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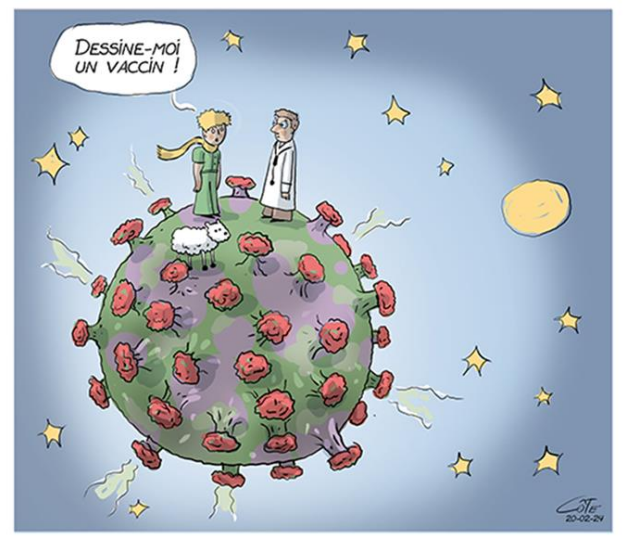
UPDATE ON COVID-19 VACCINATION

Seminar on Infectious Diseases

25 November 2021



Dr Chloé Wyndham-Thomas, Epidemiology of Infectious Diseases

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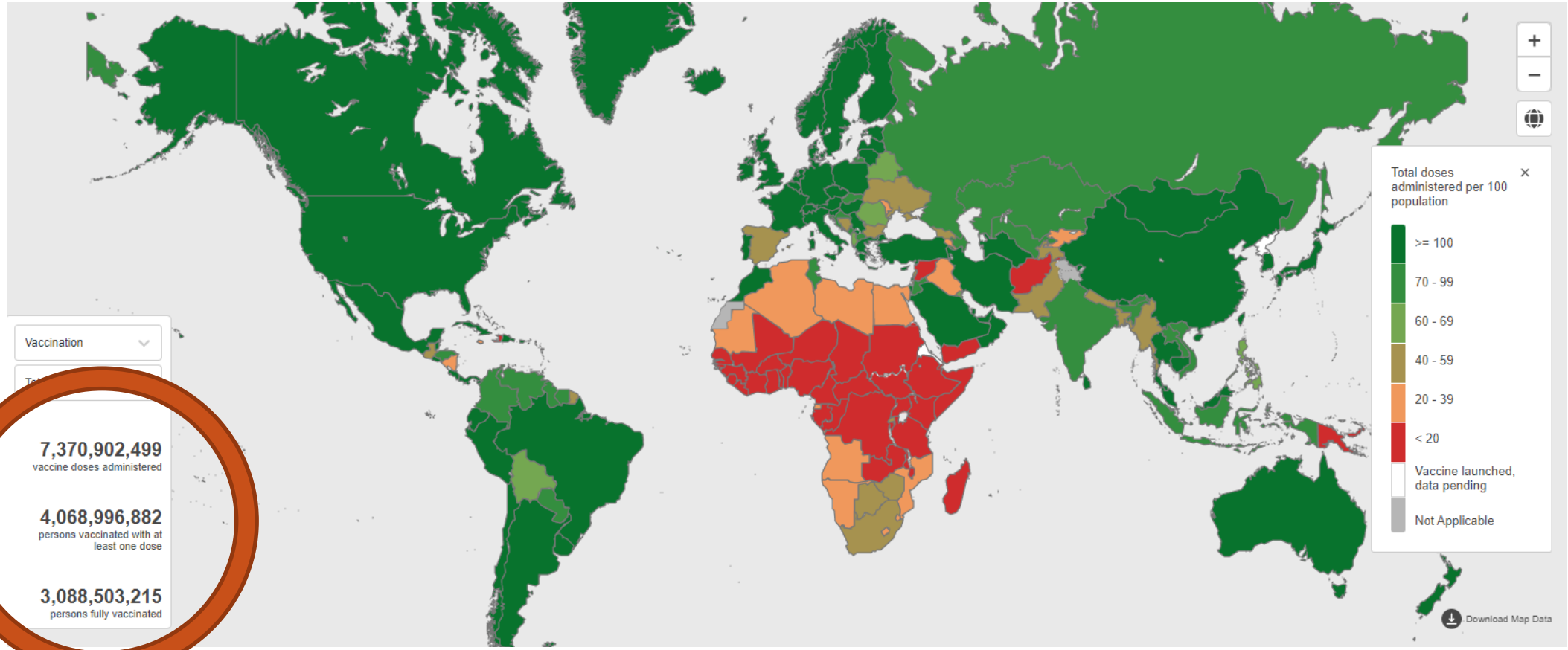
8 December 2020 (UK)→ 22 November 2021



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World Health Organization

https://covid19.who.int

COVID-19 Vaccines in use

4 vaccines authorized for use in Eu

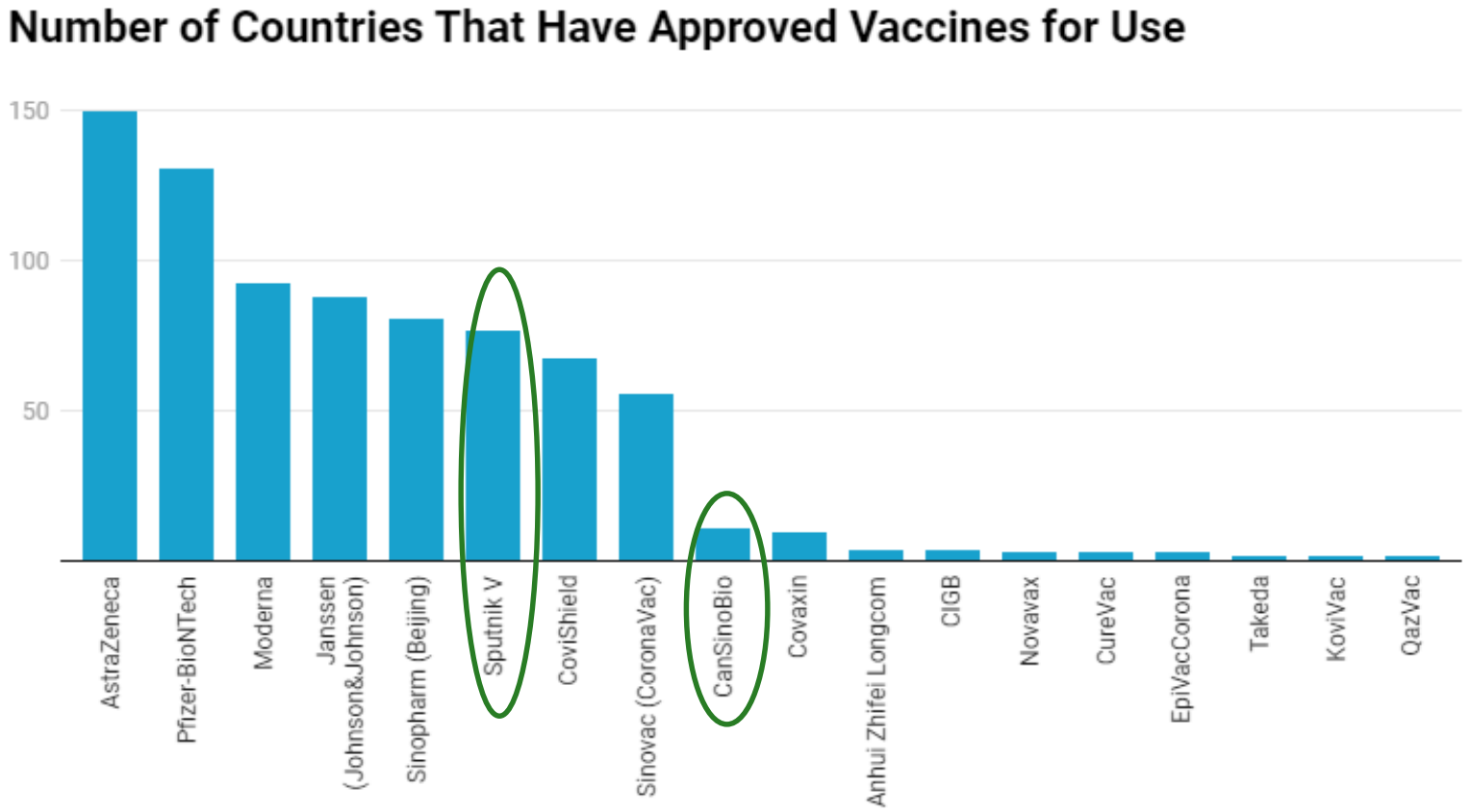
- Comirnaty (mRNA)
- Vaxzevria (nr viral vector)
- Spikevax (mRNA)
- COVID-19 Vaccine Janssen (nr viral vector)

+4 on WHO Emergency use listing

https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued

- Covidshield (nr viral vector)
- Sinovac (inactivated)
- BIBP/Sinopharm (inactivated)
- Covaxin/Bharat Biotech (inactivated)

