



NDSU CENTER FOR IMMUNIZATION RESEARCH AND EDUCATION

## COVID-19 and Vaccines: Where Are We At?

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NDSU Dept. of Public Health

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## COVID-19 Vaccines

- Are they really necessary?
- Do they really work (Delta, Omicron)?
- Are they really safe?

2

## COVID-19 Vaccines

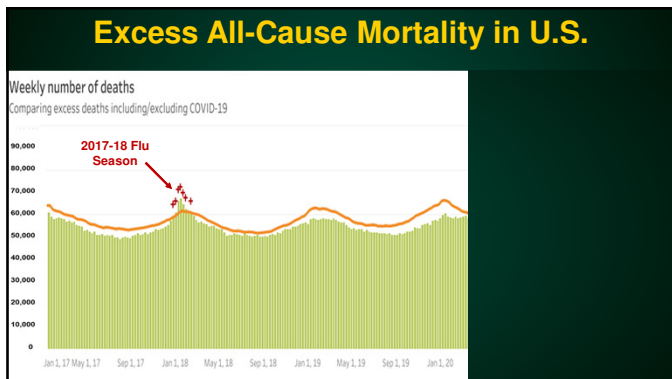
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3

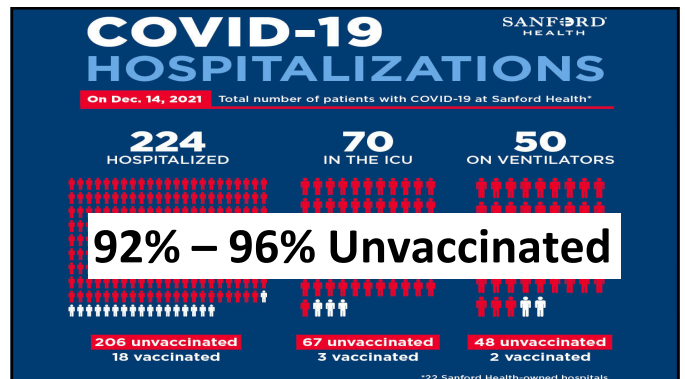
## COVID-19 Morbidity and Mortality as of 12/21/21

U.S.	ND
▪ 50,791,012 cases	▪ 1 : 4.5 tested positive
▪ 803,593 deaths	▪ 1 : 110 hospitalized
▪ 3 <sup>rd</sup> leading cause of death	▪ 1 : 382 died
▪ 2.7 - 3.7 million hospitalized (estimated)	
▪ Long-COVID?	

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I've heard more that half the people getting COVID-19 are vaccinated - Looks like the vaccines aren't working!

**Base Rate Fallacy**

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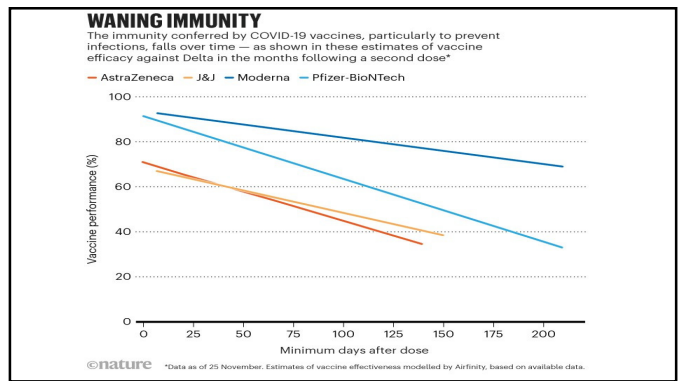
**Base Rate Fallacy:**  
 "But over 50% of the people with COVID are vaccinated?!"

**Vaccinated (N=90)**  
 Attack Rate: 7%  
 6 cases in vaccinated

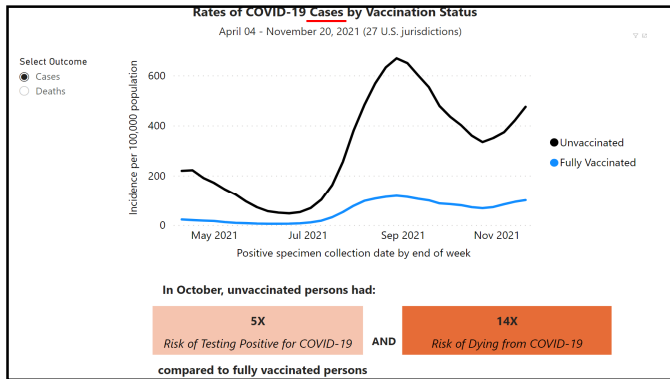
**Unvaccinated (N=10)**  
 Attack Rate: 50%  
 5 cases in unvaccinated

