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AULA MAGNA
Università degli Studi di Milano

4° CONVEGNO NAZIONALE
**LE GIORNATE DI
INFETTIVOLOGIA
PEDIATRICA**

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Con il Patrocinio di

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Pneumococco: maggiori antigeni, maggiore copertura?

Focus su immunodeficienze - Pro e contro

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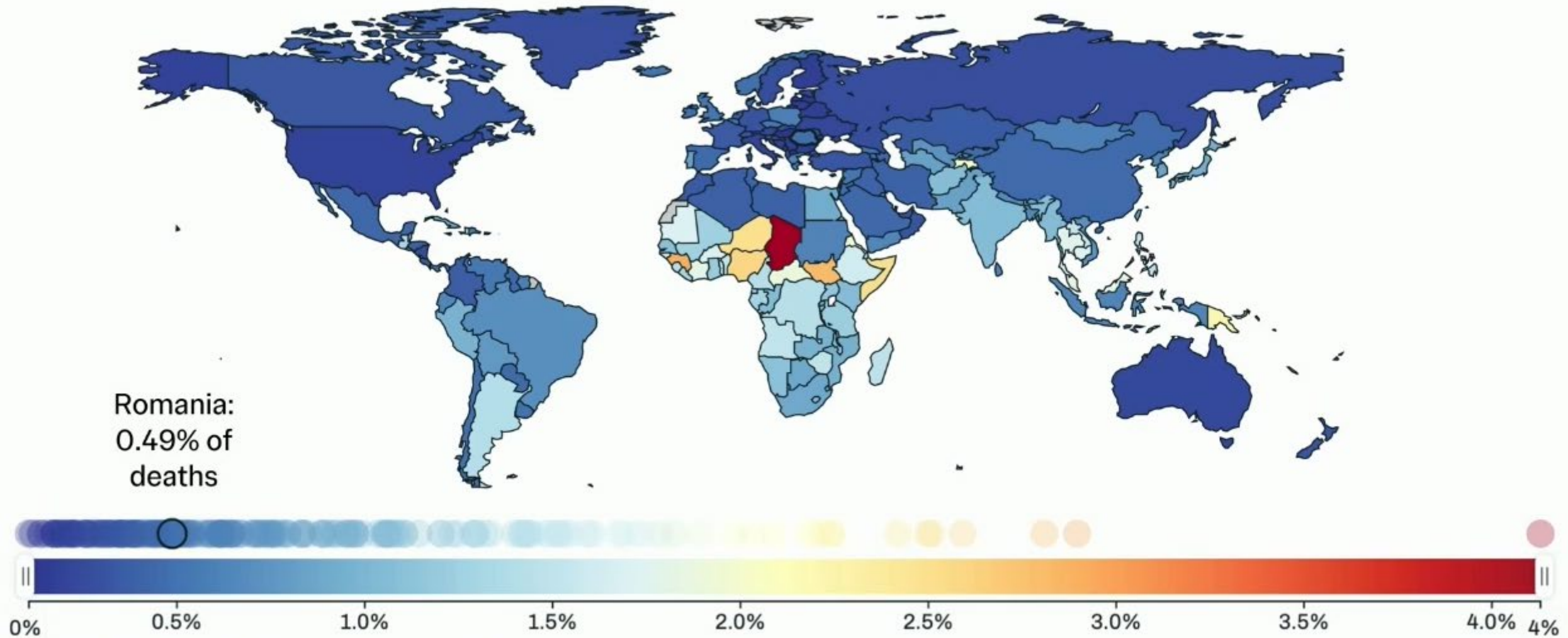
Bioteχνologie applicate dell'Università di Roma «Tor Vergata»

Co-Lead del Basic Science Working Group della Fondazione PENTA

Co-funder, Probiomics SRL, Uno spin Off dell'Università di Roma Tor Vergata

*Milano,
1 Ottobre 2026
h 9.35-9.50*

The burden of Invasive pneumococcal Disease-related deaths globally



Imperial College London

Post-vaccine genomic epidemiology of pneumococci

4

28/05/2025

IHME, 2025

Personalized vaccination are needed in vulnerable populations

(One size does NOT fit All!)

2021–2030 Global Vaccine Action Plan
is for the benefits of immunisation to be equitably extended to all people.

This approach encompasses special groups at increased risk of vaccine-preventable diseases, such as:

- preterm infants,
- pregnant women,
- **chronic and immune-compromising medical conditions**
- elderly



Invasive pneumococcal Disease in Europe and in Italy has grown in 2023!

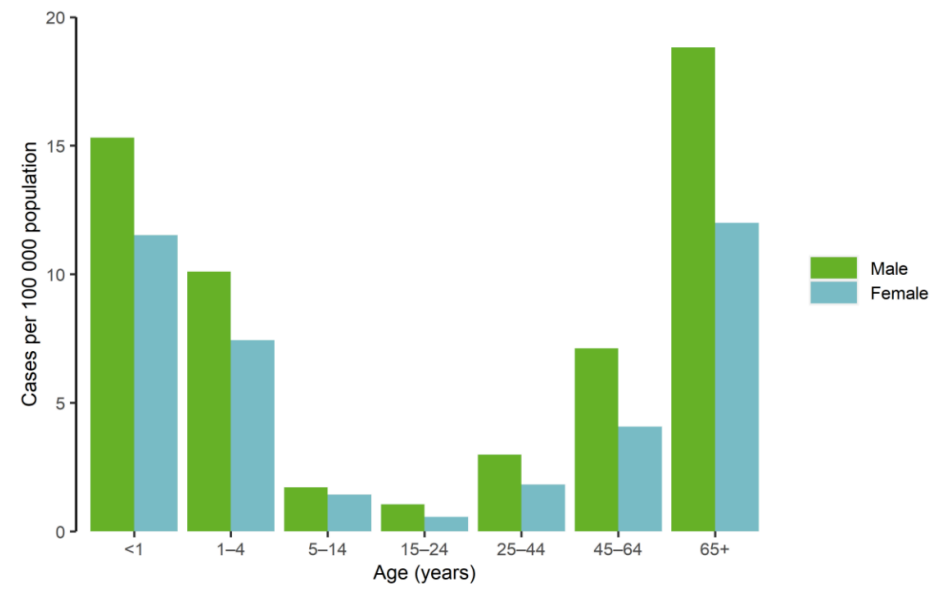
KEY facts

- In 2023, 24 567 confirmed cases of invasive pneumococcal disease (IPD) were reported in the European Union/European Economic Area.
- **6.8 cases per 100 000 population, the highest since 2019.**
- **Of cases in those under five years old for whom serotype information was available, approximately 40% were caused by a PCV13/non-PCV10 serotype. This proportion has increased over the last five years.**
- Among cases in 65 years olds and above with serotype information, 32% were caused by a PCV13/nonPCV10 serotype, 18% by a PCV20/non-PCV15 serotype and 27% by non PCV/PPV serotypes.

Table 1. Confirmed invasive pneumococcal disease cases and rates per 100 000 population by country and year, EU/EEA, 2019–2023

Country	2019		2020		2021		2022		2023		
	Number	Rate	Number	Rate	Number	Rate	Number	Rate	Number	Rate	ASR
Italy	1 671	2.8	499	0.8	472	0.8	1 032	1.7	1 783	3.0	2.5

Figure 2. Confirmed invasive pneumococcal disease cases per 100 000 population, by age and gender, EU/EEA, 2023

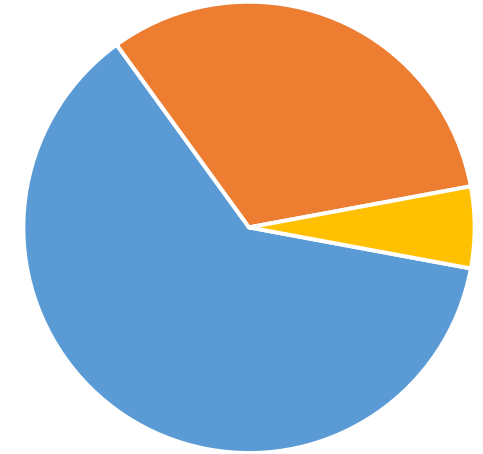


Were these cases vaccinated? What is the impact of vaccine hesitancy?

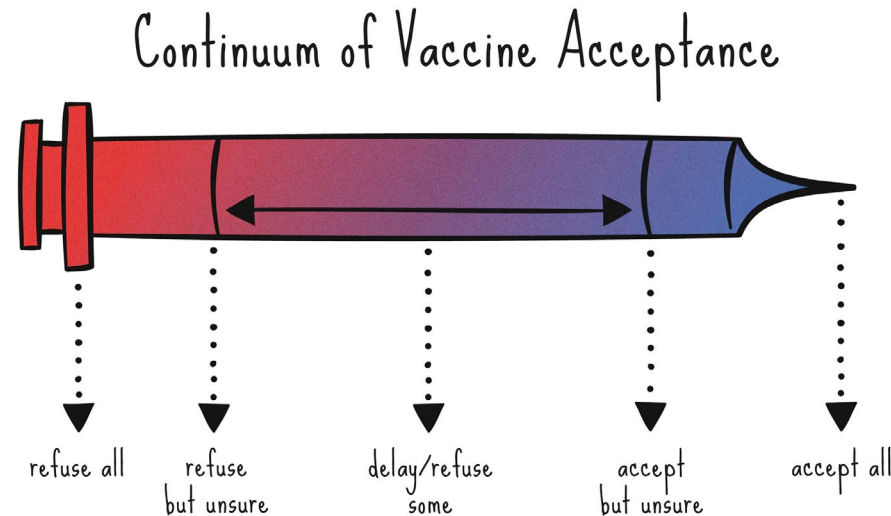
The granularity of data collected in relation to vaccination status for the study period is limited.

Vaccination status was reported for 36.3% (6 428/17 700 cases) of the IPD cases reported in 2022.

- 70.3% (4 516 cases) were unvaccinated,
- 23.2% (1 492) had received between one to four doses of a PCV or PPV vaccine
- 6.5% (420) were reported as vaccinated with an unknown number of doses.



- Unvaccinated
- Between one to four doses of a PCV or PPV vaccine
Vaccinated with unknown number of doses
- Vaccinated with unknown number of doses



Are new PCP vaccines really needed?

Table 2. Proportion of the five most frequent serotypes of confirmed cases of invasive pneumococcal disease by age group, EU/EEA, 2023

<1		1–4		5–14		15–24		25–44		45–64		65+	
Serotype	%	Serotype	%	Serotype	%	Serotype	%	Serotype	%	Serotype	%	Serotype	%
19A	17.1	19A	22.3	3	22.2	8	24.7	8	20.9	3	21.3	3	21.8
3	13.8	3	21.1	19A	15.2	19A	14.0	3	17.8	8	18.2	19A	10.8
10A	6.0	24F	7.0	8	10.8	3	12.9	19A	12.4	19A	10.0	8	10.8
33F	6.0	22F	5.4	22F	7.4	4	9.6	4	6.8	22F	7.3	22F	8.3
22F	5.5	38	5.2	23B	4.7	22F	5.1	22F	6.5	4	5.8	6C	5.0

Source: Country reports from Austria, Cyprus, Czechia, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, and Sweden.