>10 vaccines in emergency use at national level



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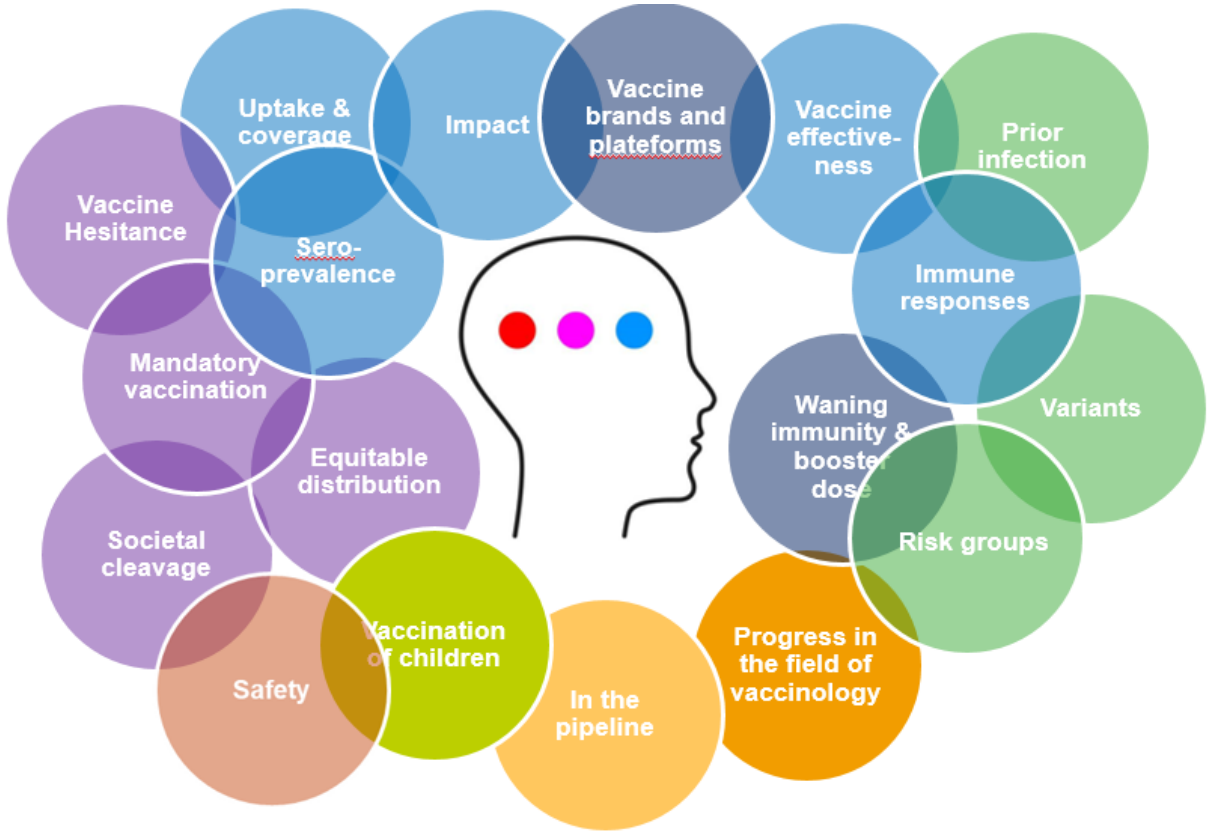
Vaccine update topics

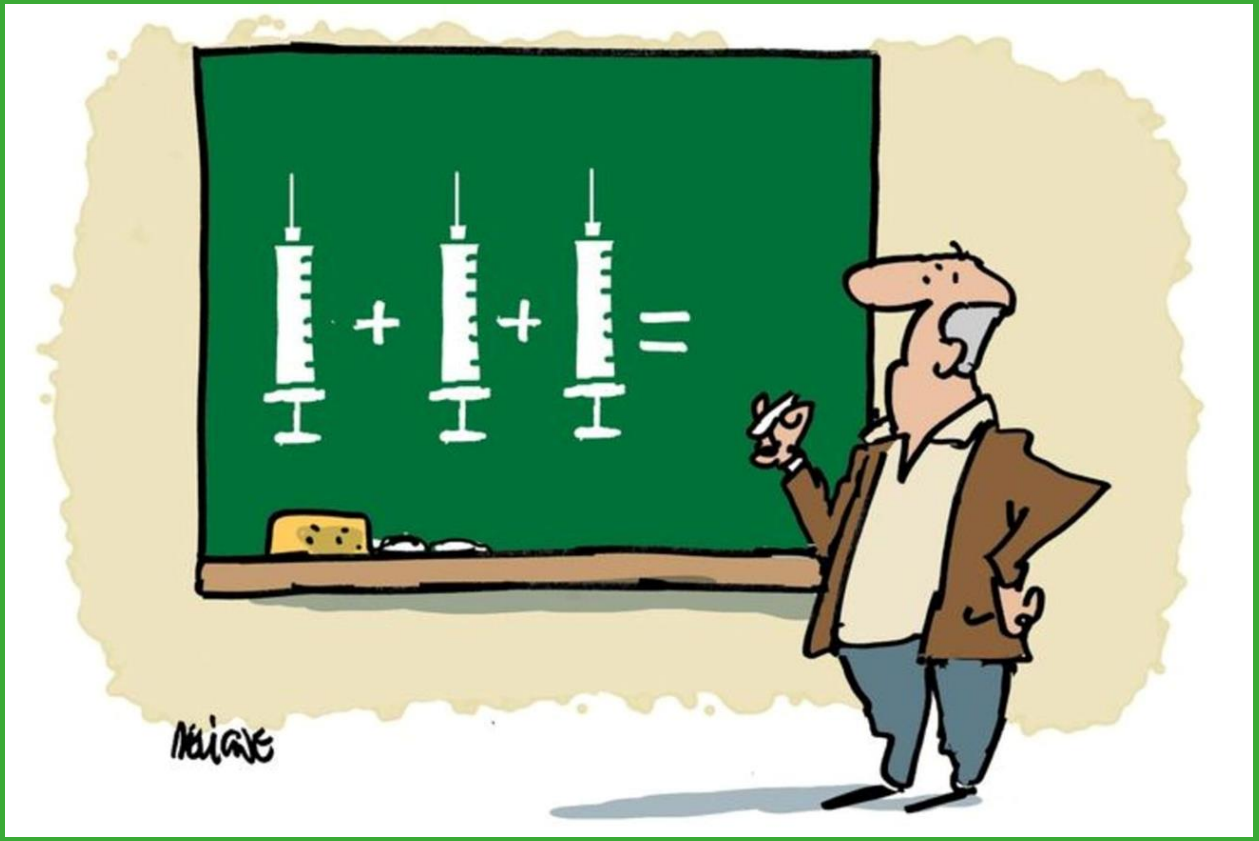
1. **Duration of protection and booster dose**

2. **Safety** :
   - Menstrual disorders & fertility
   - Myocarditis and pericarditis

3. **Vaccination in children**



ADDITIONAL-DOSE/ BOOSTER



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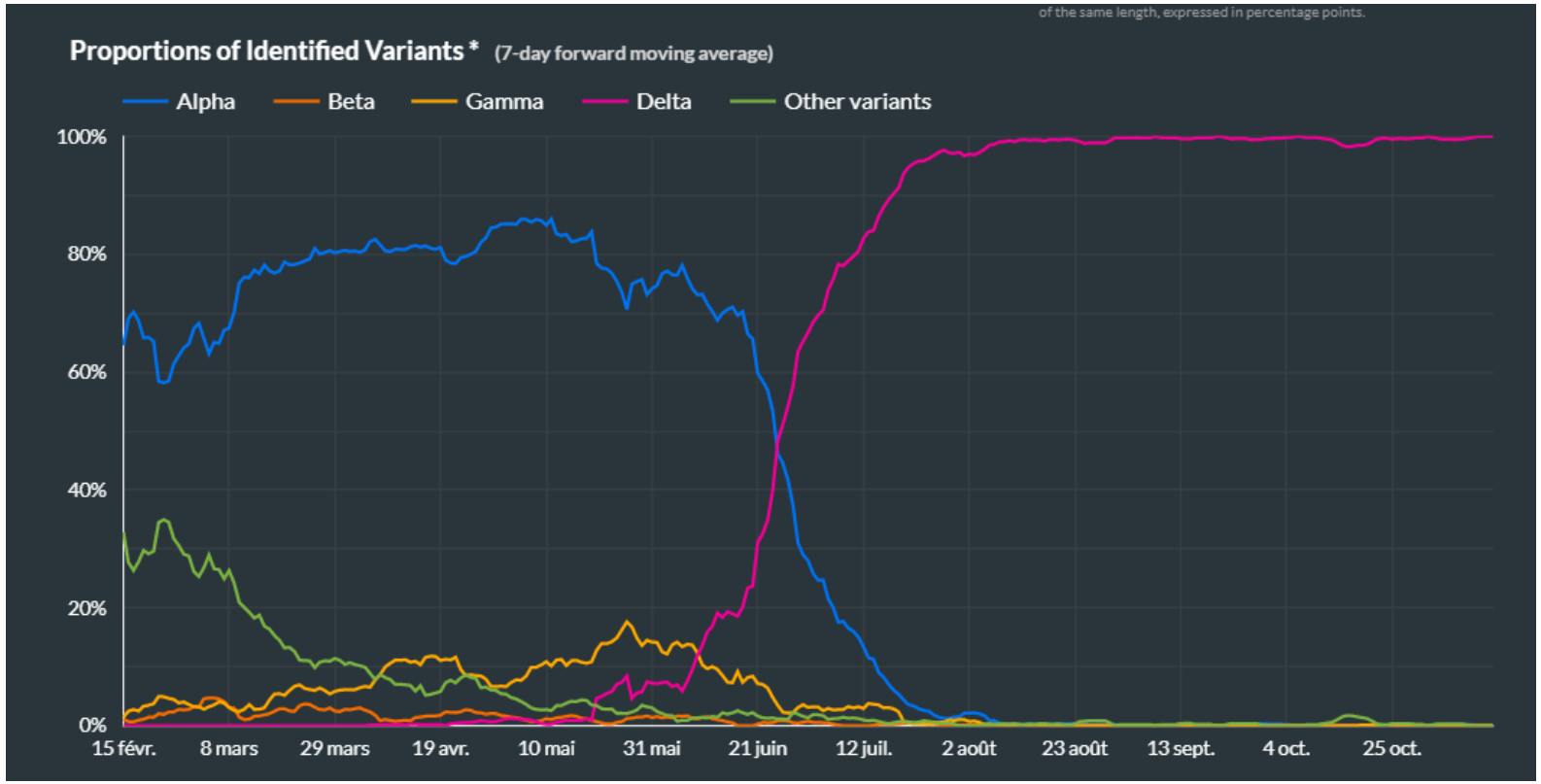
VE against Delta?



