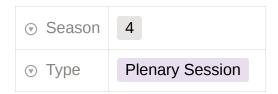
4.38: COVID-19: Boosters for Adults and Teens, Paul Offitt, Testing, Myocarditis, Campus Restrictions



We Discuss:

- Boosters, CDC study, Paul Offitt Quote | Will Science Enter a Death Spiral Post COVID19? [0:38]
- Substack [5:26]
- Testing won't save us [32:14]
- CDC pushes a flawed analysis [39:09]
- Boosting kids 12 to 17? [49:53]
- Is this a pandemic of the unvaccinated? [1:05:12]
- Kaiser Northwest Estimate of Myocarditis/Pericarditis compared to CDC's estimate | A New Study [1:25:52]
- UPDATED DATA: UK Myocarditis Authors Stratify by Sex for Men under 40- Vax vs Virus [1:31:06]
- College Campus Restrictions Have Reached Peak Madness | They will harm mental health [1:42:26]
- NIH Director tried to stop an needed scientific debate | My New STAT News Op-Ed [1:54:10]

Plenary Session 4.38 Show Notes

Overview

Boosters, CDC study, Paul Offitt Quote | Will Science Enter a Death Spiral Post COVID19? [0:38]

- YouTube
 - Watch this video on YouTube
- Paul Offitt
 - Paul Offit is an American pediatrician specializing in infectious diseases, vaccines, immunology, and virology
 - He is an inventor of a rotavirus vaccine
 - Atlantic Piece

Even allowing for this bias in the stats, for the overwhelming majority of people—including boys and young men—the risks of developing myocarditis after a booster shot are minimal. Flynn said that the only patients he would consider advising *not* to take the shot would be those who had developed myocarditis after their second dose. But not all the experts I spoke with agreed. Paul Offit, the director of the Vaccine Education Center at Children's Hospital of Philadelphia, told me that getting boosted would not be worth the risk for the average healthy 17-year-old boy. Offit advised his own son, who is in his 20s, not to get a third dose. Even with Omicron's ability to sidestep some of the protection vaccines provide, Offit said, he believes that his son is well protected against serious illness with two shots, so a third just isn't necessary.

Source

Interpretation

- This is an incredible comment from a man who has dedicated his life and career to the promotion of safe and effective vaccinations.
 - This gentleman is on record as saying that he doesn't think his own son should get a booster
 - That really should raise serious alarm bells across the community

"I think it reflects a broader conversation that needs to be had." -VP

• Substack [5:26]

- Will Science do better post COVID19?
 - The truth is we were not good long before COVID19
 - Science and politics
 - Some issues in science were wed universally with one political party or the other, but COVID-19 has amplified that
- Science is not a set of facts
 - It's a way of thinking about the world
 - Scientific topics must be approached methodically and experimentally to help clarify between different hypotheses that explain observable facts
- Confounding by indication
 - Are Observational, Real-World Studies Suitable to Make Cancer Treatment Recommendations?
 - Banerjee & Prasad; JAMA Network Open

"The only way to separate your hope and your wishful thinking from the true effect is randomization" - VP

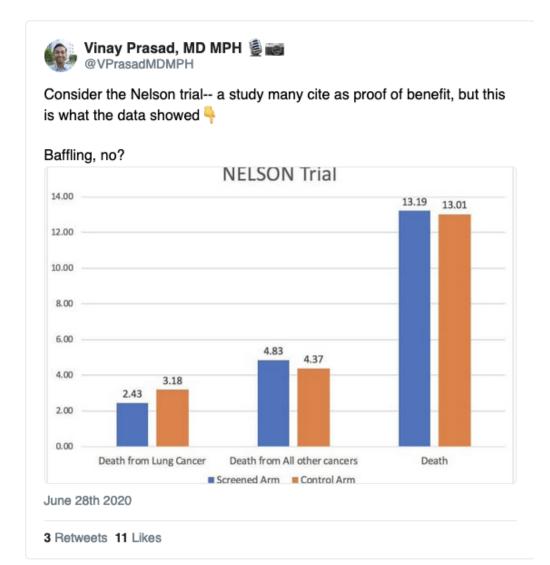
Demonizing people

- A fiasco in the making? As the coronavirus pandemic takes hold, we are making decisions without reliable data
 - By John P.A. Ioannidis; March 17, 2020; STAT
- Stealth ResearchIs Biomedical Innovation Happening Outside the Peer-Reviewed Literature?
 - By John P.A. Ioannidis; JAMA
- Kids



