THE PFIZER INOCULATIONS FOR COVID-19

MORE HARM *THAN GOOD*

Canadian Covid Care Alliance
Alliance canadienne pour la prévention
et prise-en-charge de la covid

CONTACT US

INFO@CANADIANCOVIDREALLIANCE.ORG

DEANNA MCLEOD

- Completed degree in immunology and psychology at McMaster University
- Worked in pharma for ten years in medical, marketing and sales and specialized in the field of Oncology
- Became concerned with tendency toward biased reporting by some pharmaceutical companies
- Founded an independent medical research firm in 2,000 to assist clinicians in preparing objective evidence-based guidelines
- Our firm has supported hundreds of cancer specialists in preparing more than 40 peer-reviewed publications
- Since March 2020, our team has spent more than 2,000 hours conducting COVID-related research

Principal and Founder Kaleidoscope Strategic. Inc
Founder of COVID Sense
Chair of Strategic Advisory Group CCCA

WE SUPPORT

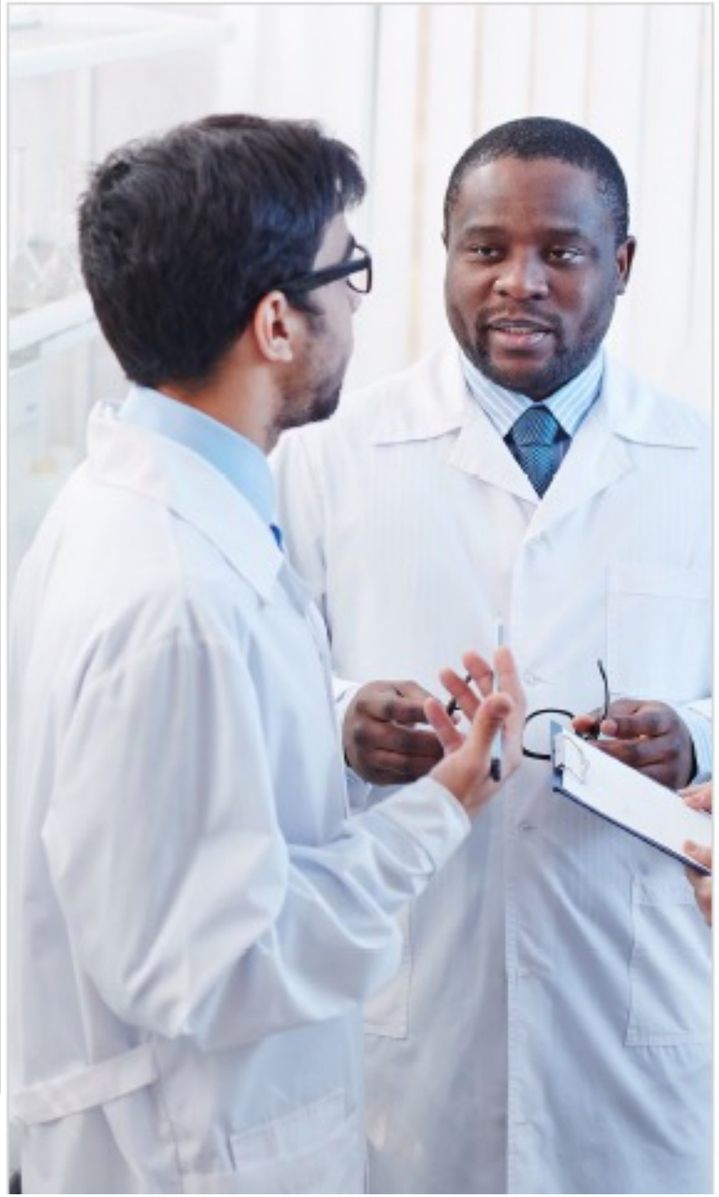
The doctor/patient relationship and personalized care

Informed consent and treatment options

Free and open **scientific discourse**

Policy that is based on the **highest levels of evidence**

Safe and effective vaccines



FIRST, DO NO HARM

The federal, provincial and municipal governments in Canada have a **responsibility to protect the health of Canadians as well as our Charter Rights and Freedoms. Any medical interventions approved by Health Canada must first be PROVEN SAFE.**

Due diligence in research, as well as **adherence to established protocols of the doctor/patient relationship, informed consent and scientific inquiry** are essential to carrying out that responsibility.

Deviating from those practices, causing harm and failing to disclose risks of harm is negligent at best.

THE HIERARCHY OF EVIDENCE

- **A randomized control trial is LEVEL 1 Evidence,** the highest form of evidence there is.
- It is considered the Gold Standard and is the **only way to PROVE something is better than the current standard of care**
- **Observational studies** of real world data are **LEVEL 3** or 4
- **Models are LEVEL 5 or lower** as they are expert opinion/speculation.

Policy should be determined by the highest level of available evidence available

HIGHER

LOWER

Level	Example of Evidence
Level 1	**Meta-analysis of homogenous RCTs randomized control trial**
Level 2	Meta-analysis of Level 2 or heterogenous Level 1 evidence prospective comparative study
Level 3	Review of Level 3 evidence case-control study retrospective cohort study
Level 4	Uncontrolled cohort studies case series
Level 5	Expert opinion case report personal observation
Foundation Evidence	Animal research, i*n vitro* research ideas, speculation

INADEQUATE PFIZER TRIAL DESIGN

Healthy Individuals

- Healthy >16 years or stable medical conditions
- No prior COVID-19
- Healthy immune systems
- No risk of severe disease

Wuhan Strain

Comparator should have been natural immunity and antiviral therapy

R 1:1

Inoculation

Placebo

3 weeks

Inoculation

Placebo

Should have assessed all cause morbidity and mortality

Selective and flawed testing

1-week

COVID-positive
PCR +
2 symptoms

Minimum Follow-up ~2 months

Primary Endpoints

- Occurrence COVID-19 7 days post dose 2
- Solicited (7 days)/unsolicited safety (1-6 months)

Secondary Endpoints

- Severe COVID-19

Population size

- Randomized 43,548
- Efficacy 36,523
- Safety 43,252

Study is NOT designed to PROVE that inoculations:

- Reduce asymptomatic disease
- COVID-19 hospitalization or death
- Reduce all-cause morbidity and mortality
- Are completely safe in the short or long term
- Can stop transmission

Trial unblinded and crossover permitted at 2 months

Polack *et al.* NEJM 2020

WRONG COMPARATOR
NATURAL IMMUNITY IS STANDARD

Preparedness Month 2018

- Healthy >16 years or stable medical conditions
- No prior COVID-19
- Healthy immune systems
- No risk of severe disease

R 1:1

Inoculation

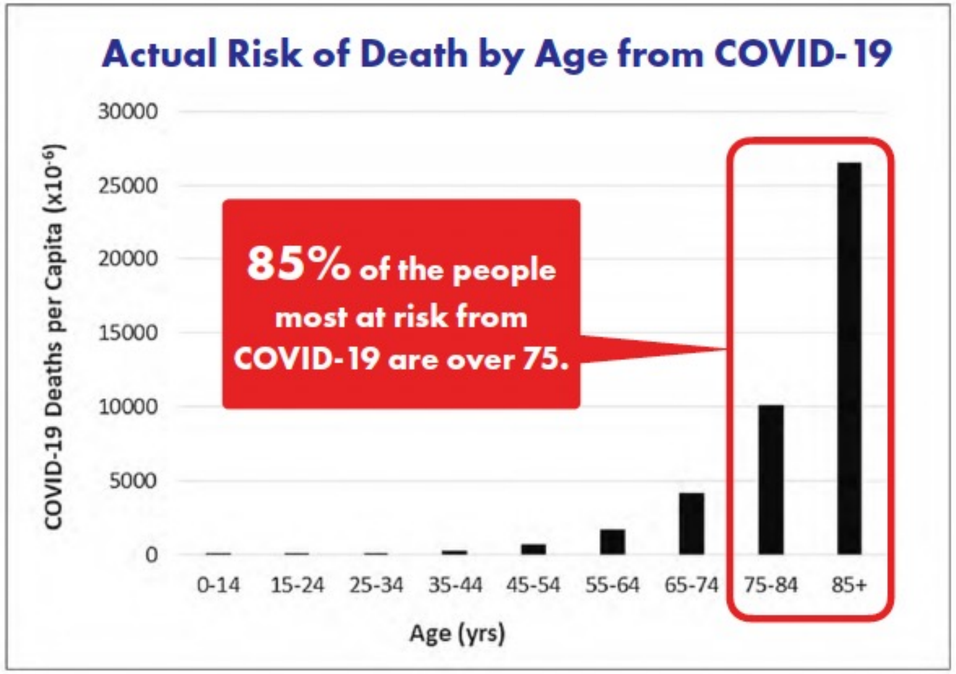
Natural Immunity & Treatment

- People have been successfully combatting coronaviruses in the form of the common cold for decades
- Maintaining a healthy lifestyle is key to maintaining a strong immune system
- Historically nutraceuticals and anti-viral therapy have been used to prevent and treat respiratory infections