Source: Sciensano. https://epistat.wiv-isp.be/covid/covid-19.html

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VE against Delta variant?

- Interim results of a living **systematic review and meta-analysis of 17 studies** (Jan-Aug 2021):
  Harder et al. Eurosurveillance, 26, 2100920 (2021) https://doi.org/10.2807/1560-7917.ES.2021.26.41.2100920

  - **VE against Delta was 10–20% lower than VE against Alpha for less severe outcomes**.
    - **asymptomatic infections**: **pooled VE estimate 63.1% (95%CI: 40.9–76.9) (2 studies)**
    - **symptomatic infection : pooled VE estimate 75.7% (95%CI: 69.3–80.8)**

  - **VE against Delta did not differ from VE against Alpha for severe disease/hospitalisation**
    - **severe disease : pooled VE estimate 90.9% (95% CI: 84.5–94.7)**

- **Full vaccination** essential - single dose provides significantly lower protection.

- **High VE for all 4 EU-approuved vaccines**: higher with mRNA vs viral-vector vaccines

Waning?

Tartof et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. Lancet. 2021;

- VE against infection was 93% [95%CI 85–97]) → 53% [95%CI 39–65] at ≥4 months
- VE against hospitalisation was 93% [95% CI 84–96]) up to 6 months
- *Delta variant results*

Chemaitelly H et al. Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar. N Engl J Med. 2021 Oct 6; (matched test-negative case-control study)

- VE against infection 77.5% (95% CI 76.4-78.6) → 20% in months 5 to 7months
- VE against any severe, critical, or fatal case reached 96% persisted for 6 months

**Similar patterns were seen for Alpha, Beta and Delta infections.*

Waning?

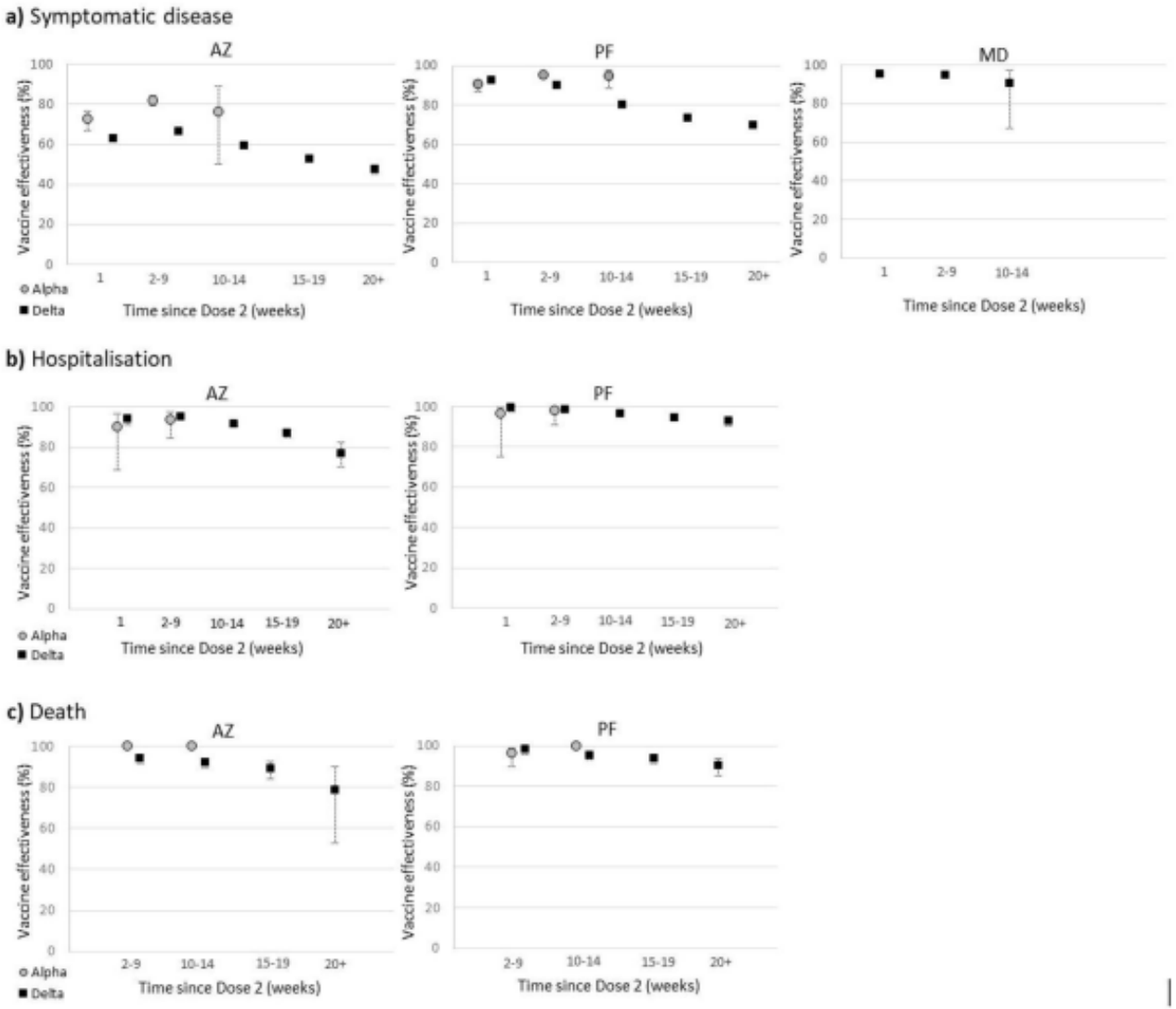
Andrews et al. Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK.
http://medrxiv.org/lookup/doi/10.1101/2021.09.15.21263583

Test-negative case-control design

*Waning of VE **against symptomatic disease** was greater for 65+ y olds vs to 40-64 y olds.

*Waning of VE against **hospitalisations** was observed among 65+ year-olds in a clinically extremely vulnerable group and 40-64-year olds with underlying medical conditions compared to healthy adults.

Figure 1. Vaccine effectiveness against Delta symptomatic disease, hospitalisation and death among individuals aged 16+ with two doses of Vaxzevria (AZ), Comirnaty (PF) or Spikevax (MD) in England and 95% confidence intervals.



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Do booster doses work?

Nordström et al. Pre-print
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3949410

- Sweden
- Retrospective cohort study including 842.974

matched pairs of vaccinated/unvaccinated individuals

Supplemental Table 2. Vaccine effectiveness against Covid-19 hospitalization or death up to 9 months after full vaccination (>14 days after the second dose)

	Vaccinated		Unvaccinated		Vaccine effectiveness, % (95% CI)	
	No. of events	IR/100000 person-days	No. of events	IR/100000 person-days	Adjusted for age and baseline date	Fully adjusted*
15-30 days (N=1,685,948)	22	0·09	136	0·56	86 (78-91)	89 (82-93)
31-60 days (N=1,549,267)	65	0·13	354	0·89	88 (85-91)	91 (88-93)
61-120 days (N=1,341,155)	102	0·09	308	0·46	87 (84-90)	90 (87-92)
121-180 days (N=575,432)	27	0·03	21	0·08	79 (61-89)	74 (47-87)
>180 days (N=327,981)	61	0·10	6	0·07	20 (-80-75)	42 (-35-75)

*Adjusted for age, baseline date, sex, home maker service, place of birth, education, and comorbidities according to Table 1.

CI denotes confidence interval. IR denotes incidence rate.

Table 2. Vaccine effectiveness against symptomatic infection up to 9 months after full vaccination (>14 days after the second dose)

	Vaccinated (N=842,974)		Unvaccinated (N=842,974)		Vaccine effectiveness, % (95% CI)	
	No. of events	IR/100000 person-days	No. of events	IR/100000 person-days	Adjusted for age and baseline date	Fully adjusted*
Total (2 doses of any vaccine) (N=1,684,958)	6,147	4·9	21,771	31·6	84 (83-84)	84 (83-84)
15-30 days (N=1,684,958)	397	1·6	4,719	19·5	92 (91-93)	92 (91-93)
31-60 days (N=1,548,326)	1,254	2·5	8,908	22·5	89 (88-90)	89 (88-89)
61-120 days (N=1,363,616)	2,436	2·6	7,522	14·4	83 (82-83)	82 (81-83)
121-180 days (N=635,402)	820	1·0	399	1·8	52 (46-58)	48 (41-54)
181-210 days (N=327,257)	718	1·2	161	2·1	42 (31-51)	32 (19-44)
>210 days (N=239,822)	522	1·0	62	1·2	23 (0-41)	23 (-2-41)
BNT162b2 / BNT162b2 (N=1,274,214)	5,062	5·1	19,121	36·4	84 (84-85)	85 (84-85)
15-30 days (N=1,274,214)	333	1·7	4,039	22·1	92 (91-93)	92 (92-93)
31-60 days (N=1,166,247)	1,095	2·9	7,982	26·7	89 (88-90)	89 (88-90)
61-120 days (N=1,032,971)	1,796	2·6	6,601	16·6	85 (84-85)	85 (84-85)
121-180 days (N=480,153)	631	1·0	292	1·7	52 (45-58)	47 (39-55)
181-210 days (N=304,298)	688	1·2	145	2·1	39 (26-49)	29 (15-42)
>210 days (N=231,006)	519	1·1	62	1·3	23 (1-41)	23 (-2-41)
mRNA-1273 / mRNA-1273 (N=153,760)	300	2·9	1,722	28·2	89 (88-91)	89 (88-90)
15-30 days (N=153,760)	20	0·9	493	22·5	96 (94-98)	96 (94-97)
31-60 days (N=139,532)	67	1·5	743	21·1	93 (91-95)	93 (90-94)
61-120 days (N=123,610)	116	1·4	418	9·0	86 (82-88)	85 (82-88)
121-180 days (N=52,254)	65	1·0	53	2·6	72 (59-80)	71 (56-81)
>180 days (N=22,755)	32	0·8	15	2·4	69 (44-83)	59 (18-79)
ChAdOx1 nCoV-19 / ChAdOx1 (N=153,194)	465	5·0	469	7·2	49 (42-55)	44 (36-52)
15-30 days (N=153,194)	33	1·4	93	4·2	66 (50-77)	68 (52-79)
31-60 days (N=144,772)	53	1·2	88	2·3	55 (36-68)	49 (28-64)
61-120 days (N=129,103)	293	3·5	262	4·9	48 (39-56)	41 (29-51)
>120 days (N=53,060)	86	1·6	26	1·4	0 (-55-36)	-19 (-97-28)
ChAdOx1 nCoV-19 / mRNA vaccine (N=103,532)†	316	4·8	442	11·8	68 (63-72)	65 (59-70)
15-30 days (N=103,532)	11	0·7	92	6·2	89 (79-94)	89 (79-94)
31-60 days (N=92,623)	37	1·2	88	4·0	74 (62-82)	72 (59-82)
61-120 days (N=76,924)	230	3·8	234	8·8	63 (55-69)	55 (45-64)
>120 days (N=49,664)	38	0·7	28	1·8	61 (36-76)	66 (41-80)

