


Janssenin adenovirusvektorin ajantasaiset turvallisuus- ja tehokkuustiedot

KRAR 13.10.2021

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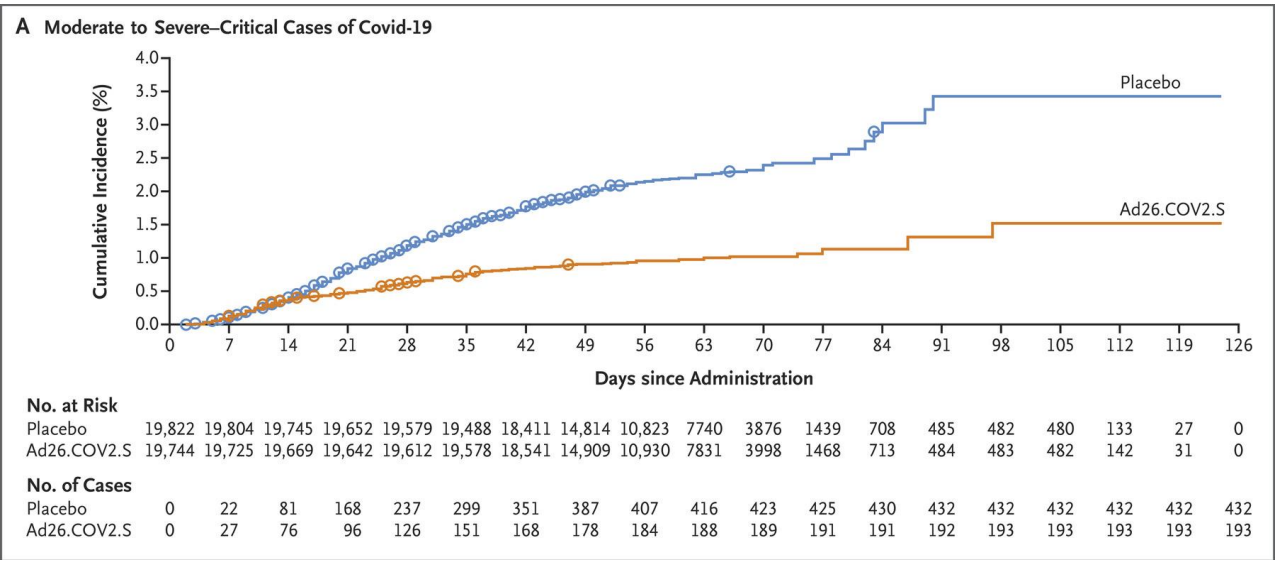
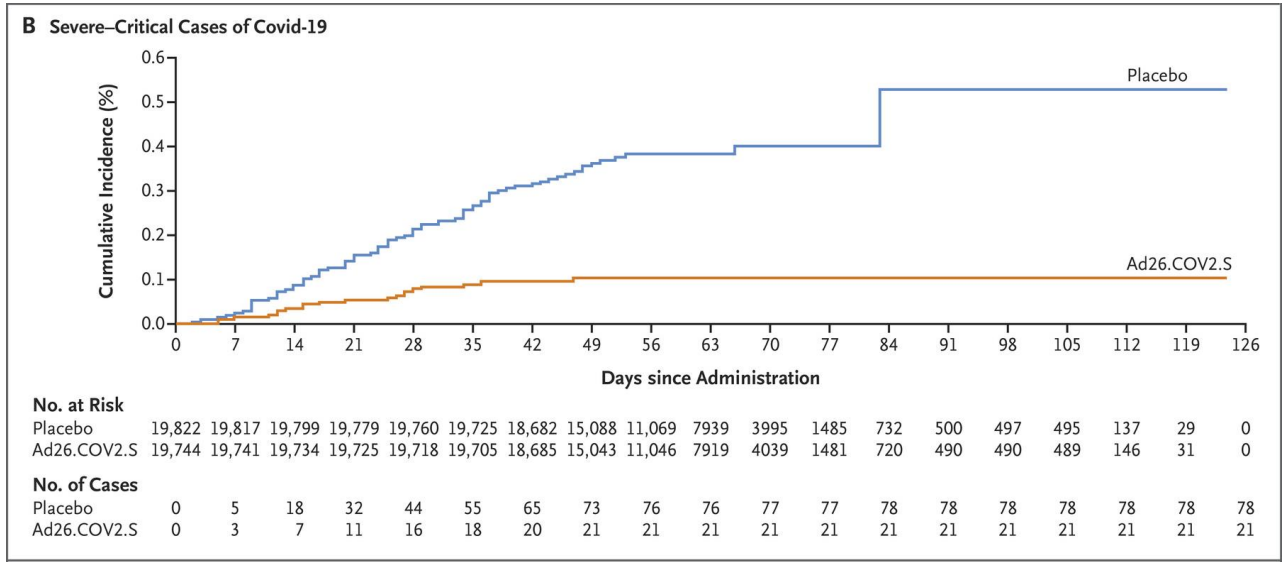
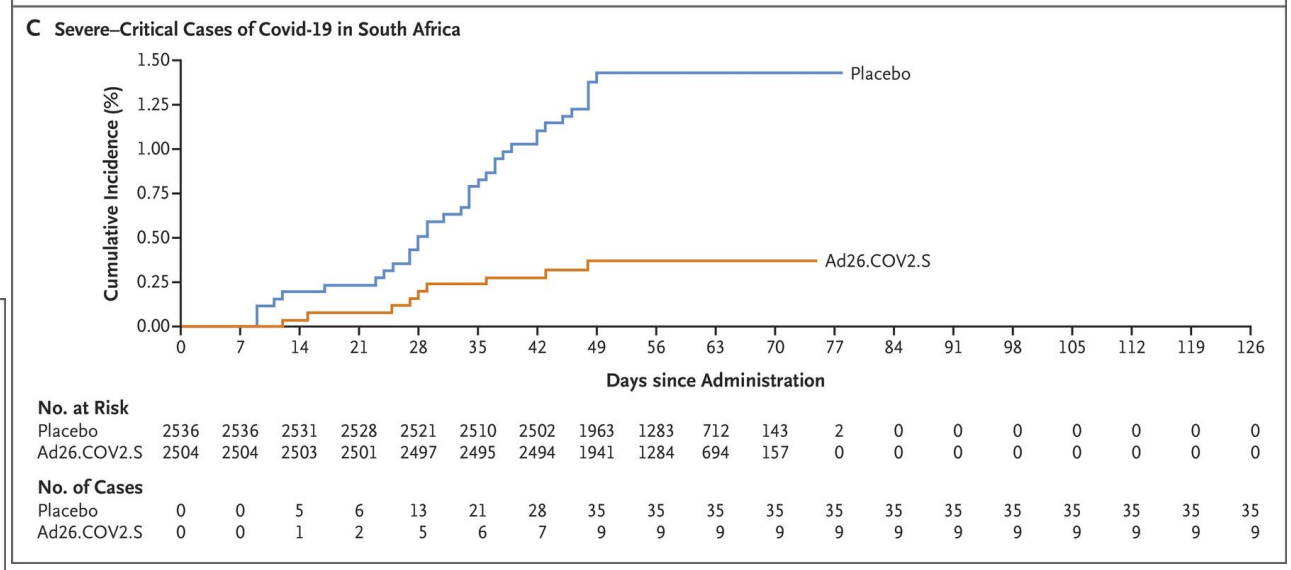
Terveyden ja hyvinvoinnin laitos

