C.H.U. *de Charleroi*
Centre de Référence VIH

Vaccination against *Streptococcus pneumoniae*, Influenza, SARS CoV2, and RSV in ageing HIV patients

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Spring BREACH meeting

22nd of April 2023

ISPPC
CHU de Charleroi

Vaccination against *Streptococcus pneumoniae*

Epidemiology of severe pneumococcal infections in Belgium

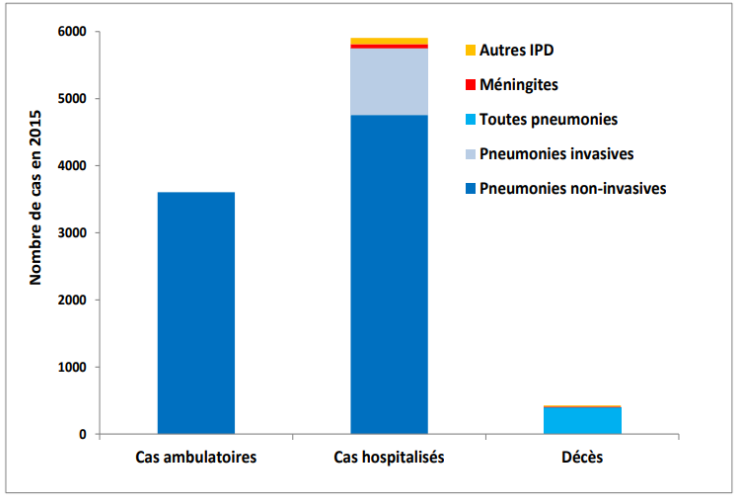
In Belgium in 2015, *Streptococcus pneumoniae* has been responsible of approximately:

- **5800 hospitalisations**
- **3600 ambulatory visits**
- **430 deaths**

Invasive Pneumococcal Disease (IPD) is a serious manifestation of infection by *Streptococcus pneumoniae* characterized by **pneumonia with bacteremia, meningitis or bacteremia**

In 2022, 1554 IPD isolates were received by the National Reference Laboratory

Figure 1 – Morbidité et mortalité liées au pneumocoque chez les adultes de plus de 50 ans en Belgique (2015)



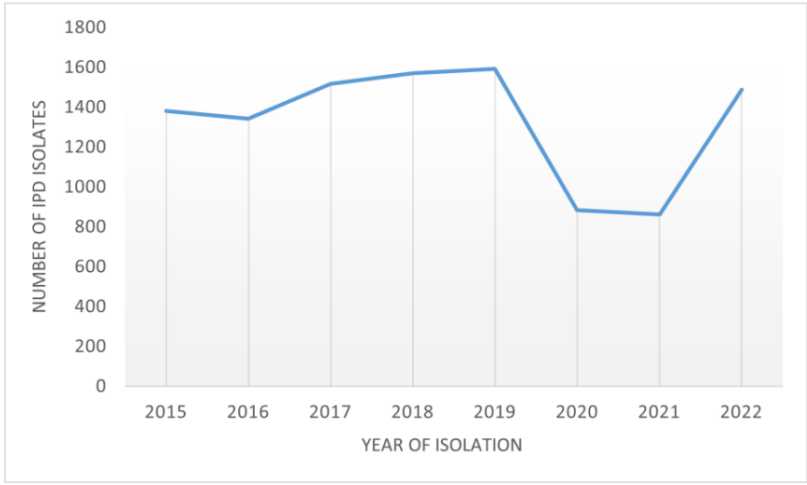


Figure 1: Evolution of the number of IPD (invasive pneumococcal disease) isolates received at the National Reference Centre from 2015 to 2022.

Quelle vaccination contre le pneumocoque chez les personnes âgées? | KCE (fgov.be)
streptoccocus_pneumoniae_2021_2021_nrc_rapport.pdf (sciensano.be)

Incidence of Invasive Pneumococcal Disease in HIV compared to others populations

Incidence of IPD higher in HIV patients also in the advanced ART era than in general population

Mortality of IPD:

- In 65 years of age: 12%
- In 85 years of age: 24%
- In HIV patients: from 0 to 25,6% depending on the studies

Population	Incidence of IPD (/100 000 person years)
General population	10
General population above 65 years of age	40
HIV in non African countries: - **Pre ART era** - **Early ART era** - **Advanced ART era**	 **746** **490** **331**
Stem cell transplantation (SCT): - **Allogeneic STC** - Autologous SCT	 **812** 696
Solid organ transplantation	414
Chronic inflammatory disease	65

Van Aalst M et al. Incidence of invasive pneumococcal disease in immunocompromised patients: a systematic review and meta-analysis. Travel Medicine and Infectious Diseases 24 (2018) 89-100. Incidence of invasive pneumococcal disease in immunocompromised patients: A systematic review and meta-analysis - ScienceDirect

The vaccines available, their serotypes coverage and efficacy

	name	Price (euros)	Market authorization date
PCV13	Prevenar 13	74,55	09 dec 2009
PCV15	Vaxneuvance	74,55	13 dec 2021
PCV20	Apexxnar	80,98	14 feb 2022
PPV23	Pneumo 23	33,66	01 dec 2015

PCV: Pneumococcal Polysaccharide Conjugate vaccine
PPV: Pneumococcal Polysaccharide vaccine

Vaccine Efficacy (VE) against IPD due to vaccine serotypes:

- **PCV13:**
  - 76% (same efficacy expected for PCV20) (KCE)
  - 75% between 65 and 85 years old
- **PPV23:** 24-45%

Serotypes Contained in Current and New Pneumococcal Vaccines

	1	3	4	5	6A	6B	7 F	9V	14	18 C	19 A	19 F	23 F	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20
PCV13	■	■	■	■	■	■	■	■	■	■	■	■	■											
PCV15	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■									
PCV20	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■				
PPSV23	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

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

Tableau 1 – Efficacité des vaccins

	PCV13[10]	PPV23
Efficacité contre les IPD		
- **dues aux sérotypes vaccinaux**	76% (13 sérotypes)	24-45% (23 sérotypes)[d, *] d'après les études[9, 11, 13, 14]
- **dues à tout sérotype**	49% (aux Pays Bas)	Pas d'étude fiable et récente
Efficacité contre les pneumonies non-invasives		
- **dues aux sérotypes vaccinaux**	41% (13 sérotypes)	Pas d'étude
- **dues à tout sérotype**	17% (non significatif)	29% (non significatif)[12,d]

