



# ACS Cervical Cancer Screening Guideline For Average Risk Individuals, 2020

# Agenda

## Welcome and Introductions

- Robert Smith, PhD, SVP, Cancer Screening, ACS

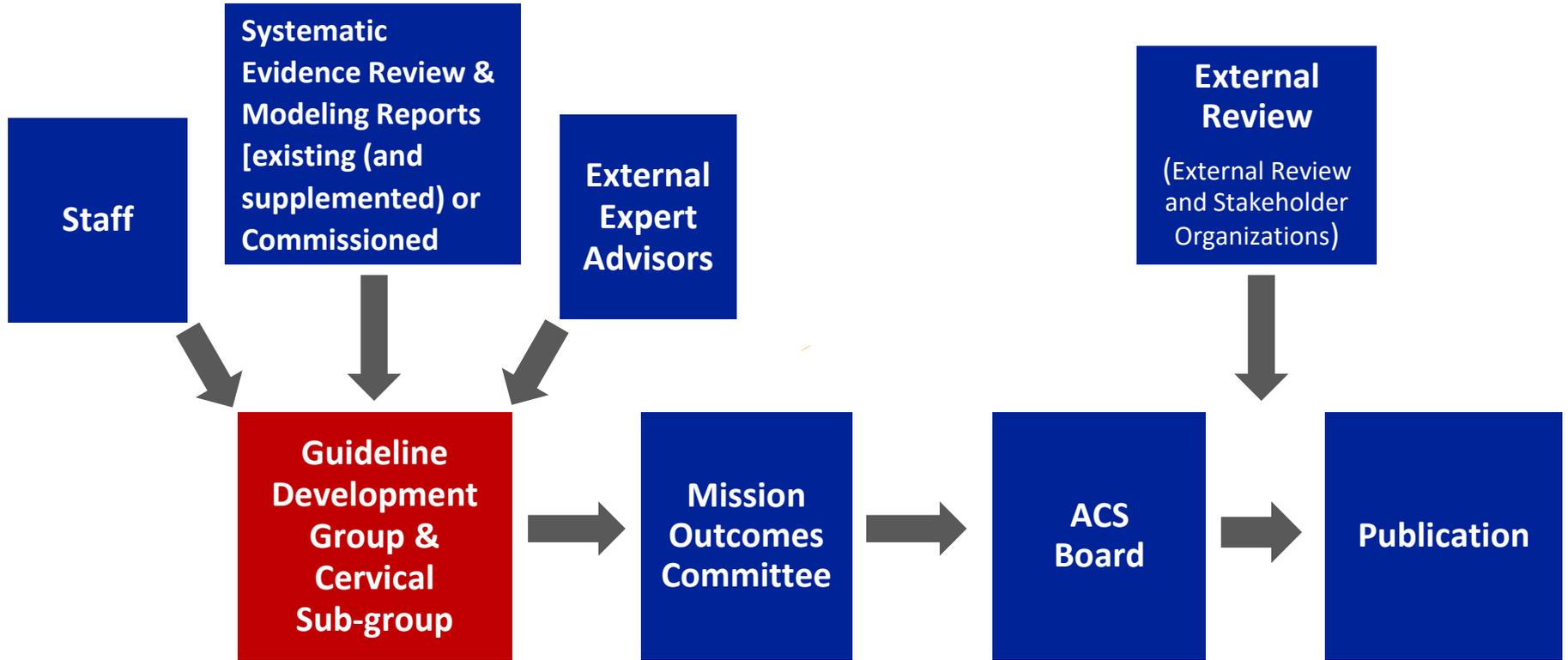
## Guideline Overview

- Robert Smith, PhD
- Debbie Saslow, PhD, Managing Director, Cancer Control Interventions-HPV/GYN Cancers

## Questions & Answers

# Guideline Overview

# ACS Guideline Development Process



# The 2020 ACS updated recommendations for cervical cancer screening apply to:

- **All asymptomatic individuals with a cervix**
- **The recommendations DO NOT apply to individuals at increased risk for cervical cancer due to immunosuppression**

# ACS 2020 Recommendations for Cervical Cancer Screening

- The ACS recommends that individuals with a cervix initiate cervical cancer screening at **age 25 years** and undergo **primary HPV testing every 5 years through age 65 years (preferred)**. If primary HPV testing is not available, individuals aged 25 to 65 years should be screened with cotesting (HPV testing in combination with cytology) every 5 years or cytology alone every 3 years (acceptable) **(strong recommendation)** .

