

# Developments in Gynecologic Disease: What Primary Care Providers should know

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- SUNY Stony Brook MD Distinction in research
- BWH/MGH Ob/Gyn residency
- BWH Gynecologic Oncology Fellowship
- Director of Minimally Invasive
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- Fellowship Program Director Gynecologic Oncology
- Director, Ambulatory Gynecologic Oncology
- Clinical focus: Minimally invasive surgical outcomes, surgical innovation
- Research focus: surgical outcomes, quality improvement



#### **DISCLOSURES**

Author for Up-To-Date



#### **OBJECTIVE:**

- Review the ever-changing landscape for HPV related disease including screening and vaccination data
- Update providers on innovations to ovarian cancer
- Increase awareness of issues of racial disparities in Endometrial cancer
- Financial toxicity for patients with gynecologic cancers



#### KEY TAKE HOME POINTS

Women who have an unknown pap smear history or who have persistent high risk HPV infections have a high risk for developing cervical dysplasia

The HPV vaccine is most effective when given before age 15. After age 26 there is little data supporting its effectiveness in large populations.

Women with abnormal bleeding need referrals to gynecologists as ultrasound is not a reliable method, especially in black populations

Newer drugs have a marked effect on survival in certain subsets of ovarian cancer patients

Women treated for gynecologic malignancies are at significant risk for financial toxicity and should be screened for financial insecurity



#### REFERENCES

Marcus, Jenna Z. MD1; Cason, Patty RN, MS, FNP-BC2; Downs, Levi S. Jr. MD, MS3; Einstein, Mark H. MD, MS1; Flowers, Lisa MD4. The ASCCP Cervical Cancer Screening Task Force Endorsement and Opinion on the American Cancer Society Updated Cervical Cancer Screening Guidelines. Journal of Lower Genital Tract Disease 25(3):p 187-191, July 2021.

U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2020 submission data (1999-2018): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; https://www.cdc.gov/cancer/dataviz, released in June 2021.



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#### Case 1

30 year old G0 presents for cervical cancer screening. You offer her:

- A. Cytology annually
- B. Co-testing q3 years
- C. Co-testing q 5 years if all results are normal
- D. Primary HPV testing if the lab has an FDA approved test (i.e. Cobas or BD onclarity) q 5 years
- E. Either c or d is acceptable



#### Who is at risk for cervical cancer?

- Persistent high risk HPV infection (especially 16/18)
- Immunosuppression
- Intercourse ≤17 y/o or ≥6 lifetime partners
- OCPs
- High parity
- Smoking



### Natural History of CIN/Dysplasia

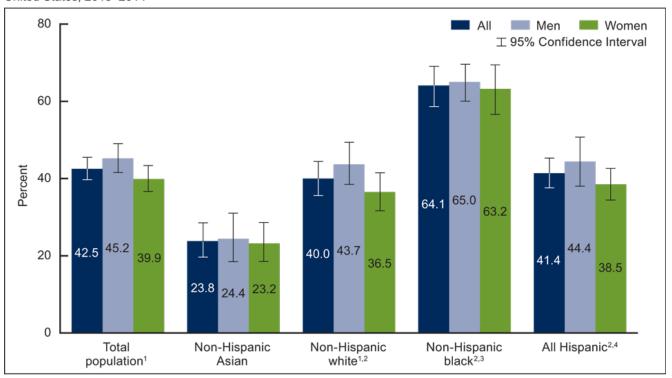
- Most HPV infections "resolve"
- Dysplasia is linked persistent high-risk (oncogenic) HPV
- Higher levels of dysplasia are more likely to progress to cancer
- Prior abnormalities of Pap or HPV indicate patient is at higher risk of progression
  - May indicate a persistent HPV infection





# Prevalence of HPV infection among females in the United States

Figure 3. Prevalence of any genital HPV among adults aged 18–59, by race and Hispanic origin and sex: United States, 2013–2014



<sup>&</sup>lt;sup>1</sup>Percentage for men is significantly higher than women.

SOURCE: NCHS, National Health and Nutrition Examination Survey, 2013–2014.



<sup>&</sup>lt;sup>2</sup>Percentage is significantly different from non-Hispanic Asian, all, men, and women.

<sup>&</sup>lt;sup>3</sup>Percentage is significantly different from non-Hispanic white, all, men, and women.

<sup>&</sup>lt;sup>4</sup>Percentage is significantly different from non-Hispanic black, all, men, and women.

NOTES: HPV is human papillomavirus. Any genital HPV means tested positive to one or more of the 37 HPV types from a penile or vaginal swab sample. Penile samples were available only for 2013–2104, so results presented were limited to that cycle. Access data table for Figure 3 at: https://www.cdc.gov/nchs/data/data-briefs/db280\_table.pdf#3.

### Screening v Surveillance: An important distinction

Screening is testing for disease among patients with no symptoms and ALL normal prior results.

Surveillance is interval testing among women and people with a cervix who have a prior abnormal test result or have received treatment.



