[è apparso online il qui sottostante articolo scientifico (testo integrale al link: https://doi.org/10.1101/2020.12.21.423721); un *BREVE COMMENTO* è che in pratica gli autori hanno scoperto che *IL CUORE UMANO E I SUOI VASI SANGUIGNI POSSONO SUBIRE DANNI ANCHE IN ASSENZA DI CORONAVIRUS; INFATTI BASTA CHE NEL SANGUE CIRCOLI LA SOLA PROTEINA SPIKE VIRALE LIBERA; MA ALLORA LA **TERAPIA** GENICA SPERIMENTALE (IL COSIDDETTO "VACCINO" COVID), CHE FA PRODURRE AL CORPO LA SPIKE, PUO' AGIRE COME **VELENO CARDIACO***]

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Original research article

1

The SARS-CoV-2 Spike protein disrupts human cardiac pericytes function through CD147-receptor-mediated signalling: a potential non-infective mechanism of COVID-19 microvascular disease

Elisa Avolio, PhD[1]; Michele Carrabba, PhD[1]; Rachel Milligan, PhD[2]; Maia Kavanagh Williamson, PhD[2]; Antonio P Beltrami, MD PhD[3]; Kapil Gupta, PhD[4]; Karen T Elvers, PhD[5]; Monica Gamez, PhD[1]; Rebecca Foster, PhD[1]; Kathleen Gillespie, PhD[1]; Fergus Hamilton, PhD[1]; David Arnold, PhD[1]; Imre Berger, PhD[4,6]; Massimo Caputo, MD[1]; Andrew D Davidson, PhD[2]; Darryl Hill, PhD[2]; Paolo Madeddu, MD[1]

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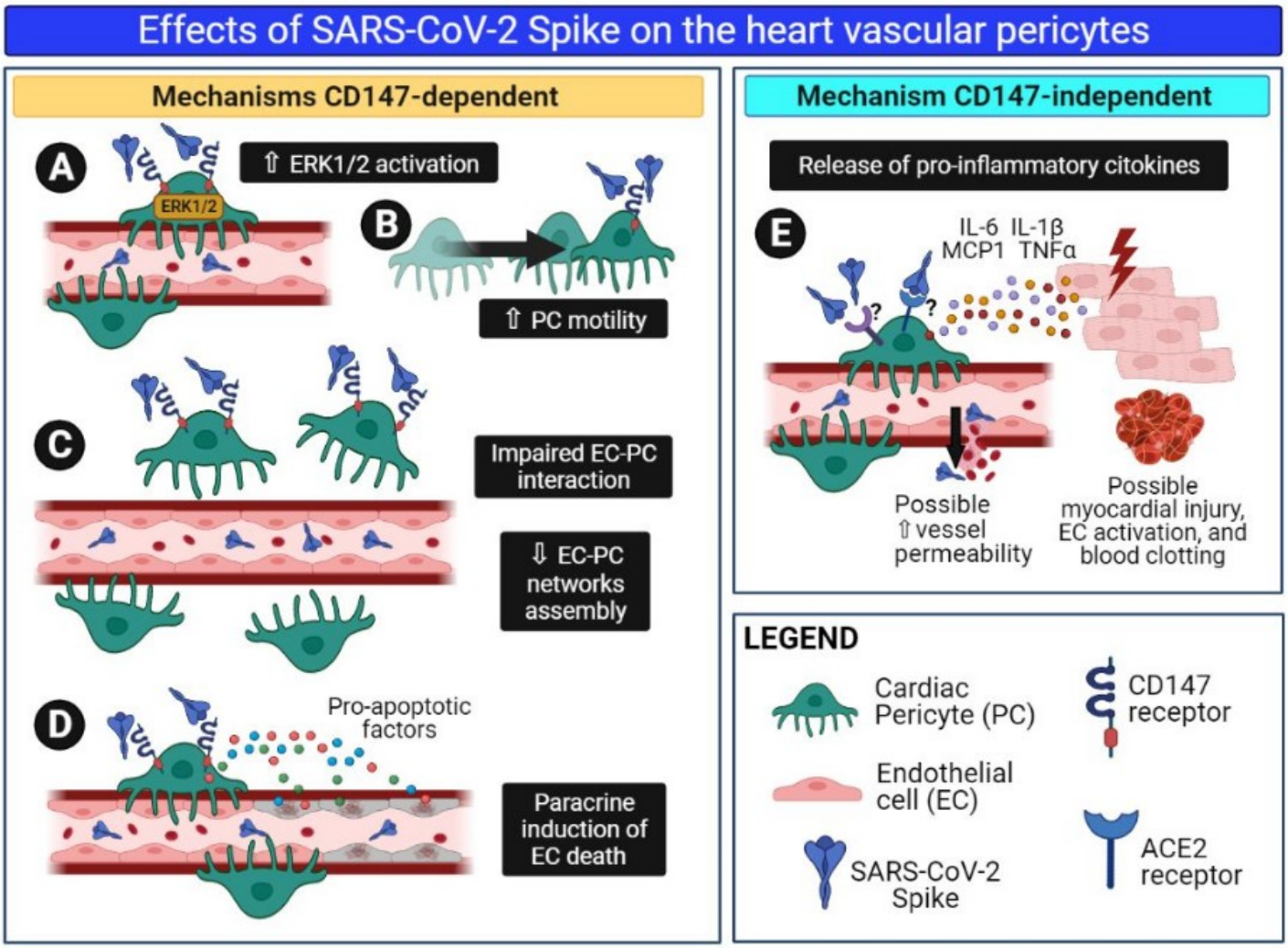

