Quali vaccinazioni occorre raccomandare per le persone con HIV e per i pazienti immunocompromessi?

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ASSENZA CONFLITTO D'INTERESSE

La Sottoscritta Laura STICCHI, in qualità di relatrice, ai sensi dell'art. 3.3 sul Conflitto di Interessi, pag. 18,19 dell'Accordo Stato-Regione del 19 aprile 2012, per conto del Provider dichiara che negli ultimi due anni ha avuto rapporti anche di finanziamento con soggetti portatori di interessi commerciali in campo sanitario:

- MSD vaccini
- Pfizer vaccini
- GSK vaccini
- Sanofi Pasteur vaccini
- Sequirus
- Merck
- Astra Zeneca
- Aj Vaccines
- Moderna
- Novavax

AGENDA

01 Burden & Clinical Challenges

Prevention Gaps/Strategic Priorities

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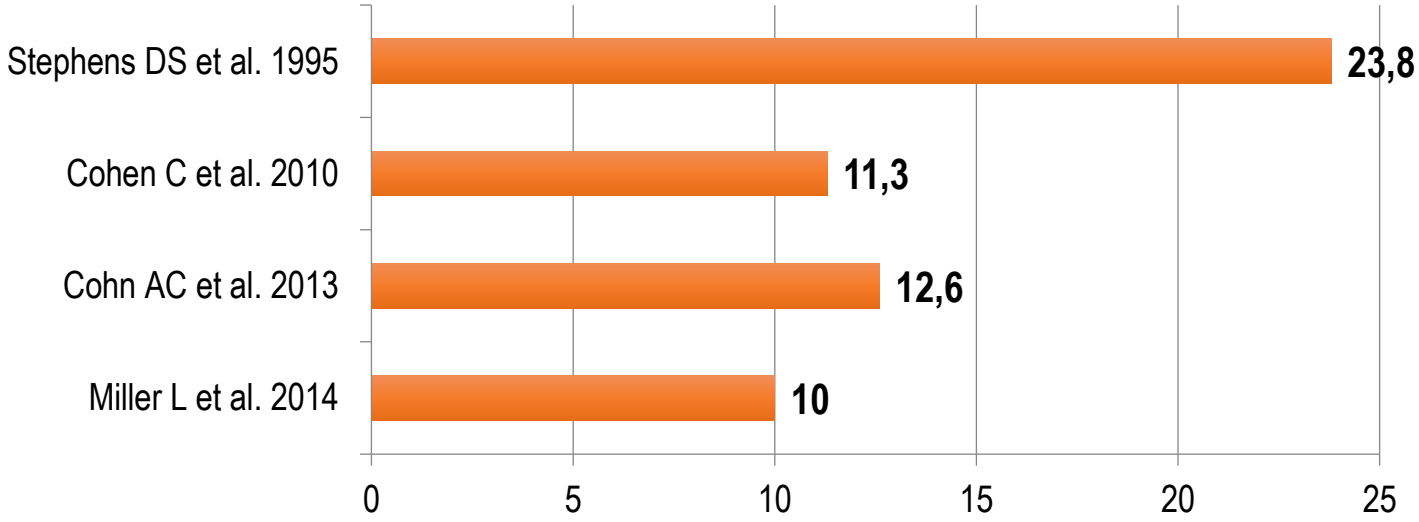
Overall incidence rate **293/100,000** person-years IPD incidence in **HIV-positive individuals** in the era of highly active antiretroviral therapy (Sadlier C, 2019)

in the risk of IPD.[7,10] Nevertheless, in the US the incidence of IPD in HIV-infected adults in the era of ART continued to be approximately 35-fold greater than the general population.[10]

Nunes et al, Human vaccines & immunotherapeutics 2012

Il rischio di Meningite meningococcica in persone con HIV

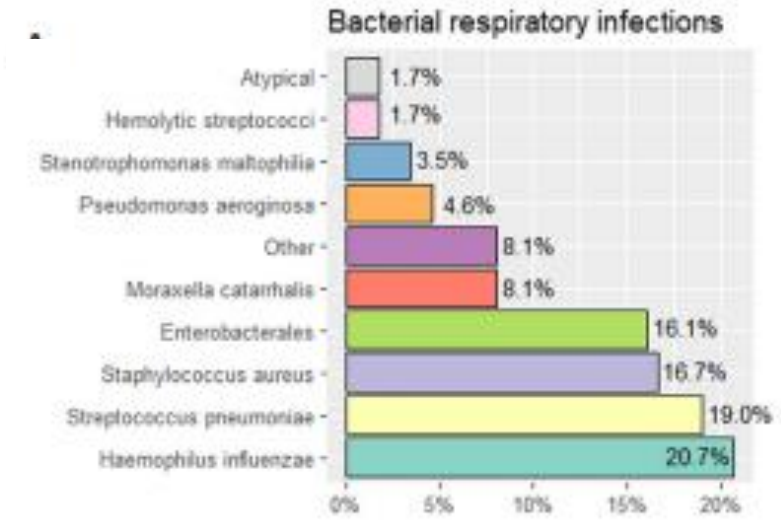


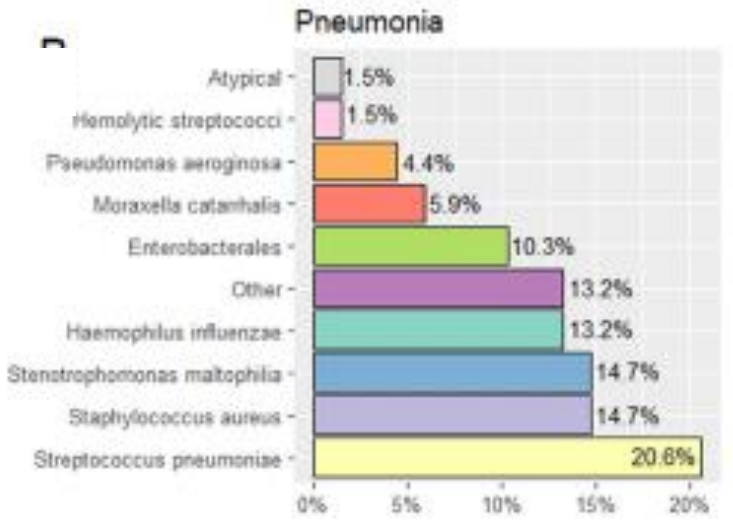
Stephens DS et al. *Ann Intern Med* 1995.
Cohen C et al. *AIDS* 2010.
Cohn AC et al. *MMWR Recomm Rep* 2013.
Miller L et al. *Ann Intern Med* 2014.

