10.30-12.30 **IV SESSIONE**

HIV

Moderatori: *F. Castelli (Brescia), F. Mazzotta (Firenze)*

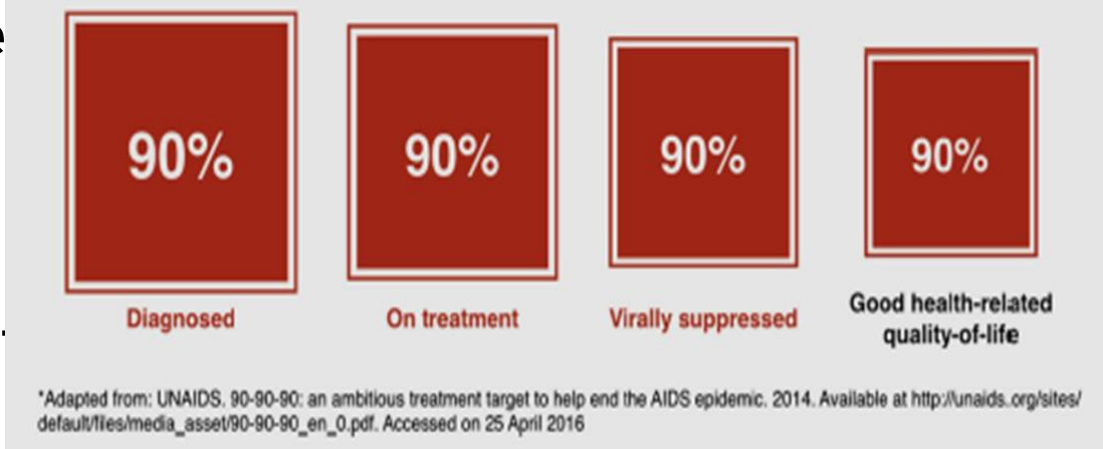
L'importanza della vaccinazione nei pazienti HIV positivi

Elena Salomoni

Ospedale S.M.Annunziata, Firenze
Azienda USL Toscana Centro

Razionale e contesto

- Clinico: maggiore fre che si punta a prevenire



- Raccomandazioni di

- E' uno degli strumenti per raggiungere il 4° 90: rientra nella "positive prevention" o "salute positiva, dignità e prevenzione" (LGI 2017)

- Implementazione a partire da quanto successo con HAV nel 2017

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
			<15% or <200mm³	≥15% and ≥200mm³							
IIV4 or RIV4	1 dose annually										
or LAIV4	Contraindicated					Precaution				or 1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 yrs									
MMR	Contraindicated*	Contraindicated			1 or 2 doses depending on indication						
VAR	Contraindicated*	Contraindicated			2 doses						
RZV		2 doses at age ≥19 years			2 doses at age ≥50 yrs						
HPV	Not Recommended*	3 doses through age 26 yrs			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
Pneumococcal (PCV15, PCV20,PPSV23)					1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)						
HepA					2 or 3 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT³ recipients only			1 dose						

HAV

L'EPATITE A IN ITALIA NEGLI ULTIMI CINQUE ANNI: DATI DALLA SORVEGLIANZA SEIEVA 2015-2019

Maria Elena Tosti[1], Annamaria Mele[2], Luigina Ferrigno[1], Luisa Romanò[3], Valeria Alfonsi[4], Franca D'Angelo[1] e Simonetta Crateri[1]
[1]Centro Nazionale per la Salute Globale, ISS
[2]Dipartimento di Sanità Pubblica e Malattie Infettive, Sapienza Università di Roma
[3]Dipartimento di Scienze Biomediche per la Salute, Università degli Studi di Milano
[4]Direzione Sanitaria, Azienda Ospedaliera Sant'Andrea, Roma

EuroPride Amsterdam, luglio-agosto 2016

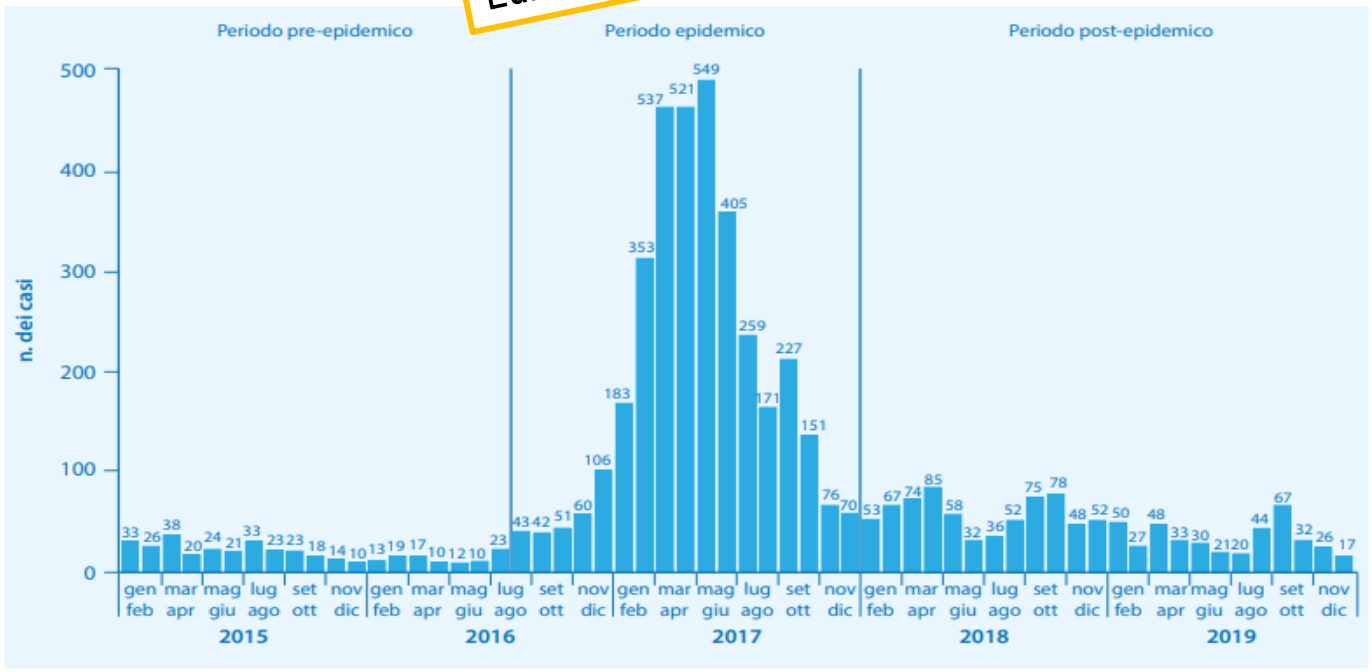


Figura - Casi mensili di epatite virale A segnalati al SEIEVA (gennaio 2015-dicembre 2019)

HAV

Influence of Human Immunodeficiency Virus Type 1 Infection on Acute Hepatitis A Virus Infection

Table 3. Titration, duration, and half-life of hepatitis A virus (HAV) viremia in HIV-1–infected and non–HIV-infected patients.

Parameter	HIV-1–infected	Non–HIV-infected	P[a]
Titration[b]			
Median	1×4^{-7}	1×4^{-3}	<.001
Range	1×4^{-5} to 1×4^{-8}	1×4^{-2} to 1×4^{-6}	—
Duration, days[c]			
Median	53	22	<.05
Range	10–89	12–54	—
Half-life, days			
Median	6.4	3.7	.09
Range	1.9–16.4	1.6–9.3	—

[a] Mann-Whitney *U* test.
[b] Dilution at which the test result became positive. Patients with serum samples that were obtained and stored in ≤10 days after onset of clinical symptoms were analyzed: 8 HIV-1–infected and 14 non–HIV-infected patients.
[c] Duration from the onset of clinical symptoms to the time that the last serum sample was obtained that was positive for HAV, provided that after this last positive sample, another serum sample with negative results was obtained in the subsequent 45 days; 11 HIV-1–infected and 9 non–HIV-infected patients met these criteria.

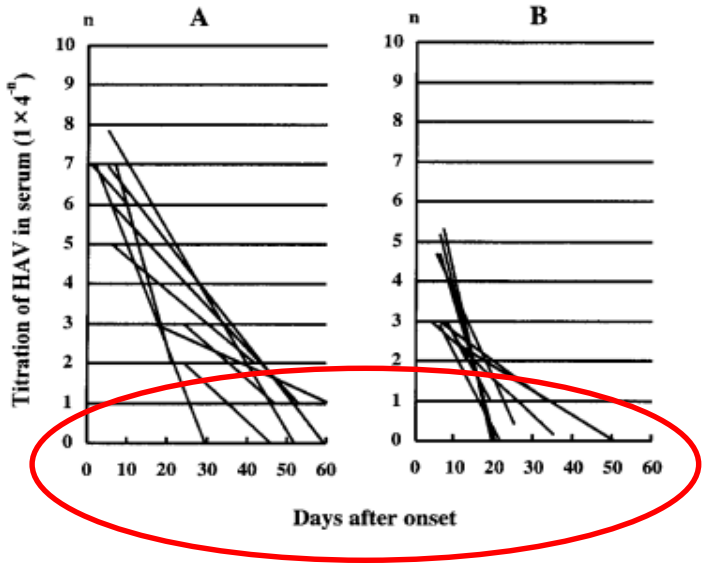


Figure 2. Decay pattern of hepatitis A virus (HAV) viremia in patients with *(A)* and without *(B)* HIV-1 infection. HAV levels were semiquantitated by use of nested PCR in serum samples diluted 1×4^{-n}. Day 0 was the day when clinical manifestations of acute HAV infection were documented. Linear regression was used to obtain the best-fitting straight line for at least 3 data points. The length of each line was determined by the initial positive point and the last positive point by day 60.