*Adjusted for age, baseline date, sex, home maker service, place of birth, education, and comorbidities according to Table 1.

† Either the BNT162b2 or mRNA-1273

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Do booster doses work?

Effectiveness of BNT162b2 (Comirnaty, Pfizer-BioNTech) COVID-19 booster vaccine against covid-19 related symptoms in England: test negative case-control study

Nick Andrews, Julia Stowe, Freja Kirsebom, Charlotte Gower, Mary Ramsay, Jamie Lopez Bernal

doi: https://doi.org/10.1101/2021.11.15.21266341

Conclusions Our study provides real world evidence of significant increased protection from the booster vaccine dose against symptomatic disease in those aged over 50 year of age irrespective of which primary course was received.

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Third doses of COVID-19 vaccines reduce infection and transmission of SARS-CoV-2 and could prevent future surges in some populations

Billy J. Gardner, A. Marm Kilpatrick

doi: https://doi.org/10.1101/2021.10.25.21265500

ORIGINAL ARTICLE

Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel

Yinon M. Bar-On, M.Sc., Yair Goldberg, Ph.D., Micha Mandel, Ph.D., Omri Bodenheimer, M.Sc., Laurence Freedman, Ph.D., Nir Kalkstein, B.Sc., Barak Mizrahi, M.Sc., Sharon Alroy-Preis, M.D., Nachman Ash, M.D., Ron Milo, Ph.D., and Amit Huppert, Ph.D.

CONCLUSIONS

In this study involving participants who were 60 years of age or older and had received two doses of the BNT162b2 vaccine at least 5 months earlier, we found that the rates of confirmed Covid-19 and severe illness were substantially lower among those who received a booster (third) dose of the BNT162b2 vaccine.

Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study

Noam Barda, Noa Dagan*, Cyrille Cohen, Miguel A Hernán, Marc Lipsitch, Isaac S Kohane, Ben Y Reis†, Ran D Balicer†*

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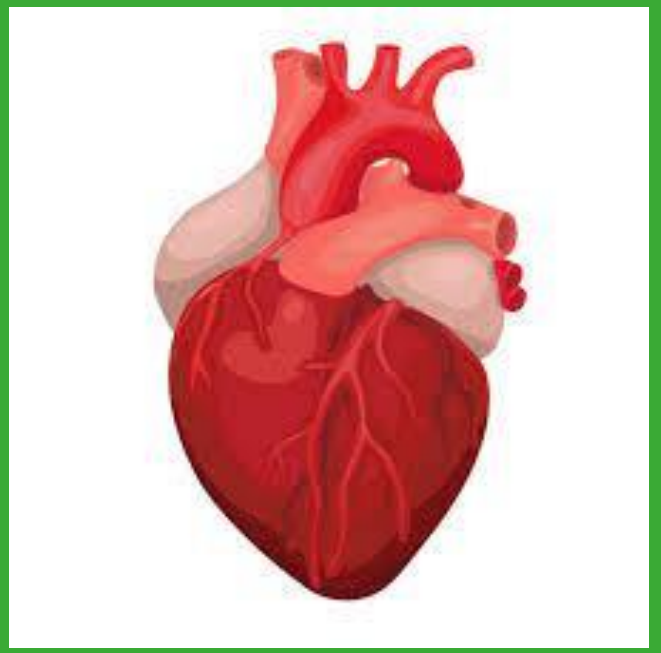
HOT TOPIC:
VACCINE SAFETY



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Menstrual disorders

BNT162b2 and ChAdOx1 SARS-CoV-2 Post-vaccination Side-Effects Among Saudi Vaccinees

Ahmed N. Alghamdi, † Mohammed I. Alotaibi, † Adel S. Alqahtani, Daifullah Al Aboud, and Ahmed S. Abdel-Moneim *

Abnormal menstrual cycle (delaying/increase hemorrhages or pain) was also reported in 0.98% (18/1846) of Pfizer-BioNTech and 0.68% (7/1028) of ChAdOx1 vaccinees

afmps
agence fédérale des médicaments et des produits de santé

- **Troubles menstruels**

L'AFMPS a reçu des notifications de troubles menstruels suite à l'administration des vaccins contre la COVID-19. Il s'agit notamment de notifications de cycle perturbé (cycle prolongé ou raccourci, saignements intermenstruels), de changements de l'intensité des saignements (menstruations plus ou moins abondantes) et de saignements post-ménopausiques. La grande majorité de ces effets indésirables n'étaient pas graves et se sont résolus spontanément.
Ce sujet a également été abordé lors de la réunion du PRAC du 5 août 2021. A ce jour, aucune relation de cause à effet ne peut être établie. Les troubles menstruels après la vaccination contre la COVID-19 continueront d'être suivis au niveau européen.

Menstrual changes after covid-19 vaccination

A link is plausible and should be investigated

Victoria Male *lecturer in reproductive immunology*

Menstrual changes have been reported after both mRNA and adenovirus vectored covid-19 vaccines,[1] suggesting that, if there is a connection, it is likely to be a result of the immune response to vaccination rather than a specific vaccine component. Vaccination against human papillomavirus (HPV) has also been associated with menstrual changes.[9] Indeed, the menstrual cycle can be affected by immune activation in response to various stimuli, including viral infection: in one study of menstruating women, around a quarter of those infected with SARS-CoV-2 experienced menstrual disruption.[10]

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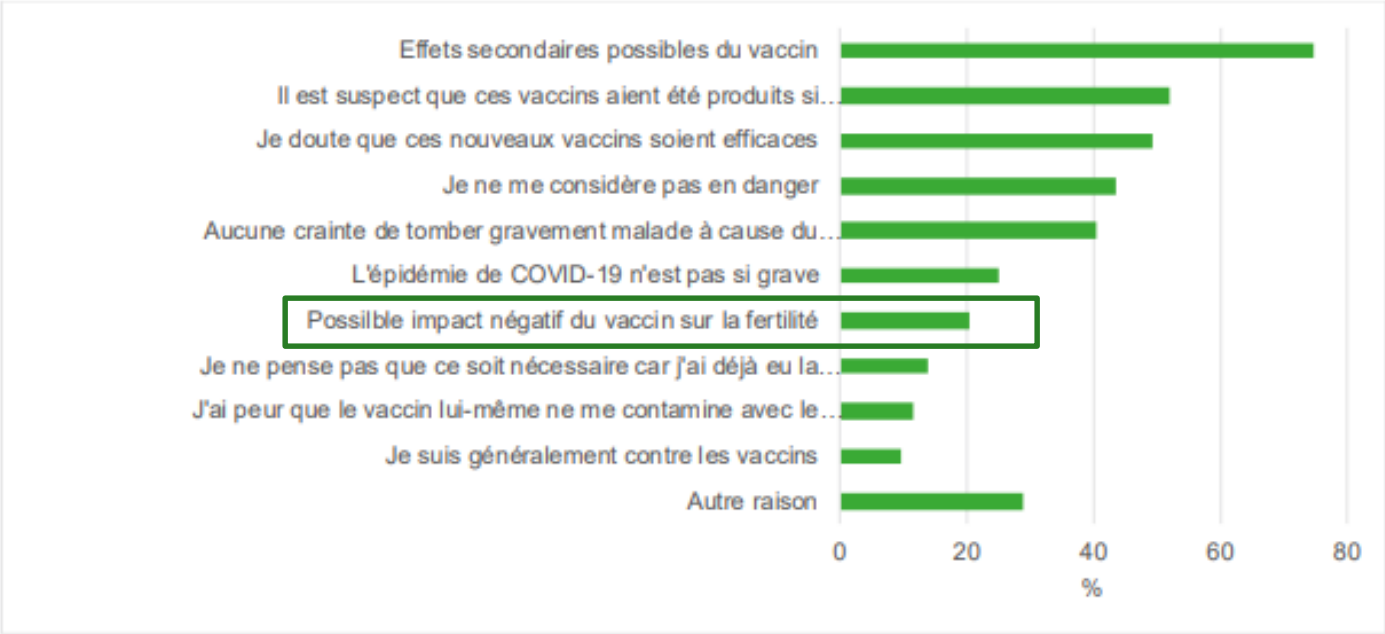
Fertility

Figure 5 | Raisons invoquées pour ne pas se faire vacciner contre le COVID-19 parmi les personnes (18 ans et plus) qui ne souhaitent pas se faire vacciner ou qui hésitent encore à le faire, 8ème enquête de santé COVID-19, Belgique 2021



Source: 8th Health interview Survey, Sciensano. https://covid-19.sciensano.be/sites/default/files/Covid19/report8_covid_19his_fr.pdf

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Fertility

THE LANCET

CORRESPONDENCE | VOLUME 398, ISSUE 10312, P1683-1684, NOVEMBER 06, 2021

Fertility rates and birth outcomes after ChAdOx1 nCoV-19 (AZD1222) vaccination

Kushalinii Hillson • Sue Costa Clemens • Shabir A Madhi • Merryn Voysey • Andrew J Pollard • Angela M Minassian ✉ • et al. Show all authors

Published: October 21, 2021 • DOI: https://doi.org/10.1016/S0140-6736(21)02282-0

Fertility was unaffected by vaccination with ChAdOx1 nCoV-19. Furthermore, compared with women who received the control vaccine, there was no increased risk of miscarriage and no instances of stillbirth in women vaccinated before pregnancy in global clinical trials of ChAdOx1 nCoV-19.

