ב"סד

חיסוני ילדים - שימוע ציבורי

DRUG DEVELOPMENT and REGULATORY PERSPECTIVE

1. **Vaccine data unverified by FDA**
2. **Changed untested formulation for everyone**
3. **Flawed risk-benefit analysis off by 26 times**
4. **Unevaluated radiation-like risk of cancer**
5. **Emerging vaccine escape variants**

Discarded standard drug development safeguards
Abandoned regulatory standards`
Little support for continued vaccination, none for mandates

David Wiseman, PhD, MRPharmS

ד"ר דוד וויזמן

Thank you to many collaborators

י"ז בסלו November 21 2021 Synechion@aol.com Dallas, TX, USA

Background

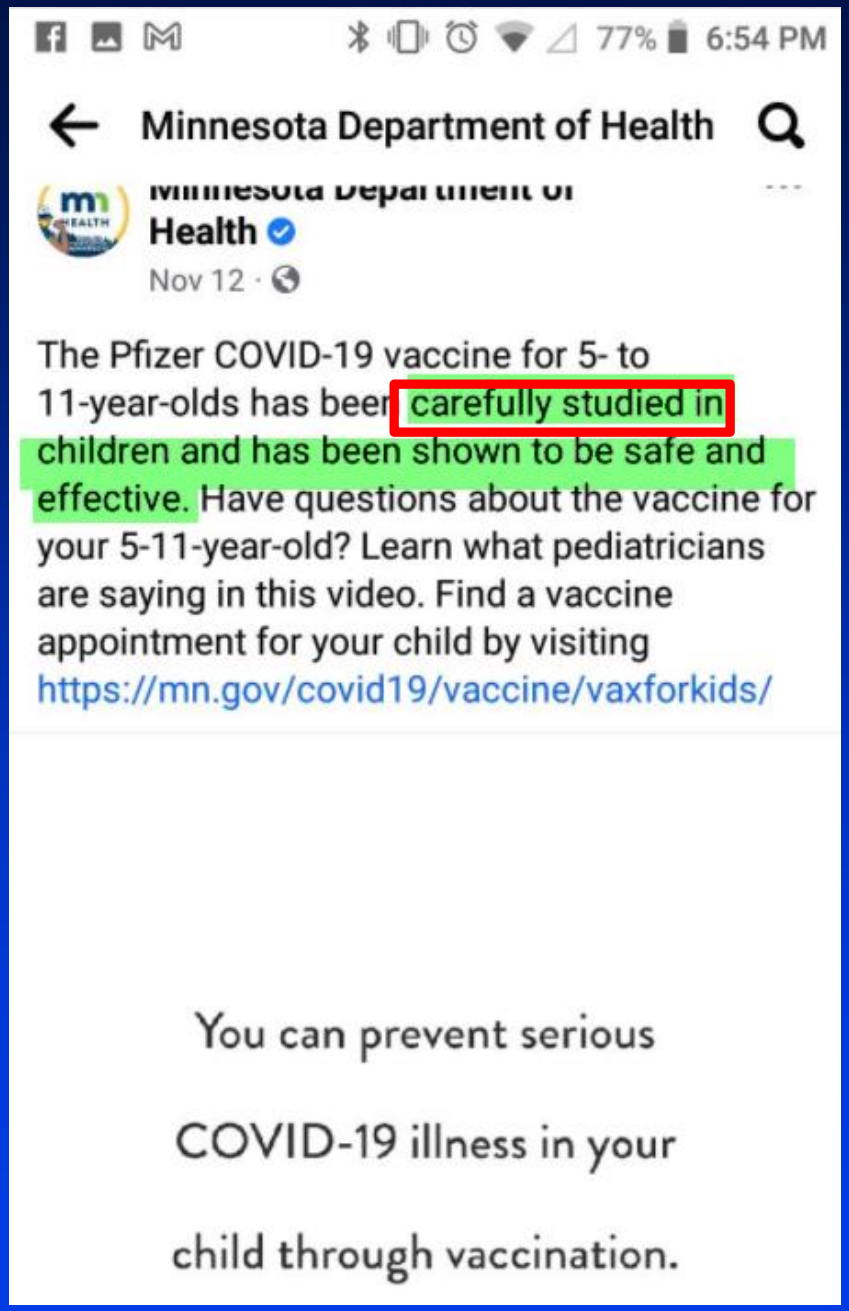
- PhD Research Bioscientist with extensive experience in medical product development in a regulated environment.
- Background in pharmacy, pharmacology, experimental pathology.
- One of top research scientists at J&J - headed a research program overseeing preclinical and clinical research, FDA submissions.
- Founded Synechion, Inc. 1996 – R&D consulting - medical product development
- Journal peer reviewer.
- Covid work includes hydroxychloroquine and ivermectin
- Numerous oral and written submissions to FDA, CDC and NIH.
- Contributor and advisor to Trial Site News

Disclosures & Acknowledgements

B

- Synechion has received consulting and research contract fees from many companies outside the area of Covid-19, including from Johnson & Johnson.
- Supports use under highest safety standards of conventional vaccines and mRNA technology.
- Thank you to my many collaborators
- Advisor and contributor to Trial Site News
- The generous support of Mr. Steve Kirsch and MetaPrep Education Group for work related to Covid-19, is greatly appreciated.

This presentation is not intended to provide medical advice.
Patients must always consult with their medical doctor before starting or changing any medical treatment.


77% 6:54 PM
Minnesota Department of Health
Health
Nov 12 ·
The Pfizer COVID-19 vaccine for 5- to 11-year-olds has been carefully studied in children and has been shown to be safe and effective. Have questions about the vaccine for your 5-11-year-old? Learn what pediatricians are saying in this video. Find a vaccine appointment for your child by visiting https://mn.gov/covid19/vaccine/vaxforkids/
You can prevent serious COVID-19 illness in your child through vaccination.

National Library of Medicine
National Center for Biotechnology Information

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PubMed.gov

((("coronavirus"[MeSH Terms] OR "coronavirus"[All Fields]) AND 2019/12[PDA

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Nov 21

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MY NCBI FILTERS

199,483 results

199,483

Page 1 of 998

RESULTS BY YEAR

1 Alpha variant **SARS-CoV-2** infection: How it all starts.

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

HOME | ABOUT

20,000

medRxiv is receiving many new papers on coronavirus SARS-CoV-2. A reminder: these are preliminary reports that have not be practice/health-related behavior, or be reported in news media as established information.

COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

20,000 Articles (15,401 medRxiv, 4,599 bioRxiv)

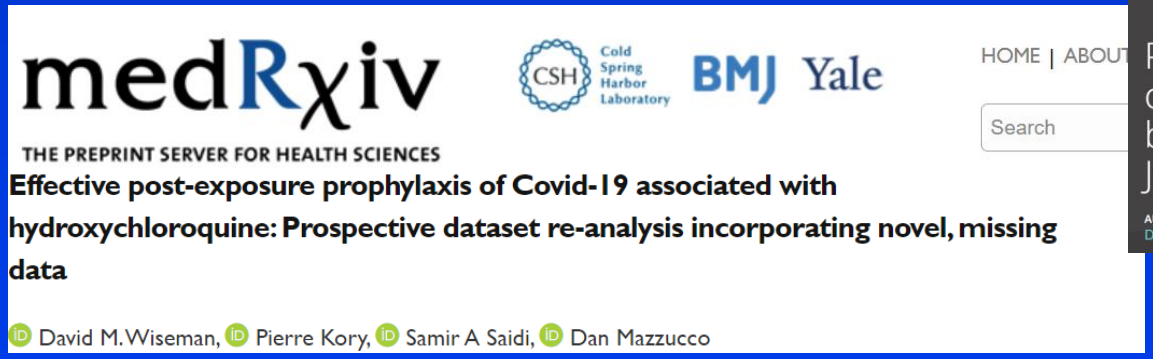
Reversal of two studies shaping policy

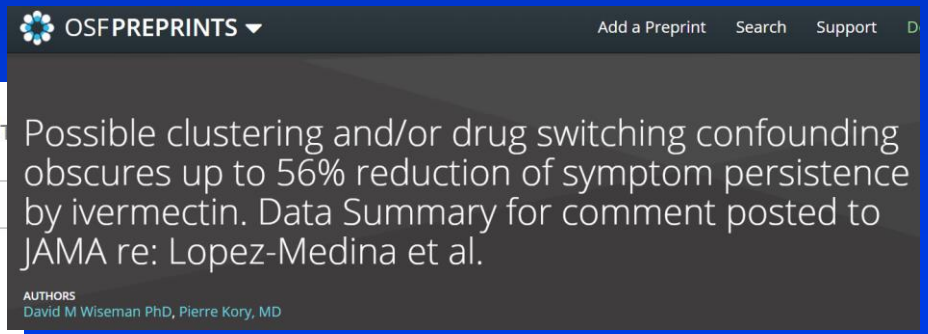
Hydroxychloroquine - PEP (NEJM, 2020)

- Cited by FDA to revoke EUA
- Actual shipping time not considered, missing data obtained from authors.
- **Correction yields 42% reduction** in C19 given <= 3 days after exposure (p=0.044)
- NEJM refuses to print our correction
- NIH failed to correct guideline
- Online smear campaign in aliased comments

Ivermectin - Early Tx (JAMA, 2021)

- Cited by WHO in their IVM policy
- Likely active/ placebo switching in households with >1 subject
- **Adjustment yields 56% reduction** in residual C19 (p=0.033)
- JAMA refuses to post AS AN ONLINE comment and to request additional data.





Bottom Line תכלס תכלית

- Any decision must consider FDA's faulty analysis
  - Whatever the risks of Covid in children, FDA has overestimated them by 26x
  - Overestimate of benefit – we find up to 4x **more risk**
  - Failure to verify data and check statistical problems
- Pfizer's efficacy could be ZERO because of study errors
- No severe cases were found in their study
- The safety data too small, too short and incomplete
- No cancer studies were done
- The formula being used is not the one that was tested,
- No safety or efficacy testing was done on the new formula.
- Its safety could be worse

Main claimed reason for vaccine

- Although small, there are risks of MIS-C/PIMS - conflicting estimates, observational studies, many assumptions
- Reduces transmission by children

  - no evidence for reduction of transmission

  - we consider risks to the individual

  - data suggest risk to children from vaccinated

Even if we accept this argument, the calculations STILL do not favor vaccination
The burden of proof is on the company to show the vaccine is safe and effective

המוציא מחברו עליו הראיה

Flawed FDA Benefit:Risk Analysis

F

FDA: 6.6 x (scenario #6) Vaccine Benefit

- FDA only included myocarditis
- Serious non-myocarditis 1.86 x
- Underestimate of myocarditis 2x
- Waning efficacy 1.05

26x fold error

- No natural immunity (42%) 1.72x
- Overestimate cases 2.1-2.7 (2.25-2.9)
- Improperly modeled waves 1.41x
- Hospital WITH not FOR Covid 1.25x (2.2)

Correct: 4x Vaccine risk

Includes:
FDA risks of MISC/ PIMS
Update CDC Pfizer data
Not included:
Scenario 4 error 1.4x
Lower efficacy due to bias

Does not include:
•underreporting non-myocarditis
•higher risk in new formula

Benefit-Risk Supports a Revision to the EUA for BNT162b2 to Include 5 to <12 Years of Age

Model-Predicted Benefit-Risk Outcomes Based on FDA Scenario 4 and CDC Risk Scenarios per One Million Fully Vaccinated Children Ages 5 to <12 Years Over 6 Months

(Assumes a rate of myocarditis in 5 to <12 year-olds equal to that of 12-15 yo which may be an overestimate)

	Benefits COVID-19 Outcomes Prevented				Risks Excess Myocarditis Cases		
Model Scenario*	**Cases[1]**	**Hosp.[1]**	**ICU[1]**	**Deaths[1]**	**VAERS[2]**	**VSD[3]**	**Optum[1]**
Males and Females – FDA Scenario 4 *VE=90% against cases VE=100% against hosp.*	**58,851**	**241**	**77**	**1**	**22**	**57**	**106**

Shows VAERS underreporting by 4.8x, and use of different database by FDA

*FDA scenario assumes the COVID-19 incidence as of September 11, 2021.