■ = Has COVID-19  
■ = Healthy

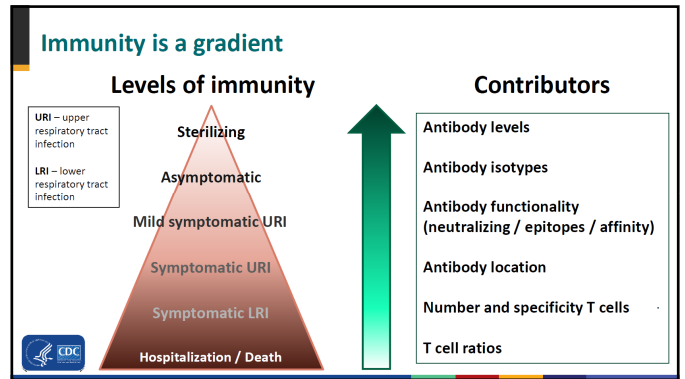
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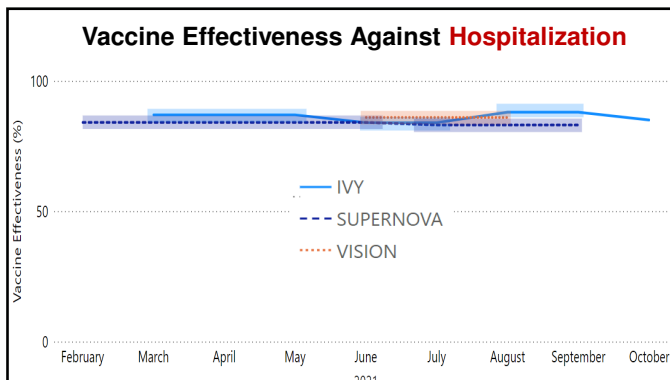
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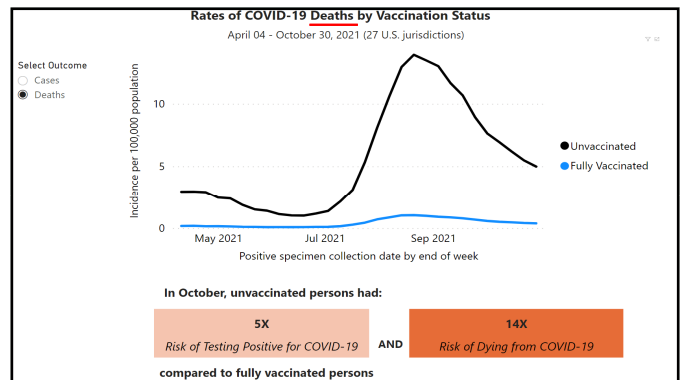
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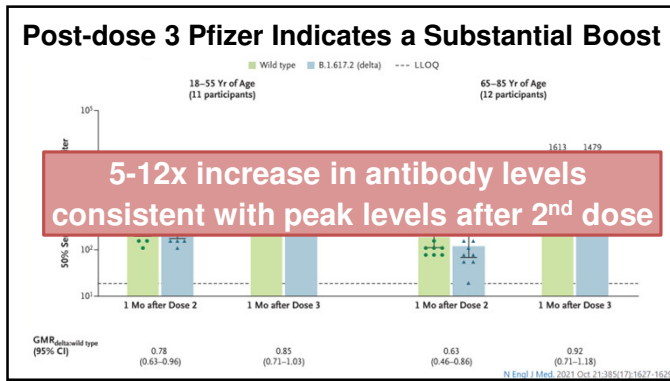


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**Many Vaccines Have “Boosters”, or Several Immunizations in a Series to Optimize the Immune Response**

Vaccine	Number of Doses in Series
DTaP	5 doses over 4-6 yrs
Tetanus booster	Every 10 years
HPV Vaccine	2-3 doses over 6 mos
Hepatitis B	3 doses over 6-18 mos
Haemophilus influenza type b (Hib)	3 doses over 15 mos
Pneumococcal vaccine	4 doses over 15 mos
Polio	4 doses over 4-6 yrs

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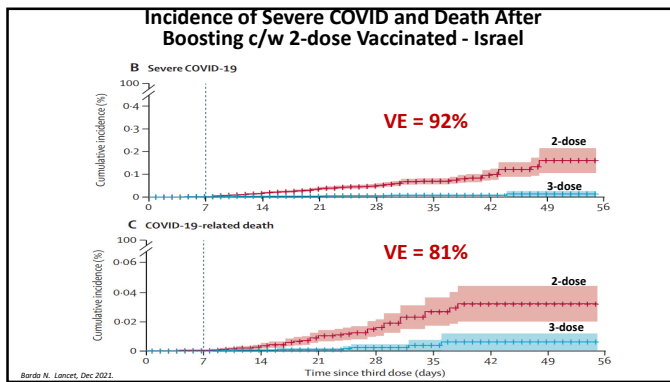


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### Clinical Studies on Booster Dose

- Pfizer trial – 10,000 study subjects. 1:1 randomization to booster vs placebo in people with prior 2-dose vaccination
- Booster Given 10-12 mos after 2<sup>nd</sup> dose, followed 2.5 mos
- **95.2% protection** against symptomatic infection
- No cases of anaphylaxis, myocarditis, or hypersensitivity

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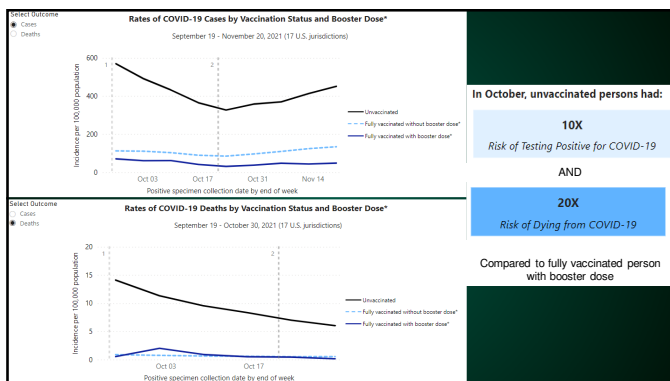
### Recent Research