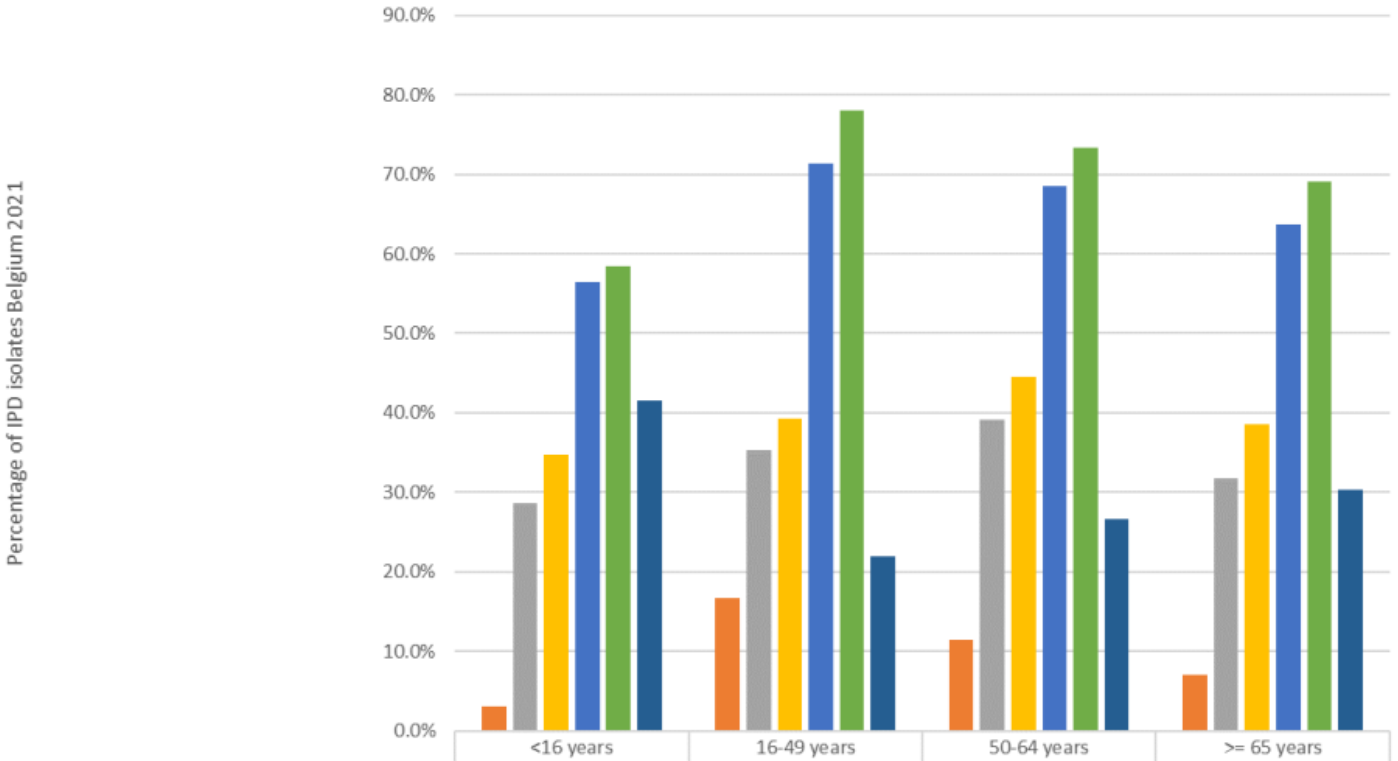
** Nous avons retenu 24% dans notre étude, venant d'une étude anglaise robuste et récente.[9]*

Quelle vaccination contre le pneumocoque chez les personnes âgées? | KCE (fgov.be)
Prevenar 13, INN-Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (europa.eu)
Polysaccharide Conjugate Vaccine against Pneumococcal Pneumonia in Adults | NEJM

Serotype coverage of the current vaccines based on the IPD isolates of the NRC in 2022

Coverage of the isolates responsible of IPD in Belgium:

- **PCV20: 56 to 71%**
- PCV13: 28 to 39%
- PPV23: 58 to 78%



	<16 years	16-49 years	50-64 years	>= 65 years
PCV10 serotypes	3.1%	16.7%	11.4%	7.1%
PCV13 serotypes	28.6%	35.3%	39.1%	31.7%
PCV15 (PCV13 + 22F + 33F) serotypes	34.8%	39.3%	44.6%	38.5%
PCV20 (PCV15 + 8, 10A,11A, 12F, 15B) serotypes	56.5%	71.3%	68.5%	63.7%
PPV23	58.4%	78.0%	73.4%	69.1%
non-vaccine serotypes (NVT)	41.6%	22.0%	26.6%	30.3%

Figure 3: Serotype coverage of the current authorized pneumococcal vaccines per age group based on the invasive pneumococcal disease isolates received at the National Reference Centre in 2021.

The recommendations of the Superior Health Council (SHC) and of the European AIDS Clinical Society (EACS)

The SHC recommends to vaccinate against Pneumococcus with PCV20:

- Patients at **high risk between 16 and 85 years old** (= patients with **immunosuppression**)
- Patients at **risk between 50 and 85 years old** (= with **comorbidites**)
- **Adults from 65 to 85 years old**

EACS recommends to vaccinate all HIV patients against pneumococcus with PCV20

Superior Health Council : advice 9674 (august 2022): Avis 9674 - Vaccination antipneumococcique (adultes) | SPF Santé publique (belgium.be)

European AIDS Clinical Society Guidelines (October 2022: V11.1): guidelines-11.1_final_09-10.pdf (eacsociety.org)

Reimbursement of PCV20 in high incomes countries

	Age	At Risk	High Risk
Luxembourg	X	X	X
Denmark		X	X
Sweden	X		X
Spain (Murica, Catalunia)	X	X	X
Greece	X	X	X
Israel	X	X	X
Canada		X	X
USA	X	X	X

Age: usually ≥ 65 years old

At Risk: chronic sicknesses (heart failure, respiratory failure, kidney failure, cirrhosis, neurologic disease with risk of aspiration, diabetes)