	ChAdOx1 nCoV-19 (n=4925)	Control (n=4830)*	Fertility rate ratio (95% CI)	p value
Pregnant women (fertility rate)†	50 (0·0102)	43 (0·0089)	1·14 (0·76–1·71)	0·53
Viable pregnancies (fertility rate)‡	32 (0·0065)	29 (0·0060)	1·08 (0·66–1·79)	0·80

Data are n (fertility rate) unless otherwise stated. *11 women vaccinated during pregnancy were included in the controls (eight received AZD1222 and three mRNA vaccines). †28 pregnant women (six in the control vaccine group and 22 in the AZD1222 group) were excluded from this fertility analysis because they were unmasked to vaccine allocation before becoming pregnant. ‡Viable pregnancies did not include pregnant women who had a termination or miscarriage.

Table 1: **Fertility rates**

	ChAdOx1 nCoV-19 (n=72)	Control (n=35)	Risk ratio (95% CI)	p value
Miscarriage, excluding Brazilian data	6/43 (14%)	5/24 (21%)	0·67 (0·23–1·97)	0·51
Termination, excluding Brazilian data	8/43 (19%)	6/24 (25%)	0·74 (0·29–1·89	0·55
Miscarriage or termination, all	23/72 (32%)	13/35 (37%)	0·86 (0·50–1·49)	0·67
Preterm birth	3/10 (30%)	0/5 (0%)	Not calculable	0·51*
Full-term birth	7/72 (10%)	5/35 (14%)	0·68 (0·23–1·99)	0·52
Ongoing pregnancy	39/72 (54%)	17/35 (49%)	1·12 (0·75–1·67)	0·68

Data are n/N (%) unless otherwise stated. *Two-sided p value.

Table 2: **Pregnancy outcomes**

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Fertility

RESEARCH Open Access

Does mRNA SARS-CoV-2 vaccine influence patients' performance during IVF-ET cycle?

Raoul Orvieto[1,2,3*], Meirav Noach-Hirsh[1,2], Aliza Segev-Zahav[1,2], Jigal Haas[1,2], Ravit Nahum[1,2] and Adva Aizer[1,2]

Abstract

Objective: No information exists in the literature regarding the effect of mRNA SARS-CoV-2 vaccine on subsequent IVF cycle attempt. We therefore aim to assess the influence of mRNA SARS-CoV-2 vaccine on IVF treatments.

Design: An observational study.

Setting: A tertiary, university-affiliated medical center.

Patients and Methods: All couples undergoing consecutive ovarian stimulation cycles for IVF before and after receiving mRNA SARS-CoV-2 vaccine, and reached the ovum pick-up (OPU) stage. The stimulation characteristics and embryological variables of couples undergoing IVF treatments after receiving mRNA SARS-CoV-2 vaccine were assessed and compared to their IVF cycles prior to vaccination.

Main outcome measures: Stimulation characteristics and embryological variables.

Results: Thirty-six couples resumed IVF treatment 7–85 days after receiving mRNA SARS-CoV-2 vaccine. No in-between cycles differences were observed in ovarian stimulation and embryological variables before and after receiving mRNA SARS-CoV-2 vaccination.

Conclusions: mRNA SARS-CoV-2 vaccine did not affect patients' performance or ovarian reserve in their immediate subsequent IVF cycle. Future larger studies with longer follow-up will be needed to validate our observations.

Keywords: COVID-19, vaccination, Ovarian stimulation, embryo quality, IVF

› Hum Reprod. 2021 Nov 3;deab238. doi: 10.1093/humrep/deab238. Online ahead of print.

Effects of COVID-19 and mRNA vaccines on human fertility

Fei Chen [1], Shiheng Zhu [1], Zhiqing Dai [1], Lanting Hao [1], Chun Luan [1], Qi Guo [1], Chaofan Meng [1], Yankun Zhang [1]

Affiliations + expand

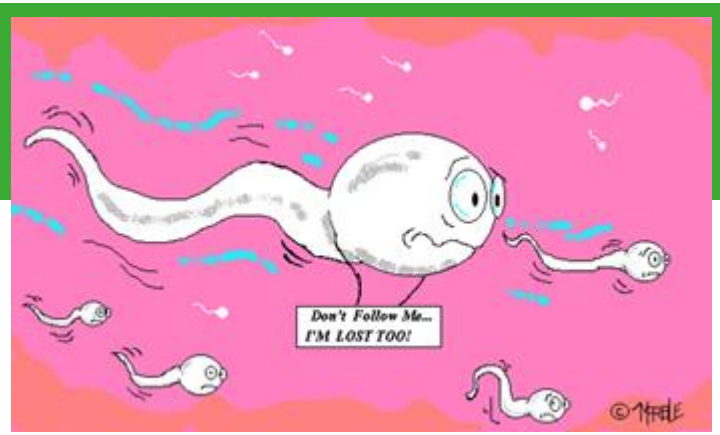
PMID: 34734259 DOI: 10.1093/humrep/deab238

› Obstet Gynecol. 2021 Nov 2. doi: 10.1097/AOG.0000000000004636. Online ahead of print.

Scientific Evidence Supporting Coronavirus Disease 2019 (COVID-19) Vaccine Efficacy and Safety in People Planning to Conceive or Who Are Pregnant or Lactating

Guillermina Girardi [1], Andrew A Bremer

Fertility



Research Letter

June 17, 2021

Sperm Parameters Before and After COVID-19 mRNA Vaccination

Daniel C. Gonzalez, BS[1]; Daniel E. Nassau, MD[1]; Kajal Khodamoradi, PhD[1]; et al

» Author Affiliations | Article Information

JAMA. 2021;326(3):273-274. doi:10.1001/jama.2021.9976

BNT162b2 mRNA Covid-19 vaccine does not impair sperm parameters

Myriam Safrai[1¥], Benjamin Reubinoff[1], Assaf Ben-Meir[1]

1. In Vitro Fertilization Unit, Hadassah Medical Organization and Faculty of Medicine, Hebrew University of Jerusalem, Israel

¥ - Corresponding author

SARS-COV-2 (Covid-19) and male fertility: Where are we?

Temidayo S Omolaoye [a], Adeloye A Adeniji [b, c], Walter D. Cardona Maya [d], Stefan S du Plessis [a, e]

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https://doi.org/10.1016/j.reprotox.2020.11.012

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Highlights

- There is altered semen parameters.
- Patients experienced testicular injury and inflammatory infiltration.
- Viral orchitis may occur, as patients experienced scrotal discomfort.
- The number of spermatozoa with DNA fragmentation is increased.
- Infection with SARS–COV-2 may lead to potential fertility issues.

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Myocarditis and Pericarditis

EPI-PHARE (France): Case control study

https://ansm.sante.fr/actualites/le-risque-de-myocardite-et-pericardite-apres-la-vaccination-covid-19-est-confirme-mais-peu-frequent-et-devolution-favorable

- 12 to 50 year olds
- Hospitalisations for myocarditis (n=919) or pericarditis (n=917) (15 May to 31 August 2021)
- Matched to > 9000 controls (age, sexe, department of residence)
- Compared the risk of hospitalization for myocarditis or pericarditis by vaccine status
- **Results:**
    - Increased risk of myocarditis within 7 days after mRNA vaccine confirmed
        - Men <30y
        - 2nd dose Spikevax

        → 132 excess cases /million administered doses

        → women <30y: 37 excess cases/million administered doses
    - ~Pericarditis
    - Generally favorable course. No deaths

NIPH
Norwegian Institute of Public Health

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NEWS

Myocarditis in boys and young men can occur more often after the Spikevax vaccine from Moderna

Published 06.10.2021

Myocarditis (inflammation of the heart muscle) is a rare side effect of mRNA vaccines. The side effect is observed especially in boys and young men and mainly after the second dose. Updated knowledge indicates that this occurs more often with the use of Moderna's vaccine Spikevax than BioNTech / Pfizer's vaccine Comirnaty. This seems to apply regardless of which mRNA vaccine was given as the first dose.

VACCINATION IN CHILDREN

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Where are children being vaccinated?

Biden Administration: 2.6 Million Kids Under 12 Have Their First COVID-19 Vaccine Shot

Roughly 10% of kids ages 5-11 are expected to have their first COVID-19 vaccine shot by the end of day Wednesday.

By Cecelia Smith-Schoenwalder | Nov. 17, 2021, at 1:38 p.m.

HEALTH OFFICIAL HAILS 'CELEBRATION DAY FOR KIDS AND PARENTS'

Israel begins vaccinating children aged 5-11

Though campaign doesn't officially kick off until Tuesday, health providers are already rolling out COVID shots for kids

By TOI STAFF
22 November 2021, 9:16 pm |

For 12 -15 y olds who do not have underlying health conditions that place them at higher risk from severe COVID-19, the JCVI considered that the size of both the risk and the benefit are at an individual level very small, and the overall advantage for vaccination, whilst present, is therefore not sufficiently large to recommend universal vaccination on their usual criteria.