"MedTwitter is completely off the mark in its appraisal of evidence for restrictions in children. The World Health Organization & UNICEF do not advise any child under 6 to be masked, and yet many American scientists believe that they ought to. They don't appreciate that there is no evidence to support such a claim; Instead, they return to the cognitive delusions of reductionism & action bias. Recently, when they finally accepted evidence that cloth masks do not work to slow viral spread in a population; they oddly called for use of more restrictive masks kn95 or equivalent in kids. These also lack any germane randomized trials to show benefit in any context at these ages." - Source

- Cancer Screening
 - Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial (NELSON Trial)
 - de Koning et al., *NEJM*



- Colorectal cancer screening at a younger age: pitfalls in the model-based recommendation of the USPSTF
 - Powell & Prasad, BMJ EBM

Politics

- These COVID issues are all political, but where will it stop? Will blood pressure medicines become political?
 - Politics is a way of creating tribes, and university professors are not immune to these temptations

"I think very few people have actually independently appraised every single study on masking before they

tell you what they think about masking" - VP

- Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review
 - By Ian T. Liu, Vinay Prasad, and Jonathan J. Darrow; CATO Institute
- The need for debate
 - The absence of discussion sponsored by the world's biggest academic research institutes has hampered policymakers' ability to navigate the science
 - One probable explanation is that universities are indebted to their donors, and their backers are participating in the tribal political science game.
 - The more their funders participate in the tribal political science game, the more afraid they are to even hold the discussion.

Testing won't save us [32:14]

- YouTube
 - Watch this video on YouTube
- Substack
 - Testing won't save us
- There are 9 considerations that they are missing when it comes to mass testing:
 - 1. No one has any tests
 - 2. Many tests have limited sensitivity
 - 3. Low pre-test probability
 - 4. The distribution of testing
 - 5. Testing is only helpful if you have the resources to make salutatory choices as a result of the information
 - 6. Risk reduction vs delaying infection

- 7. Harms of testing
- 8. Contact tracing is impossible in most circumstances
- 9. Testing creates anxiety and anchors our mind

CDC pushes a flawed analysis [39:09]

YouTube

Watch this video on YouTube

Substack

o CDC pushes a flawed analysis | Does COVID cause diabetes in kids? | A doctor analyzes an MMWR paper

Morbidity and Mortality Weekly Report (MMWR)

 Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 Years

TABLE 2. Incidence of new diabetes diagnoses by age group and sex — IQVIA PharMetrics Plus and HealthVerity claims databases, United States, March 1, 2020-June 28, 2021*

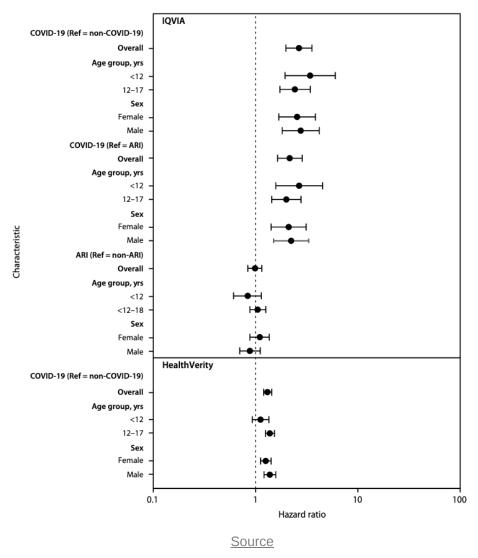
Database/ Characteristic	COVID-19			Non-COVID-19			ARI			Non-ARI		
	No. of DM cases	Person- years	Diabetes incidence [†] (95% CI)	No. of DM cases	Person- years	Diabetes incidence [†] (95% CI)	No. of DM cases	Person- Years	Diabetes incidence [†] (95% CI)	No. of DM cases	Person- years	Diabetes incidence [†] (95% CI)
IQVIA												
Overall	68	21,563	316 (241-391)	132	111,418	118 (98-139)	227	180,436	126 (109-142)	510	407,741	125 (114-136)
Age group, yrs												
0-11	20	7,662	261 (146-375)	30	39,512	76 (49-103)	56	65,810	85 (63-107)	148	147,255	101 (84-117)
12-17	48	13,886	346 (248-443)	102	71,906	142 (114-169)	171	114,626	149 (127-172)	362	260,486	139 (125-153)
Sex												
Female	34	10,849	313 (208-419)	69	56,112	123 (94-152)	125	90,835	138 (113-162)	252	203,209	124 (109-139)
Male	34	10,699	318 (211-425)	63	55,306	114 (86-142)	102	89,601	114 (92-136)	258	204,532	126 (111-142)
HealthVerity												
Overall	1120	280,767	399 (376-423)	853	281,072	304 (284-324)	§	_	_	_	_	_
Age group, yrs												
0-11	240	113,575	211 (186-239)	214	113,642	188 (164-214)	_	_	_	_	_	_
12-17	880	167,192	526 (492 -562)	639	167,430	381 (353-412)	_	_	_	_	_	_
Sex												
Female	602	140,844	427 (394-462)	478	141,018	339 (310-370)	_	_	_	_	_	_
Male	518	139,914	370 (339-403)	375	140,045	268 (242-296)	_	_	_	_	_	_

