

**MOORES CANCER CENTER** Community Outreach and Engagement

# 2025 **CERVICAL CANCER** AWARENESS SUMMIT

# **SUMMIT REMINDERS**



<u>AUDIO & ZOOM</u> <u>CHAT</u>

Keep audio muted and feel introduce yourself/ask questions in the chat!



SUMMIT RECORDING

The summit slides and recording will be shared with all attendees



<u>CERVICAL CANCER</u> <u>QUALITY IMPROVEMENT</u> <u>LEARNING</u> <u>COLLABORATIVE</u>

Stay tuned! Sign up for our 2025 QI Learning Collaborative!



## AGENDA

- Welcome
- Patient Advocacy Acknowledgment
- The Cervical Cancer Landscape in 2025,
   Margaux Stack-Babich, UCSD Health
- Advances in Radiation Therapy
   Dr. Chika Nwachukwu, UCSD Health
- Guidelines 101 Understanding New HPV Testing Recommendations

Solution Strate Strate

• Screening Case Study

GMarlen Herrera, Neighborhood Healthcare

• **Glosing Remarks and Resources** 

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#### 2025 CERVICAL CANCER AWARENESS SUMMIT

Join us virtually for the latest data on cervical cancer in our community, featuring best practices for prevention & treatment from leading experts. Don't miss this free webinar -RSVP today!

12-1:30 PM PST
MONDAY, JANUARY 27TH

🖞 VIRTUAL VIA ZOOM

#### SUMMIT TOPICS INCLUDE:

The Cervical Cancer Landscape in 2025

Guidelines 101 – Understanding New HPV Testing Recommendations

Advances in Cervical Cancer Treatment

AND MORE!



# Welcome!

3rd Annual Cervical Cancer 📏 Awareness Summit





#### CERVIVOR

Honoring our Patient Advocates





#### MARGAUX STACK-BABICH, MPH

#### UC San Diego Moores Cancer Center, Community Outreach & Engagement

The 2025 Cervical Cancer Landscape

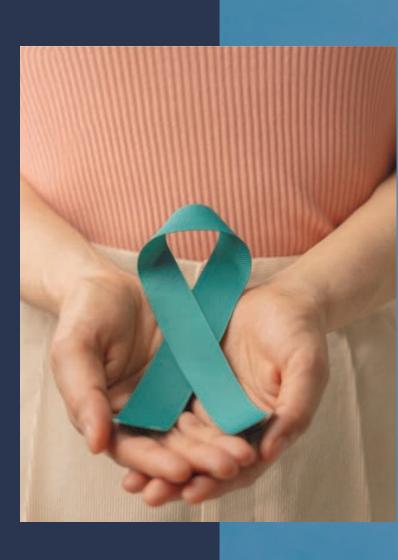


### UC San Diego

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# THE STATE OF CERVICAL CANCER IN 2025

Margaux Stack-Babich, MPH January 27th, 2025



# AGENDA

- The Global Burden of Cervical Cancer
- Cervical Cancer in...
  - The United States
  - California
  - San Diego
- Addressing the Cervical Cancer in Burden in Our Community

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# CERVICAL CANCER GLOBAL SNAPSHOT

# 660,000+

cervical cancer cases were diagnosed *globally* 

# 350,000+

lives were lost to cervical cancer globally

## 99.7%

cervical cancer cases are caused high-risk human papillomavirus (HPV) infection

World Health Organization. (n.d.). Cervical cancer. World Health Organization. https://www.who.int/news-room/fact-sheets/detail/cervical-cancer#:~:text=Cervical%20cancer%20is%20the%20fourth,350%20000%20deaths%20in%202022.



### TODAY'S CERVICAL CANCER LANDSCAPE

Death rates from cervical cancer (CC) have dropped significantly in the last 40 years due to regular <u>Pap tests</u> finding cervical precancer before it turns into cancer.

No woman should die of cervical cancer

Screening leads to fewer deaths

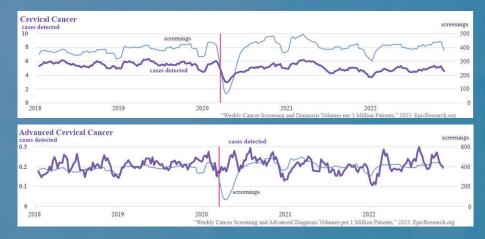
CCR, 2020 https://www.ccrcal.org/learn-about-ccr/ Joung RH, Mullett TW, Kurtzman SH, et al. Evaluation of a National Quality Improvement Collaborative for Improving Cancer Screening. JAMA Netw Open. 2022;5(11):e2242354. doi:10.1001/jamanetworkopen.2022.42354

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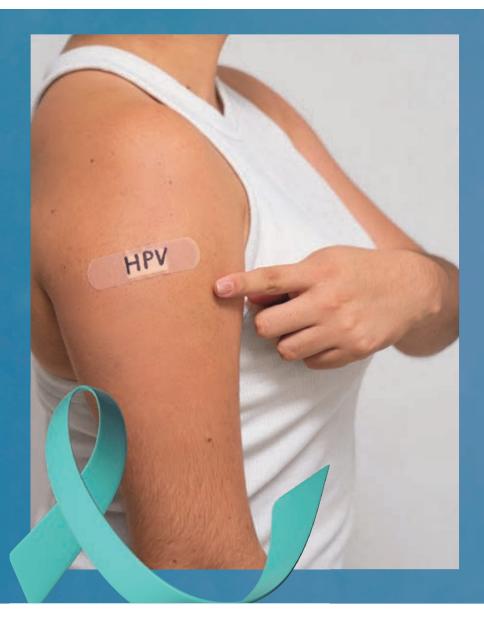
But concerningly, CC death rates in the US have stagnated, and in some regions <u>increased</u>, in recent years. Incidence rates are also increasing in 30-44yos [ACS 2024]:

- In a study published in the International Journal of Gynecological Cancer, almost **30,000** individuals were diagnosed with <u>late-stage</u> cervical cancer between 2001 to 2018
  - Estimated 2025 Diagnoses: 13,360 [ACS]
  - Estimated 2025 Deaths: 4,320 [ACS]



"IT MIGHT TAKE YEARS TO FULLY REALIZE THE IMPACT OF MISSED SCREENINGS"

Alban C, Sahakian S, Allen S, Stamp T. Missed Cancer Screenings Not Yet Associated with Increased Cancer Rates or Severity. Epic Research. https://epicresearch.org/articles/missed-cancer-screenings-not-associated-with-increased-cancer-rates-orseverity. Accessed on January 15, 2025.



### CERVICAL CANCER IN THE UNITED STATES

- Cervical cancer incidence rates are *decreasing* steeply in women in their 20s, having decreased 11% per year in women age 20-24 from 2012 through 2021, reflecting prevention by HPV vaccination
- However, cases have increased in women 30-44 years old by 1.7% per year from 2012 through 2019, highlighting the need for more emphasis on screening as well as broader uptake of the vaccine
- If diagnosed early, cervical cancer is highly treatable with a 5 year survival of 91%

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## **CERVICAL CANCER** SCREENING IN THE US, CONT.

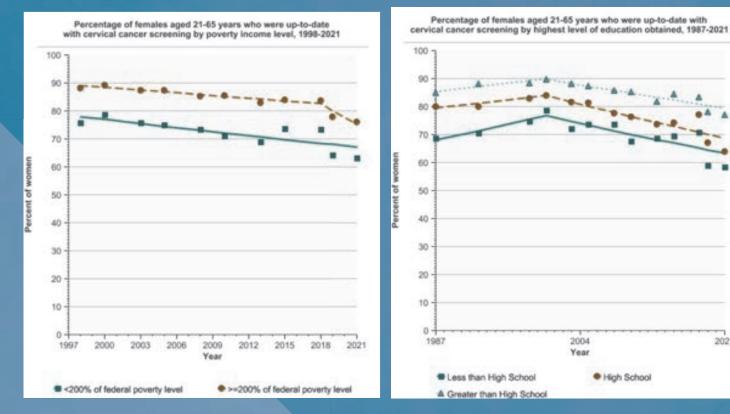
#### **Healthy People 2030 Cervical Cancer Screening Goal: 79.2**%

2021

2004

Year

High School



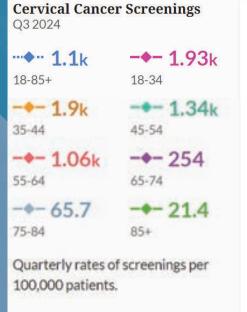
- Even at a national level, significant disparities in screening participation are seen by income level and education attainment
  - <200% of federal poverty</li> level - 63.3% up-to-date with screening
  - >=200% of federal poverty level - 76% up-to-date
  - Less than High School -58.4%
  - High School **63.9%**
  - Greater than High School -77.2%

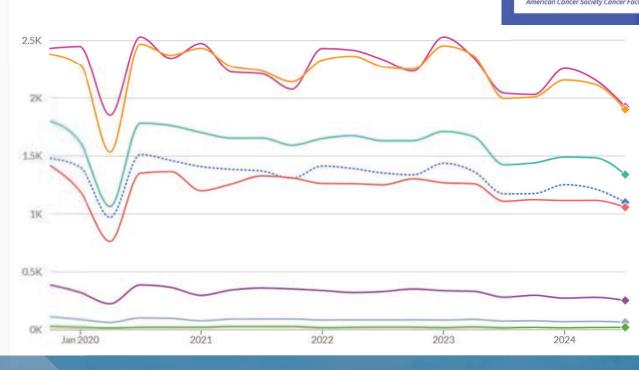
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Cervical cancer prognosis and survival rates. NCI. (n.d.). https://www.cancer.gov/types/cervical/survival

## CERVICAL CANCER SCREENING IN THE US CONT.

3K





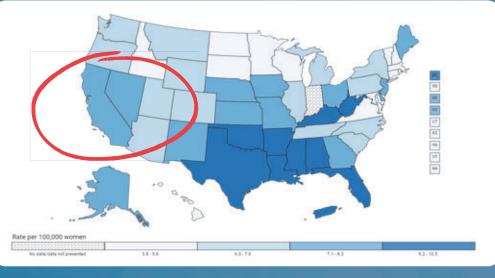
American Cancer Society American Cancer Society American Society Society American Society Society American Society Soc

American Cancer Society Cancer Facts & Figures 2024

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# **CERVICAL CANCER IN CALIFORNIA**

#### **Rate of New Cancers in the United States, 2021** *Cervix, All Ages, All Races and Ethnicities, Female*



020 BRFSS Survey DataMapuric FB, Islam MM, Hofer BM, Movisiyan AS, Morris CR, Parikh-Patel A, Keegan THM, Wun T. Heat Maps: Trends in Late-Stage Diagnoses of Screen-Detectable Cancers in alifornia Counties, 2000-2018. Sacramento, CA: California Cancer Reporting and Epidemiologic Surveillance Program, University of California Davis Comprehensive Cancer Center, University of alifornia Davis, June 2021.

State Cancer Profiles. State Cancer Profiles > Screening and Risk Factors Table. (n.d.).

Centers for Disease Control and Prevention. (n.d.). USCS data visualizations - CDC. Centers for Disease Control and Prevention

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- California cervical cancer screening rate in past 3 years, ages 21-65, 2020 data: **79.3%** 
  - Slightly above nat'l average, but still below goal
  - Average hides disparities across communities
- From 2000 to 2018 the percentage of cervical cancer cases diagnosed at a late-stage increased. In the most recent 10yr period, the proportion diagnosed latestage remained high (52.6% to 57.9%) and relatively unchanged.
- Nearly 1 in 5 new cervical cancers diagnosed from 2009-2018 were in women 65+ (*outside of screening*).
  - More of these women (71%) presented with latestage disease than younger women (48%).
  - Suggests "women have not been adequately screened prior to the upper age cutoff [of 65]."

Age-Adjusted Annual Incidence Rate (Cases per 100,000) 4.6 to 5.7 5.7 to 7.3 to 7.3

Incidence Rates for California by County

### CERVICAL CANCER IN SAN DIEGO

#### **2021 Statistics**

- 115 cases in 2021
- 45% of cases in Hispanic/Latine individuals (up from 38%)
- 11% in Asian/Asian American individuals (down from 15%)
- **85% of cases were in ages 18-64**; 15% were aged 65+

California Cancer Registry, California Department of Public Health. Maguire FB, Islam MM, Hofer BM, Movsisyan AS, Morris CR, Parikh-Patel A, Keegan THM, Wun T. Heat Maps: Trends in Late-Stage Diagnoses of Screen-Detectable Cancers in California Counties, 2000-2018. Sacramento, CA: California Cancer Reporting and Epidemiologic Surveillance Program, University of California Davis Comprehensive Cancer Center, University of California Davis, June 2021.