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Pfizer-BioNTech paediatric vaccine:

Advisory Committee on Immunization Practices (ACIP)

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/08-COVID-Oliver-508.pdf

Conclusion

GRADE: Pfizer-BioNTech COVID-19 vaccine in children aged 5–11 years

- Phase 2/3 RCT conducted among children aged 5–11 years
- **>3,000** children were vaccinated with BNT162b2
- Vaccine efficacy estimate of **90.9%** for prevention of symptomatic laboratory-confirmed COVID-19 (high certainty)
- Serious adverse events were uncommon among vaccine and placebo participants (**0.07%** vs **0.1%**). No SAEs were judged to be related to vaccination and no deaths occurred (very low certainty).
- Grade ≥3 local or systemic reactions were more common among vaccine than placebo recipients and were reported by **2.7%** of vaccine participants (moderate certainty).

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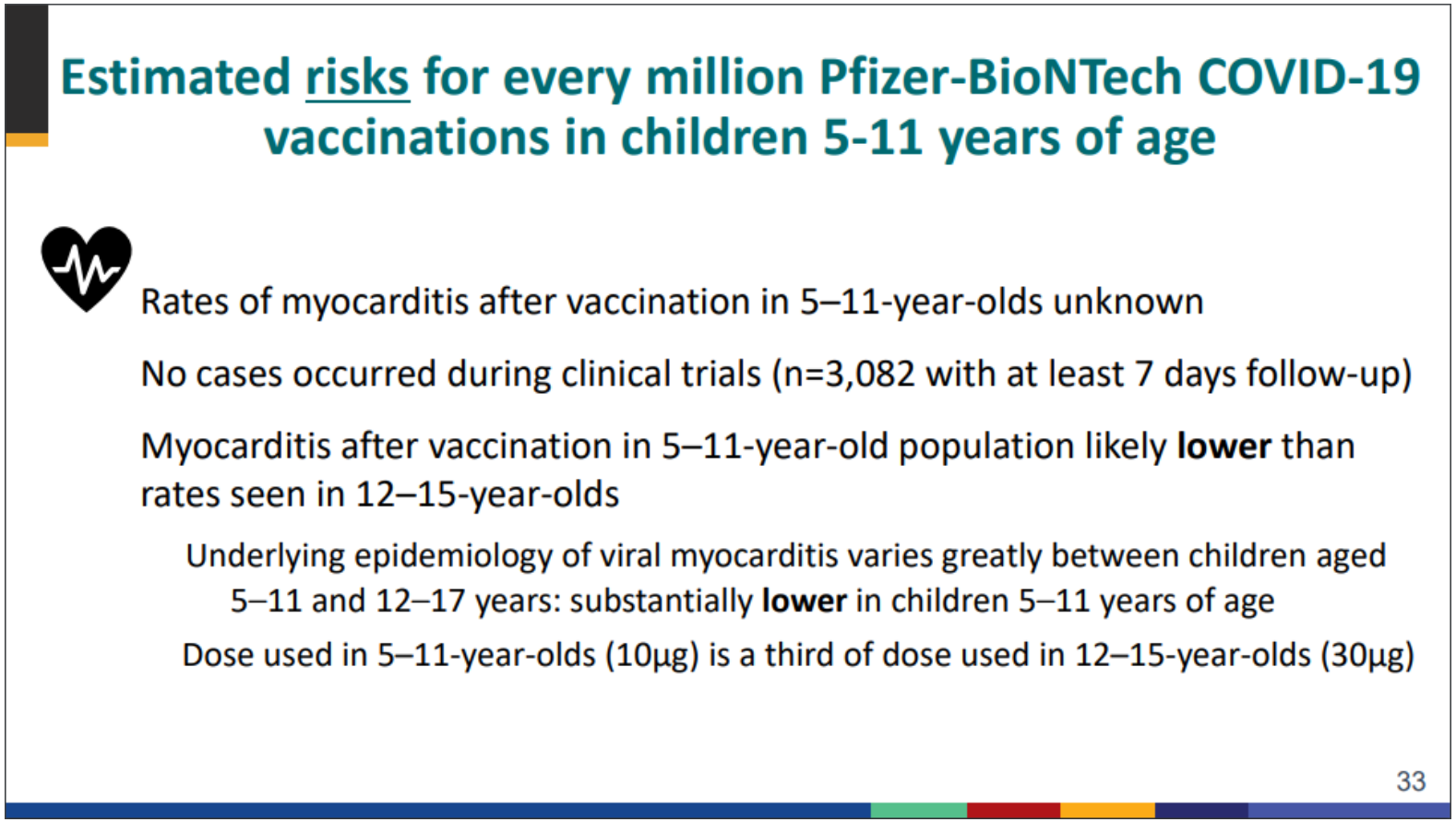
Pfizer-BioNTech paediatric vaccine:

Advisory Committee on Immunization Practices (ACIP)

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/08-COVID-Oliver-508.pdf



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In Europe?

EMA starts evaluating use of COVID-19 vaccine Comirnaty in children aged 5 to 11 Share

News 18/10/2021

EMA starts evaluating use of COVID-19 vaccine Spikevax in children aged 6 to 11 Share

News 10/11/2021

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Take-home messages

BOOSTER?

- VE against delta variant remains high : ~70% against infection & 90% against hospitalisation
- Progressive waning in VE against infection : ~ 4-6m, more marked in >60yo & viral vector
- VE against hospitalization > 6 months, possibly earlier in extremely vulnerable populations
- Real world evidence of additional benefit of booster doses

SAFETY?

- Menstrual disorders : no link to a specific vaccine, reactogenicity? Spontaneous resolution
- Fertility : currently no evidence that COVID-19 vaccines cause fertility problems in women or men
- Myocarditis/pericarditis : within 7days, <30y male, increased risk 2nd dose Spikevax

CHILDREN?

- Children: data phase III, data from US

→ Continue to promote primary vaccination and boosting of adults
→ Vaccination is not a stand alone intervention!

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Thank-you

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EXTRA SLIDES

COVID-19 Vaccines in use

COVID-19 vaccines

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Currently under rolling review

- Sputnik V (Gam-COVID-Vac)
- COVID-19 Vaccine (Vero Cell) Inactivated
- Vidprevtyn

Marketing authorisation application submitted

- Nuvaxovid (also known as NVX-CoV2373)

Authorised for use in the European Union

- Comirnaty
- Spikevax (previously COVID-19 Vaccine Moderna)
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca)
- COVID-19 Vaccine Janssen

CVnCoV (CureVac AG) withdrawal in October 2021
* NVX-CoV2373= Novavax (protein based)
* Vero-cell = Sinovac (inactivated virus)
* Vidprevtyn: Protein-based vaccine that contains a laboratory-grown S protein +adjuvant (Sanofi-Pasteur)

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And more in the pipeline

https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

World Health Organization

Summary Information on Vaccine Products in Clinical Development

1. - Number of vaccines in clinical development: 132

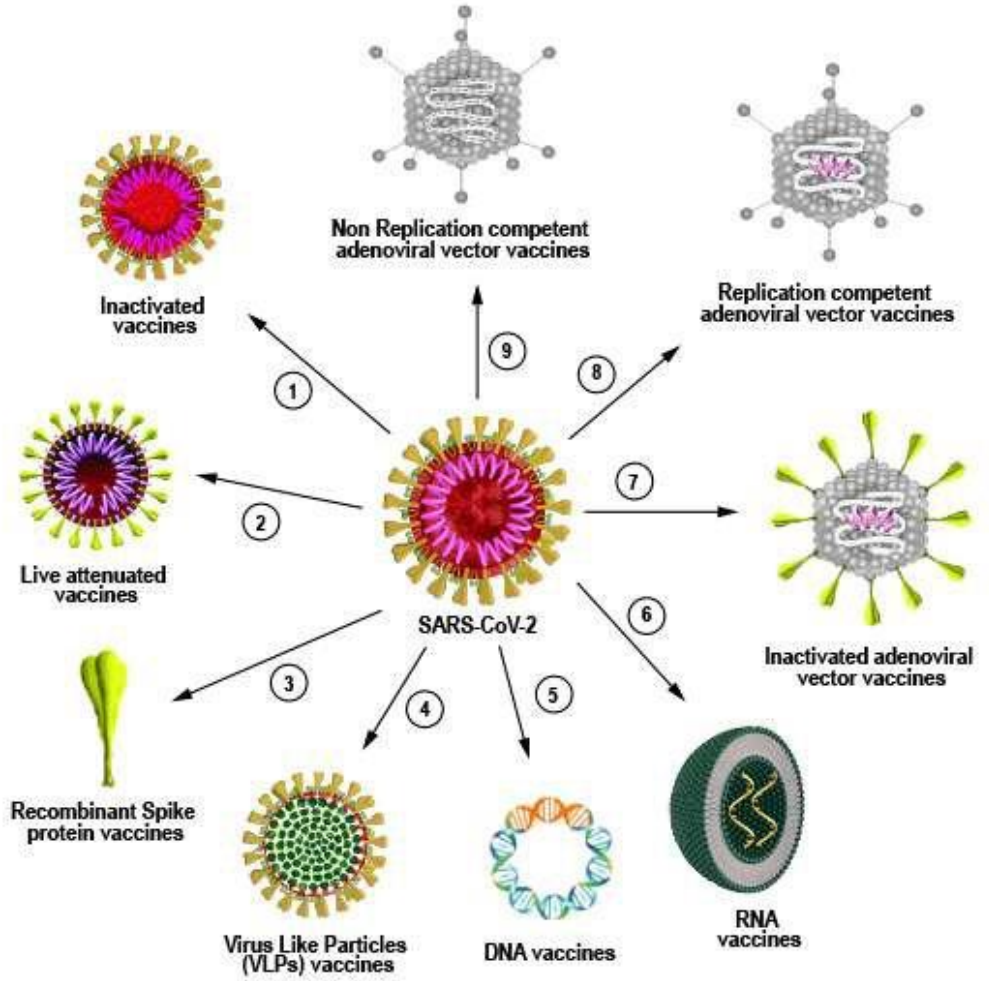
2. - Number of vaccines in pre-clinical development: 194