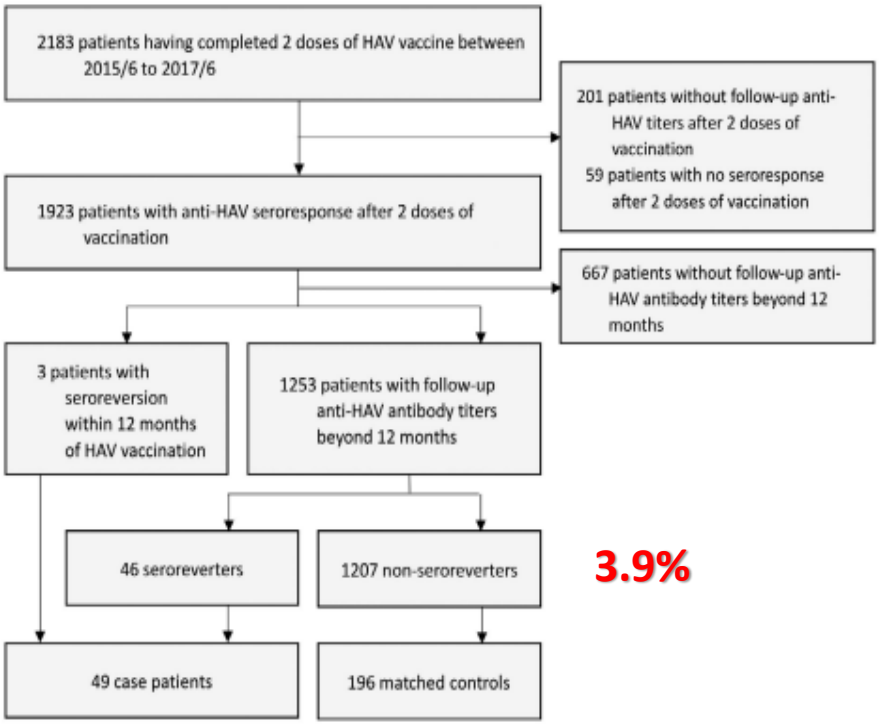
Influence of human immunodeficiency virus type 1 infection on acute hepatitis A virus infection. Ida S et al.Clin Infect Dis. 2002

HAV

HEPATOLOGY
HEPATOLOGY, VOL. 70, NO. 2, 2019
VIRAL HEPATITIS

Early Seroreversion After 2 Doses of Hepatitis A Vaccination in Human Immunodeficiency Virus–Positive Patients: Incidence and Associated Factors

Sung-Hsi Huang,[1,2] Chung-Hao Huang,[3] Ning-Chi Wang,[4] Tun-Chieh Chen,[3,5] Yuan-Ti Lee,[6,7] Shih-Ping Lin,[8] Te-Yu Lin,[4] Chi-Ying Lin,[9] Yu-Lin Lee,[10] Chen-Hsiang Lee,[11] Cheng-Pin Chen,[12] Kuan-Yin Lin,[13] Guan-Jhou Chen,[9] Chun-Eng Liu,[10] Shu-Hsing Cheng,[12,14] Po-Liang Lu,[3] Chia-Jui Yang,[15,16] and Chien-Ching Hung [2,17] on behalf of the Taiwan HIV Study Group



3.9%

- Vaccination campaign to control the outbreak in Taiwan
- From June 2015 to June 2017
- Median follow-up of 611 days

TABLE 3. Multivariable Analysis of Factors Associated With Early Seroreversion After HAV Vaccination

	aOR	*P* Value
Weight, per 10-kg increment	1.703 (1.292-2.323)	<0.001
HIV-RNA load >200 copies/mL at vaccination	2.922 (1.067-7.924)	0.035
CD4 count at vaccination, per 100-cell/mm^3 increment	0.837 (0.704-0.979)	0.034
Positive anti-HAV at month 6	0.059 (0.020-0.154)	<0.001

(lack of anti-HAV seroresponse before the second dose of HAV vaccination)

HAV

Open Forum Infectious Diseases

BRIEF REPORT

Acute Hepatitis A Viral Infection in People With HIV With Previously Documented Hepatitis A Immunity or Appropriate Vaccination: A Case Series

Stephanie E. McLaughlin,[1] Jason D. Simmons,[1] Hilary Armstrong,[2] Elysia Gonzales,[2] Robert M. Rakita,[1] Jeffrey S. Duchin,[1,2] and Rena C. Patel[1,3]

[1]Division of Allergy and Infectious Disease, Department of Medicine, University of Washington, Seattle, Washington, USA, [2]Public Health - Seattle and King County, Seattle, Washington, USA, and [3]Department of Global Health, University of Washington, Seattle, Washington, USA

Table 1. Sociodemographic and Clinical Characteristics of PWH who Contracted Acute HAV Infection Despite Previously Documented HAV Immunity or Immunization

	Patient A	Patient B	Patient C	Patient D
Age, y	65	38	48	55
Gender (sex at birth if differs from gender)	Male	Male	Male	Transgender woman (male sex at birth)
Sexual orientation	MSM	MSM	MSM	Sex with men
Housing	Stable, apartment with long-term male partner	Stable, single apartment	Stable, supportive group housing	Stable, single apartment
Illicit drug use	None	Current inhaled methamphetamine use, never IDU	Current inhaled methamphetamine use, past IDU >1 y ago	None
Occupation	Disabled	Ride-share driver	Technician for a meal service company	Unemployed
Year of HIV diagnosis (years between HIAV and HAV diagnosis)	8	14	6	28
CD4 cell count nadir	Unknown nadir	Unknown nadir	Nadir 736 cells/mL in 2018	Unknown nadir
HIV VL history	UD VL since 2012	UD VL since 2011	Intermittently UD VL	UD VL (since unknown date)
Antiretroviral medication (at time of HAV diagnosis)	Abacavir, lamivudine, raltegravir	Tenofovir, emtricitabine, bictegravir	Tenofovir, emtricitabine, dolutegravir	Abacavir, lamivudine, dolutegravir
HAV vaccination status (years before HAV	Self-reported prior vaccination	Self-reported prior vaccination (unknown date)	None documented	12, 6 (2-dose series 12 and 6 y prior)
			nknown	333
				Not known
			00, 1636	1013, UD

The patients in the case series were either vaccinated at a CD4 count >200 (Patient D) or had well-c with long-standing undetec loads at the time of HA (Patients A–C).

Vaccination

- As vaccine responses may be significantly lower in persons with HIV (i.e. lower seroconversion rates, faster titer decline), do not use rapid schedules (e.g. rabies, tick-borne encephalitis, HAV/HBV) and consider antibody titres to assess their effectiveness if vaccinated at CD4 count < 200 cells/μL or unsuppressed viremia (e.g. rabies, tick-borne encephalitis, HAV, meningococci). Be attentive to observe boosters and all post-exposure measures (particularly after potential rabies exposure)

Acute Hepatitis A Viral Infection in People With HIV With Previously Documented Hepatitis A Immunity or Appropriate Vaccination: A Case Series. McLaughlin S et al. Open Forum Infect Dis. 2021.

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
			<15% or <200mm³	≥15% and ≥200mm³							
IIV4 or RIV4	1 dose annually										
or LAIV4	Contraindicated					Precaution				or 1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 yrs									
MMR	Contraindicated*	Contraindicated			1 or 2 doses depending on indication						
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RZV		2 doses at age ≥19 years			2 doses at age ≥50 yrs						
HPV	Not Recommended*	3 doses through age 26 yrs			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
Pneumococcal (PCV15, PCV20,PPSV23)					1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)						
HepA					2 or 3 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT³ recipients only			1 dose						

Pneumococco

Adults aged 19–64 years with immunocompromising conditions have 9–18 times the risk of pneumococcal disease compared with healthy adults.

	Rate per 100,000 person-years, 2013–2015		
	Healthy[1]	**High-risk[2]**	**Rate Ratio**
18–49 years			
Hospitalized IPD	0.6 (0.5, 0.7)	8.6 (6.7, 11.2)	**15.4 (11.3, 20.9)**
Hospitalized pneumococcal pneumonia	1.2 (1.1, 1.3)	21.1 (17.9, 24.9)	**17.6 (14.4, 21.5)**
50–64 years			
Hospitalized IPD	1.9 (1.6, 2.1)	16.4 (14.4, 18.7)	**8.8 (7.4, 10.6)**
Hospitalized pneumococcal pneumonia	3.9 (3.5, 4.2)	43.0 (39.7, 46.6)	**11.1 (9.9, 12.6)**

Reference: Pelton et al. CID 2019
IPD=invasive pneumococcal disease
1. Adults without any conditions with risk-based pneumococcal vaccine indications
2. Adults with immunocompromising condition or with cochlear implant

Kobayashi M, Advisory Committee on Immunization Practices, National Center for Immunization & Respiratory Disease . October 19, 2022

Pneumococco

PPSV23 recommended for use in the United States:

- since the 1980s for adults aged ≥65 years and for younger adults with underlying conditions that increase their risk for pneumococcal disease

PCV13 recommended for use in the United States:

- in 2010 for use in children
- In 2012 for adults with immunocompromising conditions in series with PPSV23
- In 2014 extended to all adults aged ≥65 years

Pneumococcal Vaccines: PCVs vs. PPSV23

	PCV	PPSV23
Duration of protection	**No decline for 5 yrs**[1]	Variable findings, waning reported as early as **2 years** since vaccination[2]
Vaccine Effectiveness vs. Vaccine-type IPD	Supported by clinical efficacy/effectiveness data	Supported by clinical efficacy/effectiveness data; limited effectiveness reported in immunocompromised adults[3]
Vaccine Effectiveness vs. Vaccine-type non-invasive/non-bacteremic pneumonia	Supported by clinical efficacy data • **Moderate** protection (45%: 95% CI 14 to 63)[4]	**Variable** clinical effectiveness data • Modest protection (18%: 95% CI -4 to 35%) from a meta-analysis[5]

1. Patterson et al. Trials in Vaccinology 2016.
2. World Health Organization. Strategic Advisory Group of Experts on Immunization 5-7 October 2020. https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_October_2020.pdf?ua=1
3. French et al. NEJM 2000; Andrews et al. Vaccine 2012; Rudnick et al. Vaccine 2013; Djennad et al. EClinicalMedicine 2018
4. Bonten et al. NEJM 2015
5. Farrar et al. https://www.medrxiv.org/content/10.1101/2022.10.06.22280772v1.full

Pneumococco

IPD Rates in PWH in PCV13 Era:
IPD Incidence in Adults ≥19 Yr With IPD, ABCs

IPD Serotypes	IPD Incidence/100,000 in PWH			% Change vs 2008-2009 (95% CI)	
	2008-2009	2011-12	2017-2018	2011-2012	2017-2018
All IPD	306.7	222.8	183.0	-27 (-36 to -18)	-40 (-48 to -32)
PCV13 serotypes	143.9	80.0	39.6	-44 (-55 to -33)	-73 (-79 to -66)
PPSV23-unique serotypes	73.9	75.4	79.2	3 (-19 to 30)	8 (-15 to 35)
Nonvaccine serotypes	90.0	66.9	64.2	-25 (-41 to -6)	-28 (-43 to 11)

Kobayashi. IDWeek 2021. Abstr 70.