- VE against moderate to severe/critical disease
  - 14pv rokotteesta 66.9% (59-73.4%
  - 28pv rokotteesta 66.1% (55-74.8%)
- VE against severe/critical disease
  - 14pv rokotteesta 76.7% (54.6-89.1%)
  - 28pv rokotteesta 85.4% (54.2-96.9%)

- Efficacy continued to increase through 8 weeks after administration, especially for severe–critical Covid
- No evidence of waning efficacy among the 3000 participants followed for 11 weeks or among 1000 participants followed for 15 weeks







Sadoff G., Gray G., Vandebosch A. et al.; Safety and efficacy of single-dose Ad26.COV2.S vaccine against covid-19; N Eng J Med 2021; June 10 (ENSEMBLE trial)

ENSEMBLE 1 study:

- safety and efficacy of a single-dose vaccine
- Median follow-up time: four months, with 23 percent of the participants with follow-up of greater than six months
- VE against disease caused by variants
- VE against reference strain: severe/critical disease 93%, moderate to severe/critical disease 58%

ENSEMBLE 2 study:

- safety and efficacy of a two-dose vaccine regimen (56 day interval)
- Median follow-up time: 36 days since second vaccination, with 29 percent of participants having at least two months of follow-up after receipt of their second dose

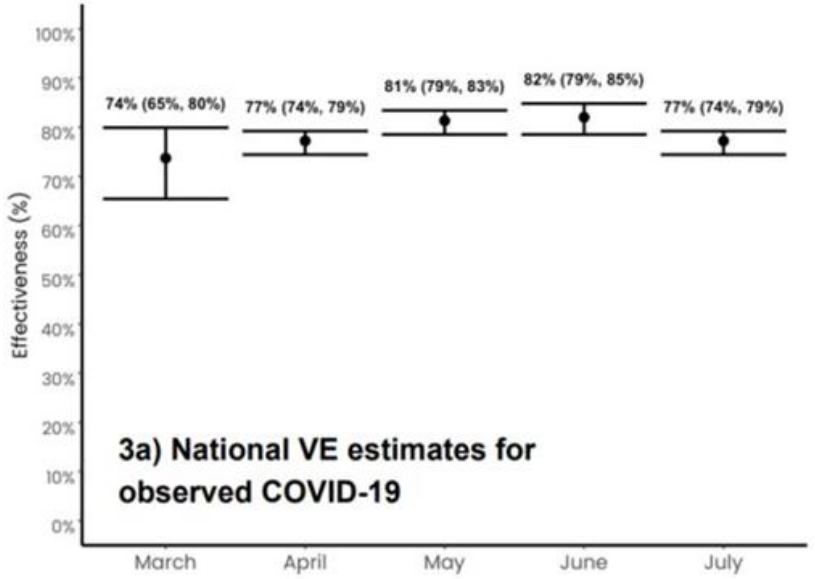
	ENSEMBLE 1 single dose	ENSEMBLE 2 two doses
VE against severe/critical disease	72% (56%-82%; n=27 cases vaccine arm, n=93 cases placebo arm)	100% (33%-100%, n=0 cases vaccine arm, n=8 cases placebo arm)
VE against moderate to severe/critical disease	53% (47%-58%; n=433 cases vaccine arm, n=883 cases placebo arm)	75% (55%- 87%; n=14 cases vaccine arm, n=52 cases placebo arm

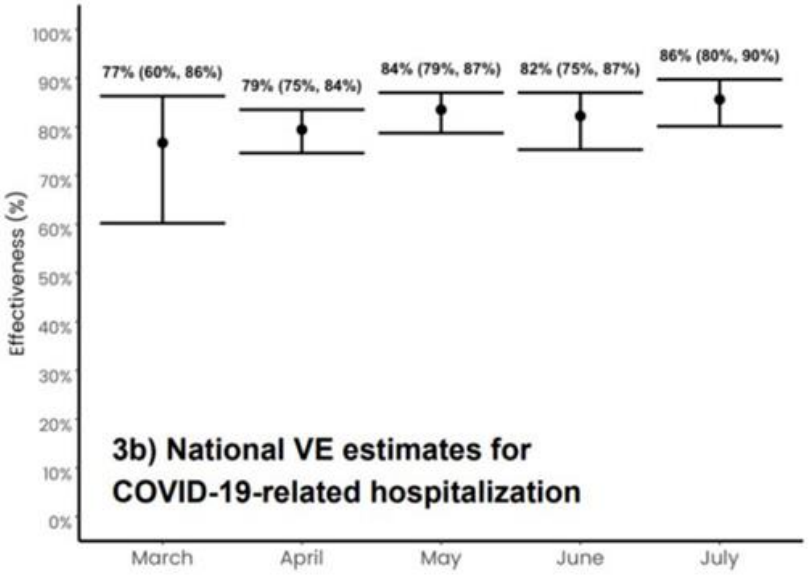
When a booster of the J&J vaccine was given two months after the first shot, antibody levels rose to four to six times higher than observed after the single shot