Abbreviations: ARI = acute respiratory infection; DM = diabetes mellitus, ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification. Groups in IQVIA included patients aged <18 years with or without COVID-19 (COVID-19; non-COVID-19, respectively) and patients aged <18 years with or without ARI (ARI; non-ARI, respectively), during March 1, 2020–February 26, 2021, determined using presence or absence of ICD-10-CM codes for COVID-19 and ARI. The non-COVID-19 group was matched 5:1 to the COVID-19 group by age, sex, and month of encounter. The ARI group was matched 5:1 to the COVID-19 group by age and sex, and a random encounter date was selected. The non-ARI group was matched 2:1 to the ARI group by age and sex, and a random encounter date was selected. In HealthVerity, among patients aged <18 years, those with COVID-19 (COVID), determined by ICD-10-CM code or by a positive SARS-CoV-2 test result during March 1, 2020-June 28, 2021, were matched 1:1 to those with a negative SARS-CoV-2 test result (non-COVID-19) during the same period by age, sex, and month of encounter.

Source

[†] Cases per 100,000 person-years. § Dashes indicate no prepandemic data available for ARI and non-ARI in the HealthVerity database.

FIGURE. Hazard ratio for the association between COVID-19 or acute respiratory infection and new diabetes diagnosis among patients aged <18 years, by age group and sex — IQVIA PharMetrics Plus and HealthVerity claims databases,* United States, March 1, 2020–June 28, 2021 $^{\uparrow,5,1}$



Issues

- The whole analysis hinges on the idea that age-sex matched kids without covid should be comparable to the kids who got covid in terms of risk of diabetes
- 2. They don't have the true denominator
- 3. Kids who seek medical care for COVID19 may get more blood tests than those without COVID19, and perhaps more than those with other respiratory viruses in yesteryear

- 4. The HealthVerity database is particularly odd, as the kids who get tested but test negative might be very dissimilar from those with COVID19
- 5. Lastly, the CDC uses this study to push vaccination

Boosting kids 12 to 17? [49:53]

- YouTube
 - Watch this video on YouTube
- The Dialogue
 - This is for the cohort of 12 to 17 year olds who already have had two doses of the Pfizer product five months after the second dose
 - Some argue that you must think deeply about society; what is the net advantage of having a larger population, especially a larger population of teenagers, on pandemic dynamics?
 - It's difficult to predict the effect of having a booster recommendation like this for the individual in the nursing home on the third party

"No one knows what the impact of these decisions will have on the broader pandemic trajectory" - VP

- We don't know what this booster policy may mean for the broader population dynamics
 - For that reason, we generally don't make broad sweeping medical decisions for individuals based on what it might mean for other people when the models and assumptions are speculative
 - When it comes to regulatory science and vaccine science, you need to operate with incredible caution
 - You need to also preserve long term credibility and institutional credibility

Is this a pandemic of the unvaccinated? [1:05:12]

