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1. **#ACIP** is meeting this afternoon to discuss the recently **@US_FDA** authorization of Covid boosters for youths aged 12 to 15. I'll be live tweeting. The agenda is here <https://t.co/kVtuGFx6Pt> and the meeting can be monitored here: <https://t.co/rsFDXVw45q>
2. Slide presentations for today's **#ACIP** meeting can be found here, though most of them aren't yet up: <https://t.co/cJUEWk3Dpv>
3. At present there are 13 of the 15 **#ACIP** voting members in attendance. Chair Grace Lee says others may join later. This meeting was set up at short notice and members have had to scramble — as they have multiple times through the pandemic — to clear time for this meeting.
4. Peter Marks, director of **@FDACBER**, (and subject of a **@statnews** Q&A yesterday) is going to address **#ACIP**. <https://t.co/i2RamfkDbX>
5. Before he does, Amanda Cohn, former secretary to **#ACIP**, is speaking. Gist: There are going to be fewer ACIP meetings going forward. So far in the pandemic, ACIP members have met a total of 24 days to address **#Covid** vaccine issues. (They typically meet between 9-12 days a yr)
6. Cohn said going forward, some of the changes to the vaccine authorizations and authorizations that **@US_FDA** pushes out will go directly to **@CDCDirector** for her approval (or not, but that's not super likely). Cohn didn't explain which types of decisions would skip **#ACIP**...
7. ... but 2 changes **@US_FDA** authorized this week (a change of the interval for the Pfizer booster to 5 months from 6 months & a 3rd dose for children 5-11 yo who are moderately to severely immunocompromised) may serve as an example. Walensky signed off without asking **#ACIP**.
8. **@US_FDA** doesn't consult its vaccine advisory panel, **#VRBPAC**, on everything. Perhaps this is moving **#ACIP** more towards that model.
The workload on this panel has been crushing over the past couple of years. All these people have jobs where they're needed.
9. So now there are 14 of 15 **#ACIP** members present.
And Peter Marks is up now. Saying it makes sense to boost sooner in the face of Omicron, which has some capacity to evade immunity and requires higher antibody titers to fend off.
10. Sharon Alroy-Preis, from Israel's health ministry, is now presenting data on Israel, which is ahead of the US on administering boosters.
11. There seem to be technical problems. The sound has been cutting in and out. **#ACIP**
12. Alroy-Preis said the data from Israel on myocarditis after Pfizer vaccine is really reassuring for booster shots in young teens. They've given +41,000 doses and have recorded only 2 cases of myocarditis.

attn: **@matthewherper** <https://t.co/c42h6VIBzH>

Booster safety data results: reassuring



Over 41,610 doses administered

Active Surveillance - Myocarditis:

1. 13 Y/O male – three days following booster dose (medical history includes pericarditis in 2019)
2. 15 Y/O male – four days following booster dose

Both were released to follow-up in good condition.

Two non-serious reports:

1. Restriction of movement in vaccinated arm
2. Headache

13. @CDCgov's John Su is presenting data on adverse events reported to VAERS after vaccination in kids 5-11 yo.
<https://t.co/WIU6wEfKET>

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%)			Serious reports† (n=100, 2%)		
Rank	Adverse event (not mutually exclusive)	n (%)	Rank	Adverse event (not mutually exclusive)	n (%)
1	No adverse event	1,183 (27)	1	Fever	29 (29)
2	Product preparation issue	925 (21)	2	Vomiting	21 (21)
3	Incorrect dose administered‡	704 (16)	3	Troponin increased	15 (15)
4	Underdose	326 (7)	4	Chest pain	12 (12)
5	Vomiting	320 (7)	5	Echocardiogram normal	12 (12)
6	Fever	296 (7)	6	Blood test	11 (11)
7	Headache	260 (6)	7	C-reactive protein increased	11 (11)
8	Syncope	256 (6)	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.