# ACS 2020 Recommendations for Cervical Cancer Screening

- Cotesting or cytology-alone testing are acceptable options for cervical cancer screening because access to an FDA-approved primary HPV test may be limited in some settings.
- As the United States makes the transition to primary HPV testing, the use of both cotesting and cytology for cervical cancer screening will not be included in future guidelines.

# ACS 2020 Recommendations for Cervical Cancer Screening

The ACS recommends that individuals with a cervix can discontinue screening at age 65 if:

- They have documented adequate negative prior screening in the 10-y period before age 65 y (***qualified recommendation***), and
- There is no history of CIN 2+ within the past 25 y.

\*Older than age “65 years” means that cervical screening is not recommended in women age 66 years and older

# ACS 2020 Recommendations for Cervical Cancer Screening

Individuals older than age 65 y\* without conditions limiting life expectancy for whom sufficient documentation of prior screening is not available *should be screened until criteria for screening cessation are met.*

Cervical cancer screening may be discontinued in individuals of any age with limited life expectancy.



\*Older than age “65 years” means that cervical screening is not recommended in women age 66 years and older

# What Changed? (2020 vs 2012)

- HPV testing alone every 5 years is the preferred screening strategy
  - ✓ In 2012, Cotesting (HPV test + cytology) every 5 years was preferred. *Now, cotesting is acceptable*
  - ✓ In 2012, Cytology every 3 years for aged 21-29y was acceptable. *Now, cytology alone every 3 years is acceptable after age 25*
- Starting cervical cancer screening at age of 25y
  - ✓ Age 21y in 2012

# What has not Changed?

Recommendation to exit cervical cancer screening at age 65y

- Criteria for exiting screening based on 10 years of prior adequate negative screening with the most recent test occurring within the recommended interval for the test used:
  - ✓ 2 consecutive, negative HPV tests or
  - ✓ 2 negative cotests or
  - ✓ 3 negative cytology tests

# What Informed the GDG\* Decisions?

- **Quality of evidence**
- **Balance between desirable and undesirable effects**
- **Values and preferences**

# Recent Developments in Cervical Cancer Prevention

Introduction of HPV testing for cervical cancer screening, first for cotesting with cytology and subsequently as a stand-alone screening test.

- ✓ **2 primary HPV tests approved by FDA**
- ✓ USPSTF recommends primary HPV testing for cervical screening starting at age 30y (2018).

