Lasten koronarokottamisen turvallisuuskatsaus

Maija Kaukonen, Dos, EL
Ylilääkäri, Jaostopäällikkö
Fimea

11.1.2022

Annettuja rokotemääriä < 18 vuotiaille

ETA –alue (ECDC 5.1.2022)

- > 18 000 000 ensimmäistä rokoteannosta annettu < 18 v
- > 4 000 000 ensimmäistä rokoteannosta annettu 10-14 v
- > 970 000 ensimmäistä rokoteannosta annettu 5-9 v
- > 2000 ensimmäistä rokoteannosta annettu 0-4 v

USA (CDC 19.12.2022)

- > 8 600 000 rokoteannosta 5-11 v
- > 18 700 000 rokoteannosta 12-15 v

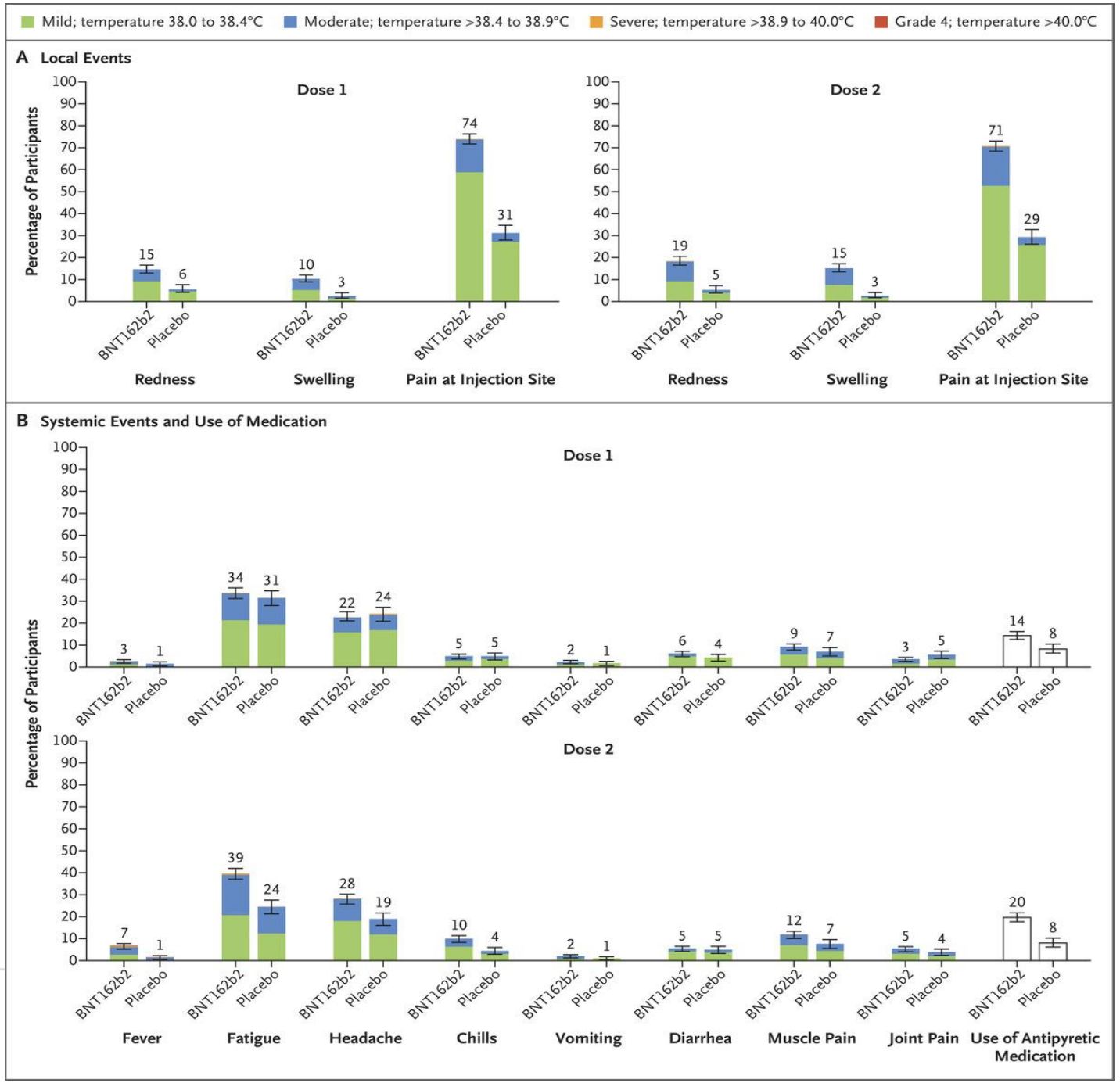
Comirnaty Pfizer-BioNtech 5-11 vuotiaat

1517 lasta sai aktiivirokotetta
751 lasta sai placeboa

Mieto kuume – 38.0 - 38.4 °C
Kohtalainen kuume – >38.4 - 38.9 °C
Vakava kuume – >38.9 - 40.0 °C
Grade 4 – >40.0 °C

