Guideline Adoption in Safety-net Care: Understanding the Prevention, Screening, and Management of Cervical Cancer in Safety-Net and Health Resources and Services Administration-Supported Settings of Care

Multilevel Approaches to Achieving Equity in Cervical Cancer Prevention, Screening, and Treatment in Federally-Supported Safety-Net Settings of Care

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Federal Cervical Cancer Collaborative



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Multi-agency Federal Cervical Cancer Collaborative

"Cervical cancer is preventable through vaccination and screening. Making vaccination and screening widely accessible is important to reduce cervical cancer disparities. We in the NCI Division of Cancer Epidemiology and Genetics are delighted to be a part of this important and unique Federal partnership across the Department of Health and Human Services that allows for a rapid translation of decades of etiologic studies on HPV and cervical cancer into clinical practice."

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Executive Summary

"We have the tools to eradicate cervical cancer through prevention and screening and we can implement them in our communities at highest risk of this disease. ORWH strongly supports this interagency collaborative effort to bring the Cancer MoonshotSM initiative to HRSA safety-net settings of care and strengthen approaches to cervical cancer prevention, screening, and treatment for all women."

Janine Clayton, MD, FARVO, Associate Director for Research on Women's Health and Director,
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The 2022 estimates for new cases and deaths for cervical cancer in the United States are 14,100 and 4,280, respectively. The percentage of women screened for cervical cancer in the US in 2018 (81 percent) remained below the Healthy People 2020 target (93 percent).¹ Persistent human papillomavirus (HPV) infections of the cervix are a necessary cause of cervical cancer, though most individuals with HPV infections do not develop cervical cancer.² Cervical precancer, when detected via screening, can be successfully treated, which prevents cancer in most cases. Invasive cancer is rare in the US with more than 90 percent of potential cases prevented by screening.³ The 2010 Affordable Care Act eliminated cost as a barrier to cervical cancer screening. However, 19 percent of women in the US are not up to date with established screening guidelines, and disparities persist among medically underserved populations.⁴ Reasons for underscreening are multifactorial, including (1) belief that

screening is unnecessary, (2) lack of insurance or medical access, (3) socioeconomic, and (4) cultural barriers.⁷⁻¹²

As a direct outgrowth of the Cancer MoonshotSM, a multi-agency federal partnership represented by multidisciplinary expertise, formed the Federal Cervical Cancer Collaborative to support the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) in their effort to reduce the disparities in cervical cancer and improve equitable cervical cancer screening among the geographically isolated and economically, and medically vulnerable populations. The Federal Cervical Cancer Collaborative aims to implement the outcomes and realize the vision of the Cancer MoonshotSM in safety-net settings of care. This partnership is comprised of the HRSA Office of Women's Health, NIH National Cancer Institute (NCI), NIH Office for Research on Women's Health (ORWH), HHS Office of Population Affairs in the Office of the Assistant Secretary for Health, HRSA Office of Intergovernmental and External Affairs, and CDC Division of Cancer Prevention and Control.

A landscape analysis was conducted to identify facilitators and barriers to effective cervical cancer screening in low-resource settings for underserved patient populations. Findings of the landscape analysis will inform the development of technical assistance materials for HRSA-supported settings of care and other safety-net settings of care. The federal partnership's aim is to offer provider-facing technical assistance material that addresses prevention, screening, and management of abnormal screening tests in alignment with the 2019 American Society for Colposcopy and Cervical Pathology (ASCCP) Risk-Based Management Consensus Guidelines has the potential to accelerate the reach and care for at-risk populations and save lives. ¹³ Additionally, the impact of interrupted routine cancer care and decreased screening due to the COVID-19 pandemic accelerates the partnership's interest in improving health outcomes for populations served by federally supported healthcare clinics.

Three overarching questions guided the landscape analysis:

- 1. What is the current range of approaches used to manage abnormal cervical cancer screening tests and other evidence of cancer precursors in safety-net settings of care, including HRSA-supported settings of care?
- 2. What is the readiness of safety-net settings of care, including HRSA-supported settings of care, to implement ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening tests and cancer precursors?
- 3. What are the patient, provider, and system-level barriers and facilitators for safety-net settings of care, including HRSA-supported settings of care, to accept and adopt new clinical guidelines?

Adoption in Safety-Net Care: Understanding the Prevention, Screening, and Management of Cervical Cancer in HRSA-Supported Settings of Care

"HRSA is committed to improving health outcomes and achieving health equity through access to quality services, a skilled health workforce an innovative high-value programs. Central to this commitment is ensuring safety-net settings of care can deliver cancer screening, prevention, and treatment in culturally and linguistically appropriate ways."

Nancy Mautone-Smith, MSW, LCSW, Director, Office of Women's Health,
 Health Resources and Services Administration

Purpose

HRSA, with the support of other federal agencies represented on the Federal Cervical Cancer Collaborative, is committed to strengthening its approach to providing the highest quality cervical cancer screening and management in relevant HRSA-supported settings of care. An expert roundtable series and technical assistance materials, such as a provider toolkit, will be developed and provided to encourage and support HRSA-supported clinics with 2019 ASCCP Risk-Based Management Consensus Guidelines adherence. The first step toward improving clinic capacity to adopt the cervical cancer consensus guidelines is to understand the latest outcomes of demonstration programs and research on the current state of prevention, screening, and treatment of abnormal cervical cancer screening tests and cancer precursors in populations experiencing substantial disparities served by its clinics.