Pneumococco

PPSV23 recommended for use in the United States:

- since the 1980s for adults aged ≥65 years and for younger adults with underlying conditions that increase their risk for pneumococcal disease

PCV13 recommended for use in the United States:

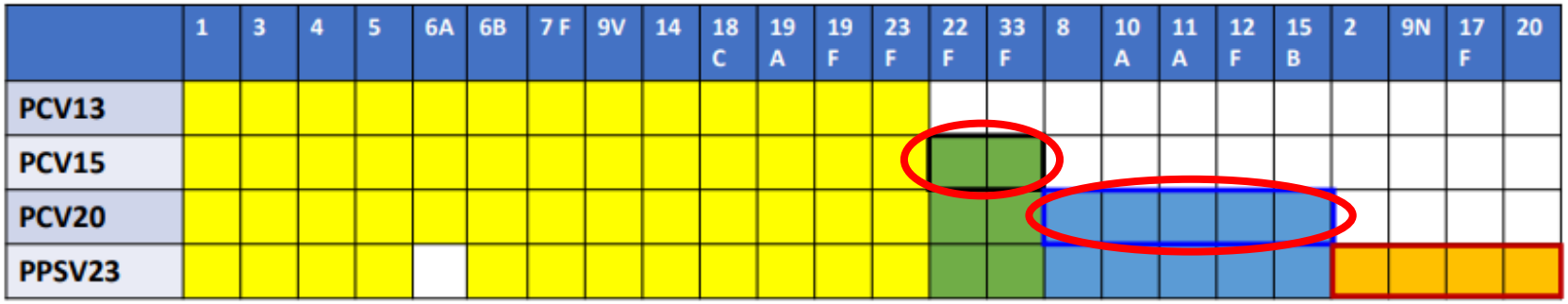
- in 2010 for use in children
- In 2012 for adults with immunocompromising conditions in series with PPSV23
- In 2014 extended to all adults aged ≥65 years

PCV20 (Wyeth Pharmaceuticals LLC) and **PCV15** (Merck Sharp & Dohme Corp.) were licensed for adults aged ≥18 years:

- in June 2021 by the Food and Drug Administration (FDA)
- in February 2022 by the European Medicine Agency (EMA)

Pneumococco

Serotypes Contained in Pneumococcal Vaccines

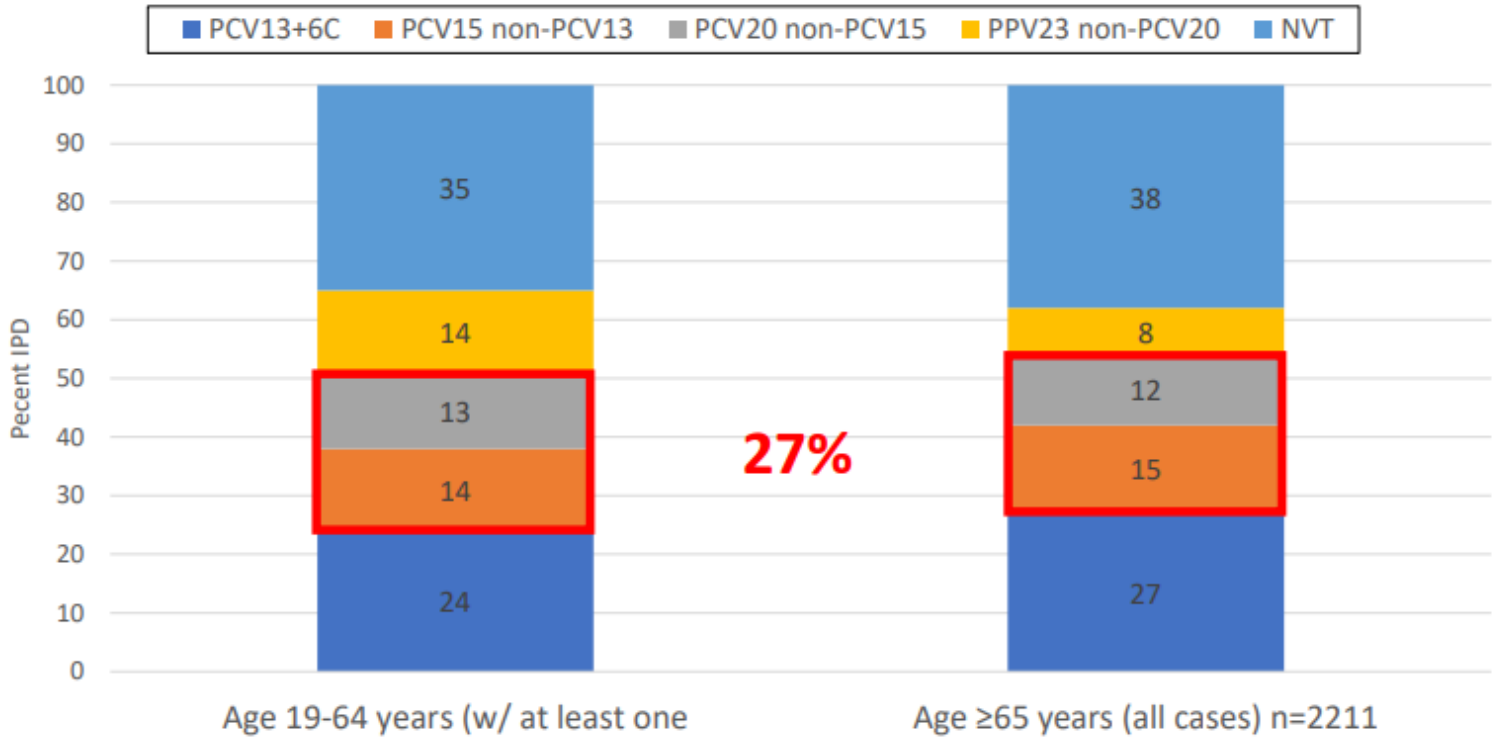


- **PCV15**: contains PCV13 serotypes and 22F and 33F
- **PCV20**: contains PCV13 serotypes and 22F, 33F, **8, 10A, 11A, 12F, and 15B**
- **PPSV23 non-PCV20**: includes serotypes **2, 9N, 17F, and 20**

Kobayashi M, Advisory Committee on Immunization Practices, National Center for Immunization & Respiratory Disease . October 19, 2022

Pneumococco

Pneumococcal serotypes contained in PCV20 but not in PCV13 caused 27% of Invasive Pneumococcal Disease in Adults in 2018–2019



CDC Active Bacterial Core surveillance

PCV15 non-PCV13 serotypes: 22F, 33F
PCV20 non-PCV15 serotypes: 8, 10A, 11A, 12F, 15B
PPSV23 non-PCV20 serotype: 2, 9N, 17F ,20

Kobayashi M, Advisory Committee on Immunization Practices, National Center for Immunization & Respiratory Disease . October 19, 2022

Pneumococco

IPD Rates in PWH in PCV13 Era: Frequency of Vaccine-Type IPD Incidence in Adults ≥19 Yr of Age

% Vaccine-Type IPD, 2017-2018	PWH
PCV13 type*	35
PCV15 unique	15
PCV20 unique	17
PPSV23, non-PCV20†	11
Nonvaccine type	22

32%

*PCV13 serotypes 1, 5, and 14 were not detected.
†PCV23, non-PCV20 serotype 2 was not detected.

- **PCV13 serotype 19A** was:
  - *Most* common in 2008-2009, accounting for **22%** of all IPD in PWH
  - *Less* common in 2017-2018, accounting for **5%** of all IPD in PWH
  - $P < .002$

Kobayashi. IDWeek 2021. Abstr 70.

Pneumococco

CDC, 2022

Pneumococcal (PPSV23; PCV15, PCV20)	***Yes!*** Adults with HIV infection need to get either PCV20 alone, or PCV15 followed 1 year later by PPSV23. If you have previously received either PCV13 and/or PPSV23, your healthcare provider can determine what additional doses you may need.

- PCV20
- PCV 15 → PPV23

EACS, 2022

Streptococcus pneumoniae	Higher rate and severity of invasive disease. Vaccine explicitly recommended for all persons with HIV	One dose of a conjugated vaccine: PCV-13, PCV-15 or PCV-20a for all persons according to availability and national guidelines, also if pre-vaccinated with PPV-23 polysaccharide vaccine. For patients vaccinated with PCV-13 or PCV-15 one dose of PPV-23 at least 2 months after the conjugate vaccine may be considered in some national guidelines for all persons with HIV