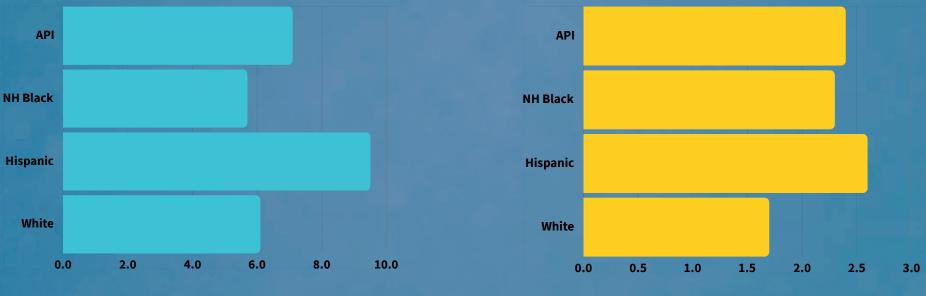
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	American Indian / Alaska Native	Asian / Pacific Islander	Non- Hispanic Black	Hispanic	Non- Hispanic White
California County	Rate per 100,000	Rate per 100,000	Rate per 100,000	Rate per 100,000	Rate per 100,000
San Diego County	* <u>a</u>	7.1	5.7	9.5	6.1

### **CERVICAL CANCER IN SAN DIEGO CONT.**

#### CERVICAL CANCER INCIDENCE IN SAN DIEGO COUNTY, RATE PER 100,000 INDIVIDUALS (2012-2021)

#### CERVICAL CANCER MORTALITY IN SAN DIEGO COUNTY, RATE PER 100,000 INDIVIDUALS (2012-2021)



CCR, 2020 https://www.ccrcal.org/learn-about-ccr/

Although cases were not high enough to determine local incidence and mortality rates in San Diego County, national data shows American Indian and Alaska Natives are nearly 2x as likely to develop cervical cancer compared to white women and 4x as likely to die from it.

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### OUR SAN DIEGO HRSA CERVICAL SCREENING RATES

CC HRSA 2017	CC HRSA 2018	CC HRSA 2019	CC HRSA 2020	CC HRSA 2021	CC HRSA 2022	CC HRSA 2023
59.22%	57.59%	48.31%	36.47%	38.82%	49.95%	
56.47%	62.70%	64.81%	64.12%	58.29%	59.91%	61.28%
58.28%	57.44%	56.74%	51.96%	55.34%	55.99%	55.63%
74.92%	66.25%	64.91%	56.00%	60.08%	56.18%	60.87%
56.22%	63.69%	70.56%	51.39%	65.50%	67.17%	73.58%
66.12%	74.85%	71.41%	65.70%	65.91%	61.97%	68.18%
60.20%	63.51%	67.04%	61.48%	63.23%	64.14%	65.22%
44.82%	48.65%	48.20%	55.69%	55.22%	63.57%	69.27%
39.46%	38.10%	43.75%	51.04%	14.18%	43.62%	33.08%
60.96%	62.57%	62.82%	67.00%	65.00%	65.20%	65.57%
32.83%	32.04%	24.90%	20.08%	17.50%	15.99%	14.86%
56.67%	62.58%	67.24%	56.94%	67.41%	70.00%	73.59%
55.51%	57.50%	57.56%	53.16%	52.21%	56.149	58.28%

*Cumulatively, screening rates for San Diego federally qualified health centers increased 2.14% from 2022 to 2023* 

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### IMPROVING PREVENTION IN SAN DIEGO: HPV VACCINATION & SCREENING

100-

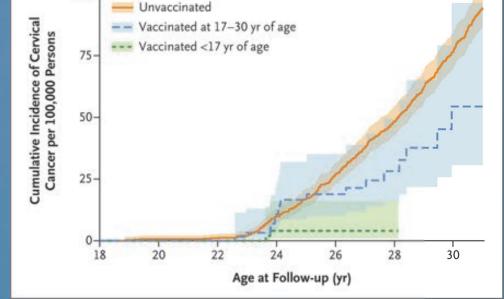
#### HPV vaccination is cervical cancer prevention

Cervical cancer incidence rates dropped by 65% from 2012 through 2019 in women age 20-24 years.



This age group was the first to receive the HPV vaccine. This decline foreshadows steep reductions in HPV-associated cancers.

who Carlow Facto A Piguren 2022



**HPV Vaccination Status** 

UC San Diego MOORES CANCER CENTER Community Outreach and Engagement **Takeaway?** The HPV vaccine works – comprehensive vaccination of youth is cervical cancer prevention in the next generation, and catch-up vax/on time screening for older cohort not eligible for HPV vaccine

Lei, J., Ploner, A., Elfström, K. M., Wang, J., Roth, A., Fang, F., Sundström, K., Dillner, J., & Sparén, P. (2020). HPV vaccination and the risk of invasive cervical cancer. New England Journal of Medicine, 383(14), 1340-13

### **KEY TAKEAWAYS**

Any person with a cervix is at risk for cervical cancer. But our richly diverse community of the SD border region is home to multiple, intersecting populations that face increased risk of cervical cancer

#### Suggested Strategies

- Community Outreach via CHWs and Promotoras in the area
- Patient Navigation
- Provider
   Training/Telemonitoring
- Accessible and free health screenings

Cervical cancer screening rates have not fully recovered from pandemic drops, increasing risk for under-screened women.

• Without action, precancers & cancers will go undetected.

Improving outreach & care delivery through quality improvement can improve screening uptake.

• Team-wide, multi-level interventions are most comprehensive for improving screening delivery and managing abnormal results for all patients.

Everyone has a role in making San Diego cervical cancer free!

03.

02.

01.

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# THANK YOU!

Margaux Stack-Babich, MPH mstackba@health.ucsd.edu





### JYOTI MAYADEV, MD

#### UC San Diego Health, Radiation Oncologist and Professor of Radiation Medicine and Applied Sciences

Advances in Cervical Cancer Treatment



# ADVANCES IN CERVICAL CANCER TREATMENT

Jyoti Mayadev, MD Professor, Radiation Medicine and Applied Sciences Assistant Vice Chair, Developmental Therapeutics Director of Gynecologic Brachytherapy University of California, San Diego



# Disclosures

 Consulting/Honorarium: Merck, AstraZeneca, Primmune, Varian Medical Systems, Agenus Bio, KORTUC

#### • Grants:

- NCI: RO1: 2.5M (Zamarin/Mayadev)
- R50: 887K (Mayadev)
- Curebound (Mayadev/Advani/Eskander/Vijayanand)
- NRG Oncology
- MCC CCSG funding

#### Outline

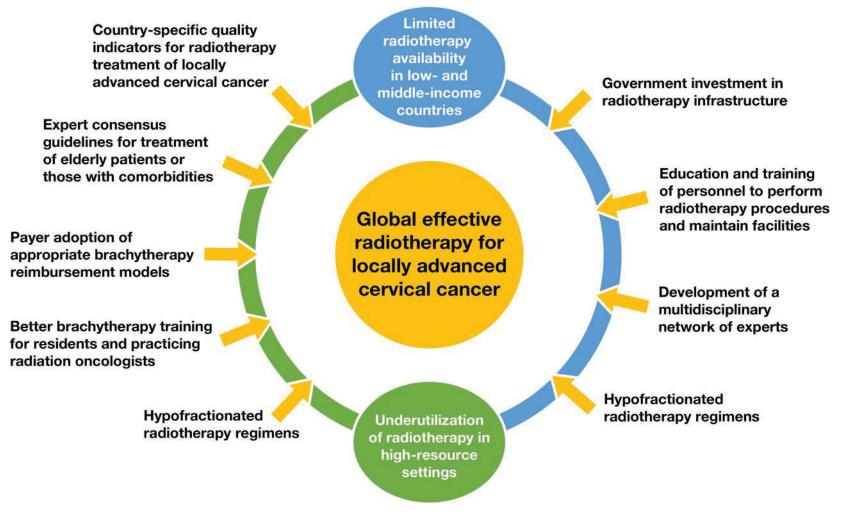


KEY ADVANCES IN CERVICAL CANCER THERAPEUTIC STRATEGY IN NODE POSITIVE

FUTURE DIRECTIONS



### Challenges and solutions to achieving effective radiotherapy for locally advanced cervical cancer.



Mayadev et al. Int J Gynecol Cancer 2022;32:436-445

GYNECOLOGICAL CANCER

### WHO 2020 Initiative to Eradicate Cervical Cancer

- 4 or fewer per 100 000 women
- Yr 2030 to put all countries :
- 90% of girls vaccinated with the HPV vaccine by age 15
- 70% of women screened with a high-quality test by ages 35 and 45
- 90% of women with cervical disease receiving treatment.



#### 

SUBSCRIBE FOR \$1/WEEK

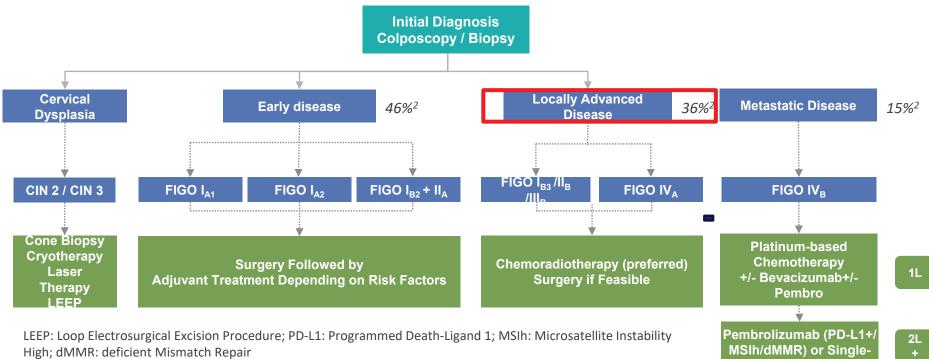
### An Alternative to the Pap Smear Is Here, No Speculum Required

Starting this fall, women will be able to use a simple swab to screen for cervical cancer. The method offers an alternative to a procedure that many dread — and promises to address disparities in who develops the disease.

Listen to this article · 9:13 min Learn more



#### **Cervical Cancer: Summary of Treatment**



LEEP: Loop Electrosurgical Excision Procedure; PD-L1: Programmed Death-Ligand 1; MSIh: Microsatellite Instability High; dMMR: deficient Mismatch Repair

<sup>1</sup> NCCN Cervical Cancer Guidelines v2.2019

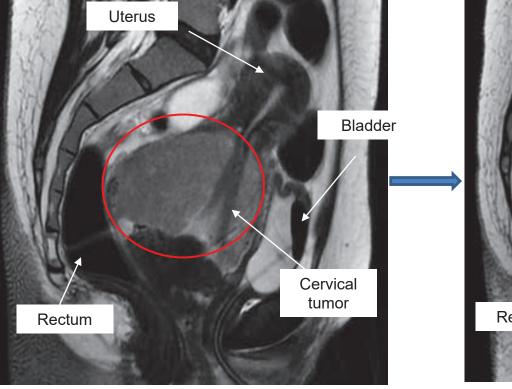
<sup>2</sup> SEER Cancer Stat Facts: Cervical Cancer. National Cancer Institute. Bethesda, MD