This report summarizes a landscape analysis of previous efforts funded by HHS agencies to enhance access to cervical cancer screening services in underserved and rural areas through research, demonstration programs, and public health initiatives. Findings of the landscape analysis will provide practical information to directly inform: (1) gaps in research, policy, and practice; (2) the framework of the Cervical Cancer Roundtable Meetings; and (3) technical assistance materials to support the implementation of evidence-based approaches to enhance the effectiveness of cervical cancer screening and response in HRSA-supported settings of care. This approach has potential utility for other safety-net settings of care and other programs screening for preventable cancers, including cervical cancer and other cancers.

Background

The National Institutes of Health National Cancer Institute leads the <u>Cancer Moonshot</u>SM, which aims to accelerate cancer research and make more therapies available to more patients, while also improving NCI's ability to prevent cancer and detect it at an early stage. As an offshoot of the Cancer Moonshot, the Federal Cervical Cancer Collaborative aims to implement and realize the vision of the Cancer Moonshot in safety-net settings of care. The Federal Cervical Cancer Collaborative is led by HRSA Office of Women's Health with NIH NCI, NIH ORWH, HHS Office of Population Affairs in the Office of the Assistant Secretary for Health, HRSA Office of Intergovernmental and External Affairs, and Centers for Disease Control and Prevention Division of Cancer Prevention and Control. The Federal Cervical Cancer Collaborative was formed to address the overarching problem of delays in the implementation of

evidence-based screening and management guidelines for cervical cancer in low-resource settings serving underserved patient populations.

Examples of safety-net settings of care and HRSA-supported settings of care and programs include the <u>Health Center Program</u>, <u>Rural Hospital Programs</u>, Rural Health Clinics Programs and the <u>Ryan-White</u> <u>HIV/AIDS Program</u>. In terms of reach, the Health Center Program is comprised of nearly 1,400 healthcare clinics operating approximately 13,000 service delivery sites in all US states and territories.

HRSA's programs serve communities representing populations that are medically underserved, geographically isolated, economically disadvantaged, and who experience inequities in healthcare across the entire cancer care continuum. Other factors attributable to the inequitable cervical cancer care are associated with social determinants of health, cultural differences, language barriers, access to primary care services, provider shortage¹⁴⁻¹⁹, and ongoing changes in cervical cancer prevention and control practices (see Figure 1) and guidelines.

The Federal Cervical Cancer Collaborative intends to develop multilevel approaches to achieve equity in cervical cancer prevention, screening, and treatment for the vulnerable populations in federal safety-net settings of care.

Methods

The Federal Cervical Cancer Collaborative conferred on a set of questions (Table 1) and methods to guide the landscape analysis to identify evidence-based or promising interventions in cervical cancer screening in medically underserved populations and to identify gaps in screening services and research. From September 2020 to February 2021, a landscape analysis was conducted and included a thorough review of HHS funding in cervical cancer research, with a particular focus on screening interventions in low resource settings and at-risk populations, to inform the goals and priorities of creating technical assistance resources for providers of HRSA's cervical cancer screening program. Evaluation activities of the landscape analysis included reviews of the literature and currently federally funded grants related to cervical cancer and other types of cancers with screening guidelines and summary reviews of demonstration programs. Consultations with select HHS and NCI staff and grantees that conduct cancer screening research filled gaps in knowledge of current approaches to enhance the effectiveness of screening medically underserved populations not only for cervical cancer but also for other cancers that have screening guidelines. Data sources from the NCI included its grant portfolio and the Evidence-Based Cancer Control Programs. Other data sources included The Community Preventive Services Task Force (CPSTF) Community Guide, the Patient-Centered Outcomes Research Institute reports on Cervical Cancer Screening Behavioral Intervention Studies in Low Resource Settings, CPSTF, and the CDC NBCCEDP) screening program summaries. Consultations with NCI staff and grantees that conduct screening research filled gaps in knowledge of current approaches to the 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and cancer precursors.

Summary of Key Findings

What is the current landscape approach used to manage abnormal cervical cancer (and other cancers) screening tests and cancer precursors in safety-net settings of care, including HRSA-supported settings of care?

Management of Abnormal Cervical Cancer (and Other Cancers) Screening Tests

"Growing guideline complexity may exacerbate existing disparities in cervical cancer outcomes because health systems, clinics, and providers have limited resources to address the needs of vulnerable population subgroups (minorities, uninsured, and women living in poor neighborhoods) who are less likely to be adequately screened or followed up."

-Jasmin Tiro, PhD, Professor, University of Texas Southwestern Medical Center

Strategies to Promote Cervical Cancer Screening in Rural Settings

There is a strong relationship between geographic location and strategies used to support access to cervical cancer screening. Interventions include community health workers, patient navigation strategies (including educational materials, sessions, and peer counseling), small media initiatives, letters or calls, assessment and addressing of barriers to screening, language translation, appointment scheduling and reminders, mailed supplies and kits, transportation and appointment attendance as needed, point-of-care prompts, tailoring according to at-risk population needs, and other strategies.²⁴ Interventions focused on promoting uptake of initial or one-time screening rather than continuous guideline-concordant screening and management.