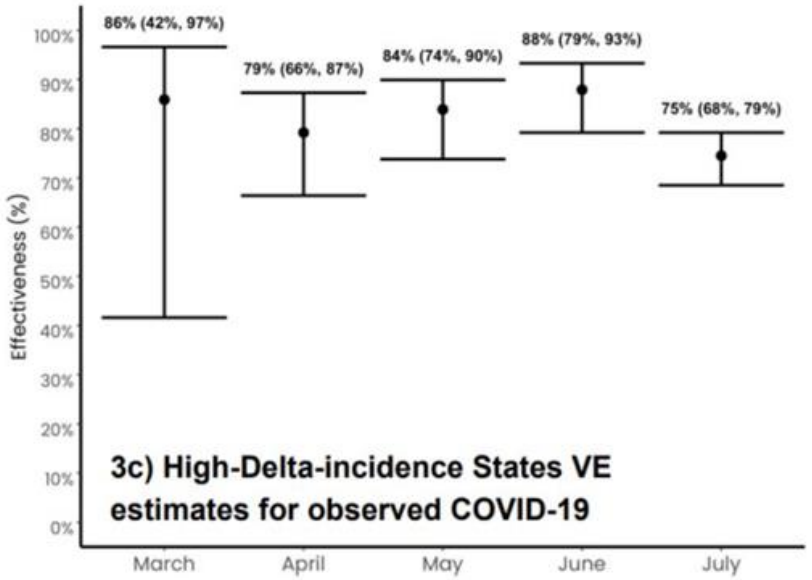
When a booster of the J&J vaccine was given six months after the single shot, antibody levels increased nine-fold one week after the booster and continued to climb to 12-fold higher four weeks after the booster.

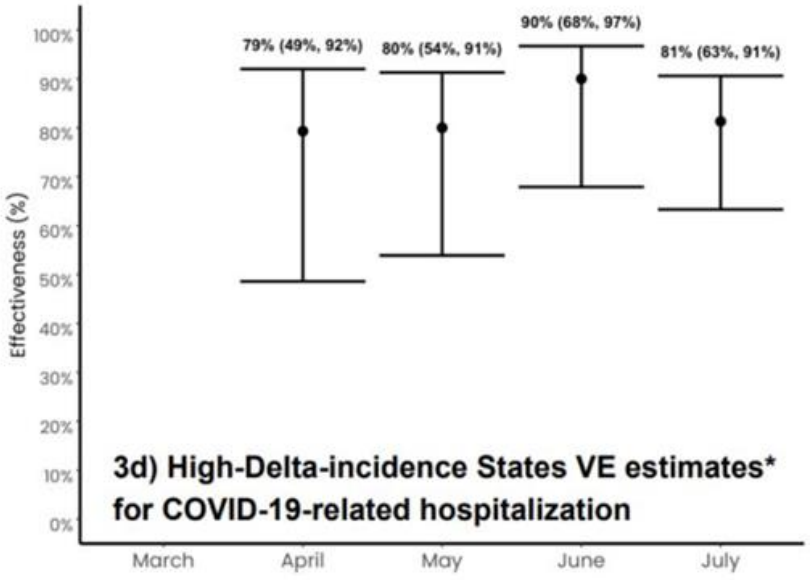
https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_johnson_announces_real-world_evidence_and_phase_3_data_confirming_strong_and_long-lasting_prote.pdf