PHASE 3= 28

3. - Candidates in clinical phase

Filter: All — Select phase of development (default is all)

Platform		Candidate vaccines (no. and %)	
PS	Protein subunit	47	36%
VVnr	Viral Vector (non-replicating)	19	15%
DNA	DNA	15	11%
IV	Inactivated Virus	17	13%
RNA	RNA	21	16%
VVr	Viral Vector (replicating)	2	2%
VLP	Virus Like Particle	5	4%
VVr + APC	VVr + Antigen Presenting Cell	2	2%
LAV	Live Attenuated Virus	2	2%
VVnr + APC	VVnr + Antigen Presenting Cell	1	1%
BacAg-SpV	Bacterial antigen-spore expression vecto	1	1%
		132	



COVID-19 Vaccines in use

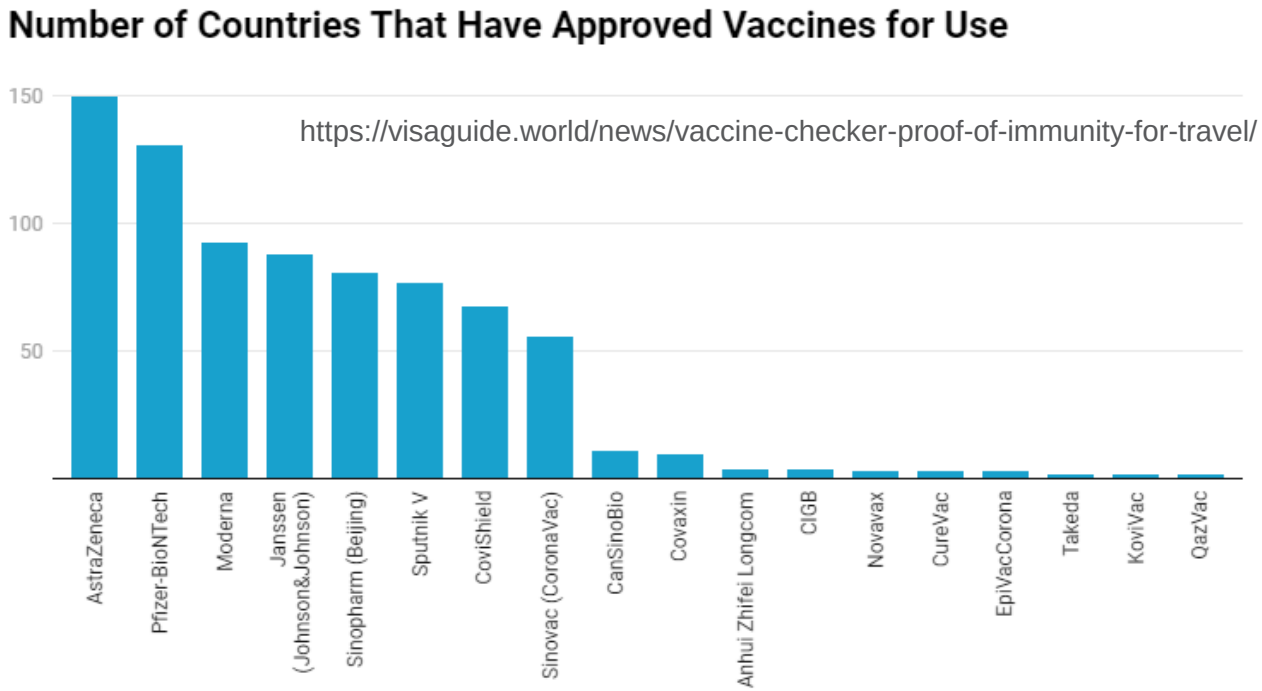
8 vaccines on WHO Emergency use listing

https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued

- 4 Vaccines authorized for use in Europe +
- Covidshield (nr viral vector)
- Sinovac (inactivated)
- BIBP/Sinopharm (inactivated)
- Covaxin/Bharat Biotech (inactivated)

>10 vaccines in emergency use at national level:

- Sputnik V: Russia, nr viral vector rAd26 and rAd25
- CanSinoBio : China, nr viral vector Ad5
- Anhui Zhifei Longcom : China, protein subunit
- CIGB : Cuba, protein subunit
- Novavax: USA, protein-based (auth. in Indonesia)
- EpiVaccorona= Siberia, synthesized peptides
- KoviVac = Russia, Live attenuated vaccinated
- QazVac = Kazakhstan vaccine, viral inactivated
- Takeda = Japan's "Moderna"
- ZyCoV-D : India, DNA vaccine



https://covid19.trackvaccines.org/vaccines/27/

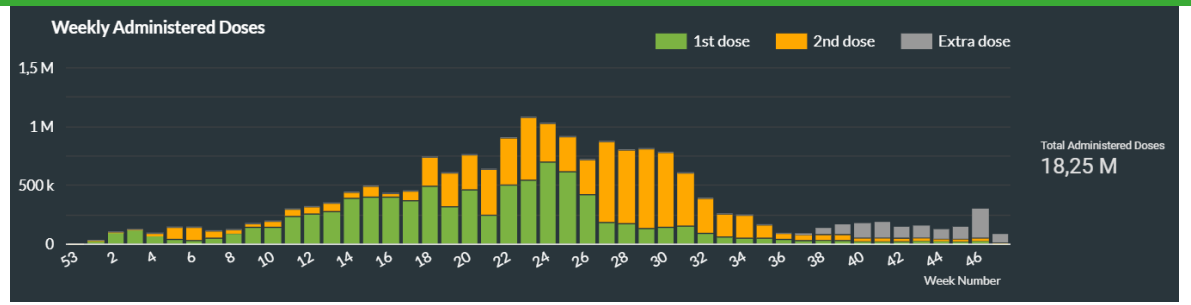
Additional/booster doses in EU and Belgium

Comirnaty and Spikevax: EMA recommendations on extra doses and boosters

Share

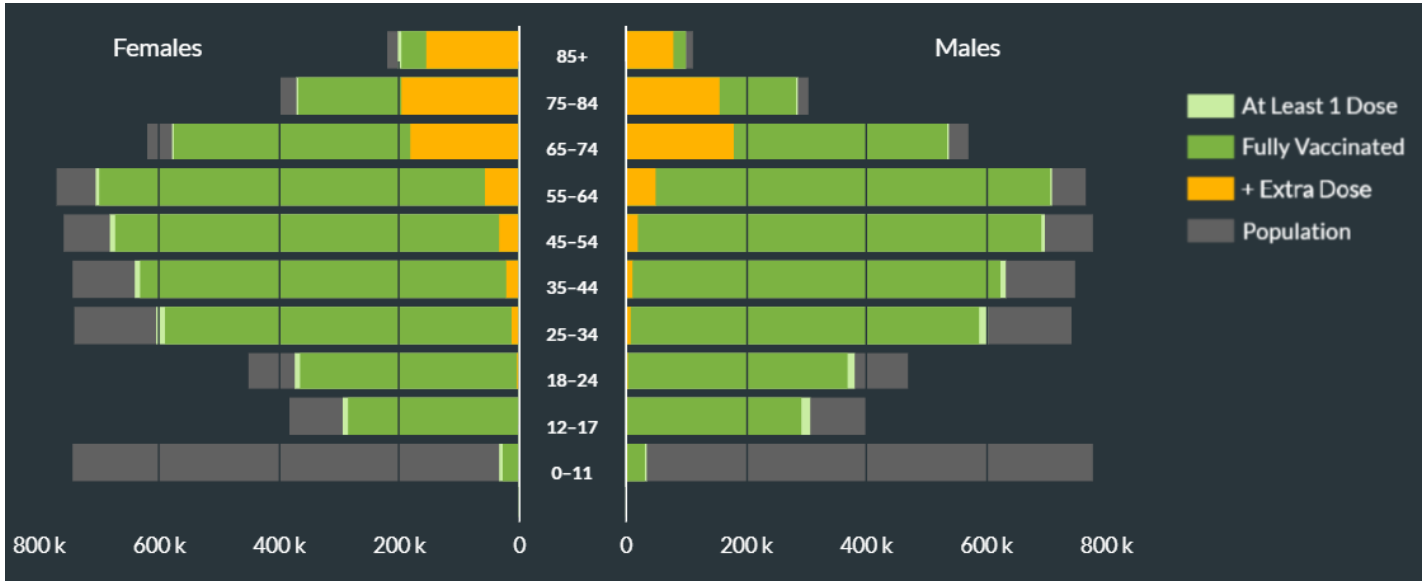
News 04/10/2021

EMA's human medicines committee (CHMP) has concluded that an extra dose of the COVID-19 vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) may be given to people with severely weakened immune systems, at least 28 days after their second dose.