12-15 –vuotiaat

- Injektiokohdan kipu (> 90 %)
- Väsymys (>80 %)
- Päänsärky (>40%)
- Lihaskivut (>30%)
- Vilunväristykset ja nivelsärky (>20%)

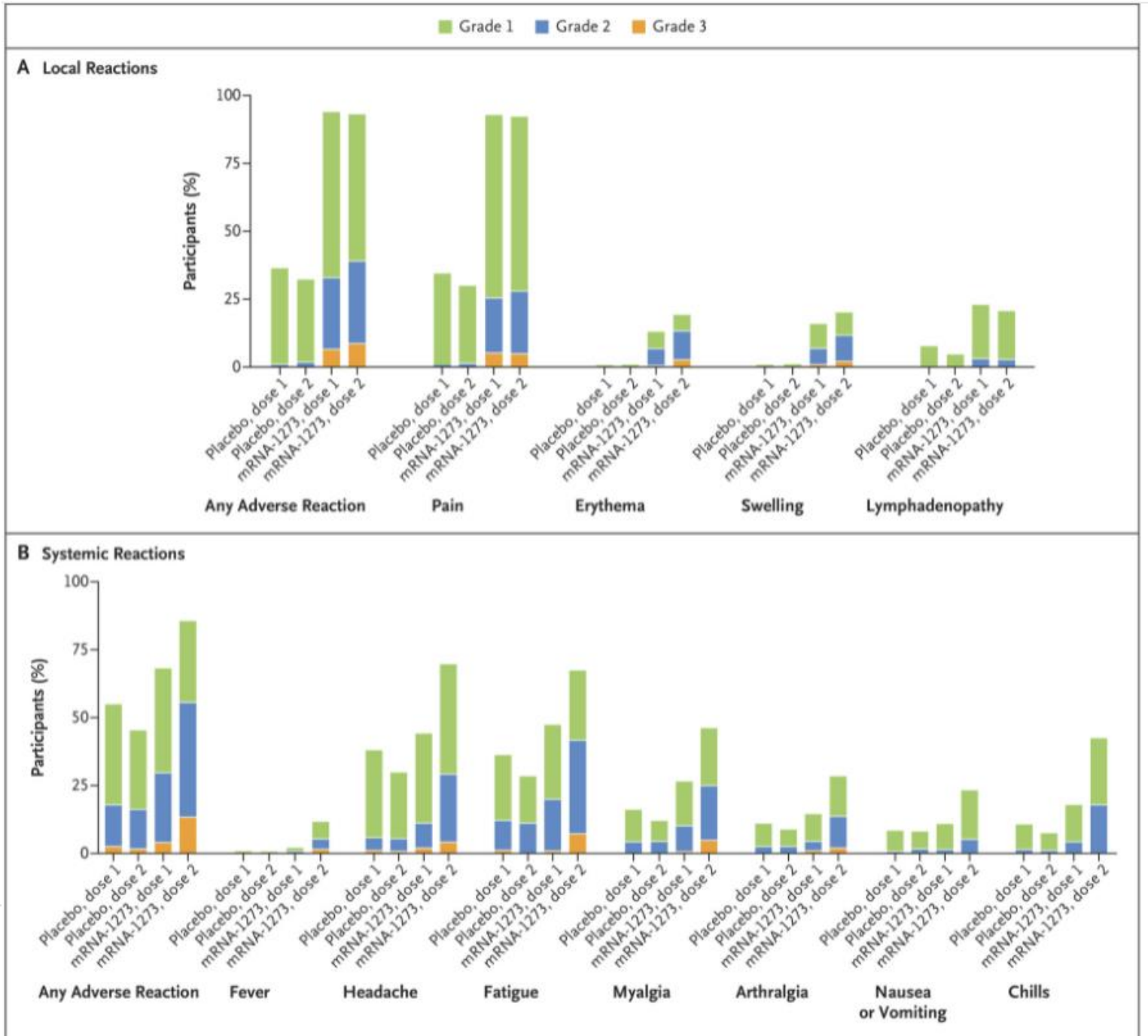


Spikevax – Moderna 12-17 -vuotiaat

2489 nuorta sai aktiivirokotuksen

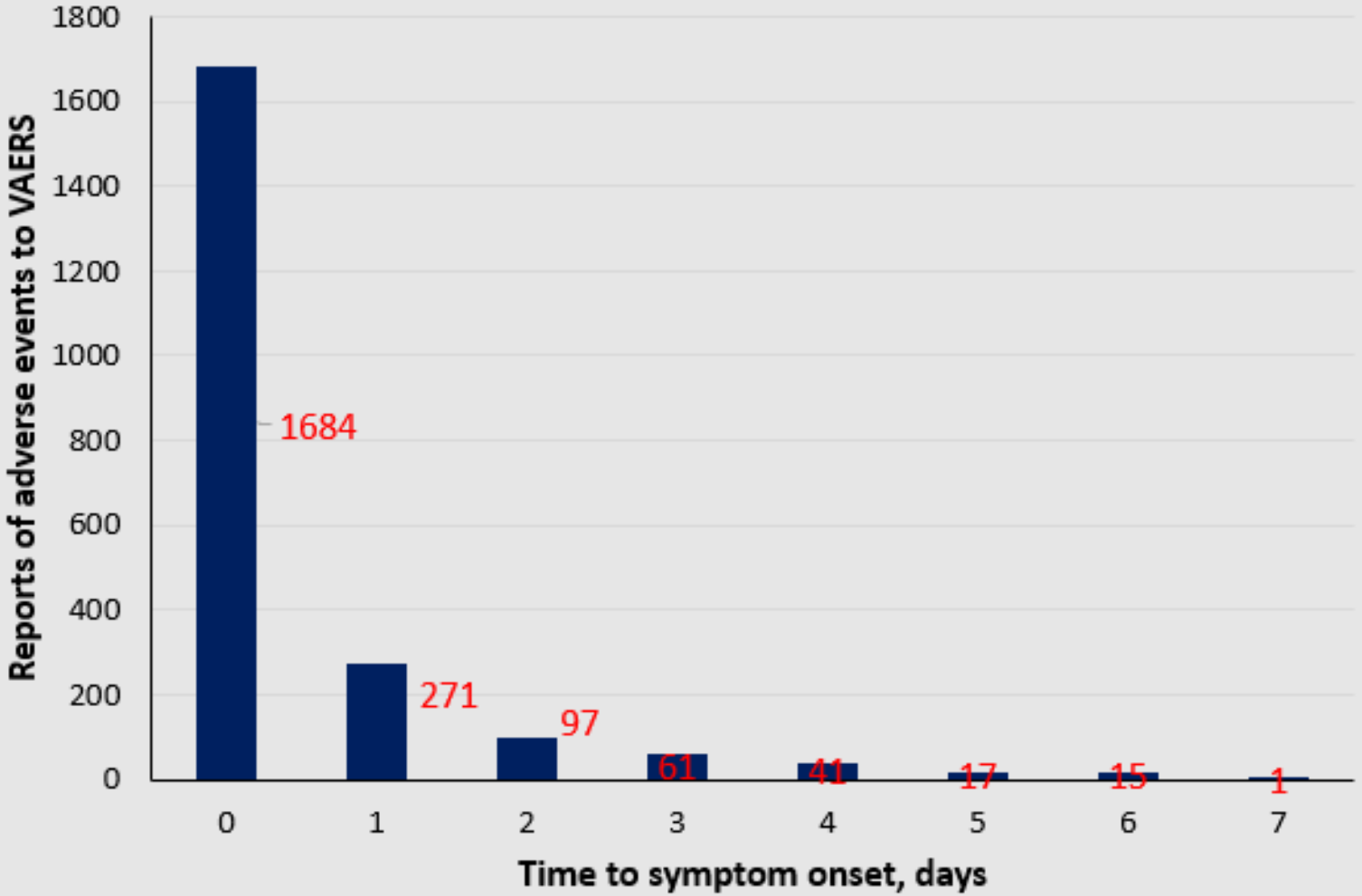
1243 nuorta sai plaseboa

12-17 –vuotiaat
Injektiokohdan kipu (97 %)
Päänsärky (78 %),
Väsymys/uupumus (75 %),
Lihaskipu (54 %),
Vilunväristykset (49 %)
Kainaloiden turpoaminen/arkuus (35 %)
Nivelkipu (35 %)
Pahoinvointi/oksentelu (29 %)
Injektiokohdan turvotus, punoitus (>25 %)
Kuume (14 %)



