

ACS Cancer Conference 2025

March 12-14 | Phoenix, AZ

Head/Neck Quality Measure: Assessing HPV Status as a Standard for Quality Care Delivery

Sara I. Pai, MD, PhD FACS

on behalf of the **CoC Head and Neck Disease Team**

Professor of Surgery

Yale University School of Medicine

New Haven, CT

Disclosures

Advisory Boards/Consultant

Abbvie
Astrazeneca
Cue Biopharma
EMD Serono
Incendia/Parthenon
Inovio
Merck
Newlink Genetics
Oncolys BioPharma
Recurrent Respiratory Papilloma Foundn (RRPF)
Replimmune
Sensei Bio
Scopus Biopharma

Grant/Research Support

Abbvie
Astrazeneca
Cue
Sensei Bio
Tesarco

Investigator-Initiated Clinical Trials

ASTX Pharmaceuticals
Astrazeneca
Cue
Immune Design
Merck

Educational Talks

EMD Serono

Senior Editor of Journals

Cancer Research



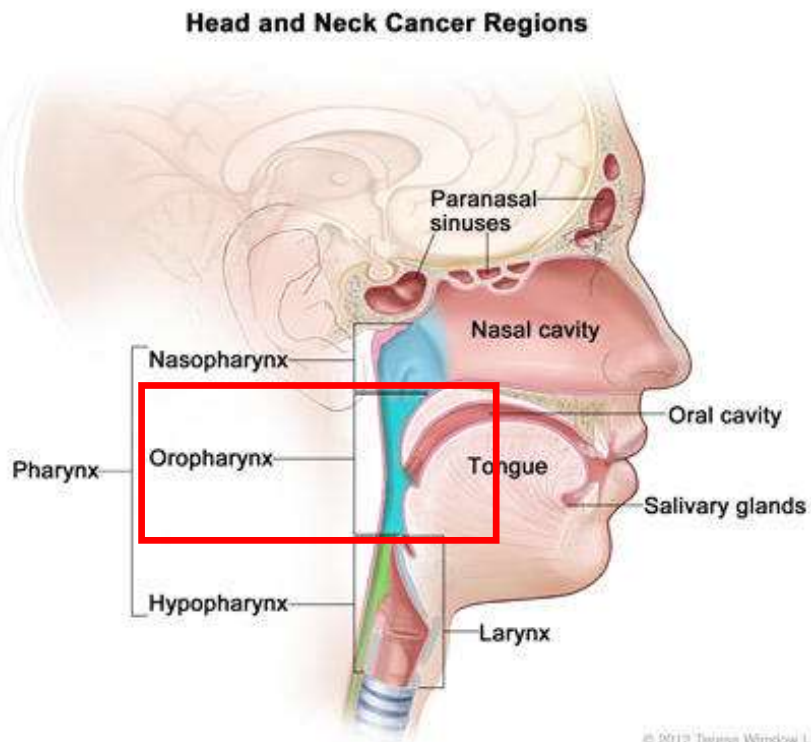
© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

CoC Head and Neck Disease Committee

- | | |
|----------------------|----------|
| • Beth Beadle, MD | ASTRO |
| • Laura Freedman, MD | ASTRO |
| • Evan Graboyes, MD | AHNS |
| • Bruce Haughey, MD | AHNS |
| • Saral Mehra, MD | AHNS |
| • Sara Pai, MD, PhD | SITC |
| • Randle Reese, MD | AAES |
| • Drew Ridge, MD | AHNS/CoC |

© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

Quality Measures: Past, Present, and Future



- **Present**

For patients with surgically managed head and neck squamous cell cancer who received adjuvant radiation treatment, the radiation is initiated within 6 weeks of surgery.

- **Future**

For patients with newly diagnosed oropharyngeal squamous cell carcinoma, p16 status by immunohistochemistry (IHC) is documented.