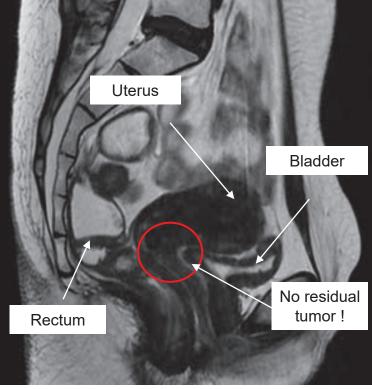


MSIh/dMMR) or Single-

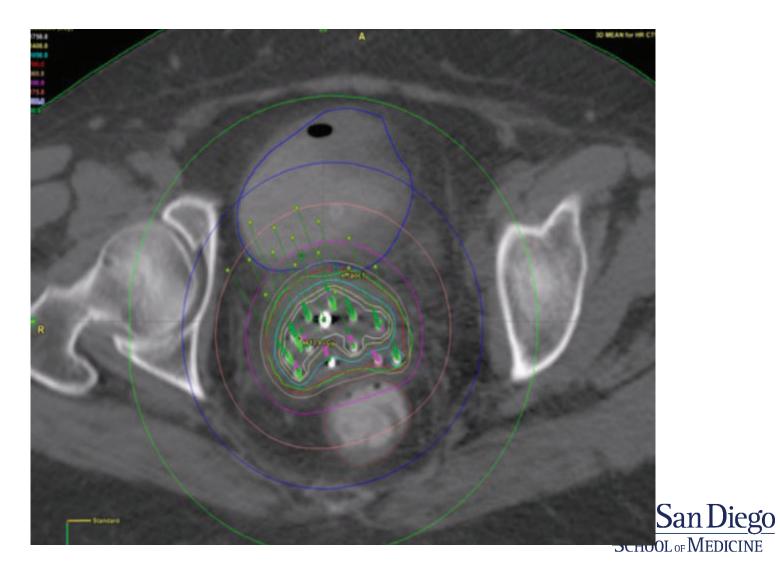
agent Chemotherapy

# Sustained treatment effect for all?



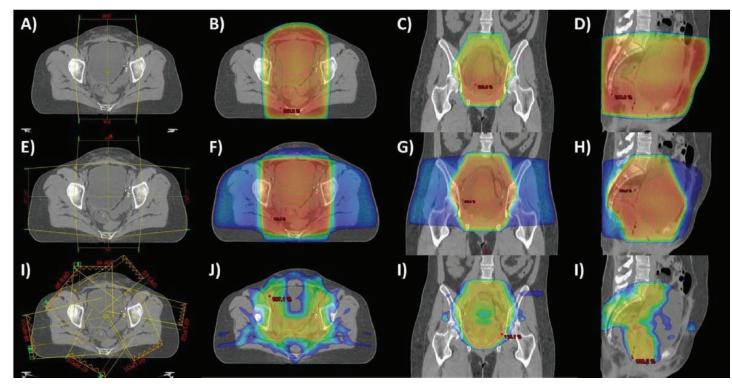


#### After chemoradiaiton



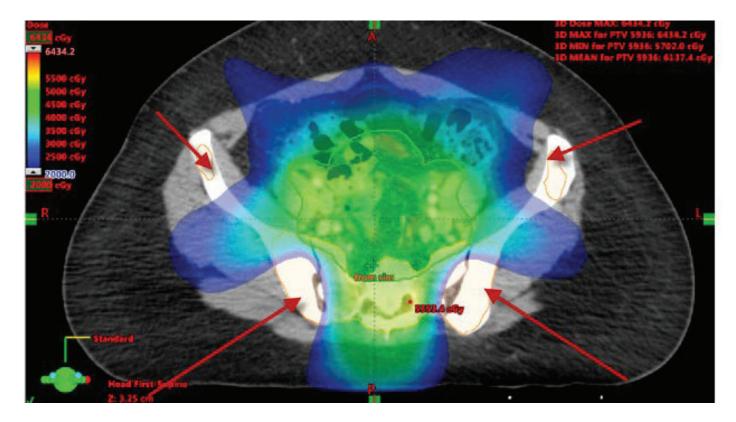
# **Radiation Strides: IMRT**

 Dosimetric/clinical evidence, IMRT can reduce gastrointestinal, genitourinary, and hematological toxicities compared with 3D-conformal radiotherapy



Hymel et al. Critical Reviews in Hem/Onc doi:10.1016/j.critrevonc.2014.12.015

# IMRT: Technological Advances Through Clinical Trials







Mell et al. Int J Radiation Oncol Biol Phys 2017 Mundt et al. Int J Radiat Oncol Biol Phys. 2002

# **ARTIA Cervix Adaptive Trial**

ARTIA-Cervix (VAR-2021-04) Protocol Document



#### STUDY SCHEMA

Stage IB2-IVA cervical cancer (without pelvic lymph nodes)

Adaptive IMRT Planning

- Total dose: 4500 cGy / 25 fx
- Optional parametrial boost (not to exceed 960cGy) will be administered after complete delivery of primary EBRT prescription

Baseline patient reported outcomes (PRO) prior to EBRT

Ethos daily adaptive EBRT (25 fx as prescribed, 5 fx/week) Standard of care concurrent Cisplatin chemotherapy (weekly)

Week 5 EBRT PRO (~ fx23-25, to be completed prior to BT & PMB)

Optional parametrial boost (PMB) per discretion of treating physician

Standard of care Image guided brachytherapy (BT)



#### Definitions

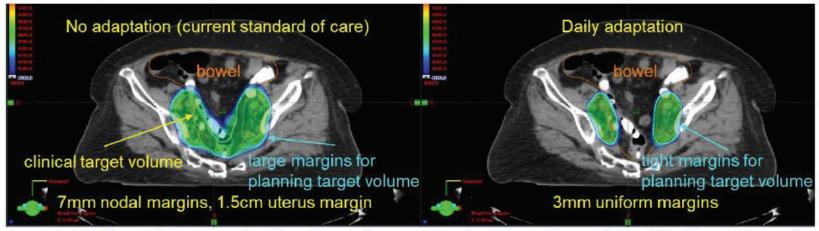
BT: Brachytherapy EBRT: External beam radiation therapy IMRT: Intensity modulated radiation therapy PMB: Parametrial boost PRO: Patient reported outcome

Follow-up PRO (3,12,24 months)

Mayadev et al, IJROBP ; Issue 2, supplement e533, October 01, 2023

PI: Mayadev, ARTIA: Varian industry study, multi institutional

# Adaptive Radiation Cervical Cancer



Bowel dose reduction from decreasing treatment margins. The 3 mm margins on the right can only be safely accomplished with daily adaptation to internal anatomical changes.

Mayadev et al, IJROBP; Issue 2, supplement e533, October 01, 2023

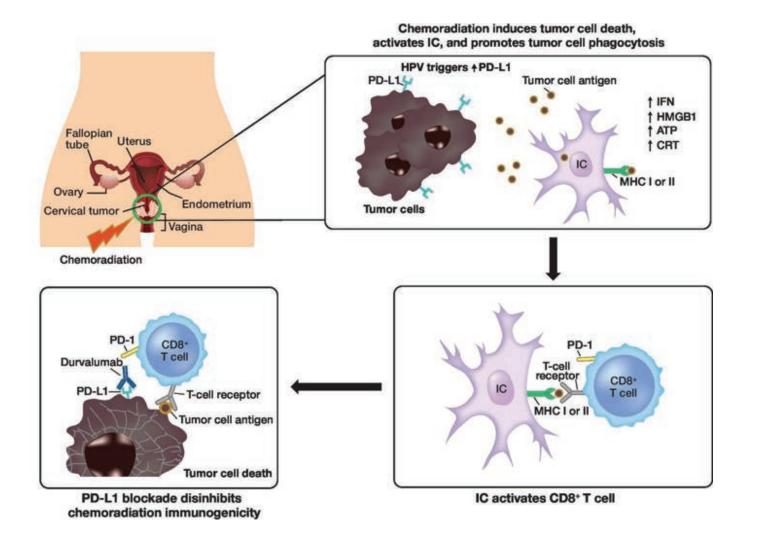


Figure 1; Mayadev et al., IJGC Vol 30, 2019 https://doi.org/10.1136/ijgc-2019-001135 GOG 9929: A PHASE I TRIAL OF SEQUENTIAL IPILIMUMAB AFTER CHEMORADIATION FOR THE PRIMARY TREATMENT OF PATIENTS WITH LOCALLY ADVANCED CERVICAL CANCER STAGES IB2/IIA WITH POSITIVE PARA-AORTIC LYMPH NODES ONLY AND STAGE IIB/IIIB/IVA WITH POSITIVE LYMPH NODES

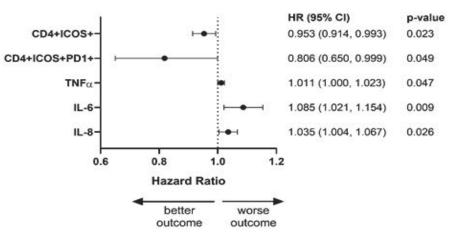
Jyoti Mayadev, M.D. (Principal Investigator): NCI funded Russell Schilder, M.D. (Mentor) William Brady, PhD. (NRG Statistics) Diane DaSilva, PhD. (Translational Component)

# GOG 9929 Results

- 34 pts enrolled, 21 received at least 2 doses of ipi
- There were 2 pts/19 pts (9.5%) with acute grade 3 toxicity (lipase, rash), which self-resolved.
- Most of the acute toxicities were grade 1-2 GI distress, rash, endocrinopathies.
- 1 year OS 90%, PFS 81%.
- There was no difference in CD4 and CD8 T cell levels nor CTLA-4 expression with sequential ipi.
- CRT itself increased ICOS and PD-1 expression.

# **Immune Related Biomarkers**

- PDL-1
- Immune



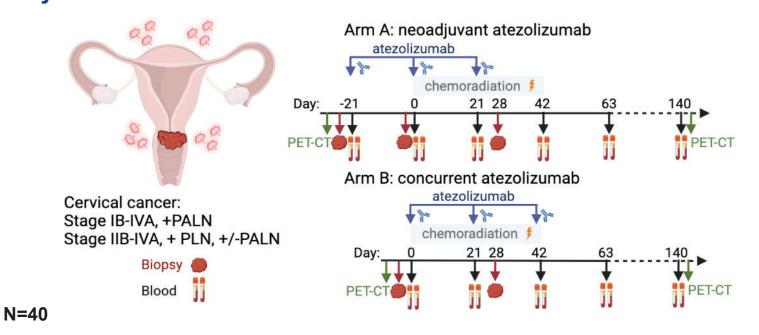
**Figure 1.** Association of changes in immune biomarkers with progression-free survival on GOG-9929. Increased changes (baseline to post-CRT values) in immune parameters were related to PFS using adjusted Cox proportional hazards models. Figure shows hazard ratios with 95% confidence intervals (lower limit, upper limit) and associated p-values for statistically significant associations found for immune activation markers and plasma cytokines. Expansion of the CD4+ICOS+ and CD4+ICOS+PD-1+ subsets post-CRT are associated with lower risk of progression while increases in inflammatory cytokines TNFa, IL-6, and IL-8 post-CRT are associated with higher risk of tumor progression.

DaSilva, Enserro, Mayadev et al. Clinical Cancer Research Nov 2020

## NRG GY017: ANTI PD-L1 (ATEZOLIZUMAB) AS AN IMMUNE PRIMER AND CONCURRENTLY WITH EXTENDED FIELD CHEMORADIOTHERAPY FOR NODE POSITIVE LOCALLY ADVANCED CERVICAL CANCER

PI: Jyoti Mayadev, MD Translational PI: Dmitriy Zamarin, MD, PhD Collaboration CRADA: Genentech Adaptive Biotechnologies FUNDED: NCI/CTEP NCI: CRDL AWARD: Mayadev

# NRG-GY017: Neoadjuvant Atezolizumab and concurrent vs. concurrent with chemoradiation in patients with locally-advanced high-risk cervical cancer PI: Mayadev



# In each arm, atezolizumab was administered for a total of 3 doses with no maintenance

Mayadev et al., Nature Communications, Jan 2025

#### **NRG-GY017: Patient and tumor characteristics**

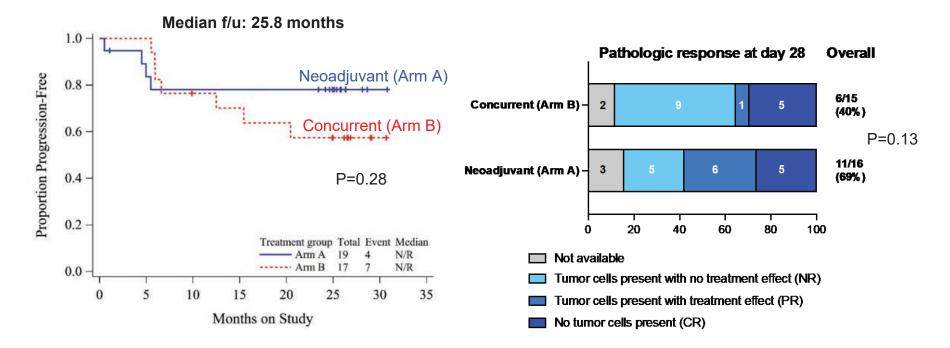
	Arm A	Arm B	Total	p value
	(neoadjuvant)	. ,	(n=36)	
Age (median, min-max)	(n=19) 56 (35-71)		47.5 (24-71)	<0.0E
Ethnicity	50 (55-71)	43 (24-00)	47.3 (24-71)	< 0.05
,	7 (26 90/)	1 (5.9%)	0 (22 20/)	<0.05
Hispanic or Latino	7 (36.8%)	1 (5.9%)	8 (22.2%)	
Not Hispanic or Latino	11 (57.9%)	16 (94.1%)	27 (75.0%)	
Not Reported	1 (5.3%)	0 (0.0%)	1 (2.8%)	
Race				ns
Black or African American	3 (15.8%)	4 (23.5%)	7 (19.4%)	
White	14 (73.7%)	13 (76.5%)	27 (75.0%)	
Not Reported	2 (10.5%)	0 (0.0%)	2 (5.6%)	
Performance status				ns
0	13 (68.4%)	13 (76.5%)	26 (72.2%)	
1	6 (31.6%)	4 (23.5%)	10 (27.8%)	
Histology				ns
Adenocarcinoma NOS	4 (21.1%)	1 (5.9%)	5 (13.9%)	
Adenosquamous	1 (5.3%)	2 (11.8%)	3 (8.3%)	
Squamous Cell Carcinoma	14 (73.7%)	14 (82.4%)	28 (77.8%)	
FIGO stage				ns
IB	3 (15.8%)	3 (17.6%)	6 (16.7%)	
IIB	12 (63.2%)	10 (58.8%)	22 (61.1%)	
IIIB	3 (15.8%)	4 (23.5%)	7 (19.4%)	
IVA	1 (5.3%)	0 (0.0%)	1 (2.8%)	