YouTube

- Watch this video on YouTube
- Is this a pandemic of the unvaccinated?
 - We know very clearly, that there are things that you can do to lower your risk of severe outcomes for SARS-CoV-2 (e.g., vaccination)
 - What about symptomatic disease?
 - Omicron has changed this dynamic entirely
 - However, in regard to hospitalization and death, the status of being unvaccinated is a massive risk factor
 - But is this still a pandemic of the unvaccinated?
 - As Omicron continues to spread, the unvaccinated individuals who survive and develop natural immunity will become more resilient to future strains

"So if you think about it as the issue is, 'the average person out there is unvaccinated → that's the problem.'

That's probably a misguided way. It's the vulnerable people who even when they get vaccinated, they may be very vulnerable next year" - VP

• They're the individuals you want to concentrate on, and it's not meant to be disparaging; it's not anyone's fault that people contract COVID-19

5 versus 10 days of quarantine [1:13:09]

- YouTube
 - Watch this video on YouTube
- Thoughts

"If I don't know that masking kids in school lowers the spread of SARS-CoV-2, I would have ran a cluster randomized control trial" - VP

- It is not intuitive.
 - It's not clear that five days is going to be much worse than 10 days, etc.

Principles

- 1. When you have a wide scale home testing, you're going to get a lot of positive results
 - a. You want to strike a balance between a sensible precaution, and also having an ample labor force
 - i. If you go from 10 days to five days, you're going to free up a lot of people sooner
- 2. Testing for the virus is not sort of a homogenous thing
 - a. The distribution of testing is not egalitarian, it's not fair, and may not even be rational
- 3. By shrinking the period of time, not only do you have an impact on a person's ability to propagate the virus, you're also changing the incentive to seek testing in the first place

"Some of our draconian mandates that make us feel good about that we're doing something and sending a message may actually erode health outcomes more broadly"- VP

Kaiser Northwest Estimate of Myocarditis/Pericarditis compared to CDC's estimate | A New Study [1:25:52]

- YouTube
 - Watch this video on YouTube
- Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods
 - Sharff et al., medrxiv
- Methods

Methods:

We assembled a cohort 12 to 39 years old patients, insured by Kaiser Permanente Northwest, who received at least one dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) between December 2020 and October 2021. We followed them for up to 30 days after their second dose of an mRNA vaccine to identify encounters for myocarditis, pericarditis or myopericarditis. We compared two identification methods: A method that searched all encounter diagnoses using a brief text description (e.g., ICD-10-CM code I40.9 is defined as 'acute myocarditis, unspecified'). We searched the text description of all inpatient or outpatient encounter diagnoses (in any position) for "myocarditis" or "pericarditis." The other method was developed by the Centers for Disease Control and Prevention's Vaccine Safety Datalink (VSD), which searched for emergency department visits or hospitalizations with a select set of discharge ICD-10-CM diagnosis codes. For both methods, two physicians independently reviewed the identified patient records and classified them as confirmed, probable or not cases using the CDC's case definition.

Source

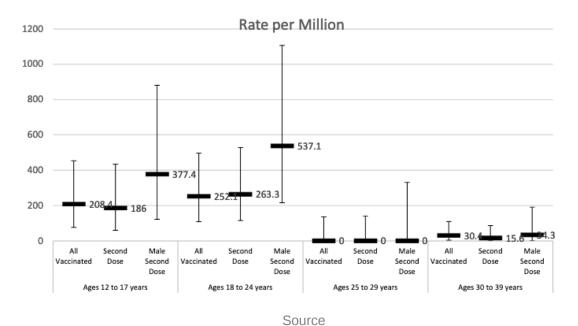
 The author's strength is that she is employing an electronic medical record search that extends beyond the ICD 10 codes

Takeaways

- 1. What does this have to do with the CDC method?
 - a. The CDC is missing an ICD code
 - b. Some people were hospitalized outside of surveillance center sites
 - c. These bills are still being processed even 30 days after immunization, so there may be an increase from all three sources together