Eligibility Criteria

DENOMINATOR

Oropharyngeal cases	Primary Site		C01.9, C02.4, C02.8, C05.1, C05.2, C09.0, C09.1, C09.8, C09.9, C10.0, C10.2, C10.3, C10.8, C10.9
Squamous cell carcinomas	One of two combinations must be met	1	Histology Code
			8050, 8051, 8052, 8070, 8071, 8072, 8073, 8074, 8075, 8076, 8078, 8082, 8083, 8084, 8085, 8086
			Behavior Code
			3
		2	Histology Code
			8070
Adults	Age at Diagnosis		18 – 120
	Behavior Code		3

NUMERATOR

Description	Data Items	Selection Criteria
Marker p16 IHC is collected via high-risk human papillomavirus	Schema Discriminator 2	1, 2

p16-mediated oropharyngeal cancers are a distinct cancer with different risk factors

Oral Cancer Risk in Relation to Sexual History and Evidence of Human Papillomavirus Infection

Stephen M. Schwartz, Janet R. Daling, David R. Doody, Gregory C. Wipf, Joseph J. Carter, Margaret M. Madeleine, Er-Jia Mao, E. Dawn Fitzgibbons, Shixuan Huang, Anna Marie Beckmann, James K. McDougall, Denise A. Galloway

Journal of the National Cancer Institute, Vol. 90, No. 21, November 4, 1998

Aetiological parallel between tonsillar and anogenital squamous-cell carcinomas

Marten Frisch, Robert J Biggar

THE LANCET • Vol 354 • October 23, 1999

Evidence for a Causal Association Between Human Papillomavirus and a Subset of Head and Neck Cancers

Maura L. Gillison, Wayne M. Koch, Randolph B. Capone, Michael Spafford, William H. Westra, Li Wu, Marianna L. Zahurak, Richard W. Daniel, Michael Viglione, David E. Symer, Keerti V. Shah, David Sidransky

Journal of the National Cancer Institute, Vol. 92, No. 9, May 3, 2000

Table 1 Major differences between head and neck squamous cell carcinomas (HNSCCs) by human papillomavirus (HPV) status

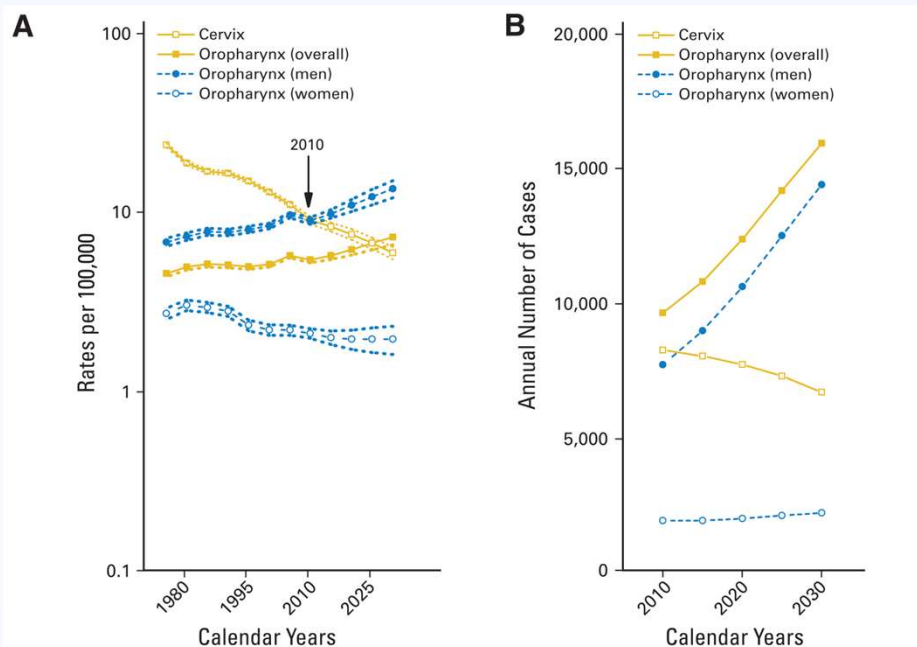
	HPV-positive HNSCC	HPV-negative HNSCC
Risk factors	High-risk sexual practices	Cigarette and alcohol use
Tumor site	Lingual and palatine tonsils	Nonoropharyngeal sites
Histopathology	Basaloid, nonkeratinizing, poorly differentiated	Keratinizing, moderately differentiated
Molecular genetic alterations		
P53 pathway disturbances	Degradation of wt p53 by E6	TP53 mutations, 17p LOH
Rb pathway disturbances	Degradation of wt Rb by E7	p16 ^{INK4A} -promoter hypermethylation, 9p LOH
Relative responsiveness to chemoradiation	Better	Worse
Relative prognosis	Improved	Worse

Abbreviations: HPV, human papillomavirus; LOH, loss of heterozygosity; Rb, retinoblastoma; wt, wild type.