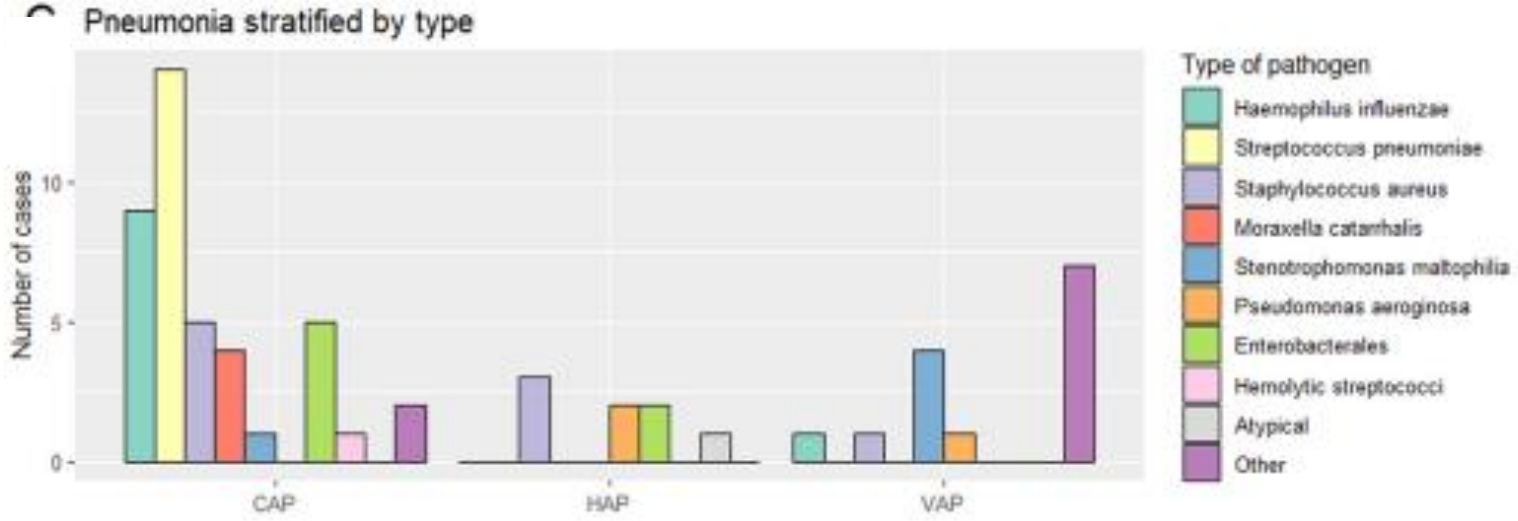
Burden of Respiratory Infections in People Living with HIV

- PLWH face a **5-fold higher pneumonia risk** than the general population, even with CD4 counts >500 cells/mm³.
- Severe respiratory infections (SARI) in PLWH are frequently polymicrobial (47% co-detections), involving pathogens like *Mycobacterium tuberculosis*, *Pneumocystis jirovecii*, and respiratory viruses (RSV, influenza).
- In high HIV prevalence settings, the risk of SARI is **13–19 times** higher compared to non-HIV.
- Viral respiratory infections are frequent: in one study, 33% of HIV-infected patients hospitalized for respiratory symptoms had a viral infection, often with severe course (41% ICU admission, 59% mechanical ventilation, 11% mortality)
- Mortality is higher in non-SARI cases (36% vs. 4%), potentially due to delayed care-seeking.

Incidence of bacterial respiratory infection and pneumonia in people with HIV with and without airflow limitation







Heidari et al., 2024

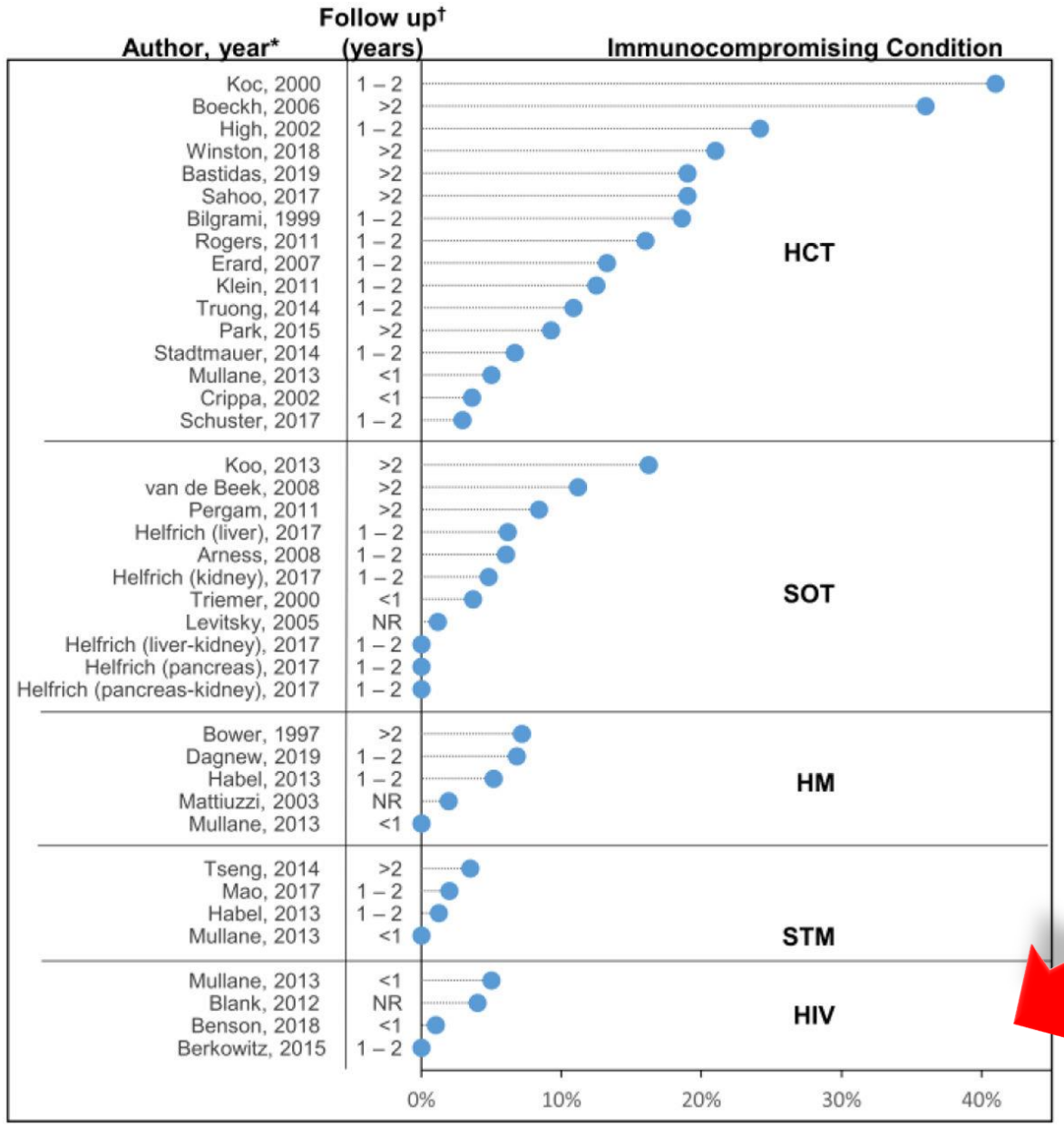
Etiology, clinical, and epidemiological characteristics of severe respiratory infection in people living with HIV

Etiology and percentage of co-detection with other pathogens among SARI and non-SARI patients

Etiology	Isolates	SARI	Codetection	Non-SARI	Codetection
Viral detection	22	9		13	
Rhinovirus	11	4	50%	7	43%
HMPV	2	2	50%	0	–
RSV	5	1	50%	4	100%
PIV-2	1	1	–	0	–
Influenza A	2	0	–	2	100%
Influenza A(pdm09)H1N1	1	1	100%	0	
Other pathogens					
Mycobacterium tuberculosis	13	6	67%	7	43%
Streptococcus pneumoniae	7	4	50%	3	100%
Pneumocystis jirovecii	5	4	75%	1	–
Cryptococcus neoformans	4	1	100%	3	75%
Legionella pneumophila	1	1	–	0	–
Pseudomonas aeruginosa	1	0	–	1	100%
Total	53	25		28	
% codetection	33%	26%		41%	