1. FDA Briefing Document. EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age. VRBPAC October 26, 2021.
2. Su JR. Myopericarditis following COVID-19 vaccination: Updates from the Vaccine Adverse Event Reporting System (VAERS); Slide 7 (7-day risk period post Dose 2). ACIP Meeting October 21, 2021. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf
3. Klein N. Myocarditis Analyses in the Vaccine Safety Datalink: Rapid Cycle Analyses and "Head-to-Head" Product Comparisons; Slide 18 (12-17 year olds; 21-day risk period post Dose 2). ACIP Meeting October 21, 2021 Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/08-COVID-Klein-508.pdf

CC-32

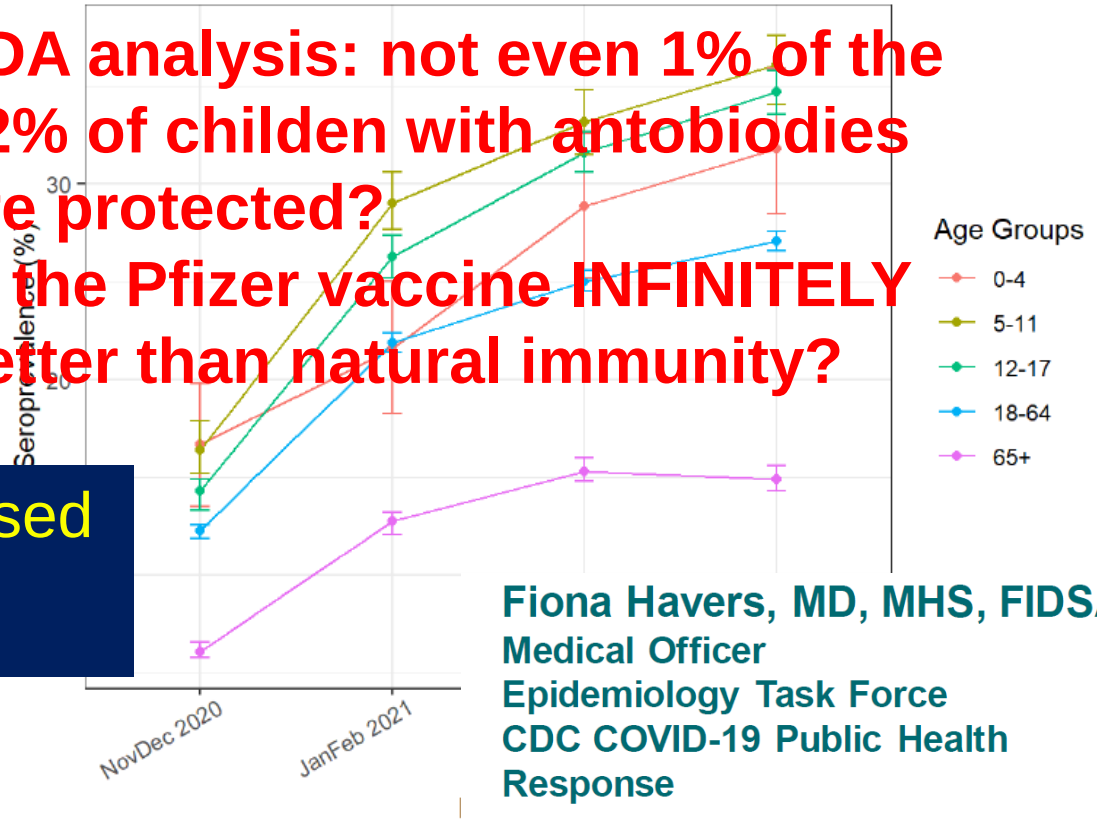
Slide 32 from Pfizer's Dr. Gruber (arrows added) VRBPAC Oct 26

Weighted SARS-CoV-2 Infection-Induced Seroprevalence: 15 U.S. jurisdictions by Age Group, Nov 2020–Jun 2021

- Children consistently have higher seroprevalence estimates than adults
- Age 5–11 have the highest seroprevalence, but confidence intervals overlap with other pediatric age groups
- Age 5–11 seroprevalence increased from 13% in Nov–Dec 2020 to 42% in
  - Ages 0–17 years: Median **6.2** (Range: 4.7–8.9)

Age 5–11 seroprevalence increased […] 42% in May-June 2021

FDA analysis: not even 1% of the 42% of childen with antobiodies are protected?
Is the Pfizer vaccine INFINITELY better than natural immunity?



Fiona Havers, MD, MHS, FIDSA
Medical Officer
Epidemiology Task Force
CDC COVID-19 Public Health Response

* Restricted to jurisdictions that provided age data for >90% of individual cases: CA, IL, NV, NJ, NC

VRBPAC Meeting
October 26, 2021

CDC: post C19 natural immunity: "*information not collected*" on reinfection of C19 recoverees

https://aaronsiri.substack.com/p/cdc-admits-crushing-rights-of-naturally

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

"Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that this information is not collected.

2nd Letter Subject: Final Response Letter

CDC Failed Mission

CDC works … to protect America from health, … threats,
To accomplish our mission, CDC conducts critical science

cdc.gov/about/organization/mission.htm

trialsitenews.com/an-open-letter-to-dr-grace-lee-cdc-acip-chairperson-on-transparency/

TrialSiteNews

News Opinion Editorial Video Community About Us

An Open Letter to Dr. Grace Lee, CDC ACIP Chairperson on Transparency

Wiseman Ph.D., M.R.Pharm.S.
November 19, 2021

5 Comments

Former top FDA official: *The FDA failed In Its duty to ensure vaccines Are safe for children*

- Was professor of pharmacology and biotechnology at the Yale University School of Medicine,
- Was FDA medical officer
- Appointed by White House to FDA's Senior Executive Leadership Team as senior advisor to the FDA Commissioner for drug safety, drug epidemiology, science policy, and regulatory affairs.

מחקר יעילות מבוסס רק על רמת נוגדנים וריאנט דלתה מול זן USA_WA1/2020

I

No immune correlate of protection

Exploratory Analysis: Geometric Mean Titer (Delta Variant and USA_WA1/2020 Strain)

FDA

Participants Without Evidence of Infection up to 1 Month After Dose 2, Phase 2/3 – 5-11 Years of Age, Subset of Evaluable Immunogenicity Population

Assay* Target	Time Point	BNT162b2 10 µg N=34 GMT (95% CI)	Placebo N=4 GMT (95% CI)
USA_WA1/2020	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
USA_WA1/2020	1 month post-Dose 2	365.3 (279.0, 478.4)	10.0 (10.0, 10.0)
B.1.617.2 (Delta)	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
B.1.617.2 (Delta)	1 month post-Dose 2	294.0 (214.6, 405.3)	10.0 (10.0, 10.0)

*SARS-CoV-2 plaque-reduction neutralization (PRNT) assay

Analysis not verified by FDA

המחקר טרם עבר אימות; הניתוח לא אושר על ידי ה-FDA

Assay not yet validated; Analyses not verified by FDA

ניתוח יעילות חיסון ילדים 5-11

Serious potential bias: observer but not double blinded
Disproportionate exclusion/deviations in vaccine group

Supportive Efficacy Analysis
(Data accrued through October 8, 2021)

FDA

No severe cases or deaths

(5-11 Years of Age Evaluable Efficacy Population)

	BNT162b2 10 µg (N[a]=1305) n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=663) n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2	3 0.322 (1273)	16 0.15 (637)	**90.7 (67.7, 98.3)**

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.

הניתוח לא אושר על ידי ה-FDA

Analyses not verified by FDA

Analysis not verified by FDA

Would you put your child in this car seat?

G

LABEL ON SEAT

This car seat is 91% effective at reducing children's automobile injuries.

However the government have not checked our testing.

The testing we did was with a different car seat from the one we are selling you.

The government agree with us that the changes are minor, even though we did no crash dummy tests.

Generic car seat for illustration only, not intended to identify any particular brand

If you would not put your child in this seat why would you vaccinate your children with a vaccine whose performance has not been checked by FDA??

Using Pfizer data we find FDA overestimated one component of benefit by up to 2.7 times (revised 2.9)

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	Prevented COVID-19 Cases	Prevented COVID-19 Hospitalizations	Prevented COVID-19 ICU Admissions	Prevented COVID-19 Deaths	Excess Myocarditis Cases	Excess Myocarditis Hospitalizations	Excess Myocarditis ICU Admissions	Excess Myocarditis Deaths
Males & Females	**Overestimate x**					**Largest Benefit-Risk = 192/29=6.6**		
Scenario 1	45,773	2.1 192	62	1	106	58	34	0
Scenario 2	54,345	2.5 250	80	1	[illegible]	58	34	0
Scenario 3	2,639	- 21	7	0	106	58	34	0
Scenario 4	58,851	2.7 241	77	1	106	58	34	0
Scenario 5	45,773	2.1 [illegible]	62	3	106	[illegible]	34	0
Scenario 6	45,773	2.1 192	62	1	53	29	17	0

Cases prevented/million = [(16/663) – (3/1305)] * 1,000,000 = 21833

FDA OVERESTIMATE prevented cases up to 58,851/21,833 = 2.7x

	BNT162b2 30 µg (N=1305) n1[a] Surveillance Time[c] (n2[d])	Placebo (N[a]=663) n[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (95% CI)
First COVID-19 occurrence from 7 days after Dose 2	3 0.322 (1273)	16 0.159 (637)	**90.7 (67.7, 98**

CDC revision 11/2/21 = 3/1461 16/714 = 2.25 to 2.9X

Were the studies double-blinded?

Does it matter?

medical-dictionary.thefreedictionary.com › double

Double-blind study | definition of double-blind study by ...

dou·ble-blind stud·y. **a study in which neither the patients, the experimenter, nor any other assessor of the results, knows which participants are subject to which procedure, thus hel**

Administrator non-blinding could bias protocol exclusion decisions

The study staff […] dispensing, preparing, and **administering** the study interventions will be **unblinded**. All other study and site personnel, including the investigator, investigator staff, and participants, will be blinded […] Because BNT162b2 and placebo are different in physical appearance, the study intervention syringes will be administered in a manner that prevents the study participants from identifying the study intervention type based on its appearance. […] Contact between the unblinded dispenser and study participants and unblinded administrator and study participants **should be kept to a minimum**.

007 children's protocol (similar for 001 >12)

Table 12. Efficacy Populations – Phase 2/3 Initial Enrollment Group – 5 to <12 Years of Age

Children's 007 Study

	Vaccine Group (as Randomized)		
	NT162b2 10 µg n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Participants without evidei			
Participants excluded fron			
Reason for exclusion[c]			
Did not receive 2 vaccina			
Evaluable efficacy populati			
Participants without evidei			
Participants excluded fron			
Reason for exclusion[c]			
Did not receive all vaccin			
Dose 2			
within the predefined window (19-42 days after Dose 1)			
Had other important protocol deviations on or prior to 7 days after Dose 2	47 (3.1)	4 (0.5)	51 (2.2)

a. n = Number of participants with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Participants may have been excluded for more than 1 reason.

Why is there an imbalance for exclusions? Could significant bias from non-blinding of administrator mean efficacy is really ZERO?

Participants without evidei			
Participants excluded fron	Reason for exclusion[c]		
Reason for exclusion[c]			
Did not receive 2 vaccina	Did not receive all vaccinations as randomized or did not receive Dose 2	31 (2.0)	18 (2.4)
Evaluable efficacy populati			
Participants without evidei	within the predefined window (19-42 days after Dose 1)		
Participants excluded fron			
Reason for exclusion[c]	Had other important protocol deviations on or prior to 7 days after Dose 2	47 (3.1	4 (0.5)
Did not receive all vaccin			

VACCINES AND RELATED BIOLOGICAL PRODUCTS

ADVISORY COMMITTEE BRIEFING DOCUMENT

Meeting Date: 26 October 2021

fda.gov/media/153409/download

Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age

Emmanuel B. Walter, M.D.
Elizabeth D. Barnett, M.D.
B.S., D.C.H., M.D., et al., for the C4591007 Clinical Trial Group

No mention of blinding in article text

The NEW ENGLAND JOURNAL of MEDICINE

an ongoing phase 2–3 randomized trial

Metrics November 9, 2021
DOI: 10.1056/NEJMoa2116298

PF-07302048 (BNT162B2 RNA-Based COVID-19 Vaccine)
Protocol C4591007
Final Protocol, 05 February 2021

Except appended protocol: OBSERVER BLINDED

"intervention will be administered by an unblinded administrator"

A PHASE 1, OPEN-LABEL DOSE-FINDING STUDY TO EVALUATE SAFETY, TOLERABILITY, AND IMMUNOGENICITY AND PHASE 2/3 PLACEBO-CONTROLLED, OBSERVER-BLINDED SAFETY, TOLERABILITY, AND IMMUNOGENICITY STUDY OF A SARS-COV-2 RNA VACCINE

Study intervention should be administered intramuscularly into the deltoid muscle, preferably of the nondominant arm. Study intervention will be administered by an **unblinded** administrator.

FDA thinks it is double-blinded

FDA briefing document 10/26/21 p4

mRNA/per dose, administered 3 weeks apart. This EUA request initially included safety data from 1,518 BNT162b2 recipients and 750 placebo (saline) recipients 5-11 years of age who are enrolled in the Phase 2/3 portion (Cohort 1) of an ongoing randomized, double-blinded, placebo-controlled clinical trial C4591007. Among Cohort 1 participants, 95.1% had safety follow-up ≥2

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

Stephen J. Thomas, M.D., Edson D. Moreira, Jr., M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Pérez Marc, M.D., Fernando P. Polack, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., et al., for the C4591001 Clinical Trial

The NEW ENGLAND JOURNAL of MEDICINE

Pivotal adult 001 study is "observer blinded"

FDA thought it was double-blinded

...oing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we

The EUA request includes safety and efficacy data fro... double-blinded and placebo-controlled trial of BNT162b2 in approximately 44,000 participants. ...eive two 30-µg doses, at 21 days apart, of ...2 or placebo. The trial end points were

FDA Briefing document VRBPAC 12/10/20

FDA still thinks it is double-blinded

4.3 Effectiveness and safety of a 2-dose primary series of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12-15 years of age

On May 10, 2021, FDA authorized the use of Pfizer-BioNTech COVID-19 Vaccine in individuals 12-15 years of age based on safety and effectiveness data from an ongoing Phase 2/3 randomized, double-blinded and placebo-controlled trial of the Pfizer-BioNTech COVID-19 Vaccine in 2,260 participants 12-15 years of age.