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14. Su says of 18.7M doses of Pfizer vaccine given to kids 12-15 yo, there were 265 cases of myocarditis.
<https://t.co/Wt1QcqsuBC>

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children and adolescents ages 12–15 years* (as of Dec 19, 2021)

- 265 reports of myocarditis verified to meet case definition
 - Median age: 14 years (IQR: 13–15 years)
 - Median time to onset: 2 days (IQR: 1–3 days)
 - After dose 1 = 41; after dose 2 = 221
 - 238 (90%) males, 27 (10%) females
 - 251 hospitalized patients (241 discharged home)
 - 224 patients with known outcomes
 - 208 (92%) recovered from symptoms at time of report
 - 16 (8%) mostly reported improved, or resolved, symptoms, but ongoing physical restrictions or still under investigation
 - Doses administered = 18,707,169§

Preliminary reports of myocarditis (N=317)

Under review† (n=19)

Did not meet definition† (n=33)

Met definition† (n=265)

* Reports of children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021

† Awaiting medical records and/or healthcare provider interview; some still processing

‡ Adjudicated after healthcare provider interview and/or medical record review

§Doses administered among children and adolescents ages 12–15 years May 12–Dec 16, 2021

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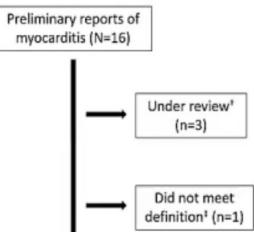
15. Data moving quickly. Bit hard to keep up.

In children aged 5-11 yo, there have been 12 cases of myocarditis out of 8M doses administered.

But it's early days still in vaccination of this age group, Su says. <https://t.co/gaWRpbtvLY>

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children ages 5–11 years* (as of Dec 19, 2021)

- 12 reports of myocarditis verified to meet case definition
 - Median age: 10 years (IQR: 9–11 years)
 - Median time to onset: 2 days (IQR: 2–3 days)
 - After dose 1 = 2; after dose 2 = 9; not reported = 1
 - 8 (67%) males, 4 (33%) females
 - All discharged home
 - 8 recovered from symptoms at time of report
 - 4 still recovering at time of report
 - None reported a vaccination error
- Doses administered = 8,674,378[§]



* Reports of children ages 5–11 years vaccinated Nov 3–Dec 19, 2021

[†] Awaiting medical records and/or healthcare provider interview; some still processing

[‡] Adjudicated after healthcare provider interview and/or medical record review

[§] Doses administered among children ages 5–11 years Nov 4–Dec 16, 2021

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16. Here are the reporting rates for myocarditis among children and teens. <https://t.co/rEITgF6ODe>

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

Age group	Males		Females	
	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.

[§] Estimated background rate of 10–100 myocarditis cases per 100,000 persons per year 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.

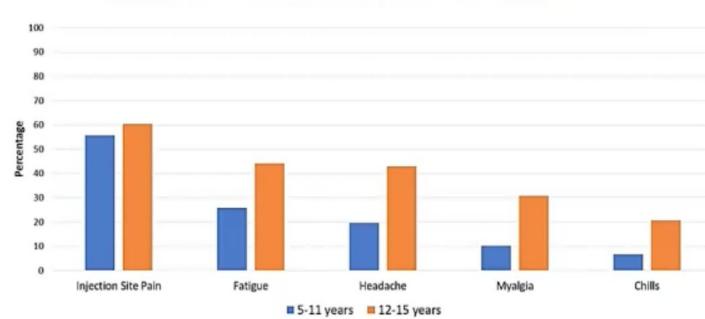
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17. @CDCgov's John Su says most of the cases of myocarditis seen in after vaccination are mild. But he acknowledged that one patient died. In this case the myocarditis was only diagnosed after death & it's not yet clear what caused the death & how/if myocarditis contributed.

18. #ACIP member Sarah Long cautioned against drawing too many conclusion about the rate of myocarditis after boosters (ie that there are few) in children 12 to 15 yo because it's still very early.

19. @CDCgov's Anne Hause is presenting data from CDC's Vsafe program now. Seems like side effects are pretty mild in younger children. <https://t.co/NCR5KI7Ip7>

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*



* The dosage for children ages 5–11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg). Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021.

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20. Ironically, I just got a text from Vsafe asking me to do a weekly check in on how I feel after my booster shot. I can't do it because the links Vsafe has sent me for the past 3 weeks don't work.