¹ Inadequate follow-up after an abnormal screening or diagnostic test is defined as receiving one or more Pap or co-test with an abnormal result (ASC-US/HPV+ or worse) and (1) did not have a colposcopy within 1 year after the first abnormal screening test in the study window, or (2) did not have a treatment procedure within 6 months after a colposcopy result of CIN 2/3 or greater, or (3) did not have a colposcopy within 1 to 1.5 years after a treatment during the study window (if time permitted).²⁰

A 2010-2012 systematic screening and assessment (SSA) conducted by the CDC of its grantees and partners of the CDC's NBCCEDP identified multiple successful cervical cancer screening strategies, such as health education and promotion, client and provider reminders, case management, patient navigation and provider assessment and feedback. The NBCCEDP provides low-income, uninsured, and underserved women free access to timely breast and cervical cancer screening and diagnostic services. Through the NBCCEDP, CDC supports 70 grantees—all 50 states, the District of Columbia, 6 U.S. territories, and 13 American Indian/Alaska Native tribes or tribal organizations—to help low-income, uninsured, and underinsured women gain access to timely breast and cervical cancer screening, diagnostic, and treatment services through funding screening, diagnostic services, and patient navigation for eligible women. Additionally, the NBCCEDP focuses on factors at the interpersonal, organizational, community, and policy levels that influence screening. However, after further evaluation, only a few of its grantees have adequate resources to implement strong practices in three domains (health education and promotion, quality assurance and quality improvement, and case management/patient navigation) of the SSA.²⁵

In 2020, several departments of HHS launched key activities to strengthen their abilities to better serve rural populations. ²⁶ Key activities to inform program development and value-based care delivery include:

- A Rural Action Plan developed by HRSA's Rural Health Task Force. The plan includes new or expanded activities to provide a roadmap to strengthen coordination across HHS to better serve the millions of Americans who live in rural communities.²⁷
- CMS announced the Community Health Access and Rural Transformation Model, which aims to transform rural healthcare delivery systems and enable local community collaboration by providing upfront seed money to redesign systems of care and align across providers and payers based on their unique needs.²⁸
- HRSA's Health Center Program developed and is implementing new social determinants of health measures for reporting on the number of patients that screen positive for food insecurity, housing insecurity, financial strain, and lack of transportation/access to public transportation. This will provide the first national dataset on social risk factors among health center patients. A toolkit (funded by HRSA) is included here, https://www.naHC.org/researchand-data/prapare/toolkit/.

Impact of HPV DNA Test to Detect Cervical Cancer

Little is known about how the rapid evolution of HPV technologies and changing guidelines affect clinical practices, patient outcomes, and disparities experienced by vulnerable racial/ethnic minorities, low-income, under-, and uninsured populations. Data is needed to understand: (a) at what levels (patient, provider, clinic, neighborhood) variation in screening delivery and management of abnormal results is occurring; (b) how and what multilevel programs and policies influence adherence to guidelines for average-risk individuals, and (c) how we can optimize precision screening for subgroups of individuals with altered risk, including HPV-vaccinated individuals and those who are immunocompromised due to

comorbidities.²⁹⁻³¹ Current guidelines do not consider HPV vaccination status since only the first vaccinated cohorts have entered the screening age. For immunocompromised individuals, guidelines recommend more frequent screening with either screening modality (Pap alone or co-testing) for individuals 30 years or older.³²

HPV self-sampling is accurate for detecting precancerous cervical lesions and is an emerging option for individuals who do not/cannot access clinic-based/speculum-exam-based cervical cancer screenings. These individuals may include low-income and never/under-screeners, those who identify as transgender, Latina, and individuals with a history of sexual assault.³³

Few datasets are available concerning the health service delivery considerations of offering primary HPV screening by self-collection into federally qualified health centers – centers that serve a high proportion of individuals at elevated risk of insufficient screening and subsequently of cervical cancer. The NIH award UH3 CA202663, Demonstration and Implementation of Self-Collection for HPV Testing in a Federally Qualified Health Center System, will identify potential facilitators and barriers of offering HPV self-collection in federally qualified health centers in North Carolina. This study will evaluate health service delivery factors related to conducting electronic medical record review to identify patients overdue for cervical cancer screening and providing HPV self-collection kits to these patients to increase cervical cancer screening.

The NCI's <u>Last Mile Initiative</u> proposes a public-private partnership to improve cervical cancer screening coverage to underserved and never-screened/under-screened individuals by expanding the current FDA-approved indication of use for HPV tests to include prescription-based self-collection of cervicovaginal specimens for HPV testing.³⁴

What is the readiness of safety-net settings of care, including HRSA-supported settings of care, to implement ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening tests and cancer precursors?