High Risk: Immunosuppression, hemoglobinopathy, cochlear implant or cerebrospinal fluid leak

CONSEIL SUPERIEUR DES MALADIES INFECTIEUSES (CSMI) (public.lu)
Use of pneumococcal vaccines in adults, including the use of 15-valent and 20-valent conjugate vaccines: NACI public health level recommendations. - Canada.ca

Cost effectiveness PCV20 and PCV13

Cost effectiveness evaluation of PCV20 by the National Advisory Committee on Immunization (NACI) of Canada:

- **Best results with PCV20 alone: at age 65 and 75: cost effectiveness ratio from 6500$ to 17400$**

⇒ PCV20 is recommended by the Canadian NACI for:

- **Above 17 years old**: patients with **immunocompromising conditions**
- **Above 49 years old**: patients with **risk factors** placing them at higher risk of pneumococcal disease
- **Above 64 years old**: **all**

KCE study of 2016 did not show that the use of PCV13 was cost effective in a larger population.

Nevertheless, a cost effectiveness of PCV13 vaccination **in Belgian adults aged 65-84 years old at elevated risk** of pneumococcal infection showed a **cost per QALY gained of 17 126 euros**. In probabilistic sensitive analysis, use of PCV13 was cost effective in 97% of 1000 simulations.

⇒ **An evaluation of the cost effectiveness of PCV20 by KCE** in different populations defined by SHC (age above 64 and/or high risk patients above 15 and/or moderate risk patients above 49 years old, or at risk patients aged 65 to 84) **would allow to define for which population PCV20 would prove its cost effectiveness and justify a reimbursement in Belgium**

Use of pneumococcal vaccines in adults, including the use of 15-valent and 20-valent conjugate vaccines: NACI public health level recommendations. - Canada.ca
Use of conjugate pneumococcal vaccine – 15 valent (PNEU-C-15) and 20 valent (PNEU-C-20) in adults: NACI recommendations: Economic evidence supplementary appendixrecommendations. - Canada.ca
Quelle vaccination contre le pneumocoque chez les personnes âgées? | KCE (fgov.be)
Cost-effectiveness of PCV13 vaccination in Belgian adults aged 65-84 years at elevated risk of pneumococcal infection | PLOS ONE

Request of reimbursement of PCV20 and proposals of the Monitoring Committee of the HIV plan

Pfizer submitted a request of reimbursement of PCV20 to the belgian authorities following the **criterias** described by the advice 9674 **of the SHC**

Cost effectiveness data calculated by Pfizer: *4981 euros/QALY*

Impact of the vaccination of the belgian population within the criterias of the SHC calculated by Pfizer :

- *4470 pneumococcal infections avoided*
- *2234 hospitalizations for pneumococcal infections avoided*
- *227 deaths avoided*

The monitoring committee of the HIV plan :

- recommends to allow the **reimbursement of PCV20 to the HIV patients above 64 years old already in 2023** knowing that these patients cumulate 2 risk factors (HIV and older age), and to all HIV patients later on.
- **suggests to the KCE to study the cost effectiveness of PCV20 in different at risk populations**
- **Observes that PCV20 is already reimbursed in various high incomes countries and neighbouring countries** (Luxembourg) and that cost effectiveness evaluation have already showed positive results in Canada

Future vaccine: PCV21 (V116 by MSD)

V116 targets serotypes that accounted for **85%** of all invasive pneumococcal disease in individuals **65 years of age** and older in the United States as of 2019: **V116 includes 8 serotypes not found in currently licensed pneumococcal vaccines**: 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B

Designed to cover in adults the serotypes that will continue to circulate because not present in the vaccine administered to the children

Phase 1 and 2 :

- No severe adverse events
- The vaccine was non-inferior to PPSV23 for the 12 serotypes common to both vaccines and superior to PPSV23 for the nine unique serotypes in V116

Several phase 3 studies (STRIDE) **started** in adults 18 of age and older:

- among them: "**Safety and Immunogenicity of V116 in Adults Living With Human Immunodeficiency Virus** (HIV) (V116-007, STRIDE-7)"

	Serotype Composition																													
PCV7	4	6B	9V	14	18C	19F	23F																							
PCV13	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A																	
PCV15	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F															
PPSV23	4	6B	9V	14	18C	19F	23F	1	3	5		7F	19A	22F	33F	2	8	9N	10A	11A	12F	15B	17F	20						
PCV20	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F		8		10A	11A	12F	15B								
V116									3		6A	7F	19A	22F	33F		8	9N	10A	11A	12F		17F	20	15A	15C	16F	23A	23B	24F	31	35B

With the courtesy of MSD

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 - The Lancet Infectious Diseases

Safety and Immunogenicity of V116 in Adults Living With Human Immunodeficiency Virus (HIV) (V116-007, STRIDE-7) - Full Text View - ClinicalTrials.gov

Vaccination against Influenza

HIV and influenza

Risk:

- **Higher rate of severe influenza and pneumonia**
- **ART reduces the rates of hospitalisations and mortality** but the risk remains comparable to that of other high risk groups for which annual influenza is recommended

Response:

- The **level of HIV RNA, but not the CD4 cell count, was an independent predictor of vaccine response**.

Recommendations:

- EACS ans SHC recommend the vaccination of **all HIV patients** with a 4-valent vaccine

guidelines-11.1_final_09-10.pdf (eacsociety.org)
BHIVA guidelines on the use of vaccines in HIV-positive adults 2015
Avis 9158 patients ID et vaccination | SPF Santé publique (belgium.be)
Randomized, Double-Blind Comparative Trial of Subunit and Virosomal Influenza Vaccines for Immunocompromised Patients | Clinical Infectious Diseases | Oxford Academic (oup.com)

Influenza vaccines

EU recommendations for 2023-24 seasonal flu vaccine composition:

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus *(in 2022 the recommended strain was: A/Victoria/2570/2019 (H1N1)pdm09-like virus)*
- an A/Darwin/9/2021 (H3N2)-like virus
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

High Dose (HD) (60 µg of Ag per strain) vs Standard Dose (SD) (15 µg/strain)

- **With HD, 24,2% less biologically proved influenza than with SD in +65 years old**
- **In HIV patients: higher seroprotection rates after vaccination with the high dose group** for the H1N1 (96% vs 87%), H3N2 (96% vs 92%) and influenza B (91% vs 80%)
- **Reimbursement HD in Belgium: +65 YO institutionalized**