21. Nicola Klein of Kaiser Permanente Northern California is now presenting on myocarditis or pericarditis seen in the KPNC system in children aged 12-17 after Pfizer vaccination (doses 1 and 2). <https://t.co/PMIE7MIHvS>

Myocarditis/Pericarditis Chart Review Summary

- Chart review completed through **December 30, 2021** for 53/75 cases aged 12-17 years (22 pending)
 - ✓ Cases identified any time after dose 1 or 2 of Pfizer COVID-19 vaccine
- Initial chart review followed with adjudication by an infectious disease clinician and/or a cardiologist
 - ✓ Confirm incident following vaccination
 - ✓ Meet CDC case definition (myocarditis, pericarditis, or myopericarditis)
 - ✓ Evaluate level of certainty for myocarditis
- **Adjudication confirmed 47/53 (89%) myocarditis/pericarditis cases**
 - ✓ 43 validated cases among 12-17-year-olds, with onset 0-21 days after vaccination
 - ✓ 39 validated cases among 12-17-year-olds, with onset 0-7 days after vaccination

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22. Klein says most of the cases were admitted to hospital; all were later discharged. Most were released in 1-3 days.

<https://t.co/GIDehwWIYB>

Characteristics of Validated Myocarditis/Pericarditis Cases Aged 12-17 Years in the 0-21 Days after Pfizer COVID-19 Vaccine (N=43)

Level of Care and Status	No. (%)
Highest level of care	
Emergency department	4 (9%)
Admitted to hospital (not ICU)	28 (65%)
Admitted to ICU	11 (26%)
Length of hospital stay, median days (range)	2 (0-7)
0 days (same day discharge)	3 (7%)
1 day	12 (28%)
2 days	8 (19%)
3 days	8 (19%)
4 days	5 (12%)
5 days*	4 (9%)
≥6 days*	3 (7%)
Discharged to home	43 (100%)
Follow-up visit noted at the time of chart review	31 (72%)

*All cases with a length of stay ≥5 days were admitted to the ICU

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23. Klein says so far there are no safety signals that have come to light for children 5-11 yo. For teens aged 12-17, the myocarditis risk is almost exclusively after dose 2, when it appeared at a rate of about 70 cases per 1M doses administered. <https://t.co/JWKbBTdclW>

Summary of the Analyses of COVID-19 Vaccine Safety Among 12-17 and 5-11-Year-Olds

- Among 12-17-year-olds, the rate ratio for myocarditis/pericarditis was elevated during days 0-7 after Dose 2.
 - The excess risk was 0.3 cases per million 1st doses.
 - The excess risk was 70 cases per million 2nd doses
- The VSD has administered 431,485 Pfizer doses to children aged 5-11 years.
- In the VSD, there have been no safety signals among 5-11-year-olds.

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24. Klein said there were no deaths recorded among the children in the KPNC system who developed myocarditis following Covid vaccination.

#ACIP is now on a 10-minute break. Reconvening at 2:50 for the public comment session. The meeting is running a little late.

25. I took down a previous post in this thread. I had tweeted that I could not report to Vsafe — the links haven't worked for me recently. It turns out it's because I am out of the US at present. So, my bad, not Vsafe's. Apologies.

26. Getting rid of my earlier tweet required me to zap several and repost them so as not to break the thread. Sorry for the confusion this may cause.

27. #ACIP is back. @CDCgov's Evelyn Twentyman is now presenting on the interim clinical consideration for use of #Covid19 vaccines.

The move to a 5 month interval for the Pfizer booster was motivated by the threat of Omicron, she said.
<https://t.co/hMldEBLvvr>

Pfizer-BioNTech booster 5 months after completion of a primary series of COVID-19 vaccination for those eligible

- People who have completed a primary series *and booster* may be better protected against symptomatic infection with Omicron than those without booster^{1,2}
- Two studies from Israel document the effectiveness of Pfizer-BioNTech booster dose 5 months after primary series against severe illness³ and death⁴ secondary to COVID-19
- 188 million (73%) of U.S. adults aged ≥18 years are fully vaccinated; 38% of those have received a booster⁵
- 4.74 million (57%) of U.S. adolescents* ages 16-17 are fully vaccinated with Pfizer-BioNTech COVID-19 vaccine; 6% have received a booster⁶
- Rare occurrences of myocarditis in people aged ≥16 years following a booster dose at 5 months occurred at less than half the rate observed following 2nd dose⁷

1 Andrews et al *MedRxiv preprint* 14 Dec 2021; 2 Ferguson et al *Report* 49 16 Dec 2021; 3 Bar-On et al *NEJM* 23 Dec 2021; 4 Arbel et al *NEJM* 23 Dec 2021; 5 CDC COVID Data Tracker, 4 Jan 2022; 6 CDC Immunization Data Lake 3 January 2022; 7 Israel Ministry of Health Vaccine Safety Update 15 Dec 2021

* Vaccination data is not available for Idaho

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28. Wow. This must be making things complicated at sites where booster shots are being administered.