FDA ▶Pfizer, 23/08/2021
BLA Approval 125742/0

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

2

- Required Pediatric Assessment(s)

attenzione:
Pfizer rimane NON approvato e NON autorizzato; la FDA ha approvato solo *Comirnaty*

We note that you have fulfilled the pedi
years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

studio 5: la FDA esige che Pfizer quantifichi entro il 2024 i danni cardiaci provocati ai "vaccinati" in Europa

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June 30, 2022

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- Required Postmarketing Correspondence under Section 505(o)
- Required Postmarketing Final Report under Section 505(o)
- Supplement contains Required Postmarketing Final Report under Section 505(o)

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an Annual Status Report of Postmarketing Requirements/Commitments and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm .

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 6
505(o)(3)(E)(21
CFR 601.70.
must also inc
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studies or cli
section 505(o

C'è uno studio di **sicurezza** fino al 2025 **per** gravide e neonati **NON VACCINATI** ("*non interventional*") esposti ai vaccinati

LEGGI **QUI**

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."

Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

Final Protocol Submission: January 29, 2021

Study Completion: June 30, 2023

Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

Final Protocol Submission: March 22, 2021

Study Completion: December 31, 2022

Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- Postmarketing Commitment – Correspondence Study Update
- Postmarketing Commitment – Final Study Report
- Supplement contains Postmarketing Commitment – Final Study Report

https://www.israelnationalnews.com/News/News.aspx/309762

Natural infection vs vaccination: Which gives more protection?

Nearly 40% of new COVID patients were vaccinated - compared to just 1% who had been infected previously.

il rischio di essere re-infettati da SARS-CoV-2 aumenta del 672% dopo l'inoculazione del "vaccino"

Tags: Vaccine, Coronavirus

Contact Editor David Rosenberg , Jul 13 , 2021 9:24 AM

Coronavirus patients who recovered from the virus were far less likely to become infected during the latest wave of the pandemic than people who were vaccinated against COVID, according to numbers presented to the Israeli Health Ministry.

According to a report by Israel's Channel 13, Health Ministry data on the wave of COVID outbreaks which began this May show that Israelis with immunity from natural infection were far less likely to become infected again in comparison to Israelis who only had immunity via vaccination.

More than 7,700 new cases of the virus have been detected during the most recent wave starting in May, but just 72 of the confirmed cases were reported in people who were known to have been infected previously – that is, less than 1% of the new cases.

Roughly 40% of new cases – or more than 3,000 patients – involved people who had been infected despite being vaccinated.

With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with COVID.

By contrast, Israelis who were vaccinated were 6.72 times more likely to get infected after the shot than after natural infection, with over 3,000 of the 5,193,499, or 0.0578%, of Israelis who were vaccinated getting infected in the latest wave.

According to the report by *Channel 13*, the disparity has confounded – and divided – Health Ministry experts, with some saying the data proves the higher level of immunity provided by natural infection versus vaccination, while others remained unconvinced.

https://www.biorxiv.org/content/10.1101/2021.07.13.452194v2

18-08-2021

New Results

A drug candidate for treating adverse reactions caused by pathogenic antibodies inducible by COVID-19 virus and vaccines

Huiru Wang, Xiancong Wu, Yuekai Zhang, Qiuchi Chen, Lin Dai, Yuxing Chen, Xiaoling Liu

doi: https://doi.org/10.1101/2021.07.13.452194

Abstract | Preview PDF

nuovo farmaco per combattere il danno di *auto-attacco* causato dal "vaccino" covid, che fa produrre anticorpi i quali invece di proteggere il paziente lo aggrediscono

Summary

In a recent study, we reported that certain anti-spike antibodies of COVID-19 and SARS-CoV viruses can have a pathogenic effect through binding to sick lung epithelium cells and misleading immune responses to attack self-cells. We termed this new pathogenic mechanism "Antibody Dependent Auto-Attack" (ADAA). This study explores a drug candidate for prevention and treatment of such ADAA-based diseases. The drug candidate is a formulation comprising

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24-08-2021

Abstract

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape [1,2]. Outbreak investigations suggest that vaccinated persons can spread Delta [3,4]. We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined v

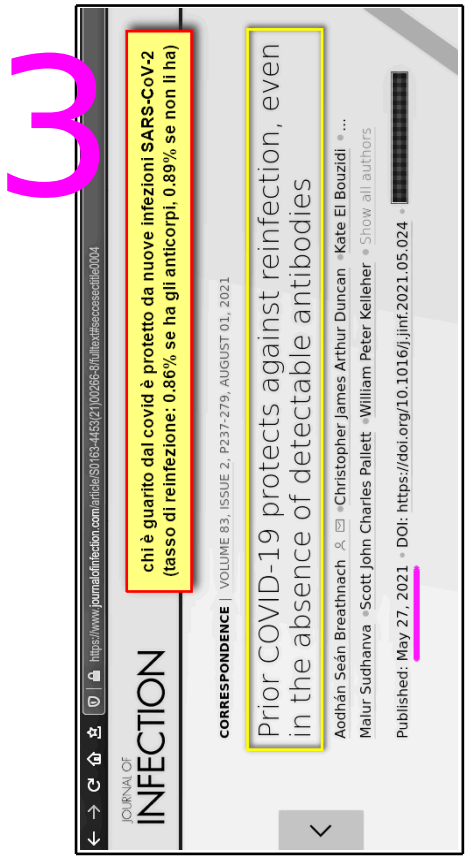
nel 2021 le infezioni SARS-CoV-2 sono per il 95% da varianti delta; dai tamponi (Ct<25) risulta che gli asintomatici "vaccinati" sono molto più contagiosi (82%) degli asintomatici non "vaccinati" (29%), mentre tra i sintomatici il divario è minimo (69% "vaccinati", 68% non "vaccinati")

Main text

We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; Figure 1A) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (Figure 1B).