- PCV20
- PCV 13 → consider PPV23
- PCV 15 → consider PPV23

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Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
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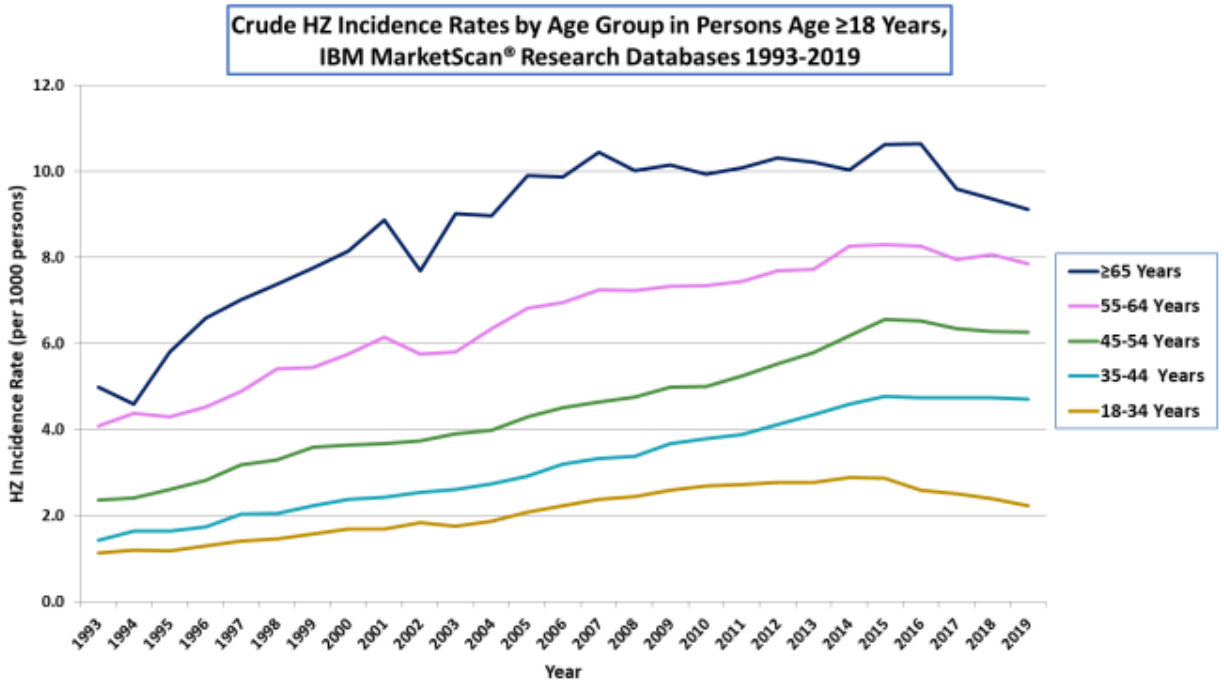
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT³ recipients only			1 dose						

HZ

HZ Incidence Common in Adults and Increases with Age

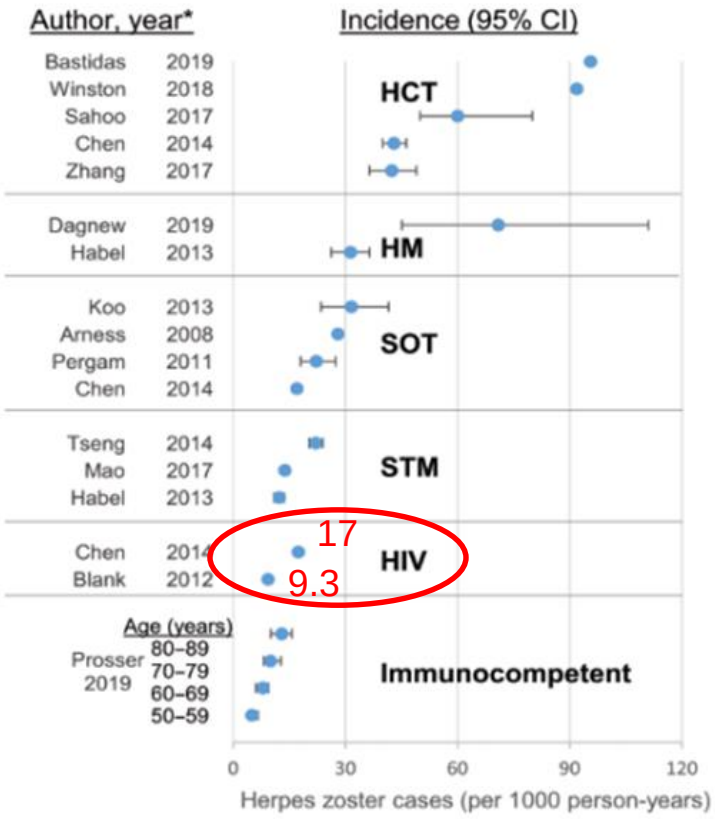
~1 million HZ cases per year in U.S. during pre- HZ vaccine era[1]



1. Harpaz et al. Prevention of Herpes Zoster, *MMWR*, June 6, 2008, Vol 57, #5
2. CDC, unpublished data; Updated from Harpaz et al. *Clinical Infectious Diseases*, Volume 69, Issue 2, 15 July 2019, Pages 341–344, https://doi.org/10.1093/cid/ciy953

HZ

- Median HZ incidence estimates for these IC groups exceeded those reported for immunocompetent adults >50 years



McKay et al. Herpes zoster risk in immunocompromised adults in the United States: A systematic review. CID 2020;71(7):e125–34.

Figure 3. Herpes zoster incidence rates among patients with selected immunocompromising conditions. *Studies with low or medium risk of bias.

HZ

Journal of *Clinical Medicine*

MDPI

Review

Incidence of Herpes Zoster in HIV-Infected Patients Undergoing Antiretroviral Therapy: A Systematic Review and Meta-analysis

Han-Chang Ku [1,2], Yi-Tseng Tsai [1,2], Sriyani-Padmalatha Konara-Mudiyanselage [2], Yi-Lin Wu [2,3], Tsung Yu [4,*] and Nai-Ying Ko [5,*]

Table 2. Subgroup analysis of HZ incidence in different categories.

Subgroup Category	No. of Studies	RR (95% Confidence Interval)	I^2 (%)	*p* Value
Overall HZ	11	2.30 (1.56–3.05)	99.3	0.001
Sex				
Male	6	0.68 (0.52–0.80)	97.5	0.001
Female	6	0.32 (0.20–0.48)	97.5	0.001
Income				
High income	8	2.64 (1.62–3.65)	99.5	0.001
Low income	2	1.33 (−0.56–3.22)	99.3	0.001
AIDS history				
Yes	4	0.40 (0.28–0.54)	98.3	0.001
No	4	0.60 (0.46–0.72)	98.3	0.001
Observation years				
>7 years	5	2.50 (1.29–3.71)	99.6	0.001
≤7 years	5	2.24 (1.09–3.40)	99.1	0.001
HIV risk factor				
Heterosexual	4	0.41 (0.31–0.52)	76.5	0.005
IDUs	4	0.35 (0.20–0.54)	88.7	0.001
MSM	4	0.32 (0.19–0.49)	90.2	0.001
CD4 count				
CD4 < 200	4	0.78 (0.55–0.91)	95.6	0.001
CD4 > 200	4	0.21 (0.06–0.51)	97.0	0.001
ART use				
Pre-ART	6	6.22 (3.59–8.85)	99.6	0.001
Post-ART	6	2.00 (1.04–2.95)	99.2	0.001

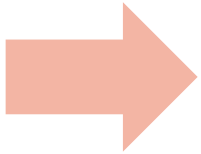
x 3-5 volte popolazione generale

Incidence of Herpes Zoster in HIV-Infected Patients Undergoing Antiretroviral Therapy: A Systematic Review and Meta-analysis. Ku HC et al. J Clin Med. 2021 May

HZ

Recommend RZV Regardless of Previous Vaccination With ZVL

- ZVL *(Zostavax)*
  - No longer available as of November 2020
  - Live, attenuated
  - 1 dose given subcutaneously
  - Indicated for adults aged ≥60 yr



- **RZV *(Shingrix)***
  - **FDA approved in October 2017; the only shingles vaccine currently available in the US**
  - **Recombinant, adjuvanted**
  - **2 doses given intramuscularly, 2-6 mo apart**
  - **Indicated for immunocompetent adults aged ≥50 yr or ≥18 yr with immunocompromise**

Dooling. MMWR Morb Mortal Wkly Rep. 2018;67:103. www.cdc.gov/vaccines/vpd/shingles/index.html. Zoster vaccine recombinant PI.

Duration of Protection and Timing of RZV After ZVL

- Studies examined safety of RZV given ≥5 yr after receiving ZVL; shorter intervals not studied, but no data or theoretical concerns with shorter intervals
- At 3 yr post vaccination, ZVL efficacy waned substantially to 38% in individuals aged ≥70 yr and 18% in those aged ≥80 yr; **recommend RZV regardless of prior ZVL vaccination**

Prevention, % (95% CI)	ZVL	Median Follow-up Period, Yr	RZV*	Median Follow-up Period, Yr
Shingles				
▪ Aged 50-59 yr	70 (54-81)	1.3	97 (90-99)	3.2†
▪ Aged 60-69 yr	64 (56-71)	3.1	97 (90-100)	3.2†
▪ Aged ≥70 yr	38 (25-48)	3.1	91 (87-95)	3.7
PHN				
▪ Aged ≥50 yr	–		91 (76-98)	3.2†
▪ Aged ≥70 yr	67 (43-81)	3.1	89 (69-97)	3.7

Dooling. MMWR Morb Mortal Wkly Rep. 2018;67:103. www.cdc.gov/vaccines/vpd/shingles/index.html. Zoster vaccine recombinant PI.

Recommend RZV With or Without Evidence of Previous Chickenpox

- Worldwide, more than 99% of adults aged ≥50 yr have immunity to VZV
- In the US, ACIP considers those born before 1980 to have natural VZV immunity via childhood exposure
- CDC and ACIP **recommend shingles vaccination regardless of whether or not patients recall having a naturally occurring varicella (chickenpox)**

- VZV serology testing not recommended, but if tested and seronegative, do not give RZV
  - Instead, follow recommendations for varicella vaccine
- Patients with previous history of shingles can receive RZV to prevent further episodes**, even if experiencing PHN**
  - **If patient currently has shingles rash, wait for rash to resolve before giving RZV**

Dooling. MMWR Morb Mortal Wkly Rep. 2018;67:103. www.cdc.gov/vaccines/vpd/shingles/index.html. Zoster vaccine recombinant PI.