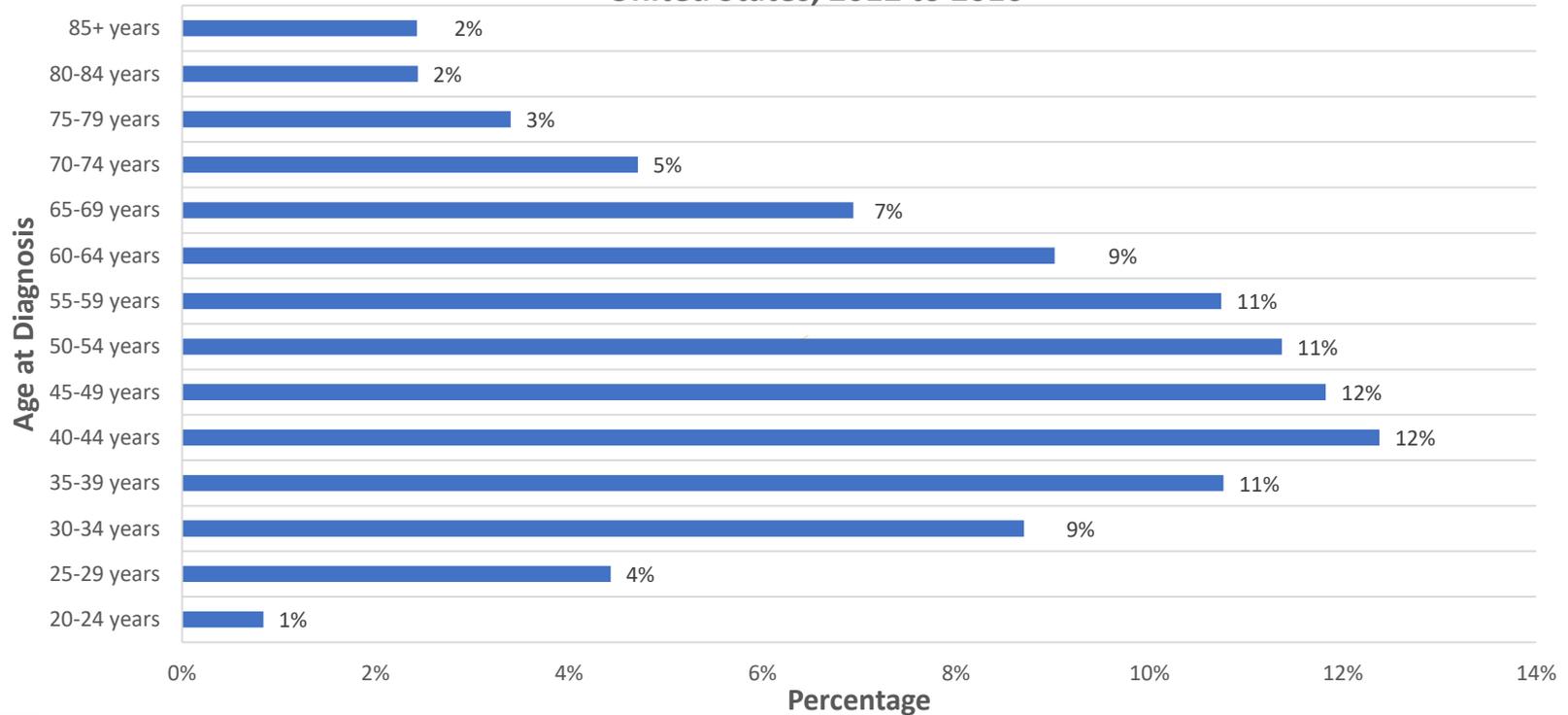
# Recent Developments in Cervical Cancer Prevention

## Introduction of the human papillomavirus (HPV) vaccine (2006)

- NHIS 2016 data--48.5% of females aged 19-26 years reported having previously received of at least one dose of HPV vaccine.
  - 51.6% among females aged 19-21 years.
- NIS-Teen Survey 2017-2018 data--Among adolescents aged 13–17 years, coverage with  $\geq 1$  dose of vaccine increased from 65.5% to 68.1%.

