COVID-19 Vaccine in School-Age Children

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COVID-19 Vaccine in School-Age Children

Discussion today:

- Safety profile
- Known adverse effects of the vaccine

COVID-19 Vaccine in School-Age Children

Background

- Pfizer/BioNTech vaccine
  - Only vaccine product currently available in the US for use in persons under age 18
  - “mRNA” vaccine
  - Originally authorized (under EUA) for those age 16-and-older
  - Later expansion of EUA for use in those age 12-15, and then age 5-11

COVID-19 Vaccine in School-Age Children

Background

- Pfizer/BioNTech vaccine
  - Regimen:
    - Two doses (separated by three weeks) for most healthy individuals
    - Immune-compromised persons aged 12-and-up receive three doses
    - All individuals 12-and-up receive a booster dose after 5 months
  - Dose varies:
    - Children aged 5-11 receive 1/3 the dose that those 12-and-up receive

COVID-19 Vaccine in School-Age Children

Vaccine Safety

- Monitoring
  - VAERS (Vaccine Adverse Event Reporting System)
  - V-Safe
  - VSD (Vaccine Safety Datalink)
- Different advantages & limitations with each system

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Vaccine Safety

- VAERS (Vaccine Adverse Event Reporting System)
  - Passive reporting system (to easily gather community reports of possible adverse effects of vaccine)
  - Any person is allowed to report
  - Any possible event may be reported, *regardless of the plausibility of the event being associated with vaccination*

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Vaccine Safety

- VAERS (Vaccine Adverse Event Reporting System)
  - Strengths:
    - Early detection of possible safety issues
    - Can detect rare events not seen in studies
  - Limitations:
    - Passive reporting, no systematic data collection
    - Variable information quality
    - No data collected on unaffected individuals … therefore cannot determine rates, risk, causation, etc

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Vaccine Safety

- VAERS (Vaccine Adverse Event Reporting System)
  - Primarily serves as a vehicle to look for signals of possible issues
  - Any detected signals must be followed up with standard research to determine whether any association between vaccine and adverse events actually exists

To date, there have been no concerning safety signals in children associated with use of COVID-19 vaccine

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Vaccine Safety

- V-Safe
  - Smart phone-based monitoring program for COVID-19 vaccine safety in the US (run by the CDC)
  - Voluntary enrollment
  - Uses text messages & web surveys to check in with vaccine recipients on possible adverse effects of vaccine:
    - Local injection site reactions (pain, redness, swelling, etc)
    - Systemic reactions (fatigue, headache, joint pain, etc)
    - Health impacts (needed care, missed work/school, unable to perform usual activity)

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Vaccine Safety

- V-Safe
  - Limitations
    - Again – voluntary, with data not systematically collected
    - Population that enrolls and reports may not be representative of the vaccinated population in the US