"For the first time, the ASCCP guidelines included data from underserved women reflecting the dynamic and inclusive nature of the ASCCP guidelines. We used data from the CDC's National Breast and Cervical Cancer Early Detection Program, a program with focus on underserved women and exceptional racial/ethnic diversity, to assess program data to help validate and refine the recommendations that typically use a large integrated health network. Our findings showed that there was an increased risk for certain abnormal results among women who were not up to date with screening. This risk was updated in ASCCP guidelines to reflect this finding.³⁵"

- Mona Saraiya, MD, MPH, Medical Officer, CDC Division of Cancer Prevention and Control

Strategies for Establishing Effective Partners in Cervical Cancer Screening

Health Centers (HC) with highly integrated care with specialists had higher rates of screening for colorectal and cervical cancers and were more likely to report successful HC/specialist communication

than the least integrated HCs.³⁶ Integration between HCs and specialists may enhance communication across health care providers and improve cancer screening rates and follow-up of abnormal findings. Strategies used by HCs to support the integration of HCs and specialty care providers include:³⁶

Improving Referrals

- Establish agreements with specialists about the types of referrals specialists will accept or information the health center will provide when making a referral.
- Make appointments with specialists on behalf of HC patients.
- Participate in electronic consults (e-consults) with specialists.
- Remind HC patients of upcoming appointments with specialists.

Aligning goals with specialists

• Participate in quality improvement projects or health promotion initiatives with specialists.

Exchanging information

- Send data electronically to specialists.
- Read specialists' electronic health records in real time.

Improving access

- Specialists on-site at the health center provided any care during the past 6 months.
- Few affiliations with local hospitals or health systems among HC physicians impact HC's ability to obtain timely specialty care for patients.
- Participate in telemedicine (excluding e-consults) with specialists.
- Electronic tools and the electronic medical record will help safety-net settings of care to deliver guideline concordant care.

Strategies to Assess Likelihood of Successful Public Health Programs

Programs, including smallpox eradication, tuberculosis control, tobacco control, polio eradication, and others, have made progress in public health programs by addressing these six areas:³⁶

- 1. Innovation to develop the evidence base for action.
- 2. A technical package of a limited number of high-priority, evidence-based interventions that together will have a major impact.
- 3. Effective performance management, especially through rigorous, real-time monitoring, evaluation, and program improvement.
- 4. Partnerships and coalitions with public- and private-sector organizations.
- 5. Communication of accurate and timely information to the health care community, decision makers, and the public to effect behavior change and engage civil society.
- 6. Political commitment to obtain resources and support for effective action.

Understand the Payor Landscape

Eligibility requirements such as household income and employment status vary for free cancer screening programs and may result in an individual being responsible for costs of screening appointment, labs, ra

and follow-up visits/procedures. Additionally, lack of awareness of and availability of no-cost screening programs and lack of understanding of health insurance policies contribute to low screening and diagnostic evaluation rates among low-income and uninsured populations. These factors underscore the need for providers in low-resource settings to understand the limitations of free screening programs and to be knowledgeable of local resources that reduce out-of-pocket costs associated with screening appointments such as childcare and transportation.

"It is important for safety-net settings of care to understand the payor landscape for low-income populations. The discovery of an abnormal cervical cancer screening test may require a referral to a gynecological, specialty clinic or academic health center. Different federal and state payors cover different services of the cervical cancer screening process. It is important to understand if the referring entity has the infrastructure in place to collect funds from various payors across the continuum of care. For example, family planning clinics mostly use family planning funds so they cannot provide diagnostic care. Parkland Hospital and Health System and Denver Health are safety-net health systems that have the infrastructure in place to provide services and receive payment for cervical cancer across the entire spectrum of care."

- Jasmin Tiro, PhD, Professor, University of Texas Southwestern Medical Center

What are the patient, provider and system-level barriers and facilitators for safety-net settings of care, including HRSA-supported settings of care, to accept and adopt new clinical guidelines?

Patient-Level Facilitators

Successful patient strategies include culturally tailored messages, cultural mediators, patient navigation, text, and telephone call appointment reminders, use of small and mass social media messages and technology, self-collection for HPV-based cervical screening, outreach workers, home visits, transportation service, client incentives such as reduced costs, group and one-on-one education.^{33,39} We learned about the extent to which several research studies and demonstration projects improved the uptake of cervical cancer screening in safety-net clinical settings (Table 2) and NCI-funded evidence-based cervical cancer screening programs (Table 3).

Individuals in the CDC's NBCCEDP often have changes in income or insurance status, affecting their program eligibility. After initial screening, some individuals may have received subsequent screening and diagnostic services outside of the NBCCEDP. A gap in follow-up of abnormal findings may exist.

Provider-Level Facilitators

Successful provider-level interventions within CDC's NBCCEDP include identifying individuals at high risk for cervical cancer, reminder letters and phone calls for screening, one-on-one education on breast and cervical cancer screening, and enhanced clinic staff communication with doctors on which patients need to be screened (Table 4).

The CDC frequently communicates information to state programs regarding changes in screening and management guidelines. The CDC's NBCCEDP workgroups meet regularly to promote education and training around evidence-based guidelines. Providers in NBCCEDP largely appear to be practicing according to current guidelines for follow-up of ASC-US Pap tests.³⁹

The CPSTF Community Guide reports provider-oriented intervention strategies for breast, cervical, and colorectal cancer screenings and plays an important role in getting patients screened for cancer. Recommendations include provider assessment of how many of their patients receive screening services and giving them feedback on their performance, which can boost screening rates for all three cancers. Informing providers that a patient is due or overdue for services is another effective way to get more people screened. These reminders and recalls can be added to patient medical records or delivered to the provider in other ways.^{25, 38}

Multiple primary care provider strategies were found to be the most effective means for providers to increase colorectal cancer screening rates. Multiple strategies include use of standard reminder prompts for cancer screening, having a systematic process to generate lists of patients due for screening, having a special staff member to manage cancer screening, and using at least one out of the two government cancer screening reports.⁴⁰

