funded by NCI.
- Messaging should be coordinated across state and federal government agencies.
- Some people may find the ability to self-sample for HPV testing to be liberating. However, focus groups with different patient populations, including minority populations, suggest that many patients are resistant to the idea. Many women are worried about losing their annual pelvic exams and their relationship with their providers. These concerns also are being expressed on social media platforms. Many women equate the pelvic exam with a Pap smear and do not understand that pelvic exams

address other things (e.g., ovarian health, sexually transmitted diseases [STD]). Communications about self-sampling must make it clear to patients that they can still have annual wellness visits and pelvic exams. ACA requires coverage of wellness visits separately from a pelvic exam.

- Navigators, community health workers, and other lay healthcare professionals can help educate and assist patients with respect to self-sampling. They also can ensure patients receive appropriate follow-up in a timely manner by helping address logistical barriers. Coordination is particularly important when patients transition between programs or systems; for example, once a patient receives a diagnosis through the Breast and Cervical Cancer Early Detection Program, she is transferred to the Centers for Medicare & Medicaid Services (CMS) for coverage of treatment. Navigation also is particularly useful in low-income and/or low-literacy populations. Many community health centers have promotoras or community health workers who could play this role.
- Thought should be given to how cancer screening and prevention can be integrated into community health needs assessments done by health systems, health departments, and NCI-designated cancer centers.
- The ability to test for both HPV and other STDs in the self-collected sample may appeal to patients. This should be technologically feasible. However, STD testing via self-collected cervical specimen may not offer much advantage over urine-based STD testing, which already is available.

Regulatory Considerations

- In order to allow self-sampling, companies with primary HPV tests must initiate discussions with FDA to expand their tests' approval to include self-collected specimens. The companies also must prepare Pre-Submissions that describe allowable specimens, where the specimens will be collected, and other technical assurance information. NCI is trying to facilitate these interactions because this is an important public health issue.
- FDA is supportive of exploring self-sampling for HPV testing. FDA has established a framework during the COVID-19 pandemic for home collection of respiratory samples, and this could be adapted for other analytes, including cervical self-sampling. Companies need to approach FDA to move this forward; FDA cannot spearhead the effort.
- Patient advocates could provide testimony to FDA about the importance of self-sampling. This was recently done for contraceptive technologies. Consumers also may be able to encourage companies to pursue approval for self-collected specimens.

Cost, Insurance, and Reimbursement

- The cost of HPV testing varies; it is usually between $15 and $60.
- Reimbursement models that incentivize appropriate care during and after self-sample HPV testing are needed. Communication with patients about results and follow-up care is critical.
- Follow-up and diagnostic tests often are associated with copays and deductibles, and these costs often are a barrier for patients. If these services are covered by insurance without cost-sharing, premiums likely will increase. It would be helpful to determine the impact on premiums. A previous ACS assessment found that the impact was relatively small for cancer. Insurance companies would need to consider all cancers and other diseases for which screening tests are available. It would not be possible to change coverage for cancer screening follow-up without changing the cost-sharing structure for other diseases.
- One option may be for foundations or other philanthropic organizations to assist with the costs of follow-up services through grants or another mechanism (e.g., Patient-Centered Outcomes Research Institute Foundation, Prevent Cancer Foundation, Blue Cross Blue Shield foundations); however, coordinating care through foundations may be impractical and overly complicated.

- There are Internal Revenue Service (IRS) regulations about the types of support patients can receive (e.g., based on insurance coverage).
- USPSTF may need to weigh in on self-sampling for HPV testing to ensure coverage without copay under ACA.

USING TECHNOLOGY TO IMPROVE SCREENING, MANAGEMENT, AND COMMUNICATION WITH PATIENTS

EHR Tools to Support Screening

- EHR prompts have been shown to be effective, although it is important that they are well designed. Prompts and tools should be based on guidelines and incorporate all relevant patient information. The goal should be to improve patient care and support provider workflows. EHR vendors should be urged strongly to develop and make these tools available. The EHR vendor business model centers on customization, so external pressure may be needed to encourage them to develop common tools.
- There are EHR modules for screening, but these often are developed and/or purchased at the institutional level. It would be better if effective tools were more widely available. Many health centers continue to track follow-up using Excel spreadsheets and calendar reminders, which is inefficient.
- EHRs often are not integrated with laboratory information management systems. Many laboratories are working to modernize their systems and adopt Fast Healthcare Interoperability Resources (FHIR) standards.
- The need for interoperability and integrated systems could be discussed at the Panel's Innovation Meeting, which will take place in early 2021.
- The Health Center Controlled Networks (HCCN) use EHRs to assess social determinants of health. The community health centers pool resources, including EHR templates, through HCCN.
- CDC is working to create a cervical cancer screening and management tool based on public algorithms that incorporates information on past HPV and Pap test results. One objective of the project is to promote development of quality measures for disease management, not just screening. An environmental scan of IT and clinical stakeholders will be done, and the tool will be pilot tested.
- Reminding patients when they are due for appointments is helpful.