Cui *et al.* Nat Rev Microbiol 2019; Kahn & McIntosh Pediatr Infect Dis J 2005; Osterhaus & Mackenzie *et al.* BMC 2020;~~B~~ Mousa JEBIM 2016; PHO 2019 – Antivirals for Influenza; Polack *et al.*, ~~Phase III~~ NEJM 2020; Singh *et al.* Front Nutr 2021; WHO 2021 - Nutrition

Baden et al., Phase III COVE Study, Jan 2021

NOT TESTED IN ELDERLY
NOT PROVEN SAFE



COVID-19 Deaths per capita by age in the United States (as of Jun 5, 2021). Population-based on U.S. CDC WONDER Bridge-Race Population Estimate 2019. Data obtained from https://wonder.cdc.gov/bridged-race-v2019.html

Pfizer Trial Demographics

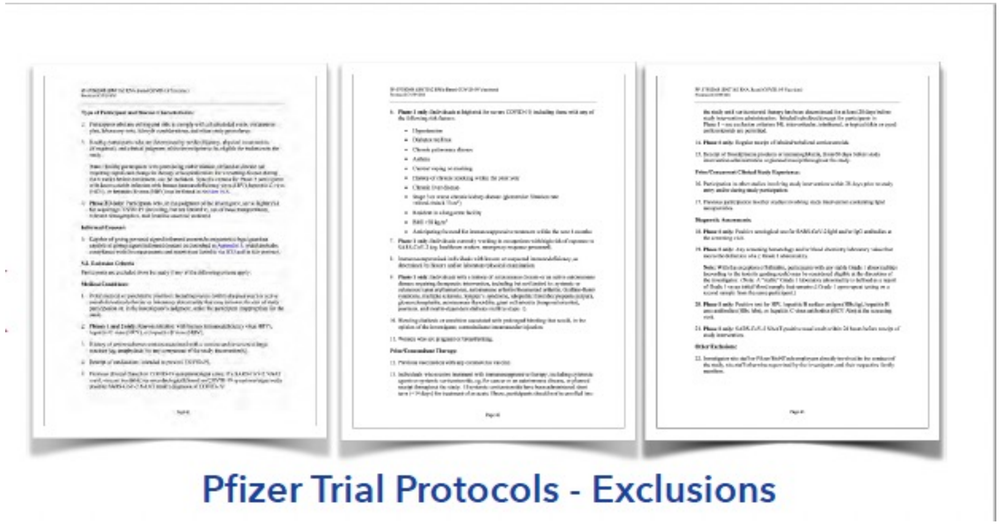
Demographics (population for the primary efficacy endpoint). The number of participants who received vaccine and placebo, stratified by age.

AGE GROUP	Pfizer-BioNTech COVID-19 Vaccine (N = 18,242) n (%)	Placebo (N = 18,379) n (%)
≥12 through 15 years[b]	46 (0.3 %)	42 (0.2 %)
≥16 through 17 years	66 (0.4 %)	68 (0.4 %)
≥16 through 64 years	14,216 (77.9 %)	14,299 (77.8 %)
≥65 through 74 years	3176 (17.4 %)	3226 (17.6 %)
≥75 years	804 (4.4 %)	812 (4.4 %)

Yet 75+ year olds represent only 4% of trial subjects.

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)
https://labeling.pfizer.com/ShowLabeling.aspx?id=14471

NOT TESTED IN SICK
NOT PROVEN SAFE



Pfizer Trial Protocols - Exclusions

REAL WORLD CO-MORBIDITIES

95% of people who have died with COVID-19 have had **at least 1 co-morbidity** listed as cause of death. The **average is 4 co-morbidities**.

https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR3-wrg3fTKK5-9tOHPGAHWFVO3DfslkJ0KsDEPQpWmPbKtp6EsoVV2Qs1Q#Comorbidities

PFIZER TRIAL CO-CONDITIONS

Only **21% had a co-existing condition.**

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577?articleTools=true

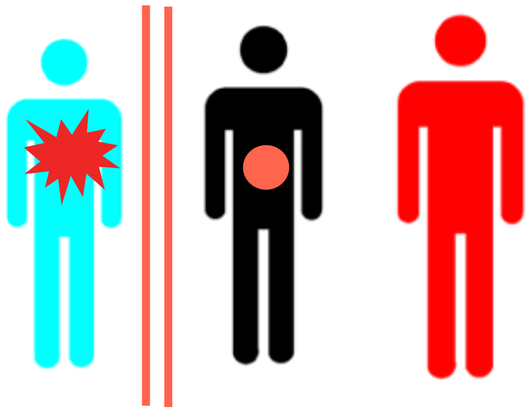
IMPLICATIONS FOR ROLL OUT

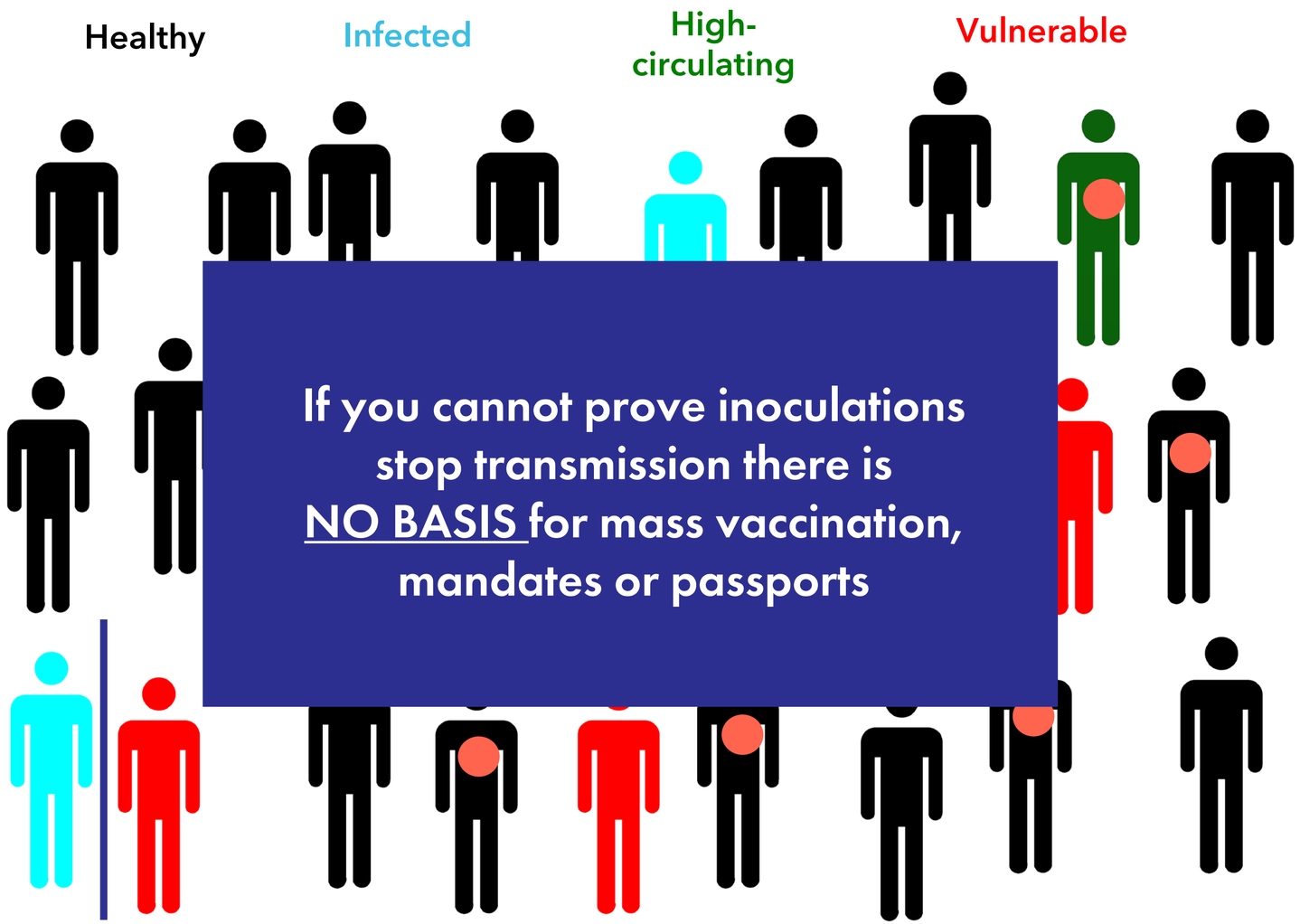
- We are told the inoculations are "safe." Yet **many health conditions** - in fact a list several pages long - **were excluded from the trials**, including pregnant or breastfeeding women, people with allergies, with psychiatric conditions, immunocompromised people, people with bleeding disorders, people who had previously tested positive for COVID-19, people who had been prescribed steroids, etc., so there has never been any data to make safety claims about those people. Yet **they are also not excluded from mandates and vaccine passports.**
- The vaccines were **tested on the healthy**, and then immediately **given to the frailest members of the society** - the elderly with multiple health conditions. This is unscientific and unethical.