Looked at over 1.14 million people in Israel over age 60, 2 versus 3 doses

- 91% protection** against infection
- 95% protection** against severe disease

October 7, 2021  
*N Engl J Med. 2021; 385:1993-1999*

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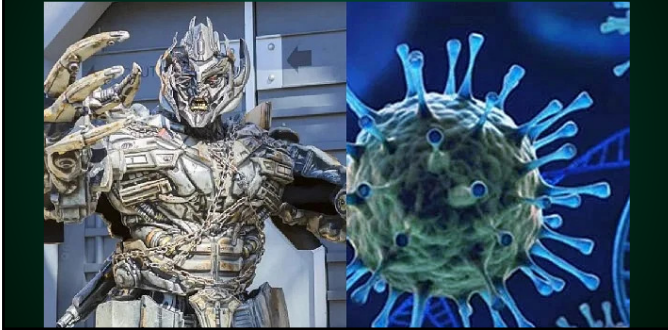
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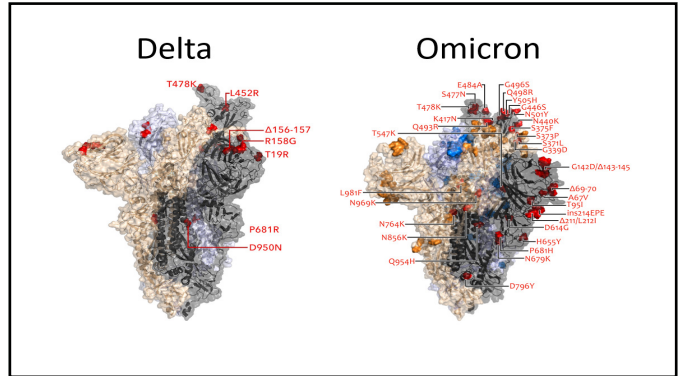
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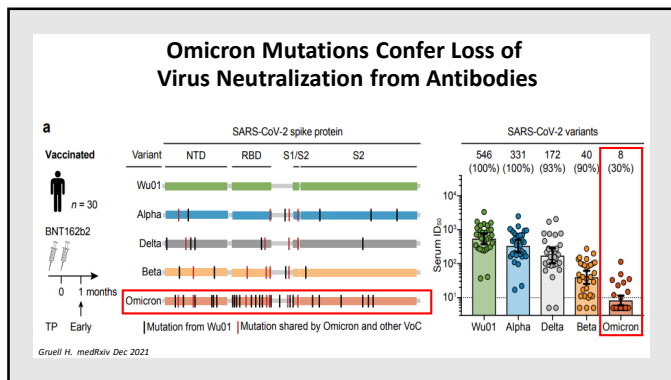
### Omicron – Isn't that one of the Transformers?



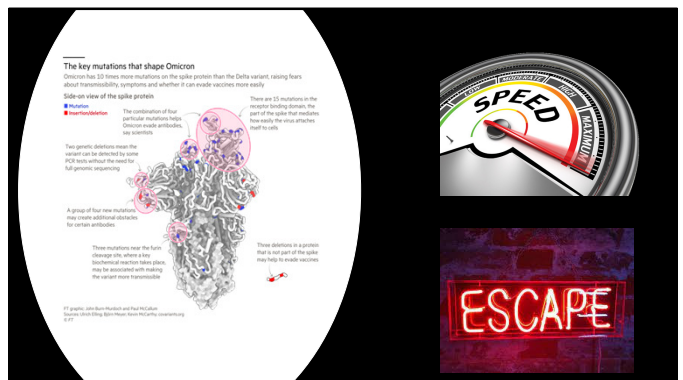
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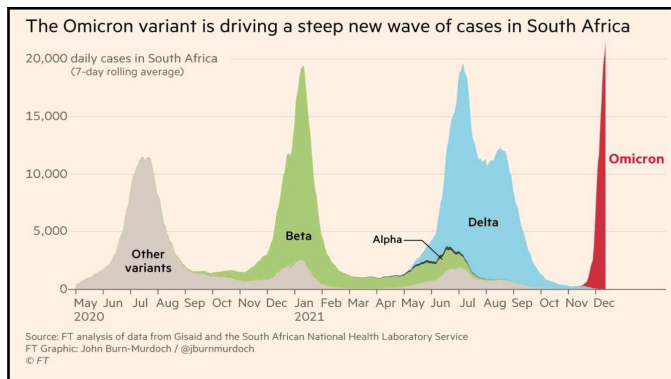
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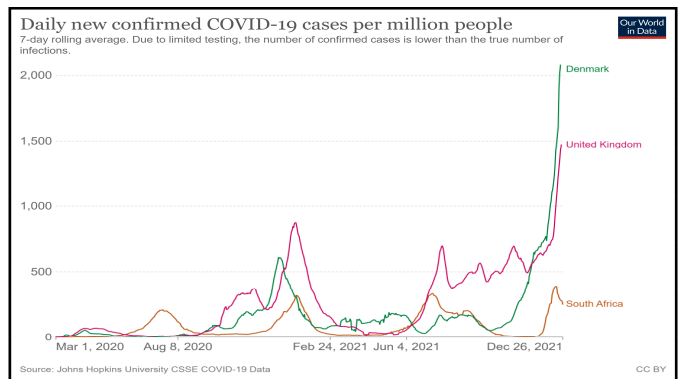
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**Increased risk of SARS-CoV-2 reinfection associated with emergence of the Omicron variant in South Africa**

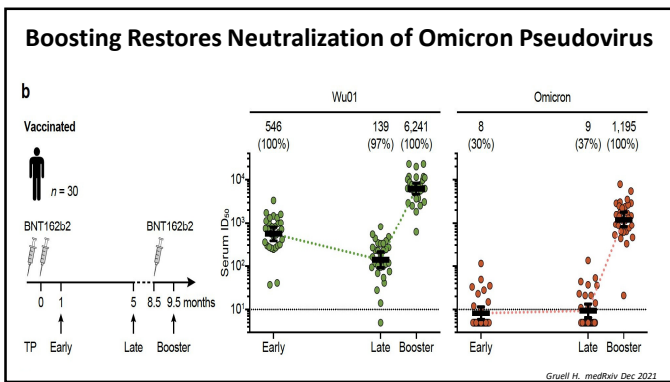
**2021-12-01**

Juliet R.C. Pulliam<sup>1,\*</sup>, Cari van Schalkwyk<sup>1</sup>, Nevashan Govender<sup>2</sup>, Anne von Gottberg<sup>2,3</sup>, Cheryl Cohen<sup>2,4</sup>, Michelle J. Groome<sup>2,3</sup>, Jonathan Dushoff<sup>1,5</sup>, Koleka Mlisana<sup>6,7,8</sup>, Harry Moultrie<sup>2,3</sup>