- Individuals 18 or older who received a single dose of Ad26.COV2.S between March 1, 2021 and July 17, 2021
- approximately 390,000 people who received single-shot vaccine versus approximately 1.52 million unvaccinated people
- **VE of 81 percent (CI, 79%-84%) for COVID-19-related hospitalizations**
- **VE of 79 percent (CI, 77%-80%) for COVID-19-related infections**









Polinski JM., Weckstein AR., Batech M. et al; Effectiveness of single-dose AD26.COV2.S COVID vaccine; preprint; posted 2021, Sep 16; https://doi.org/10.1101/2021.09.10.21263385

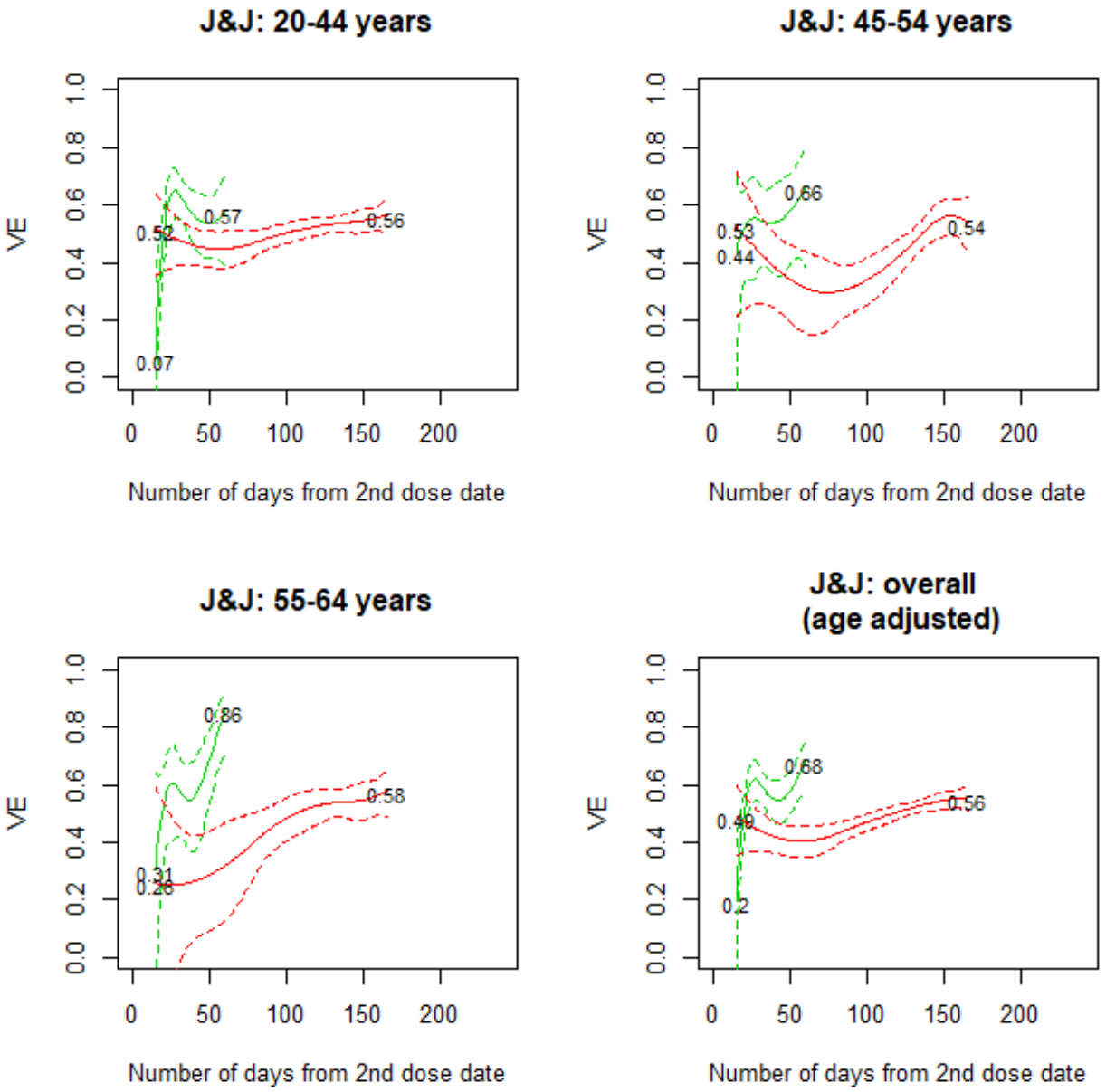
ACIP-kokous 22.9.2021

- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/04-COVID-Link-Gelles-508.pdf

Johnson & Johnson (J&J, Janssen) VE against symptomatic infection by age group and time since vaccination in pre-Delta and Delta periods

- Pre-Delta (March 13–May 29) with 95% CIs in dotted lines
- Delta (July 18–August 31) with 95% CIs in dotted lines

- VE increases with time in both periods
- No clear Delta effect on VE
- Curves look similar across age groups



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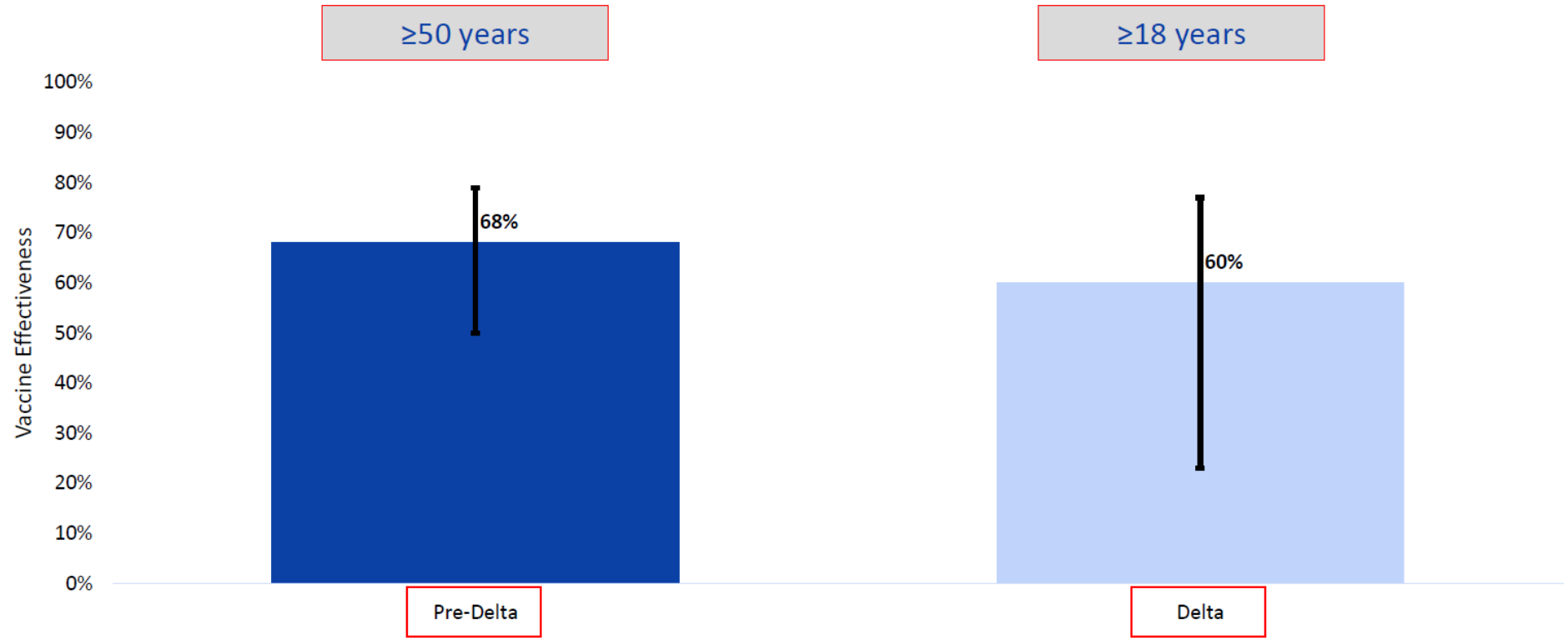
VISION Network: VE against hospitalization by time period and age group, *Johnson & Johnson/Janssen*