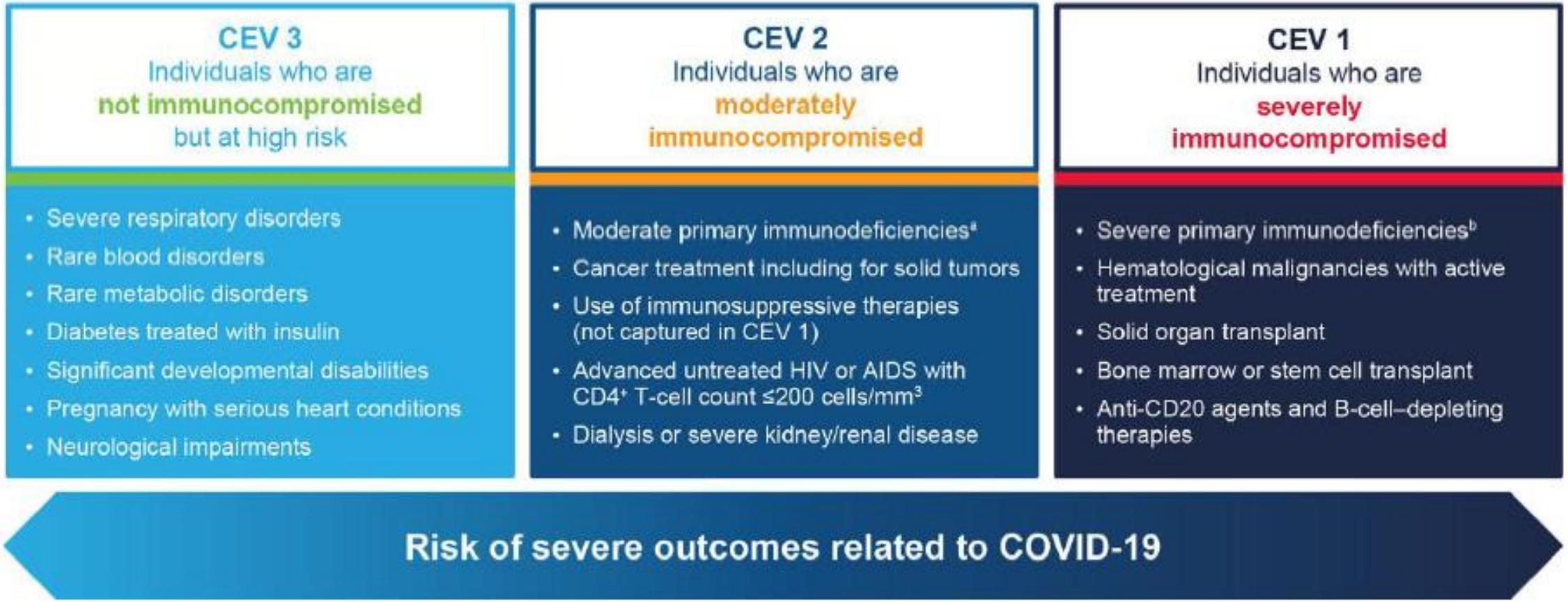
Pecego et al, 2020

Herpes zoster (cumulative incidence) among patients with selected immunocompromising conditions



McKay et al, 2020

Spectrum of COVID-19 risk continuum
for the clinically extremely vulnerable immunocompromised population



Antinori et al, 2023

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OBIETTIVI E STRATEGIE

Obiettivi del PNPV 2023-2025 sono:

- Mantenere lo status polio-free
- Raggiungere e mantenere l'eliminazione di morbillo e rosolia
- Rafforzare la prevenzione del cancro della cervice uterina e delle altre malattie HPV correlate
- Raggiungere e mantenere le coperture vaccinali target rafforzando Governance, Reti e percorsi di prevenzione vaccinale
- Promuovere interventi vaccinali nei gruppi di popolazione ad alto rischio per patologia, favorendo un approccio centrato sulle esigenze del cittadino/paziente
- Ridurre le diseguaglianze e prevedere azioni per i gruppi di popolazione difficilmente raggiungibili e/o con bassa copertura vaccinale
- Completare l'informatizzazione delle anagrafi vaccinali regionali e mettere a regime l'anagrafe vaccinale nazionale
- Migliorare la sorveglianza delle malattie prevenibili da vaccino
- Rafforzare la comunicazione in campo vaccinale
- Promuovere nei professionisti sanitari la cultura delle vaccinazioni e la formazione in vaccinologia.

Italian National Immunization Plan (PNPV 2023-25)

	Cardiov.	Resp.	Diab.	Renal	Liver	Pregn.	Aspl.	IC	SOT cand.	HIV <200	HIV >200	HSCT
MMR												
Var												
Zoster (RZV)				Chronic renal failure and on dialysis								
dTpa												
Flu												
Pneum												
Hib												
Men												
HBV												
HAV												
HPV												

Contraindicated

Recommended

Taylor & Francis
Taylor & Francis Group

Human Vaccines & Immunotherapeutics

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/khvi20

Recommendations of the Italian society for infectious and tropical diseases (SIMIT) for adult vaccinations

Massimo Andreoni, Laura Sticchi, Silvia Nozza, Loredana Sarmati, Andrea Gori, Marcello Tavio & Society for Infectious and Tropical Diseases (SIMIT)

Immunocompromising conditions	Associated risk	Vaccination
HIV infection	-Increased risk and severity of vaccine-preventable infections[149] -Higher risk of invasive pneumococcal disease[150] -Infection with the hepatitis B virus (HBV) is more likely to progress to cirrhosis and hepatocellular cancer[149]	**YES**, if CD4 ≥ 200/mmc The following vaccines: - **MMR, varicella, inactivated Influenza, Hepatitis B, meningococcal** (Men ACWY and Men B), **PVC/PPV23, Hib, HPV, Rotavirus, HAV** (co-presence of other risk factor), **Tdap** CDC,[47] INHS,[50] SIMIT[151] -**Zoster** (recombinant, adjuvanted) STIKO[17] -All inactivated vaccines can be administered safely to immunocompromised persons[47] -**COVID-19** CDC,[28] ECDC,[29] **NO**, if CD4 < 200/mmc The following live attenuated vaccines: -MMR, varicella, live attenuated influenza vaccine, yellow fever, Ty21a oral typhoid, rotavirus, zoster live attenuated CDC,[47] INHS,[50]

0030088-27/09/2023-DGPRE-DGPRE-P

Ministero della Salute

DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA
Ufficio 5 - Prevenzione malattie trasmissibili e profilassi internazionale

OGGETTO: indicazioni e raccomandazioni per la campagna di vaccinazione autunnale/invernale 2024/2025 anti COVID-19.

Visti i documenti internazionali e nazionali (citati nell'allegato 2), con particolare riferimento alle raccomandazioni dell'OMS e dell'Emergency Task Force di EMA sull'aggiornamento dei vaccini COVID-19 rispetto alla variante JN.1 del SARS-CoV-2 per la campagna di vaccinazione 2024/2025, tenuto conto dell'attuale quadro epidemiologico, nel richiamare anche la Circolare "Prevenzione e controllo dell'influenza: raccomandazioni per la stagione 2024-2025", si forniscono le seguenti indicazioni e raccomandazioni:

0003951-10/02/2025-DGPRE-DGPRE-P

Ministero della Salute

DIPARTIMENTO DELLA PREVENZIONE, DELLA RICERCA E DELLE EMERGENZE SANITARIE
Ex-DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA
Ufficio 5 - Prevenzione malattie trasmissibili e profilassi internazionale

Oggetto: aggiornamento delle indicazioni sulla strategia vaccinale contro Mpox

- la vaccinazione, come **profilassi pre-esposizione**, viene offerta a:

- Personale di laboratorio con possibile esposizione diretta a Mpox virus (MPXV);
- Personale sanitario addetto all'assistenza di pazienti con Mpox a rischio di esposizioni ripetute a MPXV;
- Persone che si debbano recare nei paesi interessati da focolai Mpox, e che non possono escludere contatti stretti con la popolazione colpita dalla malattia o che prevedano un lungo soggiorno nelle aree interessate in cui vi sia documentata circolazione di MPXV. Per l'aggiornamento sulla situazione epidemiologica fare riferimento alla pagina web "2022-24 Mpox (Monkeypox) Outbreak: Global Trends", disponibile al link: https://worldhealthorg.shinyapps.io/mpx_global/;
- Uomini cisgender gay, bisex, donne transgender e persone di genere non binario, con partner sessuali multipli o anonimi;
- Donne cisgender o transgender lavoratrici del sesso;
- Uomini cisgender che hanno rapporti eterosessuali con partner multipli, anonimi o con lavoratrici del sesso;
- Donne cisgender che hanno rapporti eterosessuali con partner multipli o anonimi;
- Persone che partecipano ad attività di sesso di gruppo o in concomitanza di eventi di aggregazione di massa, soprattutto se in un'area geografica in cui è stata documentata la trasmissione del MPXV;
- Persone che partecipano a incontri sessuali in locali/club/cruising/saune e persone con esposizione professionale in predette *sex-venue;*
- Persone con recente infezione sessualmente trasmessa (almeno un episodio negli ultimi 6 mesi);
- Persone con abitudine alla pratica di associare gli atti sessuali al consumo di droghe chimiche (Chemsex).