EU recommendations for 2023-2024 seasonal flu vaccine composition | European Medicines Agency (europa.eu)
EU recommendations for 2022-2023 seasonal flu vaccine composition | European Medicines Agency (europa.eu)
Efficacy of High-Dose versus Standard-Dose Influenza Vaccine in Older Adults | NEJM
Improved Immunogenicity With High-Dose Seasonal Influenza Vaccine in HIV-Infected Persons: A Single-Center, Parallel, Randomized Trial: Annals of Internal Medicine: Vol 158, No 1 (acpjournals.org)

Influenza and HIV: reimbursement criterias of the SD vaccine in Belgium

Public price SD: 16,71 euros, *(HD 43,76 euros)*

Price with reimbursement: 4,08 euros (VIPO: 2,45 euros) *(HD 11,14 and 6,62 euros)*

Reimbursement criterias (IV paragraph 700000):

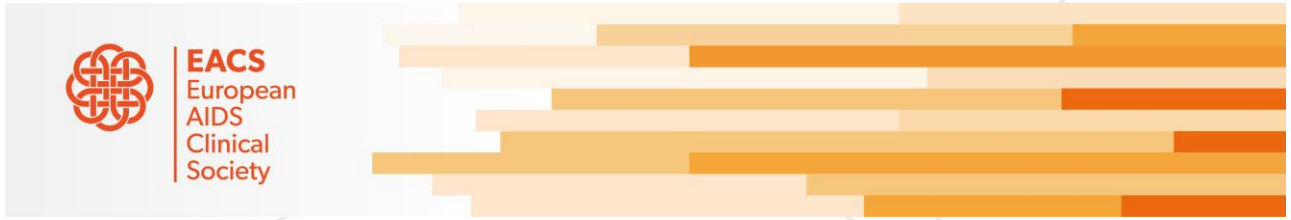
- ❑ **Category A: group 1: at risk of complications:**
  - A1.2) all patients from 6 months of age with a chronic disease : …, **immune deficiency.**
- ❑ Category A: group 3: **cohabitant :**
  - A3.1) **of people of group 1**

Delivered with reimbursement

- if written on the prescription: « **Régime du tiers payant applicable/ derdebetalingsregeling van toepassing** ».
- or **directly by the pharmacy** for patients of **group A**, B and C if registered in the shared pharmaceutical file of the patient.

Vaccination against SARS CoV2

EACS statement on risk of COVID-19 for people living with HIV (PLWH) and SARS-CoV-2 vaccine advice for adults living with HIV (15 January 2021):



- More pronounced **immunodeficiency (CD4 <350/µl)** associated with an **increase risk for severe COVID-19** (OR: 2,85).
- **Increased risk of mortality** in hospitalized PLWH with **CD4 <200/µl**
- **Risk factors for severe COVID-19**: age, chronic medical problems (Hypertension, obesity, diabetes, cardiovascular and chronic lung disease)

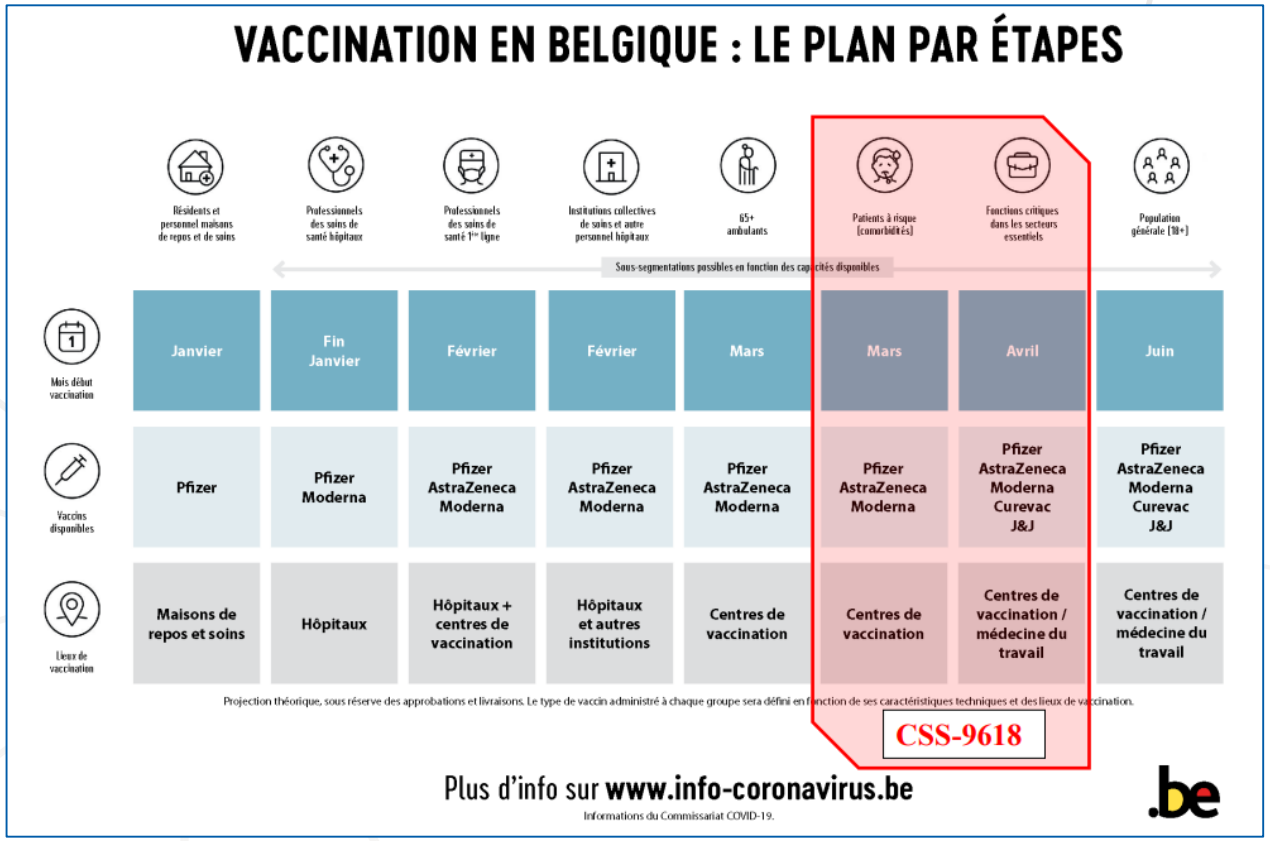
⇒**“PLWH with uncontrolled HIV infection or advanced immunodeficiency need priority consideration for SARS CoV2 vaccination”**