# Rationale – Disease Burden of Cervical Cancer

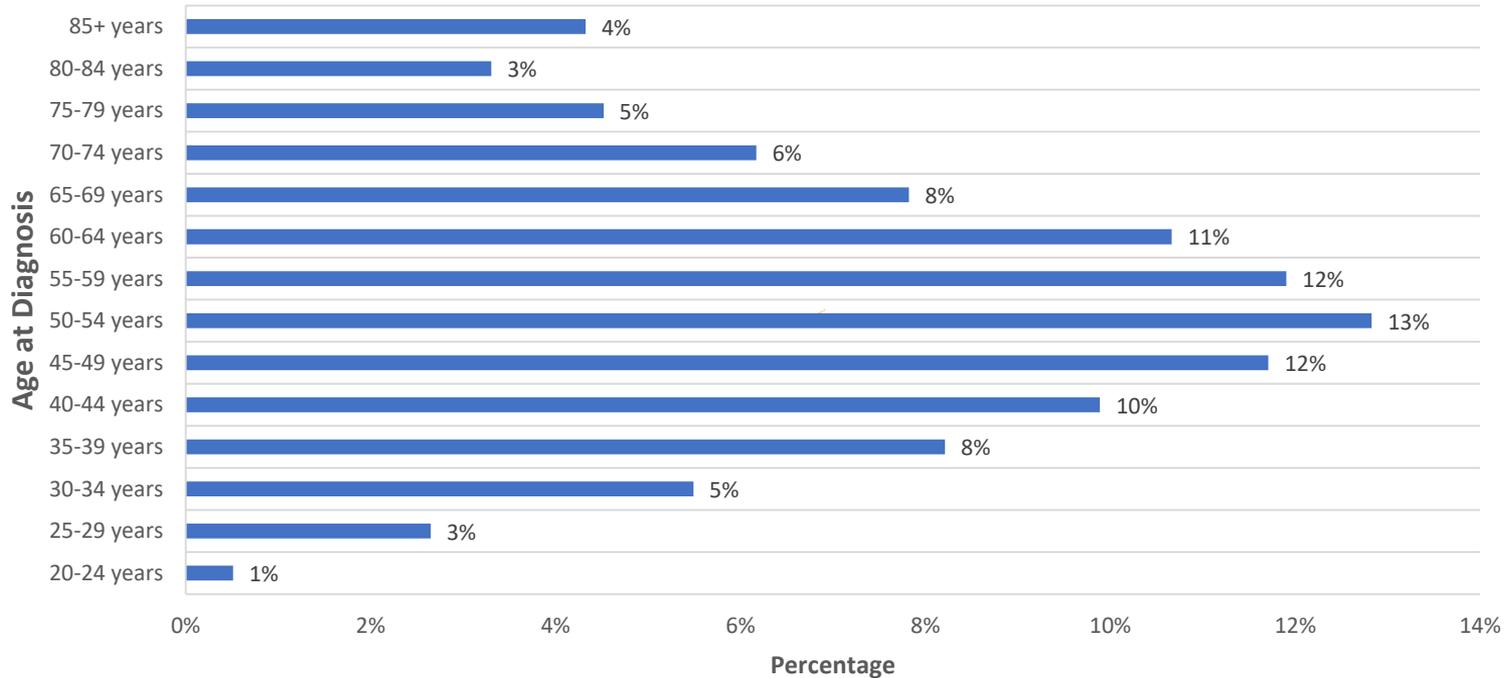
Distribution of Cervical Cancer Cases by Age at Diagnosis,  
United States, 2012 to 2016



Source: Fontham ETH, Wolf AMD, Church TR, et al. Cervical Cancer Screening for Individuals at Average Risk: 2020 Guideline Update from the American Cancer Society. CA Cancer J Clin. 2020; 0: 000-000 [epub ahead of print]. URL to be:

# Rationale – Disease Burden of Cervical Cancer

Distribution of Cervical Cancer Deaths by Age at Diagnosis, 2012-2016



Source: Fontham ETH, Wolf AMD, Church TR, et al. Cervical Cancer Screening for Individuals at Average Risk: 2020 Guideline Update from the American Cancer Society. CA Cancer J Clin. 2020; 0: 000-000 [epub ahead of print]. URL to be:

# Starting at age 25 y

## Why not screen at age 21-24y?

- The incidence of cervical cancer in 21-24y very low.
- Observational studies show small if any potential benefit of screening.
- High incidence of transient infections, and risk of adverse reproductive outcomes of treatment in young women.
- Increasing vaccinated screening-age population.
  - Observational studies on screening outcomes from countries with higher vaccine uptake and early US data show a protective effect in vaccinated women.
  - Cytology-based screening less efficient in vaccinated populations.

# Starting at age 25 y

## Why not screen at age 21-24y?

- ✓ Starting screening at 21y has a much higher burden of additional colposcopies per life-year gained, and there was a favorable benefit-to-harm balance for beginning screening at age 25 years.

GDG considered recommendation for screening 21-24y based on vaccine status. However,

- ✓ Ascertaining vaccine status is problematic:
  - Concerns about variability in access to vaccine registries.
  - Challenges in transfer of records from pediatric to adult care.

GDG judgement that the small potential benefits do not outweigh the potential harms for this age group.

# Evidence for Testing Strategy

**Primary HPV testing every 5 years is the preferred cervical cancer screening strategy.**

- Based on superior sensitivity, the ability to better predict future risk of disease, and reduced performance of cytology in an increasingly vaccinated population.
- Cotesting every 5 years (*the preferred option in the 2012 guideline update*) and cytology alone every 3 years remain **acceptable options for now**, if primary HPV testing is not available.
- Cotesting and cytology alone are expected to be phased out as the US makes the transition to full implementation of primary HPV testing for screening.