Risk of Exacerbating Disparities

- Technology may be able to help address disparities (e.g., telemedicine to support patients in rural or remote settings). On the other hand, reliance on technology may exacerbate health disparities. The digital divide has been referred to as a social determinant of health. Barriers can include low computer literacy and limited access to technology (e.g., broadband, data).
- People adopt technology at different rates. Those who are low utilizers of technology may be more difficult to reach through patient portals or other online tools.
- One federally qualified health center (FQHC) sent patient navigators to people's homes to allow them to access the Internet for telehealth appointments during the COVID-19 pandemic. Some patients also may benefit from technology training or support.
- FQHCs report on performance measures using the Uniform Data System (UDS). They also report what EHR vendors they use. Most FQHCs use one of the large EHR vendors. Like other health systems, individual FQHCs need to purchase EHR templates through their vendors. Centers pool resources through the HCCN in some cases.

- It may be a good idea to use mobile platforms to communicate with patients, including about self-sampling. Most people have a mobile phone or smartphone, even in resource-constrained settings.
- There has been flexibility regarding reimbursement for telehealth services during the COVID-19 pandemic. There also have been efforts to make telehealth services available in multiple languages.

Education and Training

- There is a lack of patient education about new guidelines. Educational materials and tools should be at an appropriate reading level and adequately tested. They also should explain that HPV is associated with non-cervical cancers (e.g., head and neck, anal).
- Patient-targeted educational materials should be available in a variety of formats (e.g., web, printed, apps, newspapers, radio) and tailored to different populations (e.g., low-literacy individuals, racial/ethnic groups, gender minorities). Traditional media outlets like radio and television may help reach older populations, particularly in communities of color.
- Messages should be framed in ways that speak to and align with patient values (e.g., preserving fertility).
- Updates to both patient- and provider-targeted educational materials are needed when there are guideline updates.
- There may be opportunities to enhance knowledge of cancer screening through medical education programs for physicians and other advanced practice providers. The Accreditation Council for Graduate Medical Education sets standards for medical education. Specialties design curricula for their residency programs. For example, ACOG designs curriculum through the Council of Resident Education in Obstetrics and Gynecology (CREOG).

RISK-BASED APPROACH TO SCREENING AND MANAGEMENT

- There is a general lack of understanding of disease risk, and most people do not have a good idea of their personal risk. Risk is often understood to be dichotomous, while it is actually a continuum from very low to very high. Providers can help patients understand their risks for various diseases.
- Many people do not perceive themselves to be at risk for cervical cancer. The best way to address this issue may be to ensure that people have a relationship with a healthcare provider. Providers can discuss risks for cervical cancer and other diseases with their patients. It would be challenging to raise awareness of one disease or set of guidelines outside of the medical context.
- Many people do not seek care unless they have symptoms. Preventive care should be promoted.
- Many community health centers provide enabling services (e.g., transportation, translation, patient navigation, extended clinic hours) to improve access. Boards of community health centers are required to comprise at least 51 percent community members to ensure that the values of the community are represented.
- Some patients face political determinants of health or policy-related access barriers. For example, there are not policies that prevent immigrant populations or some others from being discriminated against in healthcare settings. Some people also have faced violence in medical settings. The Panel could consider issuing a broad recommendation that nondiscrimination policies for all populations be implemented in healthcare.
- Some low-income populations do not have access to patient-centered medical homes or specialists, so it is important that all providers have access to the best risk-based recommendations. Clinical decision support based on a patient's results and history should be integrated into laboratory information systems.

- Risk-based screening guidelines should help reduce overscreening as well as underscreening. Many people overestimate their risk for cervical cancer, which may lead to overscreening. This is relevant during the COVID-19 pandemic when it is important to balance multiple risks when making decisions about screening.

REDUCE SARS-COV-2 INFECTION RISK IN CLINICAL SETTINGS

- Cervical cancer screening rates fell dramatically near the start of the COVID-19 pandemic in the United States. Kaiser Southern California screening rates are now at about 80 percent, up from about 1 percent at the lowest point. Rates of screening recovery likely are variable across healthcare systems. Similar patterns have been observed for other cancer screening tests.
- The decision to resume cervical cancer screening should take into account both cervical cancer and COVID-19 risk. In areas with high rates of COVID-19, people with very low risk of cervical cancer based on past screening results and personal history may be advised to wait to resume screening. People who have been screened every 3 years and have multiple consecutive negative tests can extend their screening interval to 5 years with virtually no added risk. It would be in these patients' best interest to advise them to wait to return to screening. This could be done in healthcare systems with robust records; however, it was acknowledged that many healthcare systems, particularly those serving at-risk populations, do not have the ability to identify people who may be able to safely delay screening.
- Healthcare systems have experienced significant financial strain due to COVID-19. It may not be in their best interest to dissuade people from being screened as soon as possible; however, physicians should recommend what is in the best interest of their patients.
- Many of the communities experiencing the highest rates of COVID-19 also experience systemic racism.
- Many healthcare systems still do not have adequate PPE.
- Challenges related to cervical cancer screening and COVID-19 must be addressed as soon as possible; ideally, before the Panel recommendations are released.
- The disruption caused by COVID-19 provides opportunity to reset and recommit to eliminating cervical cancer, which is the goal of the NCI Accelerating Cervical Cancer Control initiative. Efforts should be made to ensure that screening is done appropriately and effectively so that no one is over- or underscreened.