EACS Statement 15 January 2021 | EACSociety

Prioritization of at risk groups for SARS CoV2 vaccination (phase 1b) (SHC 9618) (February 2021)

Priority level 1: 45-64 years old with comorbidites and **18-64 years old with high risk comorbidites**:

- PLWH with CD4 <350/µl (Increased risk of hospitalisation and of severe COVID)
- PLWH with CD4 <200/µl (Increased mortality risk)



Additional and booster vaccination for immunocompromised patients

An **additional dose** was recommended in Belgium at **the end of August 2021 for immunocompromised patients** to complete the standard primary series (KCE, 2021):

- **PLWH with CD4 counts <200/µl**

In March 2022, the SHC (9691) recommended a **booster vaccination** for **all immunocompromised patients over 12 years of age at least 3 months after the additional dose** (extended primary three-dose series):

- **PLWH with CD4 counts <200/µl**

Rapid review of the evidence on a COVID-19 booster dose after a primary vaccination schedule | KCE (fgov.be)
Report 9691 - Booster vaccination for immunocompromised patients | FPS Public Health (belgium.be)

Immunogenicity of Comirnaty in HIV patients

Immunogenicity to Comirnaty is good in HIV patients in comparison with others immunocompromised patients and **not inferior to controls** (1, 2)

In a 3rd study, **patients under ART with CD4 <200/µl had a significantly lower seropositivity** than patients with CD4 >200 (3).

Table 3
Numbers and proportions of seroconversion (modified per protocol; n=466) after two doses of BNT162b2 vaccine in healthy controls and five different groups of immunocompromised patients.[1]

	Controls	All immunocompromised patients	PID	HIV	HSCT	SOT	CLL
Seroconverted (n)	78	280	55	78	61	36	50
Seronegative (n)	0	108	20	1	11	47	29
Total (n)	78	388	75	79	72	83	79
Proportion of seroconverted (CI)	100	72.2	73.3	98.7	84.7	43.4	63.3
(%), P-value	(95.4-100)	(67.4 – 76.6)	(61.9-82.9)	(93.1-100)	(74.3-92.1)	(32.5-54.7)	(51.7-73.9)
	Ref.	P<0.001	P<0.01	P=1	P<0.01	P<0.01	P<0.01

Abbreviations: PID: primary immunodeficiency, HIV: human immunodeficiency virus, HSCT, hematopoietic stem cell transplantation, SOT: solid organ transplantation, CLL: chronic lymphocytic leukemia, CTRL: healthy controls, CI: 95% confidence interval (estimated).
[1] P-values of the differences vs. healthy controls were calculated, Fisher's exact test.

1. Safety and efficacy of the mRNA BNT162b2 vaccine against SARS-CoV-2 in five groups of immunocompromised patients and healthy controls in a prospective open-label clinical trial - PubMed (nih.gov)
2. Immunogenicity and safety of the BNT162b2 mRNA COVID-19 vaccine in people living with HIV-1 - PubMed (nih.gov)
Antibody Response in Immunocompromised Patients After the Administration of Severe Acute Respiratory Syndrome
3. Prospective Evaluation of Coronavirus Disease 2019 (COVID-19) Vaccine Responses Across a Broad Spectrum of Immunocompromising Conditions: the COVID-19 Vaccination in the Immunocompromised Study (COVICS) (nih.gov)

Second booster automn winter 2022-23: recommendations of the SHC

1. **Primary vaccination plus first booster dose** remains priority **for all adults** and for children and adolescents **at risk** of severe outcomes
2. The SHC recommends that **all risk groups** be vaccinated with an **additional booster by the end of September 2022** at the latest
3. SHC recommends an **interval of at least 3 months but preferably 6 months** for the administration of an **additional mRNA booster dose**
4. the SHC recommends a **booster vaccination** be given **regardless of history of COVID-19 infection**, and **at least 14 days after recovery** of symptomatic COVID-19
5. **Risk groups for Autumn / Winter season 2022 – 2023 COVID-19 vaccination:** ***Next slide***
6. **Omicron adapted versions of mRNA vaccines**: composition defined by WHO
7. **Simultaneous vaccination against influenza is safe and effective** (SHC 9675)

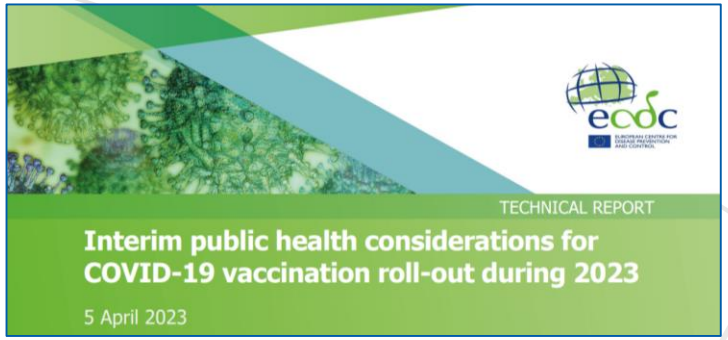
Report 9721 - COVID-19 vaccination: Autumn / Winter season 2022 – 2023 | FPS Public Health (belgium.be)

Second booster automn winter 2022-23: recommendations of the SHC

5. Risk groups for Autumn / Winter season 2022 – 2023 COVID-19 vaccination:

- **Category A**: COVID-19 proactive mass vaccination campaign recommended by the SHC:
  - **Group 1:** people with **increased risk** of death or severe forms of the disease (hospitalization, ICU, death)
    - Any person **aged 65 years and over or living in LTCF**
    - Any patient with **immunosuppression** due to disease or treatment (SHC 9691)
    - Any patient with **at least one comorbidity** as defined earlier (all levels of priority 1, 2, and 3 - SHC 9618)
    - All **pregnant women** regardless of the stage of pregnancy (SHC 9622)
  - **Group 2**: all "**persons active in the care sector**", in and outside care institutions (SHC 9597 and 9611)
  - **Group 3**: People living in the **same household as people at high risk** of severe disease
- **Category B**: The SHC recommends an additional COVID-19 booster dose for **people aged between 50 and 64 with some risk factors** like obesity (BMI ≥ 30 kg/m2), smoking or excessive alcohol consumption (SHC 9438)
- **Category C**: COVID-19 additional booster possible on safety profile data (but not recommended yet by the SHC) for children, adolescents and adults until 64 years old in good health