System-Level Facilitators

Successful interventions reducing structural barriers include reducing administrative barriers, assisting with appointment scheduling, flexible clinic hours, setting up alternative screening sites using mobile mammography vans, adding screening hours, addressing transportation barriers, offering childcare, providing language translation services, patient navigators, quality improvement specialist, interoperable electronic health records with built in referral pathways between clinics and referring institutions, and other administrative services.³⁸

NCI is funding R01CA163830, *Patient Navigation 2.0: Addressing the Challenge of Scaling Navigation Through Checklist-Based Implementation* which developed a checklist implementation strategy that scales implementation of patient navigation across cancers and builds a sustainable team-based checklist that will support coordination and integration of social determinants of health-related efforts across community oncology and community social service settings. The primary outcome is an adjusted, composite proportion of social determinants of health-related barriers resolved and completion of U.S. Preventive Services Task Force recommended cancer-related screenings, behavioral counseling, and immunizations, collected via chart review and patient surveys.⁴¹

"Patients delaying [cancer screening] tests last year 'may turn one public health crisis into many others."

- Ned Sharpless, MD, Director, National Cancer Institute, National Institutes of Health

What is Known about De-Implementation of Cervical Cancer Screening Practices?

De-implementation research is broadly defined as the scientific study of factors, processes, and strategies for reducing, replacing, or stopping the use of ineffective or low-value clinical practices in healthcare delivery settings.⁴³

Use of ineffective or low-value clinical practices may have negative impact on patients, healthcare providers, healthcare teams, healthcare organizations, and healthcare systems.³² Recent data indicate that older adults continue to receive routine screenings inconsistent with national guidelines. It is estimated that more than 45 percent of older adults in the US reported being screened for colorectal, cervical, or breast cancer after the recommended upper age limit, and over-screening for cervical and breast cancer was more common in urban areas among patients with a usual source of healthcare.⁴²⁻⁴⁵

Research on de-implementation of ineffective, unproven, low-value, practices is understudied. In 2020, the NCI issued the funding opportunity announcement, <u>De-Implementation of Ineffective or Low-value Clinical Practices along the Cancer Care Continuum</u>, to solicit research applications that will study the de-implementation of ineffective or low-value clinical practices, programs, treatments, or interventions ("practices") along the cancer care continuum from detection to end-of-life.⁴²

Discussion

It is important to address disparities that remain in cervical cancer screening among at-risk medically underserved populations. This report addresses the multiple factors that detract from equitable guideline-concordant screening services for at-risk populations and draws attention to the need to depart from opportunistic to a risk-based screening approach. Individuals are not a monolith, and to the extent possible, screening and management should be deliberately designed to be responsive to patients' social determinants of health with appropriately tailored interventions. If strategies are not created to address disparities in cervical cancer screening, the burden of cervical cancer will persist and potentially increase in populations whose healthcare needs are unmet.

New understanding from investments in innovative research strategies and emerging technologies to strengthen capacity to deliver impactful screening programs is on the horizon. Additionally, the Federal Cervical Cancer Collaborative is monitoring results of currently funded cervical cancer screening research and programs to apply findings, as applicable, to update its approach to technical assistance development and support safety-net settings of care.

The findings in this report are subject to limitations. The landscape analysis was primarily focused on currently awarded research grants and demonstration projects and a less exhaustive review of the literature. The literature review focused on identifying recent systematic reviews that aligned with research questions that guided the analysis. Individual original research studies may have inadvertently been omitted from our review.

Conclusion

Progress is being made with increasing cervical cancer screening that includes the use of HPV testing among women aged 30-64 years old, but utilization remains low among women aged 21-29 years old.⁴⁶⁻⁴⁷ Over half of the new cervical cancer cases in the US are among individuals who have never been

screened or who are infrequently screened, reflecting barriers presented by socioeconomic disparities and geographic inaccessibility, among other factors.⁴⁶ Factors related to persistent underscreening include missed opportunities to screen, a "one-size-fits-all" screening approach, inadequate clinical infrastructure, and complex screening guidelines. Low-resource settings are unable to provide the full spectrum of tools needed to reach population sub-groups (racial and ethnic minorities, the socioeconomically disadvantaged, individuals residing in rural and isolated areas, uninsured, and individuals living in poor neighborhoods) who are less likely to be adequately screened or followed up.

Poorly represented in screening research and demonstration projects include the homeless, transgender, individuals with a history of sexual assault, and those who only receive obstetric care based on culture or other reasons. Understanding how to improve cancer screening among these individuals is needed to close gaps in concordant screening guideline care.

Lack of health insurance is a critical screening barrier. Eligibility to participate in federal cervical cancer screening and early detection and Medicaid programs varies by state and may fluctuate over time, resulting in gaps in care and missed opportunities throughout the continuum of care. Adoption of policies and programs providing financial support during brief periods of patient ineligibility are needed to timely address screening, prevention, and treatment of cervical cancer.