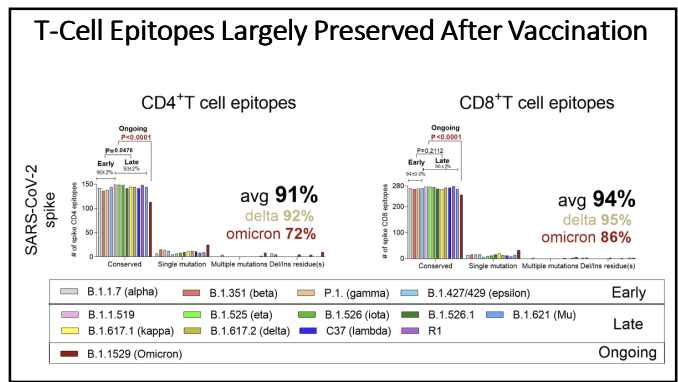
<sup>1</sup> South African DSI-NRF Centre of Excellence in Epidemiological Modelling and Analysis (SACEMA), Stellenbosch University, South Africa  
<sup>2</sup> National Institute for Communicable Diseases, Division of the National Health Laboratory Service, South Africa  
<sup>3</sup> School of Pathology, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa  
<sup>4</sup> School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

**HR for reinfection/primary infection = 2.39 (CI<sub>95</sub>: 1.88-3.11)**

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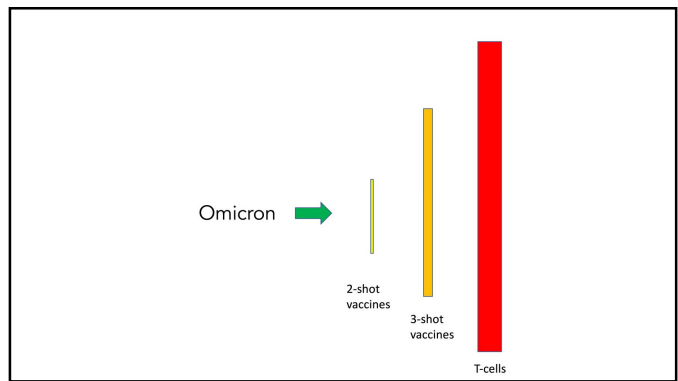
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### Risk of Hospital Admission with Omicron vs Delta

Outcome	Hazard Ratio (95% CI)
UKHSA <sup>1</sup>	0.38 (0.30 - 0.50)
Imperial College Study	0.55 (0.51 - 0.59)
Scotland Cohort Study	0.36 ( 0.22 - 0.56)
S.A. Discovery Health	0.70 <sup>2</sup>

1. adjusted for age, date, sex, ethnicity, travel, and vaccination status  
2. c/w 1<sup>st</sup> wave, no adjustment for vaccination or other factors

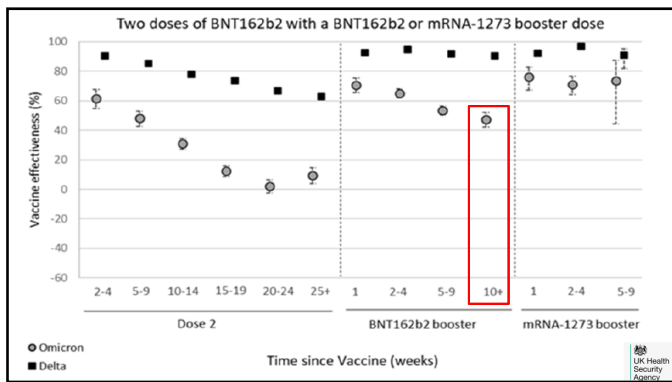
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### COVID ADMISSIONS IN KIDS HIGHER WITH OMICRON

Pediatric hospitalizations up 395% in NYC amid COVID surge: What to know about kids and omicron

Experts say it is more critical than ever for children to get their COVID vaccine shots.

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### Boosters

- Restores in vitro neutralization
- 76% protection against infxn, may fade with time
- Likely 85%-90+% protection against severe illness

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### CDC Guidance on Booster Dosing

- Recommended now for everyone ≥ 18 yo (only Pfizer boost approved for 16-17 yo)
- Should particularly target:
  - Long-term care residents
  - Age ≥ 65
  - Underlying medical conditions
  - Frontline workers

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### So which booster should I get!?

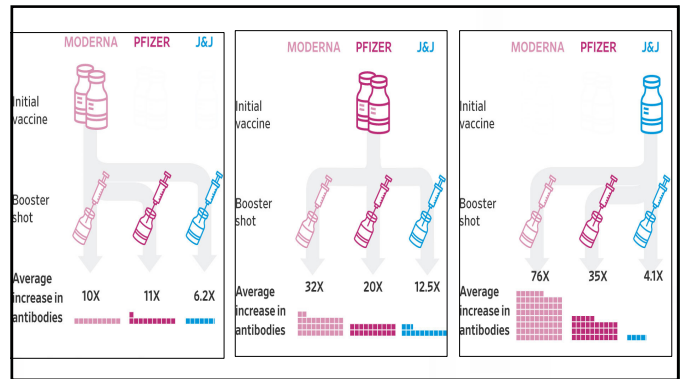
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**CDC allows for mix and matching dosing for booster shots**

Individuals may choose which COVID-19 vaccine they receive as a booster.