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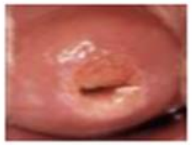
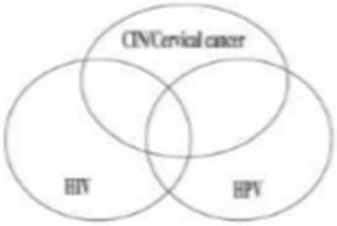
Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
			<15% or <200mm³	≥15% and ≥200mm³							
IIV4 or RIV4	1 dose annually										
or LAIV4	Contraindicated					Precaution				or 1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 yrs									
MMR	Contraindicated*	Contraindicated			1 or 2 doses depending on indication						
VAR	Contraindicated*	Contraindicated			2 doses						
RZV		2 doses at age ≥19 years			2 doses at age ≥50 yrs						
HPV	Not Recommended*	3 doses through age 26 yrs			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
Pneumococcal (PCV15, PCV20,PPSV23)					1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)						
HepA					2 or 3 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT³ recipients only			1 dose						

HPV

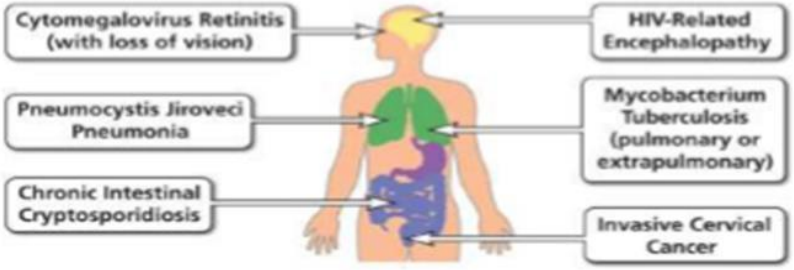
1988 → suspected the relationship between HIV infection and **cervical neoplasia**

- 1993 → Cervical cancer was classified an AIDS-defining malignancy early in the AIDS epidemic after recognition of high rates of precursor lesions in women with AIDS
- Cervical cancer is now the most common AIDS-related malignancy in women





Examples of **AIDS-Defining Conditions**



CONDIZIONI CLINICHE AIDS-DEFINENTI CDC' 93 STADIO C

- Candidosi bronchi, trachea o polmoni
- Candidosi esofagea
- Carcinoma della cervice invasivo
- Coccidiomicosi, disseminata o extrapolmonare
- Criptococcosi extrapolmonare
- Criptosporidiosi, cronica intestinale (>1mese)
- Malattia da citomegalovirus (oltre a fegato, milza o linfonodi)
- Retinite da citomegalovirus (con perdita del visus)
- Istoplasmosi disseminata o extrapolmonare
- Isosporiasi cronica intestinale (>1mese)
- Sarcoma di Kaposi
- Linfoma di Burkitt
- Linfoma primario encefalico
- *Mycobacterium avium* complex o *Mycobacterium Kansasii* a localizzazione disseminata o extrapolmonare
- *Mycobacterium tubercolosis* qualsiasi localizzazione
- Polmonite da *Pneumocystis carinii*
- Polmonite ricorrente
- Leucoencefalopatia multifocale progressiva
- Setticemia da salmonella, ricorrente
- Toxoplasmosi encefalica
- Wasting syndrome HIV correlata

HPV

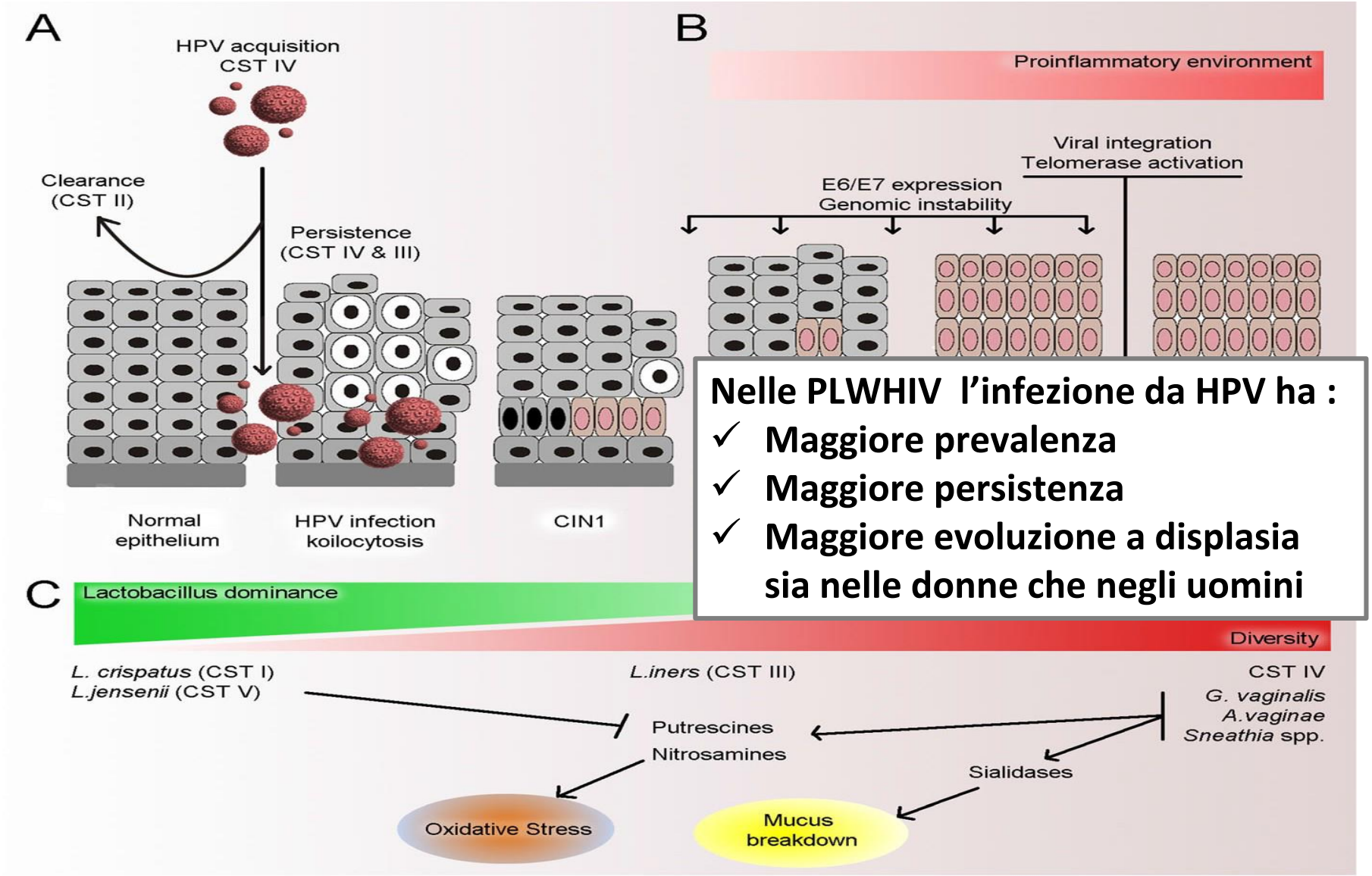
Ruolo eziologico delle infezioni persistenti da HPV per sede tumorale

Sede tumorale	Frazione di popolazione attribuibile all'HPV (%)	Sesso	Casi totali stimati in Italia nel 2017	Casi attribuibili all'HPV	Sopravvivenza a 5 anni
Cavità orale	<10	Maschi	3.000	270	57%
		Femmine	1.600	144	61%
		Totale	4.600	414	59%
Orofaringe	31	Maschi	1.500	465	37%
		Femmine	400	124	47%
		Totale	1.900	589	39%
Laringe	2,4	Maschi	4.000	96	69%
		Femmine	500	12	70%
		Totale	4.500	108	69%
Ano	88	Maschi	100	88	53%
		Femmine	200	176	57%
		Totale	300	264	56%
Pene	50	Maschi	500	250	74%
Cervice uterina	100	Femmine	2.300	2.300	68%
Vulva	25	Femmine	1.200	300	59%
Vagina	78	Femmine	200	156	39%
Tutti		Maschi	9.100	1.169	
		Femmine	6.400	3.212	
		Totale	**15.500**	**4.381**	

TABELLA 30. Stima del numero di casi incidenti in Italia nel 2017 per i quali è documentato un ruolo eziologico delle infezioni persistenti da *Papilloma virus* umano (HPV), sulla base della frazione di popolazione attribuibile all'HPV (PAF). Per le sedi tumorali è presentata anche la sopravvivenza relativa a 5 anni.

AIRTUM, I Numeri Del Cancro In Italia 2017

HPV



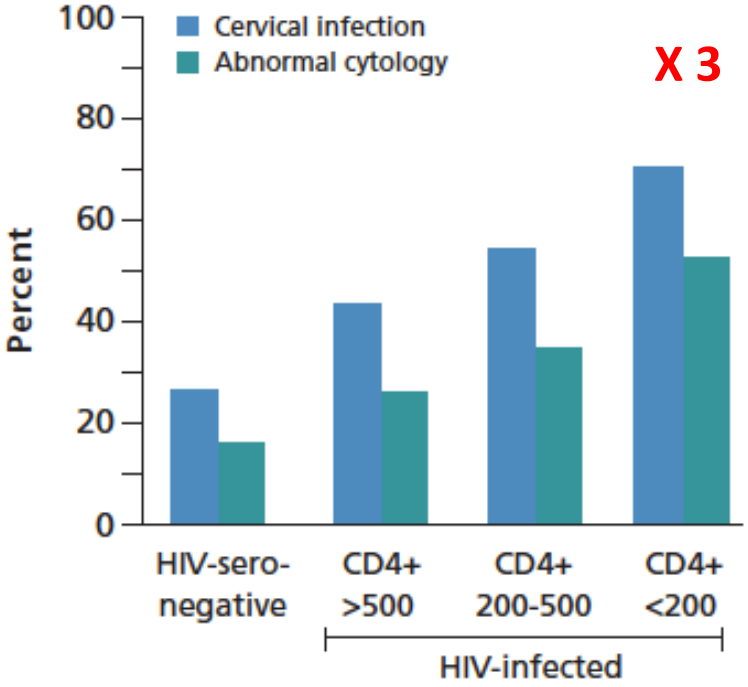
Nelle PLWHIV l'infezione da HPV ha :

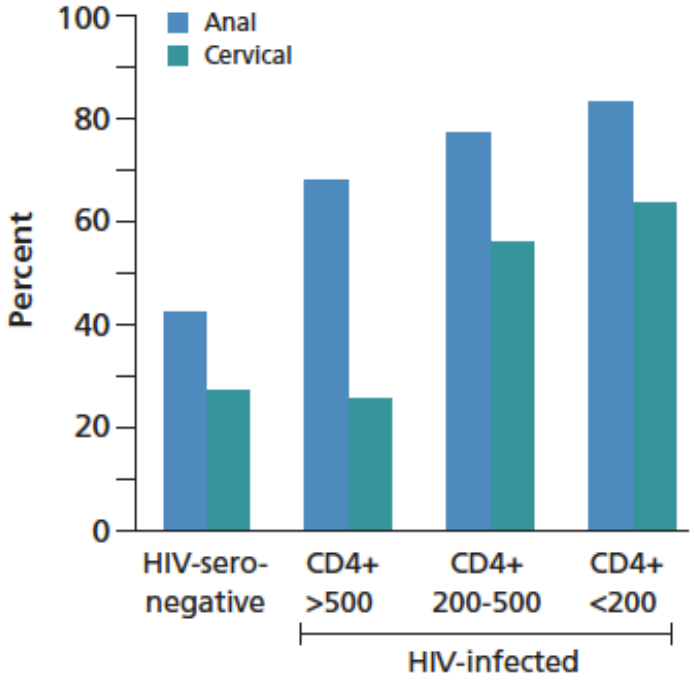
- ✓ **Maggiore prevalenza**
- ✓ **Maggiore persistenza**
- ✓ **Maggiore evoluzione a displasia sia nelle donne che negli uomini**

Mitra A, MacIntyre DA, Marchesi JR, Lee YS, Bennett PR, Kyrgiou M. The vaginal microbiota, human papillomavirus infection and cervical intraepithelial neoplasia: what do we know and where are we going next? Microbiome. 2016;4:58. doi:10.1186/s40168-016-0203-0.