# Women who do <u>not</u> qualify for routine "screening"

- Women who are immunosuppressed
- Women previously treated for CIN2/ CIN3 or any HPV related disease (vulvar, vaginal, anal)
- Women for whom you do not know their exact screening history also remain at higher risk and cannot return to "routine screening."
- Women who have any abnormal genital tract symptoms



### Comparison of Current Screening Guidelines & Recommendations for Average-risk Individuals

	American College of Obstetricians and Gynecologists (ACOG), 2020	US Preventive Services Task Force (USPSTF), 2018	American Cancer Society (ACS), 2020		
Age to start screening	21		25		
Screening test options and intervals	Ages 21-65: Cytology alone every 3 years  OR  Ages 21-29: Cytology alone every 3 years  Ages 30-65: Cytology plus HPV testing every 5  years  OR  Ages 21-29: Cytology alone every 3 years  Ages 30-65: HPV testing alone every 5 years		Ages 25-65+ Preferred: HPV testing alone every 5 years OR Acceptable: Either Cytology plus HPV testing every 5 years OR		
Age to end screening	Gytology alone every 3 years  65  if 3 consecutive negative Pap tests OR 2 negative cytology plus HPV tests OR 2 negative HPV tests AND no abnormal tests within the prior 10 years with the most recent within the prior 5 years AND no CIN2+ within the prior 25 years				

# New Screening and Management Guidelines: USPSTF, ACS, ASCO and ASCCP

#### Old:

- Based on cytology
- Algorithm based
- Relied on Expert opinion

#### New:

- Primarily HPV based with reflex to cytology or HPV16/18 genotyping
- Frequency and management are based on "risk" which relies on prior results



#### What is Primary HPV Screening?

- Primary HPV testing is testing for HPV first, followed by a triage test such as cytology and/or HPV genotyping, if the initial test is positive.
- The presence of a high risk HPV type indicates a risk for developing a cervical precancer or cancer—especially if the HPV test remains positive over time (years)
- There are only a few HPV tests that are currently FDA approved for primary testing.
- Historically cervical cancer screening was done with either Pap testing (cytology) or Pap plus HPV test (co-testing)

#### Advantages of Primary HPV Screening

### Improved sensitivity for CIN3+ over cytology alone (↑detection by 50%)

 Minimal loss of sensitivity over cotesting for CIN 3+. Difference not statistically significant for cancer diagnosis

#### More efficient than co-testing

Similar reduction in cancer but requires far fewer tests overall

#### Potential for self-collection

#### Improve access

Wright TC, et al. The ATHENA human papillomavirus study: design, methods, and baseline results. Am J Obstet Gynecol. 2012;206(1):46.e1-46.e11.

Wright TC, et al. Primary cervical cancer screening with human papillomavirus: End of study results from the ATHENA study using HPV as the first-line screening test. Gynecol Oncol. 2015;136(2):189-97.

Huh WK, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: Interim clinical guidance. Obstet Gynecol. 2015;125(2):330-337.

Castle PE, et al. Variable risk of cervical precancer and cancer after a human papillomavirus-positive test. Obstet Gynecol. 2011;117(3):650-656

Gage JC, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. J Natl Cancer Inst. 2014;106(8);dju 153.

Fontham ETH, Wolf AMD, Church TR, Etzioni R, Flowers CR, Herzig A, Guerra CE, Oeffinger KC, Shih YT, Walter LC, Kim JJ, Andrews KS, DeSantis CE, Fedewa SA, Manassaram-Baptiste D, Saslow D, Wender RC, Smith RA. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. CA Cancer J Clin. 2020 Sep;70(5):321-346.

#### Disadvantages of Primary HPV Screening

Requires integrated infrastructure

Only two tests are FDA approved for primary HPV testing (Cobas and BD Onclarity)

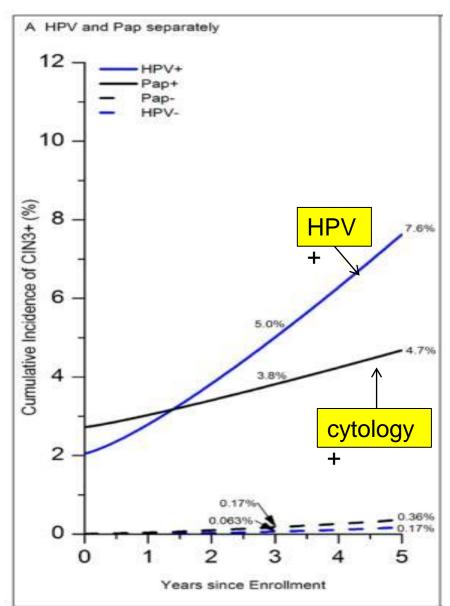
- 1. Wright TC, et al. The ATHENA human papillomavirus study: design, methods, and baseline results. Am J Obstet Gynecol. 2012;206(1):46.e1-46.e11.
- 2. Wright TC, et al. Primary cervical cancer screening with human papillomavirus: End of study results from the ATHENA study using HPV as the first-line screening test. Gynecol Oncol. 2015;136(2):189-97.
- 3. Huh WK, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: Interim clinical guidance. Obstet Gynecol. 2015;125(2):330-337.
- 4. Castle PE, et al. Variable risk of cervical precancer and cancer after a human papillomavirus-positive test. Obstet Gynecol. 2011;117(3):650-656.
- 5. Gage JC, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. J Natl Cancer Inst. 2014;106(8);dju 153.
- 6. Fontham ETH, Wolf AMD, Church TR, Etzioni R, Flowers CR, Herzig A, Guerra CE, Oeffinger KC, Shih YT, Walter LC, Kim JJ, Andrews KS, DeSantis CE, Fedewa SA, Manassaram-Baptiste D, Saslow D, Wender RC, Smith RA. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. CA Cancer J Clin. 2020 Sep;70(5):321-346.

