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Consortium for Infectious Disease Control

A neutral, third party platform supporting infectious disease projects, providing continuing medical education, coordinating initiatives, and undertaking research Winnipeg, Manitoba, Canada January 8, 2020

What do we need to know about HPV and Adult Males?

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Executive Director, Consortium for Infectious Disease Control Winnipeg, MB Director, Canadian Network on HPV Prevention Co-Chair, International Indigenous HPV Alliance

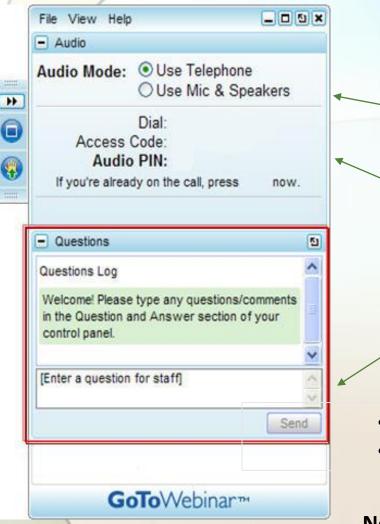
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Webinar Objectives



- 1. Discuss HPV infection and HPV-related disease manifestations in men, including MSM
- 2. Compare HPV prevention options between genders
- 3. Discuss screening for HPV-related disease in men

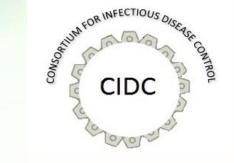
Housekeeping



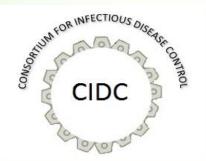
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The webinar **Slides and Recording** will be archived at: <u>https://www.CIDCgroup.org</u>

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Moderator





Dr. Marc Steben, MD

- Chair, Canadian HPV Prevention Network
- Family Physician, Family Medicine Group La Cité du Parc Lafontaine
- Montreal, Quebec, Canada

Presenter





Dr. Joel Palefsky, MD

- Professor, Medicine and Infectious Disease Specialist
- School of Medicine, University of California San Francisco
- Vice-Chair elect of the AIDS Malignancy Consortium
- Past President, International Papillomavirus Society
- San Francisco, California, USA

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Consortium for Infectious Disease Control Webinar

January 8, 2020

Joel Palefsky, M.D., F.R.C.P.(C) Professor of Medicine University of California, San Francisco

Disclosures

Merck and Co.- grant support, travel support Antiva Biosciences- grant support Vir- grant support, consultant, stock options Ubiome- grant support Inovio- travel support

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The Clinical Spectrum of HPV-Related Disease in Males

- Genital warts¹
- Penile intraepithelial neoplasia (PIN) and carcinoma^{1,2}
- Anal intraepithelial neoplasia (AIN) and carcinoma^{1,3}
- Some oropharyngeal cancers (tongue, tonsillar, throat, and soft palate)^{1,4}



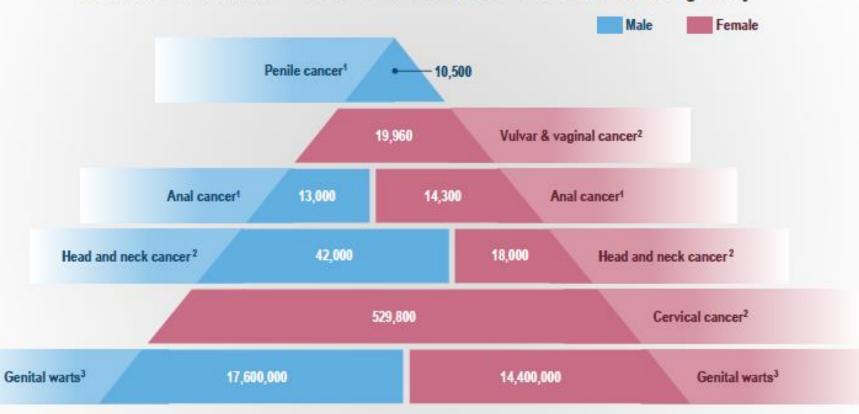
HPV = human papillomavirus.

Top left and bottom left: Reprinted with permission from NZ DermNet (www.dermnetnz.org); Top right: Used with permission from Alex Ferenczy, MD; bottom right: Rosen CA, Anderson D, Murry T. Evaluating Hoarseness: Keeping Your Patient's Voice Healthy. American Family Physician. June 1988;57(11):2775–82. Used by permission.

1. Giuliano AR et al. *Vaccine*. 2008;26(suppl 10):K17–K28. 2. Gross G et al. *Med Microbiol Immunol*. 2004;193(1):35–44. 3. Frisch M et al. *N Engl J Med*. 1997;337(19):1350–1358. 4. Gillison ML et al. *J Natl Cancer Inst*. 2000;92(9):709–720.