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (Figure 1C). Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; CI: 48-97%), and 158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals. Time from symptom onset to testing did not vary by vaccination status (p=0.40; Supplemental Figure 2). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious virus.

Combined with other studies [2–5], these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-



https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

Preprints with THE LANCET

Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam

31 Pages • Posted: 10 Aug 2021

Nguyen Van Vinh Chau

Hospital for Tropical Diseases

Nghiem My Ngoc

nel 2021 (da quando ci sono i "vaccini" covid), la carica virale SARS-CoV-2 negli operatori sanitari ospedalieri vaccinati contagiosi è cresciuta di 251 volte rispetto al 2020 (quando tali "vaccini" non c'erano), e gli anticorpi cosiddetti "neutralizzanti" indotti dai "vaccini" ora non sono più in grado di influire sulla carica virale né sui sintomi del covid

Abstract

Background: Data on breakthrough SARS-CoV-2 Delta variant infections are limited.

Methods: We studied breakthrough infections among healthcare workers of a major infectious diseases hospital in Vietnam. We collected demographics, vaccination history and results of PCR diagnosis alongside clinical data. We measured SARS-CoV-2 (neutralizing) antibodies at diagnosis, and at week 1, 2 and 3 after diagnosis. We sequenced the viruses using ARTIC protocol.

Findings: Between 11th–25th June 2021 (week 7–8 after dose 2), 69 healthcare workers were tested positive for SARS-CoV-2. 62 participated in the clinical study. 49 were (pre)symptomatic with one requiring oxygen supplementation. All recovered uneventfully. 23 complete-genome sequences were obtained. They all belonged to the Delta variant, and were phylogenetically distinct from the contemporary Delta variant sequences obtained from community transmission cases, suggestive of ongoing transmission between the workers. Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases infected with old strains detected between March-April 2020. Time from diagnosis to PCR negative was 8–33 days (median: 21). Neutralizing antibody levels after vaccination and at diagnosis of the cases were lower than those in the matched uninfected controls. There was no correlation between vaccine-induced neutralizing antibody levels and viral loads or the development of symptoms.

Interpretation: Breakthrough Delta variant infections are associated with high viral loads, prolonged PCR positivity, and low levels of vaccine-induced neutralizing antibodies, explaining the transmission between the vaccinated people. Physical distancing measures remain critical to reduce SARS-CoV-2 Delta variant transmission.

il "vaccino" covid aumenta il rischio di infettarsi, di ammalarsi, e di morire

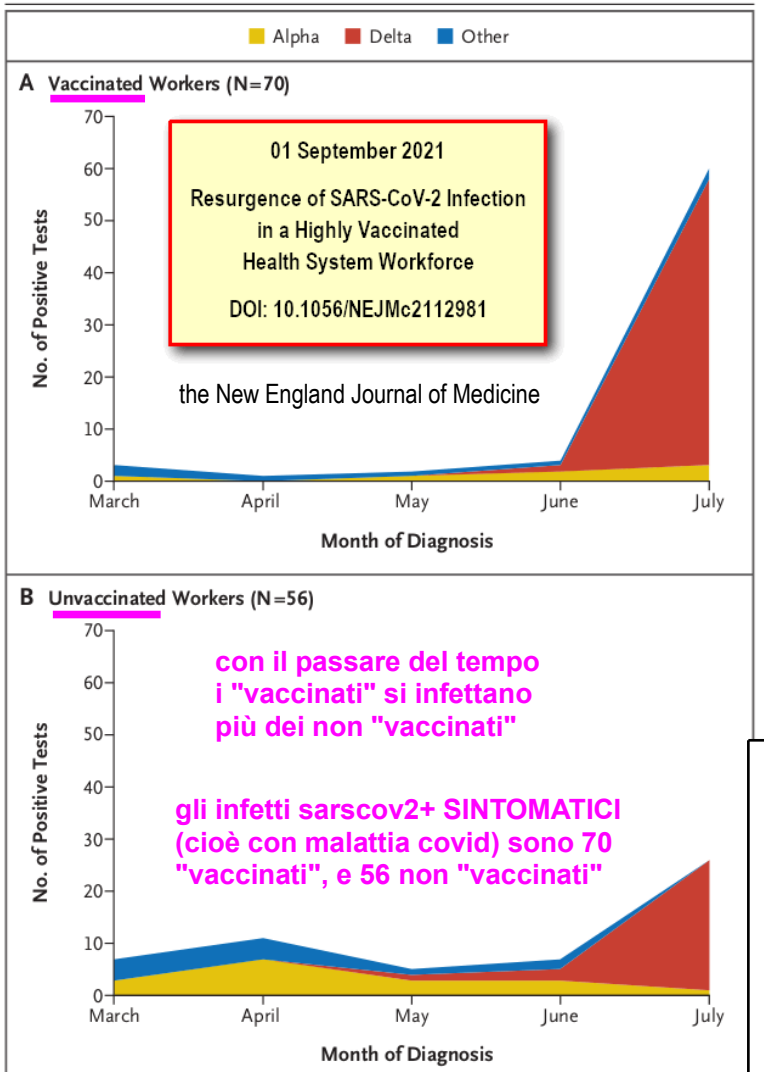


Figure 1. SARS-CoV-2 Variants among Symptomatic Health Workers.
Shown is the distribution of the B.1.1.7 (alpha), delta, and other SARS-CoV-2 variants according to vaccination status and month of diagnosis among health workers at University of California San Diego Health, March through July 2021. The number of workers indicates those who were symptomatic and had available variant data, and the number of positive tests indicates those that included data on variants.