- la vaccinazione potrà essere offerta anche come **profilassi post-esposizione**, a persone con esposizione nota o presunta al virus Monkeypox (MPXV), idealmente entro 4 giorni e fino 14 giorni dall'esposizione; oltre i 14 giorni dall'esposizione l'opportunità alla vaccinazione sarà valutata caso per caso;

Vaccination and Trust in the National Health System among HIV+ Patients: An Italian Cross-Sectional Survey

Pathogenic Agent	Not Vaccinated	Yes, I Am Vaccinated	Natural Immunity	Do Not Know
Hepatitis A	19.61 (30)	48.37 (74)	3.27 (5)	28.76 (44)
Hepatitis B	16.67 (26)	53.21 (83)	4.49 (7)	25.64 (40)
Tetanus (booster)	16.67 (26)	58.33 (91)	0 (0.00)	25.00 (39)
Diphtheria	19.23 (30)	46.79 (73)	0.64 (1)	33.33 (52)
Pertussis	17.42 (27)	50.32 (78)	0 (0.00)	32.26 (50)
HPV	31.17 (48)	44.16 (68)	0 (0.00)	24.68 (38)
Pneumococcus	16.88 (26)	57.14 (88)	0 (0.00)	25.97 (40)
Influenza	48.70 (75)	33.77 (52)	0.65 (1)	16.88 (26)
Varicella	14.94 (23)	30.52 (47)	33.12 (51)	21.43 (33)
Measles	11.61 (18)	62.58 (97)	0 (0.00)	25.81 (40)
Mumps	16.88 (26)	25.97 (40)	24.03 (37)	33.12 (51)
Rubella	18.18 (28)	23.38 (36)	21.43 (33)	37.01 (57)
Poliomyelitis	21.43 (33)	37.66 (58)	1.30 (2)	39.61 (61)
Meningococcus	17.31 (27)	53.21 (83)	0 (0.00)	29.49 (46)
Type B Haemophilus Influenza	29.41 (45)	22.22 (34)	0 (0.00)	48.37 (74)
Herpes Zoster	50.00 (76)	13.16 (20)	7.24 (11)	29.61 (45)

Bert et al, 2023

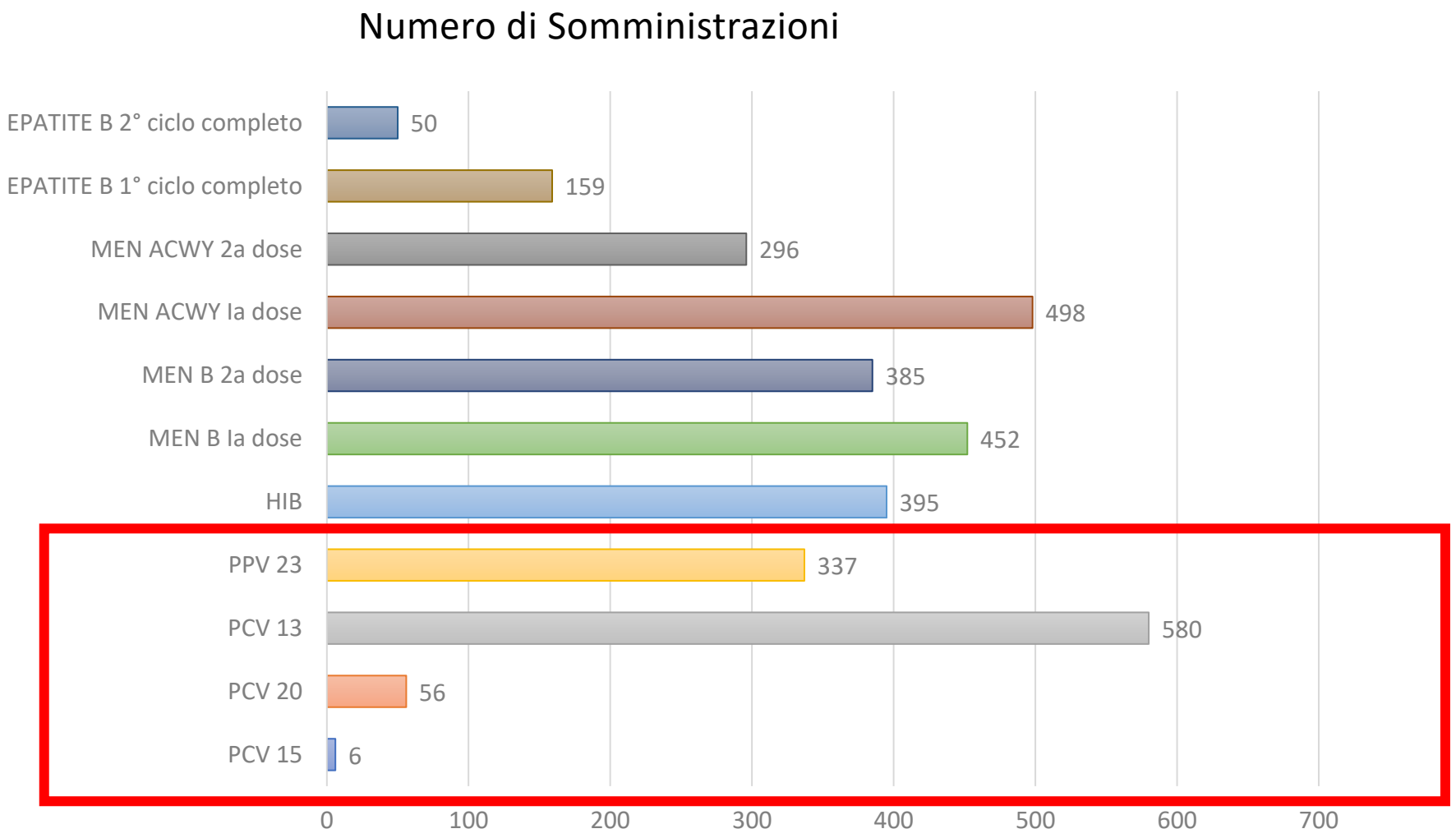
Vaccination and Trust in the National Health System among HIV+ Patients: An Italian Cross-Sectional Survey

Trust in the Italian NHS, % (n) (N = 160).