FDA Briefing document VRBPAC Oct 26

So does Pfizer sometimes:

"double-blinded placebo follow-up,"
p41 re: 001 study - Oct 26 VRBPAC briefing document

Similar potential statistical bias in adult 001 study - administrator non-blinding: much lower efficacy?

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 D Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection - Evaluable Eff Population

Pre-specified Age Group	BNT162b2 N[a] = 18198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a] =18325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All participants	8	162	95.0
	2.214 (17411)	2.222 (17511)	(90.3, 97.6)[e]

fda.gov/media/144245/download

Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	

Vaccines and Related Biological Products Advisory Committee Meeting
December 10, 2020

FDA Briefing Document

Pfizer-BioNTech COVID-19 Vaccine

s Randomized

	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
	21823 (100.0)	21828 (100.0)	43651 (100.0)
	21768 (99.7)	21783 (99.8)	43551 (99.8)
ose	20314 (93.1)	20296 (93.0)	40610 (93.0)
cy	55 (0.3)	45 (0.2)	100 (0.2)
	54 (0.2)	45 (0.2)	99 (0.2)
	1 (0.0)	0	1 (0.0)
	20566 (94.2)	20536 (94.1)	41102 (94.2)
Participants without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Participants without evidence of infection prior to 14	18678 (85.6)	18563 (85.0)	37241 (85.3)
			49 (5.8)
			48 (5.8)
			1 (0.0)
			7 (92.3)
			6 (92.3)
			74 (7.7)
Participants excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

[a]n = Number of participants with the specified characteristic.

Allegations of serious errors and scientific misconduct in related Pfizer vaccine study: British Medical Journal Nov 2 2021

FEATURE

Check for updates

Madrid, Spain
Cite this as: *BMJ* 2021;375:n2635
http://dx.doi.org/10.1136/bmj.n2635
Published: 2 November 2021

BMJ INVESTIGATION

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight. **Paul D Thacker**

- Potential unblinding
- Data integrity issues and falsification
- Poor follow up for adverse events
- Unreported protocol deviations
- Vaccines not being stored at proper temperatures
- Targeting of Ventavia staff for reporting problems

SAFETY DATA – Children 5-11

Small number of patients
Very short follow up

- ~1,500 vaccine recipients - > 2 months follow up
- ~ 1,600 vaccine recipients - 2.4 weeks follow-up

Missing Data

Study for subclinical myocarditis using troponin levels

BNT162b2
VRBPAC Briefing Document

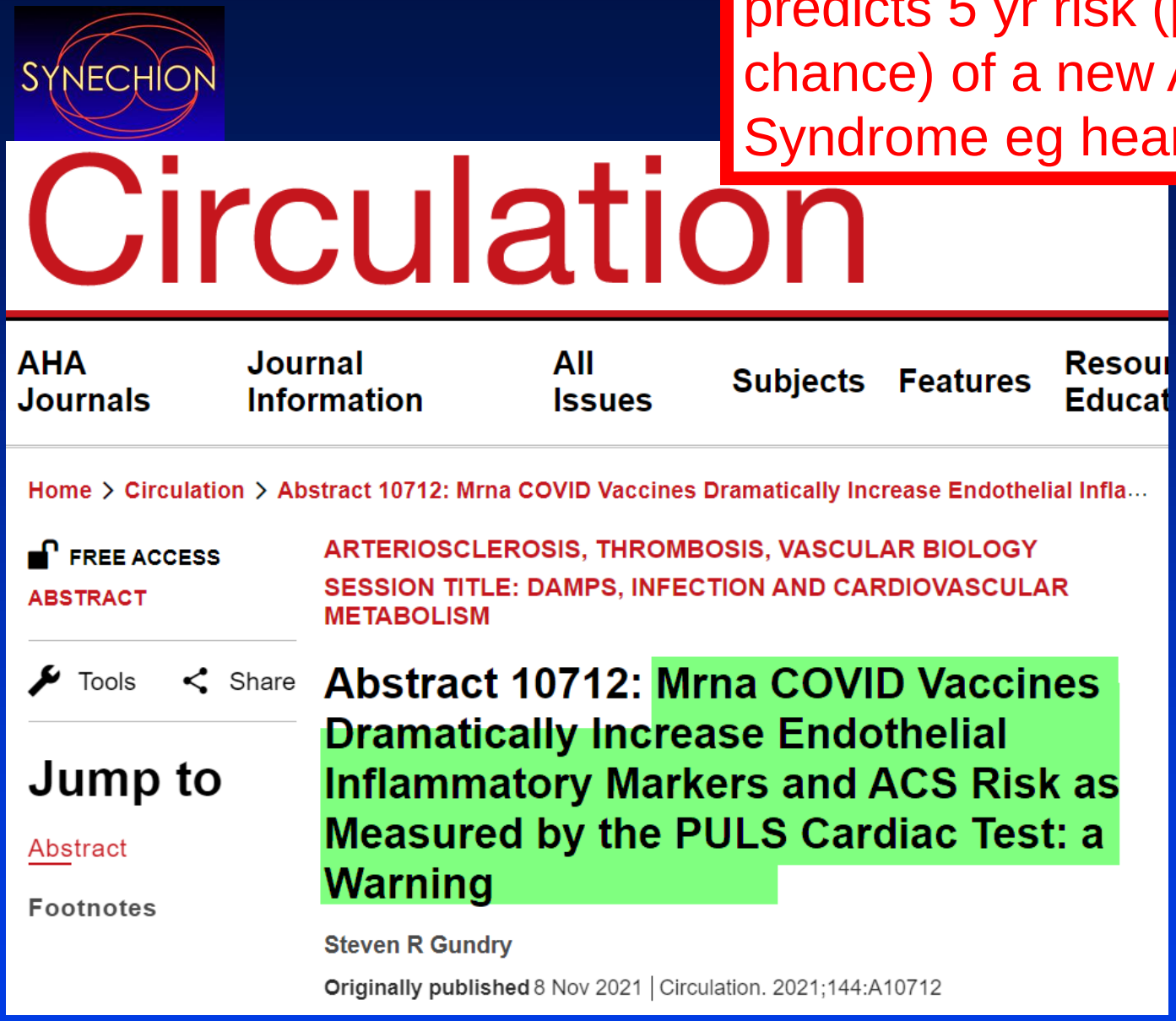
4. PHARMACOVIGILANCE

Upon approval, Pfizer/BioNTech will include the booster dose into the ongoing pharmacovigilance activities previously agreed with the FDA for the primary two-dose schedule. These activities are succinctly summarized in Table 10.

Table 10. Studies Contributing to Pharmacovigilance

C4591007 substudy: A Phase 3 substudy of 750 participants 5 to <12 years of age (randomized 2:1 to receive BNT162b2 10 µg or placebo) and 500 participants 12-15 years of age (open label receipt of BNT162b2 30 µg).	To obtain serum samples within the first ~4 days after vaccination for potential Troponin I testing, in order to evaluate the frequency of subclinical myocarditis amongst individuals 5 to 15 years of age.

predicts 5 yr risk (percentage chance) of a new Acute Coronary Syndrome eg heart attack.



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ABSTRACT

ARTERIOSCLEROSIS, THROMBOSIS, VASCULAR BIOLOGY

SESSION TITLE: DAMPS, INFECTION AND CARDIOVASCULAR METABOLISM

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Abstract

Footnotes

Abstract 10712: Mrna COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac Test: a Warning

Steven R Gundry

Originally published 8 Nov 2021 | Circulation. 2021;144:A10712

increased PULS score from 11% to 25% 5 yr ACS risk.

566 patients
28-97

If FDA knew about European problems with Moderna why did they not tell VRBPAC on October 26?

SYNECHION

P

FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age

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For Immediate Release October 29, 2021

Moderna and Pfizer are very similar

October 29 2021

moderna

Moderna Provides Update on Timing of U.S. Emergency Use Authori for Adolescents

October 31, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 31, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotech (mRNA) therapeutics and vaccines, today provided an update that the U.S. Food and Drug Administra require additional time to complete it vacci (mRNA-1273) at the 100 µg

On Friday evening, the FDA informe myocarditis after vaccination. The F is of paramount importance to Mode FDA for their diligence.

time to evaluate recent international analyses of the risk of myocarditis after vaccination.

"לעולם לא נלמד עד כמה החיסון בטוח עד שנתחיל לתת אותו"

"We're never going to learn about how safe the vaccine is until we start giving it."

Dr. Eric Rubin

ד"ר אריק רובין, העורך האחראי של כתב העת

Editor New England Journal of Medicine

FDA Panel Member

Published in NEJM the day after children's vaccine VRBPAC

The NEW ENGLAND JOURNAL of MEDICINE

Noa Dagan, M.D.
Noam Barda, M.D.
Ran D. Balicer, M.D.
Clalit Research Institute
Tel Aviv, Israel
rbalicer@clalit.org.il

CORRESPONDENCE **October 27 2021**

Adverse Effects after BNT162b2 Vaccine and SARS-CoV-2 Infection, According to Age and Sex

This letter was published on October 27, 2021, at NEJM.org.

jwatch.org/about/sponsor-distribution

NEJM Journal Watch

SPECIALTIES & TOPICS BLOGS CME SPECIAL FEATURES ARCHIVES/PDFs

Companies That Sponsor Distribution

The following companies sponsor distribution of one or more NEJM Journal Watch publications in selected countries.

- Pfizer

Lacks age bracket detail - risks for 16-19? poor peer review

		Vaccination									
		Females					Males				
Age Range		Total N (both study groups combined)	Events in Unvaccinated Group	Events in Vaccinated Group	Risk Ratio	Risk Difference (per 100,000)	Total N (both study groups combined)	Events in Unvaccinated Group	Events in Vaccinated Group	Risk Ratio	Risk Difference (per 100,000)
Myocarditis											
	16-19	88180	0	0	??		94176	0	5	??	
16-39	20-29	174396	1	0	NA	-0.63 (-1.90 to 0.00)	198224	1	9	4.95 (1.01 to 16.57)	8.62 (2.82 to 14.35)
	30-39	191226	0	0	??		232758	3	4	??	
Pericarditis											
	16-19	88146	0	0	??		94144	1	4	??	
16-39	20-29	174316	0	1	NA	0.54 (0.00 to 1.89)	198864	3	8	2.67 (1.03 to 9.26)	5.28 (0.17 to 10.33)
	30-39	191010	0	0	??		232452	1	3	??	

Risk aggregated
Not age granular

Total risk difference = 16-39 years males
= 86.2 myocarditis + 52.8 pericarditis =139 per million
Alt: 8 excess cases/(94176/2) = 169/MM in 16-19 only

Detail needed to account for rolling matching

Vaccine Adverse Event Reporting System (VAERS): Reporting rates (per 1 million doses administered) of myocarditis among males after mRNA COVID-19 vaccines, 7-day risk period (N=797)*

- **169,740,953** doses of mRNA vaccine administered to males (dose 1 and dose 2) *
- Reporting rates exceed background incidence**

Highest % is among males aged 16-17 years: 0.007%

	Pfizer (Males)		Moderna (Males)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	4.2	39.9		
16-17	5.7	69.1		
18-24	2.3	36.8	6.1	38.5
25-29	1.3	10.8	3.4	17.2
30-39	0.5	5.2	2.3	6.7
40-49	0.3	2.0	0.2	2.9

Average rate 16-39 both doses = 32.9
12-15 as % of average rate for 16-39 = 44.1/32.9 = 1.339
Rate in 12-15 (assume = 5-11) expected from Dagan = 139 x 1.339 = 186/ million

Dr. Matthew Oster, CDC at FDA-VRBPAC

FDA Risk Benefit Analysis: OCT 26

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	Prevented COVID-19 Cases	Prevented COVID-19 Hospitalizations	Prevented COVID-19 ICU Admissions	Prevented COVID-19 Deaths	Excess Myocarditis Cases	Excess Myocarditis Hospitalizations	Excess Myocarditis ICU Admissions	Excess Myocarditis Deaths
Males only								
Scenario 1	44,790	203	67	1	179	98	57	0
Scenario 2	54,345	250	82	1	179	98	57	0
Scenario 3	2,639	21	7	0	179	98	57	0
Scenario 4	57,857	254	83	1	179	98	57	0
Scenario 5	44,790	203	67	3	179	98	57	0
Scenario 6	44,790	203	67	1	89	49	29	0

Our calculation from Dagan = 186/ million (or ALT calc = 170/MM for 16-19)
Similar to 179 here (vs. CDC objection to FDA)

- **Confirms FDA scenario #6 should be rejected**
- **Consistent with VAERS underreporting by at least 4.8x**
- **Does not include non-myocardial events**
- **Dagan (Israeli data) likely higher due to censoring and other biases**

The NEW ENGLAND JOURNAL of MEDICINE

Oct 8 2020

[CDC…] has suffered dramatic testing and policy failures.