Invasive pneumococcal disease - Annual Epidemiological Report for 2023

Are new PCP vaccines really needed?

Yes Indeed! Incidence of vaccine preventable (VP) and non VP PCP over the last 10 years

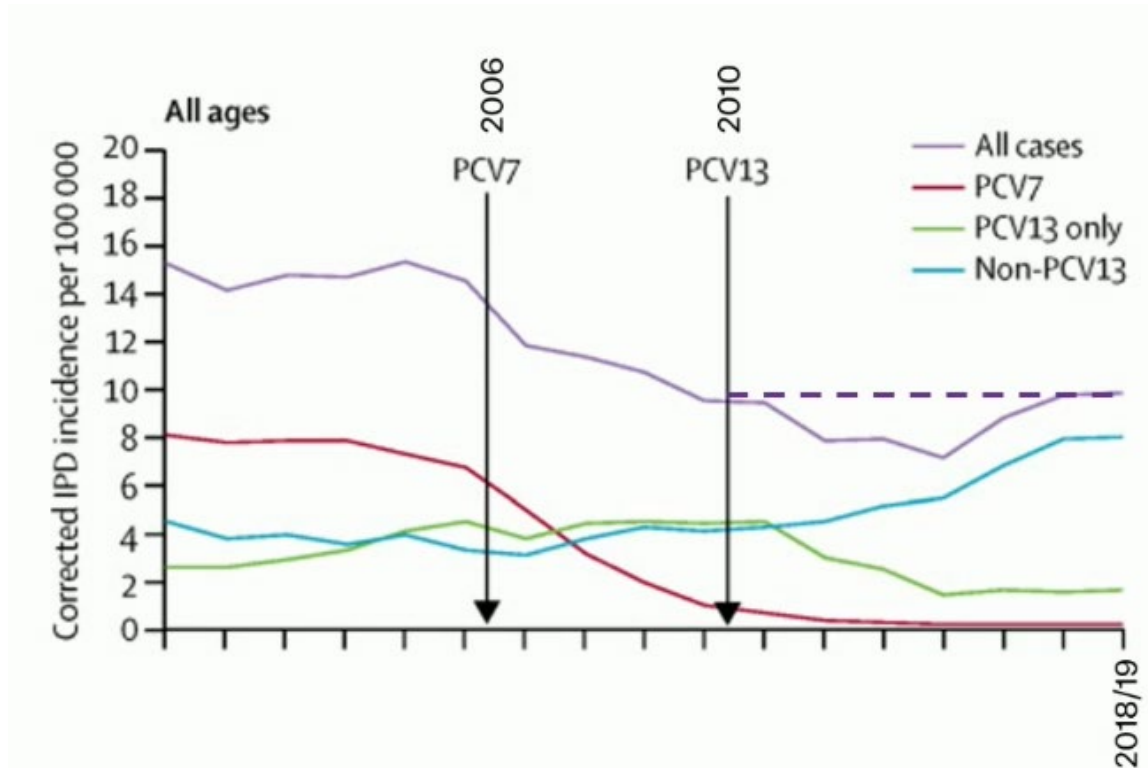
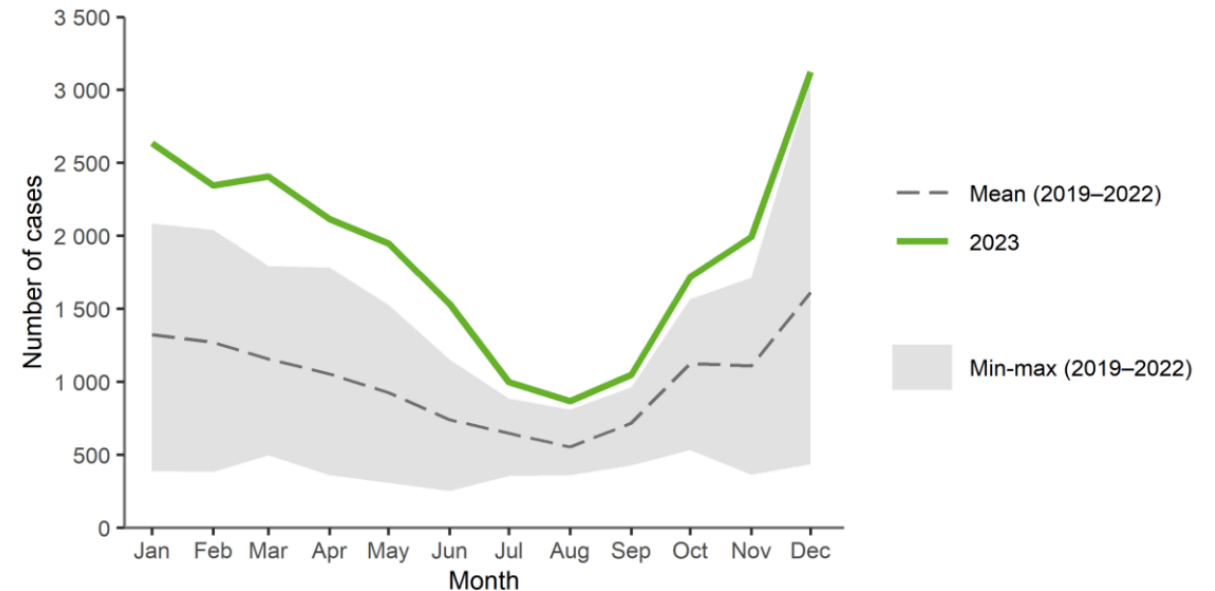


Figure 4. Confirmed invasive pneumococcal disease cases by month, EU/EEA, 2023 and 2019–2022



The jungle of PCV(s): Major novelty are PCV20 and V114... but V116 is in the way.

Table 1. Clinical pneumococcal vaccines approved or in trial.

I sierotipi PCV15 non-PCV13 rappresentano infatti, secondo dati recenti della sorveglianza nazionale, circa l'11% dei casi di patologia invasive pneumococcica nei bambini di età inferiore ai 5 anni.

i sierotipi presenti nel vaccino PCV20 (Non PCV13) sono responsabili del 70% dei casi di malattia pneumococcica invasiva (IPD). Di questi, il 38% è attribuibile esclusivamente ai sette sierotipi aggiuntivi presenti nel PCV20.

	Manufacturer	Serotypes		
	Merck	1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F		
	Novac Biotech Ltd.	1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F		
	GSK	1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F		
	Pfizer	4, 6B, 9V, 14, 18C, 19F, and 23F		
PCV13 (PREVNAR 13™)	Pfizer	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F	CPS-protein conjugate	Approved
PCV20 (PREVNAR 20™)	Pfizer	1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F	CPS-protein conjugate	Approved
V114 (VAXNEUVANCE™)	Merck	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	CPS-protein conjugate	Approved
WEUPHORIA	WALVAX®	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F	CPS-protein conjugate	Approved
PNEUMOSIL	Serum Institute of India	1, 5, 6A, 6B, 7F, 9V, 14, 19A, 19F, and 23F	CPS-protein conjugate	Approved
V116 ¹²⁴	Merck	3, 6A, 6C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20, 22F, 23A, 23B, 24F, 31, 33F, and 35B	CPS- protein conjugate	Phase 3
VAX-24 ⁵⁸	Vaxcyte	1, 2, 3, 4, 5, 6A, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20B, 22F, 23F, and 33F	CPS-protein conjugate	Phase 3
AFX3772 ⁶⁰	GSK + Affinivax	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 2, 8, 9N, 10A, 11A, 12F, 15B, 17F, 20B, 22F, and 33F	MAPS™	Phase 3
CPS-EPA ^{iGTcc 63}	Omniose	8, 9V, and 14		

Approvato il 27/05/2025 (Capvaxive) negli adulti >65 anni

Is V116 approved in children and adolescents 2-17yo? Yes!

 **MERCK**

Media > News releases > News release



U.S. FDA Approves an Additional Indication for CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) in Children and Adolescents Aged 2 through 17 at Increased Risk for Pneumococcal Disease

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Home > PediatricDrugs > Article

21-Valent Pneumococcal Conjugate Vaccine V116 (CAPVAXIVE®): Pediatric First Approval

AdisInsight Report | Published: 27 July 2026
Volume 28, pages 563–567 (2026) [Cite this article](#)

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HUMAN VACCINES & IMMUNOTHERAPEUTICS
2026, VOL. 22, NO. 1, 2684089
<https://doi.org/10.1080/21645515.2026.2684089>

 **Taylor & Francis**
by Informa

RESEARCH ARTICLE

OPEN ACCESS 

A phase 3, randomized study to evaluate the safety, tolerability, and immunogenicity of V116 in children and adolescents with increased risk of pneumococcal disease (STRIDE-13)

Vinita Jagannath^a, Jayani Pathirana^a, Carlos Alberto Perez Yepes^b, Eduardo Lopez-Medina^c, Juan Andres Navarro^d, Piotr Korbal^e, Wanatpreeya Phongsamart^f, Ayano Inui^g, Anu Kantele^h, Jibrán E. Atwiⁱ, Bruce Tapiero^j, Derya Alabaz^k, Fernando Baquero-Artigao^l, Tiantian Zeng^a, Danielle Euler^a, Melanie Papa^a, Doreen Fernsler^a, Jun Park^a, Alejandra Esteves-Jaramillo^a, Heather L. Platt^a, and the STRIDE-013 Study Group*

CAPVAXIVE is indicated for:

- Active immunization for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B in individuals 18 years of age and older and individuals **2 through 17 years of age who are at increased risk for pneumococcal disease;**
- Active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B in individuals 18 years of age and older.

V116 vs PPSV23 in children at risk for invasive pneumococcal disease. Safety and efficacy data are available.

Table 1. Baseline demographics and clinical characteristics.

	V116 (n = 527)	PPSV23 (n = 347)	Total (n = 874)		V116 (n = 527)	PPSV23 (n = 347)	Total (n = 874)
Sex (n (%))				Risk conditions of interest (n (%))			
Female	219 (41.6)	140 (40.3)	359 (41.1)	1	508 (96.4)	330 (95.1)	838 (95.9)
Age in years (n (%))				2+	19 (3.6)	17 (4.9)	36 (4.1)
≥2 to <6	165 (31.3)	107 (30.8)	272 (31.1)	Prior PCV primary regimen			
≥6 to <18	361 (68.5)	240 (69.2)	601 (68.8)	3 + 1 regimen	201 (38.1)	140 (40.3)	341 (39.0)
≥18 ^a	1 (0.2)	0 (0.0)	1 (0.1)	2 + 1 regimen	303 (57.5)	189 (54.5)	492 (56.3)
Median (range)	8.0 (2 to 18)	7.0 (2 to 17)	8.0 (2 to 18)	Other ^b	23 (4.4)	18 (5.2)	41 (4.7)

V116 was compared with PCV13 (3 doses) or PCV13 (2 doses) +PPSV3 regimens

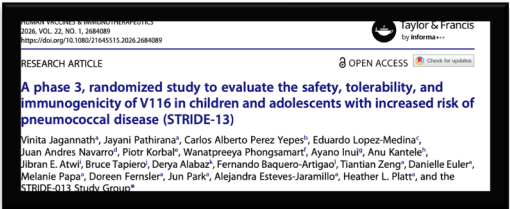
Table 2. Safety summary.