# THE SWITCH: REFLEX CYTOLOGY V REFLEX HPV



#### **HPV testing** predicts future risk better than cytology

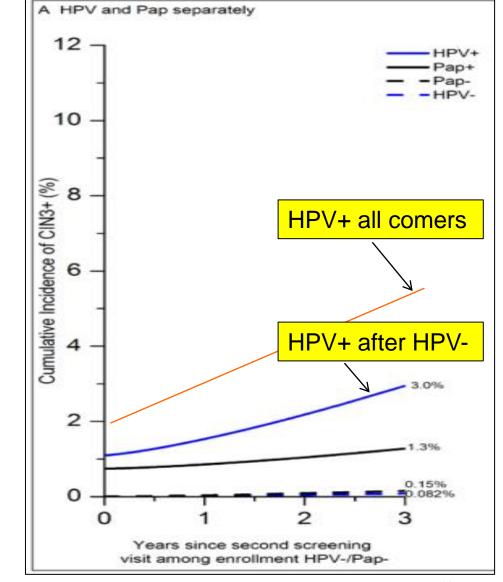
- •331,818 women over 2003-2009
- Followed for 5 years for CIN3+
- Both HPV and cytology predicted risk on the date of screening
- •HPV predicted 5-year risk of CIN3 and cancer





#### **New HPV infection** confers lower CIN<sub>3</sub>+ risk

- •331,818 women over 2003-2009
- Risk of CIN3+ at 3 years
  - •5% with unknown prior HPV result
  - •3% with negative prior HPV result





#### Primary HPV Screening Compared to Co-Testing

Primary HPV screening results in similar reduction in cancer rates compared to co-testing, with far fewer tests

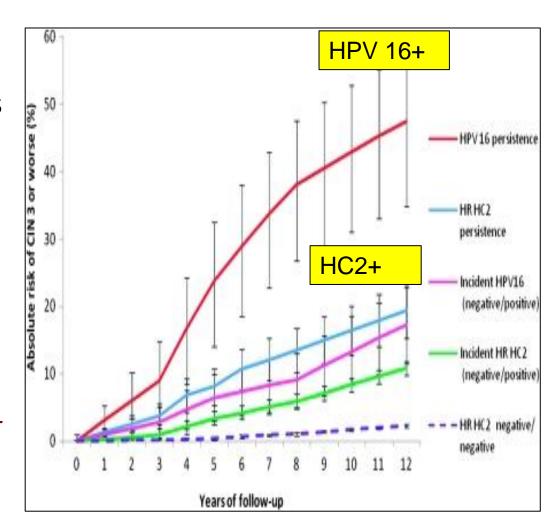
Strategy	Total Tests	Colpos	CIN 2,3	Cancer Cases	Cancer Deaths
No screening	0	0	0	18.86	8.34
Cyto q 3 y age 25-65	13,313	564	142	2.60	0.86
Cyto q 3 y from age 21 then Cotest q 5 y age 30-65	19,806	1,630	201	1.08	0.30
HPV q5 y age 25-65	10,954	1,775	195	0.94	0.28

<sup>\*</sup>Per 1,000 persons with a cervix, screened over a lifetime.

Fontham ETH, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. CA Cancer J Clin. 2020;70(5):321-346.