EDITORIALS

[FDA] has been shamefully politicized, appearing to respond to pressure from the administration rather than scientific evidence.

Medical journals are an extension of the marketing arm of pharmaceutical companies
Richard Smith BMJ

medical
Dying in a Leadership Vacuum

The Editors

Journals have devolved into information laundering operations for the pharmaceutical industry,
Richard Horton, *Lancet*

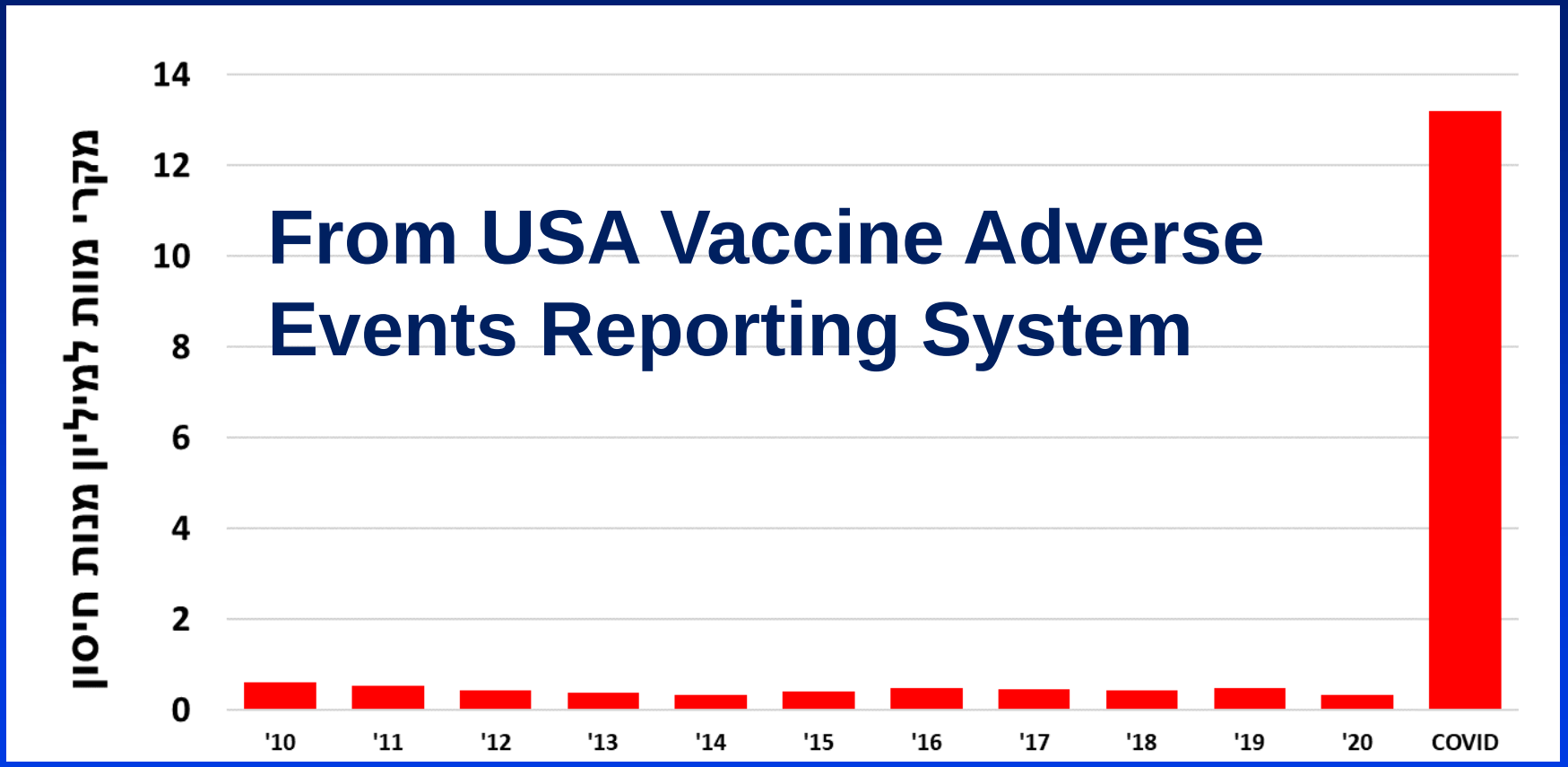
See other former editors:
Marcia Angell, NEJM
Jerome P. Kassirer NEJM

Five pools of vaccine associated deaths (USA)

Type	Note	Total
Non –C19 vaccinated	Under-reported in VAERS	20,000-62,000
C19 deaths in vaccinated	Israel MOH + Dagan et al.	25,000-85,000
Non-vaccinated infected by transmission from vaccinated		Unknown
All-cause deaths - vax		Unknown
All-case deaths – non-vax		Unknown
Total		45,000-147,000

- Compare with estimate of 140,000 lives saved due to the vaccines to May 2021 (Gupta et al.)
- Note asymmetric reporting, reporting deaths <14d as unvaccinated, assymmetric testing

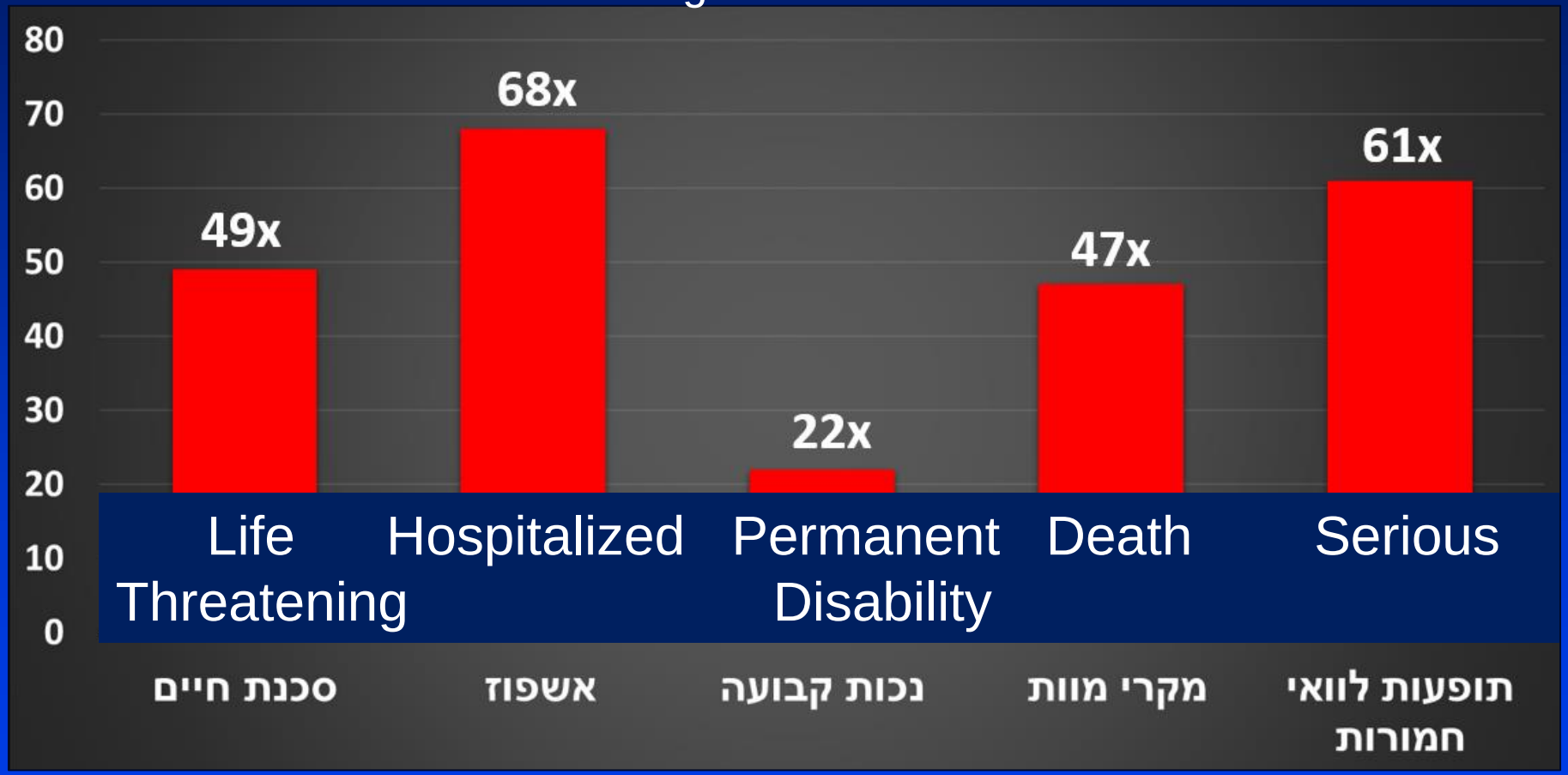
מקרי מוות לאחר חיסון שדווחו ל-VAERS
למיליון מנות חיסון, 2010-2021 (כל חיסון, כל הגילאים)



Note: Comparison includes all reports to FDA/CDC Vaccine Adverse Events Reporting System (VAERS) from Pfizer COVID-19 Vaccine through Oct. 8, 2021 to total reports from 5 flu seasons: 2015/16-2019/20. Reports with indication of COVID-19 infection were excluded.

תופעות שדווחו לאחר חיסון למיליון מחוסנים: יחס פייזר מול שפעת, גילאי 12-17

Side effects reported after vaccination per million vaccinated: Pfizer to influenza ratio, ages 12-17



Note: Comparison includes all reports to VAERS from Pfizer COVID-19 Vaccine through Oct. 8, 2021 to total reports from 5 flu seasons: 2015/16-2019/20. Reports with indication of COVID-19 infection were excluded.

תופעות שדווחו לאחר חיסון למיליון מחוסנים:
יחס פייזר מול שפעת, גילאי 12-17

Pfizer-to-Flu Reporting Ratios / Million Fully Vaccinated, 12-17

Disorder Type	יחס פייזר : שפעת	תופעות הקשורות
Menstruation & uterine bleeding	722x	להפרעות במחזור ודימומים רחמיים
Vulvovaginal	442x	למערכת המין
Endocrine gonadal function	372x	למערכת הרבייה
Reproductive tract	77x	לתפקוד אברי המין
Myocardial	3,584x	לשריר הלב
Coronary artery	320x	לעורק הכלילי
Cardiac valve	154x	למסתמי הלב
Embolism and thrombosis	180x	לתסחיפים ופקקת
Central nervous system vascular	179x	לכלי הדם במערכת העצבים המרכזיו

Note: Comparison includes all reports to VAERS from Pfizer COVID-19 Vaccine through Oct. 8, 2021 to total reports from 5 flu seasons: 2015/16-2019/20. Reports with indication of COVID-19 infection were excluded.

Z

סינדרום פוסט-חיסוני

Post Covid Vaccine Syndrome

pCoVS

Short and long term vaccine - associated effects may become a major public health issue.

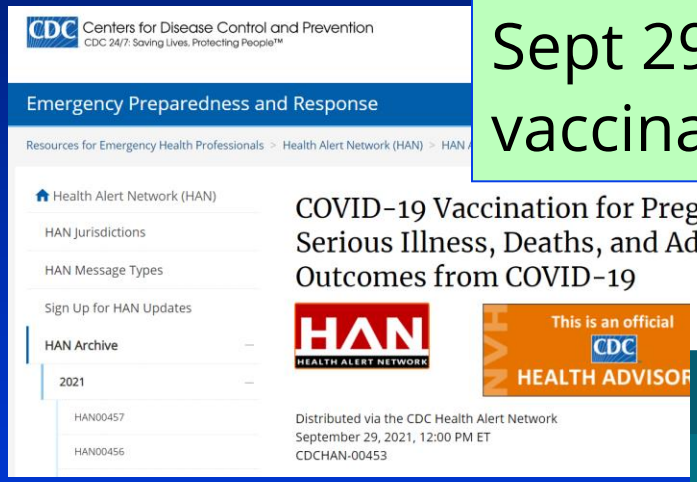
A syndrome occurring after injection of antigen-inducing, gene therapy vaccines to SARS-Cov-2 virus. The syndrome is currently understood to manifest variously as cardiac, vascular, hematological, musculoskeletal, intestinal, respiratory or neurologic symptoms of unknown long-term significance, in addition to effects on gestation. Manifestations of the syndrome may be mediated by the spike protein antigen induced by the delivered nucleic acids, the nucleic acids themselves, or vaccine adjuvants.

Package Insert vs. CDC – *strongly*?