There Is a High HPV Disease Burden Among Males and Females Globally

Estimated annual new HPV-related disease cases in males and females globally



Published HPV prevalence rates were applied as follows: Parkin D et al. Vaccine. 2006 (penile, vulvar, anal, cervical cancers); WHO/ICO 2010 (head and neck cancer); De Vuyst H et al. Int J Cancer. 2009 (vaginal cancer); Greer CE et al. J Clin Microbiol. 1995 (genital warts).

 Parkin DM et al. Vaccine. 2006;24(Suppl 3):S3/11–S3/25. 2. WHO/ICO Information Centre on HPV and Cervical Cancer (HPV Information Centre). Human Papillomavirus and Related Cancers in World. Summary Report 2010. http://www.who.int/hpvcentre/en/. Accessed June 21, 2012. 3. World Health Organization (WHO). Executive summary: the state of world health. 1995. http://www.who.int/whr/1995/media_centre/executive_summary1/en/index3.html#. Accessed June 7, 2012. Cancers always/nearly always associated with HPV

- Cervical cancer
- Anal cancer

Cancers with parallel etiologic pathways (HPV+ or HPV-)

- Oropharyngeal cancer
- Penile cancer
- Vulvar cancer

Penile cancer

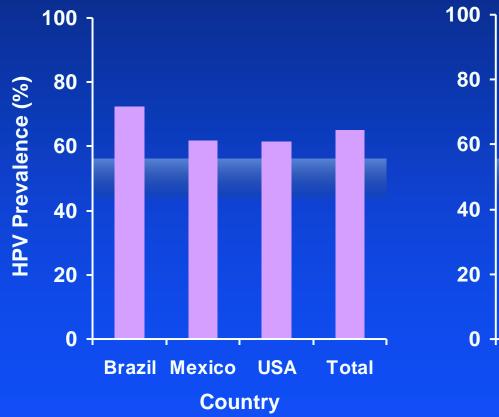
- About 40% of cases are HPVrelated
- Associated mortality of 41%²
 - Survival is ≤2 years without treatment.³
 - Patients often seek treatment late.³
- Treatment is associated with substantial psychological and sexual dysfunction⁴

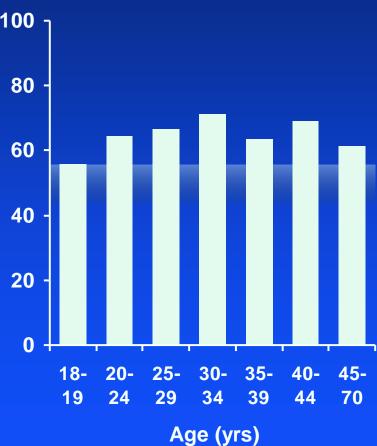


Image used with permission from Alex Ferenczy, MD. 1. Hernandez BY et al. Cancer. 2008;113(suppl 10):2883–2891. 2. Rippentrop JM et al. Cancer. 2004;101: 1357–1363; 3. Misra S et al. Lancet Oncol. 2004;5:240–247. 4. Maddineni S et al. BMC Urology. 2009;9:8. This information is for educational purposes only and NOT to be used in any promotional program.

HPV Prevalence in Males Enrolled in the HPV Infection in Men (HIM) Study (N=1,160)

By Country



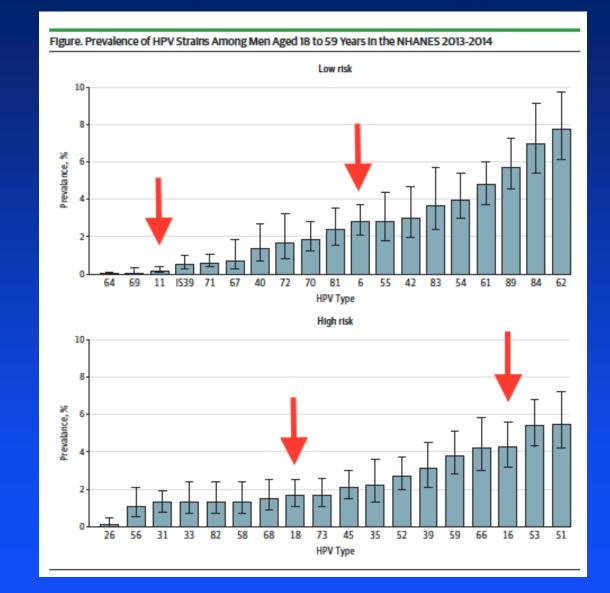


By Age

HPV = human papillomavirus.