	Arm A (neoadjuvant)	Arm B (concurrent)	Total	p value
	(n=19)	(n=17)	(n=36)	
Baseline PET/CT median SUV max for cervix	18.85	16.5	18.3	
Para-aortic lymph node metastases (PET/CT)				0.29
No	7 (36.8%)	10 (58.8%)	17 (47.2%)	
Yes	9 (47.4%)	5 (29.4%)	14 (38.9%)	
Not available	3 (15.8%)	2 (11.8%)	5 (13.9%)	
Pre-treatment PD-L1 (SP263) <u>immune</u> score				0.59
Negative (<1%)	2 (10.5%)	3 (17.6%)	5 (13.9%)	
Positive (≥1%)	8 (42.1%)	9 (52.9%)	17 (47.2%)	
missing	9 (47.4%)	5 (29.4%)	14 (38.9%)	
Pre-treatment PD-L1 (SP263) <u>tumor cell s</u> core				0.02
Negative (<1%)	7 (36.8%)	2 (11.8%)	9 (25.0%)	
Positive (≥1%)	3 (15.8%)	10 (58.8%)	13 (36.1%)	
missing	9 (47.4%)	5 (29.4%)	14 (38.9%)	

\*4 patients were randomized, but never received study treatment and were not eligible for the analyses.

#### Arm A (neoadjuvant) enrolled patients that were likely to be older, Hispanic or Latino, had lower PD-L1 tumor cell positivity, and had a higher proportion of PALN positivity\* (\*not statistically significant)

#### **Clinical outcomes**



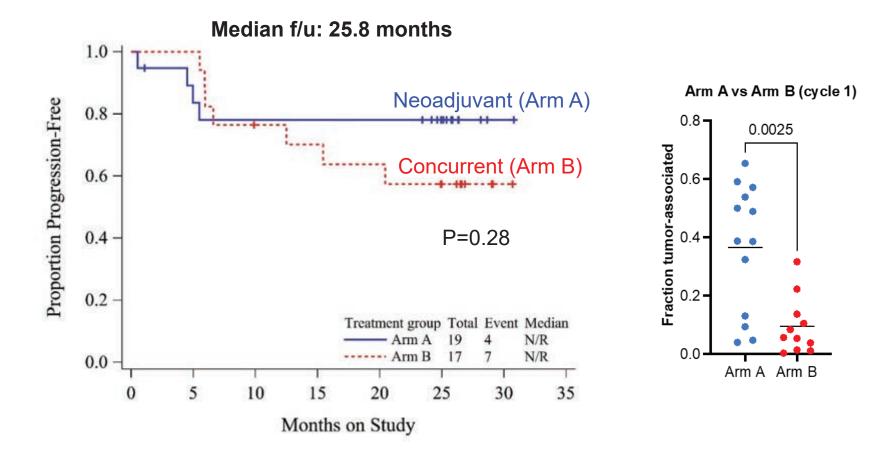
\*Pathologic response assessment was performed after 3 doses of atezolizumab in Arm A vs. 2 doses of atezolizumab in arm B.

Spearman correlation coefficient between pathological response and 2-year DFS: 0.55 (p=0.0018)

There was no statistically-significant association between pre-treatment PD-L1 score and clinical outcomes.

Mayadev SGO 2022 Plenary ; Zamarin SGO 2023 Plenary

#### **NRG GY017 Results**

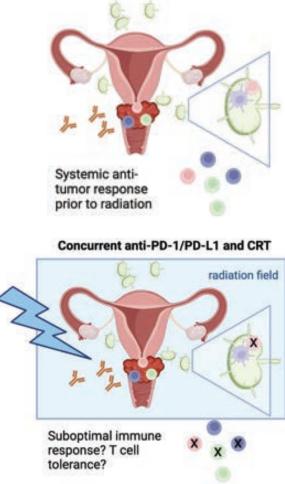


Mayadev et al., Nature Communications Jan 2025

#### **Summary and conclusions**

- Administration of atezolizumab with CRT resulted in a favorable 2-year DFS in both arms, with the atezolizumab priming arm (Arm A) trending toward superior pathological response and DFS.
- Neoadjuvant administration of atezolizumab led to early systemic expansion of tumor-associated TCR clones, possibly indicative of early systemic anti-tumor response
- CRT had minimal impact on tumor-associated TCR clones in concurrent CRT arm (Arm B) and resulted in contraction of atezolizumab-expanded tumor-associate TCR clones in Arm A, potentially implying deleterious consequences for the immune response

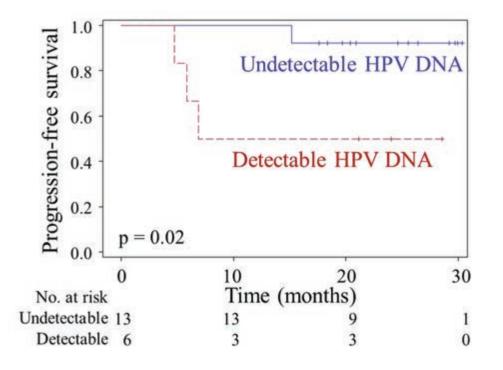




Mayadev SGO 2022 Plenary ; Zamarin SGO 2023 Plenary

# ctDNA as a predictor for response

- Circulating tumor-derived HPV DNA as a predictive and prognostic biomarker in locally advanced node positive cervical cancer
- Data in HN SCCA ctDNA predictive for recurrence



Han et al, JCO Prec Oncol, 2018; 2:1-8

NCI R01 Subaward (Mayadev 2023-2026): Prediction of ctDNA in locally advanced cervical cancer using biospecimens from NRG GY017

### CALLA Study Design

#### 15 countries, 120 sites

#### **Eligible population**

- Women aged ≥18 years
- Histologically confirmed cervical adenocarcinoma, squamous carcinoma, or adenosquamous carcinoma
- High-risk LACC (FIGO 2009)
  - Stages IB2 to IIB, node positive (N≥1)
  - Stages IIIA to IVA with any node (N $\geq$ 0)
- WHO ECOG performance status of 0 or 1

#### **Stratification factors**

#### Disease stage

- FIGO Stage IB2-IIB and LN+
- FIGO Stage ≥III and LN–
- FIGO Stage ≥III and LN+
- Region of world

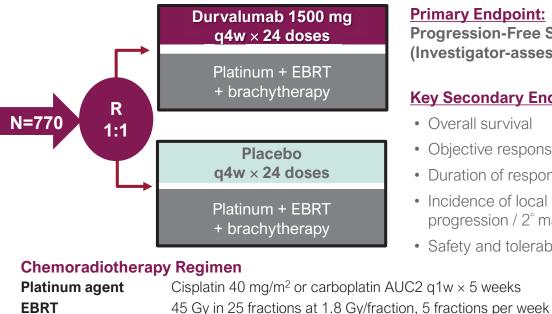
#### **Key Milestones**

First patient in February 2019 Last patient in December 2020 Data cutoff January 20, 2022 <sup>a</sup>According to RECIST 1.1 or histopathologic confirmation of local tumor progression.

High-dose rate: 27.5–30 Gy; Low/pulsed-dose rate: 35–40 Gy

Monk (first) Mayadev (senior) Lancet Oncology Dec 2023

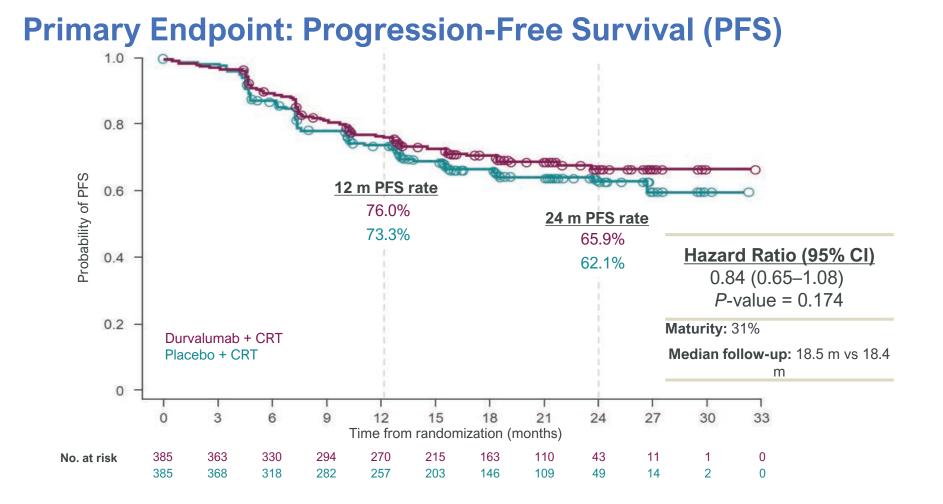
**Brachytherapy** 



**Primary Endpoint: Progression-Free Survival**<sup>a</sup> (Investigator-assessed)

#### **Key Secondary Endpoints:**

- Overall survival
- Objective response rate
- Duration of response
- Incidence of local or distant progression / 2° malignancy
- Safety and tolerability



Monk (first) Mayadev (senior) Lancet Oncology Dec 2023

#### **Early- and Late-Onset Radiotherapy Toxicities**

<u>Lany-Onset (21 year after last date of K1)</u>				
	Durvalumab + CRT (n = 385)		Placebo + CRT (n = 384)	
MedDRA Preferred Term >5% in both arms	All Grade n (%)	Grade ≥3 n (%)	All Grade n (%)	Grade ≥3 n (%)
Any AE possibly related to EBRT, BT, or both	291 (75.6)	116 (30.2)	287 (74.7)	106 (27.6)
Diarrhea	124 (32.2)	4 (1.0)	135 (35.2)	0 (0.0)
Anemia	106 (27.5)	43 (11.2)	108 (28.1)	32 (8.3)
Nausea	71 (18.4)	3 (0.8)	78 (20.3)	0 (0.0)
Neutrophil count decreased	59 (15.3)	22 (5.7)	70 (18.2)	27 (7.0)
White blood cell count decreased	60 (15.6)	37 (9.6)	70 (18.2)	40 (10.4)
Decreased appetite	44 (11.4)	4 (1.0)	36 (9.4)	0 (0.0)
Vomiting	44 (11.4)	1 (0.3)	51 (13.3)	1 (0.3)
Platelet count decreased	37 (9.6)	7 (1.8)	51 (13.3)	9 (2.3)
Neutropenia	28 (7.3)	14 (3.6)	28 (7.3)	8 (2.1)
Constipation	23 (6.0)	0 (0.0)	27 (7.0)	0 (0.0)
Weight decreased	23 (6.0)	1 (0.3)	26 (6.8)	1 (0.3)

#### Early-onset (≤1 year after last date of RT)

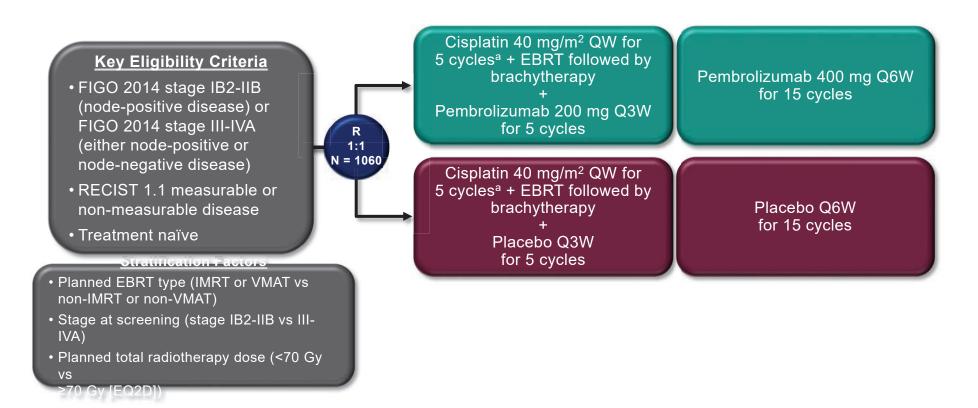
#### Late-onset (>1 year after last date of RT)

	Durvalumab + CRT (n = 385)		Placebo + CRT (n = 384)	
MedDRA Preferred Term ≥1% in any arm	All Grade n (%)	Grade ≥3 n (%)	All Grade n (%)	Grade ≥3 n (%)
Any AE possibly related to EBRT, BT or both	37 (9.6)	7 (1.9)	36 (9.4)	4 (1.0)
Rectal hemorrhage	5 (1.3)	0 (0.0)	1 (0.3)	0 (0.0)
Gastroenteritis radiation	5 (1.3)	0 (0.0)	1 (0.3)	1 (0.3)
Radiation proctitis	4 (1.0)	1 (0.3)	6 (1.6)	0 (0.0)
Urinary incontinence	4 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cystitis radiation	0 (0.0)	0 (0.0)	4 (1.0)	2 (0.5)
Urinary tract infection	2 (0.5)	1 (0.3) <sup>a</sup>	0 (0.0)	0 (0.0)

<sup>a</sup> Grade 5 event.