ECDC recommendations for next autumn-winter season and the Australian example



Autumn 2023 vaccination campaign:

"Vaccination efforts should focus on **protecting those aged over 60 years and other vulnerable individuals** irrespective of age (such as those with underlying comorbidities and the immunocompromised) during the autumn/winter seasons 2023"

Example of the actual Australian recommendations :

ATAGI 2023 Booster Advice*

Age	At risk**	No risk factors
<5 years	Not recommended	Not recommended
5-17 years	Consider	Not recommended
18-64 years	Recommended	Consider
≥ 65 years	Recommended	Recommended

*mRNA bivalent booster preferred; for ages in which a bivalent vaccine is not approved, use a vaccine approved for that age group. A 2023 booster dose should be given 6 months after a person's last dose or confirmed infection.

**Includes those with a medical condition that increases the risk of severe COVID-19 illness (refer to ATAGI clinical guidance) or those with disability with significant or complex health needs or multiple comorbidities which increase the risk of poor outcomes from COVID-19.

Interim public health considerations for COVID-19 vaccination roll-out during 2023 (europa.eu)

ATAGI 2023 booster advice | Australian Government Department of Health and Aged Care

Vaccination against Respiratory Syncytial Virus (RSV)

RSV: characteristics and epidemiology

RNA virus: 2 subtypes (A and B) simultaneously present in most outbreaks with A subtype causing more severe disease

Transmission: direct contact and large droplet aerosols

Incubation period: usually 4 to 6 days (2 to 8 days).

Risk factors in adults:

- Immunocompromised patients (severe combined immunodeficiency, leukemia, hematopoietic cell or lung transplant)
- Cardiopulmonary disease
- Persistent asthma
- Older adult patients with chronic pulmonary disease or functional disability
- Institutionalized older adults

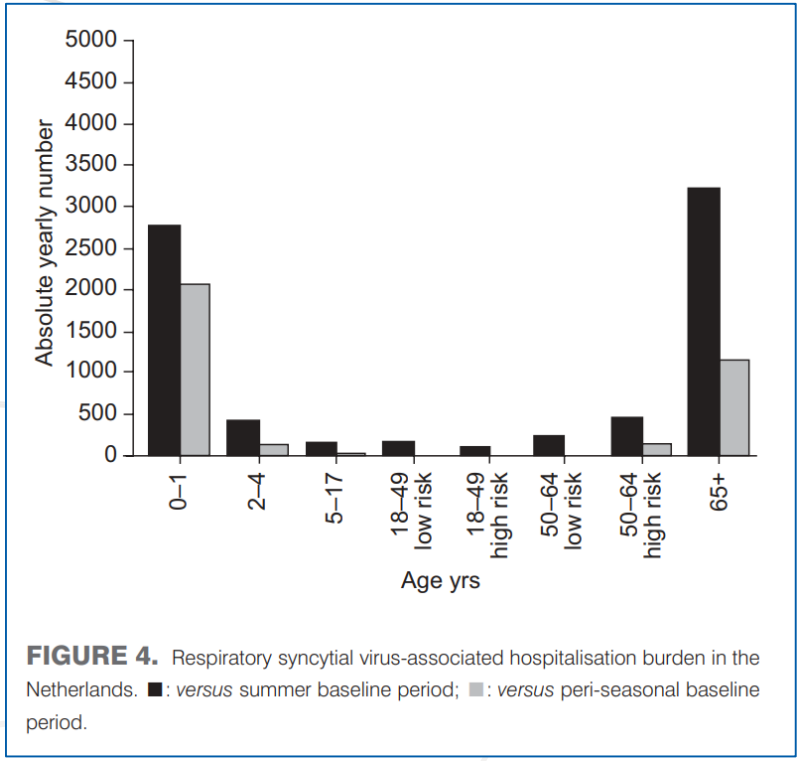
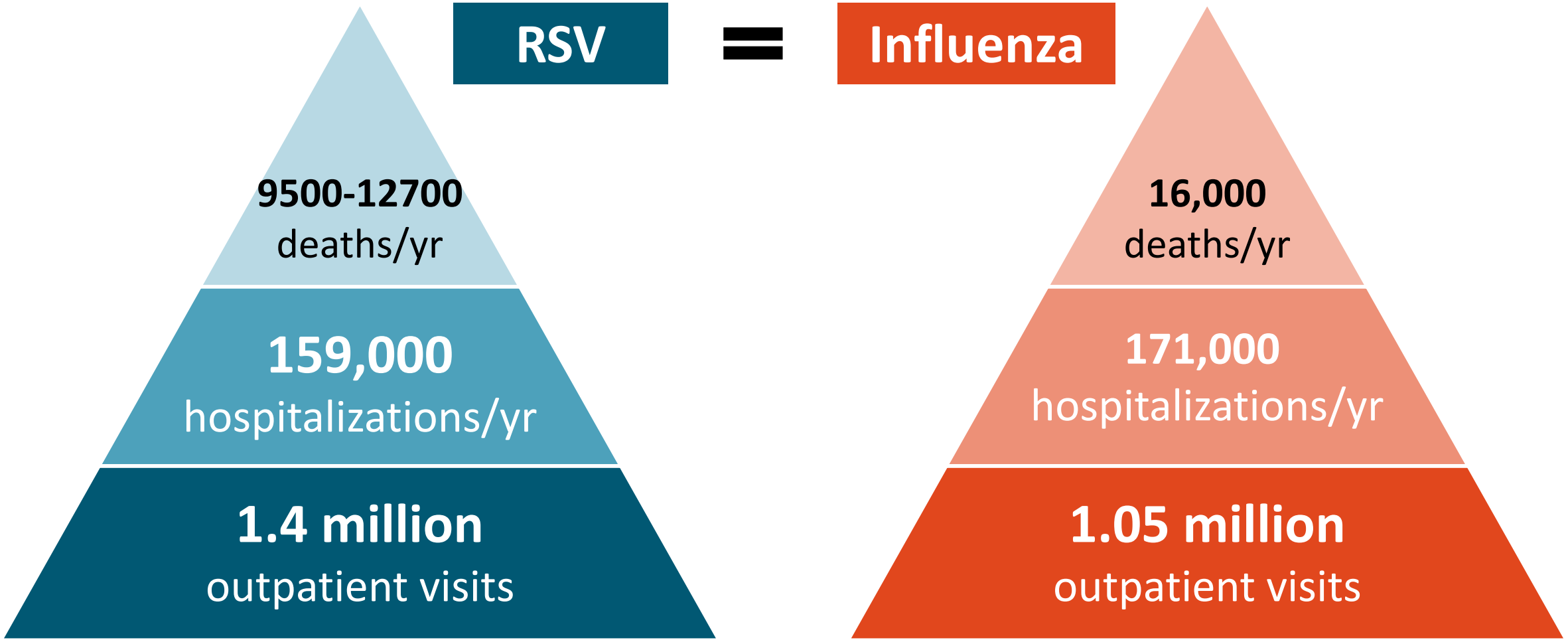