#### Long-term persistent HPV is especially high risk

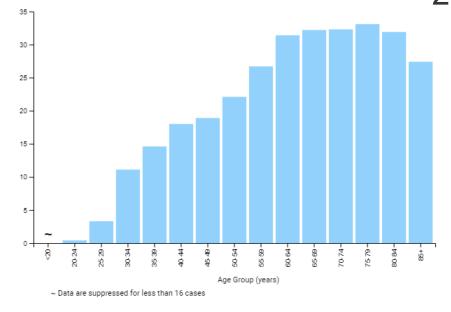
- 8656 women age 20-29 underwent co-testing years 1 & 3
- Followed for 12 years for CIN3+
- Risk of CIN3+
  - 47% persistent HPV16+
  - 19% persistent HC2
  - HPV neg 2%
- HPV history is an important risk modifier



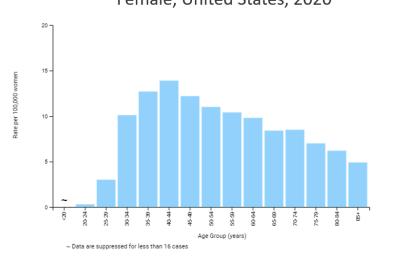




#### Rate of New HPV-associated Cancers By Age Group (years) All HPV-associated Cancers, Female, United States, 2020



Rate of New HPV-associated Cancers By Age Group (years)
Cervical Carcinoma,
Female, United States, 2020



Source - U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; <a href="https://www.cdc.gov/cancer/dataviz">https://www.cdc.gov/cancer/dataviz</a>, released in November 2023.



Rate per 100,000 women





#### **New Management Guidelines: Key Points**

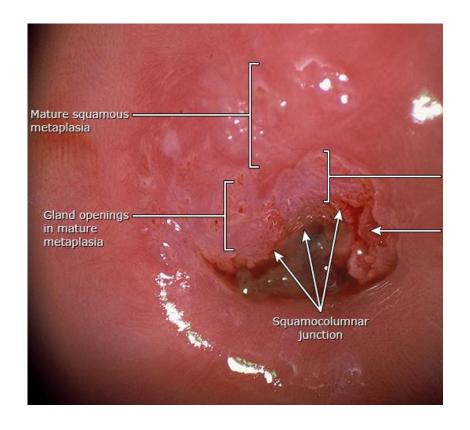
- Current test results in addition to prior HPV, cytology and histology results determine a risk group.
- New guidelines are based on a patient's risk, not just her most recent result.
- Patients with prior abnormal paps are considered <u>surveillance</u> patients and may never go back to 5-year screening intervals
- Primary HPV screening results in fewer overall test with equal efficacy in a screening population

If you get abnormal results with HPV positive testing, REFER IF YOU ARE UNSURE.



# Your contribution to cervical (and other) cancer screening

- Thorough Ob/Gyn review includes history of prior paps
- Review of Family Hx of cancer
- Ask in ROS whether any bleeding or abnormal discharge (with or without intercourse)
- Ensure that the pap smears are ADEQUATE (containing cells from the transformation zone)
- Know when to REFER.



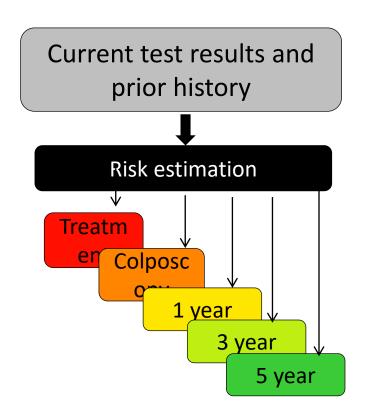


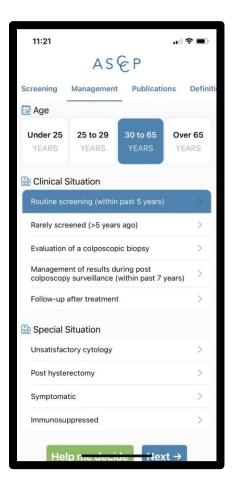






## App/Website will Reduce Complexity: https://www.asccp.org/mobile-app







#### One last comment on HPV...

### Primary Prevention:

Prevent HPV infection before exposure





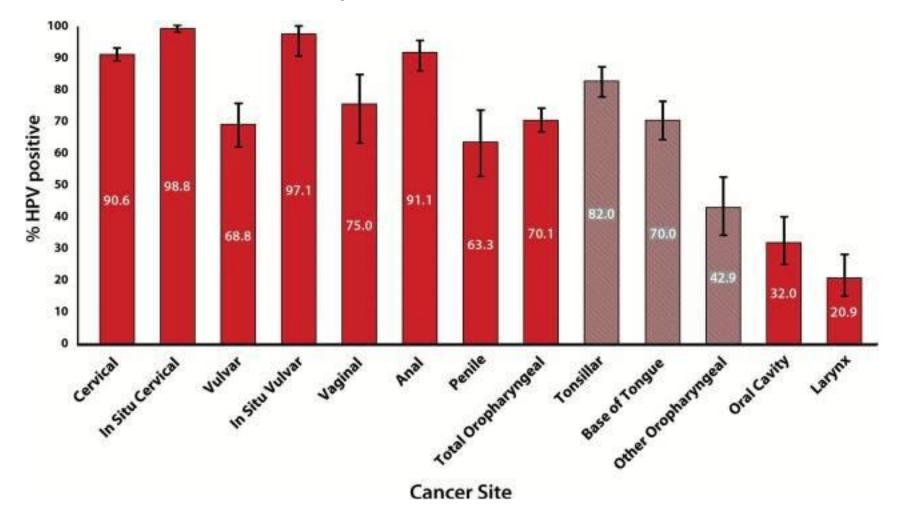
### Rationale for vaccinating early: Protection prior to exposure to HPV