	I Disagree	I Agree
I believe in the information given by NHS workers	4.38 (7)	95.63 (153)
Healthcare professionals are prepared and up-to-date on vaccines	6.92 (11)	93.08 (148)
Those who do not get vaccinated are blamed by NHS workers	59.75 (95)	40.25 (64)
The organisation of the vaccination offer is flexible in terms of timing and methods	18.87 (30)	81.13 (129)
NHS workers have an economic interest in vaccinations	80.50 (128)	19.50 (31)
NHS workers fail to provide information on vaccine risks	66.67 (106)	33.33 (53)
Vaccines are an imposition, not a free choice	74.84 (119)	25.16 (40)

Bert et al, 2023

PLWH con almeno un accesso in ambulatorio– tot. 923



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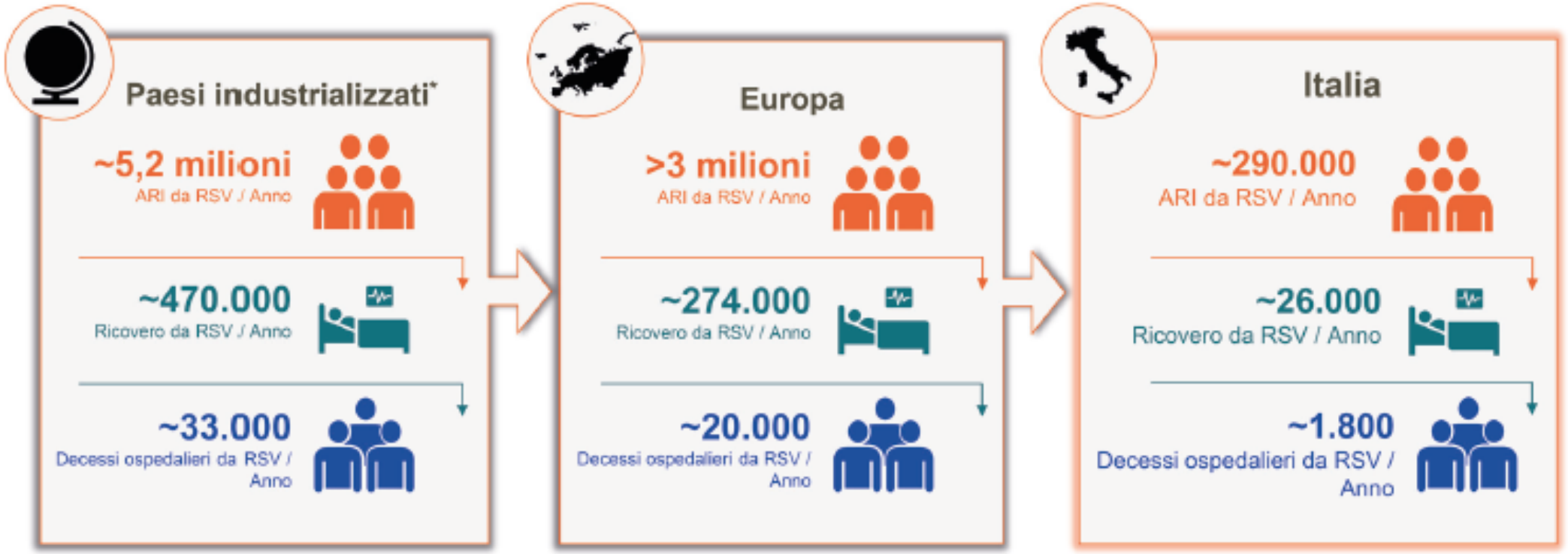
Epidemiologia in Italia

Stima dei casi, dei ricoveri e dei decessi in ospedale dovuti a infezioni respiratorie acute associate a RSV tra gli adulti di età pari o superiore a 60 anni, dati del 2019[10]



*Regioni del Nord America, Europa e Asia-Pacifico. Estimated for adults aged 60 years and older in high-income countries in 2019, using population data obtained from the United Nations [UN] Department of Economic and Social Affairs.
L'immagine è stata creata in modo indipendente a partire dai dati originali: Ref. 10: Savic M, Penders Y, Shi T, Branche A, Pirçon JY. Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: A systematic literature review and meta-analysis. Influenza Other Respir Viruses. 2023 Jan;17(1):e13031.

Giuffrida, 2025

Vaccinazione RSV negli adulti: uno sguardo all'Italia, in attesa dell'aggiornamento del Calendario Vaccinale

Gennaio 2024

Position paper del Calendario per la Vita[1]

Il Board del Calendario per la Vita ha raccomandato la vaccinazione contro il virus respiratorio sinciziale (RSV) nei soggetti:

- **≥ 75 anni**
- **≥ 60 anni affetti da patologie croniche**

Febbraio 2024

Documento SITI-SIMIT[2]

Le Società Scientifiche SIMIT-SITI hanno pubblicato un documento congiunto nel quale **auspicano che la vaccinazione venga inserita nel Calendario vaccinale** e sia raccomandata negli over 60 con co-morbosità e negli over 75

Marzo 2024

Circolare Ministeriale misure di prevenzione contro RSV[3]

Il Ministero della Salute ha pubblicato una circolare rivolta alle Regioni dove **indica tutte le strategie di prevenzione disponibili** contro RSV

Maggio 2024

Circolare ministeriale Stagione Influenzale 2024-2025[4]

La vaccinazione contro RSV negli adulti è menzionata nella circolare "Prevenzione e controllo dell'influenza: raccomandazioni per la stagione 2024-2025", ove è **indicata la possibilità di co-somministrazione con i vaccini antinfluenzali**

1.Position Paper del Board del Calendario per la Vita, https://www.igienistionline.it/docs/2024/01pp.pdf;
2. Documento SITI-SIMIT "Prevenzione delle infezioni da Virus Respiratorio Sincinziale nella popolazione italiana" http://www.igienistionline.it/docs/2024/03rsv.pdf;
3. Circolare Ministeriale «Misure di prevenzione e immunizzazione contro il virus respiratorio sinciziale (VRS)» https://www.quotidianosanita.it/allegati/allegato1711563351.pdf;
4. Circolare Ministeriale "Prevenzione e controllo dell'influenza: raccomandazioni per la stagione 2024-2025" https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2024&codLeg=100738&parte=1%20&serie=null

Proposed list of risk factors for the 50–59 recommendation is the same as that currently used for the 60–74 recommendation

Chronic cardiovascular disease

Chronic lung or respiratory disease

Diabetes mellitus
complicated by chronic kidney disease, neuropathy, retinopathy or other end-organ damage or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor

Severe obesity
(body mass index ≥40 kg/m^2)

End stage renal disease/dialysis dependence

Chronic hematologic conditions

Chronic liver disease

Neurological or neuromuscular conditions
causing impaired airway clearance or respiratory muscle weakness

Residence in a nursing home

Moderate or severe immunocompromise

Other chronic medical conditions or risk factors that a provider determines would increase risk of severe disease due to viral respiratory infection (e.g., frailty)

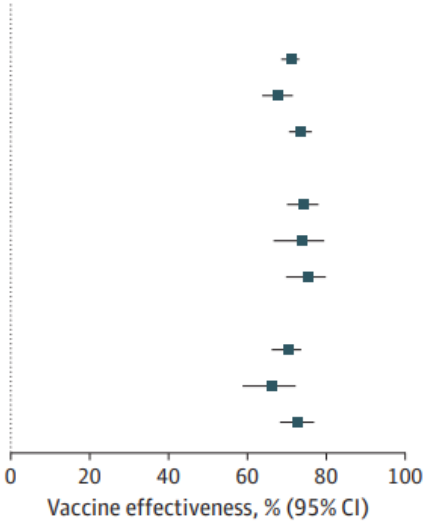
Britton A, Roper LE, Kotton CN, et al. Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:696-702. DOI: http://dx.doi.org/10.15585/mmwr.mm7332e1.