Given the recency of the 2019 ASCCP Risk-Based Management Consensus Guidelines, patient-, provider-, clinic-, and health system-level factors that hamper or facilitate screening and disease management under these new guidelines are not yet understood. Finally, self-sampling may be an effective cancer screening method for patients who cannot or prefer not to have in-person appointments and is gaining momentum in research trials as an effective screening approach for individuals who do not/cannot access clinic-based/speculum-exam-based cervical cancer screening. However, there is no clinical guideline in the US to incorporate self-sampling for HPV testing, primarily due to lack of an FDA-approval of self-sampling for HPV testing as a standard of care or an alternative screening approach. Following approval, guidelines would need change to equitably respond to such innovations in the landscape.

As access to in person care continues to fluctuate in the ongoing COVID-19 pandemic, healthcare practices including safety-net settings of care should consider triaging individuals for screening appointments based on screening history as a proxy for risk, including enhanced efforts to reach those who are past due for screening or who need follow-up.⁴⁸

Planning efforts by the federal partnership in an associated roundtable meeting series will consider findings in this report and strive to reduce the burden of cervical cancer for all individuals in the United States through meaningful and culturally targeted public health interventions.

References

- Sabatino, S. A., Thompson, T. D., White, M. C., Shapiro, J. A., de Moor, J., Doria-Rose, V. P., Clarke, T., & Richardson, L. C. (2021). Cancer screening test receipt - United States, 2018. MMWR Morb Mortal Wkly Rep, 70(2), 29-35. https://doi.org/10.15585/mmwr.mm7002a1
- 2. Siegel, R. L., Miller, K. D., & Jemal, A. (2020). Cancer statistics, 2020. *CA Cancer J Clin*, 70(1), 7-30. https://doi:10.3322/caac.21590
- 3. American Cancer Society. (2020). *Cancer Facts & Figures 2020*. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf
- 4. Sabatino, S. A., White, M. C., Thompson, T. D., Klabunde, C. N., Centers for Disease, Control, & Prevention. (2015). Cancer screening test use United States, 2013. *MMWR Morb Mortal Wkly Rep*, 64(17), 464-468. https://www.ncbi.nlm.nih.gov/pubmed/25950253
- 5. National Committee for Quality Assurance. (2018). *Cervical cancer screening (CCS)*. https://www.ncqa.org/hedis/measures/cervical-cancer-screening/
- 6. White, A., Thompson, T. D., White, M. C., Sabatino, S. A., de Moor, J., Doria-Rose, P. V., Geiger, A. M., & Richardson, L. C. (2017). Cancer screening test use United States, 2015. *MMWR Morb Mortal Wkly Rep*, 66(8), 201-206. https://doi.org/10.15585/mmwr.mm6608a1
- 7. Oscarsson, M. G., Benzein, E. G., & Wijma, B. E. (2008). Reasons for non-attendance at cervical screening as reported by non-attendees in Sweden. *J Psychosom Obstet Gynaecol*, *29*(1), 23-31. https://doi.org/10.1080/01674820701504619
- 8. Glasgow, R. E., Whitlock, E. P., Valanis, B. G., & Vogt, T. M. (2000). Barriers to mammography and pap smear screening among women who recently had neither, one or both types of screening. *Ann Behav Med*, 22(3), 223-228. https://doi.org/10.1007/BF02895117
- Eaker, S., Adami, H. O., & Sparen, P. (2001). Reasons women do not attend screening for cervical cancer: a population-based study in Sweden. *Prev Med*, 32(6), 482-491. https://doi.org/10.1006/pmed.2001.0844
- Waller, J., Bartoszek, M., Marlow, L., & Wardle, J. (2009). Barriers to cervical cancer screening attendance in England: a population-based survey. *J Med Screen*, 16(4), 199-204. https://doi.org/10.1258/jms.2009.009073
- 11. Goins, K. V., Zapka, J. G., Geiger, A. M., Solberg, L. I., Taplin, S., Yood, M. U., Gilbert, J., Mouchawar, J., Somkin, C. P., & Weinmann, S. (2003). Implementation of systems strategies for breast and cervical cancer screening services in health maintenance organizations. *Am J Manag Care*, *9*(11), 745-755. https://www.ncbi.nlm.nih.gov/pubmed/14626472
- 12. Leyden, W. A., Manos, M. M., Geiger, A. M., Weinmann, S., Mouchawar, J., Bischoff, K., Yood, M. U., Gilbert, J., & Taplin, S. H. (2005). Cervical cancer in women with comprehensive health care access: attributable factors in the screening process. *J Natl Cancer Inst*, *97*(9), 675-683. https://doi.org/10.1093/jnci/dji115
- 13. Perkins, R. B.; Guido, R. S.; Castle, P. E.; Chelmow, D.; Einstein, M. H.; Garcia, F.; Huh, W. K.; Kim, J. J.; Moscicki, A. B.; Nayar, R.; Saraiya, M.; Sawaya, G. F.; Wentzensen, N.; Schiffman, M.; 2019 ASCCP