#### Teen Sexual Activity Adolescence is a time of rapid change. % of adolescents who have had sex by each age Female Male Age



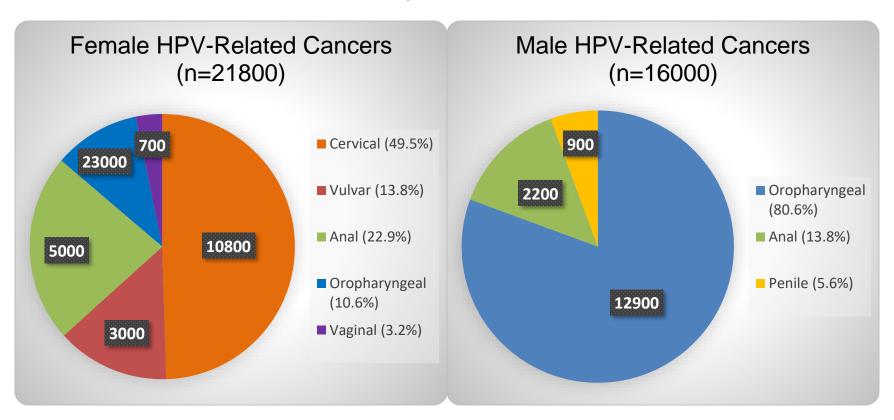


### **HPV** Detection by Cancer Site





# HPV-Attributable Cancers by Gender (U.S., 2017–2021)



Source: CDC - https://www.cdc.gov/cancer/hpv/statistics/index.htm

#### HPV Vaccination and Risk of Invasive Cervical Cancer

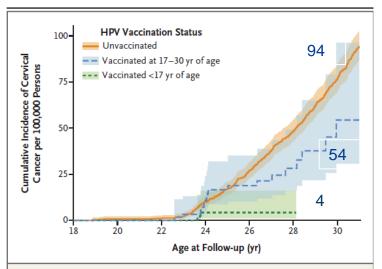


Figure 2. Cumulative Incidence of Invasive Cervical Cancer According to HPV Vaccination Status.

Age at follow-up is truncated in the graph because no cases of cervical cancer were observed in girls younger than 18 years of age.

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

#### HPV Vaccination and the Risk of Invasive Cervical Cancer

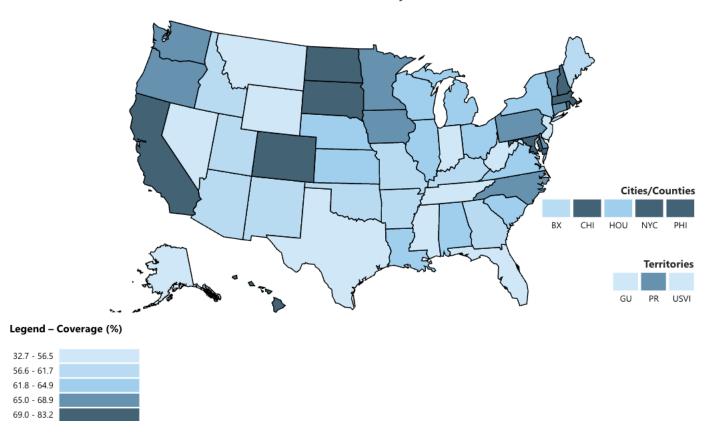
Jiayao Lei, Ph.D., Alexander Ploner, Ph.D., K. Miriam Elfström, Ph.D., Jiangrong Wang, Ph.D., Adam Roth, M.D., Ph.D., Fang Fang, M.D., Ph.D., Karin Sundström, M.D., Ph.D., Joakim Dillner, M.D., Ph.D., and Pär Sparén, Ph.D.

Table 2. HPV Vaccination and Invasive Cervical Cancer.							
HPV Vaccination Status	No. of Cases of Cervical Cancer	Crude Incidence Rate per 100,000 Person-Yr (95% CI)	Age-Adjusted Incidence Rate Ratio (95% CI)	Adjusted Incidence Rate Ratio (95% CI)*			
Unvaccinated	538	5.27 (4.84–5.73)	Reference	Reference			
Vaccinated	19	0.73 (0.47-1.14)	0.51 (0.32-0.82)	0.37 (0.21–0.57)			
Status according to age cutoff of 17 yr							
Vaccinated before age 17 yr	2	0.10 (0.02-0.39)	0.19 (0.05-0.75)	0.12 (0.00-0.34)			
Vaccinated at age 17–30 yr	17	3.02 (1.88-4.86)	0.64 (0.39-1.04)	0.47 (0.27-0.75)			
Status according to age cutoff of 20 yr							
Vaccinated before age 20 yr	12	0.49 (0.28-5.73)	0.52 (0.29-0.94)	0.36 (0.18-0.61)			
Vaccinated at age 20–30 yr	7	5.16 (2.46–10.83)	0.50 (0.24–1.06)	0.38 (0.12–0.72)			

<sup>\*</sup> The adjusted incidence rate ratios were adjusted for age as a spline term with 3 degrees of freedom, county of residence, calendar year, mother's country of birth, highest parental education level, highest annual household income level, previous diagnosis in mother of CIN3+, and previous diagnosis in mother of cancers other than cervical cancer. The 95% confidence intervals were bias-corrected percentile confidence intervals that were estimated with the use of bootstrapping with a resampling frequency of 2000 times.