	V116 n = 527	PPSV23 n = 347	V116-PPSV23% difference (95% CI)
≥1 AE; n (%)	426 (80.8)	264 (76.1)	4.8 (−0.8, 10.5)
Injection-site AEs	382 (72.5)	201 (58.2)	
Systemic AEs	313 (59.4)	204 (58.8)	
Vaccine-related AEs*; n (%)	404 (76.7)	234 (67.4)	9.2 (3.2, 15.4)
Injection-site AEs	382 (72.5)	202 (58.2)	
Systemic AEs	231 (43.8)	141 (40.6)	
SAEs; n (%)	29 (5.5)	25 (7.2)	−1.7 (−5.3, 1.5)
Serious vaccine-related AEs*	1 (0.2)	2 (0.6)	−0.4 (−1.9, 0.6)
Deaths; n (%)	0 (0.0)	2 (0.6)	−0.6 (−2.1, 0.2)

V116 was safe but presented higher reactogenicity at injection site

*Determined by the investigator to be related to the vaccine.

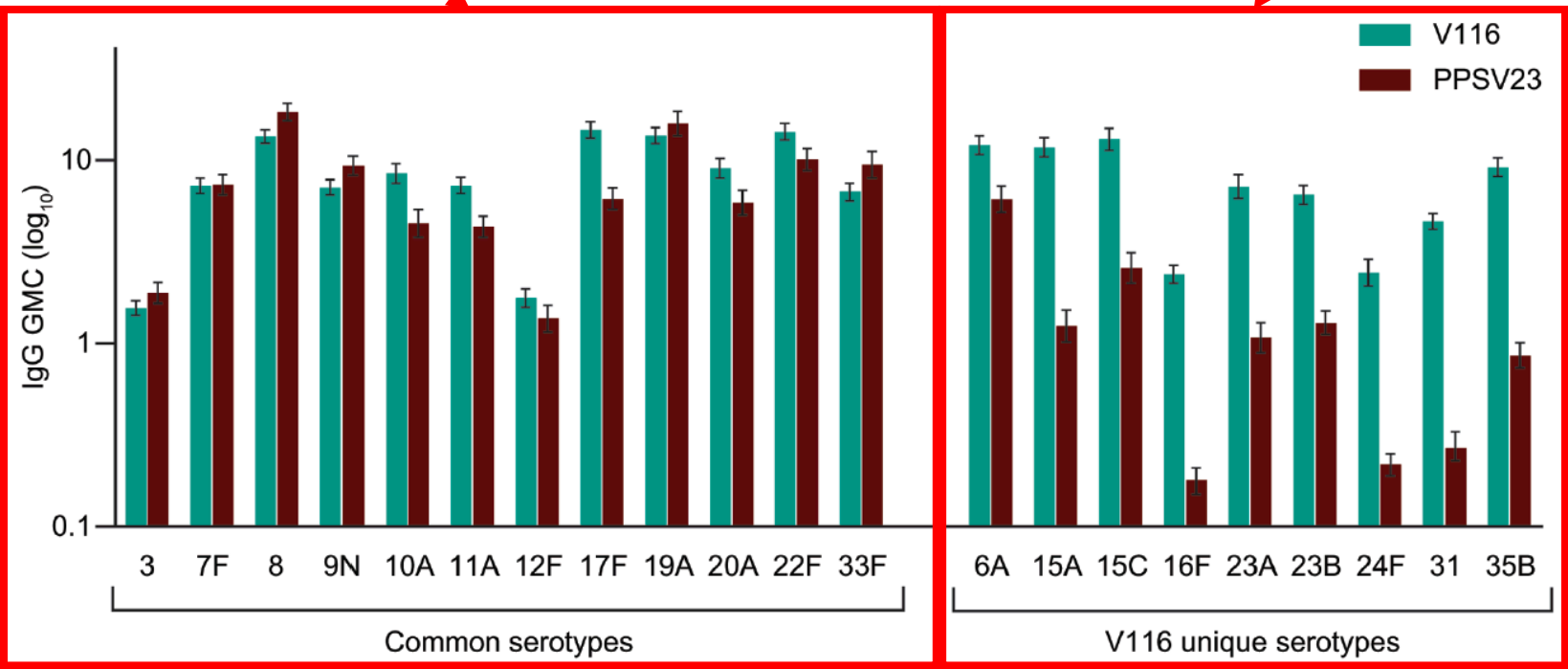
However this is not the difference made with the PCV 20



V116 vs PPSV23 in children at risk for invasive pneumococcal disease. Immunogenicity data:

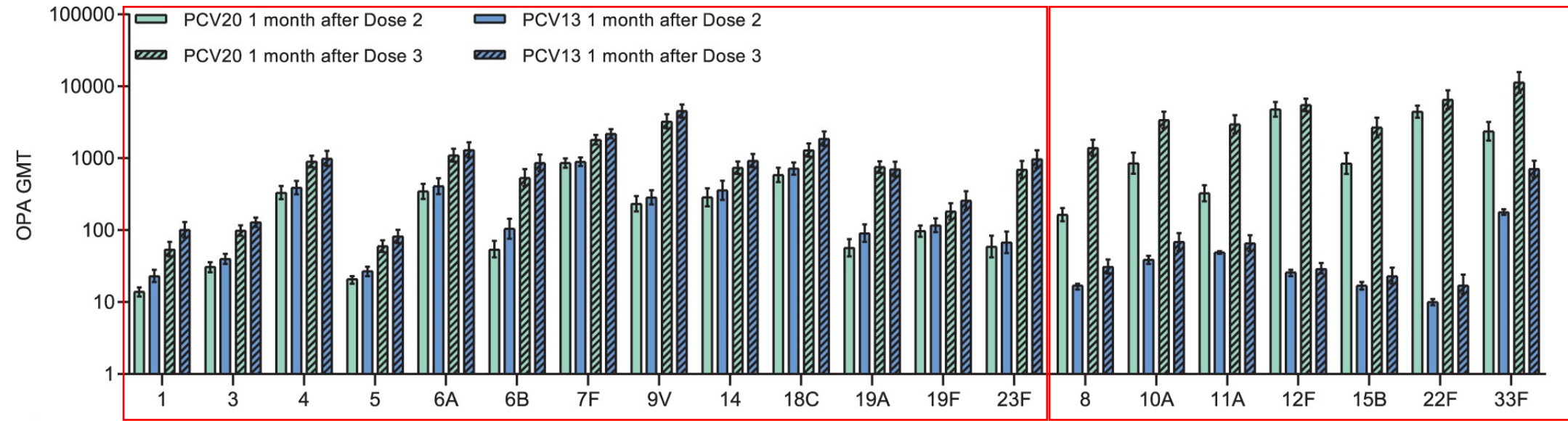
Non inferiority for common serotypes

Superiority for V116 serotypes



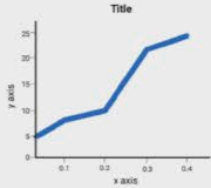
For PCV20 non inferiority data revealed the need for a 4 doses schedule

Failed in showing non inferiority for PCV13 Ag(s) for the 3-dose schedule. Superiority of non PCV13 antigens.



GMFRs from 1 month after Dose 2 to 1 month after Dose 3																				
Serotype	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	8	10A	11A	12F	15B	22F	33F
PCV20	4.0	3.2	2.8	2.9	3.0	8.8	2.2	14.5	2.5	2.2	13.2	1.9	11.2	7.1	4.0	9.8	1.2	2.9	1.4	4.8
PCV13	4.7	3.3	2.6	3.1	3.6	9.6	2.5	16.1	2.7	2.7	7.9	2.4	15.2	-	-	-	-	-	-	-

Chronic Complex Conditions



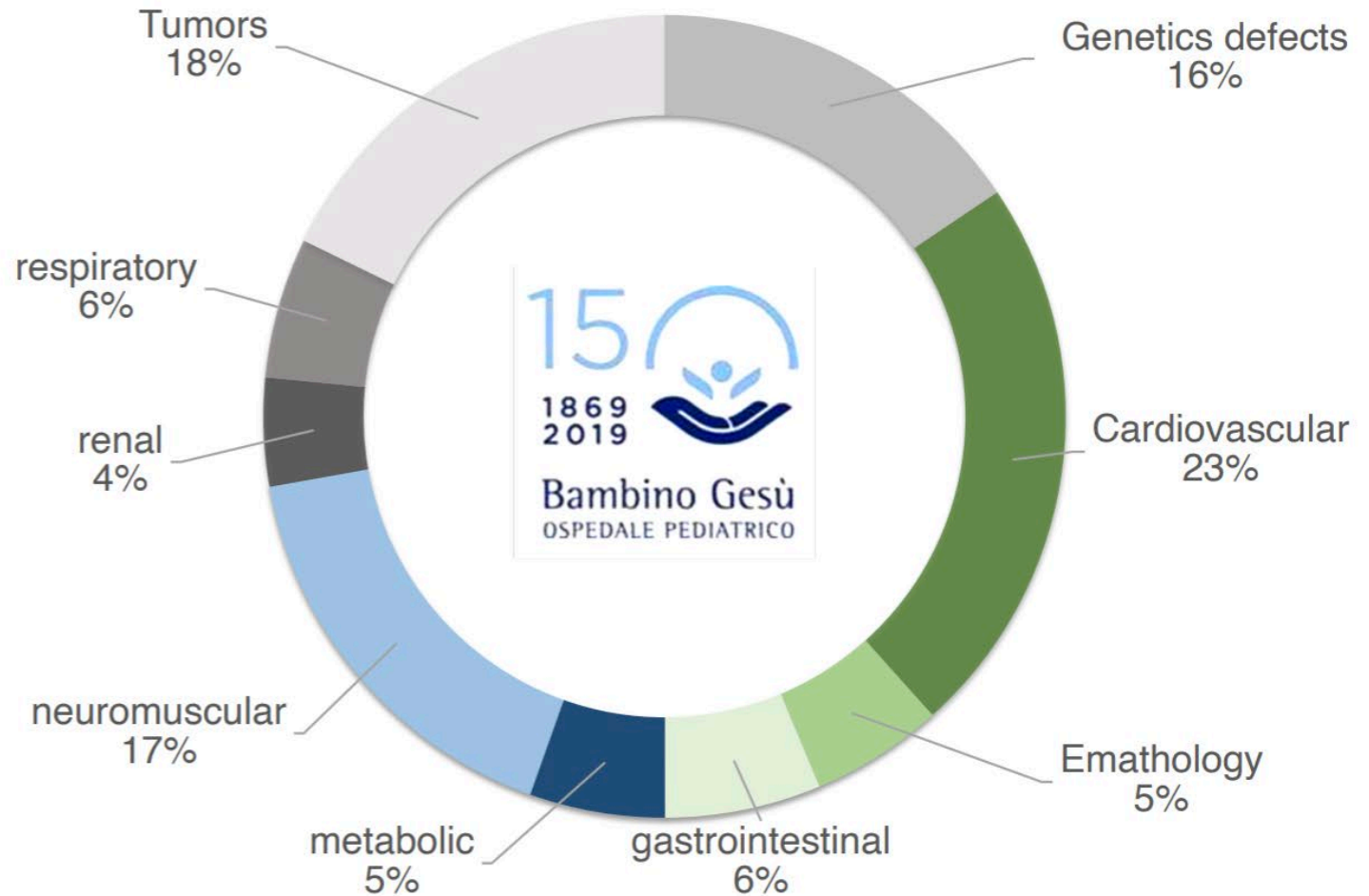
27,000
inpatient admissions



of patients have chronic
complex conditions



patients with chronic
complex conditions are
foreigners



PCV13 immunization elicits distinct immunological profiles in preterm vs full-term infants and a lower Ab response