Thomas *et al.* NEJM 2021

DON'T STOP TRANSMISSION
NO BASIS FOR MASS VACCINATION

Sterilizing vaccines prevent SPREAD of disease

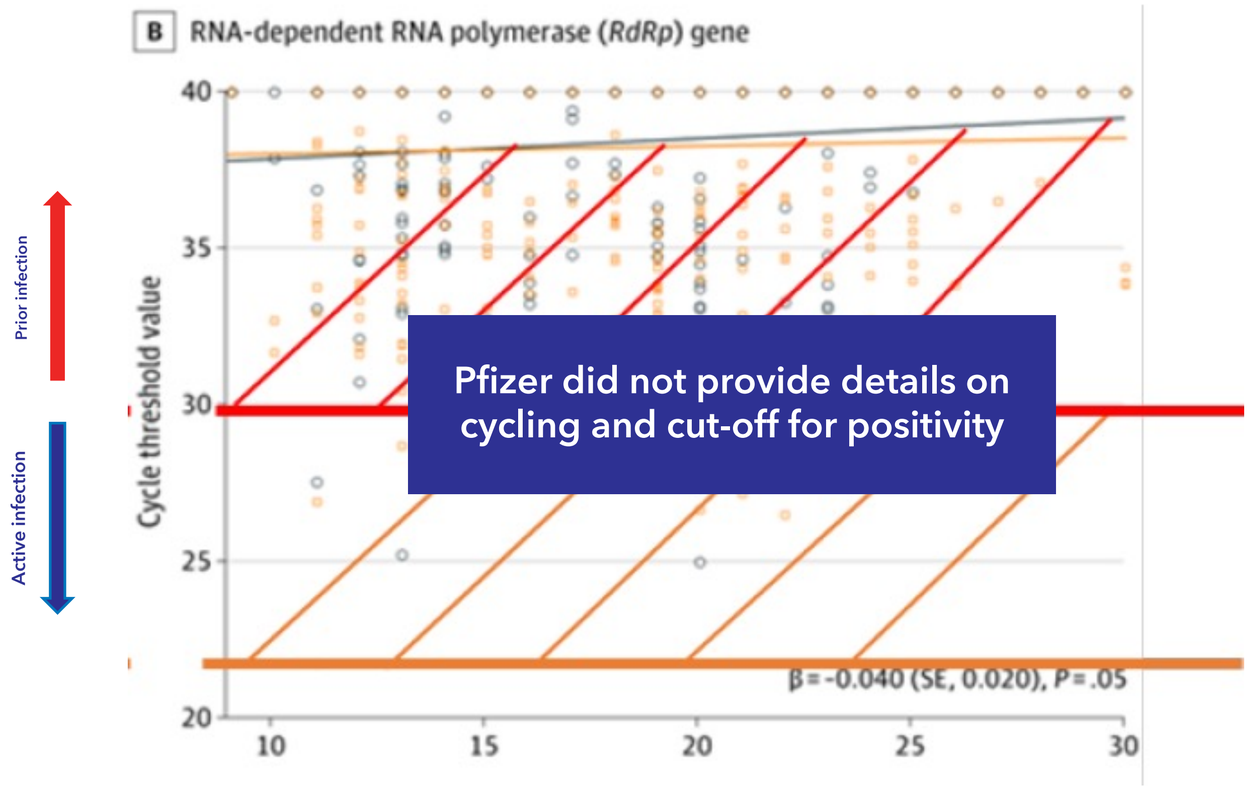




If you cannot prove inoculations stop transmission there is NO BASIS for mass vaccination, mandates or passports

WRONG TEST
SUBJECT TO FALSE POSITIVES

- Functional virological assay is gold standard for detecting active infections
- PCR never intended as a diagnostic tool and is not a clinically validated test for COVID-19 infections
- Very sensitive test that amplifies viral material. The greater the amplification cycles the more likely will to detect viral material
- Active infection detected at a cycle cut-off of between 20 and 30 cycles. Higher cut-offs may detect viral fragments rather than active infections
- Little to no standardization on how test is used and no details on its use in the mRNA inoculation trials



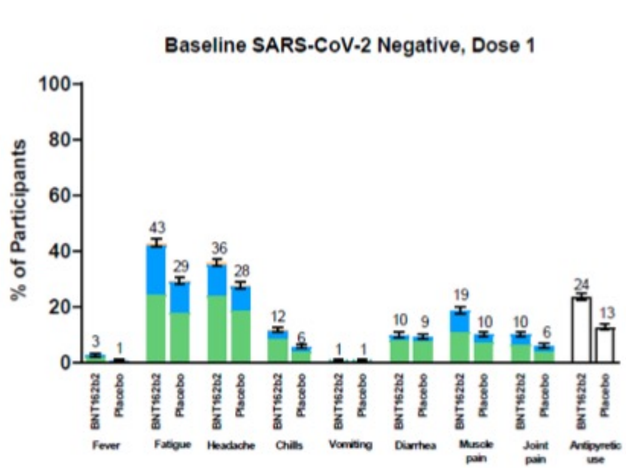
IDSMA/AMP 2021 – Joint Statement: Ct for Clinical Decision-making; Mina *et al.* Lancet 2021

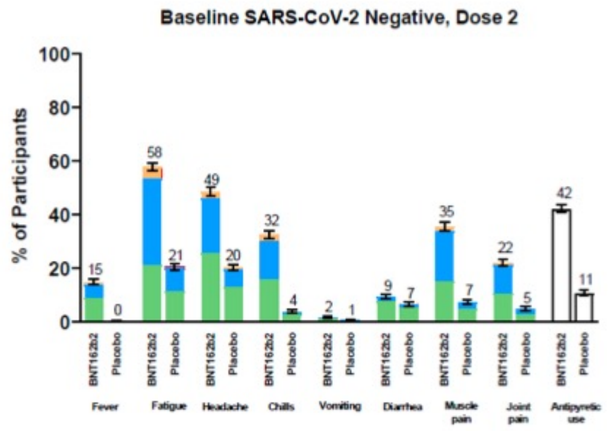
SAFETY
COVID-LIKE SYMPTOMS

COVID-19 cases following the first and second inoculation doses

Efficacy End Point	BNT162b2 (N=23,040)			Placebo (N=23,037)			Vaccine Efficacy
	No. of cases	Surveillance time	No. at risk	No. of cases	Surveillance time	No. at risk	
		1000 person-yr			*1000 person-yr*		*% (95% CI)*
Overall: first occurrence of Covid-19 after receipt of first dose	131	8.412	22,505	1034	8.124	22,434	87.8 (85.3 to 89.9)
After receipt of first dose up to receipt of second dose	46	1.339	22,505	110	1.331	22,434	58.4 (40.8 to 71.2)
<11 Days after receipt of first dose	41	0.677	22,505	50	0.675	22,434	18.2 (−26.1 to 47.3)
≥11 Days after receipt of first dose up to receipt of second dose	5	0.662	22,399	60	0.656	22,369	91.7 (79.6 to 97.4)
After receipt of second dose to <7 days after	3	0.424	22,163	35	0.422	22,057	91.5 (72.9 to 98.3)

Solicited systemic adverse effects for Pfizer BNT162b2 vaccine (<7 days)





Despite there being **more cases** of symptomatic COVID-19 in the placebo arm after the first and second dose the rates of COVID-like symptoms are **dramatically higher in the inoculation** compared to placebo arm after each shot meaning that the **inoculation is causing COVID-like morbidity**, the very thing the inoculations are intended to prevent

Baden *et al.*, Phase III COVE Study, Jan 2021

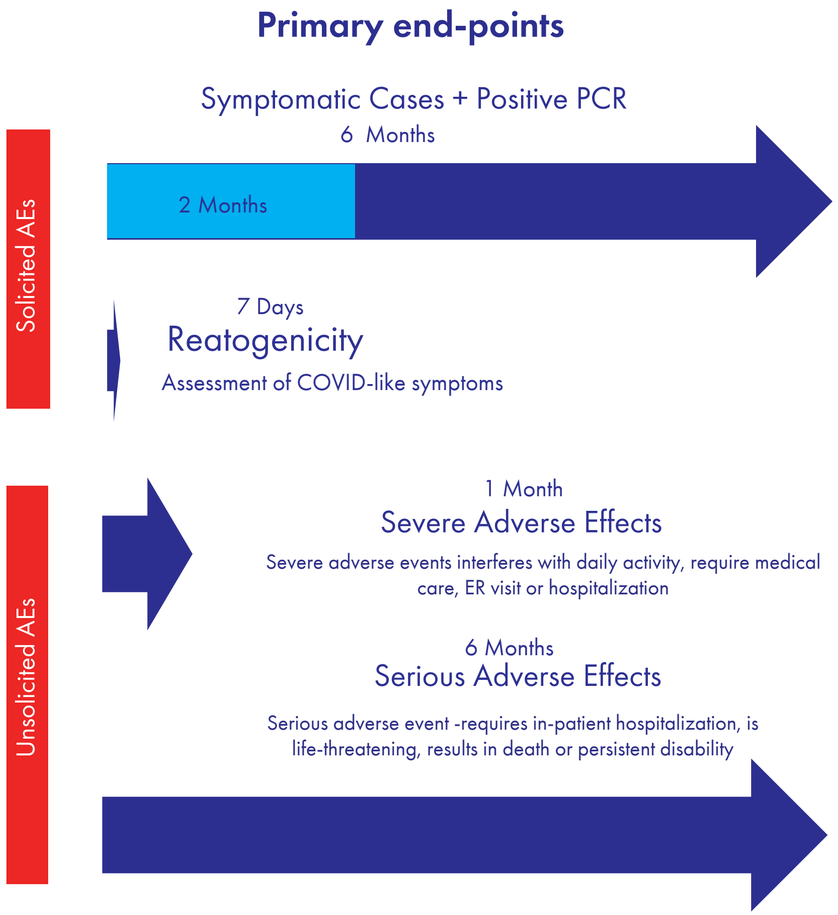
SELECTIVE TESTING
UNDER REPORTING OF SIDE EFFECTS

Cases

- When assessing cases they did not test all participants only tested those who were symptomatic and left it up to the discretion of the investigator to test
- This did not allow us to assess asymptomatic infection and introduced a concerning level of subjectivity

