Preventing Cervical Cancer in the 21st Century

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Preventing Cervical Cancer in the 21st Century
Mona Saraiya, MD, MPH

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## Cervical Cancer Burden

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Incidences</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Cases</td>
<td>More than 569,000</td>
<td>More than 12,000</td>
</tr>
<tr>
<td>Rank Among Female Cancer Cases</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths</td>
<td>More than 311,000</td>
<td>More than 4,000</td>
</tr>
<tr>
<td>Rank Female Cancers Deaths</td>
<td>4</td>
<td>14</td>
</tr>
</tbody>
</table>

- gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf
After Decades of Declining Rates, Incidence and Mortality Rates Have Levelled Off Since 2007


National Cancer Institute, Surveillance, Epidemiology, and End Results program: seer.cancer.gov/statfacts/html/cervix.html

CDC, National Center for Health Statistics
Higher rates of cervical cancer in:

- Black and Hispanic women
- Women living in nonmetropolitan areas
- Women with lower socioeconomic status
- Women who have never been screening or not screened in past 5 years

Trends in Cervical Cancer in Nonmetropolitan and Metropolitan Counties by Year of Death—United States, 2006–2015

AAPC: Average annual percent change
NS: Non-significant
Human Papillomaviruses (HPV) Cause Many Types of Cancer

- **Double-stranded DNA virus**
  - More than 120 closely related viruses
    - Some types cause cancer, and others cause genital warts
    - Types numbered in order of discovery

- **HPV infection confined to epithelium**
  - Begins in base of epithelium, cells proliferate and are not killed

- **Recombinant HPV vaccine in United States targets 9 types of HPV**
  - 2 of these types cause 90% of genital warts
  - 7 of these types cause 80% of cervical cancer
HPV Infection is Common

- **HPV infection is very prevalent in the population**
  - Almost all sexually active persons will acquire HPV
  - In the United States, approximately 79 million infected and 14 million new infections per year

- **Genital HPV is first acquired soon after onset of sexual activity**
  - 40% infected within 2 years

- **Infection is usually transient, asymptomatic**
  - 90% of infections clear within 2 years

- **Cancer is a rare outcome of HPV infection**
  - Requires persistent infection with high risk HPV types

Persistent Infection with High-risk Types Required for Progression to Precancer and Cancer

HPV: Natural History of Cervical Infection

Peak incidence of precancers in late 20s and peak incidence of cancers in early 40s

Cervical Carcinoma Histology

- Squamous cell carcinoma (SCC) begins in squamous cells
- Adenocarcinoma begins in columnar (glandular) cells
  - Harder to sample with a traditional Pap test due to location of cells

Normal Cervix

- Squamous epithelium
- Squamocolumnar junction
- Columnar epithelium
Cervical Cancer Screening

- **Pap (Papanicolaou) Test**
  - Collects cells from the surface of the cervix and looks for abnormal cells
  - Subjective test
  - Lower sensitivity

- **HPV Test**
  - Collects cells from the surface of the cervix and looks for presence of 14 types of cancer causing HPV
  - Objective test
  - Higher sensitivity
  - 7 FDA-approved HPV tests
    - 2 approved for use alone
    - None approved for self-sampling
Overall Rates Have Dropped
But Adenocarcinoma Rates Remain Unchanged

Trends in Cervical Cancer Incidence by Histology, 1999–2015

Overall Rates Have Dropped, but adenocarcinoma rates remain unchanged.

Trends in cervical cancer incidence by histology, 1999–2015. The chart shows the age-adjusted rate per 100,000 for each year from 1999 to 2015. The rates for squamous cell carcinoma have dropped overall, while the rates for adenocarcinoma have remained relatively unchanged.

National Cancer Institute, Surveillance, Epidemiology, and End Results program: seer.cancer.gov/statfacts/html/cervix.html
Our Understanding and Interventions Have Progressed

Major Events for Cervical Cancer Prevention in the United States

1950: Pap test introduced
1984: HPV linked to cervical cancer
1999: HPV test approved by FDA
2003: Pap test and HPV testing available for 30-65 year olds
2006: HPV vaccine became available
2009: No screening for under age 21
2012: Lengthened screening intervals for all ages
2018: USPSTF recommends primary HPV testing

1984: HPV vaccine became available

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2018: USPSTF recommends primary HPV testing
## Cervical Cancer Screening Recommendations and Guidelines Are Based on Age