- Risk-Based Management Consensus Guidelines Committee (2020). *Journal of Lower Genital Tract Disease*, 24(2), 102-131. https://doi.org/10.1097/LGT.0000000000000525
- 14. Lofters, A. K., Schuler, A., Slater, M., Baxter, N. N., Persaud, N., Pinto, A. D., Kucharski, E., Davie, S., Nisenbaum, R., & Kiran, T. (2017). Using self-reported data on the social determinants of health in primary care to identify cancer screening disparities: opportunities and challenges. *BMC Fam Pract*, 18(1), 31. https://doi.org/10.1186/s12875-017-0599-z
- 15. Asare, M., Flannery, M., & Kamen, C. (2017). Social Determinants of Health: A Framework for Studying Cancer Health Disparities and Minority Participation in Research. *Oncol Nurs Forum*, *44*(1), 20-23. https://doi.org/10.1188/17.ONF.20-23
- 16. Wong, S. L. (2015). Medically underserved populations: disparities in quality and outcomes. *J Oncol Pract*, *11*(3), 193-194. https://doi.org/10.1200/JOP.2015.004259
- 17. Olaku, O. O., & Taylor, E. A. (2017). Cancer in the Medically Underserved Population. *Prim Care*, 44(1), 87-97. https://doi.org/10.1016/j.pop.2016.09.020
- 18. Bureau of Health Workforce. (2021). What is Shortage Designation? Health Resources and Services Administration. Retrieved June 29, 2021, from https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation
- 19. Dean, L. T., Gehlert, S., Neuhouser, M. L., Oh, A., Zanetti, K., Goodman, M., Thompson, B., Visvanathan, K., & Schmitz, K. H. (2018). Social factors matter in cancer risk and survivorship. *Cancer Causes Control*, 29(7), 611-618. https://doi.org/10.1007/s10552-018-1043-y
- Pruitt, S. L., Werner, C. L., Borton, E. K., Sanders, J. M., Balasubramanian, B. A., Barnes, A., Betts, A. C., Skinner, C. S., & Tiro, J. A. (2018). Cervical Cancer Burden and Opportunities for Prevention in a Safety-Net Healthcare System. *Cancer Epidemiol Biomarkers Prev*, 27(12), 1398-1406. https://doi.org/10.1158/1055-9965.EPI-17-0912
- 21. Tejeda, S., Darnell, J. S., Cho, Y. I., Stolley, M. R., Markossian, T. W., & Calhoun, E. A. (2013). Patient barriers to follow-up care for breast and cervical cancer abnormalities. *J Womens Health*, 22(6), 507-517. https://doi.org/10.1089/jwh.2012.3590
- 22. Percac-Lima, S., Aldrich, L. S., Gamba, G. B., Bearse, A. M., & Atlas, S. J. (2010). Barriers to follow-up of an abnormal Pap smear in latina women referred for colposcopy. *J Gen Intern Med*, 25(11), 1198-1204. https://doi.org/10.1007/s11606-010-1450-6
- 23. Haas, J. S., Kamineni, A., Skinner, C. S., & Tiro, J. A. (2018). *Multi-level optimization of the cervical cancer screening process in diverse settings & populations (METRICS)* (1UM1CA221940-01) [Grant]. Dallas, TX.
- 24. Nelson, H. D., Cantor, A., Wagner, J., Jungbauer, R., Fu, R., Kondo, K., . . . Quinones, A. (2020). Effectiveness of Patient Navigation to Increase Cancer Screening in Populations Adversely Affected by Health Disparities: a Meta-analysis. *J Gen Intern Med*, *35*(10), 3026-3035. doi:10.1007/s11606-020-06020-9
- 25. DeGroff, A., Cheung, K., Dawkins-Lyn, N., Hall, M. A., Melillo, S., & Glover-Kudon, R. (2015). Identifying promising practices for evaluation: the National Breast and Cervical Cancer Early Detection Program. *Cancer Causes Control*, *26*(5), 767-774. https://doi.org/10.1007/s10552-015-0538-z
- 26. U.S. Department of Health and Human Services (2021). 2020 Annual Report.

 https://web.archive.org/web/20210506103628/https://www.hhs.gov/sites/default/files/2020-annual-report.pdf
- 27. U.S. Department of Health and Human Services (2020). *HHS Rural Action Plan*. https://www.hhs.gov/sites/default/files/hhs-rural-action-plan.pdf