https://www.nejm.org/doi/full/10.1056/NEJMoa2110362
https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e2.htm

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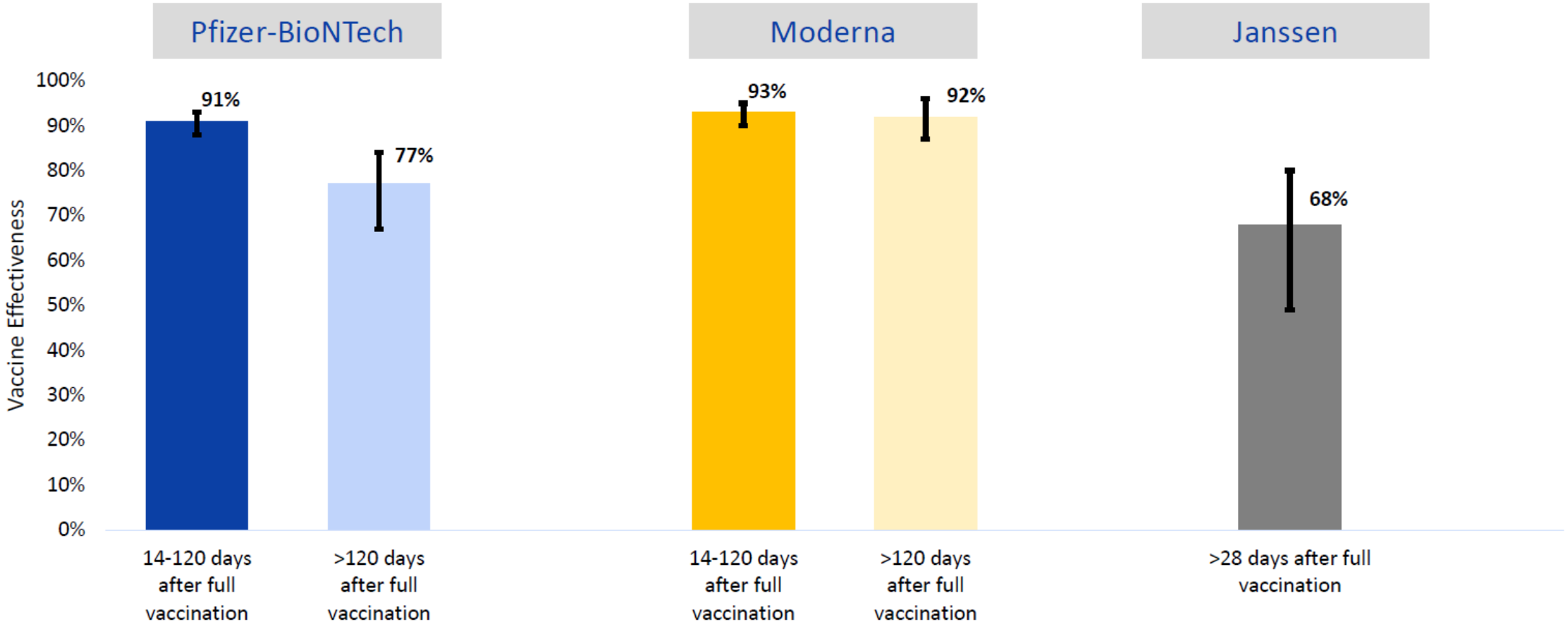
Vastaavana aikana mRNA-rokotteilla teho sairaalahoitoista tautia vastaan 80-90%

IVY Network: COVID-19 vaccine effectiveness against hospitalization by vaccine product and time since vaccination, adults ≥18 years without immunocompromising conditions



* Adjusted for admission date (biweekly), HHS region, age, sex, race/ethnicity. Not enough recipients of Janssen to assess by time since vaccination.