FIGURE 4. Respiratory syncytial virus-associated hospitalisation burden in the Netherlands. ■: *versus* summer baseline period; ■: *versus* peri-seasonal baseline period.

Epidemiology in Europe:

- In < 5 years old: around 213 000 admissions/year
  - *0-2 months old: > 40 admissions/1000/year*
- In adults: around 158 000 admissions/year
  - *75-84 yo: 2,25 admissions/1000/year*
  - *> 84 yo: 3,09 admissions/1000/year*

US Burden of RSV vs Influenza: Adults 65 Yr and Older



Slide credit: clinicaleducationalliance.com:

cea clinical education alliance

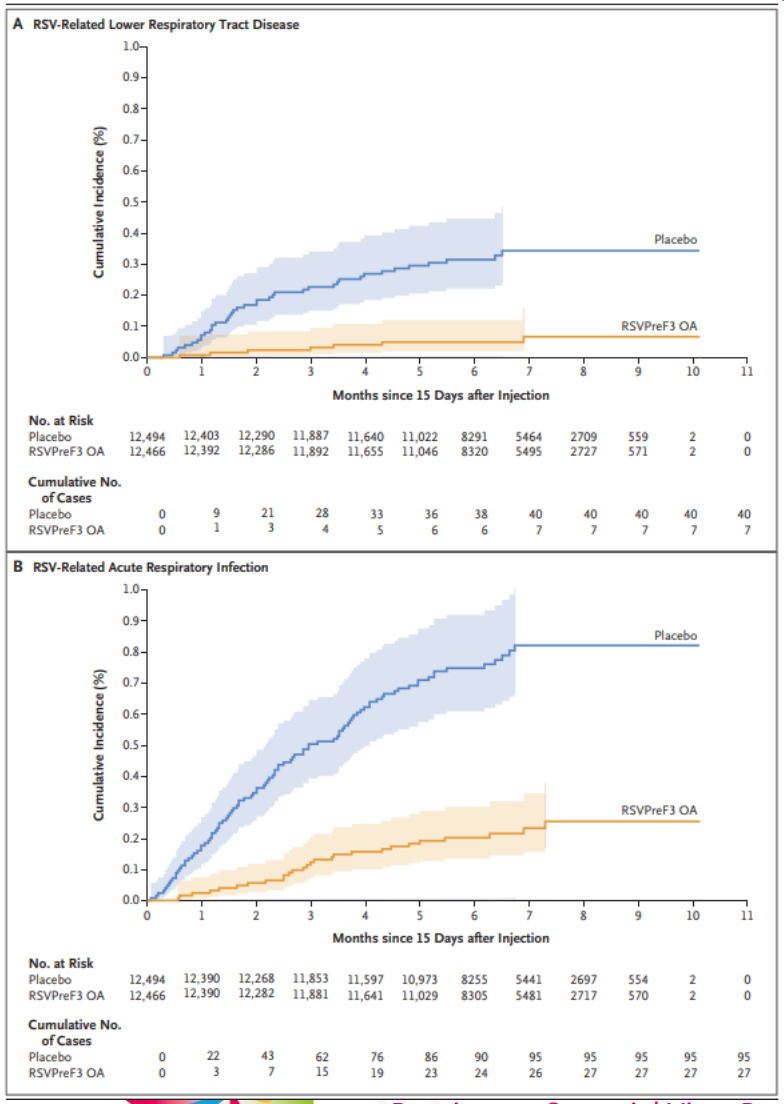
McLaughlin, OFID 2022;9:ofac300. cdc.gov/flu/about/burden/2019-2020.html.

RSV: vaccines in development for older adults

Vaccine	Company	Type of vaccine	Development phase	Vaccine efficacy (CI 95%)	Indications	Reference
Arexvy®	**GSK**	**Recombinant** RSV preF protein + AS01	**Phase 3 FDA approval waited May 23**	**82,6 (57,9-94,1)**	**≥ 60 years old**	**NEJM (1) FDA (2)**
Abrysvo®	**Pfizer**	**Recombinant** Bivalent preF protein	**Phase 3 FDA approval waited May 23**	**85,7 (32-98,7)**	**≥ 60 years old**	**NEJM (3) FDA (4)**
Ad26.RSV.preF-based vaccine	*Janssen*	*Viral vector adenovirus*	*Phase 2b Discontinued*	*80 (52,2-92,9)*	*≥ 65 years old*	*NEJM (5)*
MVA-BN-RSV	Bavarian Nordic	Viral vector: vaccine virus: Surface protein F and G	Phase 3 ongoing			JID (6) Clinicaltrials.gov (7)
mRNA 1345	Moderna	mRNA: Stabilized prefusion F glycoprotein	Phase 3	83,7% (66,0-92,2)	≥ 60 years old	Abstract ECCMID 23 (7)

1. Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults | NEJM
2. Vaccines and Related Biological Products Advisory Committee February 28 - March 1, 2023 Meeting Briefing Document- FDA: Applicant- GSK
3. Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults | NEJM
4. Vaccines and Related Biological Products Advisory Committee February 28 - March 1, 2023 Meeting Briefing Document- FDA: Applicant Pfizer
5. Efficacy and Safety of an Ad26.RSV.preF–RSV preF Protein Vaccine in Older Adults | NEJM
6. Broad Antibody and Cellular Immune Response From a Phase 2 Clinical Trial With a Novel Multivalent Poxvirus-Based Respiratory Syncytial Virus Vaccine | The Journal of Infectious Diseases | Oxford Academic (oup.com)
7. MVA-BN-RSV Vaccine Trial - Full Text View - ClinicalTrials.gov
8. Safety and efficacy of a respiratory syncytial virus vaccine (mRNA-1345), against a spectrum of symptomatic disease in adults aged ≥ 60 years. Poster O0416. ECCMID 2023.