Side Effects = Underreported

- Most common side effect was COVID-like symptoms and only assessed for 7 days
- Did not assess subclinical side effects to see if predisposing to underlying disease such as inflammation, cardiac damage or clotting
- Only measure severe or serious adverse effects for more than a month



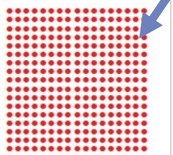
Polack *et al.* NEJM 2021

EARLY UNBLINDING OF RANDOMIZED CONTROL TRIAL = NO LONG TERM SAFETY DATA

WHAT WAS SUPPOSED TO HAPPEN

	INOCULATED GROUP	PLACEBO GROUP	
2020			July 27, 2020 Phase III Begins The participants are evenly divided into Inoculated and Placebo groups of about 21.000 each. The study is blind, so participants don't know which group they are in.
2021			
2022			
2023			May 2, 2023 End of Phase III Clinical Trial This is the point where the trial can be unblinded and the Placebo group offered the intervention if it's indicated and they consent.

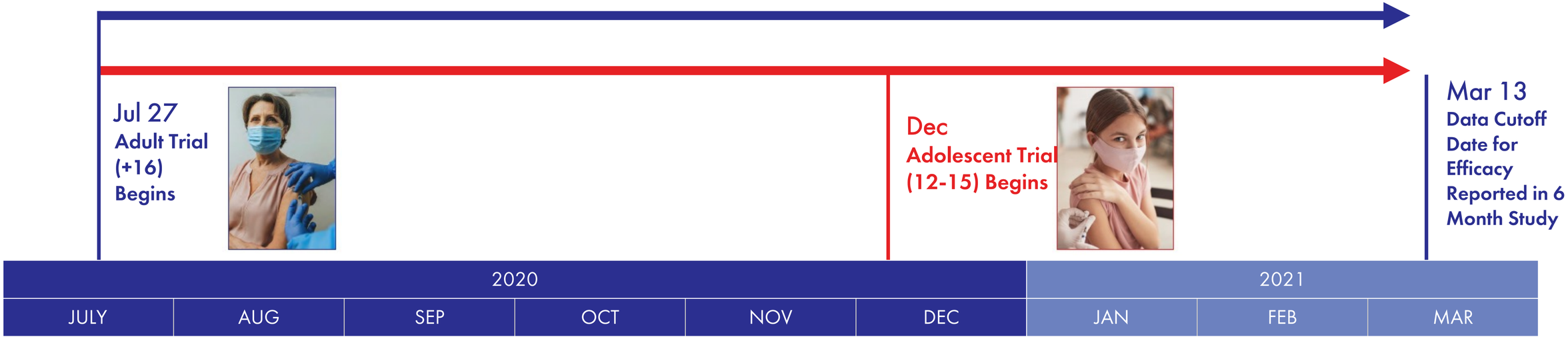
WHAT ACCTUALLY HAPPENED

	INOCULATED GROUP	PLACEBO GROUP	
2020			July 27, 2020 Phase III Begins The participants are evenly divided into Inoculated and Placebo groups of about 21.000 each. The study is blind. Dec 31, 2020 Release 2 month data report. The trial is unblinded early.
2021		NO DATA	Crossover Occurs The participants from the Placebo Group are given the opportunity to take the inoculation and by early 2021, the majority of them have crossed over to the inoculated group. It's no longer a randomized control trial, as control group is gone.
2022		NO DATA	
2023		NO DATA	May 2, 2023 End of Phase III Clinical Trial The long term safety data that was supposed to be assessed at this point is no longer possible to certain as the placebo group crossed over two years previously.

6 MONTH DATA MANIPULATION
MIXED COHORTS

Pfizer took the results from their adult trial, which started July 27, 2020 and then added the results from the 12 - 15 years old´trial, **despite the fact that the adolescent trial started four months later.**

Since it's well known that the efficacy of the inoculations wanes over time, **this gives a false boost to the efficacy numbers.** The efficacy for these two cohorts should have been reported separately, not presented as one combined result. Without this boost, their efficacy number would likely have fallen.



INCREADES RISK OF ILLNESS

Screen capture from Pfizer 6 Month Supplementary Appendix

Adverse Event	BNT162b2 (N[a]=21,926) n[b] (%)	Placebo (N[a]=21,921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c,d]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥16-year-old participants who received ≥1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting ≥1 occurrence of the specified event category. For 'any event', n=number of participants reporting ≥1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.[11]

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

A considerable increase in illness, which the Pfizer inoculations were supposed to reduce

	BNT162b2 20,998*	Placebo 21,096*	Relative Risk Change	Absolute Risk Change
Symptomatic Cases (Ongoing)	77	850	-91 %	-4 %
Severe Cases (Ongoing)	1	23	-97 %	-0.1 %
Treatment Related Adverse Effects (1 month post second dose)	5.241	1.311	+300%	+18%
Any Severe Adverse Effects (1 month post second dose)	262	150	+75%	+0.5%
Any Serious Adverse Effects (6 months post second dose)	127	116	+10%	+0.05%

* Efficacy population

Severe adverse events interferes with daily activity, require medical care, ER visit or hospitalization
Serious adverse event -requires in-patient hospitalization, is life-threatening, results in death or persistent disability

SAFETY
COVID-LIKE SYMPTOMS

Higher rates of COVID-19 in the placebo arm of Moderna trial prior to the inoculation reaching its therapeutic window, suggests some sort of bias against placebo arm

Table S18. Preliminary Analysis of Infection from Randomization, Modified Intent-to-Treat

	Placebo N=14598	mRNA-1273 N=14550	Vaccine efficacy (95% CI)
Symptomatic Covid-19	293	20	
Covid -19	269	19	
Secondary definition of Covid -19	24	1	
Positive RT-PCR at scheduled pre-dose 2*	39	15	
Total infection (symptomatic or RT-PCR+ at pre-dose 2)	332	35	89.6% (85.2%-92.6%)†
Person-years‡	3365.6	3386.6	
Incidence rate (95% CI)§	98.6 (88.3-109.8)	10.3 (7.2-14.4)	89.5% (85.1%-92.8%)

Preliminary analysis of infection from randomization performed based on the modified intent-to-treat set (data cut-off November 25, 2020). Infection was defined as symptomatic Covid-19, either Covid-19 (positive RT-PCR with two eligible systemic or one eligible respiratory symptom), or secondary/CDC definition of Covid-19 requiring one symptom, or, asymptomatic infection, as measured by positive RT- PCR at the scheduled pre-Dose 2 visit.). *Positive RT-PCR at the scheduled pre-Dose 2 visit and no Covid-19 symptoms. †From stratified Cox proportional model adjusting for the stratification factor. ‡Person-years defined as the total years from randomization date to the date of Covid-19, last date of study participation, or efficacy data cutoff date, whichever was earlier. §Incidence rate was defined as the number of participants with an event divided by the number at risk adjusted by person-years (total time at risk) in each treatment group and 95% CI calculated using the exact method (Poisson distribution) conditional on total number of events adjusted by person-years.

Intent to treat infection analysis as of randomization at min 60 days follow-up (S18)

	mRNA-1273 14,550	Placebo 14,598	Net Change 14,574
Total Infection	35 (0.2%)	332 (2.3%)	-297 (2.0%)
COVID-19 (Symptomatic & PCR+)	10 (0.1%)	293 (2%)	-283 (1.9%)
COVID-9 ([A]symptomatic & PCR+)	1 (0.1%)	24 (0.2%)	-23
COVID-9 (Scheduled <dose 2 PCR+)	15 (0.1%)	39 (0.3%)	-24 (0.16%)

COVID-19 symptoms (S18) – cough, difficulty breathing, fever, chills, arthralgia/myalgia, fatigue, headache, runny nose, sore throat, loss of smell and taste, nausea/vomiting

Solicited and unsolicited adverse reactions or events (S3, S4 & S8)