Some may prefer the vaccine type that they originally received, others may prefer to get a different booster.

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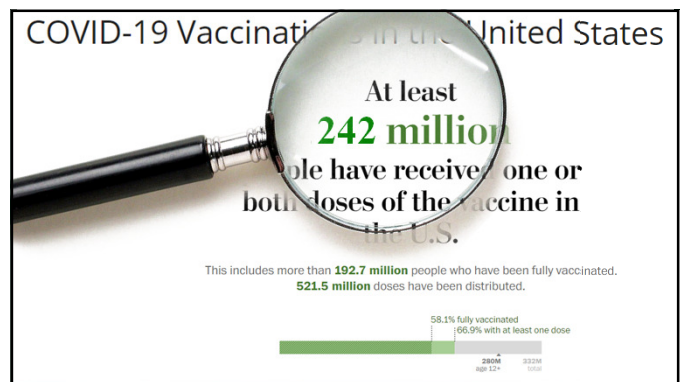


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## Multiple Layers of Pre and Post-Licensure Safety Monitoring

- Phase I-III Clinical Trials
- Vaccine Adverse Events Reporting System (VAERS)
- Clinical Immunization Safety Assessment (CISA) Project
- Vaccine Safety Datalink (VSD)
  - Rapid cycle assessments for COVID19 vaccines
- Post-licensure Rapid Immunization Safety Monitoring System (PRISM)
- V-Safe

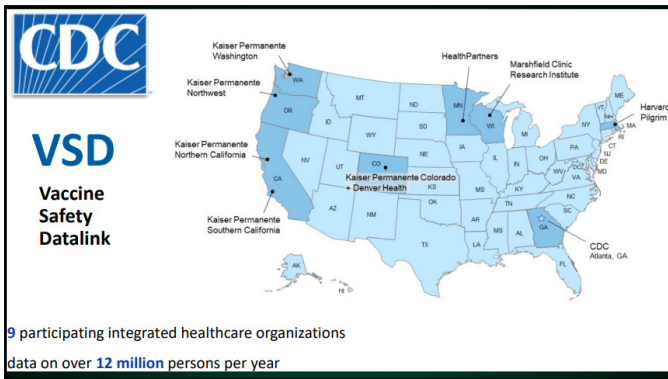
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## Multiple Layers of Pre and Post-Licensure Safety Monitoring

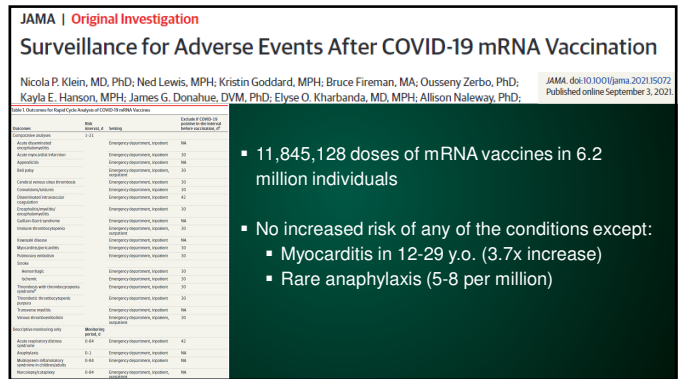
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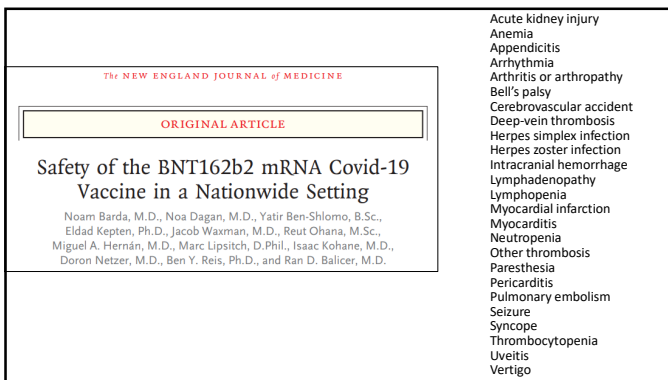




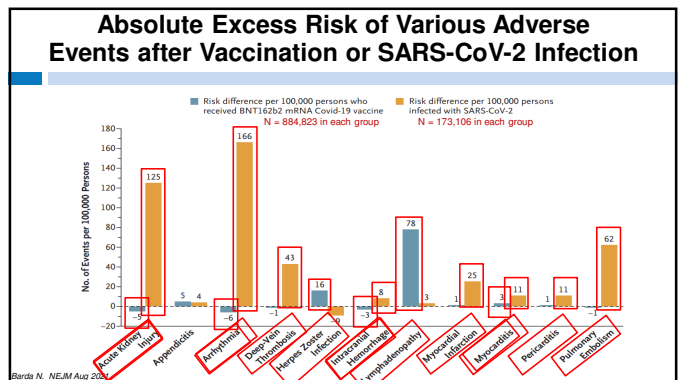
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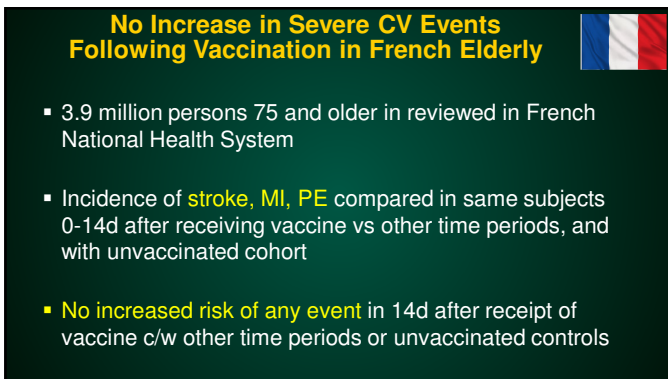
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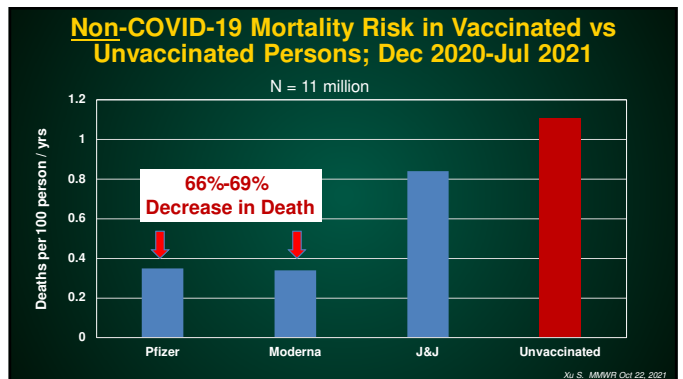
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780,225 Veterans followed > 6 mos