Mayadev et al., ASTRO 2022 Plenary

### ENGOT-cx11/GOG-3047/KEYNOTE-A18: Randomized, Double-Blind, Phase 3 Study



<sup>a</sup>A 6<sup>th</sup> cycle was allowed per investigator discretion. EBRT, external beam radiotherapy; FIGO, International Federation of Gynecology and Obstetrics; Gy, grays; IMRT, intensity-modulated radiotherapy; Q3W, every 3 weeks; Q6W, every 6 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; VMAT, volumetric-modulated arc therapy. ENGOT-cx11/GOG-3047/KEYNOTE-A18 ClinicalTrials.gov identifier, NCT04221945.



Presented by: Domenica Lorusso

### **Baseline Characteristics**

	Pembro Arm (N = 529)	Placebo Arm (N = 531)
Age, median (range)	49 y (22-87)	50 y (22-78)
Race <sup>a</sup>		
White	254 (48.0%)	264 (49.7%)
Asian	155 (29.3%)	148 (27.9%)
Multiple	78 (14.7%)	86 (16.2%)
American Indian or Alaska Native	24 (4.5%)	22 (4.1%)
Black or African American	14 (2.6%)	8 (1.5%)
Native Hawaiian or Other Pacific Islander	2 (0.4%)	1 (0.2%)
PD-L1 CPS		
<1	22 (4.2%)	28 (5.3%)
≥1	502 (94.9%)	498 (93.8%)
Missing	5 (0.9%)	5 (0.9%)
ECOG PS 1	149 (28.2%)	134 (25.2%)
Squamous cell carcinoma	433 (81.9%)	451 (84.9%)

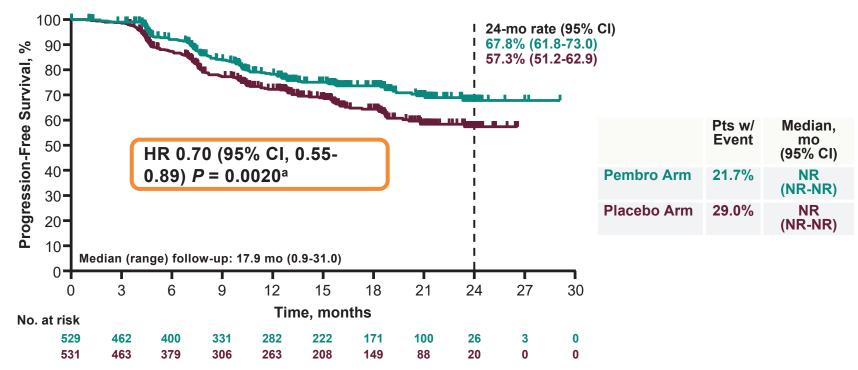
	Pembro Arm (N = 529)	Placebo Arm (N = 531)		
Stage at screening (FIGO 2014 criteria)				
IB2-IIB	235 (44.4%)	227 (42.7%)		
III-IVA	294 (55.6%)	304 (57.3%)		
Lymph node involvement <sup>b</sup>				
Positive pelvic only	326 (61.6%)	324 (61.0%)		
Positive para-aortic only	14 (2.6%)	10 (1.9%)		
Positive pelvic and para- aortic	105 (19.8%)	104 (19.6%)		
No positive pelvic or para-aortic	84 (15.9%)	93 (17 5%)		
Planned type of EBRT				
IMRT or VMAT	469 (88.7%)	470 (88.5%)		
Non-INIT and non-VMAT	00 (11.0%)	01 (11.5%)		
Planned total radiotherapy dose (EQD2)				
<70 Gy	47 (8.9)	46 (8.7)		
≥10 Gy	402 (91.1)	400 (91.0)		

<sup>a</sup>In each treatment arm, 2 patients (0.4%) had missing information for race. <sup>b</sup>Per protocol, a positive lymph node is defined as ≥1.5 cm shortest dimension by MRI or CT. Data cutoff date: January 9, 2023.



Presented by: Domenica Lorusso

### Primary Endpoint: Progression-Free Survival



Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation. "With 269 events (88.5% information fraction), the observed *P* = 0.0020 (1-sided) crossed the prespecified nominal boundary of 0.0172 (1-sided) at this planned first interim analysis. The success criterion of the PFS hypothesis was met, and thus no formal testing of PFS will be performed at a later analysis. Data cutoff date: January 9, 2023.



Presented by: Domenica Lorusso

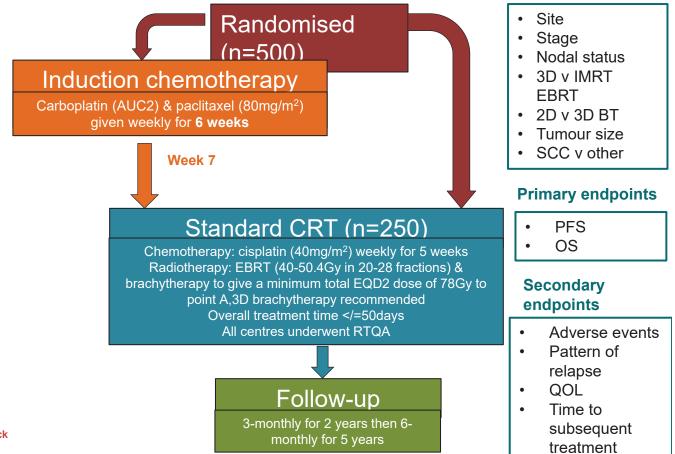
### **INTERLACE** Trial Design

#### Key eligibility criteria

- Newly diagnosed histologically confirmed FIGO (2008) stage IB1 node+,IB2 ,II,IIIB,IVa squamous, adeno, adenosquamous cervical cancer
- No nodes above aortic bifurcation
- Adequate renal/liver and bone marrow function
- Fit for chemotherapy & radical RT
- No prior pelvic RT

RT=Radiation IMRT=Intensity modulated radiation EBRT=External beam radiation BT= Brachytherapy RTQA=Radiation quality assurance

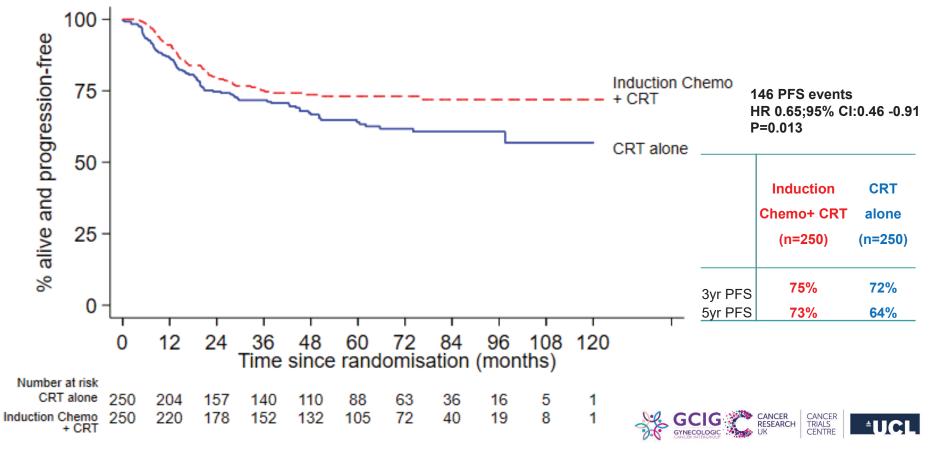
Mary McCormack



Stratified by





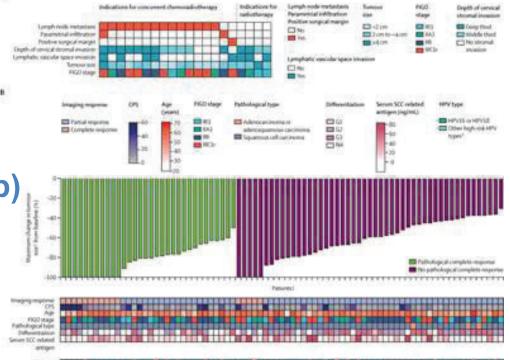


Mary McCormack



### NACI study: neoadjuvant IO/chemotherapy

85 pts China LACC Chemo and chemo/IO Cisplatin/nab-paclitaxel (cycle 2, 3 w camrelizumab) Surgery ORR 98% (19% pCR)

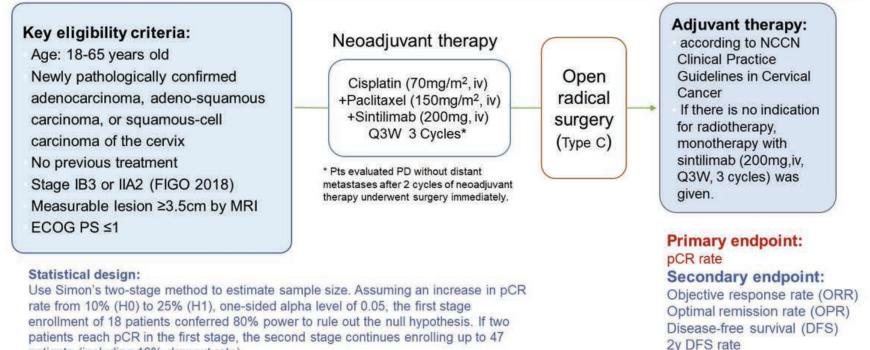


# No baseline sig feature correlation for pCR

Li K, Chen J, Hu Y, et al: Neoadjuvant chemotherapy plus camrelizumab... Lancet Oncol 25:76-85, 2024

### PACS study: neoadjuvant IO/chemotherapy Lui et al, ASCO 2024 PACS study

### PACS: study design (NCT04799639)



patients (including 10% dropout rate).

2024 ASCO

#ASCO24 PRESENTED BY: Dr. Jihong Liu

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Primary endpt: 36% pCR; 57% pPR

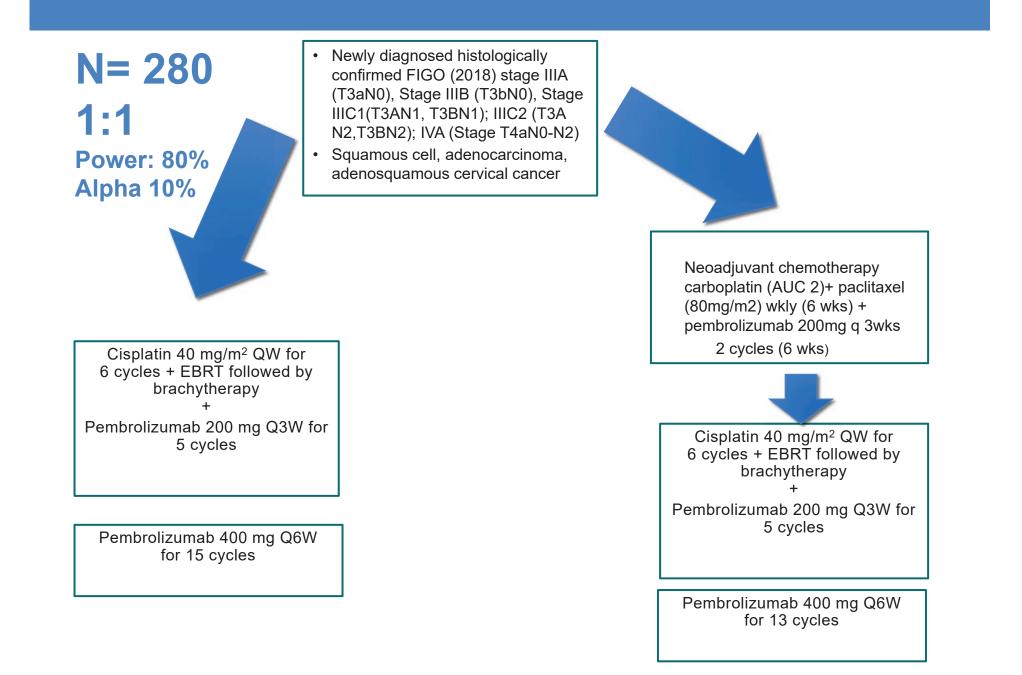
Safety

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY

KNOWLEDGE CONQUERS CANCEL

# CV2401 (NRG 037) : NEOADJUVANT PEMBROLIZUMAB AND CHEMOTHERAPY AND CHEMORADIATION VS. CHEMORADIATION FOLLOWED BY PEMBROLIZUMAB FOR LOCALLY ADVANCED CERVICAL CANCER