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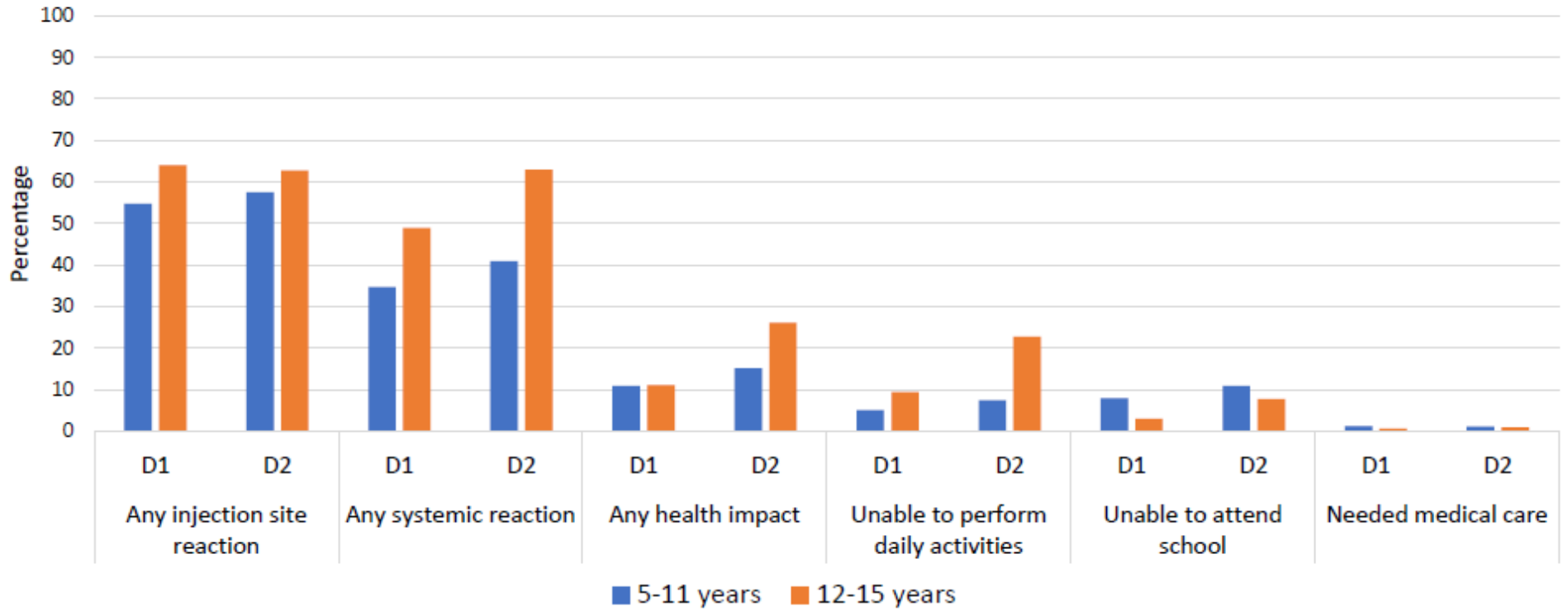
Vaccine Safety *V-Safe – Data for ages 5-15*

Reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination for children and adolescents ages 5-11 and 12-15 years,* by dose



CDC-ACIP "Safety monitoring of COVID-19 vaccine among children and young adults in v-safe", presented January 5, 2022

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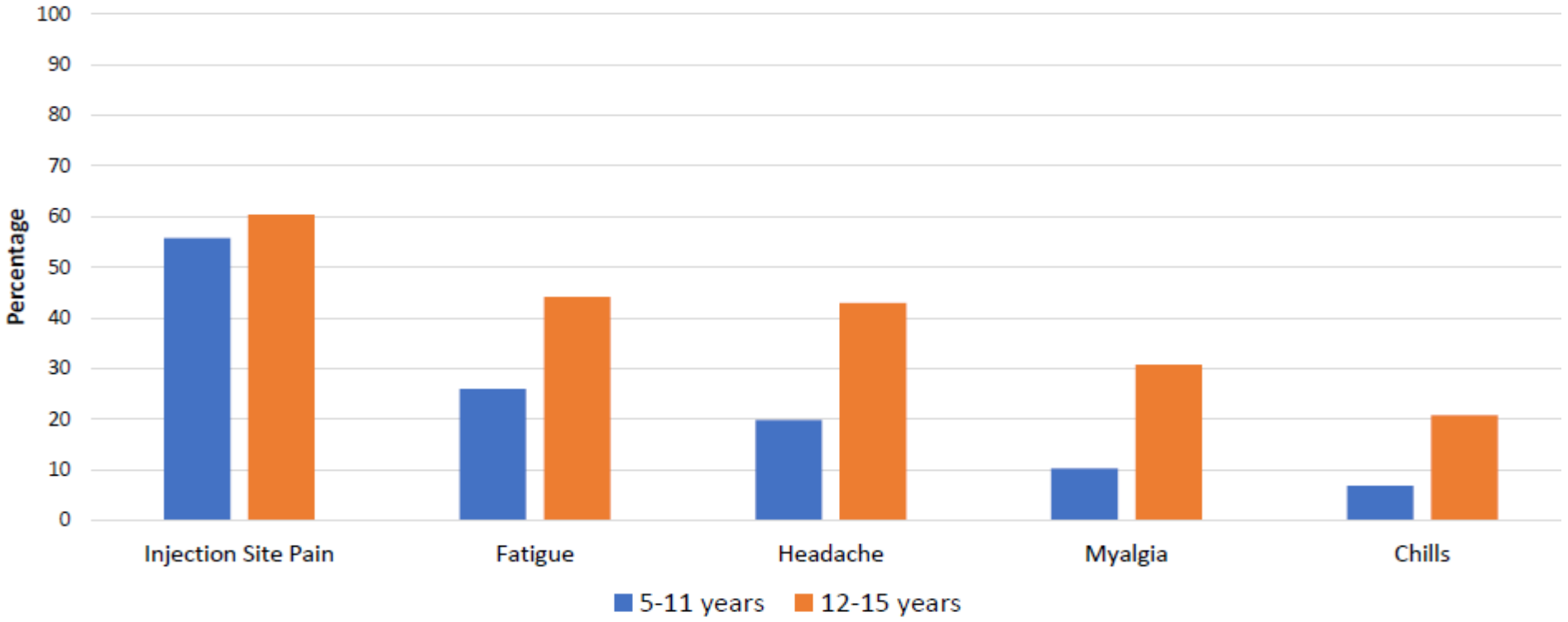
Vaccine Safety *V-Safe – Data for ages 5-15*