Suositukset tehosteannoksista

- Ranska: mRNA-rokotteella vähintään 4vk kuluttua Janssenista
- Islanti: mRNA:lla, jos ei sairastettua covidia, väh 8vk kuluttua
- Norja: mRNA:lla vähintään 8-12vk kuluttua
- Itävalta: mRNA:lla tai Janssenilla, väh 4vk kuluttua
- Saksa: mRNA:lla, vähintään 4vk kuluttua

Turvallisuus

- Hyvin yleinen: päänsärky, pahoinvointi, lihassärky, uupumus, injektiokohdan kipu
- Yleinen: yskä, nivelsärky, kuume, injektiokohdan punoitus ja turvotus, vilunväreet
- Melko harvinainen: vapina, huimaus, parestesiat, aivastelu, suunielun kipu, ripuli, ihottuma, liikahikoilu, lihasheikkous, raajakipu, selkäkipu, voimattomuus, huonovointisuus
- Harvinainen: lymfadenopatia, yliherkkyys, urtikaria, hypoestesia, tinnitus, oksentelu
- Hyvin harvinainen: GBS, TTS
- Tuntematon: ITP, anafylaksia, capillary leak syndrome

- Tromboottinen trombosytopeeninen syndrooma (TTS)
  - 70% tapauksista alle 60-vuotiailla, 44% alle 60v naisilla
  - 3 viikon kuluessa rokotuksesta
  - Sinustromboosit, splanchnic vein trombosis, valtimotukoksia
  - Noin 0,45/100 000
  - Slovenia keskeyttänyt rokotteen käytön 30.9. nuoren naisen kuolemantapauksen vuoksi

Guillain-Barré

- PRAC: yhteys rokotteella ja GBS:llä mahdollinen

Capillary leak syndrome

- Aiemmin sairastettu capillary leak syndrome vasta-aihe Janssen-rokotteelle
- EMA 9.7.2021: 3 tapausta Janssenin saaneilla 2 pv rokottamisen jälkeen
  - Yhdellä näistä aiemmin capillary leak syndrome, kaksi menehtyi
- 21.6.2021 mennessä yli 18 milj J&J-annosta annettu

ITP

- Yleensä neljän viikon kuluessa rokotuksesta
- Jos aiempi ITP, riski arvioitava ennen rokottamista ja trombosyyttitason seuranta rokotuksen jälkeen

Tulossa valmisteyhteenvetoon

- Venous thromboembolism VTE
  - Myyntilupatutkimuksissa tapauksia enemmän rokotetuilla kuin placebo-ryhmässä
  - phase 3 study (COV3001): VTE-tapauksia 26/21,894 (0.1%) Janssenin rokotteen saaneilla ja 9/21,882 (0.04%) placeboa saaneilla
    - Suurimmalla osalla vähintään yksi riskitekijä
    - Toisessa phase 3 tutkimuksessa (COV3009) ei havaittuja VTE-tapauksia
  - 9/21 PRAC: mahdollinen yhteys rokotteeseen
  - Valmisteyhteenvetoon harvinaisena haittavaikutuksena (<1/1000)
- Transversaalimyeliitti
  - 31.8.2021 mennessä 1 tapaus, jossa yhteys rokotteeseen todennäköinen, 10 tapausta, joissa yhteys mahdollinen
    - 33 miljoona annosta annettu
  - Valmisteyhteenvetoon tuntemattomana haittavaikutuksena