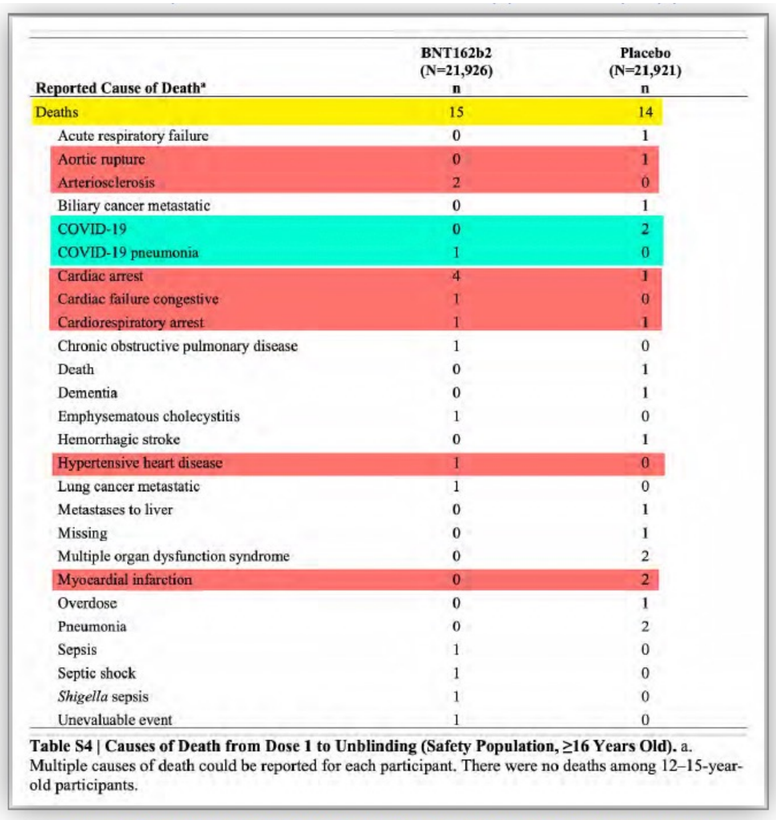
	mRNA-1273 15,150 (d1) 14,677 (d2) 15185 (un)	Placebo 15,155 (d1) 14,566 (d2) 15,166 (un)	Net Change 15,152 (d1) 14,621 (d2) 15,175 (un)
Any Solicited AR, d1 (7 days)	13,319 (87.8%)	7,284 (48%)	+6,035 (40%)
Any Solicited AR, d2 (7 days)	13,534 (92.2%)	6,232 (42.8%)	+8,302 (57%)
Unsolicited AE (28 days)	3,632 (23.9%)	3,277 (21.6%)	+355 (2.3%)

Solicited AEs – Pain, rash, swelling, lymph nodes, fever, headache, fatigue, arthralgia/myalgia, nausea/vomiting, chills
Unsolicited AEs (S10) – headache, cough, sore throat, diarrhea, arthralgia/myalgia, fatigue, injection site pain, hypertension, bradycardia

Baden *et al.*, Phase III COVE Study, Jan 2021

INCREASED RISK OF DEATH

Screen capture from Pfizer 6 Month Supplementary Appendix



Reported Cause of Death*	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

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

	BNT162b2	Placebo
Deaths before unblinding (In Table S4 of Supplementary Appendix)	15	14
Deaths after unblinding (Not in the table, but mentioned in the text of the 6 month report. See quote below)	5	
Total Deaths	20	14

"After unblinding" means when the Placebo participants were given the opportunity to "cross over" and take the BNT162b2 inoculation.*

"3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died."

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

Concerning Causes of Death

	BNT162b2	Placebo
Total COVID-19 Related Deaths	1	2
Deaths Related to Cardiovascular Events	9	5

NOT DESIGNED TO ASSESS EFFICACY
IMMUNOBRIDGING TRIALS

Trials assessing BNT162b2 were immunobridging trials and were not designed to PROVE the safety and efficacy of the inoculation relative to placebo

Trials were designed to assess the non-inferiority of the neutralizing antibody titres in children compared to young adults

30 µg	Cohort 12 - 15 years	vs	30 µg Cohort 16- 25 years
190			170
10 µg	Cohort 5- 11 years	vs	30 µg Cohort 16- 25 years
264			253

INCREASED RISK OF ILLNESS

*Adolescents are at **little to no risk of death** and a very low risk of severe disease...*

	BNT162b2 1005*	Placebo 978*	Relative Risk Change	Absolute Risk Change
Symptomatic Cases (Ongoing)	0	18	-100 %	-2 %
Severe Cases (Ongoing)	0	0	0 %	**0 %**
Treatment Related Adverse Effects (1 month post 2nd dose)	33	21	+57%	+1%
Any Severe Adverse Effects (1 month post 2nd dose)	7	2	**+249%**	**+0.4%**
Any Serious Adverse Effects (6 months post 2nd dose)	4	1	**+299%**	**+0.3%**

* Efficacy population

Severe adverse events interferes with daily activity, require medical care, ER visit or hospitalization
Serious adverse event -requires in-patient hospitalization, is life-threatening, results in death or persistent disability

SERIOUS ADVERE EVENTS

Maddie de Garay is a 12 year old trial participant who developed a serious reaction after her second dose and was hospitalized within 24 hours.

Maddie developed gastroparesis, nausea and vomiting, erratic blood pressure, memory loss, brain fog, headaches, dizziness, fainting, seizures, verbal and motor tics, menstrual cycle issues, lost feeling from the waist down, lost bowel and bladder control and had an nasogastric tube placed because she lost her ability to eat. She has been hospitalized many times, and for the past **10 months she has been wheelchair bound and fed via tube.**

In their report to the FDA, **Pfizer described her injuries as "functional abdominal pain."**

- One participant experienced an SAE reported as generalized neuralgia, and also reported 3 concurrent non-serious AEs (abdominal pain, abscess, gastritis) and 1 concurrent SAE (constipation) within the same week. The participant was eventually diagnosed with functional abdominal pain. The event was reported as ongoing at the time of the cutoff date.

Emergency Use Authorization Amendment

MYORCARDITIS IS SERIOUS

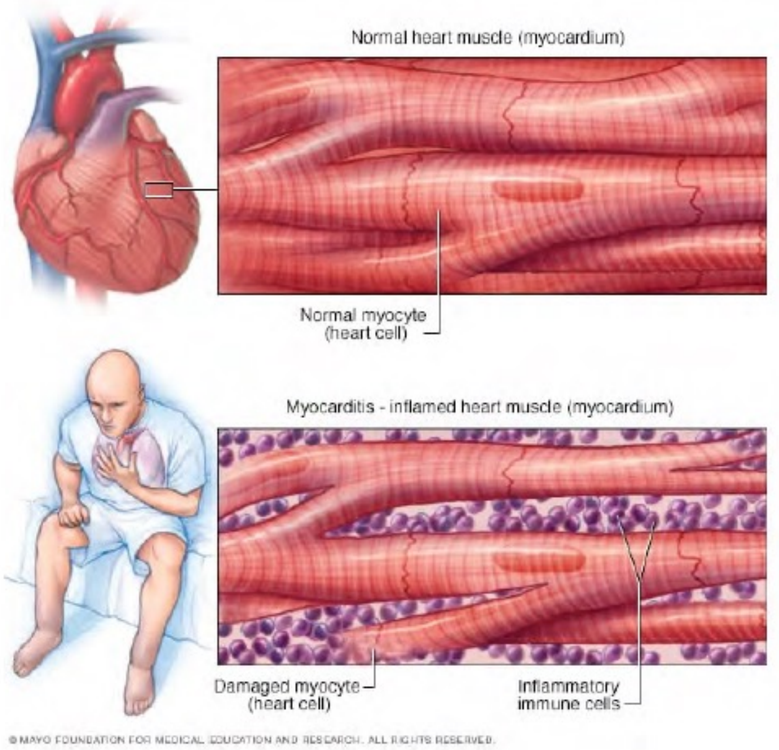
MYOCARDITIS

"Myocarditis is an inflammatory process of the myocardium. (Heart muscle.) **Severe myocarditis weakens your heart** so that the rest of your body doesn't get enough blood. Clots can form in your heart, **leading to a stroke or heart attack."**

THE US NATIONAL CENTRE FOR BIOTECHNOLOGY INFORMATION

"The mortality rate is up to 20% at 6.5 years."

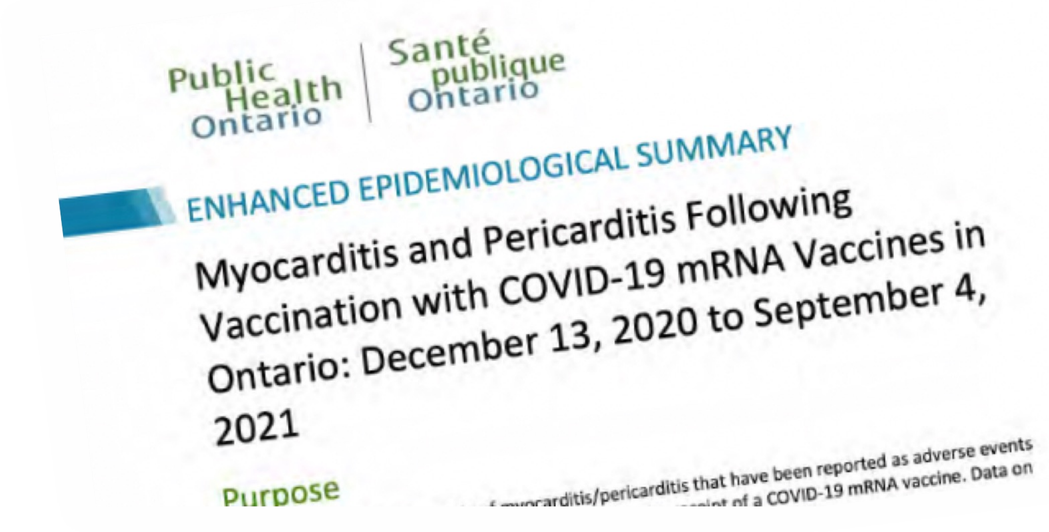
https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7



INCREASED HEART ISSUES

Ontario Public Health is well aware of this, as they published a report on it, but they seem inconsistent in their concerns.