Pai SI and Westra WH. *Annu Rev Pathol Mech Dis* 2009;4:49-70

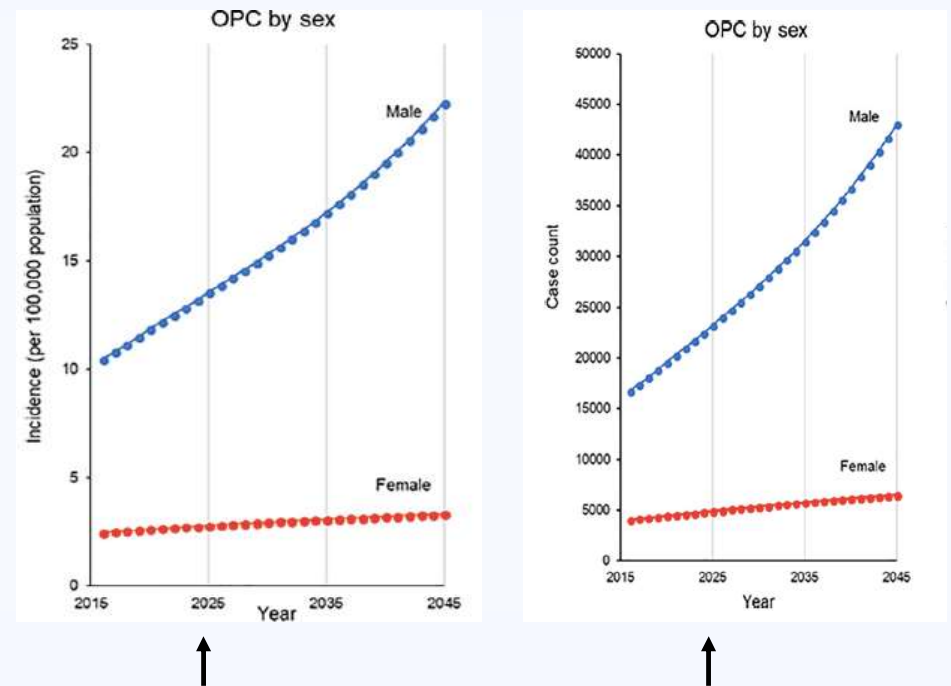
© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

p16-mediated oropharyngeal cancers are increasing in incidence



Chaturvedi AK et al, *JCO* 2011; 29:4294-4301

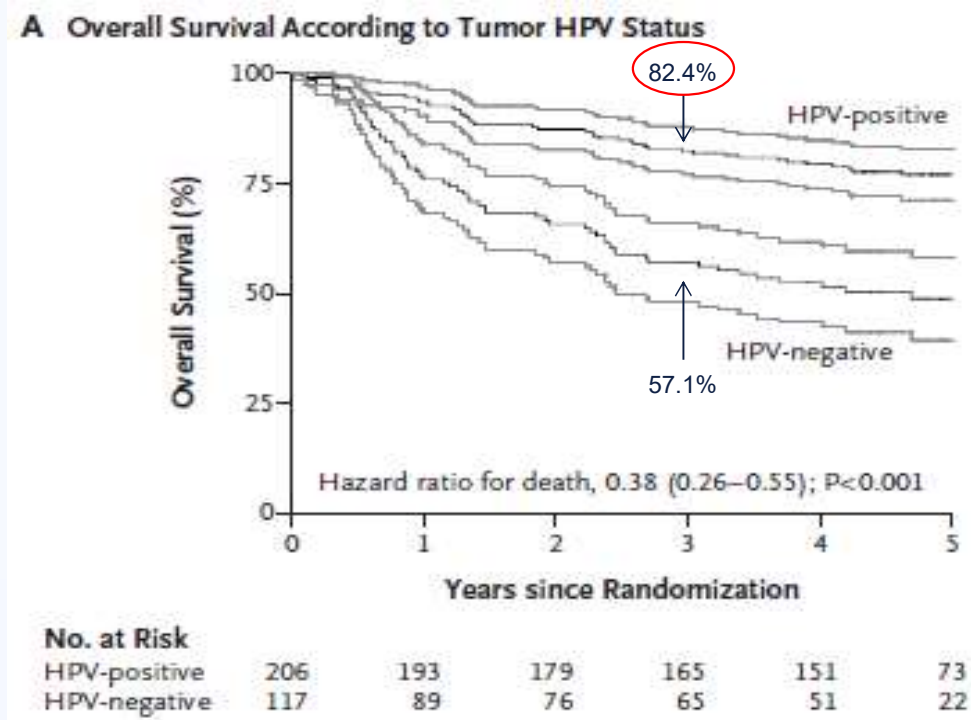
© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.