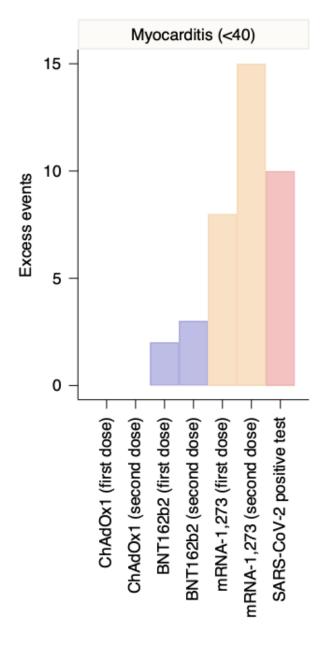
Results

Figure 1: Rate per Million

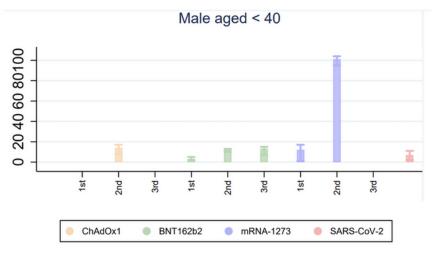


UPDATED DATA: UK Myocarditis Authors Stratify by Sex for Men under 40- Vax vs Virus [1:31:06]

- YouTube
 - Watch this video on YouTube
- Substack
 - UK Now Reports Myocarditis stratified by Age & Sex After Vaccine Or Sars-cov 2
- Nature Medicine Paper
 - Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection
 - Patone et al., *Nature Medicine*



Source



Source

Takeaways

- We need to take an approach in line with a sensible middle ground
 - It entails maximizing the advantages of vaccination products while attempting to limit the drawbacks or damage

College Campus Restrictions Have Reached Peak Madness | They will harm mental health [1:42:26]

YouTube

Watch this video on YouTube

Substack

• What we are doing to college kids is total madness

Overview

- When it comes to COVID19, there are only 3 things any of us can do:
 - 1. We can lower the risk of bad outcomes when we encounter the virus.
 - 2. We can delay the time to meet the virus
 - 3. We can engage in theater which does not delay the time to meet the virus

Categories

Category 1 (risk reduction)

- Category 2 (delay time to virus)
- Category 3 (useless, virtue signaling theater)

Coverage



Emerson College in Boston has issued a "stay in room directive" for returning students next month -- the same students already required to get "boosted" and tested twice a week. Sounds like fun

hat can I expect on campus between January 3 and

The campus will operate in a "stay in room directive" through January 18. This means students are asked to only leave their residence halls or place of residence for testing, meals, medical appointments, necessary employment, or to get mail. Students should avoid any large gatherings and not leave campus or their residence except for those situations listed above.

December 23rd 2021

574 Retweets 2,523 Likes

Source

NIH Director tried to stop an needed scientific debate | My New STAT News Op-Ed [1:54:10]

YouTube

Watch this video on YouTube

STAT

At a time when the U.S. needed Covid-19 dialogue between scientists, Francis
 Collins moved to shut it down

• Great Barrington Declaration



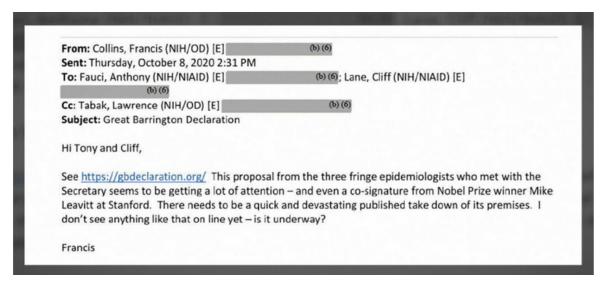
"As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection."

• John Snow Memorandum



"We are holding an emergency summit to discuss the risks posed to children as schools re-open at high rates of community transmission, with almost no mitigations in England, and most children being unvaccinated as they return. At the summit we will discuss the current schools policy in England, and the urgent steps we need to take to protect our children and communities."

- Recovery Trial
- Email



Source

• Other people mentioned:

- Venkatesh Murthy, MD
- Dr. Jeanne Ann Noble
- Gil Welch, MD
- Barry Kramer
- Walid F. Gellad, MD, MPH
- o Cody Meissner, MD
- Rochelle Walensky
- Stefan Baral

Plenary Session is a podcast on medicine, oncology, & health policy.

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