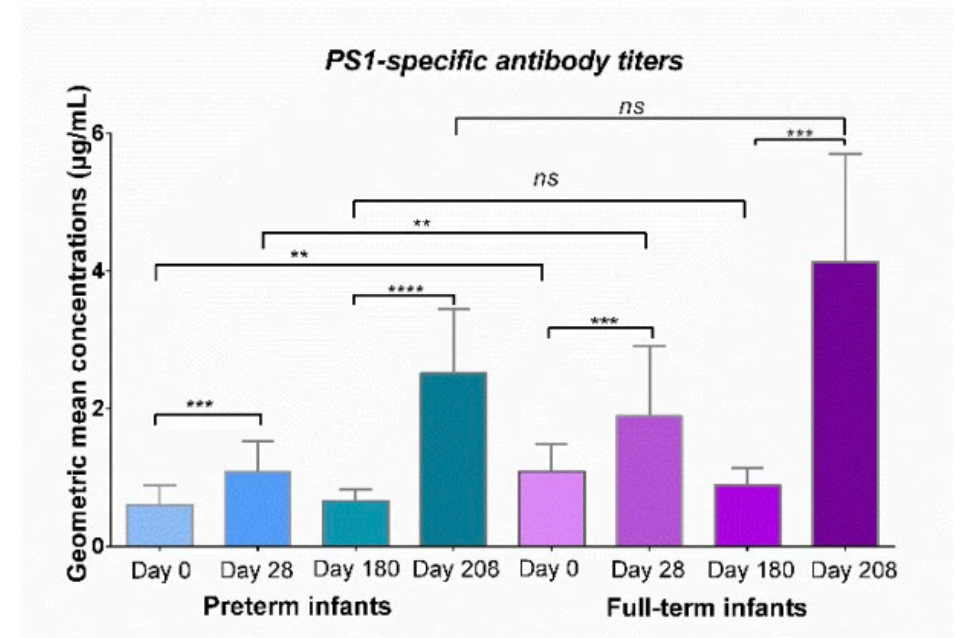


The Journal of Infectious Diseases

MAJOR ARTICLE

Systems analysis of immunity to pneumococcal vaccination in preterm and full term infants

Maria Geropeppa^{1,*,+}, Ioanna Papadatou^{1,2,*}, Kleio-Maria Verrou³, Panagiotis Lembessis³, Pantelis Hatzis^{3,4}, Marianna Tzanoudaki⁵, Lefkothea Dova⁶, Aikaterini Drougia⁷, Eleni Maragoudaki⁷, Aikaterini Skoufou⁸, Eleni-Maria Tetorou⁸, Eirini Loukatou⁸, Vasileios Giapros⁷, Christina Kanaka-Gantenbein², Tania Siahianidou², Vana Spoulou^{1,2}



What are the populations that should be protected first?

Example health condition		Example treatments
High	Receiving HCT within past 1 year or need for treatment of graft-versus-host disease after receiving HCT; haematological malignancy requiring treatment; history of lung transplant; B-cell aplasia based on an absolute CD19 ⁺ B-cell count <20 cells/mm ³ within past 6 months; T-cell aplasia based on an absolute lymphocyte count <200 cells/mm ³ within past 6 months	Receiving B cell-depleting drugs (eg, rituximab); CAR-T cell therapy within past 6 months; T cell-depleting therapy (eg, anti-thymocyte globulin) in the previous 6 months; receiving high dose of mycophenolate mofetil; receiving belatacept
Moderate	Solid organ transplant other than lung; solid tumour on treatment; HIV infection with CD4 count <200 cells/mm ³ ; primary immunodeficiency resulting in low immunoglobulins or B-cell or T-cell defects; autoimmune disease requiring high-dose corticosteroids or >1 immunosuppressive drug for disease control	Receiving anthracycline derivatives; high-dose corticosteroids (defined as >20 mg prednisone or equivalent for >4 weeks)
Low	HIV infection with CD4 count >200 cells/mm ³ ; cirrhosis; end-stage renal disease; autoimmune disease not requiring high-dose corticosteroids or >1 immunosuppressive drug for disease control	Receiving TNF; corticosteroids (<20 mg prednisone or equivalent for <4 weeks)

Adapted from Bhimraj et al,⁴ by permission of Oxford University Press. HCT=haematopoietic cell transplant. CAR=chimeric antigen receptor. *Degree of immune compromise generally correlates with vaccine immunogenicity and risk of infection (eg, higher degree of immune compromise correlates with lower vaccine immunogenicity and increased risk of infection); categorisations are adapted from categorisations for SARS-CoV-2 infection risk and might not be fully generalisable to other types of infections (eg, bacteria or fungi) or to vaccine responses (eg, TNF inhibitor use is associated with a diminished response to hepatitis B vaccination).⁵

Table: Degree of immune compromise according to immunocompromising cond

Prevention and Management of Infections in People who are Immunocompromised 1

Innovation in active and passive immunisation of people who are immunocompromised: a call to action

Joshua A Hill, Jim Boonyaratankornkit, Malgorzata Mikulska, Benjamin W Teh, William O Hahn, Ghady Haidar, Catherine Liu, Deepali Kumar, Michael G Ison, Natasha Halasa

Lancet Infect Dis 2026; 26: e16-29
Published Online August 11, 2025
[https://doi.org/10.1016/S1473-3099\(25\)00345-7](https://doi.org/10.1016/S1473-3099(25)00345-7)
See [Comment](#) page 11
This is the first in a [Series](#) of two papers about people who are immunocompromised

Conclusions/Take Home messages

- Streptococcus Pneumoniae related Disease represents one of the most important causes of invasive infectious diseases
- Immune compromised children and people at higher risk for invasive pneumococcal vaccination should be offered with updated immunizations
- Pneumococcus vaccine is a moving field and vaccination programs are keeping the pace of the genetic variance of Pneumococcus (?)
- Increasing knowledge on PCV is crucial to defeat vaccination hesitancy
- Continuous research in pneumococcus vaccination is needed!

Unit head: Paolo Palma

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Penta



What is the current definition of recurrent infection?

RRIs are common in early childhood, affecting 25% of children under 1 year of age and 6% of children in the first six years of life, constituting an important societal and economic burden.

According to the Italian Intersocietal Consensus (Chiappini et al. 34696778), RRIs in children are defined by age as follows: a) between 1 to 3 years as 6 or more respiratory tract infections (1 of which may be pneumonia, including severe pneumonia) in a year, or 2 mild cases of pneumonia confirmed by clinical and/or radiographic criteria within one year;

b) between 3 to 6 years, as 5 or more respiratory tract infections (1 of which may be pneumonia, including severe pneumonia) in a year, or 2 mild cases of pneumonia confirmed by clinical and/or radiographic criteria within one year.

b) between 6 to 12 years, as 3 or more respiratory tract infections (1 of which may be pneumonia, including severe pneumonia) in a year, or 2 mild cases of pneumonia confirmed by clinical and/or radiographic criteria within one year.

(2732519, 30419907)



PCV20 nella Popolazione pediatrica

- **Lattanti non vaccinati di età compresa tra 7 mesi e 12 mesi non compiuti**

Due dosi, ciascuna da 0,5 mL, con un intervallo di almeno 4 settimane tra loro. Si raccomanda di somministrare una terza dose nel secondo anno di vita.

- **Bambini non vaccinati di età compresa tra 12 mesi e 24 mesi non compiuti**

Due dosi, ciascuna da 0,5 mL, con un intervallo di almeno 8 settimane tra loro.

- **Bambini non vaccinati di età compresa tra 2 anni e 5 anni non compiuti**

Una singola dose da 0,5 mL.

- **Bambini di età compresa tra 15 mesi e 5 anni non compiuti con un ciclo di vaccinazione completato precedentemente con PCV**

Una singola dose (0,5 mL). Se è stato somministrato PCV13, devono trascorrere almeno 8 settimane prima della somministrazione di PCV20.

- **Bambini e adolescenti di età compresa tra 5 anni e 18 anni non compiuti indipendentemente dalla precedente vaccinazione con PCV13**

Una singola dose (0,5 mL) somministrata su base individuale secondo le raccomandazioni ufficiali.

Se è stato somministrato Prevenar 13, devono trascorrere almeno 8 settimane prima della somministrazione di PCV20.

PCV national schedule: updates.

Vaccino	2 mesi	3 mesi	4 mesi	5 mesi	6 mesi	10 mesi	12 mesi	13-14 mesi	⇒	5 anni	6 anni	11-18 anni	19-59 anni	50-64 anni	> 64 anni
DTPa	DTPa		DTPa			DTPa				DTPa		dTpaIPV	dTpa** (ogni 10 anni)		
IPV	IPV		IPV			IPV				IPV					
Epatite B	Ep. B		Ep. B			Ep. B									
Hib	Hib		Hib			Hib									
Pneumococco	PCV	(aggiuntiva) PCV*	PCV			PCV									PCV20 o PCV15/PPV
MPRV							MPRV			MPRV					
MPR							oppure MPR + V			oppure MPR + V					
Varicella															
Meningococco ACWY							Men ACWY					Men ACWY			
Meningococco B	Men B							Men B				Men B 2 dosi			
HPV												HPV: 2-3 dosi (in funzione dell'età)			
Influenza**					Influenza								Influenza		
Herpes Zoster														HZ	
Rotavirus	Rotavirus														
SARS-CoV-2**														SARS-CoV-2 ≥ 60 anni	
VRS	Anticorpo monoclonale 0-12 mesi o Vaccino in gravidanza													Vaccino VRS ≥ 75 anni	
	Vaccini per i quali è fortemente raccomndata la cosomministrazione nella stessa seduta							* In caso di uso schedula 3+1 PCV20 ** Vaccino fortemente raccomandato in gravidanza							

PCV 20

Programma di vaccinazione nei lattanti e nei bambini di età compresa tra 6 settimane e 15 mesi

Ciclo di 4 dosi (un ciclo primario di tre dosi seguito da una dose di richiamo)

Il ciclo primario per lattanti consiste in tre dosi da 0,5 mL ciascuna, con la prima dose solitamente somministrata a 2 mesi di età e con un intervallo di almeno 4 settimane tra le dosi. La prima dose può essere somministrata già a 6 settimane di età. La quarta dose (di richiamo) è raccomandata tra gli 11 e i 15 mesi di età.