Xu L et al, *Head Neck* 2019; 41(9):3226-3234

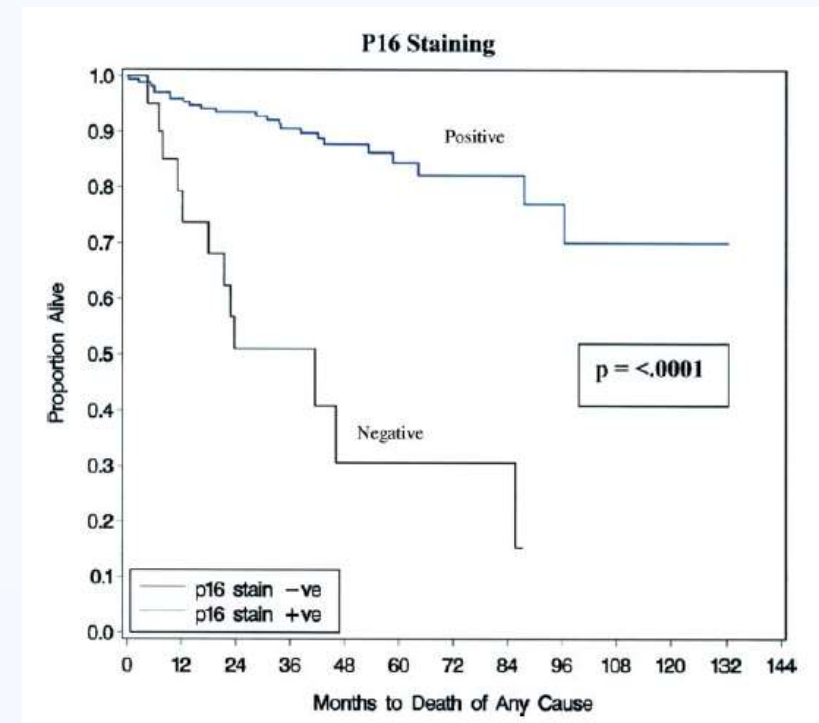
p16-mediated oropharyngeal cancers have improved clinical outcomes

Definitive Chemoradiation Therapy



Ang KK et al, *NEJM* 2010; 363:24-35

Definitive Surgical Resection



Haughey BH. et al *Head and Neck* 2011 33(12):1683-1694

p16-mediated oropharyngeal cancers have a separate AJCC staging system in 2017

Clinical TNM

T CATEGORY	T CRITERIA
T0	No primary identified
T1	Tumor 2 cm or smaller in greatest dimension
T2	Tumor larger than 2 cm but not larger than 4 cm in greatest dimension
T3	Tumor larger than 4 cm in greatest dimension or extension to lingual surface of epiglottis
T4	Moderately advanced local disease; tumor invades the larynx, extrinsic muscle of tongue, medial pterygoid, hard palate, or mandible or beyond ^b

N CATEGORY	N CRITERIA
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	One or more ipsilateral lymph nodes, none larger than 6 cm
N2	Contralateral or bilateral lymph nodes, none larger than 6 cm
N3	Lymph node(s) larger than 6 cm