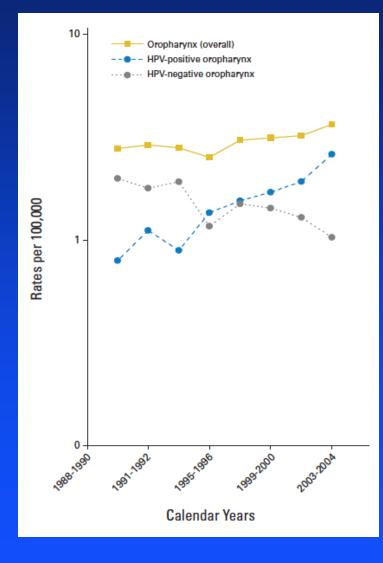
Giuliano AR et al. Cancer Epidemiol Biomarkers Prev. 2008;17(8):2036–2043.

Prevalence of penile HPV types in U.S.



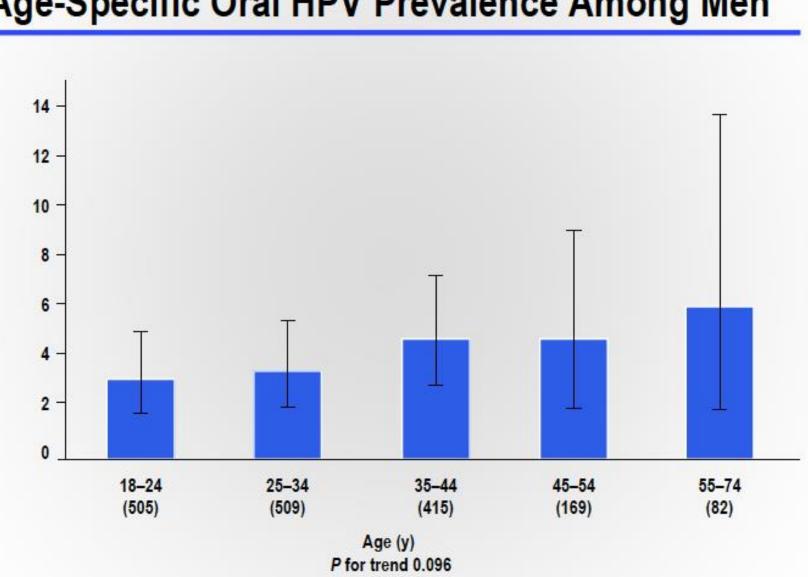
Han JJ et al. JAMA Oncol. 2017 Jan 19. doi: 10.1001/jamaoncol.2016.6192

Incidence of HPV-positive and HPV-negative oropharynx cancers in U.S.



Chaturvedi A et al. J Clin Oncol 2011; 29: 4294-4301

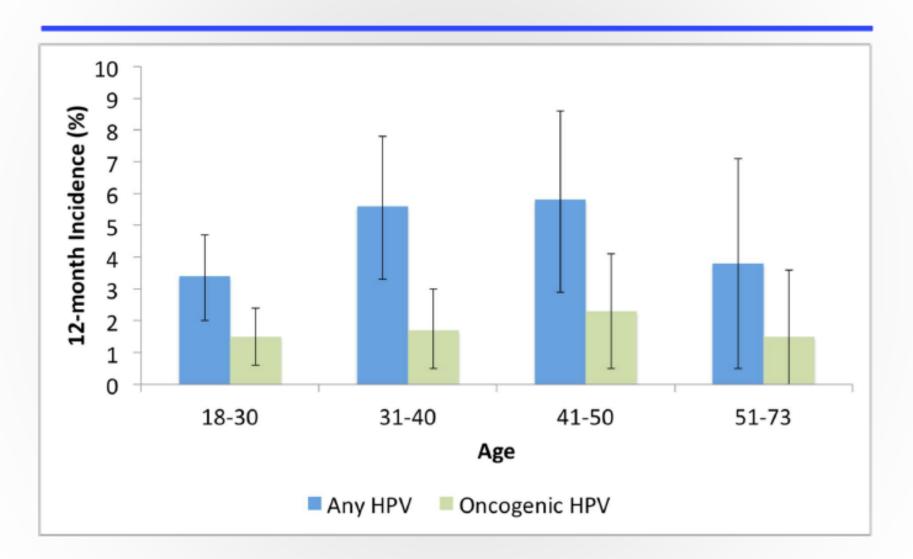
Oral HPV prevalence (%)