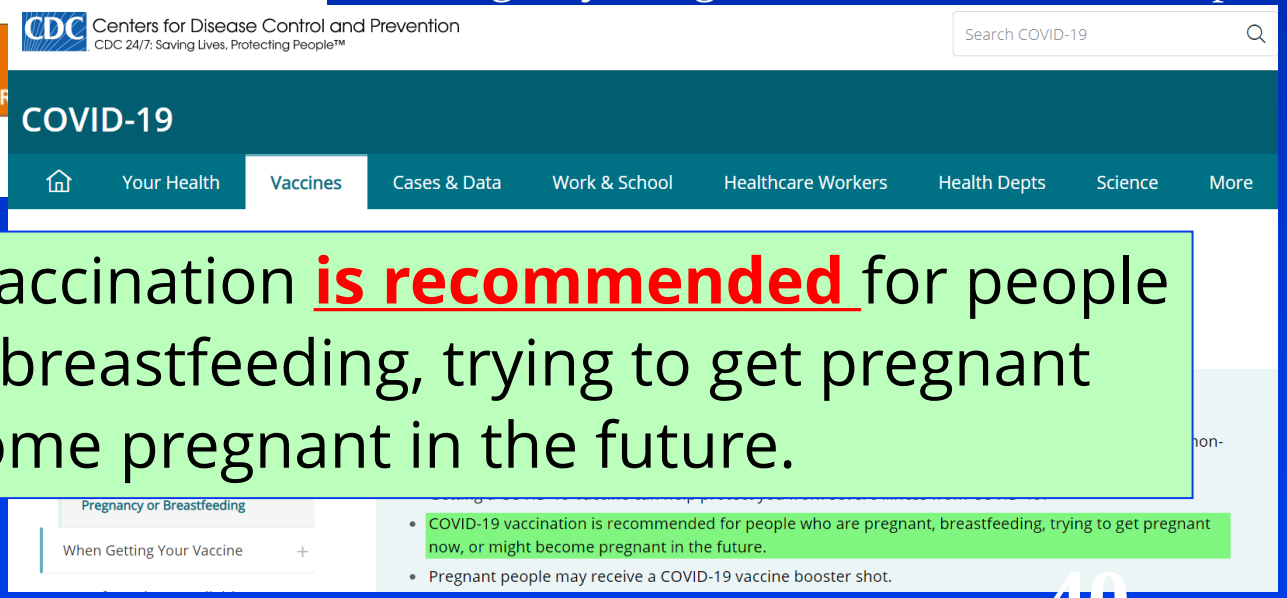
8.1 Pregnancy

Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

Sept 29: CDC **strongly** recommends COVID-19 vaccination either before or during pregnancy



emergency.cdc.gov/han/2021/han00453.asp



NOV 8: COVID-19 vaccination **is recommended** for people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.

cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

הריון: מחקרי ה-CDC Pregnancy: CDC

BB

AND Yet

CDC are conducting studies with the knowledge of participants because…..

- ***"there is an urgent need to monitor the safety of these vaccines [..] during or around the time of pregnancy."***
- We request to waive the requirement to obtain informed consent, parental permission
- cdc.gov/vaccinesafety/pdf/COVID19-acute-maternal-outcomes-508.pdf

NEVERTHELESS,

- CDC (health advisory) strongly recommends COVID-19 vaccination either before or during pregnancy

הפרעות וסת : בחסות ה-NIH
Menstrual disorders: NIH Funding

Why have NIH only recently (Aug 30) started studying…..

- ***"potential links between COVID-19 vaccination and menstrual changes."***
- *"Some women have reported experiencing irregular or missing menstrual periods, bleeding that is heavier than usual, and other menstrual changes after receiving COVID-19 vaccines."*

- In VAERS (Sept 2021)
- C19 vaccines: 7037 separate menstrual disorder symptoms in 4783 unique reports.
- Other vaccines, all years, 897 symptoms in 798 unique events.

קרצינוגניות, מוטוגניות, פגיעה בפוריות

לא נבדק בקשר COVID-19חיסון פייזר ביונטק כנגד גנוטוקסיות (carcinogenicity)לפוטנציאל לגרימת סרטן , או פגיעה בפוריות הגבר.(genotoxicity)

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility.

Package Insert תווית המוצר

Why have these studies not been done?

Ths sort of risk shares many features with damage due to radiation

Long Term Safety Concerns

- “mRNA is considered a gene therapy product by the FDA” (Moderna 2020)
- FDA Guidance: 5-15 year long term follow up for autoimmune diseases, cancers for gene therapy products

- Additionally, vital organs, including the liver and lungs, are transfected by mRNA vaccine delivery using LNPs. Expression of the antigen by these organs could recruit T cells that induce tissue damage and inflammation.
- A first clinical application will likely not be a prophylactic vaccine, because the tolerance for side effects is very low for a drug that is injected into healthy individuals Reichmuth1 et al., 2016 (Moderna founders)

The NEW ENGLAND JOURNAL of MEDICINE

CC

ORIGINAL ARTICLE

BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting

Noa Dagan,

Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting

Noam Barda, M.D., Noa Dagan, M.D., Yatir Ben-Shlomo, B.Sc.,

Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study

Noam Barda, Noa Dagan*, Cyrille Cohen, Miguel A Hernán, Marc Lipsitch, Isaac S Kohane, Ben Y Reis†, Ran D Balicer†*

SYNECHION

DD

zenodo

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August 24, 2021

Journal article Open Access

Use of a null assumption to re-analyze data collected through a rolling cohort subject to selection bias due to informative censoring

Mark Reeder

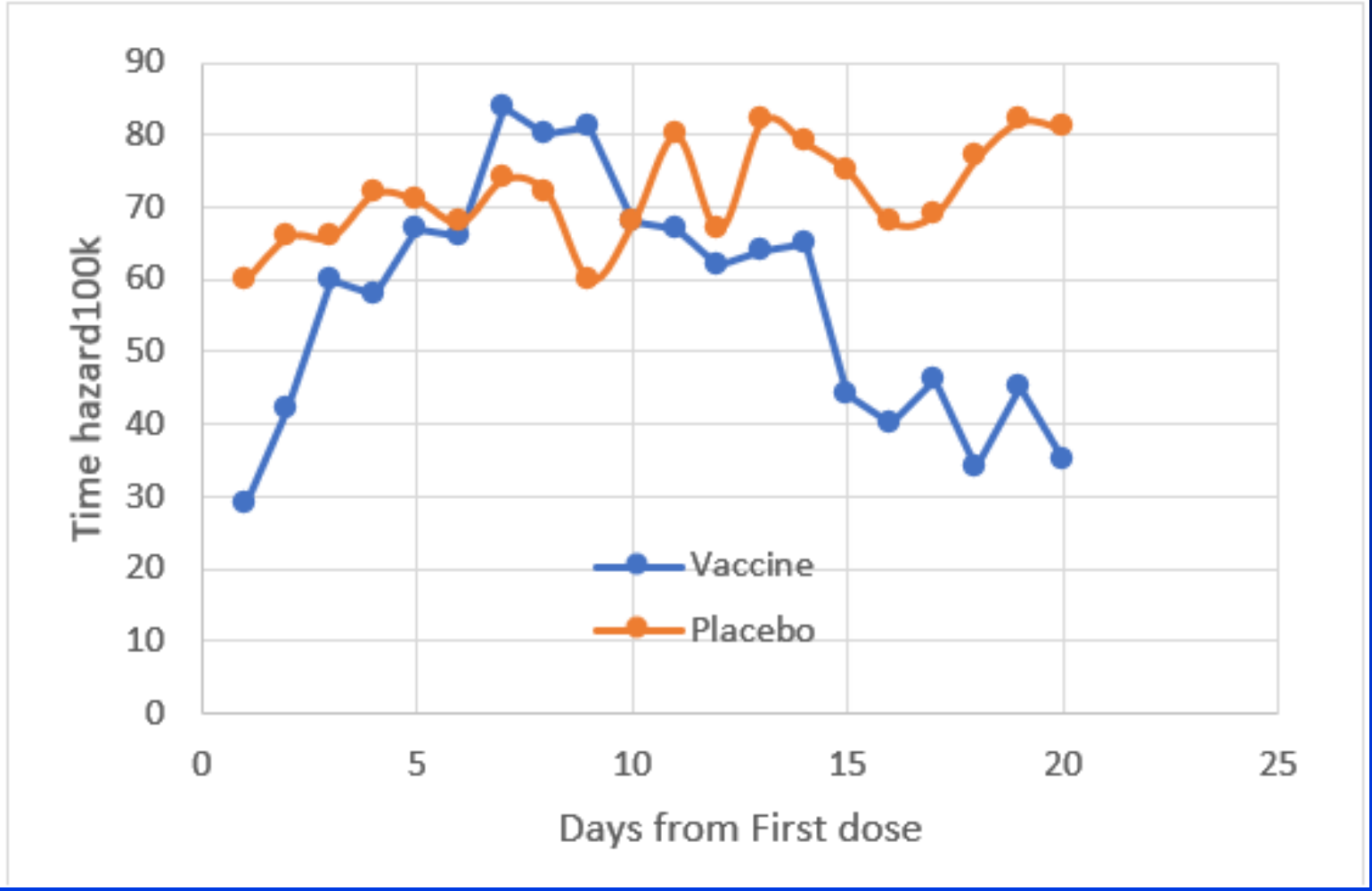
A novel method of estimating selection bias due to informative censoring for a rolling cohort utilizing matches is demonstrated for a recently published, and highly influential, study. The core reason for the bias is related to the principle

Dagan and related papers

- 1. Outcomes in Dagan et al. study, including C19 deaths were censored due to control subjects becoming vaccinated.
- 2. Selection bias - only those without covid symptoms can obtain the vaccine.
- 3. Bias is recognized but the biased data remain in their main analysis (crude 72% efficacy) while their limited sensitivity analysis (reported as 49% efficacy, though even this value depends on counting some deaths of those who obtained the vaccine as "unvaccinated") was placed in their supplement.
- 4. An alternate method to assess bias eliminating an important source of ambiguity. A specific censoring pattern, not disclosed by Dagan et al, combined with the hazard ratio (as older individuals were vaccinated earlier in the study period) could lead to a measured efficacy of zero.
- 5. Vague rules used to end follow-up would permit those with only one dose to be censored if, subsequently, C19 symptoms prevented the second dose administration

- *Figure 3: Covid-19 cases following vaccination in Dagan et al.*

FF



Dr. Herve Seligmann

Deaths among Israeli Vaccinees, Dagan e al., and MoH combined

GG

Deaths among vaccinees - Israel based on Dagan and MoH Data			
Adaptation of Seligmann March 2021	**C19 Death**	**N**	**Rate/100k**
Israel whole , includes deaths <18y	1752	Dec 20-Feb 1	
Israel adult populaton		5937684	29.5
study treatment group	9	596618	1.5
study placebo group	32	596618	5.4
remainder of pop not in study	1711	4744448	36.1
total unvaccinated pop to Feb 1		2752283	
unvaxed pop not in study		2155665	
deaths expected in unvax pop not in study	164		
add back unvaxed deaths from study	196		7.1
total vaccinated pop to Feb 1 (>=1 dose)		3185401	
vaxed pop not in study		2588783	
deaths in vaxed pop not part of study	1547		
add back death from study	1556		
deaths /100k vaxed			48.9
expected deaths in vaxed	242		
excess deaths /100k vaxed	1314		41.3
Does not account for rollover			

Baseline death assumptions	**Dagan**	**MoH prior44d**						
Assumed C19/100k deaths non-vax	**5.4**	**7.6**	**10**	**15**	**20**	**21**	**25**	**30**
Excess C19/100k deaths vaxed	44.9	41.3	37.2	28.8	20.5	18.8	12.1	3.7
Excess C19 deaths vax US 188MM	85612	77570	69991	54229	38468	35316	22707	6945

SYNECHION

HH

FranceSoir

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Journal of Medicine refuse une lettre d'avertissement du Dr Seligman

Publié le 21/05/2021 à 16:56

The NEW ENGLAND JOURNAL of MEDICINE

Medicine denies warning letter from Dr Seligman

yahoo!news

CBS NEWS

FDA authorizes COVID vaccine boosters for all adults

Alexander Tin

Fri, November 19, 2021, 7:26 AM · 4 min re

FDA U.S. FOOD & DRUG ADMINISTRATION

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd St
New York, NY 10017

Dear Mr. Patel:

FDA U.S. FOOD & DRUG ADMINISTRATION

November 19, 2021

ModernaTX, Inc.
Attention: Ms. Michelle Olsen
200 Technology Square
Cambridge, MA 02139

Dear Ms. Olsen:

Page 3 – Pfizer Inc.