<table>
<thead>
<tr>
<th>Cervical Cancer Screening Recommendations and Guidelines</th>
<th>ACS and ACOG, 2012</th>
<th>USPSTF, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screening Methods for Women Based on Age</strong></td>
<td></td>
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<tr>
<td>Ages 21-29 years</td>
<td>Pap every 3 years</td>
<td>Pap every 3 years</td>
</tr>
</tbody>
</table>
| Ages 30-65 years                                       | 1) Co-testing (HPV and Pap) every 5 years (preferred)  
2) Pap alone every 3 years                             | 1) Co-testing every 5 years  
2) Pap alone every 3 years  
3) HPV alone every 5 years                             |
| Age to start                                           | Age 21 years        | Age 21 years |
| Screening among fully vaccinated                       | Same as for non-vaccinated | Same as for non-vaccinated |

*All guidelines recommend that women who have been adequately screened can discontinue Pap at age 65.*

ACS: American Cancer Society  
USPSTF: US Preventive Services Task Force  
ACOG: American College of Obstetricians and Gynecologists
Cervical Cancer Screening Recommendations and Guidelines Are Complicated

When choosing HPV screening methods, care providers and women will need to talk through their options based on their age, risk, and preferences.
We Should Use All Available Tools to Prevent Cervical Cancer

- Cervical cancer has decreased in the United States in past century due to screening
- Significant disparities remain
- Screening technology has evolved
- Screening recommendations and guidelines are complicated
- HPV vaccination holds promise to decrease burden further
HPV Vaccination in the United States: Current Status

Melinda Wharton, MD, MPH
Director, Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
HPV Vaccine Recommendations, United States, 2006–present

2006  HPV vaccine recommended as three dose series for girls at 11–12 years of age, with catch up for adolescents and young women through 26 years of age

2011  HPV vaccine recommended as three-dose series for boys at 11–12 years of age, with catch-up through 21 years of age

2015  9-valent HPV vaccine replaced 4-valent HPV vaccine

2016  For boys and girls who start series before 15th birthday, only two doses of HPV vaccine needed

By late 2016, only 9-valent vaccine was marketed in U.S.
HPV Vaccination Rates Lag Behind Other Vaccines Recommended at Ages 11–12 Years


HPV UTD: HPV up-to-date; includes those with ≥3 doses, and those with 2 doses when the first HPV vaccine dose was initiated before age 15 years an appropriate interval between the first and second dose.
HPV Vaccination Rates Vary Widely Across the U.S.

Vaccination Coverage Among Adolescents Aged 13–17 Years By State, United States, 2017

Walker TY, Elam-Evans LD, Yankey D, et al. MMWR 2018;67:909–917
Prevalence of HPV Drops After Vaccine Introduction

Over Time Prevalence of HPV Drops Even Further

Prevalence of Vaccine-type HPV (HPV 6,11,16,18) in Females, Later and Early Vaccine Era Compared to Pre-vaccine Era

NHANES: National Health and Nutrition Examination Survey

Cervical Precancer Incidence Rates Have Decreased in Younger Women

- **CIN2+ rates lower in younger women**
  - CIN2+ rates *decreased* significantly in estimated screened women ages 18–20 and 21–24 years
  - CIN2+ rates *increased* in screened women ages 25–29, 30–34, and 35–39 years
  - Could be attributable to:
    - Longer screening intervals and/or
    - Increased sensitivity of screening or diagnostic tests

CIN2+: Precancerous lesions called “cervical intraepithelial neoplasia, grade 2 or worse; or adenocarcinoma in situ”

## Why Aren’t Kids Being Vaccinated? Improving HPV Vaccine Coverage

Parental Reasons Given for Not Vaccinating Adolescents with HPV Vaccine, Unvaccinated Adolescents* Aged 13–17 Years, NIS-Teen, United States, 2017

<table>
<thead>
<tr>
<th>Parents of Girls</th>
<th>Parents of Boys</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety concerns/side effects</td>
<td>Safety concerns/side effects</td>
</tr>
<tr>
<td>24%</td>
<td>17%</td>
</tr>
<tr>
<td>Not needed/not necessary</td>
<td>Not recommended</td>
</tr>
<tr>
<td>14%</td>
<td>15%</td>
</tr>
<tr>
<td>Not recommended</td>
<td>Not needed/not necessary</td>
</tr>
<tr>
<td>8%</td>
<td>14%</td>
</tr>
<tr>
<td>Lack of knowledge</td>
<td>Lack of Knowledge</td>
</tr>
<tr>
<td>8%</td>
<td>9%</td>
</tr>
<tr>
<td>Not sexually active</td>
<td>Not sexually active</td>
</tr>
<tr>
<td>7%</td>
<td>8%</td>
</tr>
</tbody>
</table>