Age-Specific Oral HPV Prevalence Among Men

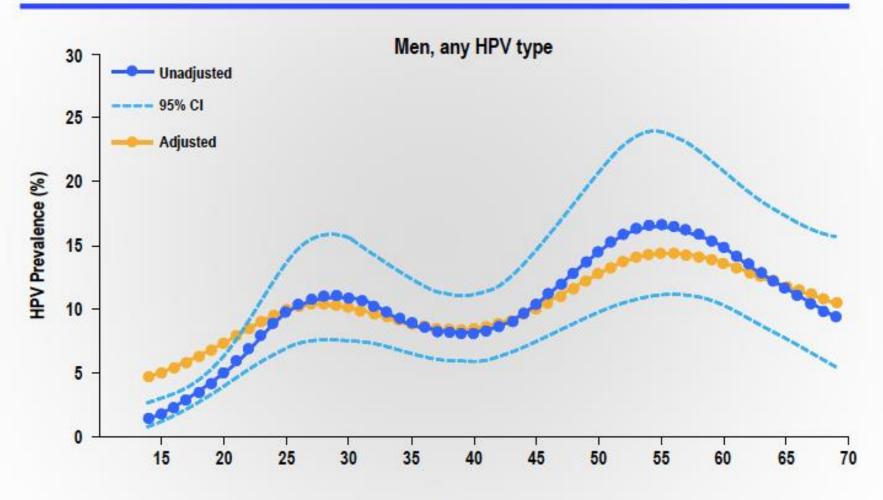
Kreimer AR et al. Cancer Epidemiol Biomarkers Prev. 2011;20:172-182.

Oral HPV Incidence is Highest in Mid-adult Aged Men



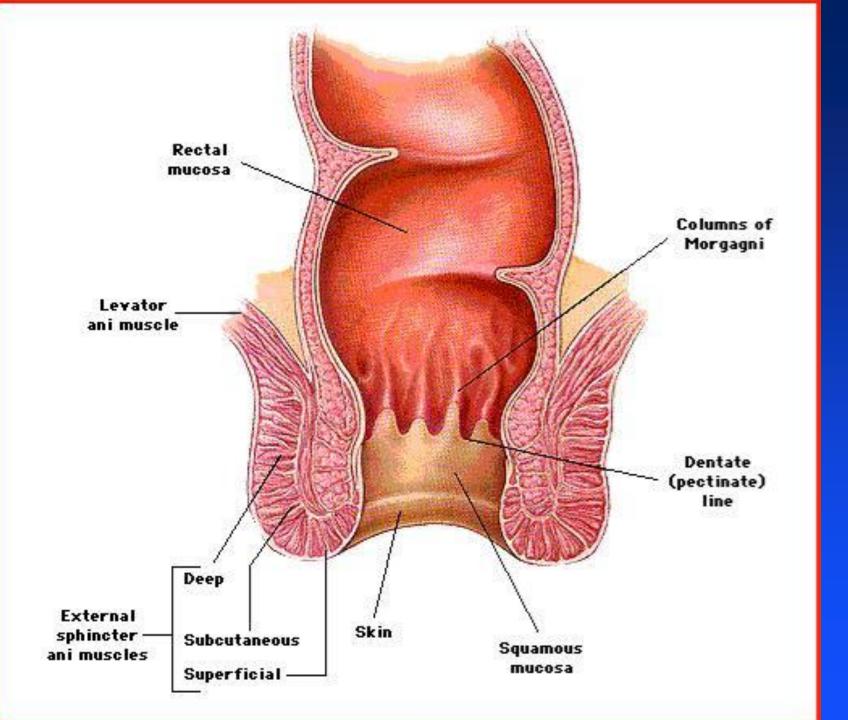
Kreimer A, Pierce Campbell, C...Giuliano AR. Lancet July 2013

Modeled Age-Specific Oral HPV Prevalence in US Men (NHANES 2009–2010)

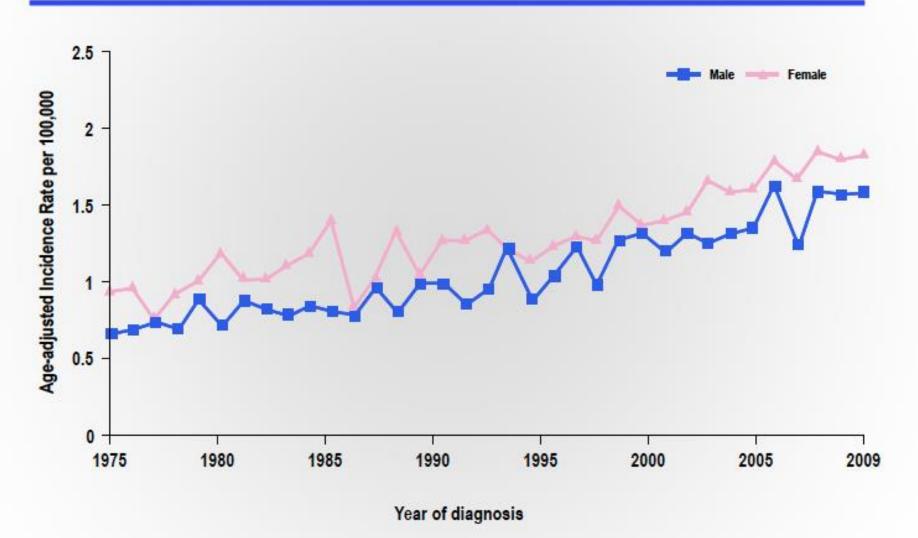


Age, Years

NHANES=National Health and Nutrition Examination Survey. Gillison ML et al. JAMA. 2012;307:693–703.