4

SARS-CoV-2 variants of concern and variants under investigation in England, Technical briefing 20, 6 August 2021 PUBLIC HEALTH

Table 5. Attendance to emergency care and deaths of confirmed and provisional Delta cases in England by vaccination status (1 February 2021 to 2 August 2021)

Variant	Age group (years)**	Total	Cases with specimen date in past 28 days	Unlinked	<21 days post dose 1	≥21 days post dose 1	Received 2 doses	Unvaccinated
Delta cases	<50	265,749	84,772	28,330	23,822	40,449	25,536	147,612
	≥50	33,736	13,803	2,989	195	5,640	21,472	3,440
	All cases	300,010	98,722	31,841	24,018	46,089	47,008	151,054
Cases with an emergency care visit§ (exclusion‡)	<50	8,449	N/A	70	756	1,127	694	5,802
	≥50	1,940	N/A	10	15	326	1,098	491
	All cases	10,391	N/A	82	771	1,453	1,792	6,293
Cases with an emergency care visit§ (inclusion#)	<50	10,975	N/A	119	953	1,368	864	7,671
	≥50	3,342	N/A	24	30	486	1,815	987
	All cases	14,319	N/A	145	983	1,854	2,679	8,658
Cases where presentation to emergency care resulted in overnight inpatient admission§ ((exclusion‡)	<50	1,970	N/A	35	136	203	153	1,443
	≥50	1,059	N/A	7	12	125	620	295
	All cases	3,030	N/A	43	148	328	773	1,738
Cases where presentation to emergency care resulted in overnight inpatient admission§ (inclusion#)	<50	3,084	N/A	61	211	298	224	2,290
	≥50	2,074	N/A	20	23	230	1,131	670
	All cases	5,159	N/A	82	234	528	1,355	2,960
Deaths within 28 days of positive specimen date	<50	71	N/A	2	4	4	13	48
	≥50	670	N/A	5	6	65	389	205

positivi al tampone morti entro 28 giorni: 18 **488 "vaccinati" e 253 non "vaccinati"**

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Previous

Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections

Posted August 25, 2021.

Download PDF

Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon

doi: https://doi.org/10.1101/2021.08.24.21262415

Rispetto alla doppia dose di "vaccino" pfizer, l'immunità naturale (da infezione sarscov2 precedente) protegge 6-13 volte di più da re-infezione sarscov2(delta), protegge 7-27 volte di più dai sintomi covid, e protegge 7 volte di più dal ricovero in ospedale per covid

Abstract | Full Text | Info/History | Metrics

Abstract

Background Reports of waning vaccine-induced immunity against COVID-19 have begun to

Infectious Diseases (except HI

Share of the population fully vaccinated against COVID-19

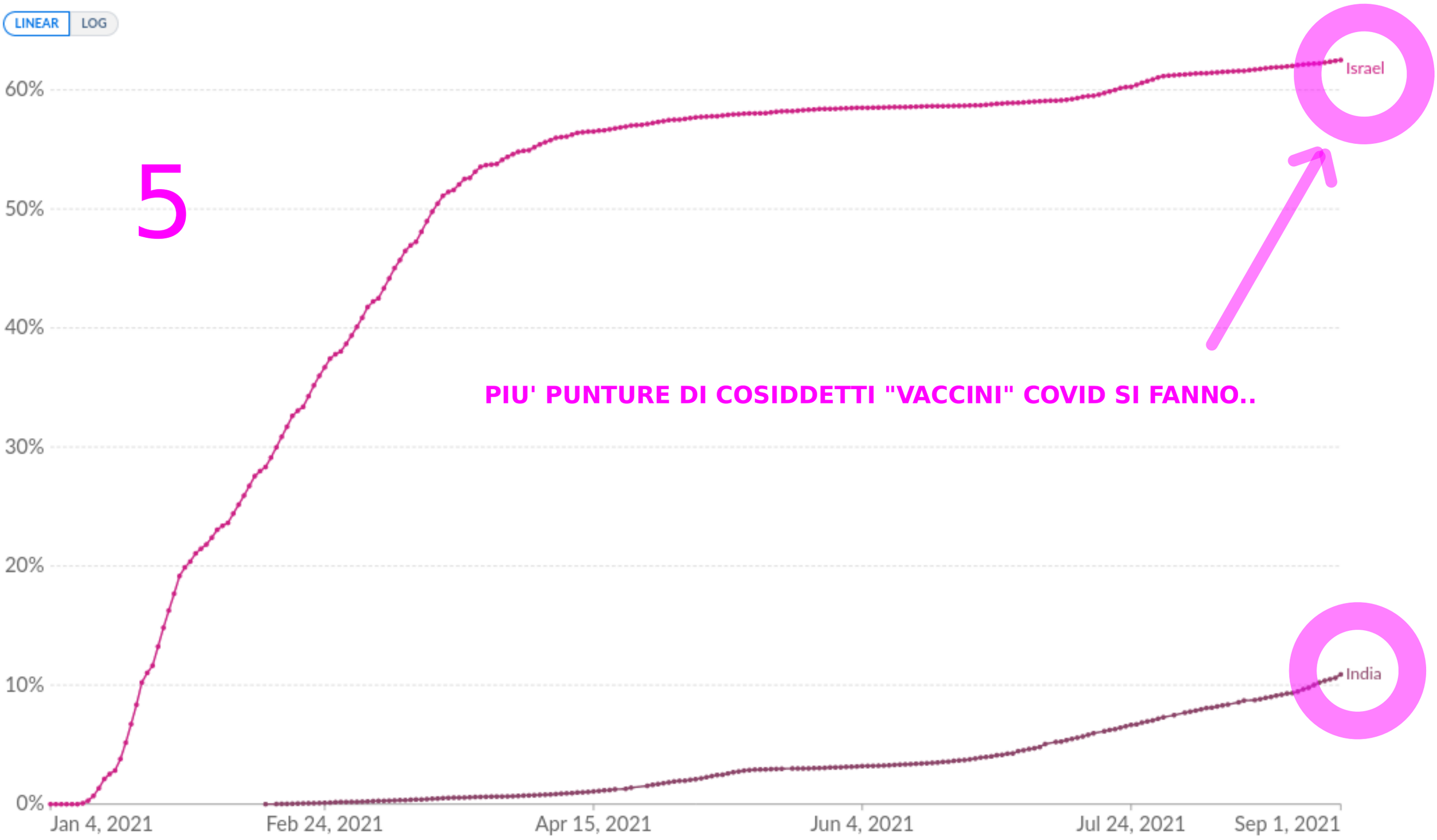
Total number of people who received all doses prescribed by the vaccination protocol, divided by the total population of the country.