NIS-Teen: National Immunization Survey-Teen
Strong Provider Recommendations Increases HPV Vaccination Rates

“Now that Sophia is 11, she is due for vaccinations today to help protect her from meningitis, HPV cancers, and pertussis.”
Comprehensive Quality Improvement Approaches

Improve HPV Vaccine Coverage

- Assess and offer feedback to providers about their vaccine coverage
- Engage all staff in the practice to support team-based efforts to improve HPV vaccine coverage
- Organize workflow to minimize burden on healthcare providers
  - Use standing orders and allow immunization-only visits
  - Identify patients scheduled to be seen who are due HPV vaccine and prompt clinicians to recommend it at that visit
- Establish reminder and recall systems
- Record all doses in EHR and state’s immunization information system

EHR: Electronic health record
Immunization Rates Over 90% Are Achievable for Adolescents

Immunization Rates for Adolescents, Denver Health, 2004–2014

≥1 Tdap

≥1 HPV (females)

≥1 HPV (males)

≥1 MenACWY

Supporting Change: The Role of Partnerships and Coalitions

- Working with national provider and quality improvement organizations
  - HEDIS 2018 reflects current ACIP schedule
- Convening national partners through the National HPV Vaccination Roundtable
  - Sharing communication resources, best practices, and other tools and materials
- Collaborating with cancer partners in national and state-level activities
  - Comprehensive Cancer Control National Partnership
  - NCI-designated cancer centers
  - State coalitions and roundtables
- Engaging integrated healthcare delivery systems
Novel Tools for Screening in High- and Low-Resource Settings

Nicolas Wentzensen, MD, PhD, MS
Deputy Chief and Senior Investigator, Clinical Genetics Branch
Division of Cancer Epidemiology and Genetics
National Cancer Institute
National Institutes of Health
National Cancer Institute Moonshot:
Accelerated Control of Cervical Cancer

High-resource settings

Challenges and Inefficiencies

Screening is not distributed equally

Inefficient screening tools

Overtreatment

Many choices lead to confusion among providers and women

Goals and Solutions

More efficient screening and triage strategies

Extend screening intervals

Reduce overtreatment

Risk-based screening and management
NCI Moonshot: Accelerated Control of Cervical Cancer

Challenges and Inefficiencies
- No sustainable multi-visit screening programs
- Limited treatment capacity
- Hardly any vaccination

Goals and Solutions
- Increase coverage through single-visit, “screen and treat” programs
- Reduce unnecessary referral to treatment
- Integrate vaccination and screening

Low-resource settings exist in high-resource countries, e.g. US rural areas
Risk-based Screening and Management Guidelines

High risk: Treatment

Medium risk: Colposcopy

Low risk: Triage or repeat testing

Minimal risk: Regular screening interval

Primary screening

Routine Screening

Triage

Repeat testing or routine screening

Colposcopy

Repeat testing
## Novel Screening and Triage Technologies

<table>
<thead>
<tr>
<th>Technology</th>
<th>Resource Setting</th>
<th>Key References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated cytology</td>
<td>High/ middle</td>
<td>Schiffman et al. Int J Cancer 2017, Yu et al. JNCI 2018</td>
</tr>
<tr>
<td>p16/Ki67 Dual stain (Automation)</td>
<td>High/ middle</td>
<td>Wentzensen et al. JNCI 2015, Clarke et al. JAMA Oncology 2018</td>
</tr>
<tr>
<td>HPV testing with extended genotyping; HPV protein</td>
<td>All</td>
<td>Schiffman et al. JNCI 2005, Schiffman et al. Int J Cancer 2016</td>
</tr>
<tr>
<td>Viral methylation</td>
<td>All</td>
<td>Wentzensen et al. JNCI 2012, Clarke et al. Clin Cancer Res 2018</td>
</tr>
<tr>
<td>Automated visual evaluation</td>
<td>Low</td>
<td>Schiffman et al. in press</td>
</tr>
<tr>
<td>Risk-based colposcopy</td>
<td>High/ middle</td>
<td>Wentzensen et al. JCO 2015, Wentzensen et al. AJOG 2018</td>
</tr>
</tbody>
</table>