Programma di vaccinazione per adulti di età pari o superiore a 18 anni

Adulti di età pari o superiore a 18 anni

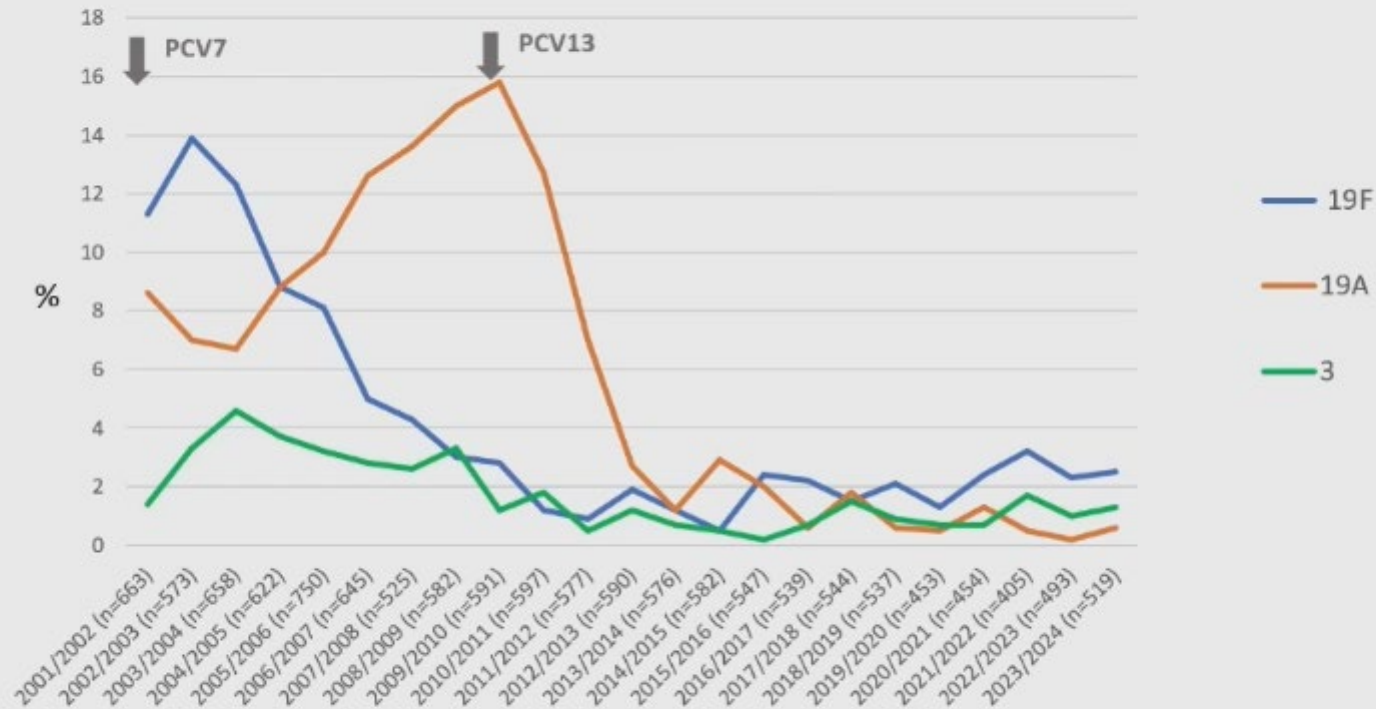
PCV 20 deve essere somministrato come singola dose ad adulti di età pari o superiore a 18 anni.

Se l'uso del vaccino pneumococcico polisaccaridico 23-valente (Pneumovax 23 [PPSV23]) è considerato appropriato, Prevenar 20 deve essere somministrato per primo (vedere paragrafo 5.1).

Table 2. Representative protein-based vaccine candidates and trials (adopted from)⁸³.

Protein	ClinicalTrials.gov Identifier	Phase	Status	Representative References
PhtD	NCT01767402	Phase I	Completed	125
PhtD-dPLY	NCT00896064	Phase II	Completed	-
PlyD1	NCT01444352	Phase I	Completed	92
PhtD	NCT01444001	Phase I	Completed	102
PcpA (Pneumococcal choline-binding protein A), PcpA + PhtD	NCT01444339	Phase I	Completed	126
PhtD + PcpA + PlyD1	NCT01764126 NCT01446926	Phase I	Completed	103
dPLY + PsaA (Pneumococcal surface adhesin A) + 24 CPS	NCT03803202 NCT04525599	Phase I/II Phase I	Completed Active	- -
PspA + PlyD	NCT04087460	Phase Ia	Active	-
dPLY + PhtD + PCV10	NCT01262872	Phase II	Completed	93–95

Main remaining PCV13 serotypes: 19F, 19A, 3



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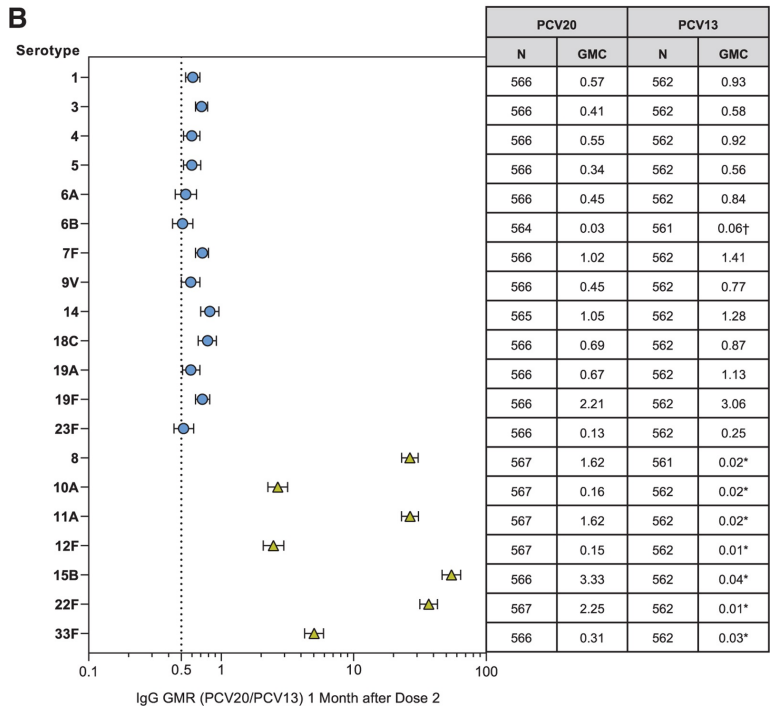
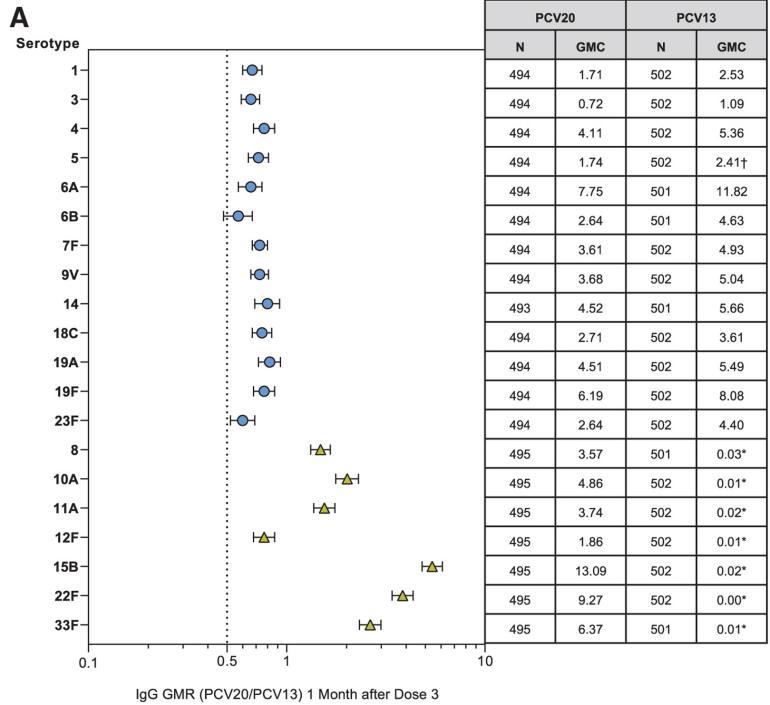


TABLE 1. Summary of Adverse Events (Safety Population)

Time Point Type	PCV20	PCV13
From dose 1 to 1 month after dose 3, n (%)	(N = 1001)	(N = 988)
Any AE	366 (36.6)	389 (39.4)
Related	7 (0.7)	7 (0.7)
Severe	8 (0.8)	7 (0.7)
From dose 4 to 1 month after dose 4, n (%)	(N = 853)	(N = 841)
Any AE	129 (15.1)	126 (15.0)
Related	0	1 (0.1)
Severe	5 (0.6)	2 (0.2)
For duration of study, n (%)	(N = 1001)	(N = 987)*
SAE	45 (4.5)	31 (3.1)

*One participant received incorrect vaccine at dose 4 and was therefore excluded in the summary denominator for SAEs across the whole study.

AE indicates adverse event; N, number of participants in the specified group and the denominator for the percentage calculations; N, number of participants reporting ≥1 occurrence of the specified event; PCV13, 13-valent pneumococcal conjugate vaccine; PCV20, 20-valent pneumococcal conjugate vaccine; SAE, serious adverse event.