# Cessation of Screening

Though rare relative to other cancers, still substantial disease burden in women aged > 65y, with significant disparities.

- Uncertain what proportion of disease is attributed to adequately screened women, but it is low.
- Women with an increasing number of negative tests have low risk for future precancers (subsequent cervical cancer).
- Sparse evidence but studies indicate that inadequate screening or not meeting exit criteria is associated with developing cervical cancer > 65y.

# Cessation of Screening

GDG judged that the benefit-to-harm balance favors discontinuing screening in women aged > 65 years who meet exiting criteria.

- Consensus that there is little benefit to continue screening in those who have been adherent to regular screening and meet exit criteria.
- The guideline stresses adherence to screening in decades leading up to age 65y and attentiveness to the criteria for exiting screening.
- If documentation of criteria insufficient to validate, then cervical screening should be performed toward the fulfillment of the exiting criteria.

# Cervical Cancer Screening Guidelines: ACS(2020); USPSTF (2018)

Recommendations	ACS, 2020	USPSTF, 2018
Age to start screening <i>S-strong Q-Qualified</i>	Aged 25y (S)	Aged 21y (A)
Screening Strategy	Aged 25y to 65y (S) Primary HPV test every 5y – preferred Cytology 3y or Cotest 5y – acceptable	Aged 21 to 29y – Cytology every 3y (A)  Aged 30 to 65 years – Cytology 3y or primary HPV 5y or Cotest 5y (A)
Exiting screening	Aged >65y – Discontinue screening if exit criteria are met. (Q) <i>Exit criteria - 2 consecutive negative HPV tests, or 2 consecutive negative cotests, or 3 consecutive negative cytology tests within the past 10 y, with the most recent test occurring within the recommended interval for the test used.</i>	Aged >65 y – Discontinue if adequate prior screening and are not otherwise at high risk for cervical cancer. (D) <i>Adequate screening defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 y before stopping screening, with the most recent test performed within 5 years.</i>
Hysterectomy – with removal of cervix	Screening not recommended	Screening not recommended

# Guideline Resources

- Cancer.org
  - Materials for patients/consumers
  - Materials for health professionals
  - Guidelines paper and patient page

Guideline:

<https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21628>

Patient Page:

<https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21629>

- Updated guidelines presentations for professional and lay audiences as needed

# Implementation—Change is a Challenge

- New difference in the starting age – ACS & USPSTF
- Need to increase public awareness of HPV vaccination and the HPV test.
- Need to increase health care providers awareness **of the screening tests.**
- Insurance coverage for HPV based testing in persons 25-29y.

# Implementation—Change is a Challenge

- The transition from cotesting to primary HPV testing faces a number of challenges:
  - Financial and other resource interests of manufacturers and laboratories
  - Some cytotechnologists and cytopathologists have opposed deemphasizing the Pap test
  - We are uncertain about the barriers faced by clinics that serve low income individuals
  - Inertia---change is not hard, it is just too much trouble

# Policy and Insurance Implications

# Insurance Coverage for Screening (Minimum Coverage)

- Affordable Care Act requires insurers across the country to cover – with no cost sharing - screening services with a USPSTF **A** or **B** rating.
- Cervical cancer screening for ages 21-29 y with cytology alone every 3y receives an A rating.
- Insurers can voluntarily offer broader coverage than USPSTF guidelines; but not required.

# Insurance Coverage for Screening (State Mandates)

- Some states require private insurers and/or state Medicaid programs to use ACS guidelines to inform cervical cancer screening requirements (automatic).
- Some states *consult* ACS guidelines; those states will require additional steps to require a coverage change.
- Bottom line: Some insurance may not cover HPV testing for screening in persons 25-29y.

# Insurance Coverage for Screening

- Very low possibility of HPV test for screening not covered by insurance.
- Consumers should understand what their insurance policy will cover and what out-of-pocket expenses they may incur.

# Q&A