PI: Jyoti Mayadev, MD Translational PI: Dmitriy Zamarin, MD, PhD Statistician: Wei Deng, PhD Collaboration: CRADA (Merck)



# Acknowledgements

### <u>Collaborators</u>

- Zamarin Lab (NRG/Mt Sinai)
- Talke Lab (UCSD ENG): Talke, Morris, Makale, Chen, Yi, students
- NRG Oncology collaborations: Moore, Henson, Leath, Aghajanian, Lea
- UCSD RMAS: Rash, Mell, Yashar, Mundt, Nwachukwu, Sharabi, Advani, Scanderbeg, Brown, Myers, Kisling, Meng, Sanghvi
- UCSD RMAS residents: Kim, Dornish (and many previous residents)
- COE: McDaniels-Davidson, Martinez, Nodora, Margaux SB
- GYN ONC: McHale, Eskander, Binder, Plaxe, Saenz
- LJI : Sharma Lab, Vijay Lab
- Funding Sources
- NCI (R50, R01, NRG Oncology NCI)
- <u>Clinical Trial Support</u>
- NRG/NCI, AZ, Merck, Varian, Adaptive,
- Genentech
- <u>Clinical Support</u>
- Heather Naylor, Brachy Team, HDR Nursing
- Lisa Kirsch
- PATIENTS









## CHIKA NWACHUKWU, MD, PHD

#### UC San Diego Health, Radiation Oncologist and Assistant Professor in the Division of Radiation Oncology

Advances in Radiation Therapy

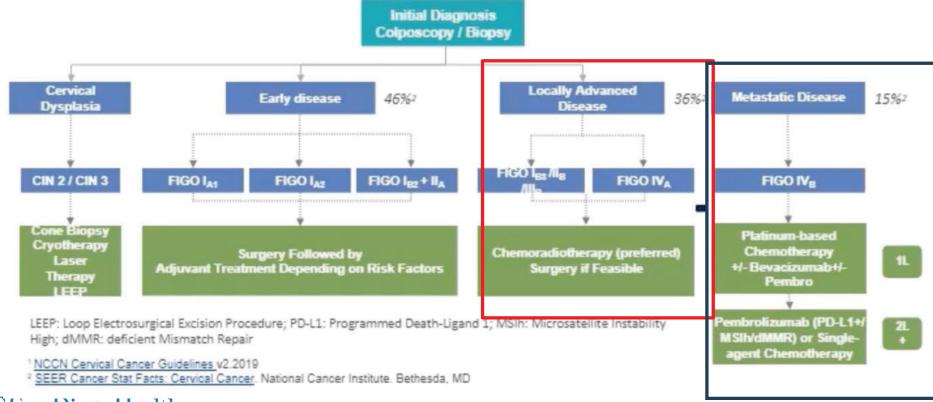


# Radiation Advances for Cervical Cancer

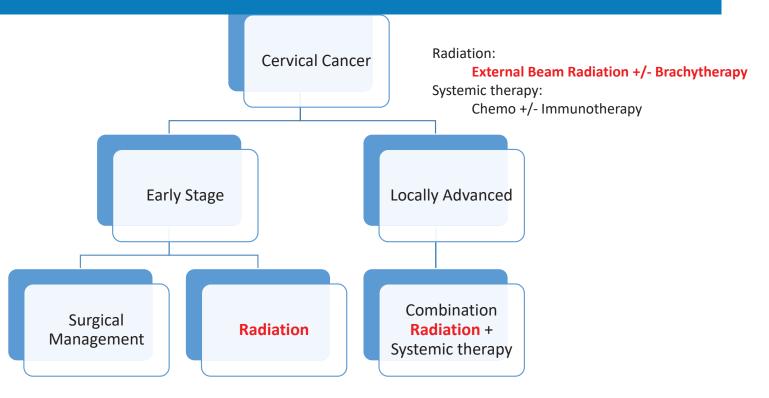
#### Chika Nwachukwu, MD, PhD

Assistant Professor Radiation Medicine & Applied Sciences Jan 27, 2025

# **Cervical Cancer Treatment Summary**



# General Management of Cervical Cancer



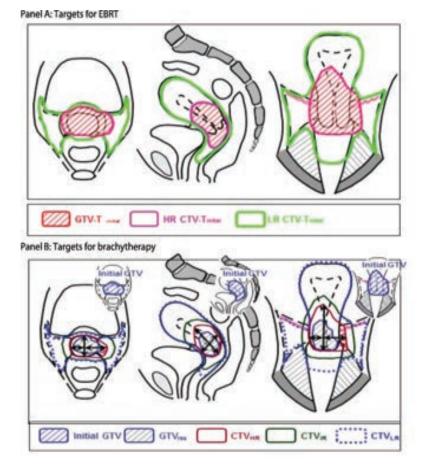
# **Radiation for Cervical Cancer**

## External Beam Radiation Therapy (EBRT)

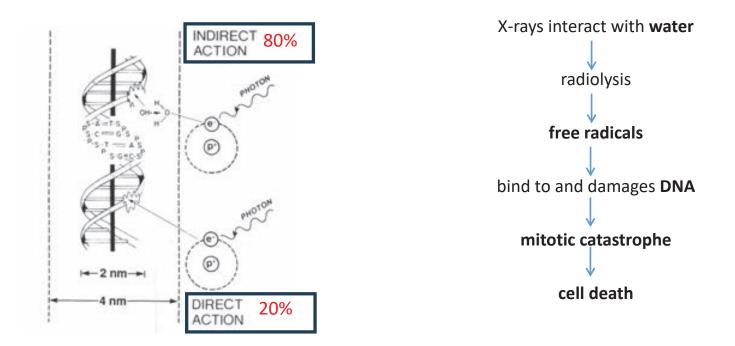
3-Dimensional Conformal Radiation Therapy (3D-CRT), Intensity Modulated Radiation Therapy (IMRT), Image-Guided Radiation Therapy (IGRT), Stereotactic Body Radiation Therapy (SBRT)

### Brachytherapy

3-Dimensional brachytherapy(3D-), Image-Guided Brachytherapy (IGBT),

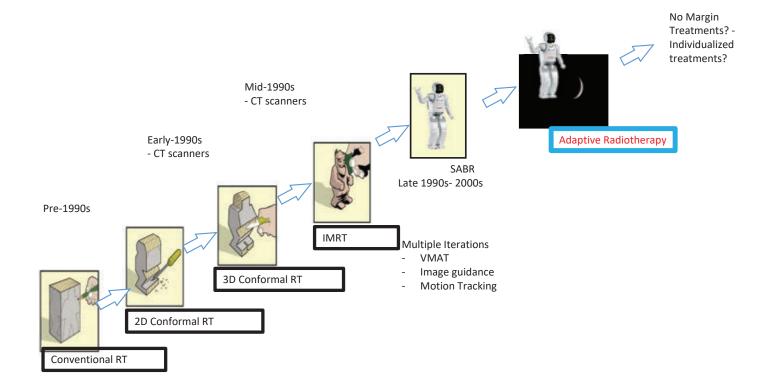


# How Radiation Therapy (RT) works

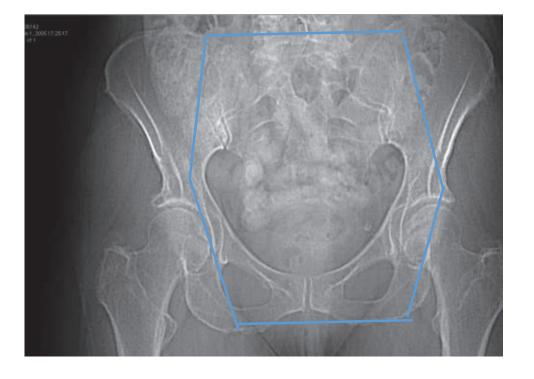


Cancer cells are more susceptible to RT due to impaired DNA repair pathways UC San Diego Health

# Milestones in Radiotherapy



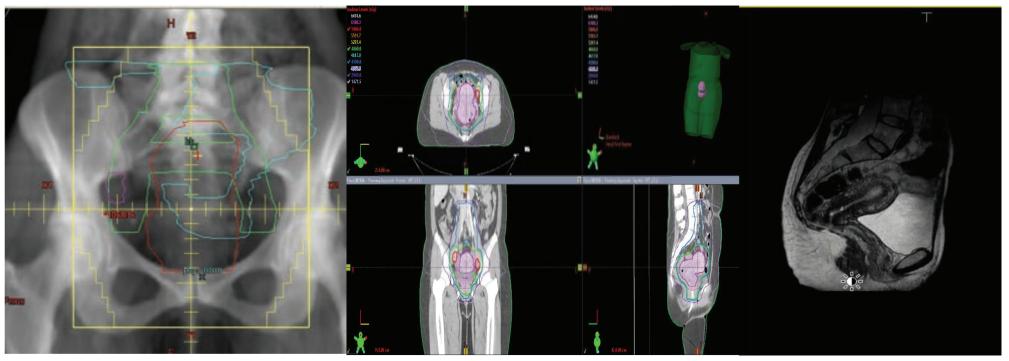
# Management of Cervical Cancer in 1980s



- Dosing: 45-50GY
- Fields : based on bony anatomy
- No routine of PET/CT or highquality imaging
- No Immunotherapy or targeted therapy

# **Evolution of Radiation Based on Imaging**

#### $2D \rightarrow 3D \rightarrow CT$ based planning --> MRI Imaging

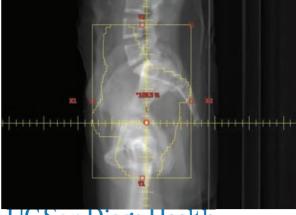


# Evolution of External Beam Radiation Therapy



# **3-D treatment planning using CT scan enables:**

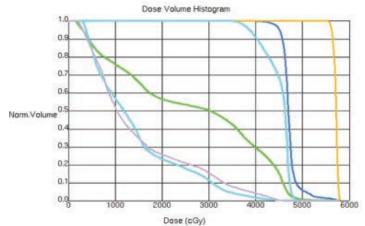
1) More accurate delineation of target and normal structures



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2) Accurate dose calculation to tumor and organs at risk of toxicity so the "quality" of the plan can be evaluated (i.e. probability of cure or toxicity)

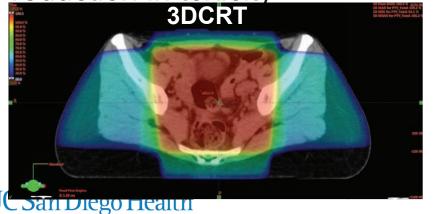




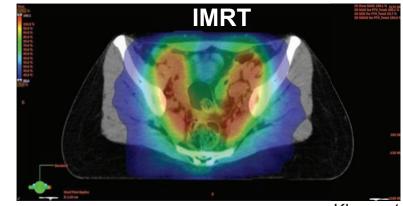
# Evolution of External Beam Radiation Therapy

Use of dynamic MLCs to create irregular (non-uniform) radiation from each field and adjust the intensity around a curved target volume

Enables dose escalation or reduction in toxicity



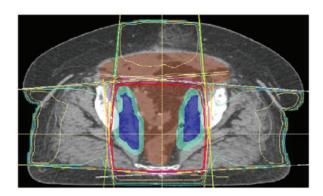


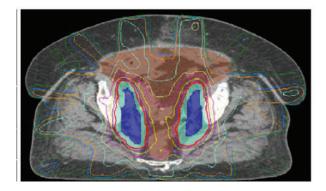


Klopp et al, 2018

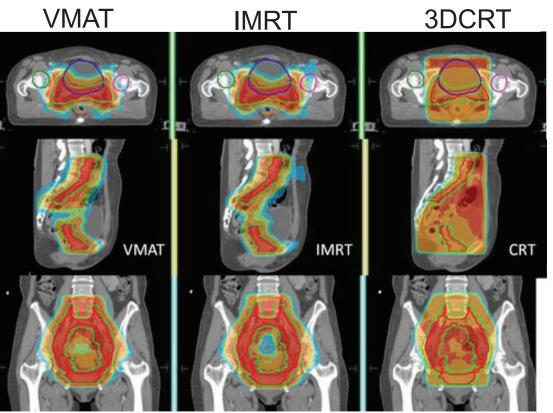
# **Reducing Radiation Treatment Volumes**