Up-to-Date HPV Vaccination Coverage among Adolescents Age 13-17 Years, 2021, National Immunization Survey-Teen



Source - U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2020 submission data (1999-2018): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; <a href="https://www.cdc.gov/cancer/dataviz">https://www.cdc.gov/cancer/dataviz</a>, released in June 2021.



# BRIGHAM HEALTH BWH BRIGHAM AND WOMEN'S HOSPITAL



## Cervical cancer prevention across the lifespan



HPV vaccination





- Ages 21-26
  - Screening + catch-up vaccination



- Ages 27-65
  - Screening
  - May offer vaccination to select patients age 27-45 on an individual basis using shared clinical decision-making



#### Case 2

A 62 yo woman presents urgently with new 3-week onset bloating, weight gain and "tight" pants. She is otherwise healthy. Her mother and maternal aunt had a history of breast cancer but no one has had testing in her family. Next steps might include?

- A. Send her to a gynecologist
- B. Draw a Ca-125
- C. Refer to a genetic counselor



D. Obtain an ultrasound or CT scan



### Case 2 (continued)

She ultimately has a CT which reveals ascites, diffuse tumor implants.

The gynecologic oncologist who assesses her must

- A. Determine surgical resectability
- B. Refer to a genetic counselor
- C. Discuss the use of chemotherapy



D. All of the above

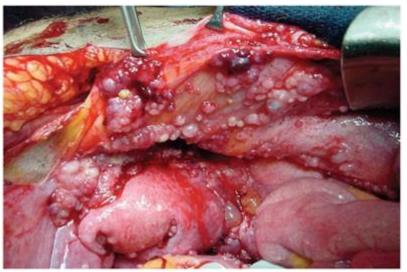


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### A brief update on ovarian cancer

- Inverse relationship between residual disease and prognosis
- Complete resection associated with the best survival
- Molecular fingerprint is a driver for treatment







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Treatment options for advanced FT/Ovarian cancer

Primary Surgery



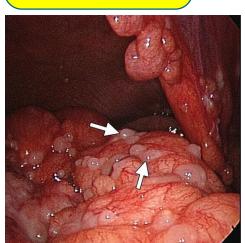
Chemotherapy

Chemotherapy

Interval Surgery

Chemotherapy







Consideration

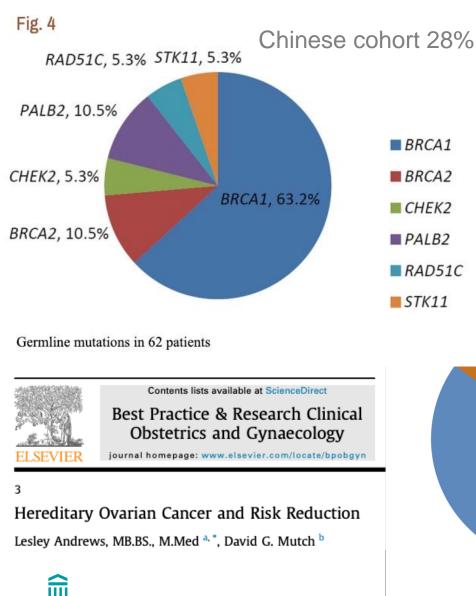
of PARPi

J Ovarian Res. 2019; 12: 80.

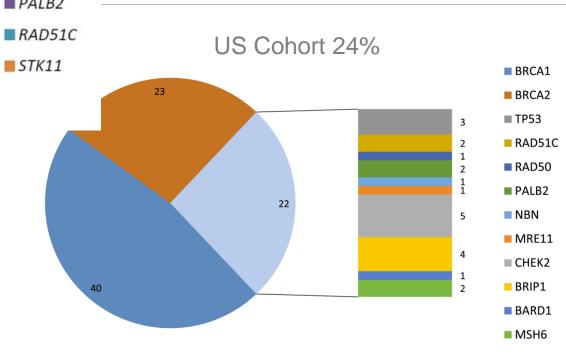
Published online 2019 Aug 31. doi: 10.1186/s13048-019-0560-y