Our World in Data

LINEAR LOG

5

PIU' PUNTURE DI COSIDDETTI "VACCINI" COVID SI FANNO..



Source: Official data collated by Our World in Data. Alternative definitions of a full vaccination, e.g. having been infected with SARS-CoV-2 and having 1 dose of a 2-dose protocol, are ignored to maximize comparability between countries.

CC BY

Jan 4, 2021 — Sep 1, 2021

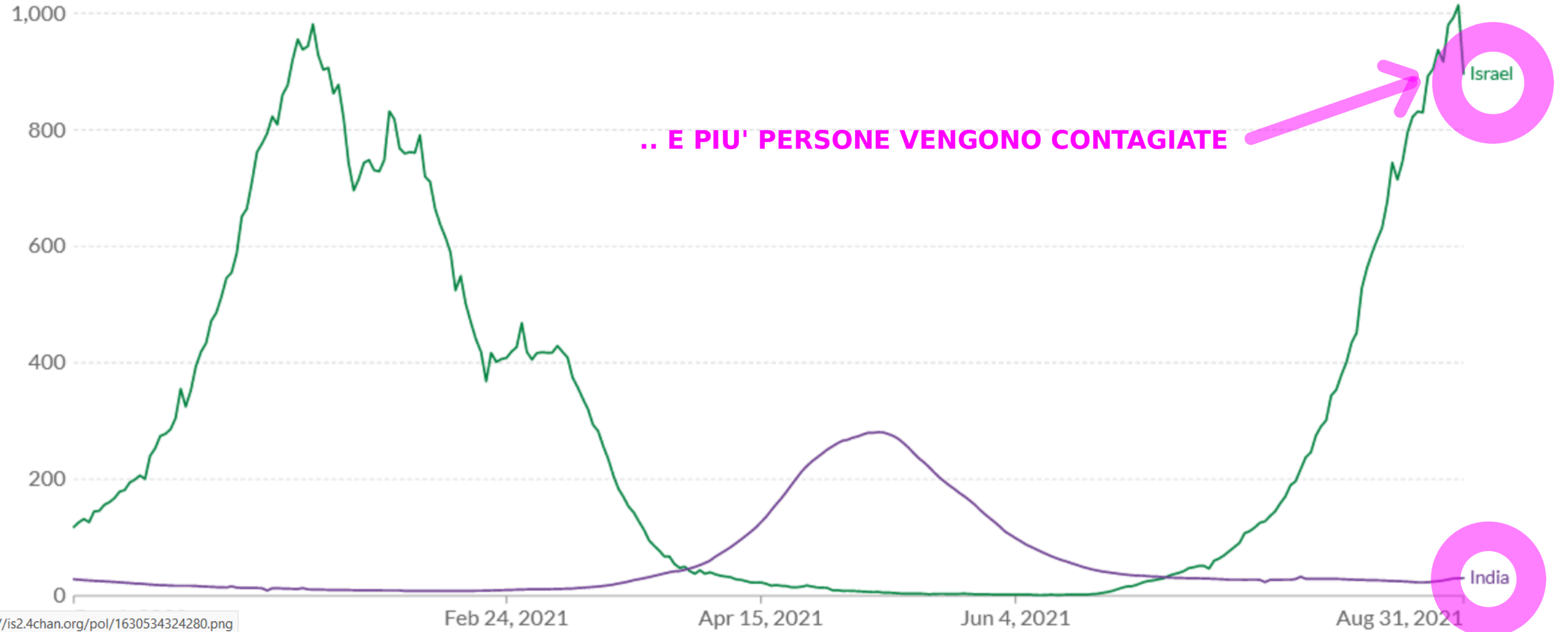
CHART | MAP | TABLE | SOURCES | DOWNLOAD

Daily new confirmed COVID-19 cases per million people

Shown is the rolling 7-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.