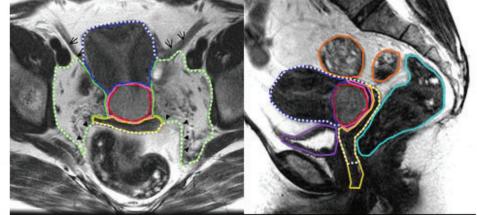
- Intensity modulated radiation therapy for cervical cancer
  - Dosimetric studies initially published
     2000-2001
  - First clinical series published in 2001
  - By 2009, 18+ retrospective studies published suggesting improved toxicity with IMRT compared to 3DCRT





# Standard of Care for Cervical Cancer





#### Lim et al 2011 IJROBP

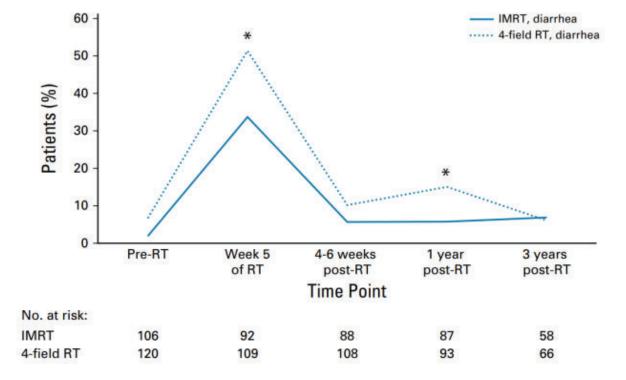
Deng et al Journal of Applied Clinical Medical Physics 2016

# IMRT for Gynecologic Malignancies

- IMRT decreases acute grade II diarrhea and late grade 2 anorexia, abdominal bloating, bowel obstruction
- Benefit greatest among pts receiving concurrent chemotherapy
- Image-guided bone marrow sparing IMRT can decrease acute grade III neutropenia: 19% with vs 54% without BM sparing

Chopra et al. PARCER *IJRO* 2020 Klopp et al. RTOG 1203/TIME-C *JCO* 2018 Williamson et al. INTERTECC *IJROBP* 2022

## IMRT for Gynecologic Malignancies

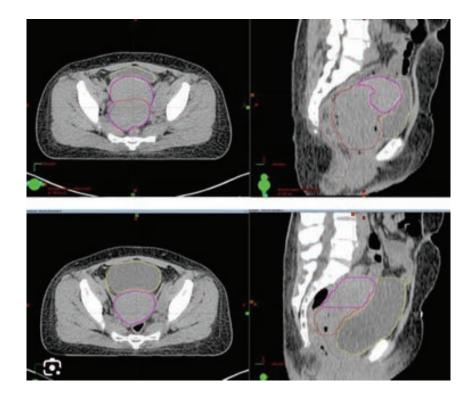


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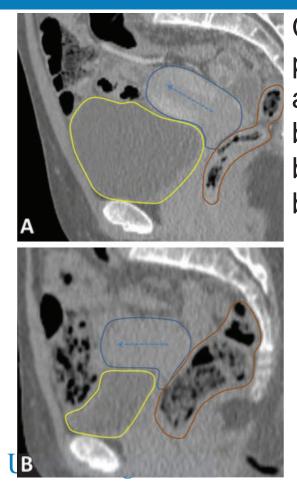
Klopp et al. RTOG 1203/TIME-C JCO 2018

## Reducing radiation treatment volumes

- Cervical cancer presents unique radiation challenge in that uterus and cervix are highly mobile structures
- Changes in target position may arise due to several reasons
  - Bladder filling
  - Rectal filling
  - Tumor shrinkage



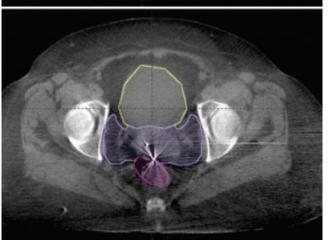
# Internal Organ motion during simulation and treatment



Contour tumor position with empty and full bladder CTs, but treat with full bladder (to push bowel out of the way)

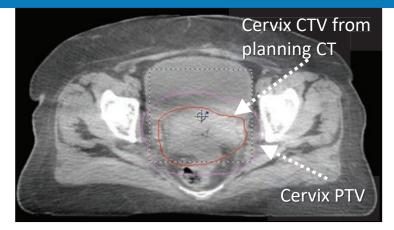
> Daily image guidance (e.g. CBCT) to assess for shifts in soft tissue anatomy enables margin reduction around tumor

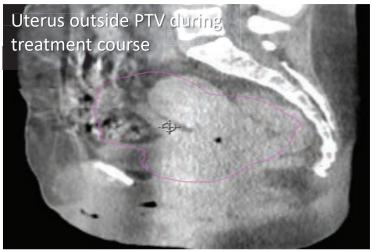
Margins: 1.5cm- uterus and cervix 1.0cm-Parametria and Vagina 0.7cm- lymph nodes



## Planning CT is a snapshot of anatomy at beginning of treatment

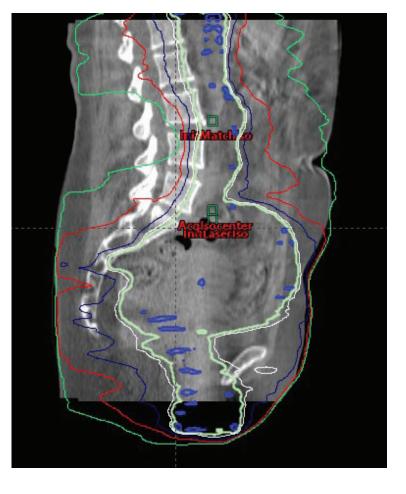
- Dramatic volume changes of bulky tumors during EBRT
  - Gradual change <u>infrequent adaptation</u> ok
- Weight changes over treatment course
  - Gradual change <u>infrequent adaptation</u> ok
- Large variability in day-to-day position of uterus, bladder, rectum (inter-fraction motion)
  - <u>Daily adaptation</u> can significantly reduce CTV-PTV margins <u>and</u> correct for changes from planning CT snapshot
- Changes in bladder filling-/rectal distention during treatment (intrafraction motion)
  - Primary driver of CTV-PTV margins with daily adaptation



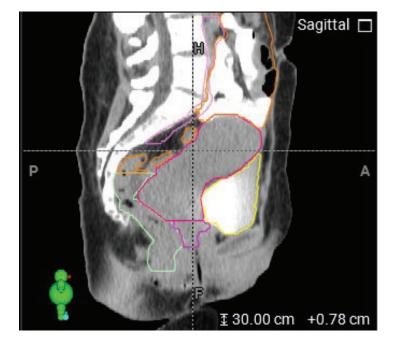


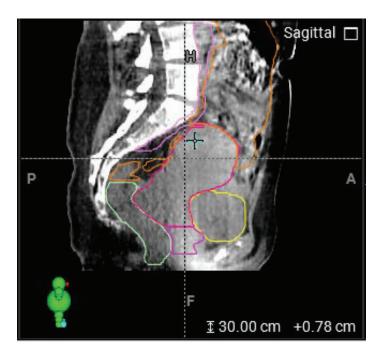
## Tumor Shrinkage during treatment





- Adaptation of Treatment Plan to interfraction organ changes
- Adaptation of Treatment plan to interfraction target changes (if/when applicable)
- Adaptation of Treatment plan to tumor or OAR function changes ( if/when applicable)
- Visualized tumor and OARs during beam delivery and adapt Treatment plan to intra-fraction changes
- Adaptive radiotherapy creates a new treatment plan for each daily fraction based on day of imaging
- Allow for tighter treatment margins



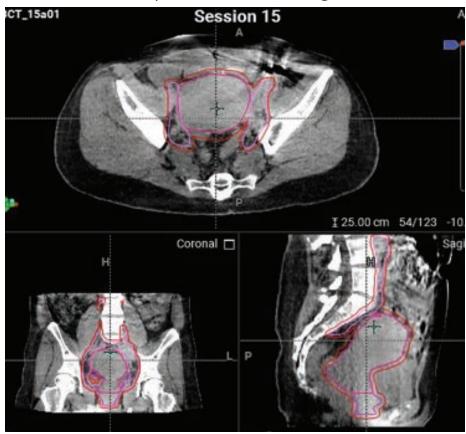


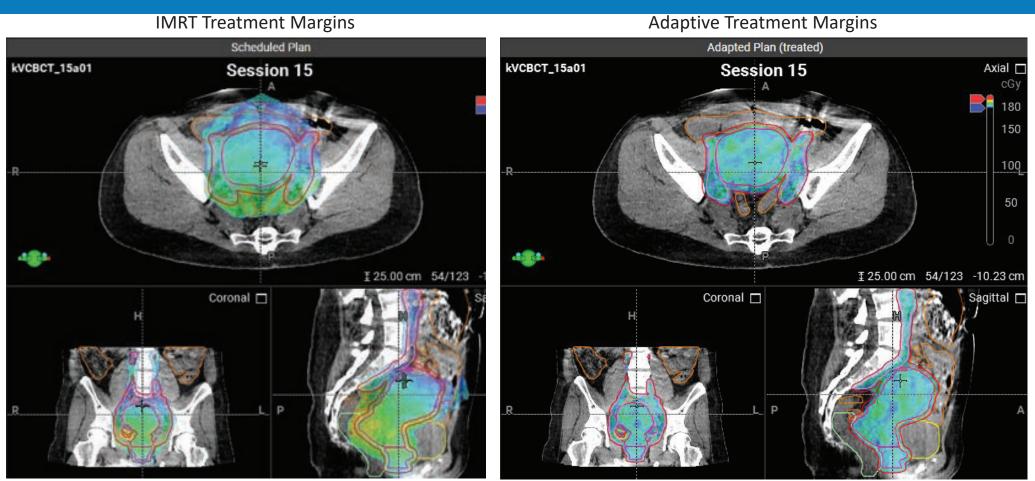
**IMRT** Treatment Margins



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Adaptive Treatment Margins





## Current Clinical Trial – Adaptive Radiotherapy

Definitions

BT: Brachytherapy

EBRT: External beam ra

IMRT: Intensity modula

PMB: Parametrial boost

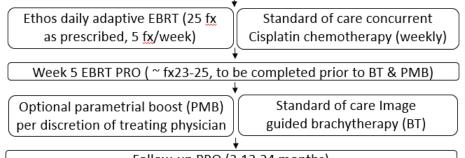
PRO: Patient reported outcome

Stage IB2-IVA cervical cancer (without pelvic lymph nodes)

Adaptive IMRT Planning

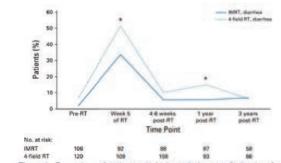
- Total dose: 4500 cGy / 25 fx
- Optional parametrial boost (not to exceed 960cGy) will be administered after complete delivery of primary EBRT prescription

Baseline patient reported outcomes (PRO) prior to EBRT



Follow-up PRO (3,12,24 months)

Primary endpoint :Acute Patient Reported Outcome (PRO) GI Toxicity (week 5 of external beam radiotherapy (EBRT)



. .

Figure 1. Percentage of patients with high-grade (acore ≥ 3) diarrhea frequency as reported by RTOG 1203<sup>23</sup>. Instrument for toxicity assessment was the PRO-CTCAE (identical to that in this protocol).