Top 5 reactions reported at least once in 0–7 days after dose 2 of Pfizer-BioNTech vaccine for children ages 5-11 and 12-15 years*



CDC-ACIP "Safety monitoring of COVID-19 vaccine among children and young adults in v-safe", presented January 5, 2022

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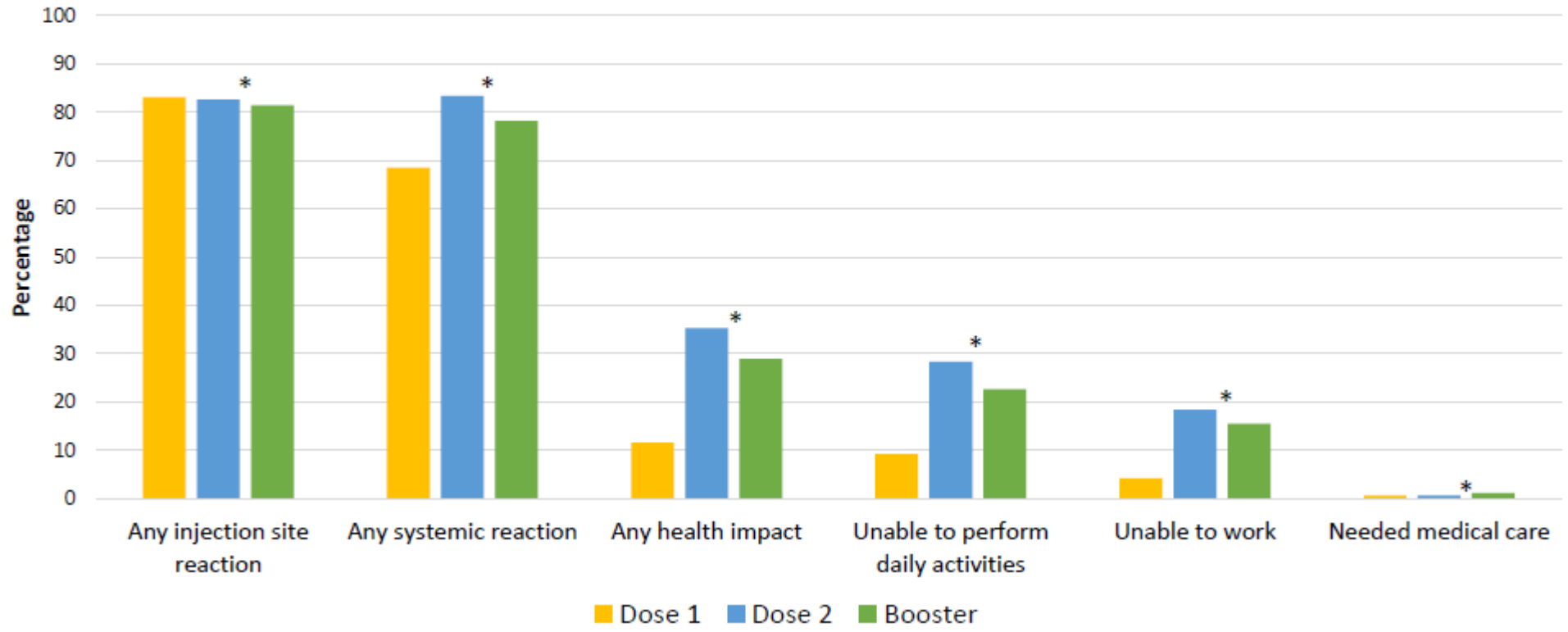
Vaccine Safety *V-Safe – Data for ages 16-24*