Our World in Data

LINEAR LOG



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https://www.nejm.org/doi/full/10.1056/NEJMc2108076?query=recirc_mostViewed_railB_article

The NEW ENGLAND JOURNAL of MEDICINE

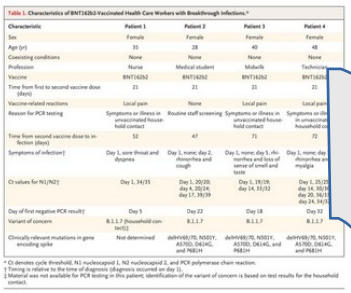
CORRESPONDENCE

Breakthrough Infections in BNT162b2-Vaccinated Health Care Workers

TO THE EDITOR:

Hacisuleyman et al.[1] described a cohort of 417 health care workers who had received the BNT162b2 (Pfizer–BioNTech) or mRNA-1273 (Moderna) mRNA vaccine. Two women in that cohort (0.48%) had breakthrough infections with SARS-CoV-2 variants. At our institution, 1137 health care workers were fully vaccinated with BNT162b2. Of these, 4 immunocompetent women (0.35%) had breakthrough infections; these infections occurred later than those in the study by Hacisuleyman et al. (at a median of 62 days after the second vaccine dose, as compared with 25 days) (Table 1).[1,2] This failure rate is higher than that in the initial phase 3 trial, in which 0.05% of vaccinated participants (8 of 17,411) had a breakthrough infection 7 or more days after the second BNT162b2 vaccine dose,[3] but is lower than in other recent studies involving health care workers.[2,4,5]

Table 1.



Characteristics of BNT162b2-Vaccinated Health Care Workers with Breakthrough Infections.

The health care workers at our institution had only mild symptoms but high viral loads (cycle thresholds

Table 1. Characteristics of BNT162b2-Vaccinated Health Care Workers with Breakthrough Infections.*

Characteristic	Patient 1	Patient 2	Patient 3	Patient 4
Sex	Female	Female	Female	Female
Age (yr)	35	28	40	48
Coexisting conditions	None	None	None	None
Profession	Nurse	Medical student	Midwife	Technician
Vaccine	BNT162b2	BNT162b2	BNT162b2	BNT162b2
Time from first to second vaccine dose (days)	21	21	21	21
Vaccine-related reactions	Local pain	None	Local pain	Local pain
Reason for PCR testing	Symptoms or illness in unvaccinated household contact	Routine staff screening	Symptoms or illness in unvaccinated household contact	Symptoms or illness in unvaccinated household contact
Time from second vaccine dose to infection (days)	52	47	71	72
Symptoms of infection†	Day 1, sore throat and dyspnea	Day 1, none; day 2, rhinorrhea and cough	Day 1, none; day 5, rhinorrhea and loss of sense of smell and taste	Day 1, none; day 3, rhinorrhea and myalgia
Ct values for N1/N2†	Day 1, 34/35	Day 1, 20/20; day 4, 20/24; day 17, 39/39	Day 1, 19/19; day 14, 33/32	Day 1, 25/25; day 14, 30/30; day 20, 36/33; day 24, 34/32
Day of first negative PCR result†	Day 5	Day 22	Day 18	Day 32
Variant of concern	B.1.1.7 (household contact)‡	B.1.1.7	B.1.1.7	B.1.1.7
Clinically relevant mutations in gene encoding spike	Not determined	delHV69/70, N501Y, A570D, D614G, and P681H	delHV69/70, N501Y, A570D, D614G, and P681H	delHV69/70, N501Y, A570D, D614G, and P681H

* Ct denotes cycle threshold, N1 nucleocapsid 1, N2 nucleocapsid 2, and PCR polymerase chain reaction.
† Timing is relative to the time of diagnosis (diagnosis occurred on day 1).
‡ Material was not available for PCR testing in this patient; identification of the variant of concern is based on test results for the household contact.

Public Health England

Protecting and improving the nation's health

SARS-CoV-2 variants of concern and variants under investigation in England

Technical briefing 20

6 August 2021

This briefing provides an update on previous briefings up to 23 July 2021

7

SARS-CoV-2 variants of concern and variants under investigation in England, Technical briefing 20, 6 August 2021 PUBLIC HEALTH

Table 5. Attendance to emergency care and deaths of confirmed and provisional Delta cases in England by vaccination status (1 February 2021 to 2 August 2021)

Variant	Age group (years)**	Total	Cases with specimen date in past 28 days	Unlinked	<21 days post dose 1	≥21 days post dose 1	Received 2 doses	Unvaccinated
Delta cases	<50	265,749	84,772	28,330	23,822	40,449	25,536	147,612
	≥50	33,736	13,803	2,989	195	5,640	21,472	3,440
	All cases	300,010	98,722	31,841	24,018	46,089	47,008	151,054
Cases with an emergency care visit§ (exclusion‡)	<50	8,449	N/A	70	756	1,127	694	5,802
	≥50	1,940	N/A	10	15	326	1,098	491
	All cases	10,391	N/A	82	771	1,453	1,792	6,293
Cases with an emergency care visit§ (inclusion#)	<50	10,975	N/A	119	953	1,368	864	7,671
	≥50	3,342	N/A	24	30	486	1,815	987
	All cases	14,319	N/A	145	983	1,854	2,679	8,658
Cases where presentation to emergency care resulted in overnight inpatient admission§ ((exclusion‡)	<50	1,970	N/A	35	136	203	153	1,443
	≥50	1,059	N/A	7	12	125	620	295
	All cases	3,030	N/A	43	148	328	773	1,738
Cases where presentation to emergency care resulted in overnight inpatient admission§ (inclusion#)	<50	3,084	N/A	61	211	298	224	2,290
	≥50	2,074	N/A	20	23	230	1,131	670
	All cases	5,159	N/A	82	234	528	1,355	2,960
Deaths within 28 days of positive specimen date	<50	71	N/A	2	4	4	13	48
	≥50	670	N/A	5	6	65	389	205