PUBLIC COMMENT AND QUESTIONS

Members of the public submitted written comments and questions, which were read and discussed by the Panel, Working Group members, and stakeholder group near the end of each workshop day.

- Patient navigators can help patients complete cervical cancer screening, including the initial test and appropriate follow-up for abnormal results. In one clinic, low-income minority patients who were provided with navigation services had higher compliance rates than did privately insured non-Hispanic white patients who were not provided navigation services. The cost savings from moving from co-testing to primary HPV testing could be used to support navigation services.
- A member of the public asked how HPV-negative cancers and precancers would be detected in a primary HPV testing paradigm. HPV-negative precancers are very rare. The preponderance of data has shown that adding cytology to HPV testing does not improve detection of cancers and precancers.
- A member of the public noted that social media include claims that moving away from Pap smears will harm women. This highlights the importance of accurate and effective messaging. The data on safety of HPV-based screening are very strong.

- A member of the public asked whether HPV test results could be standardized to allow easy interpretation within EHRs. It should be possible to create standardized reporting.
- A member of the public asked how the adequacy and predictive value of negative self-collected HPV tests can be ensured. HPV tests are similarly effective whether they are done with self-collected or provider-collected samples. It is important to note that self-collected samples cannot be used for cytology; samples for cytology must be collected from a specific area of the genital tract, which requires visualization, whereas exfoliated cells from anywhere in the vagina can be used for HPV testing.
- Concerns have been raised about the impact of delayed screening initiation and longer screening intervals on people of color, who are more likely to be diagnosed with and die from cervical cancer. If followed, the current screening guidelines should protect everyone with a cervix. Data from the CDC National Breast and Cervical Cancer Early Detection Program showed that the factors associated with cervical cancer diagnosis were time since last screening test and the result of that test; factors such as race, ethnicity, language, and insurance status were not associated with cervical cancer. These results illustrate the importance of addressing barriers to regular screening; insurance coverage is not sufficient to ensure access. Community health workers and promotoras can help address the needs of underserved populations. It is important that studies include historically marginalized populations so that guidelines based on research benefit everyone.
- A member of the public suggested pushing out routine health messages through COVID-19-related health apps. Stakeholder panel members agreed there are opportunities to use apps for "digital nudging" and as a way to send reminders and information. The COVID-19-related apps could provide a template for similar apps on cervical cancer risk and screening. Cervical cancer risk calculators require information on patient history, so patients would need access to their records to use these types of tools.
- A member of the public asked whether insurance companies could provide members with credits for completing screenings and recommended follow-up care. There is precedent for insurance companies rewarding members for certain health behaviors; however, there are IRS rules that dictate what companies can and cannot do, particularly if a member has a healthcare savings account. One factor is whether the reward is considered to be part of a plan benefit or part of a wellness platform. The comparison was drawn to auto insurance "good driver" discounts; however, it was pointed out that health and auto insurance are fundamentally different because the former covers both catastrophic and preventive care while the latter is only for catastrophic scenarios.
- A member of the public asked how women could be provided with evidence-based information on the value of the annual pelvic exam. One challenge is that "pelvic exam" can be and has been defined multiple ways, even by ACOG. It is important to be clear what is meant by pelvic exam. The main issue is that patients do not want to lose the ability to connect with their providers. It is important that well visits continue to be a covered service. The components of the well visits should be determined by the evidence.
- A member of the public asked whether use of ablation therapy should be expanded for hard-to-reach populations based on evidence that it is equivalent to excision in some settings. Ablative treatment may have a role to play in health-resource-limited settings where it is difficult to deliver care. However, current guidelines recommend excision over ablation in the United States, even for women living in relatively remote areas. Ablative treatment is more relevant in some African countries in which people travel significant distances to be screened and receive care.

CLOSING REMARKS

Panel members and Cervical Cancer Planning Subgroup Co-Chairs and members thanked the stakeholder panel for their productive input and discussion. Panel members thanked Mr. Wheeler and NCI staff for their roles in planning and implementing the meeting. The Panel and Working Group will consider the information provided during this workshop and others in the series as they develop recommendations to be included in the Panel's report to the President. Additional written testimony and comments can be submitted at any time to the President's Cancer Panel via email (PresCancerPanel@mail.nih.gov) or the Panel website (https://prescancerpanel.cancer.gov).

CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President's Cancer Panel meeting, *Improving Resilience and Equity in Cervical Cancer Screening: Lessons from COVID-19 and Beyond*, held on November 9 and 10, 2020, is accurate and complete.

Certified by: _____ Date: February 8, 2021

John P. Williams, MD, FACS
Chair
President's Cancer Panel