Reactions and health impact events reported by v-safe participants ages 16-24 years at least once in days 0-7 after Pfizer-BioNTech vaccination, by dose



CDC-ACIP "Safety monitoring of COVID-19 vaccine among children and young adults in v-safe", presented January 5, 2022

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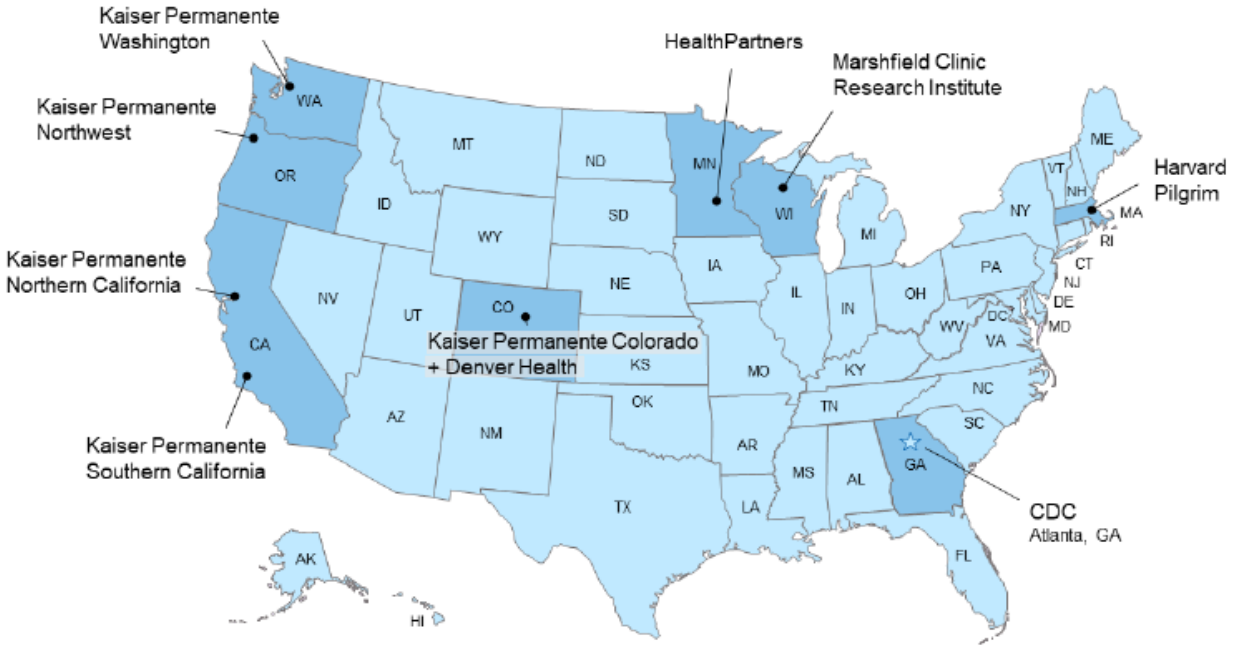
Vaccine Safety