IDEAL: focus on the recurrent infection

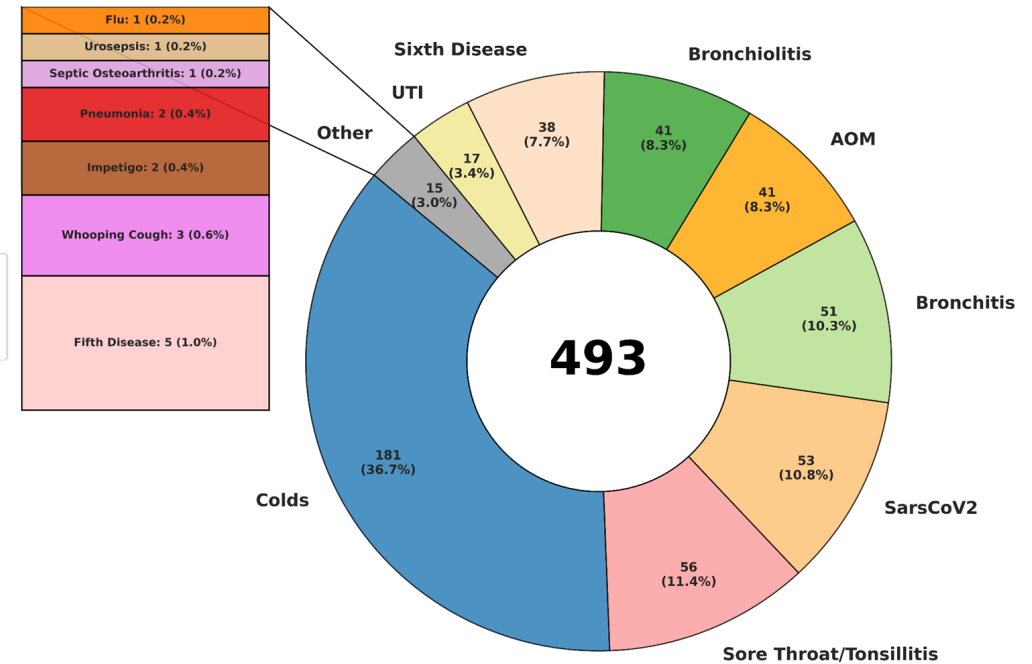
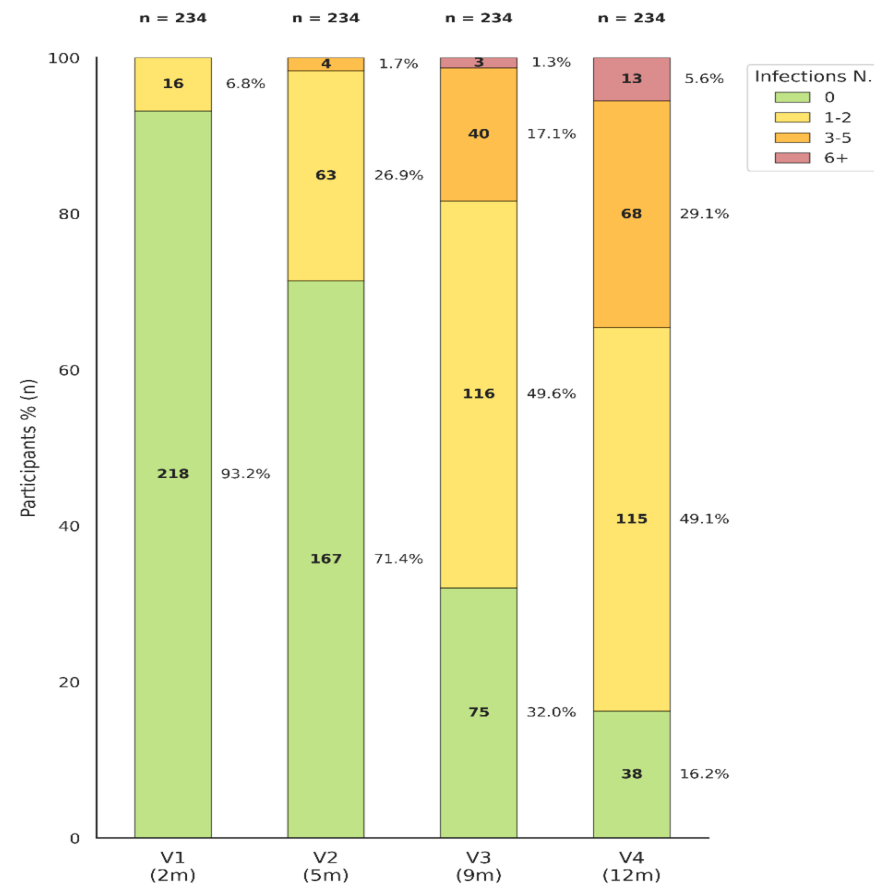
Results

From April 2023 to November 2024, we enrolled 273 participants (Fig.3).

Of these, **34.7% experienced ≥ 3 infections** during the first year of life (Fig.4A).

Specifically, the following infections were observed among participants:

- common cold (n=181),
- SARS-CoV-2 (n=53),
- bronchiolitis (n=41),
- bronchitis (n=51),
- pneumonia (n=2),
- pharyngitis/tonsillitis (n=56),
- otitis (AOM, n=41),
- urinary tract infection (UTI, n=17),
- and 1 septic osteoarthritis.



Immune Development in Early Life (IDEaL): Clinical data and biosample capture to enable multi-omic profiling of endotypes predictive of vaccine responsiveness, respiratory infection and asthma

C. Rossetti¹, D. Amodio^{1,2}, A. Angelidou^{3,4,5}, M. Sanna¹, S. Cenciarelli⁶, M.C. Marrero Cabrera¹, M. ... A. Rotulo¹, S. Thomas^{3,5}, A. Hoch³, C. Syphurs³, ... Su^{5,10}, O. Levy^{3,5,11} & P. Palma^{1,2}

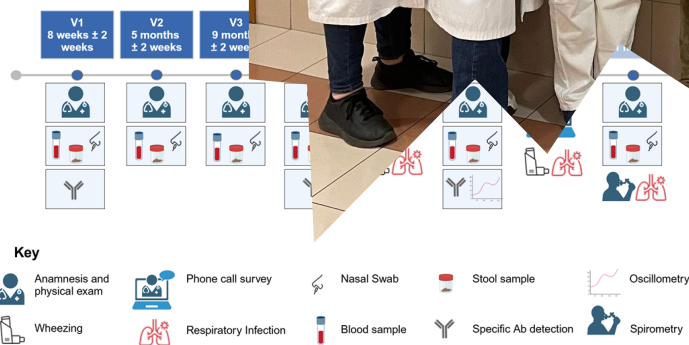
Background

The IDEaL-Rome prospective pediatric cohort, based at Bambino Gesù Children's Hospital (PBG, Rome, Italy), is part of an international, multi-center, multi-omic study to identify molecular endotypes associated with vaccine responsiveness (VR) and asthma (AS) and vaccine responsiveness (VR).

Methods

The study includes six sequential visits (V1 to V6) from birth to 6 years of age. At V1, with the mother, we collect clinical data, including birth weight, gestational age, and breastfeeding status. At V2, we collect data on respiratory infection (RI) and wheezing. At V3, we collect data on respiratory infection (RI) and wheezing. At V4, we collect data on respiratory infection (RI) and wheezing. At V5, we collect data on respiratory infection (RI) and wheezing. At V6, we collect data on respiratory infection (RI) and wheezing.

Figure 1



Results

From April 2018 to March 2023, 273 participants were enrolled. Currently, 234 subjects have completed V1, 198 V2, 158 V3, 128 V4, 108 V5, and 88 V6. The subjects have a mean age of 1.5 years. The subjects have a mean weight of 10.5 kg. The subjects have a mean height of 75 cm. The subjects have a mean BMI of 16.5 kg/m². The subjects have a mean respiratory rate of 20 breaths per minute. The subjects have a mean heart rate of 100 beats per minute. The subjects have a mean blood pressure of 90/60 mmHg. The subjects have a mean temperature of 36.5°C. The subjects have a mean oxygen saturation of 98%.



Figure 4

Conclusions

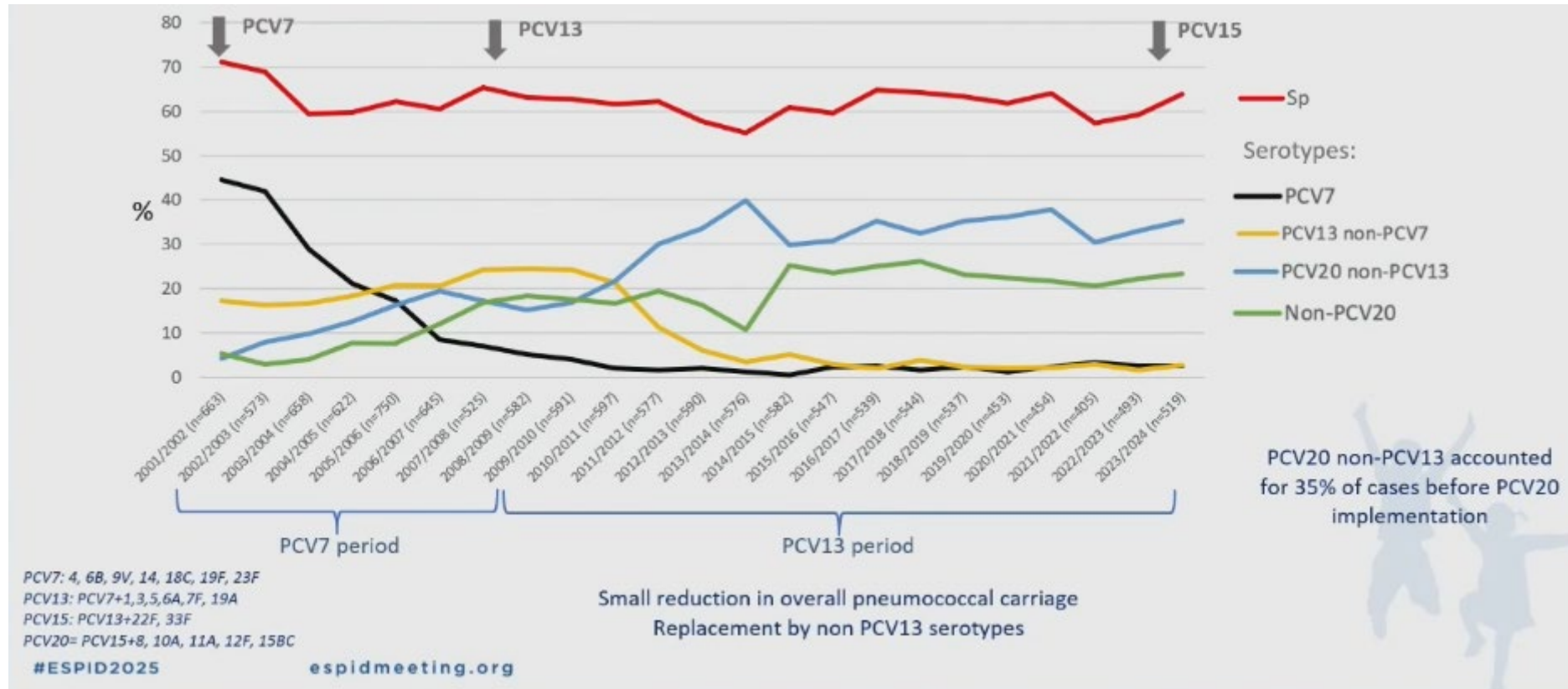
The IDEaL-Rome prospective cohort will provide a robust repository of specimens as well as clinical, immunologic, and systems biology data to enable multi-omic analyses to define endotypes related to vaccine responsiveness, respiratory infections, and asthma.