3 vaccines, 3 different booster intervals.

To say nothing of the fact that J&J recipients are so far only eligible for a 2nd booster, not a third.

<https://t.co/3GuE4o5baJ>

COVID-19 Vaccine Booster Dose by Primary Series, with Interval

Primary series COVID-19 vaccine product*	Age for vaccine booster (years)	Interval between final primary dose and booster dose	COVID-19 vaccine products that may be given as booster dose*
Pfizer-BioNTech	≥16 (may change to ≥12)	≥5 months	Pfizer-BioNTech Moderna Janssen/J&J
Moderna	≥18	≥6 months	Pfizer-BioNTech Moderna Janssen/J&J
Janssen/J&J	≥18	≥2 months	Pfizer-BioNTech Moderna Janssen/J&J

*Only Pfizer-BioNTech is authorized as primary series or booster dose for people aged ≥18 years. For the prevention of COVID-19 in those aged ≥18 years, mRNA vaccines (Pfizer-BioNTech; Moderna) are preferred over the Janssen/J&J COVID-19 Vaccine for both primary series and booster doses.

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29. #ACIP member Kathy Poehling asks if kids 5-11 who are immunocompromised (& now eligible for a 3rd dose in their primary series) will be eligible for a 4th shot 5 months later, ie a booster.

CDC's Twentyman notes that kids aged 5-11 aren't currently eligible for boosters.

30. #ACIP member Camille Kotton notes that while the discussion has been about myocarditis after vaccination, there should be consideration of the risk of myocarditis after #Covid infection. Kotton runs a clinic for transplant patients & immunocompromised people at Mass General.

31. Kotton said that while everyone is talking about how mild #Omicron infection is relative to earlier variants, she's seeing lots of life-threatening infections in immunocompromised patients, for whom Omicron is a nightmare.

32. @CDCgov's Sara Oliver is now presenting. This is the presentation that will lead to the vote on whether to recommend boosters for children 12-15 yo. <https://t.co/NCaJ4p00Cl>

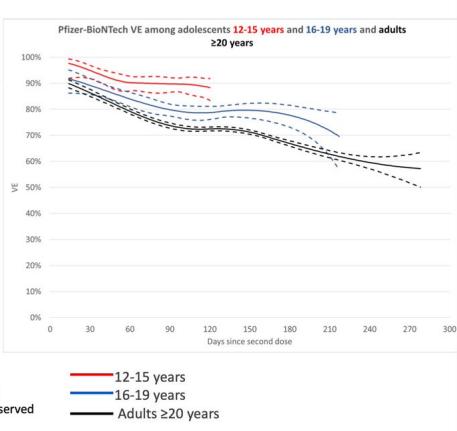
Policy question

- Should individuals **12–15 years of age** receive a Pfizer-BioNTech COVID-19 vaccine booster dose at least **5 months** after completion of the primary series, based on the balance of benefits and risks?

33. Oliver's presentation includes this slide, which shows that as with older groups, vaccine efficacy in 12-15 yrs (red line) declines over time. <https://t.co/G20EXXvIX7>

Comparison of Pfizer-BioNTech VE against symptomatic infection between adolescents 12-15 and 16-19 years and adults ≥20 years and day since the second dose, July 18-October 17

- VE is highest among ages 12-15 years, then 16-19 years, then adults ≥20 years
- VE wanes among all age groups with increasing time since vaccination
- Analysis reflects period with predominance of Delta variant



34. Here's data on myocarditis after Pfizer vaccination from Israel, broken down by age group and by dose. The rates are highest (so far) among dose 2 recipients. <https://t.co/TIVMmBAXuD>