positivi al tampone morti entro 28 giorni: **488 "vaccinati" e 253 non "vaccinati"**


8
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Pfizer Demanding Bank Reserves, Military Bases And Embassy Buildings As Collateral For COVID-19 Vaccines

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JOURNAL ON GEOPOLITICS & INTERNATIONAL RELATIONS

Pfizer Demanding Bank Reserves, Military Bases And Embassy Buildings As Collateral For COVID-19 Vaccines

February 25, 2021

How Pfizer tried to bully Argentina and Brazil in exchange for vaccines

Then, Pfizer asked to be compensated for the cost of any future civil lawsuits. If someone files a civil lawsuit against Pfizer in Argentina and wins that case, the government of Argentina and not Pfizer would pay the compensation. So, Argentina's parliament passed a new law in October 2020, but Pfizer was unhappy with its phrasing. The law said Pfizer needs to at least pay for negligence, for its own mistakes if it happens to make any in the future.

The law said Pfizer needs to at least pay for negligence, for its own mistakes if it happens to make any in the future.

Pfizer rejected this, after which Argentina offered to amend the law to define negligence more clearly – to include only vaccine distribution and delivery under negligence.

Pfizer was still not happy and demanded the law be amended through a new decree, which Argentina refused.

STAT

‘Held to ransom’: Pfizer plays hardball in Covid-19 vaccine negotiations with Latin American countries

Officials from Argentina and the other Latin American country, which cannot be named as it has signed a confidentiality agreement with Pfizer, said the company’s negotiators demanded more than the usual indemnity against civil claims filed by citizens who suffer serious adverse events after being inoculated. They said Pfizer also insisted the governments cover the potential costs of civil cases brought as a result of Pfizer’s own acts of negligence, fraud, or malice. In Argentina and Brazil, Pfizer asked for sovereign assets to be put up as collateral for any future legal costs.

Science
THE WIRE

Pfizer Demands Governments Gamble With State Assets To Secure Vaccine Deal

Officials from Argentina and the other Latin American country, which cannot be named as it has signed a confidentiality agreement with Pfizer, said the company's negotiators demanded additional indemnity against any civil claims citizens might file if they experienced adverse effects after being inoculated. In Argentina and Brazil, Pfizer asked for sovereign assets to be put up as collateral for any future legal costs.

‘Held to ransom’: Pfizer plays hardball in Covid-19 vaccine negotiations with Latin American countries

‘Good cop, bad cop’

The same demands were made of Brazil’s Ministry of Health, according to a ministry statement. Pfizer asked to be indemnified against all civil claims and asked the ministry to put up sovereign assets as collateral, as well as create a guarantee fund with money deposited in a foreign bank account. In January, the ministry refused these terms, describing the clauses as “abusive.”

PREP Act Immunity from Liability for COVID-19 Vaccinators

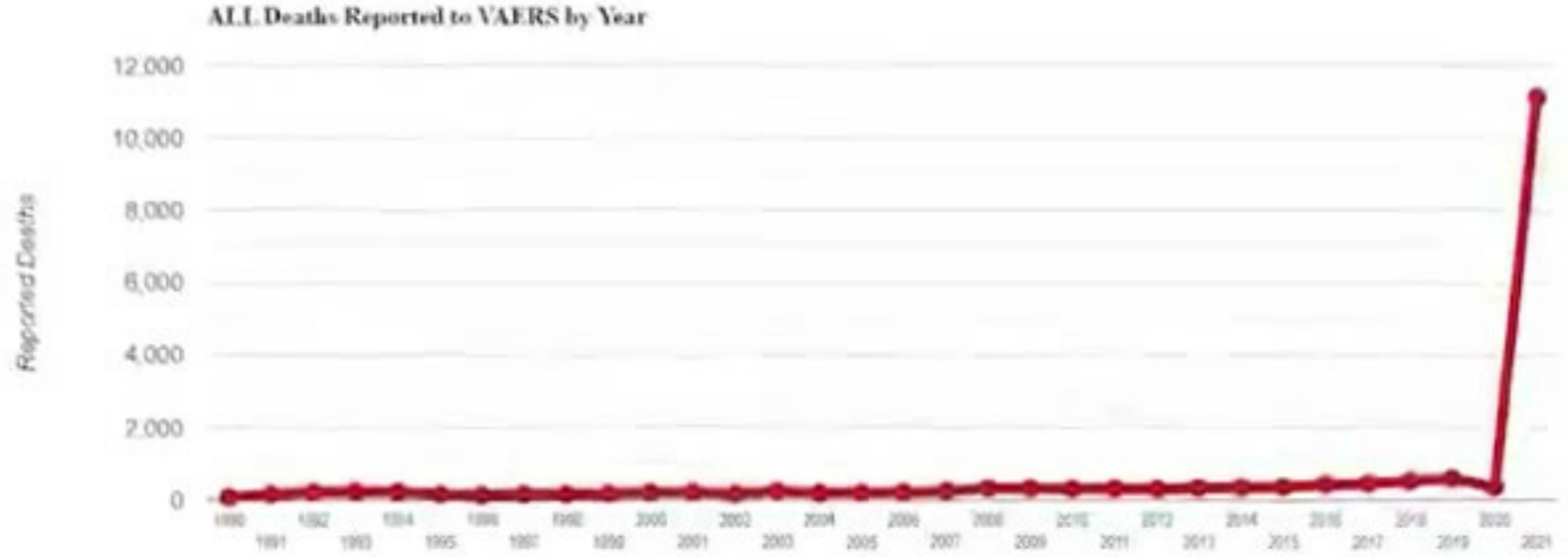
In order to expand the workforce available and authorized to administer COVID-19 vaccines, the Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity to qualified individuals.