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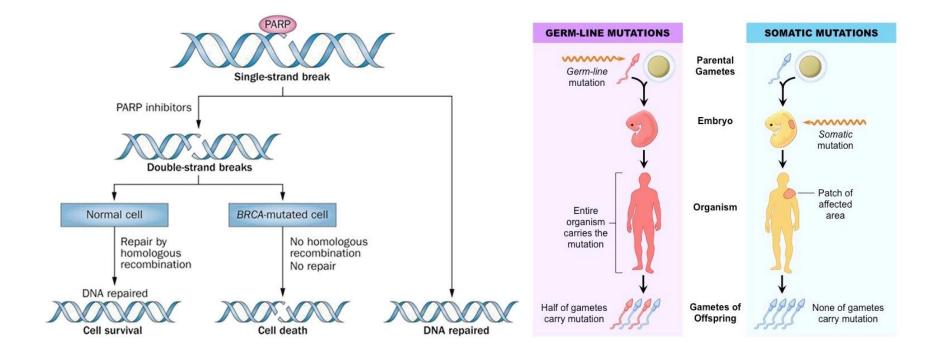
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Genetic Testing in Ovarian cancer Populations: A new normal



## Mechanism of DNA repair: the role of PARPi in homologous recombination (HR)





# Initial PARPi studies pointed to improved PFS

Study	Arms	<i>BRCA</i> mutant	HRD + (BRCAwt)	HRD neg	
VELIA Coleman N=1,140	<b>Veliparib</b> Placebo	34.7 mo** 22 mo (12 mo)	<b>22.9 mo</b> 19.8 mo (3 mo)	<b>15.0 mo</b> 11.5 mo (4.5 mo)	HR cutoff ≥33
PRIMA Gozalez-Martin N=733	<b>Niraparib</b> Placebo	22.1 mo** 10.9 mo (11 mo)	19.6 mo** 8.2 mo (7.5 mo)	8.1 mo** 5.4 mo (2.7 mo)	HR cutoff ≥42
PAOLA-1 Ray-Coquard N=806	<b>Olaparib +BEV</b> BEV	37.2 mo** 21.7 (15.5 mo)	28.1 mo** 16.6 mo (11.5 mo)	<b>16.9 mo</b> 16.0 mo (no diff)	HR cutoff ≥42
SOLO-1 Moore	<b>Olaparib</b> Placebo	>40 mo 13.8 mo (36 mo)			



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Age group affected

Types

20+ years

Serous tumor

 Mucinous tumor Endometrioid tumor

Clear cell tumor

Cvstadenofibroma

Brenner tumor

0-25+ years

Endodermal sinus

Chonocarcinoma

Teratoma

Dysgerminoma

All ages

Granulosa - theca

Fibroma

cell tumor

cell tumor

Sertoli – Levdiq



METASTASIS TO OVARIES

> 5% 5%

Variable

## Case 3

A 57 yo African American woman presents with new complaint of one episode of PMP bleeding. She is otherwise healthy. She has an u/s which reveals fibroids and an endometrial strip of 4.2 mm. Next steps might include?

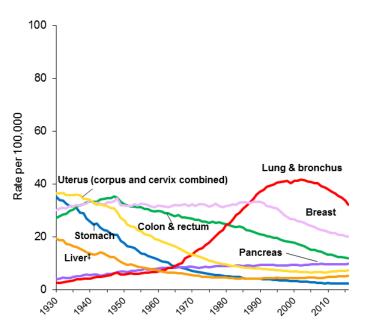


- A. Send her to a gynecologist
- B. Reassure her that this can be normal with fibroids
- C. Obtain an MRI
- D. Repeat the u/s in 3 months



## Key points on Endometrial cancer

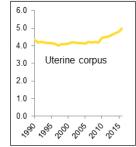
#### Trends in Cancer Death Rates\* Among Females, US,1930-2016



\*Age-adjusted to the 2000 US standard population.†Uterus includes uterine corpus and uterine cervix combined.‡Incliand other biliary.
NOTE: Due to International Classification of Diseases coding changes, numerator information for colorectal, liver, lung,

NOTE: Due to International Classification of Diseases coding changes, numerator information for colorectal, liver, lun ime.

Source: National Center for Health Statistics, Centers for Disease Control and Prevention, 2018

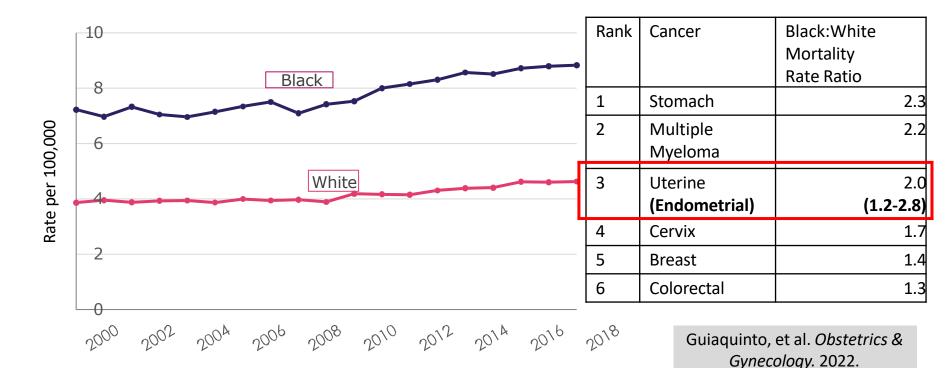


- Endometrial cancer is one of the only cancers where incidence is increasing
  - Early intervention equals improved survival
- Racial differences are now apparent and outcomes poorer