## Summary

- Goal of radiation is to treat the tumor and minimize normal tissue toxicity
- Advances in imaging and radiation has allowed improved treatment of cervical cancer while minimizing toxicity
- Adaptive radiotherapy are major advances in treatment of LACC allows us to decrease dose to organs at risk in the pelvis





## JESSICA KINGSTON, MD

UC San Diego Health, Obstetrician/Gynecologist and Professor of Obstetrics, Gynecology, and Reproductive Sciences

Guidelines 101 – Understanding New HPV Testing Recommendations



UC San Diego Health

## Guidelines 101: Understanding New HPV Testing Recommendations



Jessica Kingston, MD Clinical Professor Chief, Division of Obstetrics & Gynecology Department of Obstetrics, Gynecology & Reproductive Sciences

## **Screening Strategies**





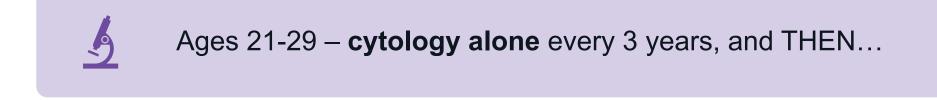
<sup>2</sup> | UC San Diego Health

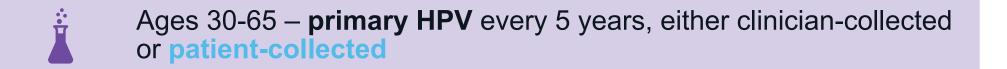
Age	2020 ACS*	2021 ACOG	2021 USPSTF	
21-24	No screening	Cytology Q3		
25-29	Preferred: HPV Q5 Acceptable: Co-test Q5 OR Cytology Q3	Cytology Can consider		
30-65	Preferred: HPV Q5 Acceptable: Co-test Q5 OR Cytology Q3	Cytology OR HPV Q OR Co-test 0	5	
65+	NO screening after adequate prior negative screening			
Hysterectomy with cervix removal	<b>No screening</b> for those who do NOT have a history of CIN2+, ACIS or cancer in the 25 years leading up to hysterectomy			

#### USPSTF 2025 – In progress...

Population	Recommendation         The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women ages 21 to 29 years and then every 5 years with clinician- or patient-collected high-risk human papillomavirus (HPV) primary screening in women ages 30 to 65 years.         As an alternative to HPV primary screening for women ages 30 to 65 years, the USPSTF recommends continued screening every 3 years with cervical cytology alone or screening every 3 years with high-risk HPV testing in combination with cytology (cotesting).	
Women ages 21 to 65 years		
Women younger than age 21 years	The USPSTF recommends against screening for cervical cancer in women younger than age 21 years.	
Women older than age 65 years	The USPSTF recommends against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. See the "Practice Considerations" section for discussion of adequate prior screening and risk factors that support screening after age 65 years.	
Women with a prior hysterectomy and no cervix	The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.	D

## **USPSTF Updates**







Alternative for ages 30-65 is to continue cytology alone every 3 years OR co-testing every 5 years

#### **Barriers to Screening**

#### Cervical cancer screening is not always accessible



- Almost 30% of those eligible in the US can't or don't get screened at recommended intervals
- Far fewer people than recommended getting HPV vaccines
- 11,500 cases diagnosed/yr, HALF not screened or inadequately screened
- Patients experiencing poverty, living in rural areas, racial and ethnic minority populations less likely to be screened
- Healthcare deserts NO regular health care access
- Preferences, religious or cultural beliefs, trauma history, disabilities/medical conditions prevent some from getting a pelvic exam
- Many providers can't do pelvic exams or don't have the infrastructure to do them

#### **Patient-collected HPV testing**



Home > News & Events > Cancer Currents Blog > FDA Approves HPV Tests That Allow for Self-Collection in a Health Care Setting

#### FDA Approves HPV Tests That Allow for Self-Collection in a Health Care Setting

On May 14, 2024, the FDA expanded the approvals of two tests that detect HPV in the cervix.

People can now be offered the option to collect a vaginal sample themselves for HPV testing if they cannot have or don't want a pelvic exam.

Collection involves a swab or brush, and must be done in a health care setting

The tests included in the approvals are Onclarity HPV and Cobas HPV

#### FDA Approved Self Collection Devices



**Copan FLOQSwabs**® (552C.RM) Used for vaginal specimens for use with the cobas® HPV or cobas® HPV tests.



**Evalyn® Brush – by Rovers Medical Devices** 

#### Worldwide use of HPV self-sampling for cervical cancer screening

B. Serrano, R. Ibáñez, C. Robles, P. Peremiquel-Trillas, <u>S. de Sanjosé</u>, L. Bruni **Preventive Medicine**, Volume 154, January 2022, 106900

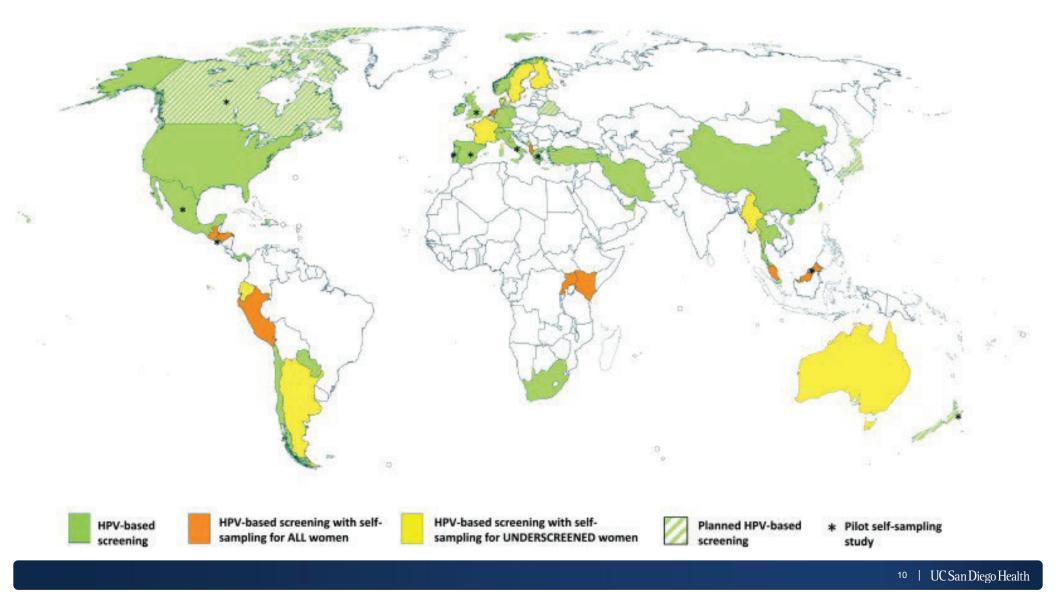
Global use of HPV self-sampling is still limited.

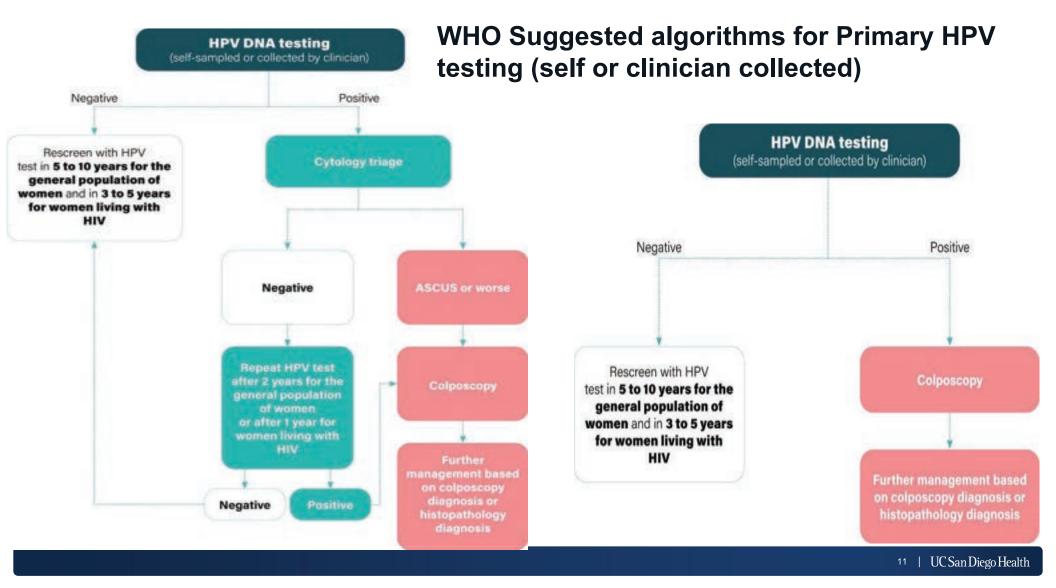
Only 17 (12%) countries with identified screening programs recommend it, 9 as the primary collection method, and 8 to reach under-screened populations.

Official recommendations for cervical cancer screening identified in 139 (69%) countries and territories.

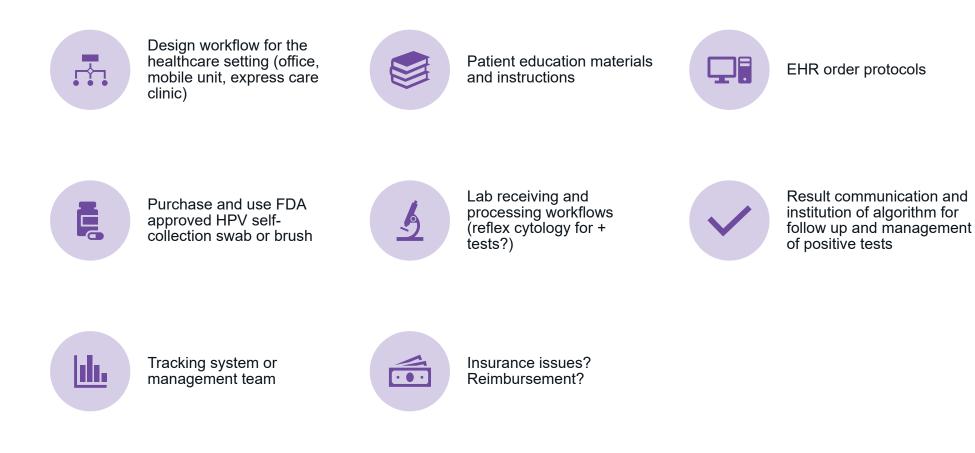
As of February 2021, 48 (24%) countries recommended primary HPV-based screening (primary HPV testing or co-testing)

6 countries (Canada, New Zealand, Belgium, Belarus, Japan and Trinidad & Tobago) reported plans in 2020 for HPV-based screening introduction in the coming 1-2 years. Among the 140, 17% had introduced such screening (three low-, five lower-middle- and 16 upper-middle-income countries), compared to 39% countries among the 62 high-income countries





#### Checklist for implementing HPV self-collection





#### MARLEN HERRERA

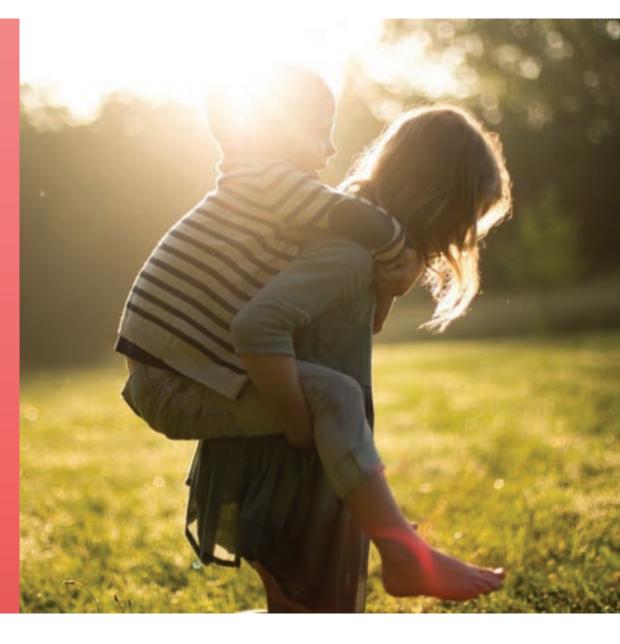
Neighborhood Healthcare, Women's Health Program Manager

Cervical Cancer FQHC Case Study





## Women's Health Cancer Navigation



Marlen Herrera

Women's Health Program Manager

#### WH Cancer Screening

- Paps and Colposcopy Notification and Tracking
- Breast Cancer Screening, Notification, and Tracking

#### **Policies Key Points:**

- **Notification:** Normal results are shared via text or letter; abnormal results are communicated by phone with a management plan per guidelines
- **Follow-Up:** Unreachable patients receive multiple contact attempts, including certified letters and chart alerts.
- **Tracking:** Abnormal results and follow-ups are logged in a tracking tool and reviewed daily.
- **Colposcopy:** Appointments are scheduled, reminders sent, and missed appointments trigger additional outreach.

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WH Cancer Navigation Team:

- 2 full time WH LVNs
- Comprehensive surveillance and follow-up
- Blend of automation and direct support, education, and outreach
- Addressing barriers to care compliance (e.g., transportation, language, fear)
- Providing a support system for patients at risk of falling out of care
- Closing gaps in the risk mitigation process.

# **THANK YOU!**

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### **CLOSING REMARKS** *and next steps!*

#### CERVICAL CANCER QUALITY IMPROVEMENT LEARNING COLLABORATIVE

• This **collaborative meets quarterly** to discuss action steps and best practices for eliminating the cervical cancer in our San Diego community

#### **EVALUATION**

• Your feedback matters. Please take a moment to complete the survey!

#### **CANCER EDUCATION 101**

 Be sure to reach out to COE at mcccoe@health.ucsd.edu for any presentation or educational needs! Sign up for our Cervical Cancer Quality Improvement Learning Collaborative!



Complete the feedback survey!



UC San Diego MOORES CANCER CENTER Community Outreach and Engagement

# THANK YOU!

*Summit slides, recording and resources coming soon!* 



#### Partnership Inquiries

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UC San Diego MOORES CANCER CENTER Community Outreach and Engagement