Effectiveness and Safety of Respiratory Syncytial Virus Vaccine for US Adults Aged 60 Years or Older

Estimated Vaccine Effectiveness Among Immunocompromised Individuals and Subgroups Against Respiratory Syncytial Virus–Associated Medically Attended Respiratory Illness, Emergency Department or Urgent Care Visits, or Hospitalizations, October 1, 2023, to April 30, 2024

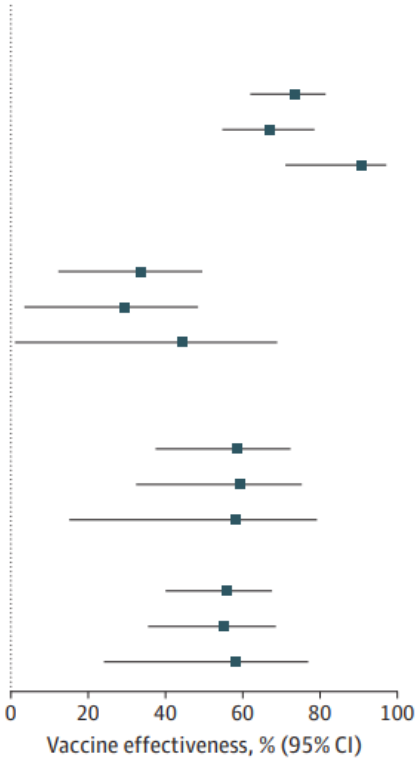
A Immunocompromised individuals

Age group, y	No. of vaccinated cases/total No. (%)	No. of vaccinated controls/total No. (%)	Vaccine effectiveness, % (95% CI)
ARI			
≥60	579/16 744 (3.5)	25 315/234 799 (10.8)	70.4 (67.8-72.7)
60-74	263/8039 (3.3)	10 978/118 038 (9.3)	67.0 (62.6-70.9)
≥75	316/8705 (3.6)	14 337/116 761 (12.3)	73.1 (69.8-76.0)
ED/UC			
≥60	155/5284 (2.9)	6461/62 343 (10.4)	73.9 (69.3-77.8)
60-74	63/2603 (2.4)	2807/32 974 (8.5)	73.3 (65.7-79.3)
≥75	92/2681 (3.4)	3654/29 369 (12.4)	75.0 (69.1-79.8)
Hospitalization			
≥60	248/8313 (3.0)	11 807/129 045 (9.1)	69.5 (65.3-73.1)
60-74	99/3518 (2.8)	4532/59 084 (7.7)	65.2 (57.3-71.5)
≥75	149/4795 (3.1)	7275/69 961 (10.4)	72.4 (67.4-76.6)



B Transplant recipients

Age group, y	No. of vaccinated cases/total No. (%)	No. of vaccinated controls/total No. (%)	Vaccine effectiveness, % (95% CI)
Solid organ transplant recipients			
ARI			
≥60	32/847 (3.8)	1492/11 614 (12.8)	73.4 (61.9-81.4)
60-74	29/634 (4.6)	1068/8449 (12.6)	66.9 (54.6-78.4)
≥75	3/213 (1.4)	424/3165 (13.4)	90.8 (71.0-97.1)
Hematopoietic stem cell transplant recipients			
ARI			
≥60	62/626 (9.9)	650/4587 (14.2)	33.4 (12.3-49.4)
60-74	48/492 (9.8)	476/3584 (13.3)	29.4 (3.5-48.4)
≥75	14/134 (10.4)	174/1003 (17.3)	44.4 (1.0-68.8)
Transplant recipients			
ED/UC			
≥60	26/450 (5.8)	453/3528 (12.8)	58.4 (37.4-72.3)
60-74	17/328 (5.2)	309/2623 (11.8)	59.1 (32.4-75.2)
≥75	9/122 (7.4)	144/905 (15.9)	57.9 (15.1-79.1)
Hospitalization			
≥60	45/798 (5.6)	1186/9943 (11.9)	55.9 (40.0-67.5)
60-74	33/592 (5.6)	835/7213 (11.6)	54.9 (35.4-68.5)
≥75	12/206 (5.8)	351/2730 (12.9)	58.1 (24.1-76.8)



- VE verso ricoveri da RSV:
  - 60–74 anni: 65,2%
  - ≥75 anni: 72,4%

Trapiantati

- Trapianto di organo solido: VE fino a 90,8% (≥75 anni)
- Trapianto di cellule staminali: VE tra 29,4% e 44,4%

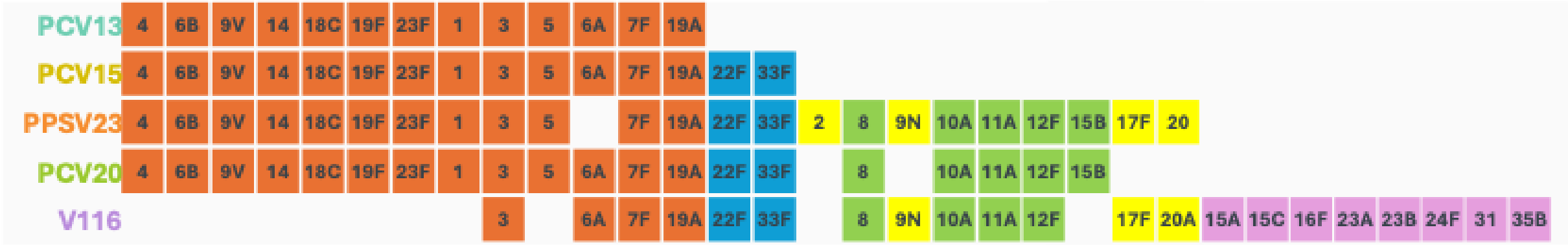
Fry et al., 2025

Union Register of medicinal products for human use

Product information

Product name:	[redacted] ACTIVE
EU number:	EU/1/25/1913
Active substance:	Pneumococcal polysaccharide conjugate vaccine (21-valent)
Indication:	[redacted] is indicated for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older. See sections 4.4 and 5.1 of the SmPC for information on protection against specific pneumococcal serotypes. The use of [redacted] should be in accordance with official recommendations.
Marketing Authorisation Holder:	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland
ATC:	Anatomical main group: J - Antiinfectives for systemic use Therapeutic subgroup: J07 - Vaccines

Sierotipi contenuti nei vaccini pneumococcici attualmente in uso e di “nuova generazione “



- V116 è un PCV composto da 21 sierotipi pneumococcici che hanno rappresentato circa l'85% delle IPD negli adulti statunitensi di età ≥65 anni sulla base dei dati pre-pandemici del 2019[1]
- V116 include polisaccaridi capsulari dei sierotipi: 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15Ca,b, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F e 35B2[2]
- V116 include 8 sierotipi non presenti nei vaccini pneumococcici attualmente autorizzati (15A, 15Ca,b, 16F, 23A, 23B, 24F, 31 e 35B) che rappresentavano circa il 30% delle IPD negli adulti statunitensi ≥65 anni nel 2019[1,2]

[b]15C is denoted here to represent the serotype protection proposed with deOAc15B as the molecular structures for deOAc15B and 15C are similar.

[c]Including pneumococcal polysaccharide vaccines.

IPD, invasive pneumococcal disease; PCV, pneumococcal conjugate vaccine; PCV13, pneumococcal conjugate vaccine, 13-valent; PCV15 pneumococcal conjugate vaccine, 15-valent, PCV20, pneumococcal conjugate vaccine, 20-valent; PPSV23, pneumococcal polysaccharide vaccine, 23-valent; US, United States; V116, pneumococcal conjugate vaccine, 21-valent.

1. **CDC**, IPD Serotype Data 2019, as compiled from data provided through Active Bacterial Core surveillance (ABCs). 2. **Platt H**, Omole T, Cardona J, Fraser NJ, Mularski RA, Andrews C, Daboul N, Gallagher N, Sapre A, Li J, Polis A, Fernsler D, Tamms G, Xu W, Murphy R, Skinner J, Joyce J, Musey L. Safety, tolerability, and immunogenicity of a 21-valent pneumococcal conjugate vaccine, V116, in healthy adults: phase 1/2, randomised, double-blind, active comparator-controlled, multicentre, US-based trial. Lancet Infect Dis. 2023 Feb;23(2):233-246. https://pubmed.ncbi.nlm.nih.gov/36116461/

Confronto della distribuzione dei sierotipi nelle forme invasive (IPD) nei vaccini autorizzati, 2018

	US[1] ≥65	Canada[2] ≥65	UK[3] ≥65	Germany[4] ≥60	France[5] ≥65	Italy[6] ≥65	Australia[7] ≥65	China[8,a] ≥50
PCV13	22.7%	25.3%	22.6%	30.4%	30.8%	38.0%	31.9%	79.5%
PCV15	38.1%	37.7%	34.4%	39.4%	41.2%	38.0%	44.6%	79.5%
PCV20	51.3%	54.6%	66.8%	64.0%	65.7%	75.8%	54.5%	83.9%
PPSV23	58.0%	61.7%	76.2%	71.7%	72.9%	82,9%	62.1%	82.7%
V116	**82.4%**	**82.7%**	**93.8%**	**83.9%**	**81.3%**	**84.2%**	**73.5%**	**27.2%**

V116 serotype composition was approached on the basis of pneumococcal disease epidemiologic surveillance data affecting adult populations to complement the effect observed from an established pediatric pneumococcal vaccination program

2018 data is used to allow for comparison at the timepoint for which data is available across countries/regions.