Time from COVID-19 vaccination to symptom onset in children ages 5–11 years (N=2,279 reports) (as of Dec 2, 2021)

- Median time to symptom onset = 0 days (i.e., day of vaccination) (IQR = 0–1 days)



Most frequently reported adverse events to VAERS following Pfizer-BioNTech COVID-19 vaccination, children ages 5–11 years* (as of Dec 19, 2021)

Non-serious reports (n=4,149, 98%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	No adverse event	1,183 (27)
2	Product preparation issue	925 (21)
3	Incorrect dose administered‡	704 (16)
4	Underdose	326 (7)
5	Vomiting	320 (7)
6	Fever	296 (7)
7	Headache	260 (6)
8	Syncope	256 (6)

Serious reports† (n=100, 2%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Fever	29 (29)
2	Vomiting	21 (21)
3	Troponin increased	15 (15)
4	Chest pain	12 (12)
5	Echocardiogram normal	12 (12)
6	Blood test	11 (11)
7	C-reactive protein increased	11 (11)
8	SARS-CoV-2 test negative	11 (11)

- Reflect vaccination errors and previously observed adverse events; workup for myocarditis or Multisystem Inflammatory Syndrome in Children (MIS-C)

* Reports among children ages 5–11 years vaccinated Nov 3–Dec 19, 2021.
† No serious reports resulted from the administration of an adult dose in error.
‡ Of reports specifying receipt of an adult dose, few reported a health outcome.

Reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech COVID-19 vaccination, 7-day risk interval*

	Males		Females	
Age group	**Dose 1**	**Dose 2**	**Dose 1**	**Dose 2**
5–11 years	0.0	4.3	Not calculated†	2.0
12–15 years	4.8	45.7	1.0	3.8
16–17 years (included for reference)	6.1	70.2	0.0	7.6

- **37,810,998** total doses 1 and 2 of vaccine administered‡
- Reporting rates exceed background incidence (peach shaded cells) §
  - Males: after dose 1 (ages 12–15 and 16–17 years) and after dose 2 (ages 5–11, 12–15, and 16–17 years)
  - Females: after dose 2 (ages 12–15 and 16–17 years)
  - Reporting rates among males substantially lower among ages 5–11 vs. 12–15 and 16–17 years

* Reports of myocarditis after doses 1 and 2 of Pfizer-BioNTech COVID-19 vaccine during a 7-day risk interval after vaccination (as of Dec 19, 2021); reports verified to meet case definition by healthcare provider interview and/or medical record review.

† Too few reports of females ages 5–11 years to calculate a stable rate.

‡ Children ages 5–11 years vaccinated Nov 3–Dec 19, 2021, children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021.

§ An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is 0.2 to 1.9 per 1 million person 7-day risk period.

Summary of VAERS findings after Pfizer-BioNTech COVID-19 booster vaccination, ages 16–24 years

- Since authorization, Pfizer-BioNTech COVID-19 vaccine booster doses have been administered to ~47,000 persons ages 16–17 years and ~930,000 persons ages 18–24 years in the United States
- Most reports (95%) were non-serious (similar to primary series)
  - Most frequently reported AEs were known and well-characterized AEs associated with Pfizer-BioNTech COVID-19 vaccination, or consistent with workup for myocarditis
  - 13 preliminary reports of myocarditis following a booster dose
    - 4 reports met CDC case definition (9 still under review)
      - All 4 reported patients had recovered from symptoms at time of report
    - Characteristics of case reports appear consistent with other reports of myocarditis after dose 1 and dose 2
- CDC will continue to monitor the safety of COVID-19 vaccine booster doses

Suomessa raportoidut nuorten (<18v) rokotehaitat Comirnaty ja Spikevax

- 12–17-vuotiailla 11.1.2022 mennessä 528 ilmoitusta
  - 139 vakavaa
  - N. 47 % Comirnatya ja n. 53 % Spikevaxia.
  - Pääsääntöisesti odotettuja haittoja: kuumetta, päänsärkyä, erilaisia ihoreaktioita ja rokotuskohdan reaktiota
  - Molemmilla rokotteilla ilmoitettu myokardiitteja
- 5-11 –vuotiailla ilmoitettu 3 ei-vakavaa haittatapahtumaa

Kiitos

Lääkealan turvallisuus- ja kehittämiskeskus
Maija Kaukonen
11.1.2022