## US Uterine Cancer Statistics by Race/Ethnicity: Mortality

For Black women, uterine cancer mortality has >> ovarian cancer mortality since **2005.** 



Data from: SEER cancer statistics review 1975-2018, Available at: seer.cancer.gov

Giaquinto et al, CA: A Cancer Journal for Clinicians, 2022 Clarke et al, JAMA Oncology, 2022



#### JAMA Oncology | Original Investigation

# Estimated Performance of Transvaginal Ultrasonography for Evaluation of Postmenopausal Bleeding in a Simulated Cohort of Black and White Women in the US

Kemi M. Doll, MD, MS; Sarah S. Romano, MPH; Erica E. Marsh, MD; Whitney R. Robinson, PhD

#### **Key Points**

**Question** Do current guidelines that direct the use of transvaginal ultrasonography as a gateway to endometrial biopsy among women with postmenopausal bleeding perform differently by patient race?

**Findings** In this study of a simulated cohort of 367 073 Black and White women with postmenopausal bleeding, the use of 4-mm transvaginal ultrasonography endometrial thickness measurements to prompt biopsy resulted in a sensitivity of 47.5% among Black women compared with 87.9% among White women, with a negative predictive value of 92% among Black women vs 98% among White women.

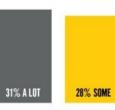
**Meaning** The findings of this study suggest that adherence to current clinical guidelines results in systematic underdiagnosis in Black women with endometrial cancer owing to measurement thresholds that fail to account for uterine fibroids and nonendometrioid histologic type.



# The cost of cancer: Financial toxicity in our patients

87% of survivors said their health care provider had NOT discussed the costs of cancer care

**59%**FACED
FINANCIAL
PROBLEMS



67%
DID NOT GET
HELP WITH
FINANCIAL
PROBLEMS



#### Common reasons for not getting help:

34% UNSURE WHERE TO GO OR WHO TO SEE

25% NOT KNOWING HELP WAS AVAILABLE

21% DOCTOR NOT MAKING A REFERRAL FOR HELP

21% NOT WANTING TO BOTHER ANYONE

#### Common types of financial problems:

64% MADE FINANCIAL SACRIFICES

59% USED RETIREMENT OR OTHER SAVINGS

39% COULD NOT COVER COSTS OF CARE

32% BORROWED MONEY OR WENT INTO DEBT

#### Worry and Distress Due to Financial Issues

**57%**FELT
FINANCIALLY
STRESSED



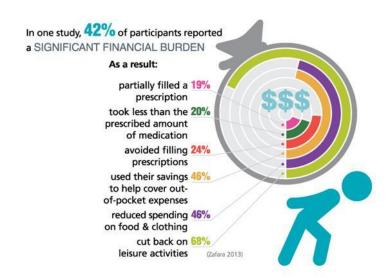






2015 Livestrong study







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#### INTERNATIONAL JOURNAL OF

### **GYNECOLOGICAL CANCER**

#### **Evaluating Meaningful Levels of Financial Toxicity in Gynecologic Cancers**

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Comprehensive Score for Financial Toxicity (COST) measures economic burden among patients with cancer<sup>1</sup>

0 - 44 scale, lower scores indicate worse financial toxicity



What level of financial toxicity correlates with meaningful cost-coping behaviors?



Analyzed survey data of patients with gynecologic cancer from Beth Israel Deaconess Medical Center (MA) and the University of Alabama at Birmingham (AL)

## Financial toxicity (FT) affects nearly half of patients with gynecologic cancer and is associated with cost-coping strategies







Economic cost-coping strategies (changing spending habits, borrowing money)

Behavioral cost-coping strategies (medication noncompliance)



1. de Souza JA, Yap BJ, Hlubocky FJ, et al. The development of a financial toxicity financial toxicity patient reported outcome in cancer: The COST measure. Cancer 2014;120(20):3245-53.

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### **Risk Factors for Financial Toxicity**

- Younger age
- Non-partnered marital status
- Black and Hispanic race and ethnicity
- Education level
- Employment/Income level
- Insurance type
- Surgery
- More imaging studies
- More outpatient visits



## <sup>53</sup>Additional References



### ASCCP.org

### ACOG:

- Updated Guidelines for Management of Cervical Cancer
   Screening Abnormalities. Practice Advisory October 2020
- ACOG Committee Opinion, Number 809. Obstetrics and Gynecology. Vol. 136, No. 2, August 2020

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