**Cytology**
- **Automated cytology**
- **p16/Ki67 Dual stain (Automation)**

**Molecular**
- **HPV testing with extended genotyping; HPV protein**
- **Viral methylation**

**Visual**
- **Automated visual evaluation**
- **Risk-based colposcopy**
Extended HPV genotyping gives information about:
- Individual risk
- Insight into how common is each type of virus

HPV16 was both high-risk and common

Other types with lower risk
- Consider different management?

p16/Ki-67 Dual Stain (DS) Is More Sensitive and Provides Insight Into Long-term Risk

- Dual stain has higher sensitivity with lower colposcopy referral compared to Pap cytology
- Dual stain provides long-term risk stratification
  - If results are negative, a woman can wait up to 3 years until next test
- Automated evaluation of DS slides improves accuracy

CIN3: Severely abnormal cells  
ASC-US+: Atypical squamous cells of undetermined significance  
NILM: Negative for intraepithelial lesion or malignancy  
Clarke MA, Cheung LC, Castle PE, et al. JAMA Oncology 2018 Oct 11
Knowing Viral Methylation Adds to Understanding of Risk

- HPV methylation adds important risk stratification on top of genotype
- Development of integrated typing and methylation assay is underway
- Evaluation in self-collected specimens

Implementing Efficient Screening Programs in Low-resource Settings

- Screen and treat (e.g., single-visit strategies) are important
- Self-sampling can expand reach
- HPV testing is ideal for primary screening, but what to use for triage?
- Immediate treatment decision is desired
- Overtreatment should be reduced, immediate treatment with ablative technologies should be maximized
- Consider age range for screening, particularly if cancer treatment options are limited
Machine-learning to Predict Precancer
Automated Visual Evaluation (AVE)

- Machine-learning-based algorithm to predict presence of cervical precancer
- Could expand “screen and treat” visits by aiding triage and diagnosis at time of visit
- Screening AUC 0.95
- Triage of HPV positive AUC 0.87

AUC: Area under the curve is a measurement of how well a test can distinguish between those with disease and those without disease. Values closer to 1 are better.
Combined Vaccination and Screening Program for Low-resource Settings

Progression of HPV Infection to Cervical Cancer Over Woman’s Lifetime

- Normal
- HPV infection
- Precancer
- Cancer

Extended age range of vaccination reduces HPV population prevalence faster

HPV screen and treat reduces cancer prevalence faster

Cervical Cancer Prevention in Border Communities

Francisco A. R. Garcia, MD, MPH
Assistant County Administrator, Pima County
Chief Medical Officer, Pima County
Professor Emeritus of Public Health, University of Arizona
Comprehensive Cervical Cancer Prevention in Vulnerable Communities

Vaccination ➔ Screening ➔ Diagnosis

Survivorship ← Surveillance ← Treatment
Relative Role of Contextual and Host Factors

Availability of services
Immigration status
Systemic obstacles
Culture/language
Insurance status
Health Literacy
Geography

HPV Persistence Type

Vulnerable Population

HPV Persistence Type

Resilient Population
Barriers Cervical Cancer Prevention

Individual Factors

- Low HPV awareness
- Poor understanding of HPV/cancer link
- Cultural issues
- Poor screening uptake
- Compromised follow-up
Barriers Cervical Cancer Prevention

**Individual Factors**
- Low HPV awareness
- Poor understanding of HPV/cancer link
- Cultural issues
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**Provider and Facilities Factors**
- Training and education
- Resource and facilities
- Advance therapeutics (chemo/rad)
- Palliation
Barriers Cervical Cancer Prevention

**Individual Factors**
- Low HPV awareness
- Poor understanding of HPV/cancer link
- Cultural issues
- Poor screening uptake
- Compromised follow-up

**Provider and Facilities Factors**
- Training and education
- Resource and facilities
- Advance therapeutics (chemo/rad)
- Palliation

**Systemic Factors**
- Access to healthcare
- Un-insurance
- Surveillance and tracking systems
- Immigration status
Pima County Cervical Cancer Prevention Coalition

- Population: Hispanic women with school aged children or grandchildren
- Providers: Federally Qualified Health Centers, Safety Net clinics, state, UA
- Outcomes: Age-appropriate screening; timely follow up; vaccination
- Methodology: Woman-centered, culturally tailored, linguistically accessible, set multi-modal community health worker interventions

Promotoras (e.g., community health workers) teaching at community site

CDC REACH Initiative: *Promotoras* Engaged in Preventing Cervical Cancer in Mexican-American Communities

- During a 5-year funding period:
- Trained 300 community health workers (CHWs), called *promotoras*
- Over 100 *promotora* group presentations per year, reaching over 2,500 women
- 370 one-on-one client CHW encounters per year
- CHW case navigation (150 per year)
- Provider education CME & technical assistance (17 presentations or consultations per year)
Incidence of Invasive Cervical Cancers Decline in Hispanics in Pima County


Arizona, 1995–2015

Pima County, 1995–2015*

* Rates are based on fewer than 10 cases in most years. Interpret with caution.