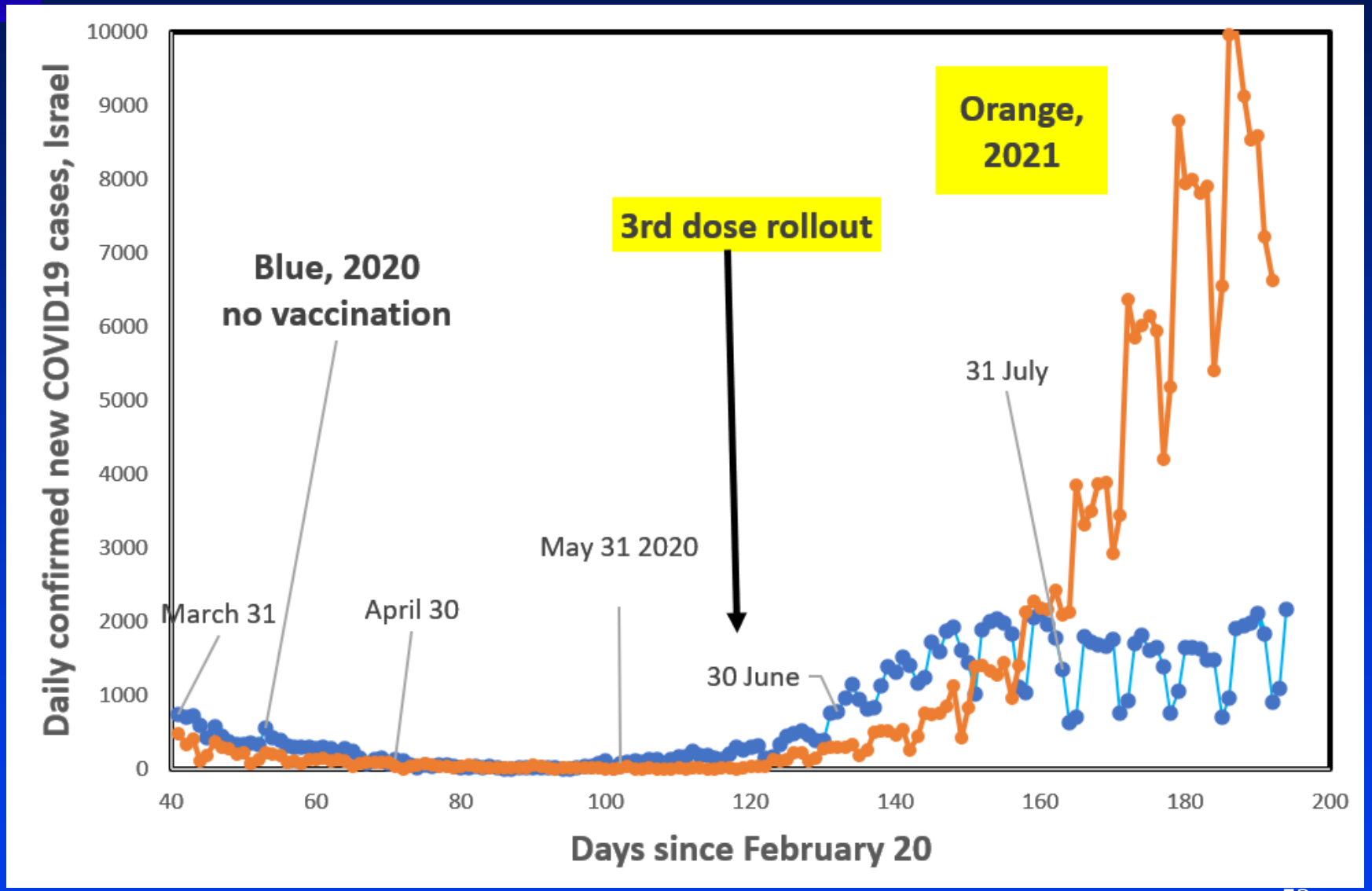
On November 19, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is again reissuing the October 29, 2021 letter of authorization in its entirety with revisions incorporated to amend the EUA for COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to authorize use of the vaccine as a single booster dose in individuals 18 years of age or older, at least 6 months after completing the primary series of this vaccine (i.e., as a homologous booster

fda.gov/media/150386/download

fda.gov/media/144636/download

Increase in Israeli daily COVID19 cases upon 3d dose rollout, compared with same period 2020.

H



מחוסנים ותיקים מפתחים קוביד-19 יותר מהר ובמידה שלא נופלת מלא מחוסנים

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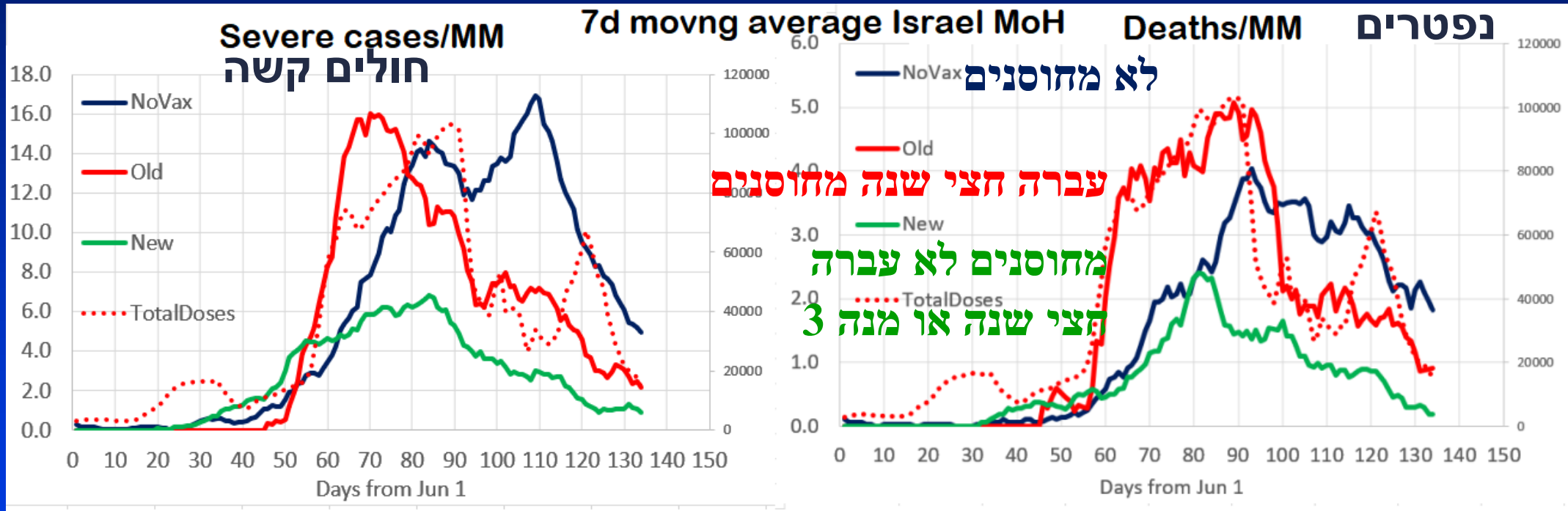
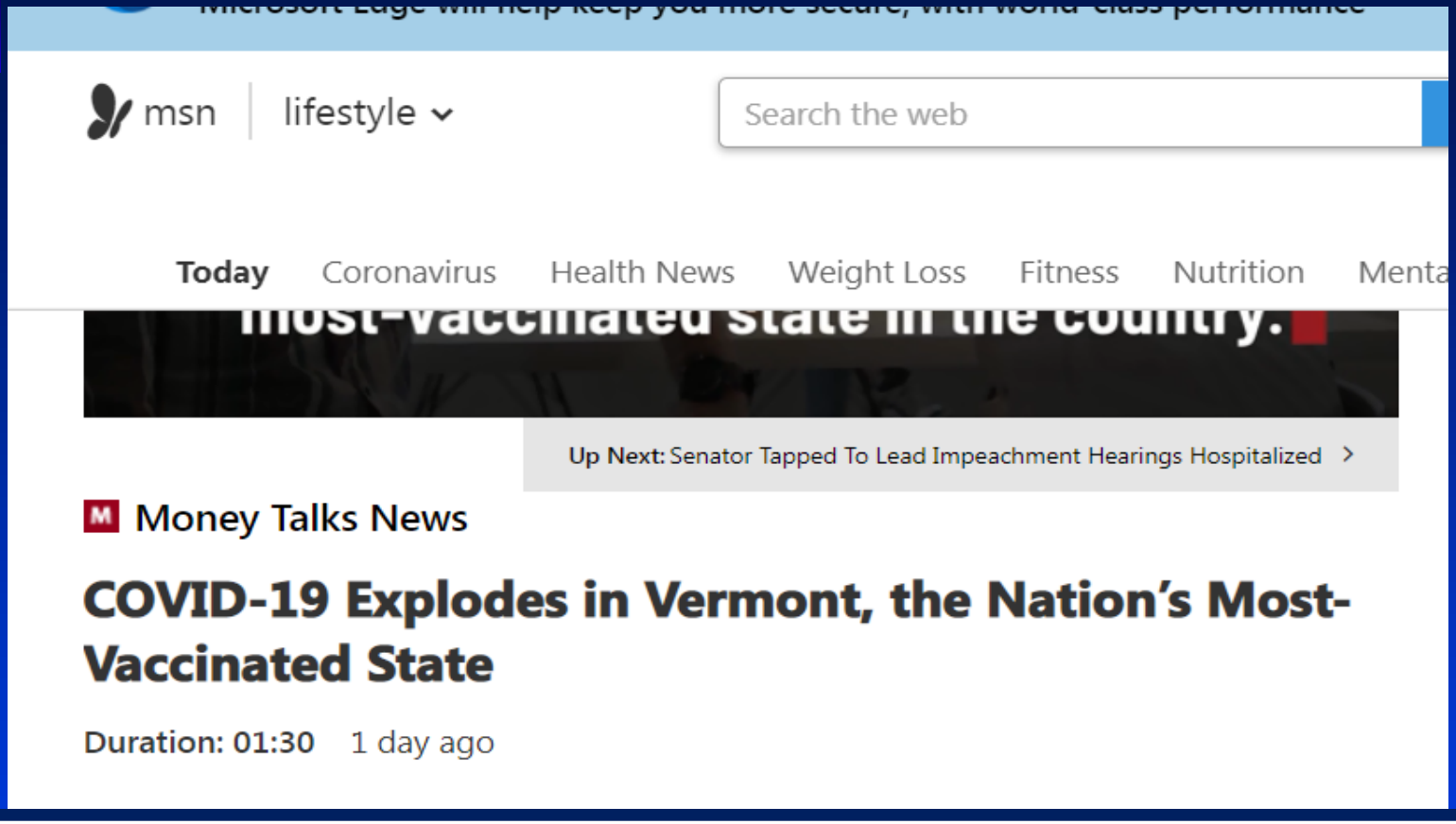
More reason for concern:

Data from Israel MoH משרד הבריאות



Non-recent vacinees develop Covid more quickly , as least as much as non-vaccinated

By six months there appears to be almost no benefit of vaccinaiton



Similar news in other states

NH, MN, IL, RI, CO,

msn.com/en-us/health/yogapilates/covid-19-explodes-in-vermont-the-nations-most-vaccinated-state/vi-AAQFkvz

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 D
Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection - Evaluable Eff
Population

Adult 001 study

fda.gov/media/144245/download

Pre-specified Age Group	BNT162b2 N[a] = 18198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a] =18325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All participants	8 2.214 (174	162 2.222 (17	95.0 (90.3, 97.6)[e]

Booster data adjusted to original study size **22 vs. 466**

Previously vaccinated fared ~3x worse than non-vaccinated in first study

Boosted fared ~3.5 x worse than primary series

Preliminary only: Selection & time biases

Booster 031 study ACIP Nov 19

Prior to 7 days a

Efficacy Endpoint	BNT162b2 (30 µg) N=4695 n	BNT162b2 (30 µg) N=4695 Surveillance Time (n)	Placebo N=4671 n	Placebo N=4671 Surveillance Time (n)	RVE (%)	RVE (95% CI)
First COVID-19 occurrence from ≥7 days after booster vaccination to <2 months after booster vaccination	6	.823 (4659)	123	0.792 (4614)	95.3	(89.5,98.3)

cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf

Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint
RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster)