HPV

La prevalenza di HPV nelle donne HIV positive aumenta con il diminuire dei CD4+





Palefsky, Topics in HIV 2007

HPV

High prevalence of anal HPV Infection and HSIL in HIV+ men and women

	Anal HPV prevalence	Anal HSIL prevalence	Anal cancer incidence
MSM	96%	43%	131/100000
MSW	59%	?	46/100000
Women	90%	28%	30/100000

MSM HIV negative: 35/100000 (X 4)

Joel Palefsky IPVC 2018, https://www.webcasts.com.au/ipvc2018-public/player/?player_id=11313

HPV

Classificazione di HPV in base al potenziale

Tipi HPV	Manifestazioni cliniche	Potenziale oncogenico
6,11	Condilomi genitali Low grade CIN	**Basso** (trascurabile)
40, 42, 53, 54, 57, 66, 84	Low grade CIN	**Basso** (trascurabile)
16, **18**, 26, 31, 33, 35, 39, 45, 51,52, 55, 56, 58, 59, 68, 73, 82, 83	Low grade CIN High grade CIN Carcinoma	**Elevato**
61, 62, 67, 69, 70, 71, 72, 81, CP6108, IS39	?	**Non definito**

2017

2. COMPOSIZIONE QUALITATIVA E QUANTITATIVA

1 dose (0,5 mL) contiene circa:

Proteina[2,3] L1 Tipo 6 di Papillomavirus Umano[1]	30 microgrammi
Proteina[2,3] L1 Tipo 11 di Papillomavirus Umano[1]	40 microgrammi
Proteina[2,3] L1 Tipo 16 di Papillomavirus Umano[1]	60 microgrammi
Proteina[2,3] L1 Tipo 18 di Papillomavirus Umano[1]	40 microgrammi
Proteina[2,3] L1 Tipo 31 di Papillomavirus Umano[1]	20 microgrammi
Proteina[2,3] L1 Tipo 33 di Papillomavirus Umano[1]	20 microgrammi
Proteina[2,3] L1 Tipo 45 di Papillomavirus Umano[1]	20 microgrammi
Proteina[2,3] L1 Tipo 52 di Papillomavirus Umano[1]	20 microgrammi
Proteina[2,3] L1 Tipo 58 di Papillomavirus Umano[1]	20 microgrammi

LG italiane 2017

Papilloma virus umano (HPV)	• Tutti, come previsto dalle schede tecniche, tenendo conto che la somministrazione in età precoce è più efficace. • Rischio condiviso con l'HIV di contrarre l'infezione e più alta percentuale, in presenza di HIV, dei relativi tumori.	A: tre dosi. B: al momento, non previsti.	Il vaccino 9-valente è da preferire alle altre formulazioni. I dati di sicurezza, immunogenicità ed efficacia sono disponibili in donne e uomini di età ≤ 27 anni non infetti, ma non in persone con risposta immunitaria ridotta.	[7-13; 23-24; 78]

EACS 2022

Human Papilloma Virus (HPV)	Shared risk with HIV of contracting infection. Higher rate of cervical and anal cancer	Vaccinate with 3 doses between ages 9 and 45 (health insurance coverage differs by country according to age, sex, sexual orientation). Use 9-valent vaccine if available. Persons treated for high grade dysplasia could benefit from a full course vaccination for secondary prevention

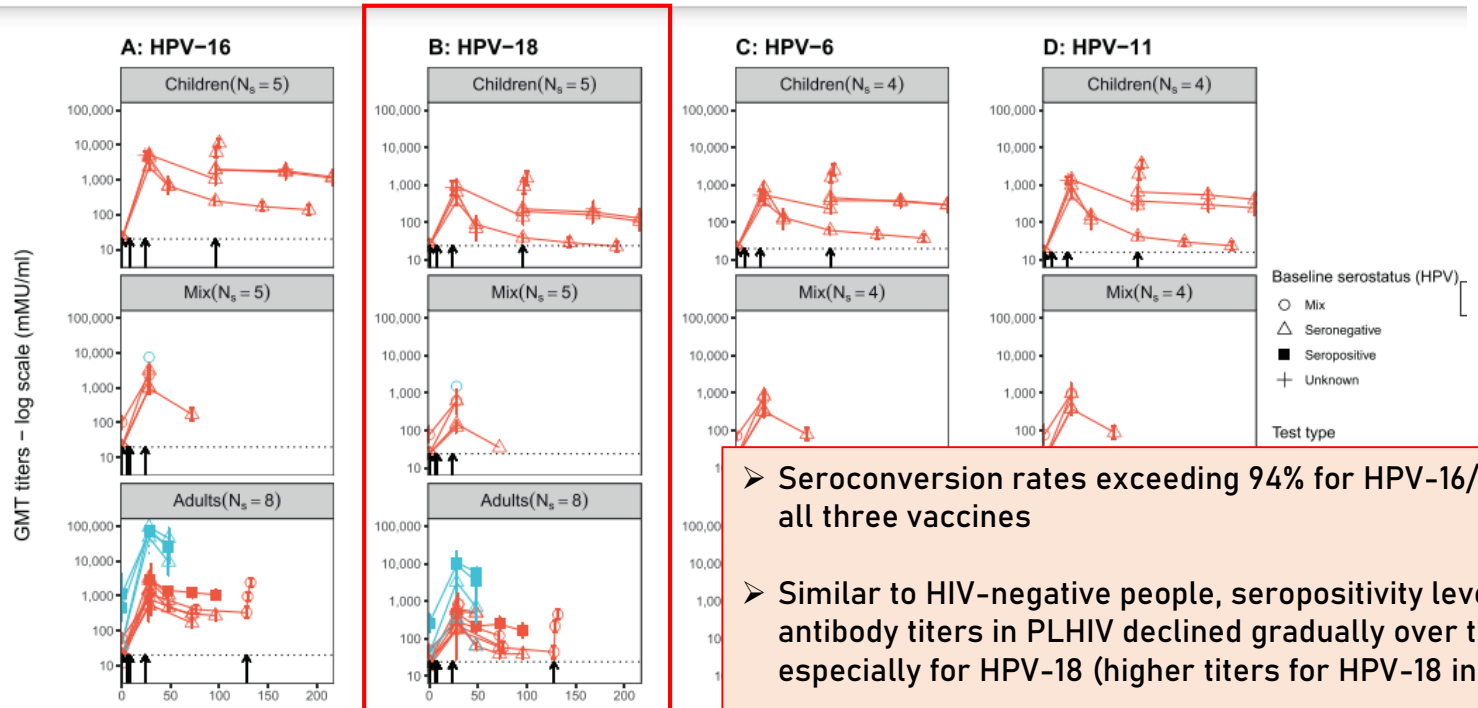
CDC 2022

Human papillomavirus (HPV)	***Yes!*** You should be vaccinated against HPV if you are 26 years or younger. Adults age 27 through 45 may also be vaccinated against HPV after a discussion with their healthcare provider. The vaccine is usually given in 2 or 3 doses (depending on the age at which the first dose was given) over a 6-month period.

HPV

Immunogenicity, safety, and efficacy of the HPV vaccines among people living with HIV: A systematic review and meta-analysis

Lisa Staadegaard,[a,1] Minttu M. Rönn,[b,1,*] Nirali Soni,[a,c] Meghan E. Bellerose,[b] Paul Bloem,[d] Marc Brisson,[e,f] Mathieu Maheu-Giroux,[g] Ruanne V. Barnabas,[h] Melanie Drolet,[f] Philippe Mayaud,[i] Shona Dalal,[d] and Marie-Claude Boily [a,c]



- Seroconversion rates exceeding 94% for HPV-16/18/6/11 for all three vaccines
- Similar to HIV-negative people, seropositivity levels and antibody titers in PLHIV declined gradually over time, especially for HPV-18 (higher titers for HPV-18 in 9vHPV)
- No strong conclusions on vaccine effectiveness in PLHIV could be reached; trials reporting on biological outcomes were scarce, reporting diverse and estimates of low quality

Immunogenicity, safety, and efficacy of the HPV vaccines among people living with HIV: A systematic review and meta-analysis. Staadegaard L et al. EClinicalMedicine. 2022