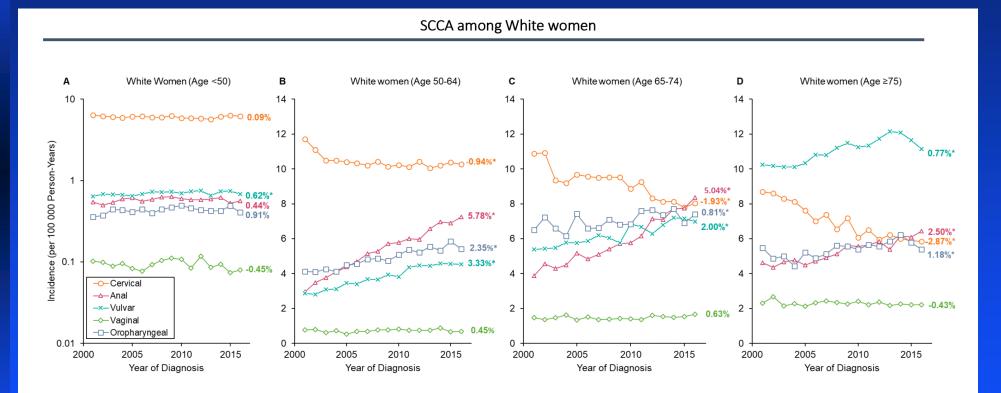


Age-Adjusted Incidence of Invasive Anal Cancer by Gender and Year of Diagnosis: United States



Howlader N et al. (eds). SEER Cancer Statistics Review, 1975-2009 (Vintage 2009 Populations). http://seer.cancer.gov/csr/1975_2009_pops09/. Accessed June 21, 2012.

Anal Cancer Incidence Is Increasing In Women

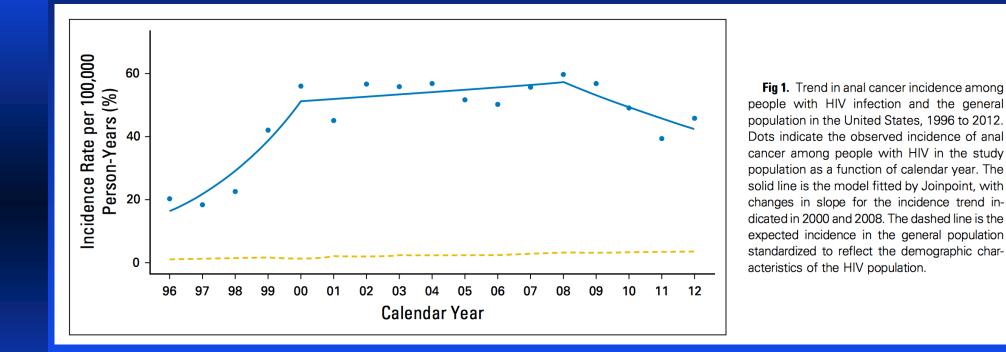


Deshmukh AA, et al. 17th International Conference on Malignancies in HIV/AIDS

Anal cancer rates in North American AIDS Cohort Collaboration on Research and Design) (NA-ACCORD) 1996-2007 Incidence/100,000 (85% CI) •HIV-infected MSM 131 (109-157) MSW 46 (25-77) 30 (17-50) Women