In Belgium:

- immunocompromised patients (81,9%)
- > 65 years
- NH residents + care facilities
- HCW (Coverage 8-20%)
- J&J



In EU:

- https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-vaccination-strategies-and-deployment-plans-Nov-2021.pdf

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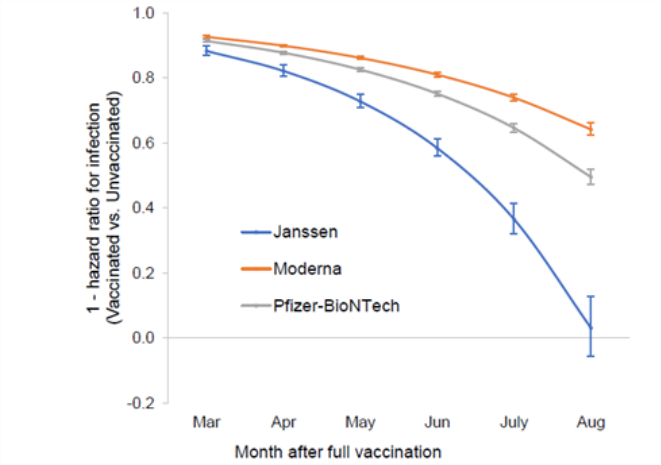
Other articles

- Cohn et al :

An analysis of health records of the Veteran Health Administration in the US showed a strong decline in VE against infection between February and October 2021 from 87.9% to 48.1% (210). The decline was the greatest for the Janssen® vaccine (from 86.4% to 13.1%), compared to Comirnaty® (86.9% to 43.3%) and Spikevax® (89.2% to 58.0%). The authors contribute the decline mostly to the emergence of the Delta variant, although that other factors such as a higher risk of infection or waning immunity might also have played a role.

Figure 1. Time dependent vaccine protection against SARS-CoV-2 infection as estimated from Cox proportional hazards models, adjusted for age, race, ethnicity, sex and comorbidity Associations are presented as 1 – hazard ratios and 95% confidence intervals. Associations for each month were estimated from contrasts using product terms for vaccination status by time to most recent RT-PCR.



- Waning of immunity has further been demonstrated in several studies assessing the evolution of SARS-CoV-2 antibodies since time of vaccination (Canaday et al., Pegu et al., Aldridge et al.)

Vaccine safety

Side effect	Brand: frequency category	Extra information
Thrombosis with Thrombocytopenia Syndrome (TTS)	Vaxzevria : Very rare side effect Janssen: Very rare side effect	• Onset usually within 3w • Younger age groups • Lower incidence after 2nd dose (In younger subjects,)
Capillary-leak syndrom *Massive leakage of plasma from blood vessels into adjacent body tissues*	Vaxzevria : Very rare side effect Janssen: Very rare side effect	• Viral-vector vaccines contraindicated in persons with history of Capillary leak syndrom
Guillain-Barré Syndrom	Vaxzevria : Very rare side effect Janssen: Very rare side effect	
Thrombocytopenia and immune-thrombocytopenia (PTI)	Vaxzevria : Very rare side effect Janssen: Very rare side effect	
Severe allergic reactions	Comirnaty : Very rare side effect Spikevax : Very rare side effect Vaxzevria : Very rare side effect Janssen: Very rare side effect	• mRNA vaccines: lipid nanoparticles (polyethylene glycol (PEG) or “macrogols” • Vaxzevria: Polysorbate80 • Janssen: Very rare side effect
Myocarditis and Pericarditis	Comirnaty : Very rare side effect Spikevax : Very rare side effect	• Onset usually within 14 days after • More often after 2nd dose and in younger male. • Acute clinical courses have been generally mild.

The frequency category ‘very rare’ = occurring in less than 1 in 10,000 persons (category of the lowest frequency foreseen in EU product information
Health professionals should be aware of these side effects for early recognition and adequate management : cfr AFMPS website + Sciensano factsheet for links
For all groups in which the Superior Health Council advised the vaccine, benefits of vaccination are estimated to largely outweigh the risks of severe adverse events

Pfizer-BioNTech paediatric vaccine:

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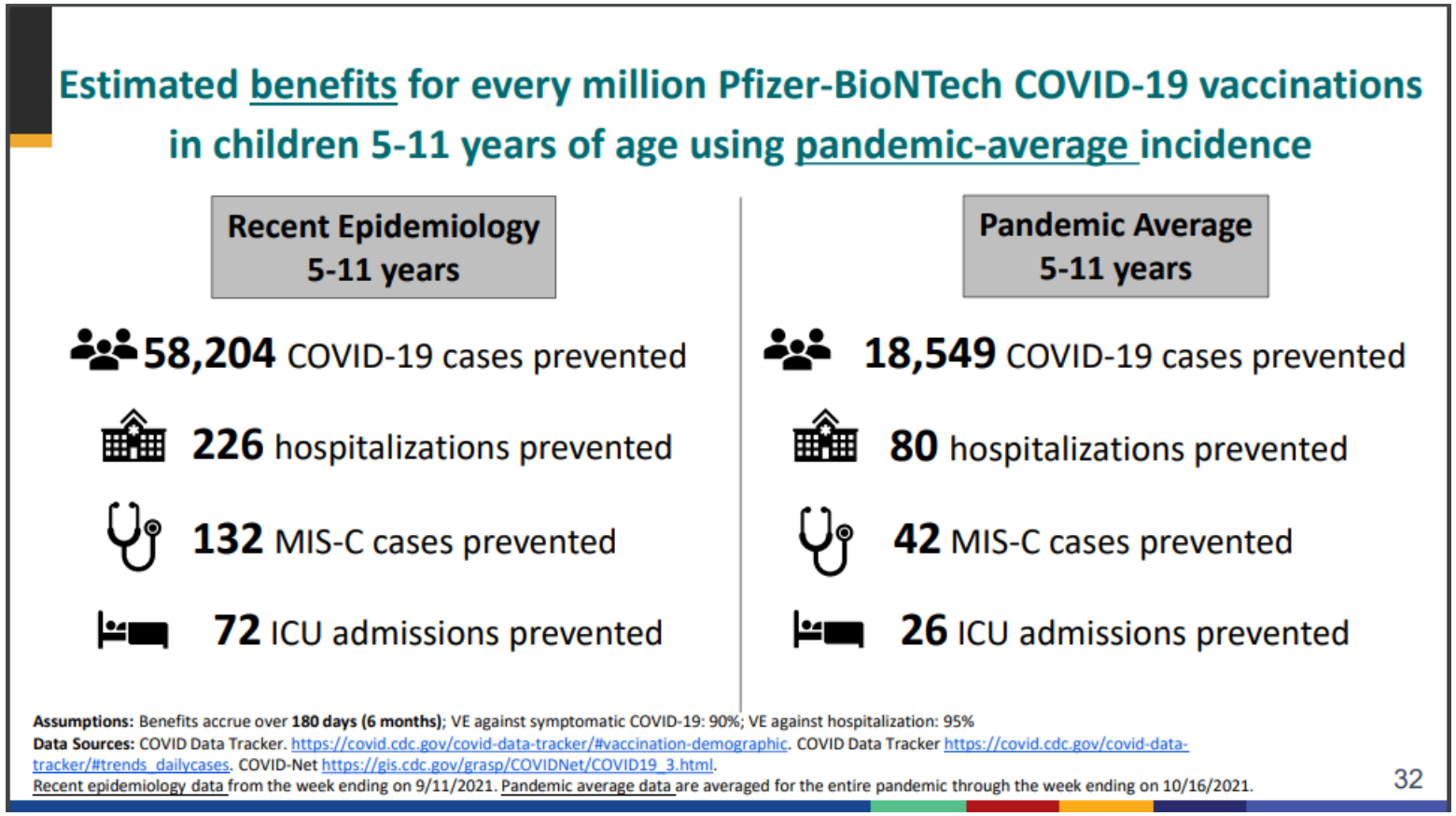

Estimated benefits for every million Pfizer-BioNTech COVID-19 vaccinations in children 5-11 years of age using pandemic-average incidence

Recent Epidemiology 5-11 years	Pandemic Average 5-11 years
58,204 COVID-19 cases prevented	**18,549** COVID-19 cases prevented
226 hospitalizations prevented	**80** hospitalizations prevented
132 MIS-C cases prevented	**42** MIS-C cases prevented
72 ICU admissions prevented	**26** ICU admissions prevented

Assumptions: Benefits accrue over **180 days (6 months)**; VE against symptomatic COVID-19: 90%; VE against hospitalization: 95%
Data Sources: COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic. COVID Data Tracker https://covid.cdc.gov/covid-data-tracker/#trends_dailycases. COVID-Net https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html.
Recent epidemiology data from the week ending on 9/11/2021. Pandemic average data are averaged for the entire pandemic through the week ending on 10/16/2021.

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Summary

COVID-19 vaccines and seropositivity

Data from Phase 3 clinical trial

- **~9%** of children in clinical trial were baseline SARS-CoV-2 seropositive
- Post-vaccination antibodies **higher** in children who were baseline seropositive
- Rates of local and systemic reactions, as well as adverse events, were **lower** in children who were baseline seropositive

Data from U.S. studies

- Approximately **38%** of children aged 5–11 years have evidence of prior SARS-CoV-2 infection based on seroprevalence estimates
- Prior infection can result in protection against infection but not 100% and likely decreases over time
- Children have a greater proportion of asymptomatic infection relative to adults[1-4]
  - Asymptomatic infection can result in lower antibody levels than severe disease

1. Viner RM, Ward JL, Hudson LD, et al. [published online ahead of print, 2020 Dec 17]. *Arch Dis Child*. 2020;archdischild-2020-320972
2. Irfan O, Muttalib F, Tang K, Jiang L, Lassi ZS, Bhutta Z. [published online ahead of print, 2021 Feb 16]. *Arch Dis Child*. 2021;106(5):440-448
3. Dawood FS, Porucznik CA, Veguilla V, et al. [published online ahead of print, 2021 Oct 8]. *JAMA Pediatr*. 2021;10.1001/jamapediatrics.2021.4217. doi:10.1001/jamapediatrics.2021.4217
4. Poline J, Gaschignard J, Leblanc C, et al.. *Clin Infect Dis*. 2021;72(12):2215-2217. doi:10.1093/cid/ciaa1044