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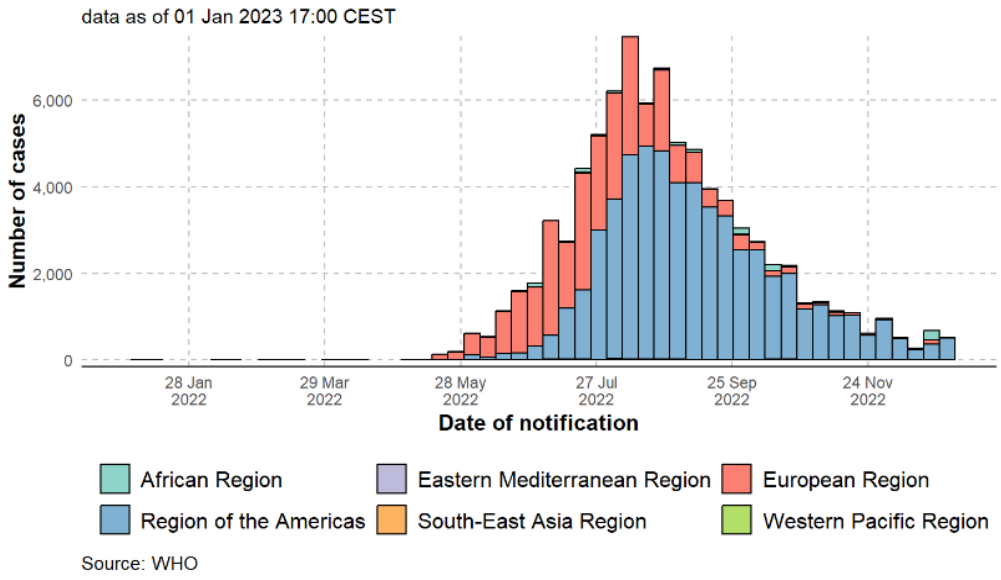
Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
			<15% or <200mm³	≥15% and ≥200mm³							
IIV4 or RIV4					1 dose annually						
or LAIV4	Contraindicated					Precaution				or 1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 yrs									
MMR	Contraindicated*	Contraindicated			1 or 2 doses depending on indication						
VAR	Contraindicated*	Contraindicated			2 doses						
RZV		2 doses at age ≥19 years			2 doses at age ≥50 yrs						
HPV	Not Recommended*	3 doses through age 26 yrs			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
Pneumococcal (PCV15, PCV20,PPSV23)					1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)						
HepA					2 or 3 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT³ recipients only			1 dose						

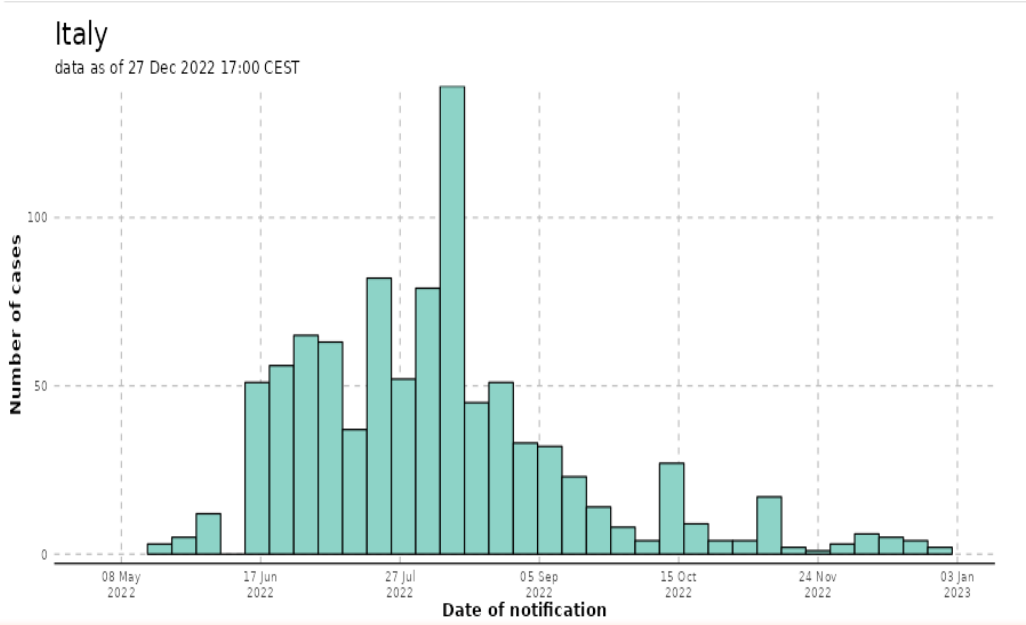
Monkeypox

Monkeypox

Epidemic curve shown for cases reported up to 01 Jan 2023 to avoid showing incomplete weeks of data.



Source: WHO



WHO, January 2023

Monkeypox

Case profiles

As of January 06 2023

	Reported values[1]		Unknown or Missing Value
	Yes	No	
Men who have sex with men	25955 (84.4%)	4808 (15.6%)	49245
HIV-Positive	16544 (48.0%)	17892 (52.0%)	45572
Health worker	1177 (4.3%)	26294 (95.7%)	52537
Travel History	2285 (14.3%)	13680 (85.7%)	64043
Sexual Transmission	14631 (69.1%)	6536 (30.9%)	58841
Hospitalised[2]	3844 (7.3%)	49030 (92.7%)	27134
ICU	42 (0.3%)	15761 (99.7%)	64205
Died	28 (0.1%)	52155 (99.9%)	27825

43%

[1] Note given true proportions of variables, yes reporting may be common than no reporting
[2] May be hospitalised for isolation or medical treatment

WHO, January 2023

Monkeypox

International Case Series of Monkeypox: Current Outbreak

- Case series describing 528 monkeypox infections from April - June 2022 in 16 countries
  - 84 cases in the Americas
  - 444 cases in Europe, Israel, Australia
- >99% were male
- 95% were gay or bisexual
- 95% had sexual contact as suspected route of transmission
- 41% were PWH

Characteristic	PWH (N = 218)
Median age, yr (range)	39 (21-62)
Male sex, n (%)	218 (100)
Sexual orientation, n (%)	
Homosexual	212 (97)
Heterosexual	2 (1)
Bisexual	4 (2)
Median CD4 cell count, cells/mm^3 (IQR)	(n = 185) 680 (513-861)
HIV-1 RNA, n (%)	(n = 190)
<50 copies/mL	180 (95)
<200 copies/mL	185 (97)
Known to be taking ART, n (%)	210 (96)

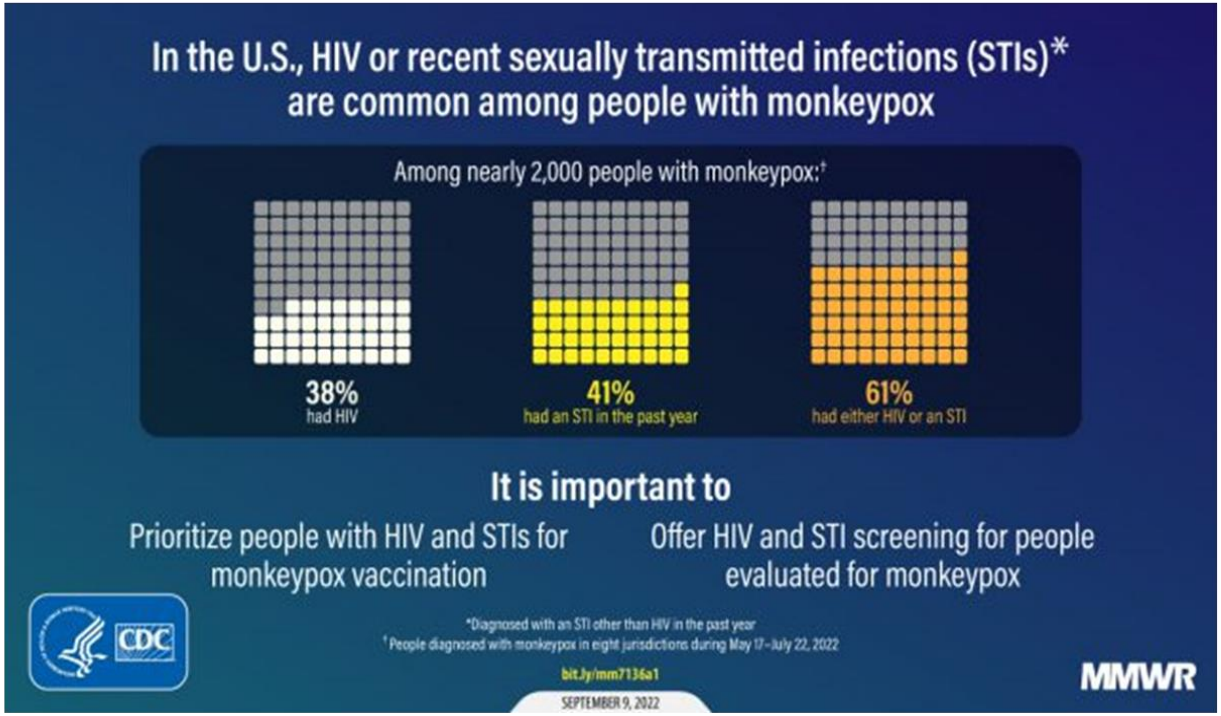
Thornhill. NEJM. 2022;387:679.

Slide credit: clinicaloptions.com

Monkeypox

CDC Data Regarding Monkeypox in PWH

- PWH have been disproportionately affected by monkeypox



- 82% had HIV-1 RNA <200 copies/mL
- 8% PWH hospitalized vs 3% without HIV
- PWH more likely to have rectal pain and other rectal manifestations

Curran. MMWR Morb Mortal Wkly Rep 2022;71:1141.

Monkeypox

Vaccination Recommendations for PWH

- Vaccination for PEP, ideally within 4 days of exposure, but up to 14 and expanded PEP (PEP++) for those who may have been more likely to be exposed

Vaccine	JYNNEOS/Imvanex (MVA-BN)	ACAM2000
Vaccine virus	Replication-deficient modified vaccinia Ankara	Replication-competent vaccinia virus
Indication	Smallpox and monkeypox	Smallpox
Recommendations in adult PWH not previously vaccinated against smallpox with: **CD4 cell count ≥200 cells/mm^3**	**0.5 mL SC/IM** or **0.1 mL intradermal** (with supply constraints) + Second dose after ≥28 days	Do not administer
Recommendations in PWH not previously vaccinated against smallpox with: **CD4 cell count <200 cells/mm^3**	**0.5 mL SC/IM** + Second dose after ≥28 days	Do not administer

cdc.gov/poxvirus/monkeypox/interim-considerations/special-populations.html.
assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1100600/recommendations-for-pre-and-post-exposure-vaccination-during-a-monkeypox-incident-26-august-2022.pdf.