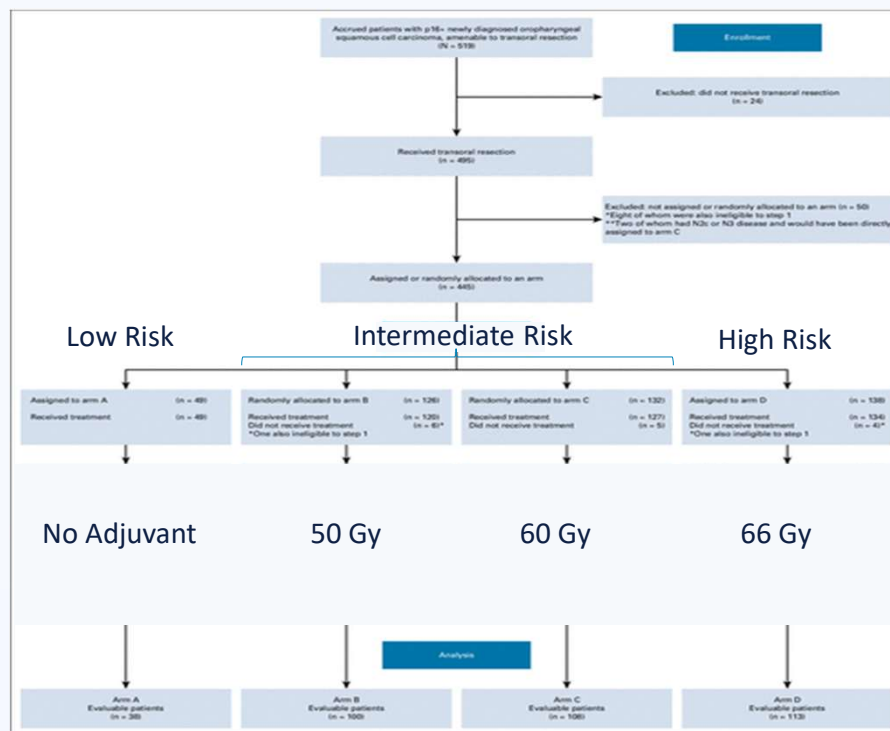
Pathological TNM

N CATEGORY	N CRITERIA
NX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastasis
pN1	Metastasis in 4 or fewer lymph nodes
pN2	Metastasis in more than 4 lymph nodes

Amin MB et al, AJCC Cancer Staging Manual, 8th ed. 2017

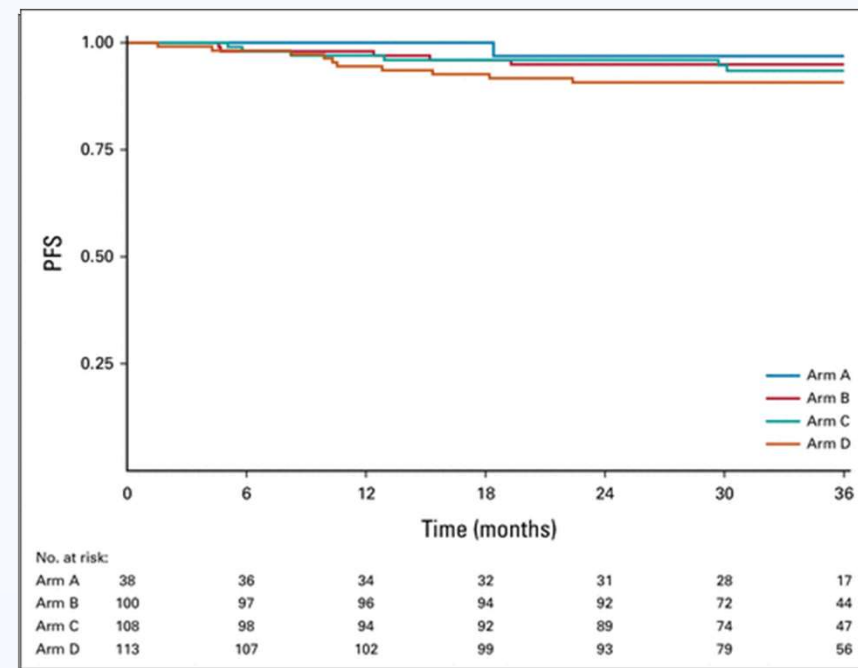
De-escalation therapies are being evaluated for p16-mediated HNCs