Myocarditis in Israel

Reported after Pfizer-BioNTech COVID-19 vaccine, as of December 15, 2021

	Age (years)	Post-dose 1	Post-dose 2	Post-dose 3	Number of 3rd dose delivered
		Rate per 100,000	Rate per 100,000	Rate per 100,000	
Females	12-15	0	0.6	0	3,156
	16-19	0	0.9	1.6	125,088
	20-24	0.4	2.0	0	171,870
	25-29	0	0.9	0	156,673
	≥30	0.1	0.4	0.1	1,658,035
Males	12-15	0.5	6.6	0	3,178
	16-19	1.2	15.3	6.5	123,355
	20-24	2.1	10.5	4.7	171,235
	25-29	1.1	8.3	0.6	162,360
	≥30	0.3	1.5	1.0	1,554,155

Rates of myocarditis after a third dose likely lower than what is seen after second dose

Data from: [הו מזוןPowerPoint \(www.gov.il\)](https://www.mos.gov.il)

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35. Oliver said a study that will be published later this week in [@CDCgov's MMWR](#) suggests that vaccination is protective against MIS-C — a multi-system inflammatory condition in kids. <https://t.co/9GQ9igNm8R>

Effectiveness of Pfizer-BioNTech COVID-19 vaccine against MIS-C

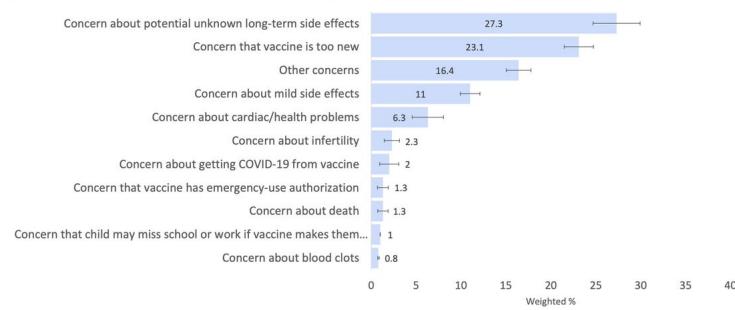
- Using a test-negative case-control design that included 102 MIS-C case-patients and 181 hospitalized controls 12–18 years of age:
 - Vaccine effectiveness of 2-doses of the Pfizer-BioNTech vaccine against MIS-C was **91%** (95% CI = 78%–97%)
 - This estimate was calculated in consideration of children hospitalized a minimum of 28 days after receipt of their 2nd dose
 - 97/102 (95%) of hospitalized children with MIS-C were unvaccinated
 - None of the five vaccinated MIS-C patients required respiratory or cardiovascular life support (invasive mechanical ventilation, vasoactive infusions, or ECMO) compared to 38/97 (39%) of unvaccinated MIS-C patients

Data in press for Friday, Jan 7th, upcoming MMWR

36. Interesting (to me, anyway) to see the reasons parents give when asked to explain their concerns about getting their teens vaccinated against Covid. It's much more vague — too new, I don't know... — than about specific risks. <https://t.co/JxGaBGnUcN>

Parental concern about safety of COVID-19 vaccines in adolescents

NIS-CCM – Oct 31, 2021 – Nov 27, 2021, n=877



CDC Preliminary & Unpublished data. National Immunization Survey. October 31, 2021 – November 27, 2021

37. #ACIP's discussion on whether to recommend that 12-15 yos be offered boosters, and whether the recommendation should be a permissive one (they *may* get one if they want) or a stronger one (they *should*) is coming up soon.

38. #ACIP member Kathy Poehling says her hospital is currently full, with sick kids waiting in the Emergency Dept for up to 18 hours before they can be admitted because of the crush of cases. "I'm leaning towards should." Lynn Bahta said she too is leaning towards should.

39. Pablo Sanchez points out that the recommendation for 16 & 17 yos is a *may*, not *should.* @CDCgov's Oliver says if #ACIP wants to vote *should* for 12-15 yos, then it would have to be for 12-17 yos, to harmonize the recommendations.

40. #ACIP member Sarah Long says given the rising rates of infections among children in the #Omicron wave, she favors a *should* recommendation for boosters for kids 12-15 yo.

But Keipp Talbot says the stress needs to be on getting more unvaxed kids dose 1 & 2.