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Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
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Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 yrs									
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HepA					2 or 3 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication,				see notes for booster recommendations						
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[3] recipients only			1 dose						

Monkeypox

Meningococco

CDC 2022

Meningococcal ACWY (MenACWY)	***Yes!*** MenACWY vaccine is recommended for all people age 2 years and older with HIV infection. The first 2 doses are given 8 weeks apart, followed by a booster dose every 5 years.
Meningococcal B (MenB)	***Maybe.*** You may need MenB if you have one of several health conditions,* for example, if you do not have a functioning spleen, and also boosters if your risk is ongoing. You also may need MenB vaccine and a booster if you are at increased risk during a MenB outbreak; check with your local health department. You may also consider getting the MenB vaccine if you are age 23 or younger (even if you don't have a high-risk medical condition) after a discussion with your healthcare provider.

Men ACWY
Men B

EACS 2022

Neisseria meningitidis	According to risk profile (travel, close contact with children, MSM)	Use conjugated[30] 4-valent vaccine (for serotypes A, C, W-135, Y; 2 doses 1-2 months apart) if available. Booster every five years if exposure continues. Polysaccharide vaccine no longer recommended. Vaccination against Meningococcus serotype B according to national Guidelines

LG italiane 2017

Meningococco	• Tutti • Rischio aumentato di contrarre l'infezione e sviluppare la malattia, documentato per le persone in AIDS. Studi recenti indicano che anche le persone con infezione da HIV hanno un rischio aumentato di malattia invasiva.	A: 2 dosi di MenACWY coniugato distanziate di 8-12 settimane. 2 dosi di 4CMenB distanziate di almeno un mese. La possibilità di co-somministrare MenACWY e 4CMenB è in fase di studio. Alla luce delle attuali conoscenze si ritiene possibile la co-somministrazione nei casi in cui un ritardo potrebbe comportare la mancata protezione della persona a rischio. Altrimenti somministrare alternativamente MenACWY e 4CMenB. B: MenACWY, non di routine. CDC (USA) (e altri) raccomandano richiami ogni 5 anni di MenACWY per le persone con fattori di rischio che permangono nel tempo, fra i quali la positività all'HIV. B: 4CMenB, non stabilito. È in fase di registrazione un altro vaccino antimeningococco B (MenB-FHbp).	Almeno uno studio ha evidenziato la sicurezza e l'immunogenicità del vaccino Men ACWY coniugato in giovani adulti con infezione da HIV. Nella popolazione generale gli studi con MenACWY e 4CMenB (vedere gli RCP dei singoli vaccini) sono, per lo più, limitati alle fasce d'età fino a 65 anni o inferiori. Tuttavia, in base alle pur contenute evidenze e all'opinione degli esperti il loro utilizzo è considerato appropriato anche in persone di età superiori a quelle indicate nelle schede tecniche.	[7-9; 11-12; 25-26; 78; 82]

Meningococco

National Center for Immunization & Respiratory Diseases

Meningococcal Vaccines Work Group Plan for Assessing the MenABCWY Vaccines

Sam Crowe, PhD, MPH
Work Group Lead

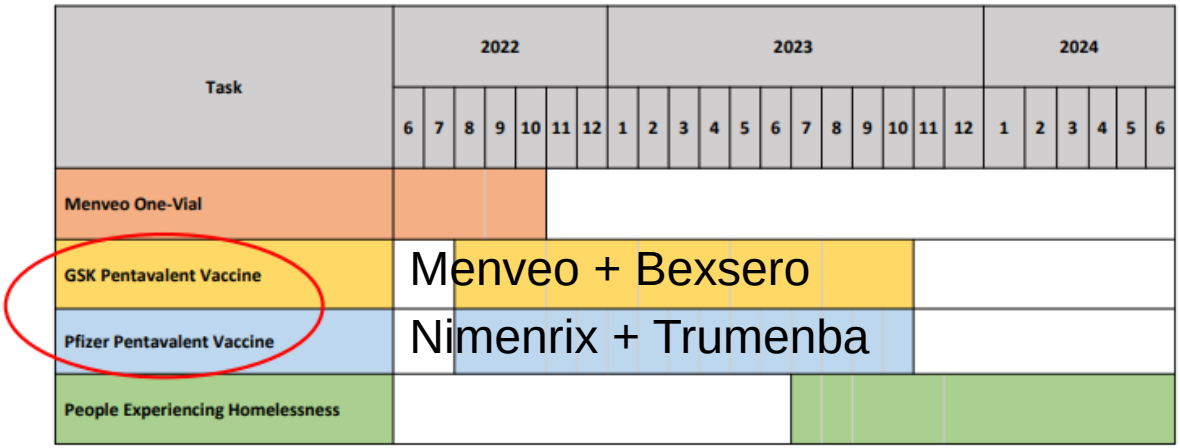
October 20, 2022

Policy Questions for Each Pentavalent Vaccine

- Should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines?
  - For example, 16 year olds[1]
- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?
  - For example, 11–12 year olds
- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only?
  - For example, during a serogroup B outbreak

[1] 16 year olds who decide to receive the MenB vaccine based on shared clinical decision making

Project Timeline



Advisory Committee on Immunization Practices, National Center for Immunization & Respiratory Disease. 2022

Centers for Disease Control and Prevention
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Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[1]	Chronic liver disease	Diabetes	Healthcare personnel[2]	Men who have sex with men
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Monkeypox

SARS-CoV-2

SARS-CoV-2

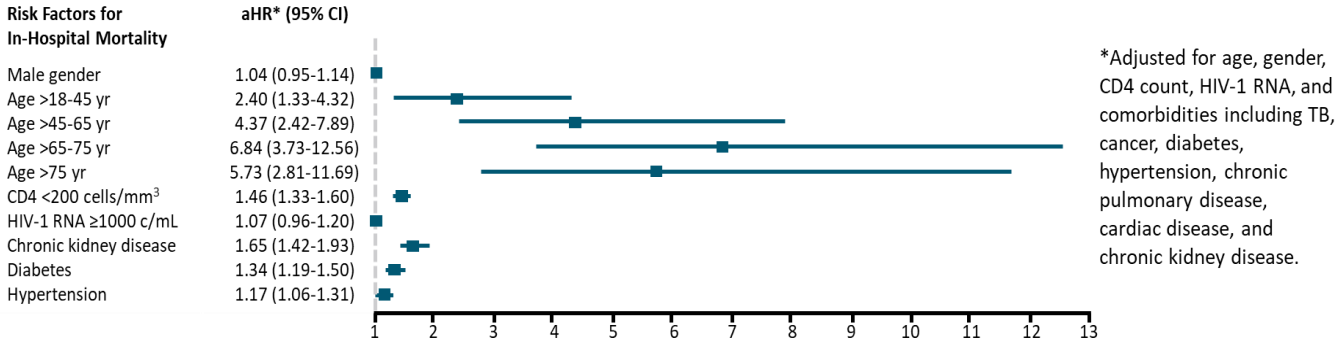
Clinical features of, and risk factors for, severe or fatal COVID-19 among people living with HIV admitted to hospital: analysis of data from the WHO Global Clinical Platform of COVID-19

Silvia Bertagnolio, Soe Soe Thwin, Ronaldo Silva, Sairaman Nagarajan, Waasila Jassat, Robert Fowler, Rashan Haniffa, Ludovic Reveiz, Nathan Ford, Meg Doherty, Janet Diaz

In-Hospital Mortality From COVID-19 Among PWH: Study Population, Methods, and Risk Factors

- WHO online platform for HCP-submitted electronic reports of hospitalized COVID-19 cases
  - 362,941 patient reports from 42 countries (96.8% in Africa); 8.2% (29,530) PWH
- Multivariable regression to determine risk of 21-day in-hospital mortality from COVID-19
- 59% PWH had ≥1 underlying condition vs 45% without HIV (*P* <.0001)
  - Among PWH: 52% had 1-2 underlying conditions; 7.1% had ≥3 underlying conditions

- PLWH had 15% greater odds of being admitted to hospital with a severe or critical COVID-19 presentation
- PLWH, once hospitalised, were 38% more likely to die in hospital than people who were HIV-negative



*Adjusted for age, gender, CD4 count, HIV-1 RNA, and comorbidities including TB, cancer, diabetes, hypertension, chronic pulmonary disease, cardiac disease, and chronic kidney disease.

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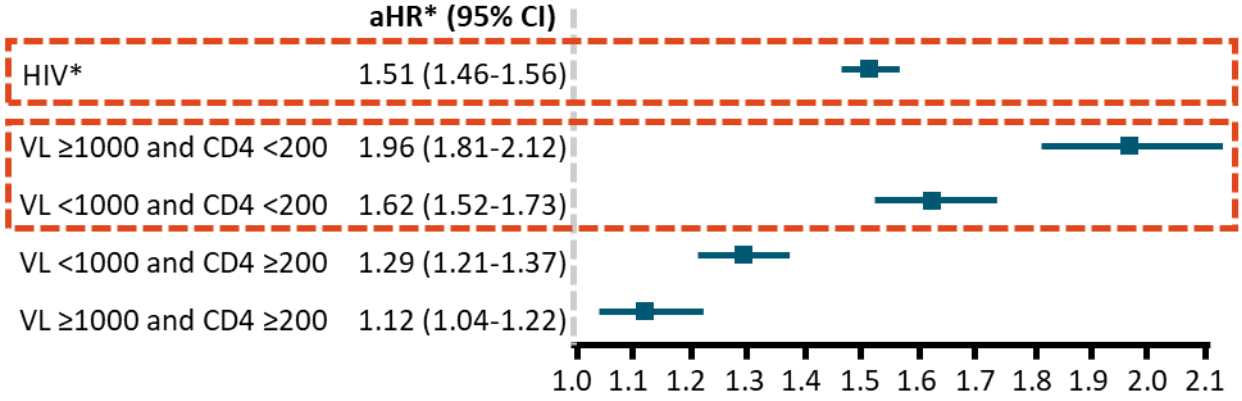
- The use of ART or viral load suppression were associated with a reduced risk of poor outcomes; however, HIV infection remained a risk factor for severity and mortality regardless of ART and viral load suppression status

Association of HIV and HIV Parameters With In-Hospital Mortality



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