- On Sep 29, 2021, Ontario Public Health recommended **young men 18-24** not to take the **Moderna shot**, because of a 1 **in 5.000 risk of myocarditis.** They suggested **Pfizer shot** instead, which has a **1 in 28.000 risk of myocarditis.**
- But as recently as May 8, 2021, **Ontario has stopped AstraZeneca shot because of a 1 in 60.000 risk of clotting side effects in adults**, which was considered too high.
- **Their priorities are inconsistent.**


Public Health Ontario | Santé publique Ontario

ENHANCED EPIDEMIOLOGICAL SUMMARY

Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021

Purpose

myocarditis/pericarditis that have been reported as adverse events ... of a COVID-19 mRNA vaccine. Data on


TORONTO SUN

Ontario

More than 100 Ontario youth sent to hospital for vaccine-related heart problems: Report

There were 54 persons aged 25-39 included in the tally and 44 persons aged 40 and over

Anthony Furey
Sep 03, 2021 • September 3, 2021 • 2 minute read • 314 Comments

coronavirus disease (COVID-19) vaccine labels are seen
, 2021. PHOTO BY DADO RUVIC /REUTERS

INCREASED RISK OF ILLNESS

*Children are **little to no risk of death from COVID-19** and* a very low risk of severe disease ....

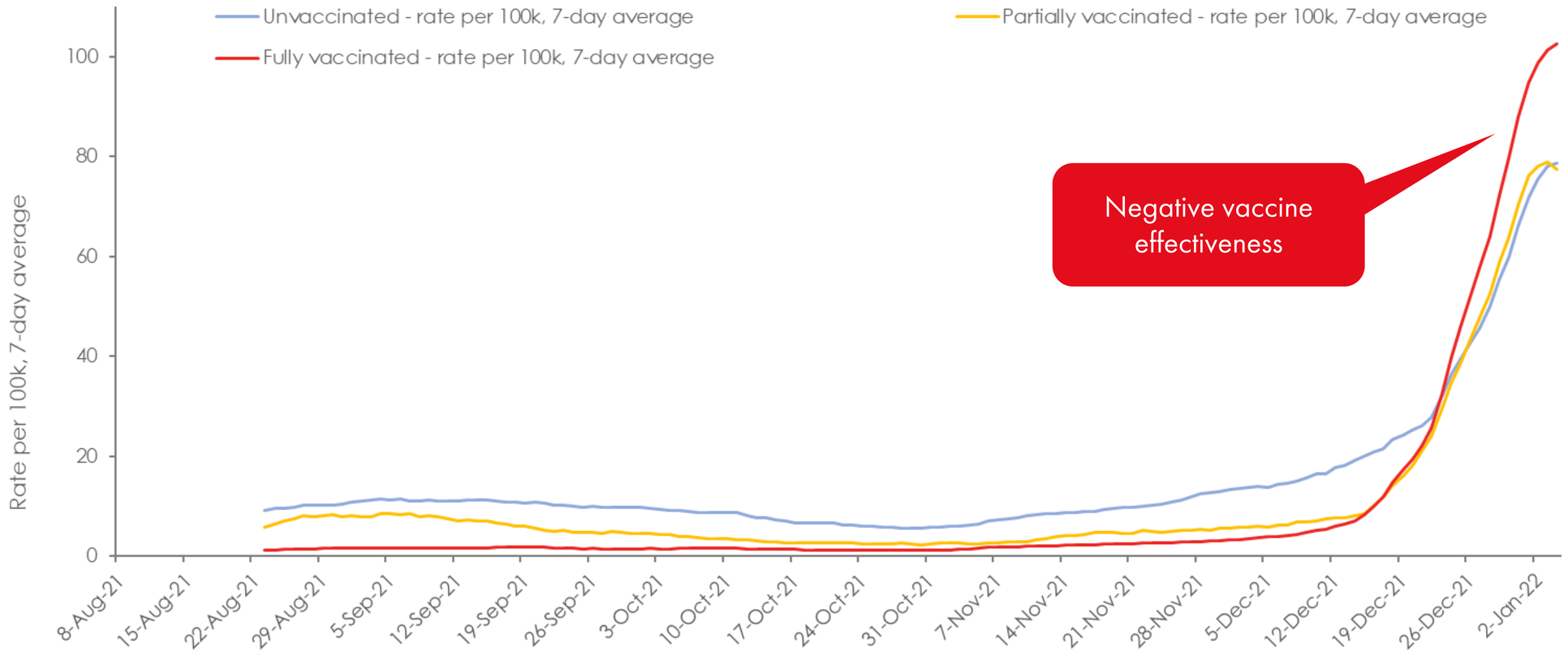
	BNT162b2 1,305*	Placebo 663*	Relative Risk Change	Absolute Risk Change
Symptomatic Cases (Ongoing)	3	16	-90 %	-2 %
Severe Cases (Ongoing)	0	0	0 %	0 %
Any Adverse Effects (1 month post 2nd dose)	46	16	+42%	+1%
Any Severe Adverse Effects (1 month post 2nd dose)	2	1	-1.2%	-0.002%
Any Serious Adverse Effects (6 months post 2nd dose)	1	1	-51%	-0.07%

* Efficacy population

Severe adverse events interferes with daily activity, require medical care, ER visit or hospitalization
Serious adverse event -requires in-patient hospitalization, is life-threatening, results in death or persistent disability

NEGATIVE EFFECTIVENESS

Proportion of Cases by Vaccination Status – August 8, 2021 – January 4, 2022



Proportion of cases among the fully vaccinated outpace both the partially vaccinated and the unvaccinated

This shows that the current vaccine is demonstrating negative effectiveness against Omicron

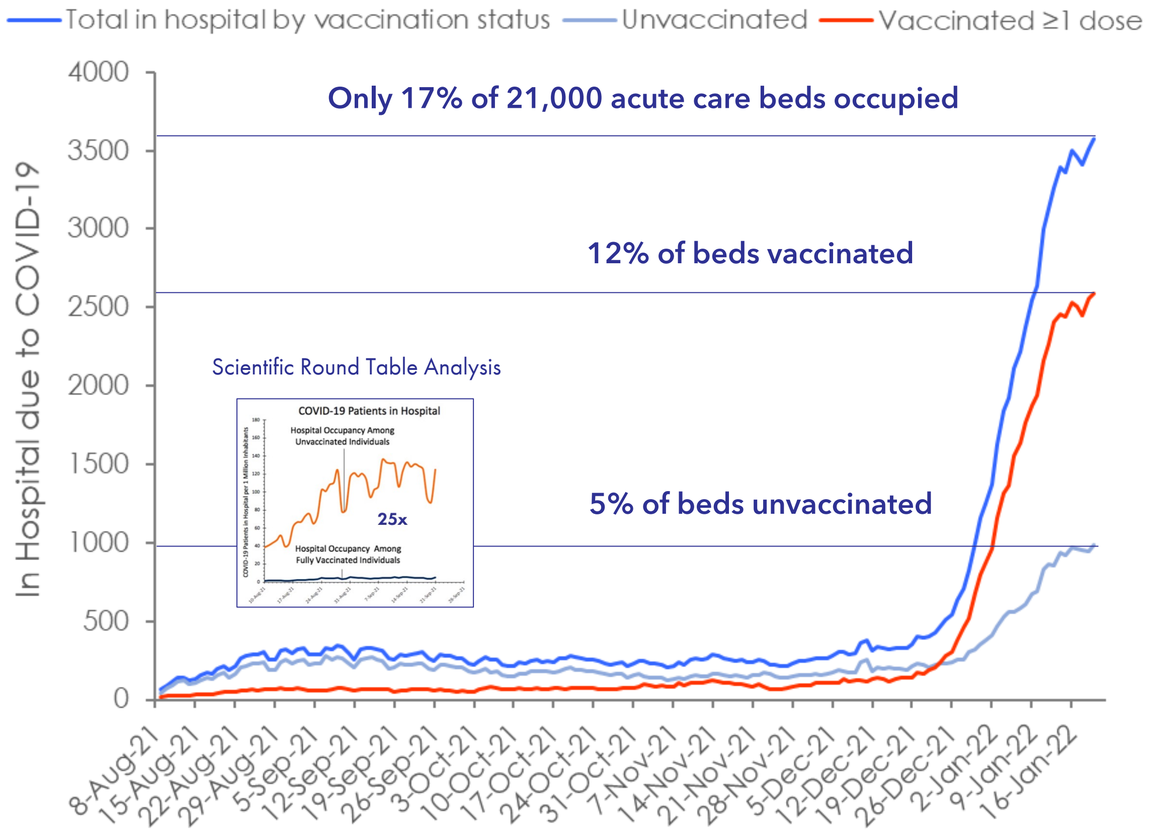
This means that those who are fully vaccinated are actually at an increased risk of catching Omicron