Courtesy of the Arizona Department of Health Services
Decreasing Rates of Cervical Cancer Mortality in Pima County

Cervical Cancer Mortality Rate (per 100k) in Arizona and Pima County, 1996–2016

Courtesy of the Arizona Department of Health Services
Rates of Cervical Cancer Mortality Declining in Pima County

Hispanic Cervical Cancer Mortality (per 100k) in Arizona and Pima County, 2006–2015

Courtesy of the Arizona Department of Health Services
Community Health Worker Interventions Improve Screening Adherence in Border Communities

### Yuma Promotora Intervention, 3-year follow-up

<table>
<thead>
<tr>
<th></th>
<th>Number (%)</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usual Care</strong>&lt;br&gt;(n=116)</td>
<td>87 (75%)</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Intervention</strong>&lt;br&gt;(n=104)</td>
<td>93 (89%)</td>
<td>2.8</td>
</tr>
</tbody>
</table>

School Based Cancer Prevention Efforts

- After-school girls’ clubs & summer camps focused on health, education, and culture
  - Tailored to urban and rural Hispanic girls
- Classes for mothers on psychosocial topics and navigating educational systems to support daughters’ academic success
- Opportunity for middle-school girl and moms to talk about sexuality, healthy development, STIs, vaccination, etc.

HPV Non-vaccinated Children in Pima County Dropped

Children Ages 13–18, Receiving Zero Doses of HPV Vaccine in Pima County, by Sex, 2006–2017

Percent

HPV vaccine approved

Year


M  F
First Dose HPV Vaccine is Reaching the Age-appropriate Children

Pima County Median Age for First Dose HPV Vaccine, by Sex, 2006–2016
Much Still to Be Done for Women At Increased Risk

Women 40 or Older Reporting Last Pap Screening More Than 5 Years Ago, by Race/Ethnicity and Rural/Urban Domicile, in AZ and NM, 2006–2008

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Domicile</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Urban</td>
<td>Rural</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>8%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>7%</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>5%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>8%</td>
<td>16%</td>
<td></td>
</tr>
</tbody>
</table>

Longer Intervals Are Being Reported Between Screenings

Percentage of BRFSS Respondents Indicating Last Pap Smear Was More Than 3 Years Prior, 2000–2016

Year

Percent


Arizona

Pima

Courtesy of Arizona Department of Health Services
Comprehensive Cervical Cancer Prevention in Communities: Lessons Learned

- Listen to women, early, often, continuously
- Find the right partners
- It’s all about access to health care—vaccination, screening, follow up
- Cervical cancer should be entirely preventable
- One cervical cancer death is one too many
Comprehensive Cervical Cancer Prevention in Vulnerable Communities

Vaccination → Screening → Diagnosis

Survivorship ← Surveillance ← Treatment
Role of Healthcare Providers in Cervical Cancer Prevention: Now and in the Future

Lisa C. Richardson, MD, MPH
Director, Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Cervical Cancer is Still a Problem in the United States


No woman deserves to die of cervical cancer.

National Cancer Institute, Surveillance, Epidemiology, and End Results program: seer.cancer.gov/statfacts/html/cervix.html

CDC, National Center for Health Statistics
Cervical Cancer is Still a Problem in the United States

No woman deserves to die of cervical cancer.

We can do better.


National Cancer Institute, Surveillance, Epidemiology, and End Results program: seer.cancer.gov/statfacts/html/cervix.html

CDC, National Center for Health Statistics
Two Proven Opportunities to Prevent Cervical Cancer

Vaccination Opportunity
11–12 years old

Screening Opportunities
21–65 years old

Normal cervical cells
HPV infection
Precancers
Cervical cancer

Most HPV infections do not turn into precancers
Precancers may still go back to normal

Call To Action For Healthcare Providers

Everyone has a role in ending cervical cancer!