Excluding COVID deaths, vaccinated had **lower mortality** than unvaccinated

Cohn BA. *Science*, Nov 4, 2021

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20,000 Nursing Home Residents followed for death, cardiac problems and neurologic problems

Vaccinated had **lower mortality** and **no differences** in other problems c/w unvaccinated

Bardeheir BH. *Vaccine*, Jun 29, 2021


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

Reporting rates exceed background incidence\*

Ages	Pfizer (Males)		Pfizer (Females)	
	Dose 1	Dose 2	Dose 1	Dose 2
12-15	4.2	39.9	0.4	3.9
16-17	5.7	69.1	0.0	7.9
18-24	2.3	36.8	0.2	2.5
25-29	1.3	10.8	0.2	1.2
30-39	0.5	5.2	0.6	0.7
40-49	0.3	2.0	0.1	1.1
50-64	0.2	0.3	0.3	0.5
65+	0.2	0.1	0.1	0.3

\* An estimated 1-10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is 0.2 to 3.9 per 1 million person 7-day risk period



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**Myocarditis in 16-24 y.o Male**  
(Risk per million/yr<sup>1</sup> or after 2<sup>nd</sup> dose mRNA Vaccine<sup>2,3</sup> or after COVID<sup>1</sup>)


1. Boehmer TK. *MMWR* Sept, 2021  
2. VAERS database per million vaccines  
3. Mevorch D. *NEJM*, Oct 2021

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**Myocarditis in Big 10 Athletes After Recent SARS CoV2**

Cardiac MRI scans on 1597 athletes after recovering from recent SARS CoV-2 infection

**2.3% of athletes diagnosed with COVID-19 myocarditis**



JAMA Cardiology Published online May 27, 2021

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**Myocarditis in Young Male: 16-24**

Vaccine best case scenario

Vaccine 1 : 20,000 (VAERS data)

Virus 1 : 43 (Big10 study)

1. Boehmer TK. *MMWR* Sept, 2021  
2. VAERS database per million vaccines  
3. Mevorch D. *NEJM*, Oct 2021

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**NATURE MEDICINE** Patone M et al, Dec 2021 **ARTICLES**

N = 38 million NHS members in UK

Number of excess events in the 1-28 days postvaccination/SARS-CoV-2 positive test per 1 million vaccinated/infected

Excess events

Myocarditis

Myocarditis (<40)

Pericarditis

Cardiac arrhythmia

1. Boehmer TK. *MMWR* Sept, 2021  
2. VAERS database per million vaccines  
3. Mevorch D. *NEJM*, Oct 2021

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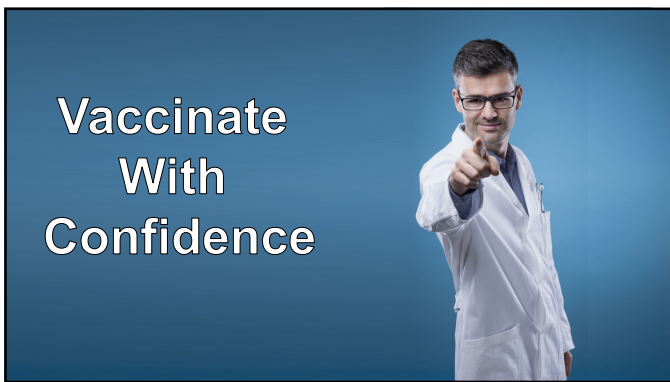
**LD1** How does this look?  
Lauren Dybsand, 7/23/2021



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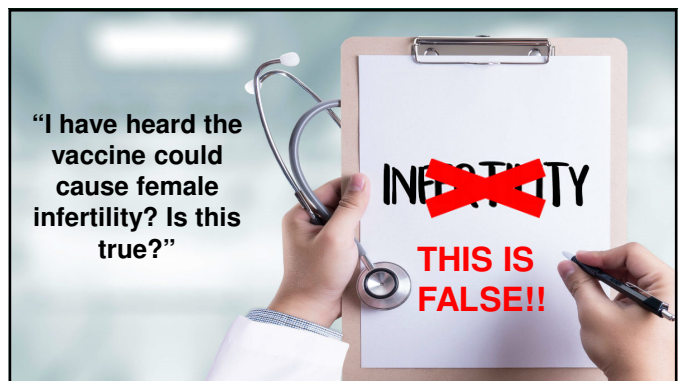
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**Delta puts pregnant women at greater risk for severe illness**

For pregnant women with symptomatic COVID-19 the risk were:

<b>66%</b> HIGHER for ICU admission	<b>63%</b> HIGHER for invasive ventilation or ECMO	<b>2X</b> HIGHER For death
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**Michael Yeadon, PhD**  
Retired pharmacologist  
researcher at Pfizer

**Spring 2020**

*"Just a common and garden virus, to which the world has over-reacted"*

- Allergy and asthma treatments  
- Let go by Pfizer in 2011

*"Their isn't going to be a 2<sup>nd</sup> wave. Viruses don't do waves, and btw, herd-immunity is almost certainly accomplished"*

*"The pandemic is all but over"*

**December 2020**

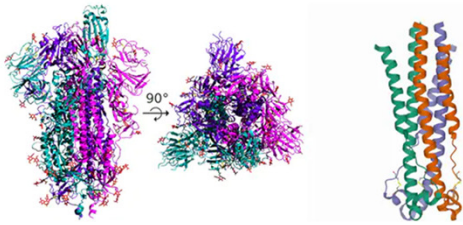
*"Female infertility could result from vaccine-induced antibodies"*



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---ALGTGIGGITTSTQFYKYL-----SQELNGDMERVADSLVTLQDQLNSLAAVVLQNRRLDLLTAERG-----  
AMQMAYRFNGIGVGTQNVLYENQKLIQFNSAIGKIQALDLSLSTASAVLGLKLVVNOQNAQALNTLVKQLSSNFGAISSVLDLNSRLD

**Spike Protein**                      **Syncytin-1**




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**v-safe**  
after vaccination  
health checker

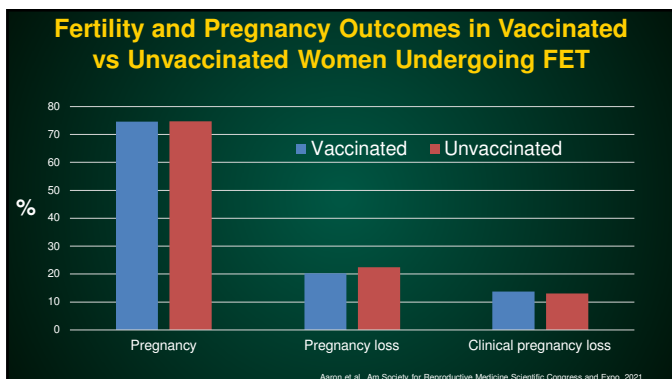
**CDC**      **V-Safe & Registry Monitoring  
People Who Report Pregnancy**

v-safe After Vaccination Health Checker Pregnant people reported, United States, as of December 6, 2021 <b>178,661</b>	v-safe COVID-19 Vaccine Pregnancy Registry Pregnant people enrolled, United States, as of December 6, 2021 <b>7,200</b>
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Results of Registry Surveillance Regularly Reported at ACIP Updates



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**Illustrative (and disturbing) little exercise:**

Google the term "infertility" or "depopulation", and the following vaccines:

1. HPV
2. Polio
3. Tetanus
4. Influenza
5. MMR

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NIH National Institutes of Health COVID-19 Research


NIH Strategic Response | Funding | Testing | Treatments and Vaccines | News and Stories

## COVID-19 Vaccines and the Menstrual Cycle

Update: October 5, 2021

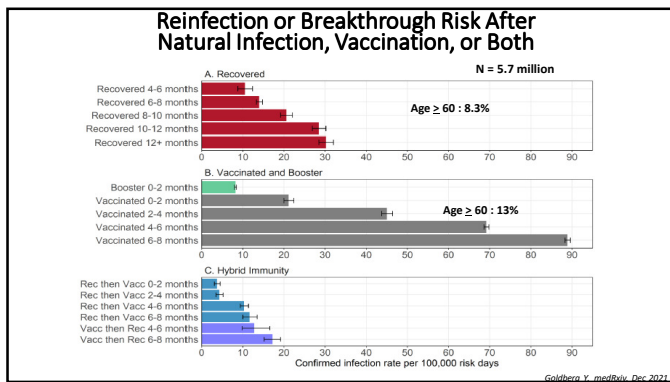
NICHD recently awarded five institutions one-year supplemental grants totaling \$1.67 million to explore potential links between COVID-19 vaccination and menstrual changes. Researchers at Boston University, Harvard Medical School, Johns Hopkins University, Michigan State University, and Oregon Health and Science University will investigate whether such changes may be linked to the COVID-19 vaccine itself or if they are coincidental, the mechanism underlying any vaccine-related changes, and how long any changes last.

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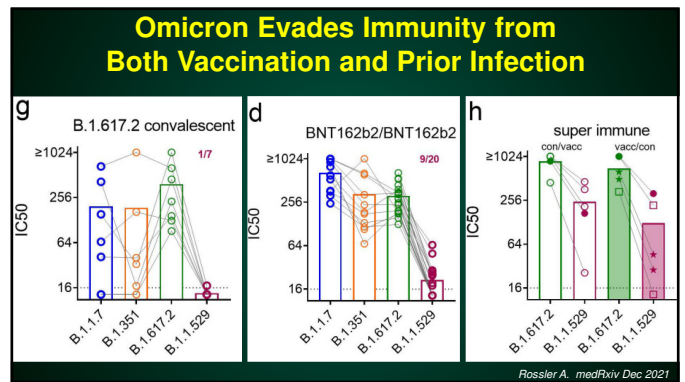