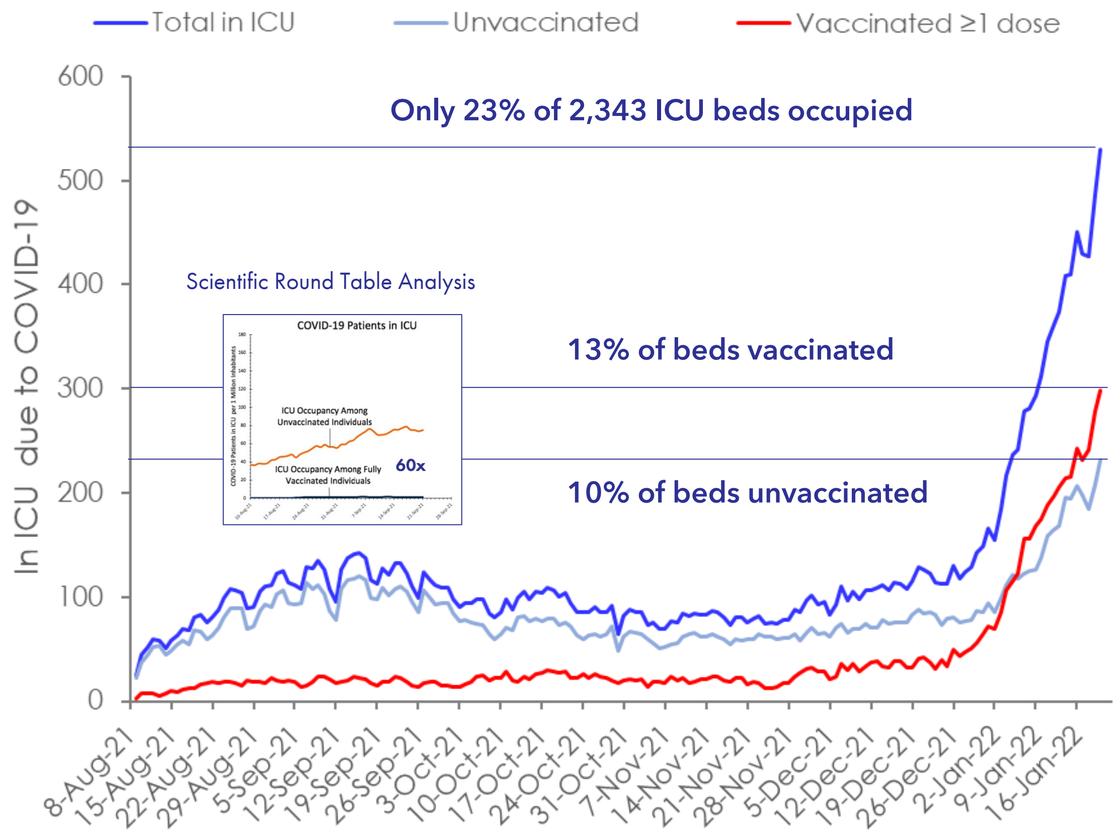
Buchan *et al.* MedRxiv.org 2021 - Effectiveness of COVID-19 vaccines against Omicron; Gov't of Ontario, M of H COVID-19 Data Catalog;

Hansen *et al.* MedRxiv.org 2021 - Effectiveness of COVID-19 vaccines against Omicron Denmark; Pfizer pharmacovigilance report through Feb 2021;

MORE HOSPITALIZATIONS IN VACCINATED

Ontario COVID-19 Hospital and ICU Admissions by Vaccination Status from August 8, 2021 to January 20, 2022





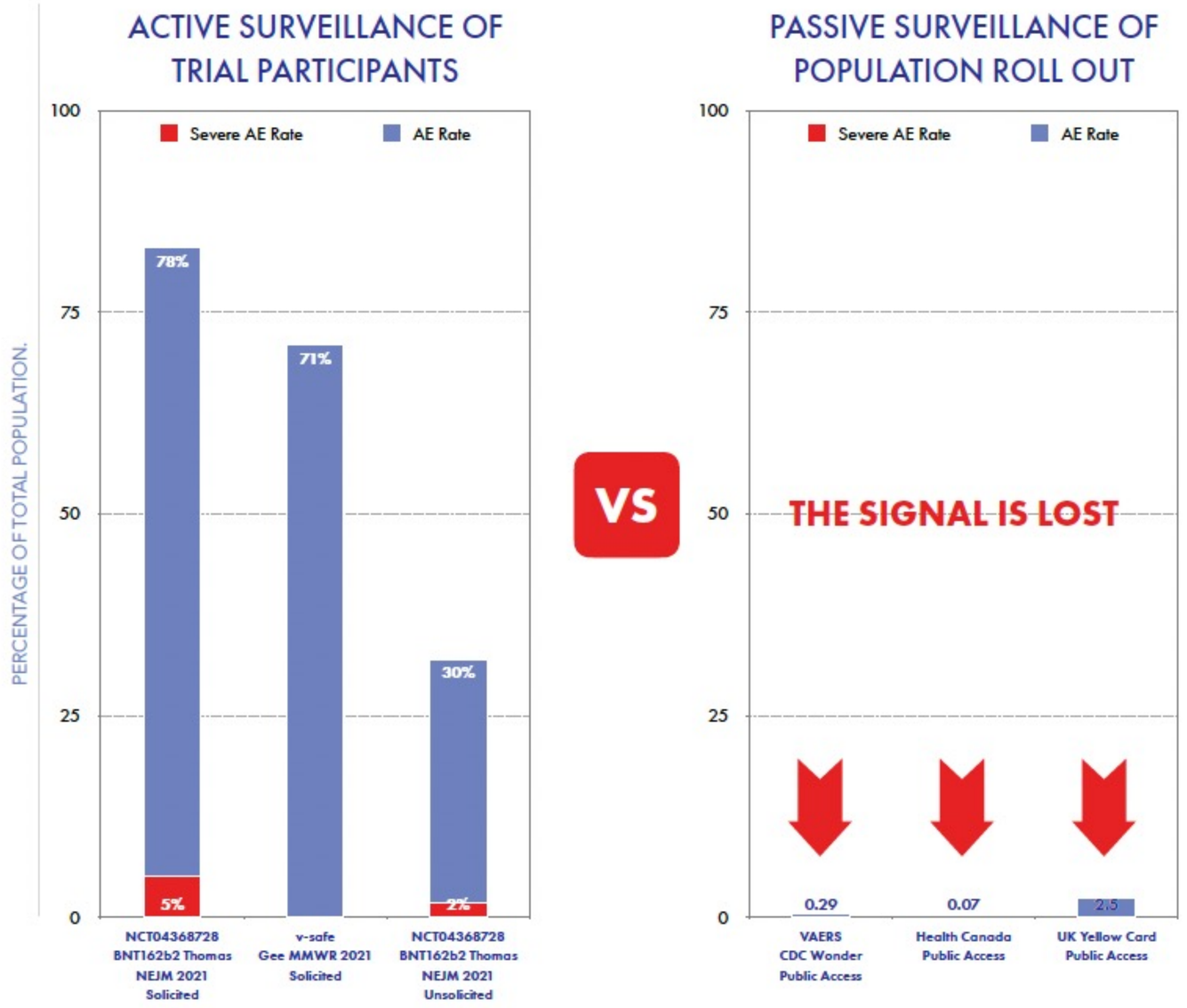
Gov't of Ontario M of H, COVID-19 Data Catalog; Science Table update of COVID-19 Projections, Prepared Sept 28, 2021

ROLL OUR SURVEILLANCE YOU DON'T FIND WHAT YOU DON'T LOOK FOR

There is a dramatic difference between passive vs active monitoring of adverse events

1. When participants were **actively** followed for adverse events (AEs) in the trials, high percentages of adverse events were reported.
2. Once the vaccine was rolled out at the population level, **passive** surveillance was used with Health Canada, VAERS or the European Yellow Card system.

When that happened, the **signal was completely lost**.



PFIZER'S POST MARKETING PHARMACOVIGILANCE REPORT

- On Nov 17, 2021, the FDA released the first batch of what will ultimately be **329,000 pages** they were ordered by a court to provide to satisfy a Freedom of Information request by a group called Public Health and Medical Professionals for Transparency who want access to the **data used by the FDA to approve Pfizer's COVID-19 inoculations**. (The FDA asked in court to have over 50 years to release the documents.)

- One **post marketing pharmacovigilance report** submitted to the FDA, where Pfizer tracked real world adverse events occurring in the first 2.5 months after Emergency Use Authorization, was particularly disturbing.
  - **Over 1,200 deaths**
  - **Over 25,000 nervous system adverse events**
  - Under "Safety concerns" Pfizer listed **Anaphylaxis** and **Vaccine-Associated Enhanced Disease**

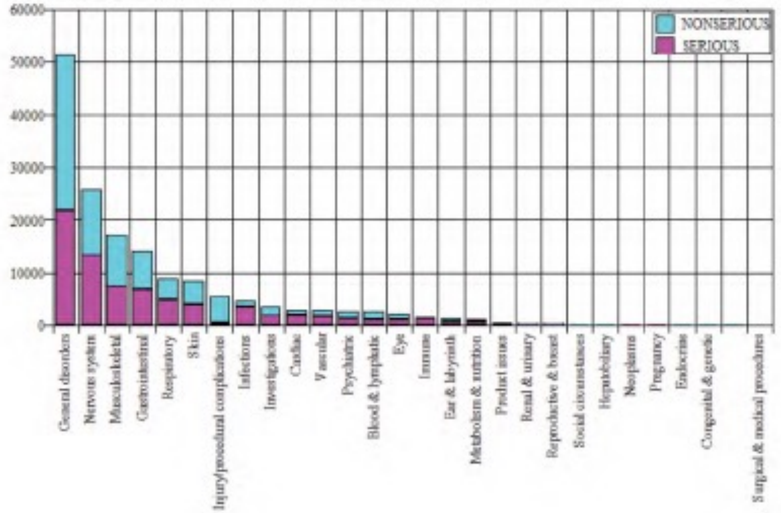
- **This document should be incriminating for any agency who saw it and called these inoculations "safe."**

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175[a]
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

THE BRITISH MEDICAL JOURNAL PUBLISHES WHISTLEBLOWER STORY

On November 2nd, the British Medical Journal released an article about their investigation into Ventavia, one of the research companies Pfizer hired to conduct the trials.