V116 is the only investigational vaccine.

[a]China epidemiology is driven by PCV13 types due to lack of pediatric NIP.

IPD, invasive pneumococcal disease; NIP, National Immunization Program; PCV13, pneumococcal conjugate vaccine, 13-valent; PCV15, pneumococcal conjugate vaccine, 15-valent; PCV20, pneumococcal conjugate vaccine, 20-valent; PPSV23, pneumococcal polysaccharide vaccine, 23-valent; UK, United Kingdom; US, United States; V116, pneumococcal conjugate vaccine, 21-valent.

1. CDC ABCs unpublished 2018 data. 2. Demczuk WB et al. *Vaccine* 2018 SUPP. 3. PHE Surveillance Report 2017/2018. 4. IPD surveillance report by Mark Van der Linden 2018-2019; 5. CNRP 2018 report; 6. ISS Mabi Surveillance Report 2018-Figure; 7. Enhanced Invasive Pneumococcal Disease Surveillance Working Group (Communicable Diseases Network Australia) 2018; 8. Fudan University, Unpublished report, 2020.

V116-007 Phase 3 Clinical Study Overview

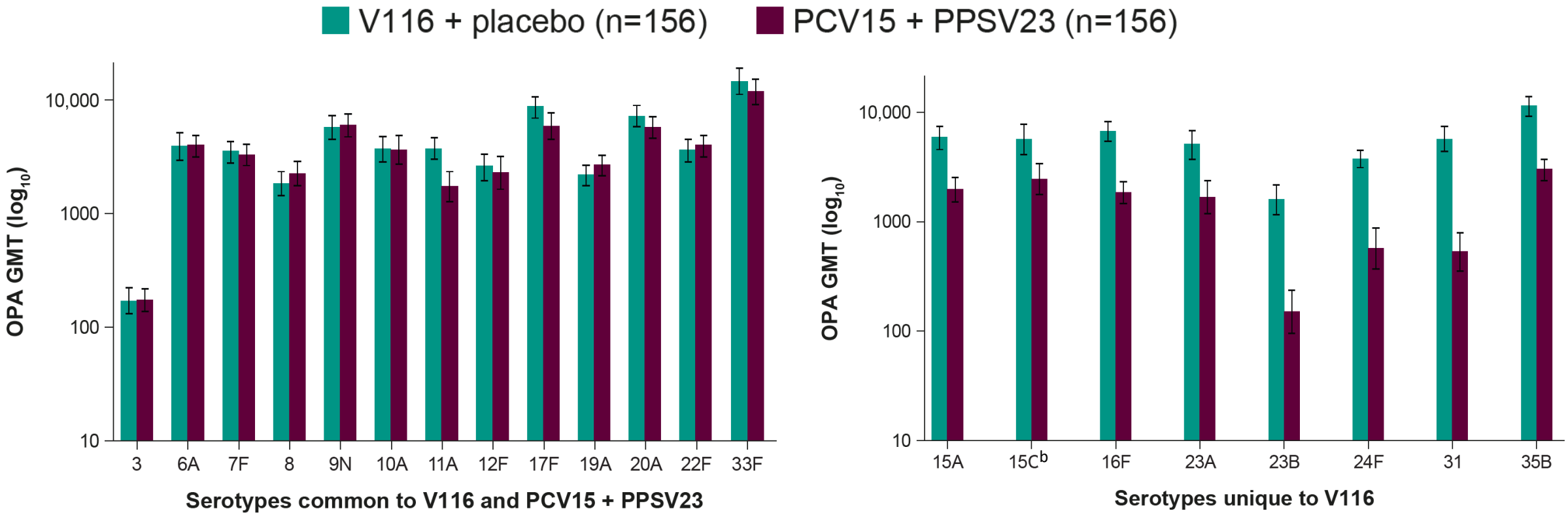
Trial	Patient Population	Interventions	Primary Endpoints
STRIDE-7 *A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Adults Living With HIV* **(NCT05393037)** **Recruitment status: Active, not recruiting** **Study start date: July 13, 2022**	**Adults living with HIV (Estimated enrollment: n=300)**	Administration of a single dose of: ▪ **V116** (4.0 µg of each PnPs antigen per 0.5 mL dose) on Day 1, a single dose of **placebo** (saline per 0.5 mL dose) for PPSV23 on Week 8, and a single dose of **PCV15** (2.0 µg of each PnPs antigen per 0.5 mL dose) between 10 to 18 months after V116 ▪ **PCV15** (2.0 µg of each PnPs antigen per 0.5 mL dose) on Day 1, and a single dose of **PPSV23** (25.0 µg of each PnPs antigen per 0.5 mL dose) on Week 8	▪ Percentage of Participants With: • Solicited injection-site events, days 1–5 • Solicited systemic events, days 1–5 • Vaccine-related SAE collected through day 194 ▪ Serotype-specific OPA GMTs for 13 serotypes common between V116 and PCV15 + PPSV23 and 8 serotypes unique to V116, up to 114 days

V116, pneumococcal conjugate vaccine, 21-valent; PCV15, pneumococcal conjugate vaccine, 15-valent; PPSV23, pneumococcal polysaccharide vaccine, 23-valent; PPS, pneumococcal polysaccharides; SAE, serious adverse event; OPA, opsonophagocytic activity; GMT, geometric mean titer

Safety and Immunogenicity of V116 in Adults Living With Human Immunodeficiency Virus (HIV) (V116-007, STRIDE-7) https://clinicaltrials.gov/ct2/show/NCT05393037?cond=V116-007&draw=2&rank=1

Immunogenicity Results

OPA GMTs; V116 Serotypes; 30 Days Postvaccination[a]



V116 elicited immune responses comparable with PCV15 + PPSV23 for the 13 common serotypes, and higher responses for the 8 serotypes unique to V116, as assessed by OPA GMTs

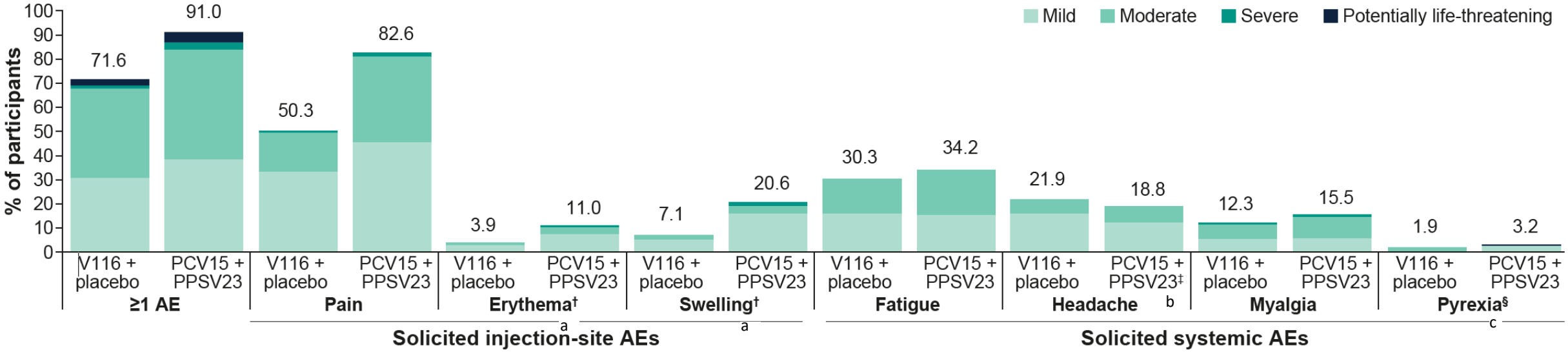
[a]

[b]Serotype 15C represents the immune response to the deOAc15B polysaccharide, as the molecular structures for deOAc15B and 15C are similar; anti-15C immune responses were assessed in this study.