Pathologic Risk Factors



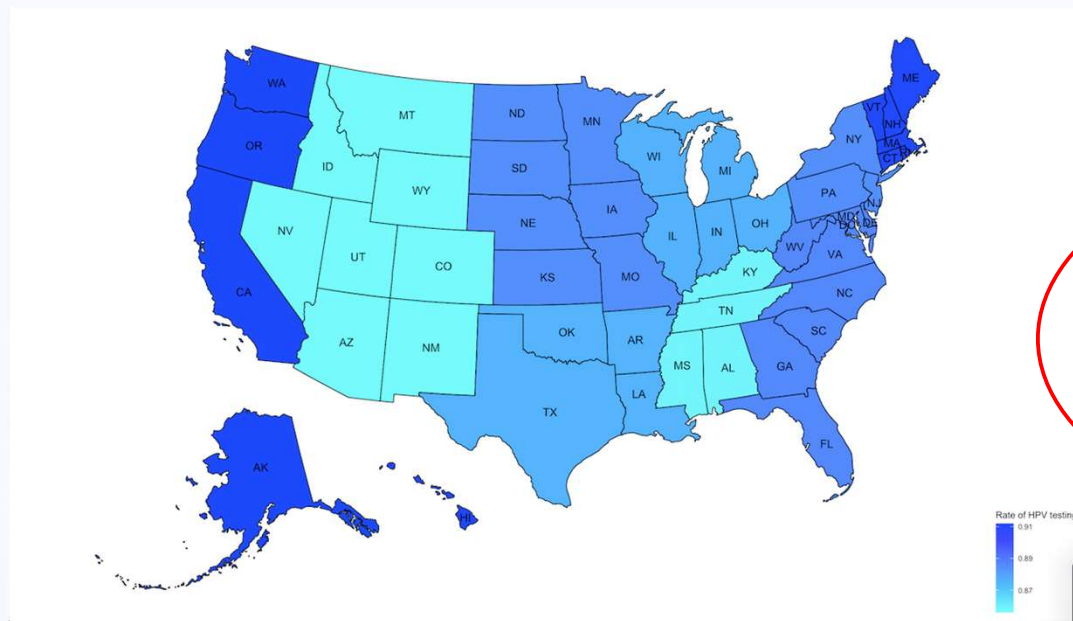
© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

Progression-Free Survival



Ferris RL et al, JCO 2021; 10-265

Significant Disparities in odds of being tested (test rate,%) for p16 Status from 2010-2021 (NCDB)



Geographic : WSC 0.57 (87%)
MNT 0.58 (86%)
ESC 0.59 (88%)
(ref =Pacific)

Sex : Female 0.79 (85%)
ref.=male

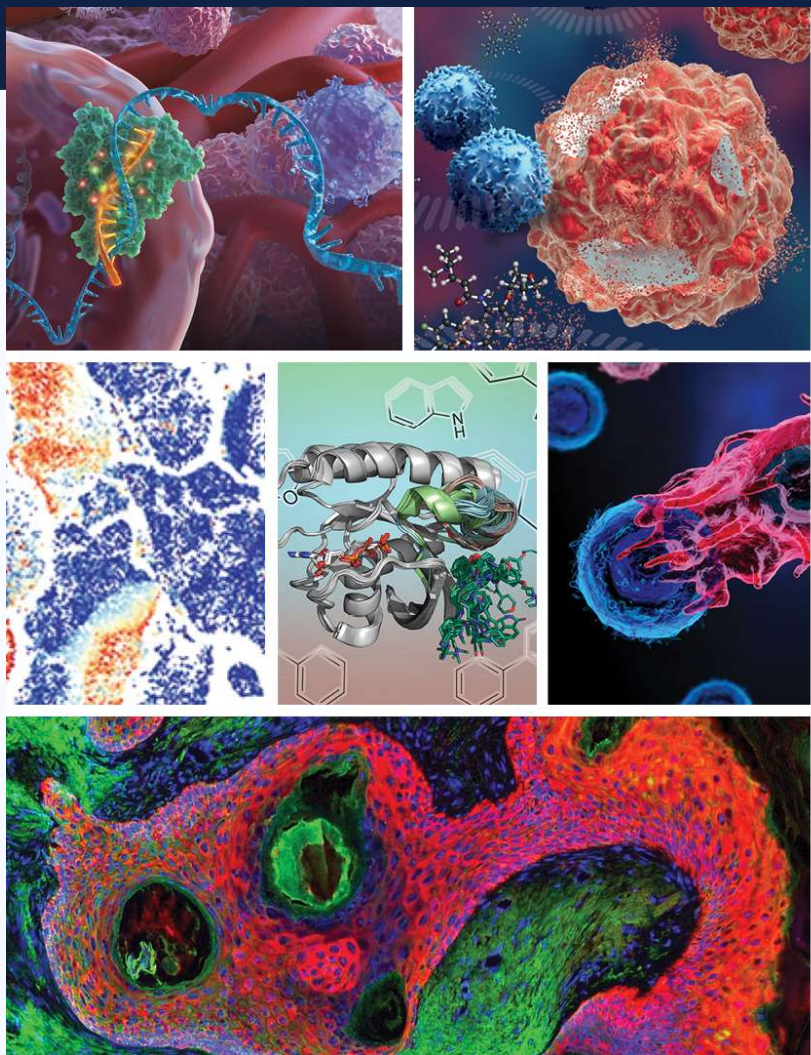
Race : Black 0.71 (83%)
Asian-Pac: 0.72 (86%)
ref.=white