Affiliations:

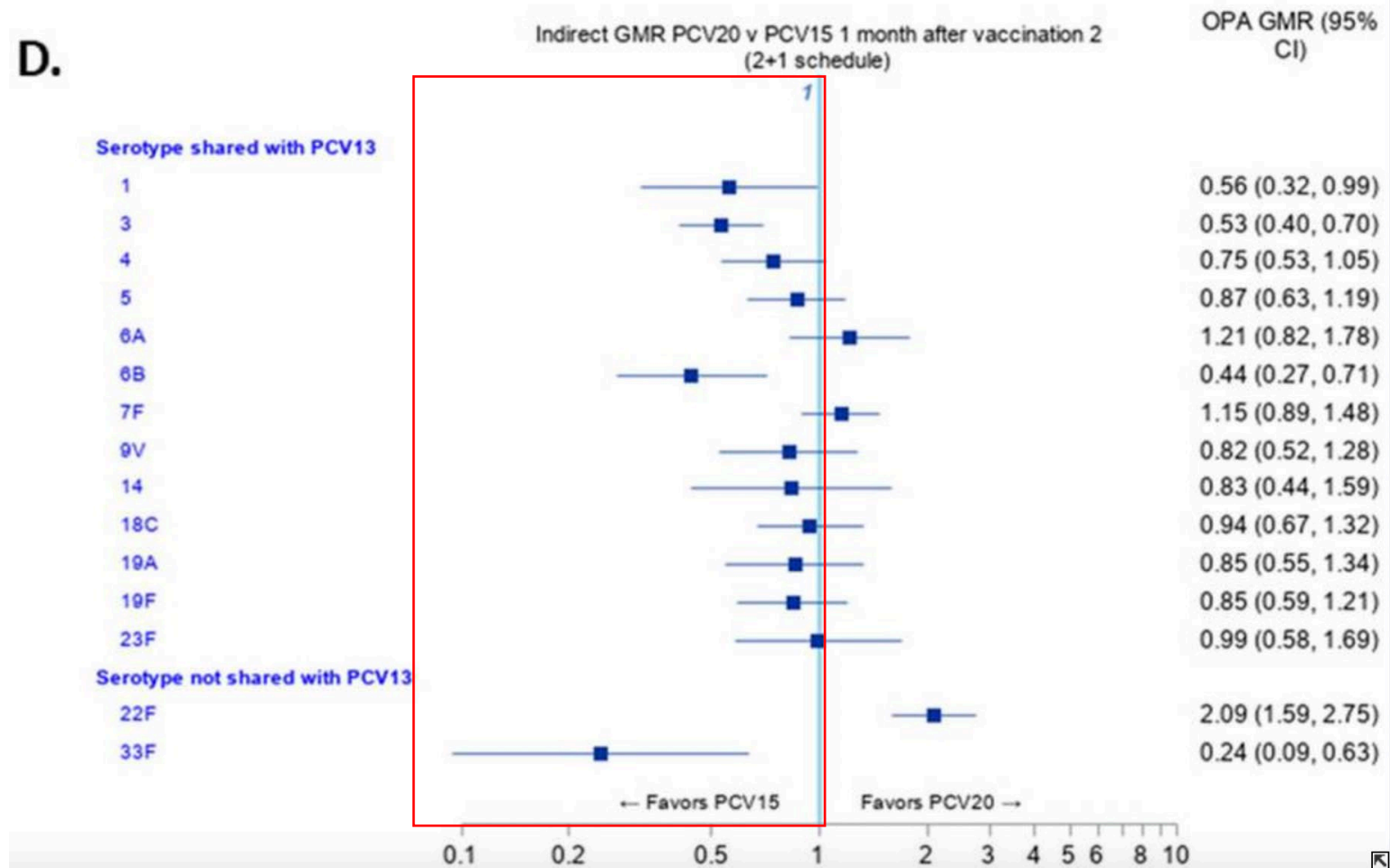
¹Clinical and Research Unit of Clinical Immunology and Vaccinology, Bambino Gesù Children's Hospital, IRCCS, Rome, Italy. ²Chair of Pediatrics, Department of Systems Medicine, University of Rome "Tor Vergata", via Montpellier, 1, 00133, Rome, Italy. ³Precision Vaccines Program, Department of Pediatrics, Boston Children's Hospital, Boston, MA, United States, 02115. ⁴Department of Neonatology, Beth Israel Deaconess Medical Center, Boston, MA, United States, 02115. ⁵Pediatric Immunohematology and Bone Marrow Transplantation Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy. ⁶Rochester Regional Health-Research Institute, Rochester, N.Y. ⁷Department of Pathology, Boston Children's Hospital and Harvard Medical School, Boston, MA, United States. ⁸Wai-Yan Respiratory Research Centre, The Kids Research Institute Australia, University of Western Australia, Perth, Australia. ⁹Channing Division of Network Medicine, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, United States. ¹⁰Broad Institute of MIT & Harvard, Cambridge, MA, United States.

The importance of the of SP carriage for SP Otitis Media

SP carriage dropped from 71% to 64% from 2001 to 2024 (data from 13086 children analyzed).

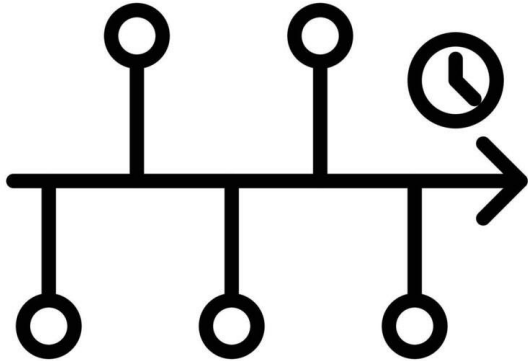


PCV 13 Ag showed a lower immnogenicity according to the 3 dose schedule of PCV20 compared to the V114



3-dose PCV20 schedule vs 3 dose PCV15 favours PCV15

Pneumococcus Vaccine program in the last 15 years in Europe and Italy



- Dal 2010 - 2017 il vaccino coniugato pneumococcico a 13 valenze (PCV13) è stato pressoché il solo vaccino coniugato pneumococcico adottato in Italia per l'immunizzazione dei nuovi nati.
- A dicembre 2021, un nuovo vaccino contro 15 ceppi di Pneumococco (PCV-15) contenente i sierotipi 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F ha ricevuto l'approvazione per la commercializzazione negli Stati membri dell'Unione Europea (UE).
- A marzo 2022 l'AIFA lo ha approvato PCV20 negli individui di età pari o superiore a 18 anni. Questo preparato presenta ulteriori vantaggi rispetto ai vaccini coniugati precedenti; infatti, gli ultimi due ceppi aggiunti (22F e 33F), in era pre-COVID erano responsabili di circa il 7% dei casi delle patologie invasive.
- Ad ottobre 2022 la Commissione Europea ha approvato l'estensione di indicazione in neonati, bambini e adolescenti da 6 settimane a meno di 18 anni di età.

Gap in knowledge: what are early predictors of recurrent infections?

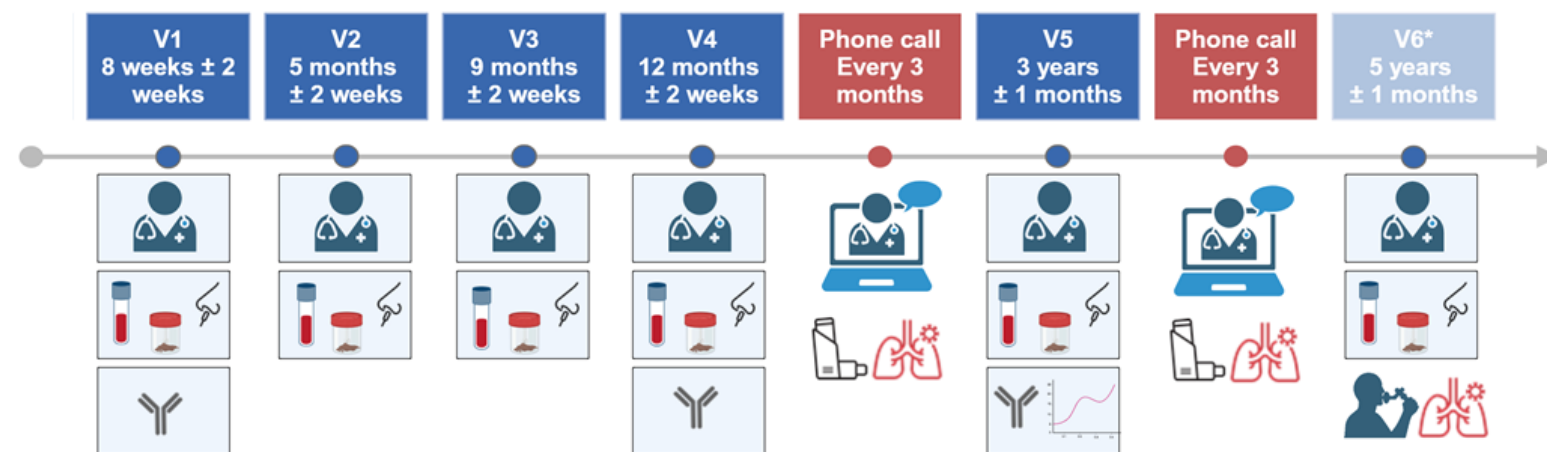


Backgorund: The IDEaL-Rome prospective pediatric cohort, based at Bambino Gesù Children's Hospital (OPBG, Rome, Italy), is part of an NIH/NIAID-supported longitudinal observational study

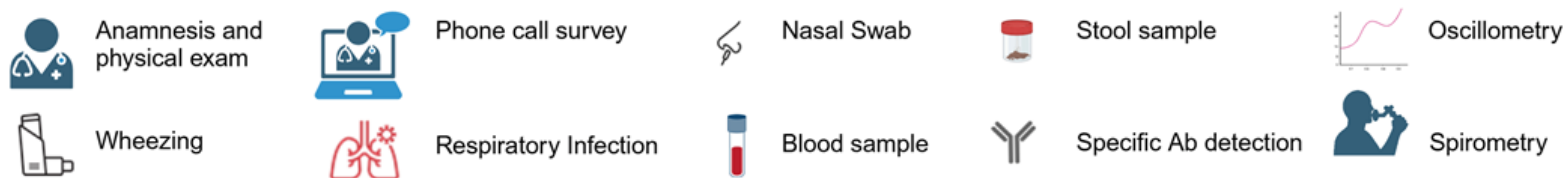
Aim: to identify molecular endotypes associated with increased susceptibility to 3 main clinical outcomes:

IDEAL Study Design

The study includes six scheduled visits over the first 5 years of age

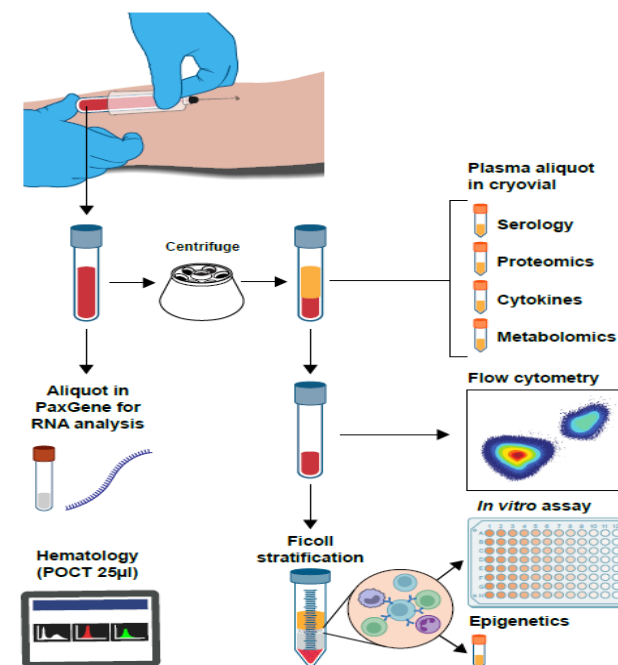


Key



Multi-OMIC investigation

- cytokine/chemokine
- proteomic
- Metabolomic
- High-dimensional immune parameters
- microbiome
- epigenetic data.