**“I’ve already had COVID. I should be protected....right?”**

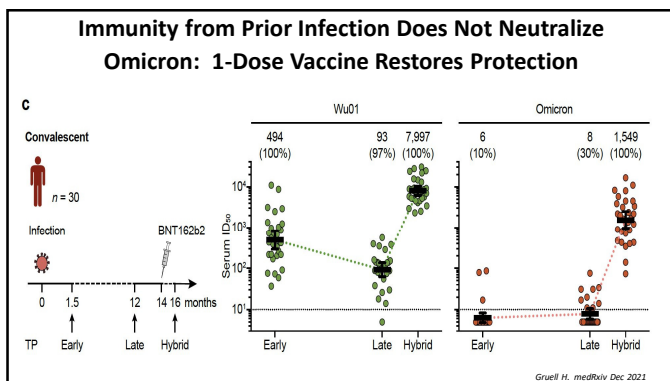
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### 6 Reasons Why You Should Consider Immunization After Prior Infection:

- Protection from prior infection is not 100%, esp in elderly and studies of efficacy were relatively short-term and pre-Delta
- Yale model suggests 50% reinfection risk within 2 years<sup>1</sup>
- Boosted vaccine recipients and vaccinated/prior-infected subjects have 10-55x higher antibody levels than prior-infection alone<sup>2,3</sup>

1. Townsend JP. Lancet Microb. 2021  
 2. Estess WK. JAMA Mar 2021  
 3. Falsley AR. NEJM Oct 2021


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### 6 Reasons Why You Should Consider Immunization After Prior Infection:

- Prior-infected subjects c/w vaccinated subjects were 5x more likely to test (+) for COVID when hospitalized w resp illness <sup>4</sup>
- Prior-infected subjects that get even 1 dose of vaccine cut their risk of subsequent infection ~ in half <sup>5,6</sup>
- Most prior-infected subjects were not able to neutralize a test-tube engineered "super-virus" with 20 different spike-protein mutations. But those who were vaccinated effectively neutralized the engineered mutant <sup>7</sup>

4. Basile CH. MMWR Nov 5, 2021  
5. Gazi S. medRxiv Jul 2021  
6. Cavansough AM. MMWR Aug 2021  
7. Abbas J. JAMA Nov 2021

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*"I have heard that over 9,000 people have died after the COVID-19 vaccine...Is this true?"*


**NO!**

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**From vs. after... what is the difference?!**



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**VAERS**

The CDC uses this system to closely monitor reports of adverse events following vaccination.

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A Typical day in America




- 2,200 heart attacks
- 2,500 blood clots (DVT)
- 2,200 strokes
- 4,900 new cases of cancer
- 8,000 deaths



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**VAERS Reports of Death After COVID-19 Vaccine by Age Group (N=9763)\***

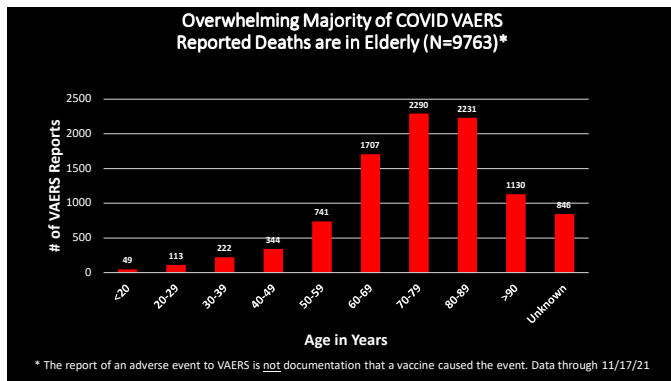


*What type of events are reported?*

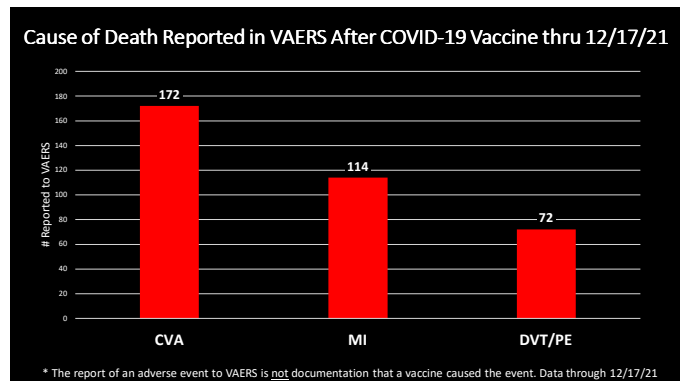
- ✓601 had cancer
- ✓313 hospice
- ✓226 falls
- ✓24 suicides
- ✓6 motor vehicle accidents
- ✓3 drownings
- ✓8 over-doses
- ✓2 gunshot wound

\* The report of an adverse event to VAERS is not documentation that a vaccine caused the event. Data through 12/17/21

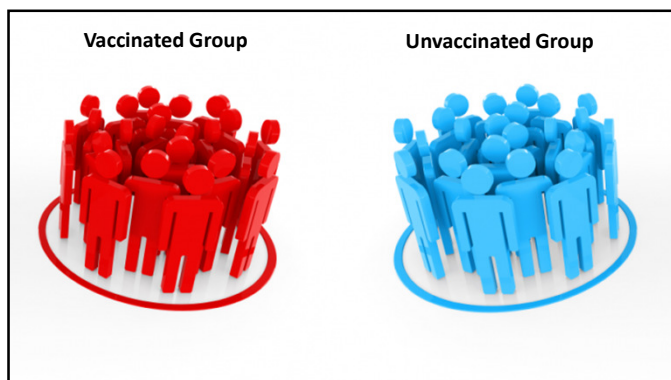
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### No Increase in Severe CV Events Following Vaccination in French Elderly

- 3.9 million persons 75 and older in reviewed in French National Health System
- Incidence of **stroke, MI, PE** compared in same subjects 0-14d after receiving vaccine vs other time periods, and with unvaccinated cohort
- **No increased risk of any event** in 14d after receipt of vaccine c/w other time periods or unvaccinated controls

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