**Community program (0.68),
Income (1.24) Insurance (1.8)**

© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

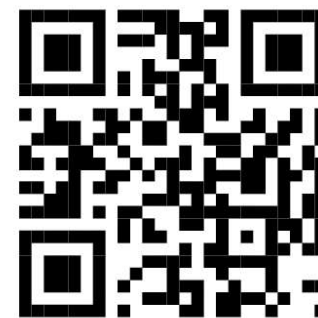
Costantino A. et al, *in press*

Thank you



CANCER RESEARCH

The Foundational Cancer Journal
Driving Transformative Science



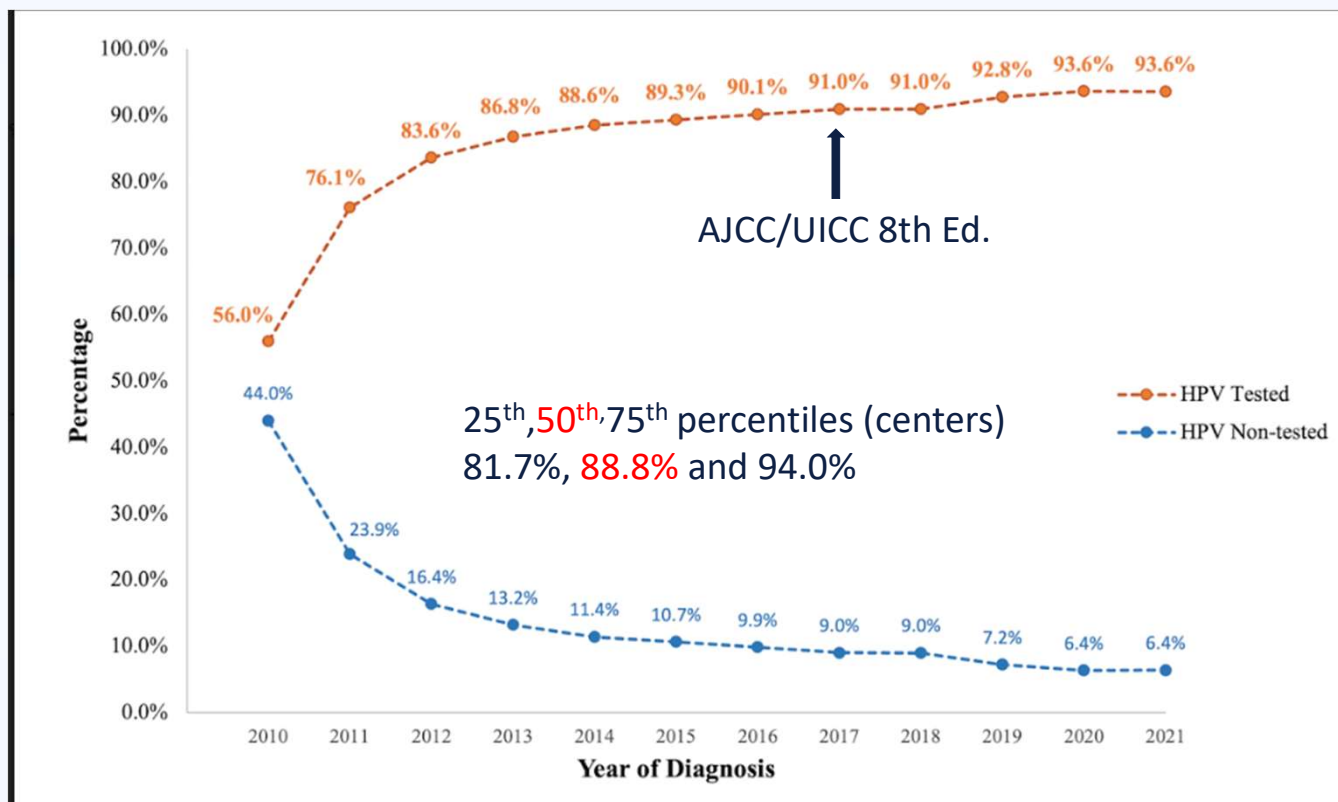
Scan Here to Submit to the Journal

AACRJournals.org

AACR American Association
for Cancer Research®

Trends in testing, 2010-2021 (NCDB)

146+k pts, 1326 facilities



© American College of Surgeons. Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

Costantino A. et al, *in press*