- 28. Centers for Medicare and Medicaid Services (2020). *Community Health Access and Rural Transformation (CHART) Model Fact Sheet* [Fact Sheet]. U.S. Department of Health and Human Services. https://www.cms.gov/newsroom/fact-sheets/community-health-access-and-rural-transformation-chart-model-fact-sheet
- Huh, W. K., Ault, K. A., Chelmow, D., Davey, D. D., Goulart, R. A., Garcia, F. A. R., Kinney, W. K., Massad, L. S., Mayeaux, E. J., Saslow, D., Schiffman, M., Wentzensen, N., Lawson, H. W., & Einstein, M. H. (2015). Use of primary high-risk human papillomavirus testing for cervical cancer screening: interim clinical guidance. *Obstet Gynecol*, 125(2), 330-337. https://doi.org/10.1097/AOG.0000000000000000669
- 30. Nguyen, M. L., & Flowers, L. (2013). Cervical cancer screening in immunocompromised women. *Obstet Gynecol Clin North Am*, 40(2), 339-357. https://doi.org/10.1016/j.ogc.2013.02.005
- 31. Committee on Practice Bulletins Gynecology. (2012). ACOG practice bulletin number 131: Screening for cervical cancer. *Obstet Gynecol*, 120(5), 1222-1238. https://doi.org/http://10.1097/AOG.0b013e318277c92a
- 32. Haas, J. S., Kamineni, A., Skinner, C. S., & Tiro, J. A. (2018). *Multi-level optimization of the cervical cancer screening process in diverse settings & populations (METRICS)* (1UM1CA221940-01) [Grant]. Dallas, TX.
- 33. Scarinci, I. C., Li, Y., Tucker, L., Campos, N. G., Kim, J. J., Peral, S., & Castle, P. E. (2021). Given a choice between self-sampling at home for HPV testing and standard of care screening at the clinic, what do African American women choose? Findings from a group randomized controlled trial. *Prev Med*, 142, 106358. https://doi.org/10.1016/j.ypmed.2020.106358
- 34. National Cancer Institute (2020). *NCI cervical cancer 'last mile' initiative*. U.S. Department of Health and Human Services, National Institutes of Health. https://prevention.cancer.gov/major-programs/nci-cervical-cancer-last-mile-initiative
- 35. Saraiya, M., Cheung, L. C., Soman, A., Mix, J., Kenney, K., Chen, X., Perkins, R. B., Schiffman, M., Wentzensen, N., & Miller, J. (2021). Risk of cervical precancer and cancer among uninsured and underserved women from 2009 to 2017. *Am J Obstet Gynecol*, *224*(4), 366 e361-366 e332. https://doi.org/10.1016/j.ajog.2020.10.001
- 36. Kranz, A. M., Ryan, J., Mahmud, A., Setodji, C. M., Damberg, C. L., & Timbie, J. W. (2020). Association of Primary and Specialty Care Integration on Physician Communication and Cancer Screening in Safety-Net Clinics. *Prev Chronic Dis*, *17*, E134. https://doi.org/10.5888/pcd17.200025
- 37. Frieden, T. R. (2014). Six components necessary for effective public health program implementation. *Am J Public Health*, 104(1), 17-22. https://doi.org/10.2105/AJPH.2013.301608
- 38. Community Preventive Services Task Force (2018). *Guide to community preventive services*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. https://www.thecommunityguide.org/content/multicomponent-interventions-recommended-increase-cancer-screening
- 39. Watson, M., Benard, V., Lin, L., Rockwell, T., & Royalty, J. (2015). Provider management of equivocal cervical cancer screening results among underserved women, 2009-2011: follow-up of atypical squamous cells of undetermined significance. *Cancer Causes Control*, *26*(5), 759-764. https://doi.org/10.1007/s10552-015-0549-9
- 40. Baxter, N. N., Sutradhar, R., Li, Q., Daly, C., Honein-AbouHaidar, G. N., Richardson, D. P., Del Giudice, L., Tinmouth, J., Paszat, L., & Rabeneck, L. (2017). Do Primary Care Provider Strategies Improve Patient Participation in Colorectal Cancer Screening? *Am J Gastroenterol*, 112(4), 622-632. https://doi.org/10.1038/ajg.2017.4

- 41. Simon, M. (2012). Patient navigation 2.0: Addressing the challenge of scaling navigation through checklist-based implementation (R01CA163830) [Grant]. Chicago, IL. https://app.dimensions.ai/details/grant/grant.2481707
- 42. National Cancer Institute (2020). *Notice of special interest (NOSI): De-implementation of ineffective or low-value clinical practices along the cancer care continuum*. (NOT-CA-20-021). U.S. Department of Health and Human Services, National Institutes of Health. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-021.html
- 43. Moss, J. L., Roy, S., Shen, C., Cooper, J. D., Lennon, R. P., Lengerich, E. J., Adelman, A., Curry, W., & Ruffin, M. T. t. (2020). Geographic variation in overscreening for colorectal, cervical, and breast cancer among older adults. *JAMA Netw Open*, *3*(7), e2011645. https://doi.org/10.1001/jamanetworkopen.2020.11645
- 44. Schneider, A., Henderson, J. T., Harper, C. C., Hsu, A., Saraiya, M., & Sawaya, G. F. (2015). Obstetrician-gynecologists' beliefs about performing less cervical cancer screening: The pendulum swings. *Am J Obstet Gynecol*, *213*(5), 744-745. https://doi.org/10.1016/j.ajog.2015.07.003
- 45. Henderson, J. T., Yu, J. M., Harper, C. C., & Sawaya, G. F. (2014). U.S. clinicians' perspectives on less frequent routine gynecologic examinations. *Prev Med*, *62*, 49-53. https://doi.org/10.1016/j.ypmed.2014.02.004
- 46. Medicaid and CHIP Payment and Access Commission (2016). *Report to Congress on Medicaid and CHIP* [Report to Congress]. https://www.macpac.gov/wp-content/uploads/2016/03/March-2016-Report-to-Congress-on-Medicaid-and-CHIP.pdf
- 47. Qin, J., Shahangian, S., Saraiya, M., Holt H., Gagnon, M., Sawaya. G. (2021).

 Trends in the use of cervical cancer screening tests in a large medical claims database, United States, 2013–2019, *Gynecologic Oncology*, *163*, 378-384.

 https://doi.org/10.1016/j.ygyno.2021.08.023
- 48. National Cancer Institute. (2020). *Improving Resilience and Equity in Cervical Cancer Screening: Lessons from COVID-19 and Beyond* [Webinar]. U.S. Department of Health and Human Services,
 U.S. National Institutes of Health. https://prescancerpanel.cancer.gov/2020/improving-resilience-and-equity-cervical-cancer-screening-lessons-covid-19-and-beyond