Boosters: immunological equivalent of heroin addiction

Attempting to boost our way out of

- waning immunity
- ever more vaccine resistant virus variants
- Deselection of natural immunity?
- increased, unevaluated risk of cumulative dosing

is

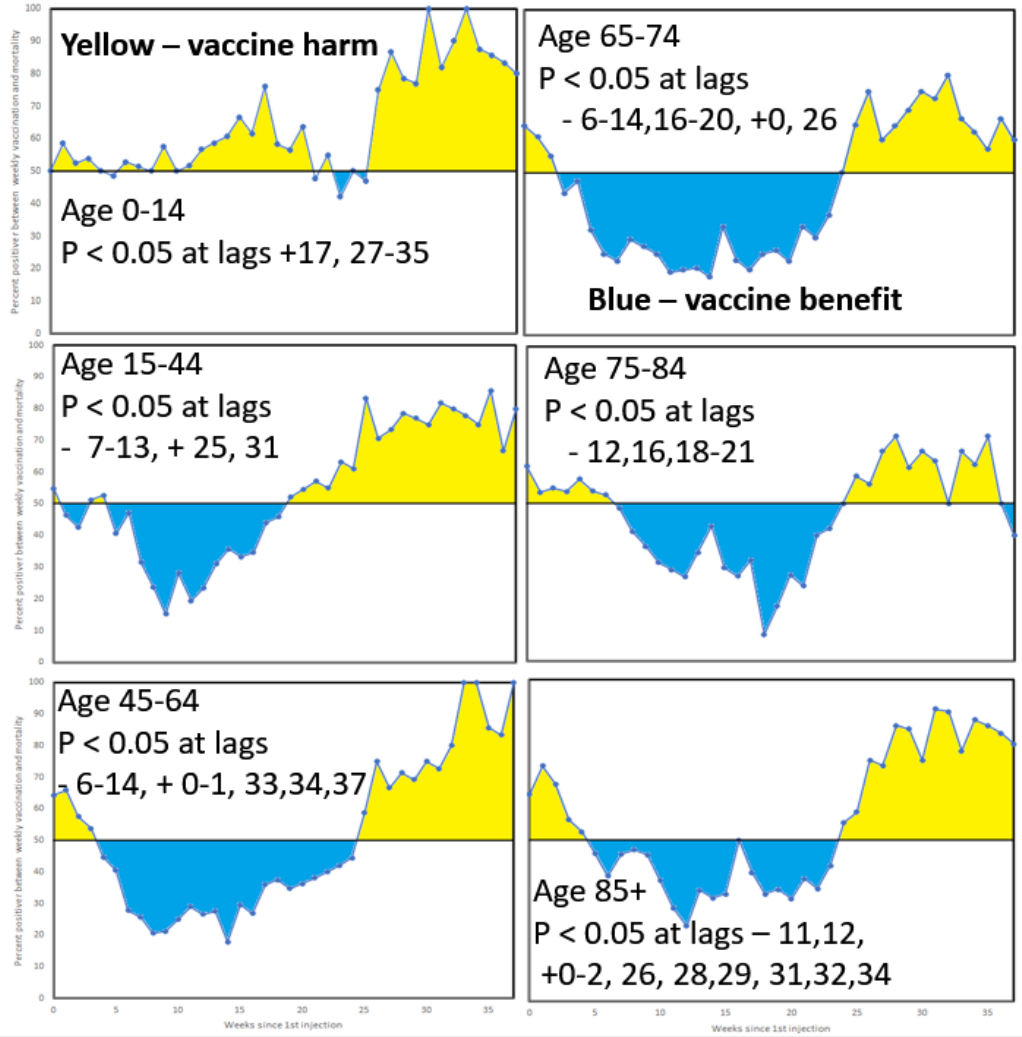
the immunological equivalent of heroin addiction

All- cause deaths correlate with vaccination. Adults benefit (blue) 4 to 26 weeks, outside of which there are detriments (yellow).

GG

In non-vaccinated children deaths correlate with adult vaccine coverage.

We may already be harming our children



Ages	%+	P<0.05 -	P<0.05+	Adv1	Adv2
0-14	59.3*	14	46*	20	26
15-44	46.5*	25*	25*	4	19
45-64	44.3*	35*	31*	3	25
65-74	39.8*	30*	17	2	24
75-84	44.6*	22	4	6	24
85+	50.9	21	15	4	24

All cause mortality is correlated with % vaccination.
From 0-~6 weeks after d1 – deaths INCREASE
From 4-6 to about 25 weeks, deaths DECREASE
> ~25 weeks, deaths INCREASE

For all age groups, except in children 0-14 (mostly unvaxed), DEATHS almost always increase.

X axis – lag time from 1st dose
Y axis – % positive weekly correlations

Data from 23 European countries via Euromomo
Dr. Herve Seligmann

New formula – Untested for safety or efficacy

The Pfizer-BioNTech COVID-19 Vaccine formulations that use Tris and PBS buffers, and which are authorized for use in individuals 12 years of age and older, contain the same modRNA and lipids, and the same quantity of these ingredients, per 0.3 mL dose. The two formulations differ with respect to certain inactive ingredients only and have been shown to be analytically comparable.[14]

Accordingly, under this EUA, for individuals 12 years of age and older, COMIRNATY (COVID-19 Vaccine, mRNA) and these two formulations of the Pfizer-BioNTech COVID-19 Vaccine, when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns.

[14] Analytical comparability assessments use laboratory testing to demonstrate that a change in product formulation does not impact a product's safety or effectiveness. For the Pfizer-BioNTech COVID-19 Vaccine, multiple different release parameters were evaluated to assess the comparability of the modified formulation (the formulation with the Tris buffer) to the originally-authorized formulation (the formulation with the PBS buffer). These release parameters ranged from product appearance to size of the lipid-nanoparticle to the integrity of the modRNA in the product. Additionally, characterization testing was performed to evaluate product composition and purity, including characteristics of the modRNA, as these are characteristics associated with the activity of the vaccine. The combination of release testing and characterization comparable to the original formulation.

"Analytically comparable"

https://cacmap.fda.gov/media/150386/download

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News

Covid-19: FDA puts Moderna's paediatric application on hold to investigate side effects

BMJ 2021

Cite this as

Pfizer did not report (perform?) ANY animal or human safety studies on new formula

FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age

Data Supports New Vaccine Formulation to Improve Stability and Storage Conditions

The FDA today also authorized a manufacturing change
formulation that uses a different buffer; buffers help ma
of how acidic or alkaline a solution is) and stability. This
refrigerated temperatures for longer periods of time, pe
vaccination providers.

The new formulation of the vaccine developed by Pfizer
commonly used buffer in a variety of other FDA-approv
including products for use in children. The FDA evaluat
the use of Pfizer-BioNTech COVID-19 Vaccine containin
does not present safety or effectiveness concerns.

The FDA evaluated manufacturing data to support the use of Pfizer-BioNTech COVID-19 Vaccine containing Tris buffer and concluded it does not present safety or effectiveness concerns.

"The studies were done using the same volume 0.2ml that is the final presentation in terms of a dosage. ***But it contains the PBS buffer****. We obviously had extensive consultations with the FDA and it was determined that clinical studies were not required because the LNP in the mRNA are the same in behavior in terms of reactogenicty and efficacy as expected."*

Dr, William Gruber (Pfizer), responding to VRBPAC member Dr. Steven Pergam, October 26, 2021 regarding which buffer version was used in the clinical trial.

Pfizer say all studies were with old PBS formula

PBS = OLD
TRIS = New

https://youtu.be/laaL0_xKmmA?t=10572

New formula – Untested for safety or efficacy

- Pfizer have changed the children's formula to use TRIS buffer solution (also for adults)
- This was NOT the formula used in the children's studies
- This change could change how the LNP particles move around the body and product stability
- **Could increase EFFECTIVE DOSE, reducing SAFETY**
- No safety or efficacy study in animals or humans were

To provide a vaccine with an improved stability profile, the Pfizer-BioNTech COVID-19 Vaccine for use in children 5-11 years of age uses tromethamine (Tris) buffer instead of the phosphate-buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride. The packaged vials for the new formulation are stored frozen at -90°C to -60°C. The frozen vials may be thawed and stored at refrigerator at 2°C to 8°C for up to 10 weeks.

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary

Ship

- ultra-cold thermal shipping container -90°C to -60°C (-130°F to 76°F) with dry ice

Store in

- ultra-cold freezer between -90°C to -60°C to expiry date
- regular freezer -25°C and -15°C (-13°F to 5°F) up to 2 weeks
- refrigerator 2°C and 8°C (36°F and 46°F) up to 1 month

After mixing

- Can be left at room temperature (2°C to 25°C [35°F to 77°F]) up to 6 hours.

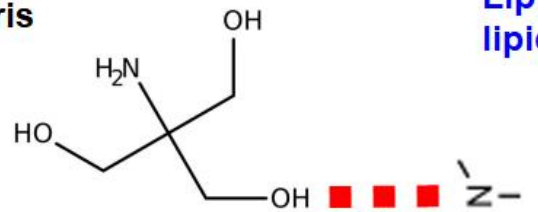
- **Complicated shipping & storage prone to error & mRNA breakdown**
- **Tris formulation may simplify this**
- **Improving stability -increase UNTESTED efficacy & EFFECTIVE DOSE?**
- **BUT also may reduce UNTESTED SAFETY to Moderna-like levels**

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

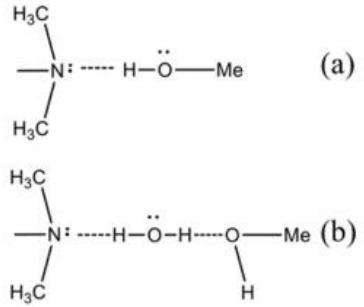
This shows how the new TRIS formula could change the LNP in the body and the way it moves around.

FDA have not considered how local pH changes could affect this.

Tris

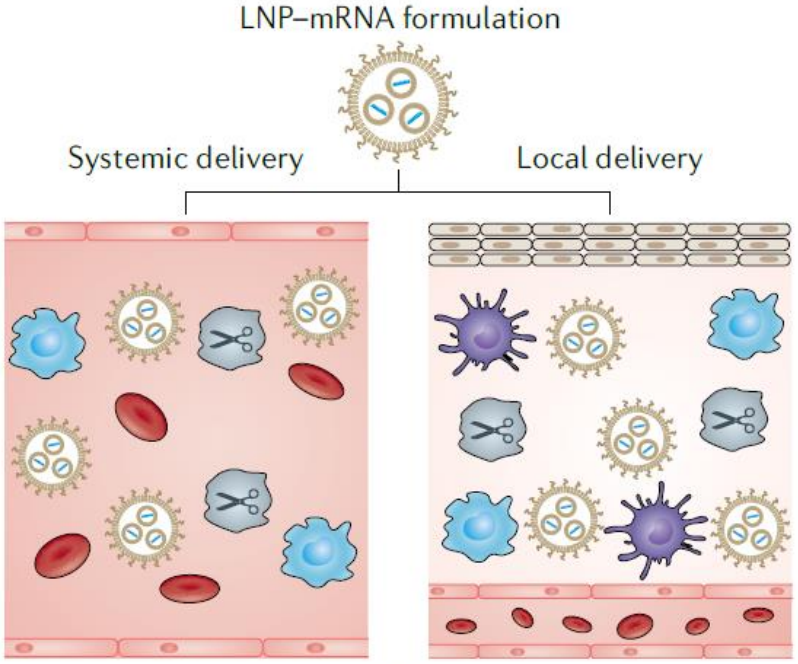


Lipid Nanoparticles have ionizable lipids in their coating



Even modest amounts of hydrogen bonding between tertiary amine of ionizable lipid and hydroxyl groups on tris could change the character of the LNP shell by changing its charge, possibly affecting site uptake and distribution, SAFETY AND EFFICACY

Ketone groups if present on the lipid could be an additional source of interaction with tris.



Tertiary amine OH bonding Fang 2018 Nature Sci Rep
LNP diagrams - Hou et al 2021 Nature Rev Mat

Theoretical scheme based on lipids discussed by Moderna scientsts

סיכום

- Highly problematic unverified data – efficacy could be ZERO
- NEW UNTESTED Formulation which could increase EFFECTIVE DOSE and safety
- Insufficient and missing safety data from Pfizer
- Abundance of concern from VAERS – myocarditis etc.
- Flawed FDA Risk-Benefit analysis
- We find 4 RISK > Benefit
- Abundance of concern from VAERS – myocarditis etc.
- There is no emergency in children – we may already be harming them
- No evidence concerning transmission risk

המוציא מחברו עליו הראיה

Interim Clinical Study Report
Protocol C4591001

Date of Current Version: 14 April 2021

Disposition, AEs, reactions for 12-15 & 16-25

Document via TrialSite News

1. TITLE PAGE

Vaccine Name and Compound Number: BNT162 RNA-Based COVID-19 Vaccines, Compound Number: PF-07302048

Report Title: Interim Report – Adolescents: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose

Table 4. Disposition of All Randomized Subjects Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age

Vaccine Group (as Randomized)

	BNT162b2 (30 µg) 12-15 Years (N=1134) n^a (%)	BNT162b2 (30 µg) 16-25 Years (N=1875) n^a (%)	Placebo 12-15 Years (N=1130) n^a (%)	Placebo 16-25 Years (N=1913) n^a (%)
Not vaccinated	3 (0.3)	6 (0.3)	1 (0.1)	7 (0.4)
Vaccinated				
Dose 1	1131 (99.7)	1869 (99.7)	1129 (99.9)	1906 (99.6)
Dose 2	1124 (99.1)	1826 (97.4)	1117 (98.8)	1836 (96.0)
Completed 1-month post–Dose 2 visit (vaccination period)	1118 (98.6)	1803 (96.2)	1102 (97.5)	1807 (94.5)
Discontinued from vaccination period but continue in the study up to 1-month post–Dose 2 visit	7 (0.6)	13 (0.7)	17 (1.5)	42 (2.2)
Discontinued after Dose 1 and before Dose 2	[redacted]			
Discontinued after Dose 2 and before 1-month post–Dose 2 visit				
Reason for discontinuation from vaccination period				
No longer meets eligibility criteria				

Table 10. Safety Population – Subjects 12 Through 15 and 16 Thro

Vaccine Group (as Administered)

	BNT162b2 (30 µg) 12-15 Years n^a	Placebo 12-15 Years n^a	Total 12-15 Years n^a	BNT162b2 (30 µg) 16-25 Years n^a	Placebo 16-25 Years n^a	Total 16-25 Years n^a
Randomized[b]	[redacted]					
Vaccinated						
Safety population						
Reactogenicity subset						