OPA, opsonophagocytic activity; GMT, geometric mean concentration; V116, investigational pneumococcal conjugate vaccine, 21-valent ; PCV15, pneumococcal conjugate vaccine, 15-valent; PPSV23, pneumococcal polysaccharide vaccine, 23-valent.

Pathirana J, et al. A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116, an Investigational Adult-Specific Pneumococcal Conjugate Vaccine, in Adults Living with HIV (STRIDE-7: Part A). Poster Presented at: ISPPD, March 17-20,2024; Cape Town, South Africa.

AEs by severity



The V116 + placebo group had a lower proportion of participants with AEs compared with the PCV15 + PPSV23 group, primarily due to a lower incidence of injection-site AEs in the V116 + placebo group

V116 + pla
site AEs an

[a]Erythema and swelling were graded according to size and presented as intensity grade as follows: mild (0 to ≤5.0 cm); moderate (>5.0 to ≤10.0 cm); and severe (>10.0 cm).

[b]One patient (0.6%) in the PCV15 + PPSV23 group experienced headaches of unknown intensity.

[c]Pyrexia was defined as maximum temperature ≥100.4 °F (38.0 °C), with ≥104.0 °F (40.0 °C) defined as potentially life-threatening pyrexia. One report of pyrexia in the PCV15 + PPSV23 group was potential life-threatening on Day 4 after PCV15 vaccination.

The participant was asymptomatic and there were no other AEs reported relating to elevated temperature.

AEs, adverse events; V116, investigational pneumococcal conjugate vaccine, 21-valent ; PCV15, pneumococcal conjugate vaccine, 15-valent; PPSV23, pneumococcal polysaccharide vaccine, 23-valent.

Pathirana J, et al. A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116, an Investigational Adult-Specific Pneumococcal Conjugate Vaccine, in Adults Living with HIV (STRIDE-7: Part A). Poster Presented at: ISPPD, March 17-20,2024; Cape Town, South Africa.

Statement on the antigen composition of COVID-19 vaccines

15 May 2025 | Statement |Reading time: 7 min (1810 words)

Key points

- Vaccination remains an important public health countermeasure against COVID-19. As per the WHO Director General's standing recommendations for COVID-19, Member States are recommended to continue to offer COVID-19 vaccination based on the recommendations of the WHO Strategic Advisory Group of Experts on Immunization (SAGE).
- SARS-CoV-2 continues to undergo sustained evolution since its emergence in humans, with important genetic and antigenic changes in the spike protein.
- The objective of an update to COVID-19 vaccine antigen composition is to enhance vaccine-induced immune responses to circulating SARS-CoV-2 variants.
- The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) advises manufacturers that **monovalent JN.1 or KP.2** vaccines remain appropriate vaccine antigens; **monovalent LP.8.1** is a suitable alternative vaccine antigen.
- In accordance with WHO SAGE policy, vaccination should not be delayed in anticipation of access to vaccines with an updated composition.

Related

Annex: Statement on the antigen composition of COVID-19 vaccines

News

Statement on the antigen composition of COVID-19 vaccines
15 May 2025

Exposure status	Population	Average follow-up time (days)	Hospitalisation for COVID-19: Number of cases	Daily rate per 100,000 people	Adjusted hazard ratio (95% CI)	Vaccine effectiveness (95% CI)	Death within 30 days of positive test: Number of cases	Daily rate per 100,000 people	Adjusted[¤] hazard ratio (95% CI)	Vaccine effectiveness (95% CI)
BNT162b2 JN.1 evaluated against any lineage										
Not vaccinated	859,216	29.8	278	1.086	1	1	84	0.328	1	1
JN.1 vaccinated	728,768	86.3	197	0.313	0.298 (0.234; 0.380)	70.2 (62.0; 76.6)	56	0.089	0.238 (0.155; 0.366)	76.2 (63.4; 84.5)
Time since vaccination										
14-30 days	728,768	17.0	43	0.347	0.326 (0.231; 0.460)	67.4 (54.0; 76.9)	11	0.089	0.250 (0.130; 0.483)	75.0 (51.7; 87.0)
31-60 days	727,524	29.7	67	0.310	0.283 (0.205; 0.391)	71.7 (60.9; 79.5)	26	0.120	0.316 (0.185; 0.541)	68.4 (45.9; 81.5)
61-90 days	696,508	27.3	58	0.305	0.253 (0.175; 0.365)	74.7 (63.5; 82.5)	12	0.063	0.137 (0.067; 0.278)	86.3 (72.2; 93.3)
>90 days	532,009	18.5	29	0.294	0.389 (0.228; 0.663)	61.1 (33.7; 77.2)	7	0.071	0.221 (0.082; 0.592)	77.9 (40.8; 91.8)
BNT162b2 JN.1 evaluated against KP.3.1.1[¤]										
Not vaccinated	859,216	29.8	66	0.258	1	1	21	0.082	1	
JN.1 vaccinated	728,768	86.3	20	0.032	0.283 (0.144; 0.556)	71.7 (44.4; 85.6)	4	0.006	0.091 (0.025; 0.326)	90.9 (67.4; 97.5)
Time since vaccination										
14-30 days	728,768	17.0	7	0.057	0.284 (0.123; 0.659)	71.6 (34.1; 87.7)	*Data too sparse*			
31-60 days	727,524	29.7	7	0.032	0.312 (0.117; 0.834)	68.8 (16.6; 88.3)				
61-90 days	696,508	27.3	6	0.032	0.256 (0.079; 0.828)	74.4 (17.2; 92.1)				
>90 days	532,009	18.5	*Data too sparse*							
BNT162b2 JN.1 evaluated against XEC[¤]										
Not vaccinated	859,216	29.8	44	0.172	1	1	9	0.035	1	
JN.1 vaccinated	728,768	86.3	33	0.052	0.232 (0.131; 0.410)	76.8 (59.0; 86.9)	8	0.013	0.237 (0.074; 0.753)	76.3 (24.7; 92.6)
Time since vaccination										
14-30 days	728,768	17.0	6	0.048	0.262 (0.106; 0.646)	73.8 (35.4; 89.4)	*Data too sparse*			
31-60 days	727,524	29.7	12	0.056	0.223 (0.107; 0.467)	77.7 (53.3; 89.3)				
61-90 days	696,508	27.3	9	0.047	0.177 (0.075; 0.420)	82.3 (58.0; 92.5)				
>90 days	532,009	18.5	6	0.061	0.366 (0.111; 1.205)	63.4 (-20.5; 88.9)				
mRNA-1273 JN.1 evaluated against any lineage										
Not vaccinated	859,216	29.8	278	1.086	1	1	84	0.328	1	1
JN.1 vaccinated	91,461	100.4	10	0.109	0.151 (0.078; 0.291)	84.9 (70.9; 92.2)	1	0.011	0.042 (0.006; 0.308)	95.8 (69.2; 99.4)

CI = confidence interval. Except where otherwise indicated, model adjustment was for age, sex, geographical region, comorbidities (none, one, two, three or more), number of previous COVID-19 booster vaccines, migration heritage, whether previously hospitalised for COVID-19, and whether previously tested positive for SARS-CoV-2. ¤Adjustment variables restricted to age, comorbidities (none, one, two, three or more), number of previous COVID-19 booster vaccines, and whether previously hospitalised for COVID-19. Due to sparse data, estimates relating to death after infection with KP.3.1.1 and XEC were unadjusted.

Hansen et al., 2025


Grazie