Comparison of the results of the phase 3 studies of GSK and Pfizer vaccines against RSV

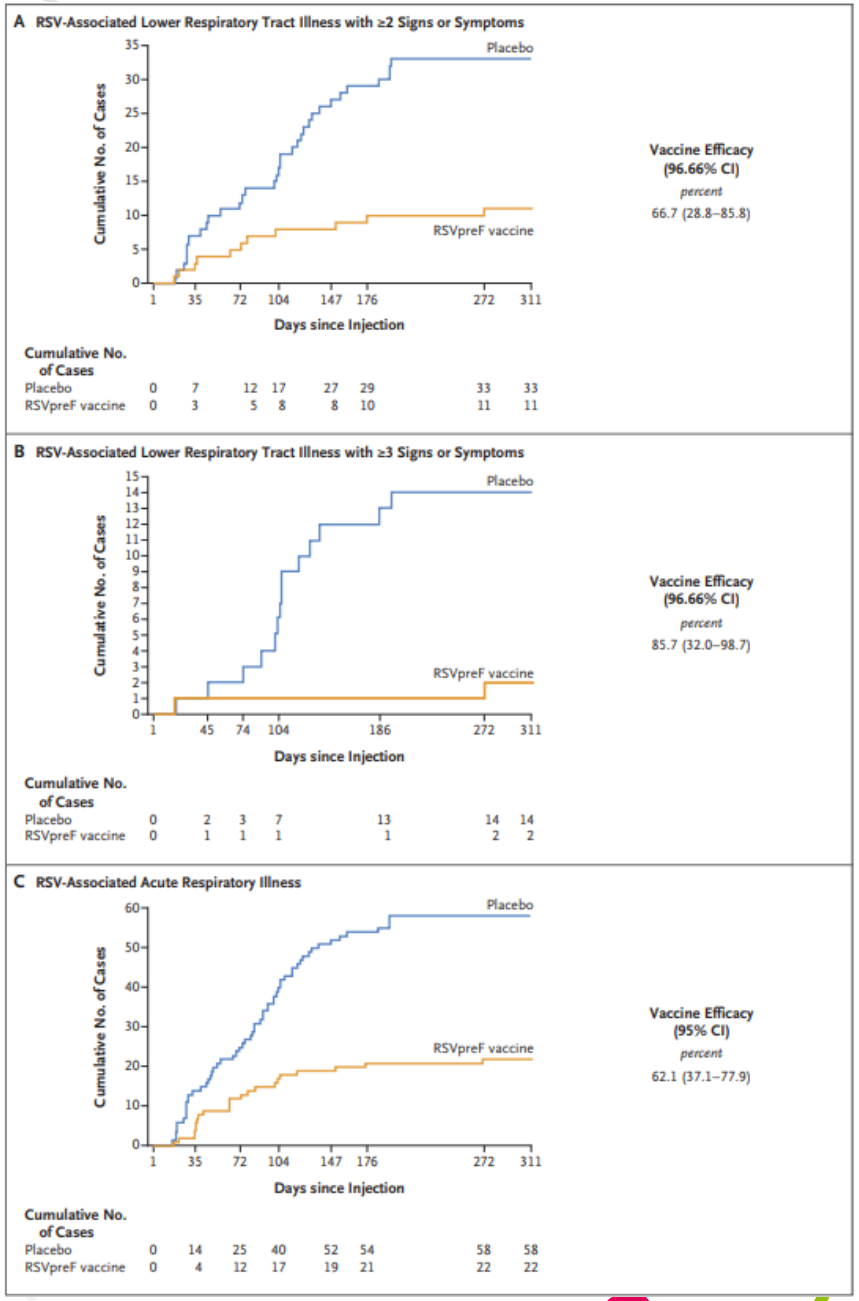


GSK : Arexvy:

- **Vaccine Efficacy:**
  - RSV related infection: 71,7%
  - Lower respiratory tract infection: 82,6%
  - Severe LWRTI: 94,1%
- More reactogenicity in the vaccine arm, without serious adverse events

Pfizer: Abrysvo: RENOIR Study:

- **Vaccine Efficacy:**
  - RSV associated illness: 62,1%
  - ≥ 2 signs or symptoms: 66,7%
  - ≥ 3 signs or symptoms: 85,7%
- Acceptable adverse events profile but 1 case of Guillain Barré and 1 case of Miller Fischer observed



Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults | NEJM
Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults | NEJM

Conclusions-summary

1. ***Streptococcus pneumoniae***:

- Indication to vaccinate **all PLWH** especially if **above 64 yo** and those with **comorbidites**
- **Reimbursement of PCV20 under evaluation**

2. **Influenza**:

- Indication to vaccinate **all adults PLWH**. Better protection of PLWH above 64 yo with HD vaccine
- **Reimbursed at 75%,** also for cohabitant, for SD but not for HD vaccine (for the moment)

3. **SARS CoV2**:

- **Primary vaccination:** 2 doses excepted for PLWH with CD4 <200/µl: extended primary three-dose series (M0-1-2)
- **Booster dose** with circulating **variant adapted vaccine** will be most probably indicated in September for patients with increased risk (above 64 YO, immunosuppressed (CD4 <350/µl) or at least one comorbidity)
- **Reimbursed at 100%**

4. **RSV**:

- **Promising results** (> 80% Vaccine Efficacy)
- Will be pretty usefull for patients above 64 yo and for patients with risk factors
- Authorization for the European market from EMA expected in September. Availability in Belgium in 2024 or 2025.

Thank you for your attention

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