Table 25. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), Subjects 12 Through 15 Years of Age – Safety Population

Vaccine Group (as Administered)

Adverse Event	BNT162b2 (30 µg) (N=1131) n^b (%)	Placebo (N=1129) n^b (%)
Any event	72 (6.4)	71 (6.3)
Related[c]	33 (2.9)	21 (1.9)
Severe	9 (0.8)	3 (0.3)
Life-threatening	1 (0.1)	1 (0.1)
Any serious adverse event	5 (0.4)	2 (0.2)
Related[c]	0	0
Severe	[redacted]	
Life-threatening		
Any adverse event leading to withdrawal		
Related[c]		
Severe		
Life-threatening		
Death	0	0

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) 12-15 Years (N=1131) n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years (N=536) n^a (%) (95% CP)	Placebo 12-15 Years (N=1129) n^a (%) (95% CP)	Placebo 16-25 Years (N=561) n^a (%) (95% CP)
Any event	[redacted]			
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
Lymphadenopathy				
CARDIAC DISORDERS				
Tachycardia				
EAR AND LABYRINTH DISORDERS				
Ear pain				
Cerumen impaction				
EYE DISORDERS				
Eye pain				
Eyelid rash				
Ocular hyperemia				
Retinal haemorrhage				
GASTROINTESTINAL DISORDERS				
Nausea				
Diarrhoea				
Abdominal pain				
Aphthous ulcer				
Lip swelling				

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Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) 12-15 Years (N=1131) n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years (N=536) n^a (%) (95% CP)	Placebo 12-15 Years (N=1129) n^a (%) (95% CP)	Placebo 16-25 Years (N=561) n^a (%) (95% CP)
Any event	[redacted]			
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
Lymphadenopathy				
CARDIAC DISORDERS				
Tachycardia				
EAR AND LABYRINTH DISORDERS				
Ear pain				
Cerumen impaction				
EYE DISORDERS				
Eye pain				
Eyelid rash				
Ocular hyperemia				
Retinal haemorrhage				
GASTROINTESTINAL DISORDERS				
Nausea				
Diarrhoea				
Abdominal pain				
Aphthous ulcer				
Lip swelling				

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Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) 12-15 Years (N=1131) n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years (N=536) n^a (%) (95% CP)	Placebo 12-15 Years (N=1129) n^a (%) (95% CP)	Placebo 16-25 Years (N=561) n^a (%) (95% CP)
Any event	[redacted]			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Injection site pain				
Pyrexia				
Chills				
Injection site erythema				
Injection site swelling				
Oedema peripheral				
Pain				
Chest pain				
Injection site bruising				
Injection site discomfort				
Injection site hypoaesthesia				
Nodule				

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Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) (N=1131) n^a (%)	Placebo (N=1129) n^a (%)
Any event	[redacted]	
BLOOD AND LYMPHATIC SYSTEM DISORDERS		
Lymphadenopathy		
EAR AND LABYRINTH DISORDERS		
Ear pain		
Cerumen impaction		
EYE DISORDERS		
Eyelid rash		
Retinal haemorrhage		
GASTROINTESTINAL DISORDERS		
Diarrhoea		
Abdominal pain		
Aphthous ulcer		
Constipation		
Gastritis		
Lip swelling		
Toothache		
Vomiting		
Oral mucosal blistering		
Rectal prolapse		
Tenderness		
Vomiting		

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Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) 12-15 Years (N=1131) n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years (N=536) n^a (%) (95% CP)	Placebo 12-15 Years (N=1129) n^a (%) (95% CP)	Placebo 16-25 Years (N=561) n^a (%) (95% CP)
Any event	[redacted]			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Injection site pain				
Pyrexia				
IMMUNE SYSTEM DISORDERS				
Seasonal allergy				
INFECTIONS AND INFESTATIONS				
Ear infection				
Appendicitis				
Conjunctivitis				
Otitis externa				

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Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 16-55 Years of Age – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) (N=13069) n^a (%)	Placebo (N=13095) n^a (%)
Any event	[redacted]	
Anorectal operation		
Antibiotic prophylaxis		
Antibiotic therapy		
Antidepressant therapy		
Antiviral prophylaxis		
Aorta coarctation repair		
Aortic aneurysm repair		
Aortic valve repair		
Aortic valve replacement		
Apicectomy		
Appendicectomy		
Arm amputation		
Arterial bypass operation		
Arterial repair		
Arterial therapeutic procedure		
Arteriovenous fistula operation		
Arthrodesis		
Arthroscopic surgery		
Arthrotomy		
Artificial crown procedure		
Artificial insemination		
Astrocytoma surgery		
Atrial septal defect repair		
Axillary lymphadenectomy		
Bartholin's cyst removal		
Benign breast lump removal		
Benign tumour excision		
Bilateral orchidectomy		
Bile duct stent insertion		
Bile duct stent removal		
Biliary stent placement		
Bladder lesion excision		
Bladder neoplasm surgery		
Bladder operation		
Bladder repair		
Blepharoplasty		

Table 12. Immunogenicity Populations – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset)

Vaccine Group (as Randomized)

	BNT162b2 (30 µg) 12-15 Years	BNT162b2 (30 µg) 16-25 Years	Placebo 12-15 Years	Placebo 16-25 Years
Randomized[a]	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Dose 2 all-available immunogenicity population	210 (75.0)	191 (68.2)	36 (72.0)	34 (68.0)
Subjects excluded from Dose 2 all-available immunogenicity population	70 (25.0)	89 (31.8)	14 (28.0)	16 (32.0)
Reason for exclusion				
Did not receive Dose 2	[redacted]			
Did not have at least 1 valid and determinate immunogenicity result after Dose 2				
Dose 2 evaluable immunogenicity population	209 (74.6)	186 (66.4)	36 (72.0)	32 (64.0)
Subjects excluded from Dose 2 evaluable immunogenicity population	71 (25.4)	94 (33.6)	14 (28.0)	18 (36.0)
Reason for exclusion[b]				
Did not receive 2 doses of the vaccine to which they were randomly assigned	[redacted]			
Did not receive Dose 2 within 19–42 days after Dose 1				
Did not have at least 1 valid and determinate immunogenicity result after Dose 2				
Did not have blood collection within 28–42 days after Dose 2				
Had important protocol deviation(s) as determined by the clinician				

14.13. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

Dose	Local Reaction	BNT162b2 (30 µg) 12-15 Years N^a	BNT162b2 (30 µg) 12-15 Years n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years N^a	BNT162b2 (30 µg) 16-25 Years n^a (%) (95% CP)	Placebo 12-15 Years N^a	Placebo 12-15 Years n^a (%) (95% CP)	Placebo 16-25 Years N^a	Placebo 16-25 Years n^a (%) (95% CP)
2	Any local reaction[c]	[redacted]							
	Redness[d]								
	Any								
	Mild								
	Moderate								
	Severe								
	Grade 4								
	Swelling[d]								
	Any								
	Mild								
	Moderate								
	Severe								
	Grade 4								
	Pain at the injection site[d]								
	Any								
	Mild								
	Moderate								
	Severe								
	Grade 4								
	Any local reaction[c]								

Table 38. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) 12-15 Years (N=1131) n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years (N=536) n^a (%) (95% CP)	Placebo 12-15 Years (N=1129) n^a (%) (95% CP)	Placebo 16-25 Years (N=561) n^a (%) (95% CP)
Any event	[redacted]			
GASTROINTESTINAL DISORDERS				
Abdominal pain				
Appendicitis				
INFECTIONS AND INFESTATIONS				
Appendicitis				
Food poisoning				
INJURY, POISONING AND PROCEDURAL COMPLICATIONS				
Fall				
NERVOUS SYSTEM DISORDERS				
Neuralgia				
PSYCHIATRIC DISORDERS				
Depression				
Suicidal ideation				

Table 31. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) (N=1131) n^a (%)	Placebo (N=1129) n^a (%)
Any event	[redacted]	
GASTROINTESTINAL DISORDERS		
Abdominal pain		
Constipation		
INFECTIONS AND INFESTATIONS		
Appendicitis		
Focal peritonitis		
NERVOUS SYSTEM DISORDERS		
Neuralgia		
PSYCHIATRIC DISORDERS		
Depression		
Anxiety		
Suicidal ideation		

Table 32. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) 12-15 Years (N=1131) n^a (%) (95% CP)	BNT162b2 (30 µg) 16-25 Years (N=536) n^a (%) (95% CP)	Placebo 12-15 Years (N=1129) n^a (%) (95% CP)	Placebo 16-25 Years (N=561) n^a (%) (95% CP)
Any event	[redacted]			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Injection site pain				
Pyrexia				
INJURY, POISONING AND PROCEDURAL COMPLICATIONS				
Exposure during pregnancy				
NERVOUS SYSTEM DISORDERS				
Headache				
PSYCHIATRIC DISORDERS				
Anxiety				
Depression				

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

Vaccine Group (as Administered)

System Organ Class Preferred Term	BNT162b2 (30 µg) (N=1131) n^a (%)	Placebo (N=1129) n^a (%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
Injection site pain		
Fatigue		
Pyrexia		
Chills		
Injection site swelling		
Nodule		
Oedema peripheral		
Peripheral swelling		
Vessel puncture site pain		
IMMUNE SYSTEM DISORDERS		
Food allergy		
INFECTIONS AND INFESTATIONS		
Ear infection		
Appendicitis		
Conjunctivitis		
Body tinea		
Candida infection		
Focal peritonitis		
Infectious mononucleosis		
Otitis externa		
Otitis media		
Pilonidal cyst		
Subcutaneous abscess		
Tinea capitis		
Vulval abscess		
Vulvovaginal mycotic infection		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		
Concussion		
Ligament sprain		
Accident		
Clavicle fracture		
Contusion		
Fall		
Muscle strain		
Procedural pain		
Tooth fracture		
Foot fracture		

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dr. Silvia Behrendt
Global Health Responsibility Agency
Austria

silvia.behrendt@ghra.ngo

EMA/468888/2021
Stakeholders and Communication

Dear Dr. Behrendt,

Subject: Comirnaty (COVID-19 mRNA vaccine (nucleoside-modifie i) ASK-91060 - Rejection letter to the requester - confirmatory application (appeal)

aaronsiri.substack.com/p/fda-asks-federal-judge-to-grant-it

Injecting Freedom

Subscribe Sign in

FDA Asks Federal Judge to Grant it Until the Year 2076 to Fully Release Pfizer's COVID-19 Vaccine Data

The fed gov't shields Pfizer from liability. Gives it billions of dollars. Makes Americans take its product. But won't let you see the data supporting its safety/efficacy. Who does the gov't work for?

Aaron Siri

Nov 17 ♡ 300 💬 197

https://aaronsiri.substack.com/p/fda-asks-federal-judge-to-grant-it

אל תסתמך על ניתוח ה-FDA

DO NOT RELY ON FDA

זֹבְחֵי אָדָם, עֲגָלִים יִשָּׁקוּן.

הפטרה פ' ויצא - הושע י"ג ב

"To kiss calves is like sacrificing humans"
(Hosea 13:2)

Research papers etc.

- Re-analysis of key HCQ study Post-Exposure Prophylaxis - Boulware et al. medrxiv.org/content/10.1101/2020.11.29.20235218v3
- Comment on the Reis et al. Early HCQ jamanetwork.com/journals/jamanetworkopen/fullarticle/2779044
- Comment on Skipper et al. Early HCQ treatment. acpjournals.org/doi/full/10.7326/M20-4207#_comments
- Reversal of key IVM early treatment Lopez-Medina et al. JAMA osf.io/bvznd/
- Letter to NIH re: HCQ studies osf.io/7trh4/
- Synergistic effects of HCQ and steroids doi.org/10.1016/j.ijid.2020.07.064
- TrialSite News Sep 10: Was evidence withheld from ACIP when they recommended the Pfizer-Vaccine? https://trialsitenews.com/the-smoking-syringe-was-evidence-withheld-from-acip-when-they-recommended-the-pfizer-vaccine/

Comments to Government Agencies

CDC-ACIP Aug 30, 2020 regulations.gov/comment/CDC-2021-0089-0023
regulations.gov/comment/CDC-2021-0089-0039

FDA VRBPAC Sept 17, 2020 downloads.regulations.gov/FDA-2021-N-0965-0016/attachment_1.pdf
youtu.be/WFph7-6t34M?t=15844

FDA VRBPAC Oct 14-15, 2020 www.regulations.gov/comment/FDA-2021-N-0965-0146
www.regulations.gov/comment/FDA-2021-N-0965-0164

CDC-ACIP Oct 21 downloads.regulations.gov/CDC-2021-0098-0071/attachment_1.pdf
youtu.be/Qoqia5YkwHc?t=8602

FDA VRBPAC Oct 26 (co-author) tinyurl.com/HoldTheLineFDA
youtu.be/laaL0_xKmmA?t=17417

CDC-ACIP Nov 2 2021 youtu.be/vLK-MIbBvTk?t=7426

Israel Ministry of Health, Nov 4 2021 https://tinyurl.com/ChildVaxSafetyIsrael
https://youtu.be/_9TxhQDa9-c?t=12736