3 main clinical outcomes will be associated to early life endotypes:

Asthma



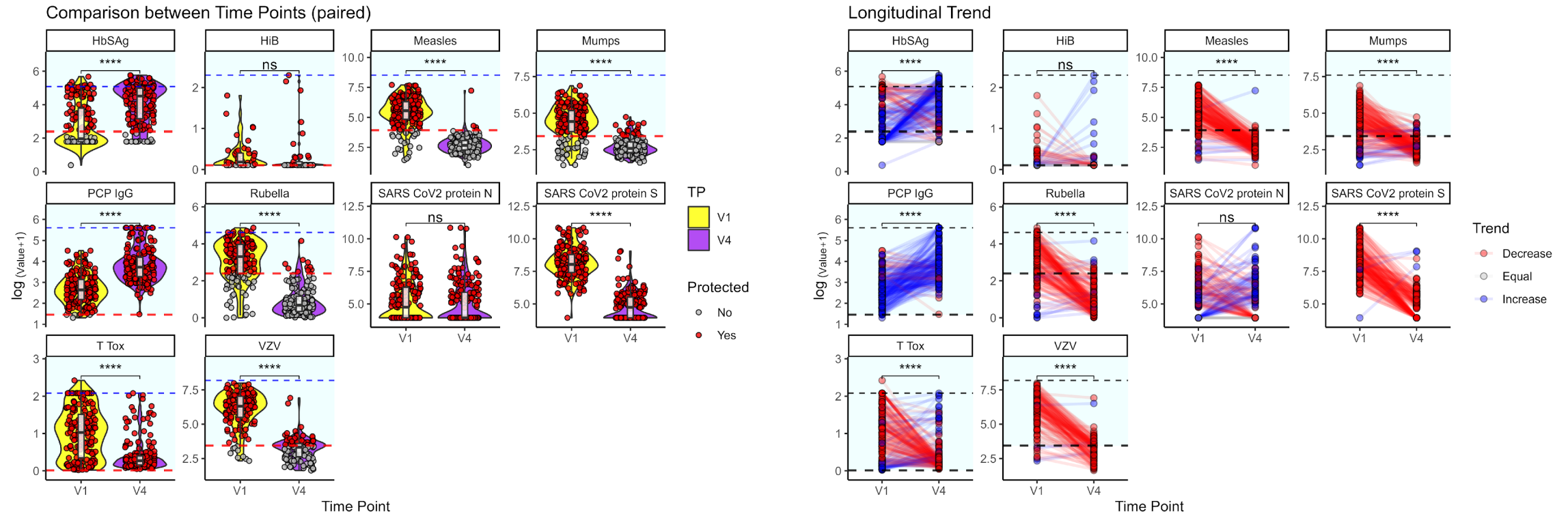
Impaired vaccine response



Recurrent Infections

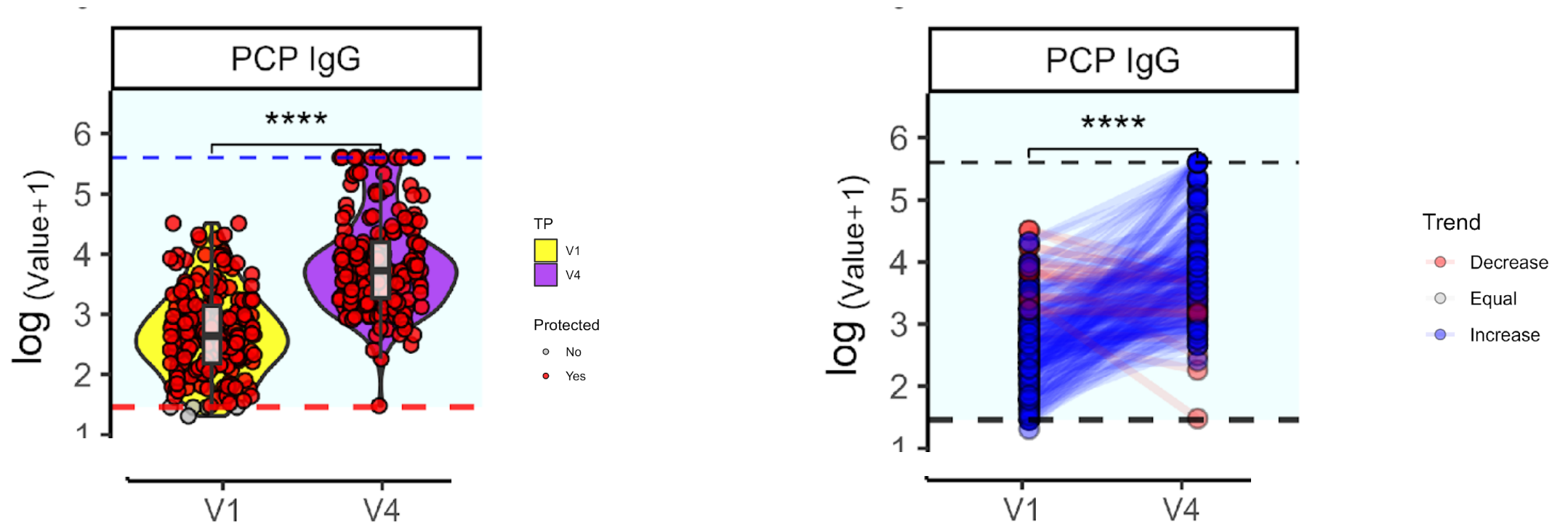


Longitudinal evaluation of mother derived and vaccine induced immunity in the IDEAL cohort



Confidential, please do not post

Vaccine induced immunity cannot be given for granted in healthy population



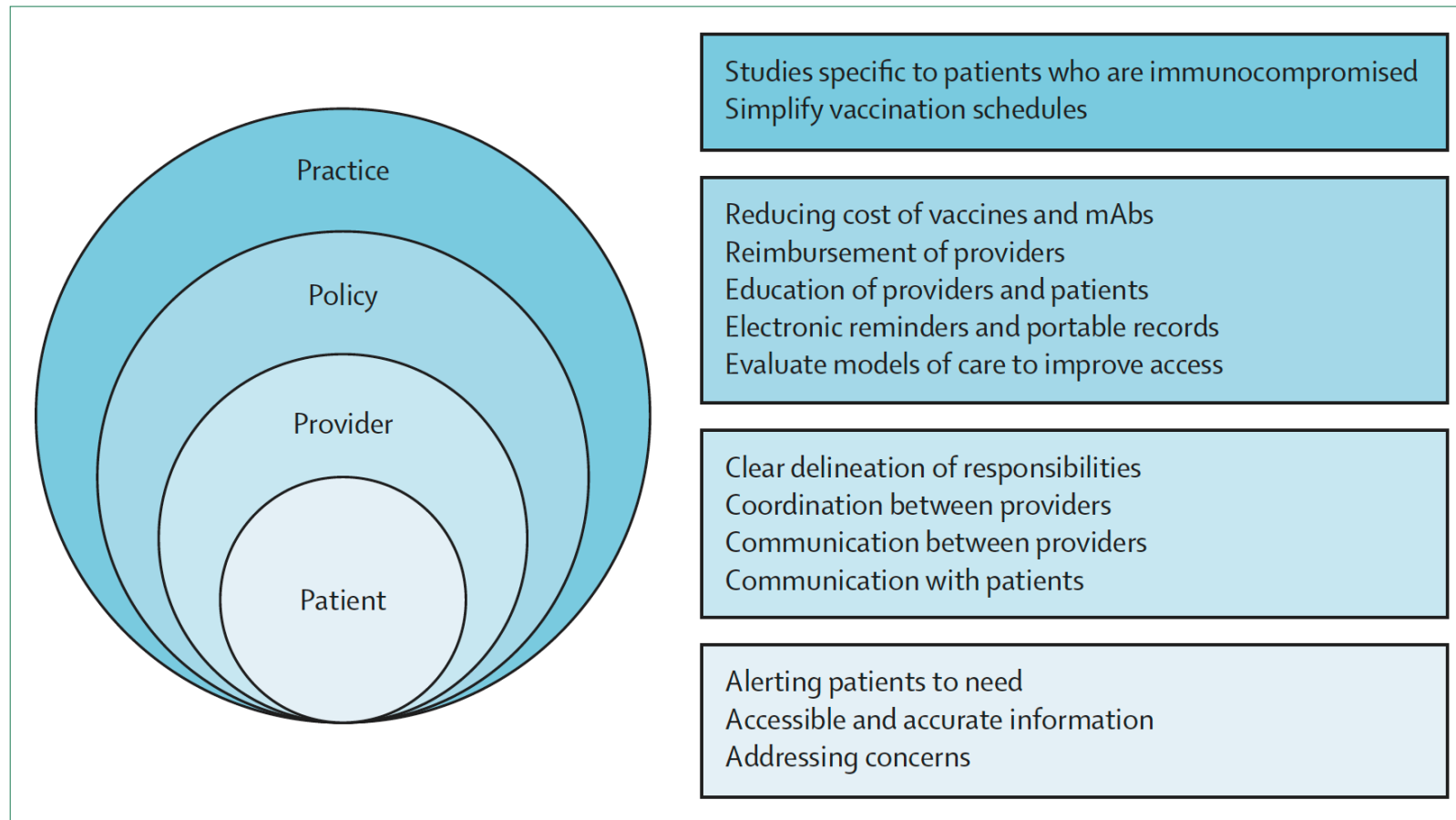


Figure 3: Approaches to enhance vaccination and mAb use in people who are immunocompromised

The figure shows examples across the spectrum of care delivery. mAb=monoclonal antibody. Figure created with BioRender.com.

The family of Pneumococcus Vaccines is growing fast

- >101 known immunologically-distinct capsules (**serotypes**)
- First polysaccharide conjugate vaccine (**PCV7**) contained 7 serotypes: **4, 6B, 9V, 14, 18C, 19F, 23B** conjugated to CRM197
- Since 2009, **PCV10** added **1, 5, 7F** and **PCV13** also added **3, 6A, 19A**
- Since 2021, **PCV15** added **22F, 33F** and **PCV20** added **8, 10A, 12F, 11A, 15B**

	Stage	PCV13	2	6C	7C	8	9N	10A	11A	12F	15A	15B	15C	16F	17F	20A	20B	22F	23A	23B	24F	31	33F	35B
PCV20 (Pfizer)	Licensed																							
PCV21 (Sanofi/SK) ¹	Ph III Infants to start 2024																							
PCV24 (GSK-Affinivax) ²	Ph II adults completed and in Ph II infants																							
PCV24 (Vaxcyte) ³	Ph III adults and II infants																							
PCV24 (Bio E) ⁴	Phase II to start																							
PCV25 (Inventrise) ⁵	Ph II adults	No 6A																						
PCV31 (Vaxcyte) ³	Ph I/II																							