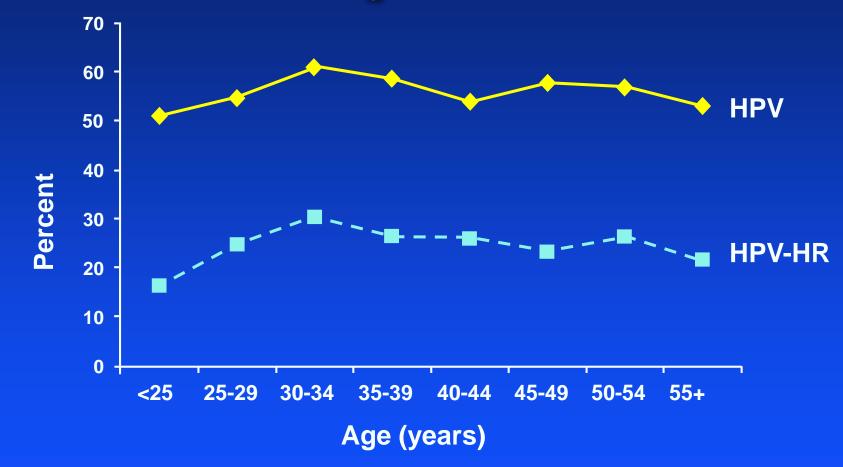
Silverberg M et al. CID, e-pub Jan 2012

Recent trends in anal cancer incidence U.S. AIDS and cancer registry match study



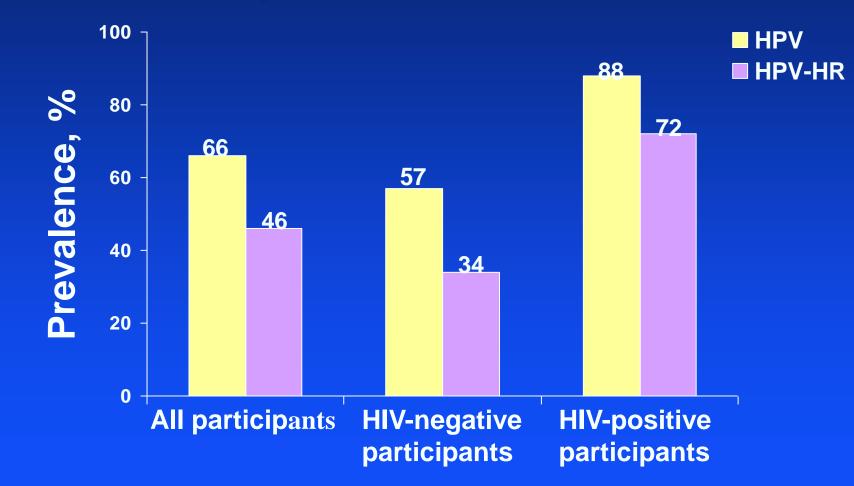
Colon-Lopez V. et al J Clin Oncol 2018; 36:68-75

Anal HPV infection by age group in sexually active HIV-negative MSM in U.S.



Chin-Hong PV et al. *J Infect Dis.* 2004;190:2070-2076

Prevalence of anal HPV among MSM in San Francisco Population-based data



Chin-Hong et al. Ann Int Med. 2008;149;300-6.

Preventing HPV infection and HPVassociated disease

- Primary prevention= HPV vaccination
- Secondary prevention= screening for and treatment of HSIL in at-risk adults

The NEW ENGLAND JOURNAL of MEDICINE

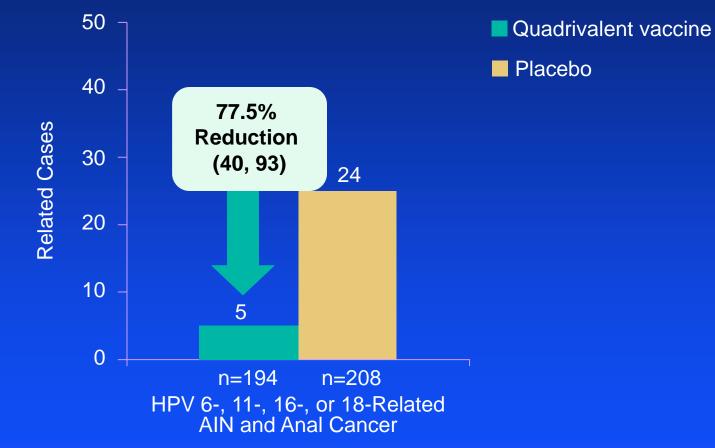
ORIGINAL ARTICLE

HPV Vaccine against Anal HPV Infection and Anal Intraepithelial Neoplasia

Joel M. Palefsky, M.D., Anna R. Giuliano, Ph.D., Stephen Goldstone, M.D., Edson D. Moreira, Jr., M.D., Carlos Aranda, M.D., Heiko Jessen, M.D., Richard Hillman, M.D., Daron Ferris, M.D., Francois Coutlee, M.D., Mark H. Stoler, M.D., J. Brooke Marshall, Ph.D., David Radley, M.S., Scott Vuocolo, Ph.D., Richard M. Haupt, M.D., M.P.H., Dalya Guris, M.D., and Elizabeth I.O. Garner, M.D., M.P.H.

Quadrivalent vaccine in males: efficacy against HPV 6/11/16/18-related AIN and anal cancer in MSM¹

Per-Protocol Efficacy Population



n = number of subjects who have at least 1 follow-up visit after month 7.