- VSD (Vaccine Safety Datalink)
  - Collaborative project between CDC and 9 integrated healthcare organizations in eight states across the US



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Vaccine Safety

- VSD (Vaccine Safety Datalink)
  - Slower data collection than VAERS and vSafe
  - Systematically-collected data
    - More likely to reflect the vaccinated population in the US
    - More detailed information on individuals
    - Unlike VAERS, this data CAN provide an indication of actual rates of adverse events

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Vaccine Safety

- VSD (Vaccine Safety Datalink)

Outcomes being assessed:

1	Acute disseminated encephalomyelitis	13	Multisystem inflammatory syndrome in children/adults (MIS-C/MIS-A)
2	Acute myocardial infarction – **First Ever**	14	Myocarditis / pericarditis – **First in 60 Days**
3	Acute respiratory distress syndrome	15	Narcolepsy / cataplexy
4	Anaphylaxis – **First in 7 days**	16	Pulmonary embolism – **First Ever**
5	Appendicitis	17	Seizures
6	Bell's palsy – **First Ever**	18	Stroke, hemorrhagic
7	Cerebral venous sinus thrombosis	19	Stroke, ischemic
8	Disseminated intravascular coagulation	20	Thrombosis with thrombocytopenia syndrome – **First Ever**
9	Encephalitis / myelitis / encephalomyelitis	21	Thrombotic thrombocytopenic purpura
10	Guillain-Barré syndrome	22	Transverse myelitis
11	Immune thrombocytopenia	23	Venous thromboembolism – **First Ever**
12	Kawasaki disease		

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Vaccine Safety

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Vaccine Safety

- VSD (Vaccine Safety Datalink)
  - Safety data in children aged 5-to-11
    - 431,485 total doses as of December 11, 2021
    - 2 possible myocarditis/pericarditis cases (1 confirmed on review at time of data presentation)
    - Small numbers of vaccine recipients with appendicitis (9) and seizures (2)
    - No statistically significant safety concerns at this point

CDC-ACIP “Vaccine Safety Datalink Rapid Cycle Analyses: Uptake and Safety of COVID-19 Vaccines in 5–11 and 12–17-Year-Olds”, presented January 5, 2022

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Vaccine Safety

- VSD (Vaccine Safety Datalink)
  - Myocarditis/pericarditis data in children aged 12-to-17
    - 1,143,821 total doses as of December 25, 2021
    - 75 possible myocarditis/pericarditis cases identified (47 of those confirmed on review at time of data presentation)
      - About 2/3 of those admitted to hospital, 1/4 to ICU
      - Median hospital stay 2 days
    - Excess myocarditis/risk = 70 cases per 1,000,000 second doses received (mostly males)
    - For 16-17 year olds, risk after booster is less than after dose #2*

CDC-ACIP "Vaccine Safety Datalink Rapid Cycle Analyses: Uptake and Safety of COVID-19 Vaccines in 5–11 and 12–17-Year-Olds", presented January 5, 2022 , except
* = FDA Review Memorandum, Pfizer-BioNTech Booster for Ages 16-17, 8 December 2021

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Vaccine Safety

- Myocarditis: *Males aged 12-to-17*

	Benefit or harm (estimated incidents)	Number of incidents per 1,000,000 (one million) vaccine doses administered
BENEFITS	COVID-19 cases prevented	5,700
	Hospitalizations prevented	215
	ICU admissions prevented	71
	Deaths prevented	2
HARMS	Myocarditis cases	~69

Gargano et al "Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021" MMWR, July 9, 2021 / 70(27);977–982

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Vaccine Safety

- Myocarditis: *Females aged 12-to-17*

	Benefit or harm (estimated incidents)	Number of incidents per 1,000,000 (one million) vaccine doses administered
BENEFITS	COVID-19 cases prevented	8,500
	Hospitalizations prevented	183
	ICU admissions prevented	38
	Deaths prevented	1
HARMS	Myocarditis cases	~10

Gargano et al "Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021" MMWR, July 9, 2021 / 70(27);977–982

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Questions