It's quite damning. The whistleblower is a Regional Director who actually reported her company to the FDA for:

- Falsifying data
- Unbliding participants
- Not following up and testing participants who reported symptoms
- Mislabelling specimens

Several other employees backed up her account. Despite all this, neither Pfizer, nor the FDA ever audited or investigated the research company, Pfizer never disclosed the problems in its EUA application, and in fact, Pfizer has now hired that same Researcher, Ventavia, to run four more COVID-19 clinical trials.

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 reports

Paul D Thacker *investigative journalist*

In autumn 2020 Pfizer's chairman and chief executive, Albert Bourla, released an open letter to the billions of people around the world who were investing their hopes in a safe and effective covid-19 vaccine to end the pandemic. "As I've said before, we are operating at the speed of science," Bourla wrote, explaining to the public when they could expect a Pfizer vaccine to be authorised in the United States.[1]

But, for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio executives later questioned Jackson for taking the photos.

Early and inadvertent unblinding may have occurred on a far wider scale. According to the trial's design, unblinded staff were responsible for preparing and administering the study drug (Pfizer's vaccine or a placebo). This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator. However, at Ventavia, Jackson told *The BMJ* that drug assignment confirmation printouts were being left in participants' charts, accessible to blinded personnel. As a corrective action taken in September, two months into trial recruitment and with around 1000 participants already enrolled, quality assurance checklists were updated with instructions for staff to remove drug assignments from charts.

In a recording of a meeting in late September2020 between Jackson and two directors a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control. "In my mind, it's something new every day," a Ventavia executive says. "We know that it's significant."

Ventavia was not keeping up with data entry queries

BMJ: first published as 10.1136/bmj.n2635

CONFLICTS OF INTEREST AMONG PFIZER REPORT AUTHORS

6 MONTH REPORT AUTHORS

Employment + Stock

N. Kitchin
J. Absalon — Corresponding Author
S. Lockhart
R. Bailey
K.A. Swanson — Last Author
S. Roychoudhury
K. Koury
W.V. Kalina
D. Cooper,
D.B. Tresnan
S. Mather
P.R. Dormitzer
U. Şahin — BioNTech founders whose stock value increased by $9 billion
W.C. Gruber
K.U. Jansen
Ö. Türeci — BioNTech founders whose stock value increased by $9 billion

Employment

A. Gurtman
J.L. Perez
S. Bouguermouh
P. Liberator
X. Xu

Grant/Consultant/ Clinical Trial

R.W. Frenck, Jr.
L.L. Hammitt
S. Ünal
S.J. Thomas — Lead Author
G. Pérez Marc
F.P. Polack

No Conflict

E.D. Moreira, Jr
H. Nell
A. Schaefer
C. Zerbini
Q. Yang

PFIZER IS MAKING BILLIONS

$33.5B+ in 2021 alone.

When the incentive is such an astronomical sum of money, it only makes sense to **ensure rigorous oversight** of the process and to ensure **as many safeguards as possible** are in place.

Their agenda is **their shareholders and their bottom line**, not public health.

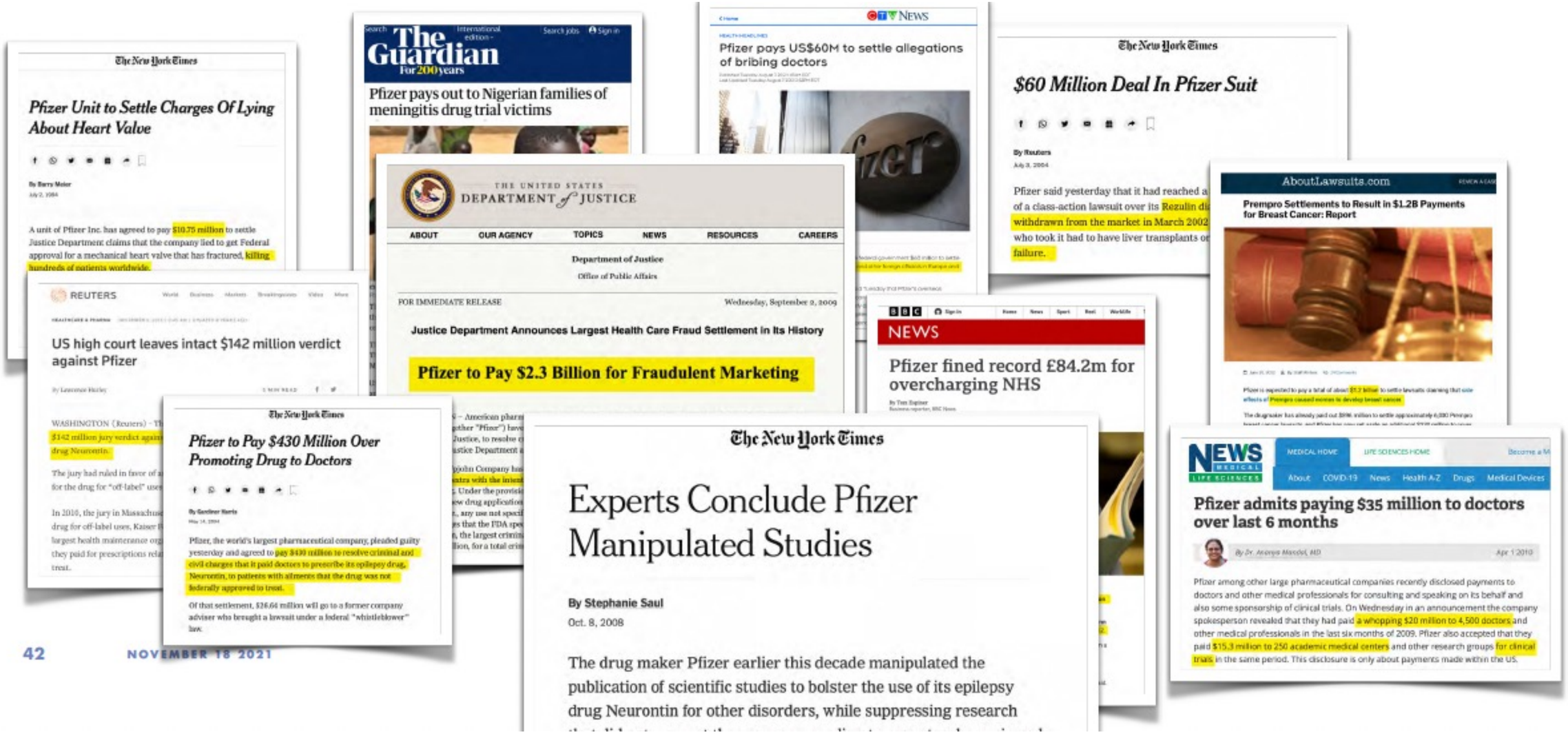
Forbes

Pfizer Expects $33.5 Billion In Vaccine Revenue In 2021

Albert Bourla, CEO of Pfizer, photographed in June 2020 JAMEL TOPPIN FOR FORBES

Biotech giant Pfizer expects to generate $33.5 billion in Covid-19 vaccine sales in 2021, up from previous estimates of $26 billion, according to its second quarter earnings reports. These projections are based on the 2.1 billion doses of the Pfizer/BioNTech vaccine which the company expects to manufacture and deliver by the end of the year.

THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE



THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE

Pfizer has been **indemnified for damages** in case their inoculations hurt and kill people, and Pfizer **profits to the tune of billions** if the trials are successful.

No reasonable, responsible person would have given Pfizer carte blanche in such a situation.

Instead, **you would engage in rigorous oversight** and **hold them to the highest scientific standards**. This was not done.

THE INOCULATIONS SHOULD BE WITHDRAWN IMMEDIATELY

- It's clear that Pfizer - and the agencies overseeing their trials - failed to follow established, high quality safety and efficacy protocols right from the beginning.
- We have presented **Level 1 evidence of harm from Pfizer's own trial data.** Any government which has approved these inoculations, much less mandated them, knew or **should have known from the available data that harm would be caused to its citizens.**
- Any government that approved this medical intervention for its citizens should have ensured that the trial had used the **appropriate clinical endpoints** and **high quality safety science.**
- **Any government official who possesses this evidence and continues to allow its citizens to be inoculated with a toxic agent is, at very least, negligent.**