¹Palefsky J, Giuliano et al. NEJM 2011, 365: 1576-85

Canadian recommendations for HPV vaccine in women and men

Table 1. NACI Recommendations for the HPV Immunization Schedule

Recommended Groups	Recommended Immunization Schedule	HPV Vaccines and NACI Evidence Grade (see <u>Table 8</u> for an explanation of NACI's grading of evidence)
Healthy (immunocompetent, non-HIV infected) Females 9-14 years of age (and healthy females ≥15 years of age in whom the first dose was administered between 9-14 years of age)	2- or 3-dose schedule	HPV2 or HPV4 (Grade A); HPV9 (Grade B)
Healthy (immunocompetent, non-HIV infected) Females ≥15 years of age	3-dose schedule	HPV2 or HPV4 (Grade A) or HPV9 (Grade B)
Healthy (immunocompetent, non-HIV infected) Males 9-14 years of age (and healthy males ≥15 years of age in whom the first dose was administered between 9-14 years of age)	2- or 3-dose schedule	HPV4 or HPV9 (Grade B)
Healthy (immunocompetent, non-HIV infected) Males ≥15 years of age	3-dose schedule	HPV4 or HPV9 (Grade B)
Immunocompromised individuals and immunocompetent HIV-infected individuals	3-dose schedule	HPV2 or HPV4 in females (Grade B); HPV4 in males (Grade B); HPV9 in females or males (Grade I)

https://www.canada.ca/en/public-health/services/publications/healthy-living/updated-recommendations-human-papillomavirus-immunization-schedule -immunocompromised-populations.html#a6, accessed Jan 3, 2020

Screening for HPV infection and HPV-associated disease in men

- There are no screening tests for oral HPV infection
 - Regular thorough dental exam

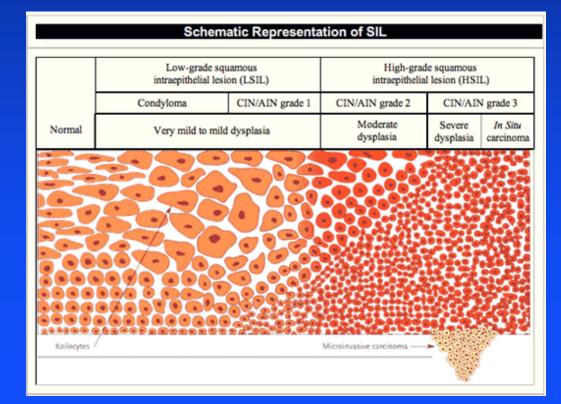


Screening for HPV infection and HPV-associated disease in men

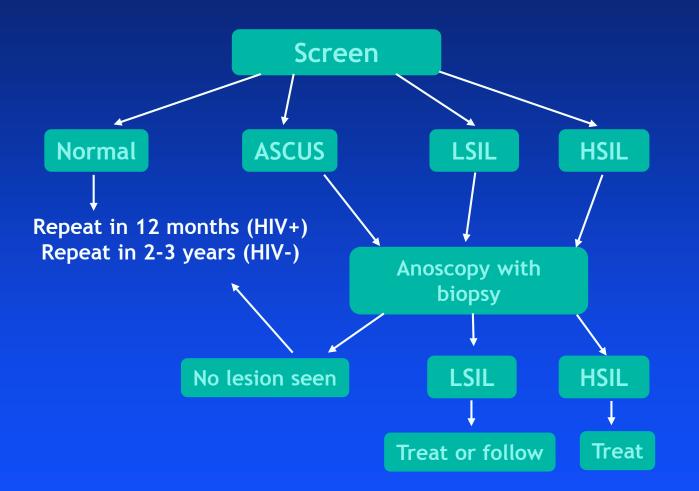
- There are no screening tests for penile HPV infection
 - Routine screening of sexual partners of women with CIN is not recommended

Screening for HPV infection and HPV-associated disease in men

There are screening tests for anal HPV infection and anal HSIL



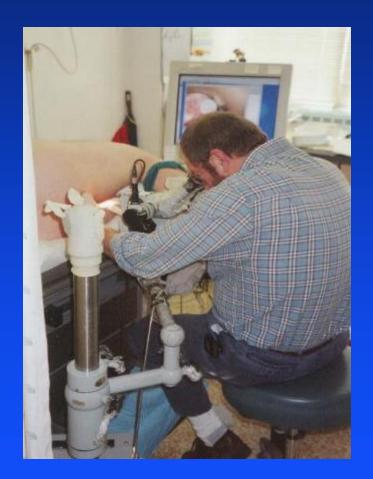
Anal cytology screening for ASIL



Chin-Hong PV et al. J Infect Dis. 2004;90:2070-2076.

High resolution anoscopy (HRA)

HRA is an officebased procedure examining the anus, anal canal and perianus using a colposcope or operating microscope with 5% acetic acid and Lugol's solution



Who should be screened?

- All HIV-positive men regardless of sexual orientation
- All HIV-negative MSM
- Women with high-grade cervical or vulvar lesions or cancer
- All HIV+ women

- All men and women with perianal condyloma
- Solid organ transplant recipients
- Over 25 years if immunosuppressed, inc. HIV
- Over 40 years if immunocompetent

ANCHOR study

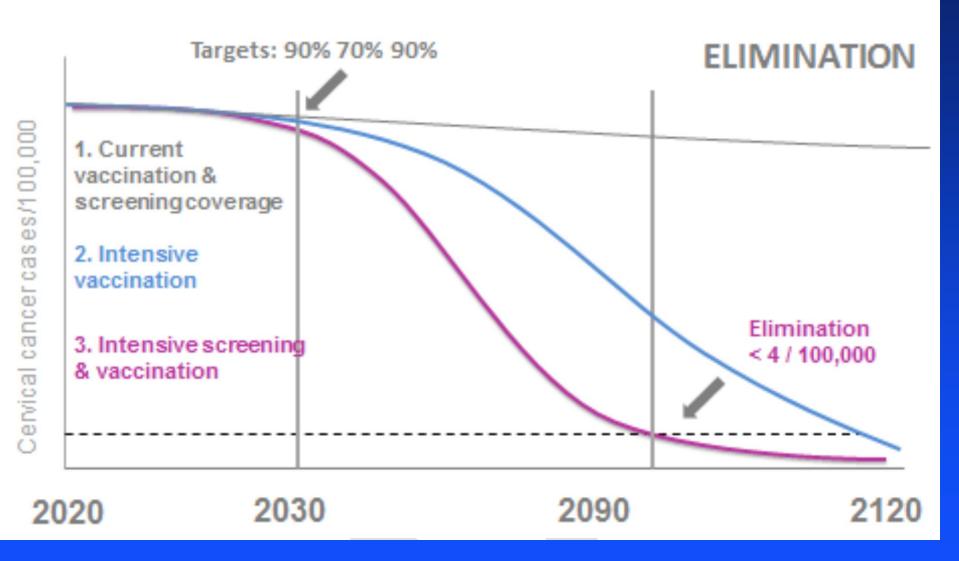
 Primary aim: To determine whether treating anal high-grade squamous intraepithelial lesions (HSIL) is effective in reducing the incidence of anal cancer in HIV-infected men and women



NCI UM1CA121947 and OAR

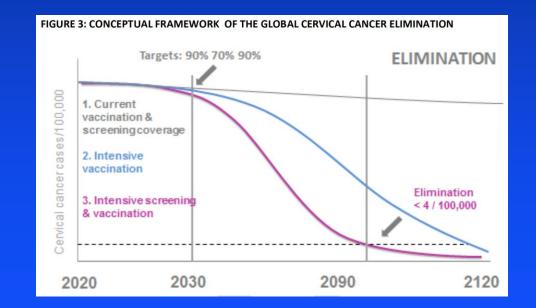
WHO call for elimination of cervical cancer

FIGURE 3: CONCEPTUAL FRAMEWORK OF THE GLOBAL CERVICAL CANCER ELIMINATION



Elimination of HPV-related cancer in men

Anal cancer: vaccination + screening if ANCHOR supports it Oropharyngeal cancer: vaccination only, likely later date of elimination



What do we need to know in men

- Natural history of anal, penile and oropharyngeal HPV infection
 - Higher antibody prevalence among MSM compared with HM
 - Circulating antibodies to natural infection are most strongly associated with anal HPV infections

Lu B et al. Cancer Epidemiol Biomarkers Prev. 2012;21(9):1542-1546

What do we need to know in men

- Natural history of pre-cancerous lesions associated with anal, penile and oropharyngeal HPV infection
 - When are they most infectious?
 - When do they progress to cancer?
 - Can they be detected reliably?
 - Will their removal prevent cancer at those sites?

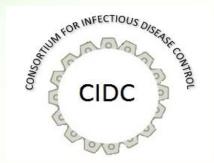
Summary

- HPV infection in men is important
 - Spread to sexual partners
 - Disease burden

- Vaccination is the best long-term approach
- Screening for anal cancer may be possible
- Screening for oropharyngeal cancer is not yet possible

Thank you!

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Barcelona, Spain

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Question & Answer Period

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CIDC

- Evaluation: <u>https://www.surveymonkey.com/r/CXC5Y3H</u>
- Slide Set, Video recording, HPV documents at: <u>www.CIDCgroup.org</u>
- Find out about news and upcoming events....

....Join the Canadian HPV Prevention Network at: www.CIDCgroup.org

(it's free! Fill out the 'Contact' form on the website)

Thank you for participating!

More Info: George Wurtak, Executive Director, CIDC <u>GWurtak@CIDCgroup.org</u>

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