When Immunity from Liability Applies

When the Secretary determines that a threat or condition constitutes a present or credible risk of a future public health emergency, the Secretary may issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of covered countermeasures to diseases, threats and conditions identified in the declaration.

GATEWAY PUNDIT
We report the truth — and leave the Russia-Collusion fairy tale to the Conspiracy media

For Second Week in a Row: More COVID-19 Vaccination Deaths than COVID-19 Deaths in the US According to CDC and VAERS Websites



Who Owns Big Pharma?

Big Pharma contributes heavily to the annual budget of the U.S. Food and Drug Administration. Big Pharma does this through application fees (user fees) for its new products.

Experts say the industry contributes about two thirds of the FDA's budget.

Big Pharma also uses its profits and an army of 1,378 paid lobbyists to spread its influence on Capitol Hill.

Notable Big Pharma Scandals

The long road to a Vioxx recall is arguably one of the most notable Big Pharma scandals in U.S. history.

Merck announced a voluntary worldwide recall of its painkiller in 2004. It came four years after evidence linked the drug to significant health risks.

The company's executives decided not to study Vioxx's cardiovascular risks. The FDA later found the drug may cause an increased risk of heart attack and stroke.

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Case Report

COVID-19 Pneumonia in Vaccinated Population: A Six Clinical and Radiological Case Series

Barbara Brogna [1,*,†], Elio Bignardi [2,†], Claudia Brogna [3,4], Chiara Capasso [5], Giuliano Gagliardi [1], Alberigo Martino [6] and Lanfranco Aquilino Musto [1]

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† These authors contributed equally to this work.

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Abstract: Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) and its related disease (COVID-19) continue to represent a challenge for humans. To date, vaccination programs have represented an opportunity to navigate the pandemic. However, the advent of new genetic COVID-19 variants has increased more attention representing a worrying threat not only for not vaccinated but also for vaccinated people as virus infections have been shown also in the last ones. Herein, we report different clinical cases and radiological findings of COVID-19 pneumonia in six fully vaccinated patients. Two patients had a history of Rituximab therapy for follicular lymphoma and with persistent positivity for SARS-CoV-2 on nasopharyngeal/oropharyngeal (NP/OP) swabs and with moderate pneumonia on the chest computed tomography (CT). One patient who resulted to be positive to delta variant 8 days after the second vaccination dose, died shortly after. Two patients were hospitalized due to the worsening of fever and dyspnea in presence of mild pneumonia on CT. In one patient mild pneumonia was found on the chest-CT performed after a lipothymic episode associated with chest pain and positive NP/OP swab tested for SARS-CoV-2. These data suggested that in fully vaccinated people, caution should be preserved, and the use of masks and social distancing should be continued in all closed environments. However, further clinical trials should be done to better understand how various factors can influence vaccine immunogenicity as the presence of virus mutations, age factors, and the presence of an immunocompromised state.

Keywords: SARS-CoV-2; COVID-19 vaccines; COVID-19 pneumonia; immunocompromised state; case reports

check for updates

Citation: Brogna, B.; Bignardi, E.; Brogna, C.; Capasso, C.; Gagliardi, G.; Martino, A.; Musto, L.A. COVID-19 Pneumonia in Vaccinated Population: A Six Clinical and Radiological Case Series. *Medicina* **2021**, *57*, 891. https://doi.org/10.3390/medicina57090891

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1. Introduction

The pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) and its related disease (COVID-19) represents a major challenge for humans. To date, COVID-19 has caused more than 3 million deaths, leading to economic troubles in several countries [1–4].

COVID-19 has a multisystem involvement affecting not only the lungs but also the cardiovascular, nervous, and gastrointestinal systems. In adults, and especially in children, COVID-19 has led to a multisystem inflammatory syndrome [1–4].

https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1

New Results

The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines

Yafei Liu, Noriko Arase, Jun-ichi Kishikawa, Mika Hirose, Songling Li, Asa Tada, Sumiko Matsuoka, Akemi Arakawa, Kanako Akamatsu, Chikako Ono, Hui Jin, Kazuki Kishida, Wataru Nakai, Masako Kohyama, Atsushi Nakagawa, Yoshiaki Yamagishi, Hironori Nakagami, Atsushi Kumanogoh, Yoshiharu Matsuura, Daron M. Standley, Takayuki Kato, Masato Okada, Manabu Fujimoto, Hisashi Arase

doi: https://doi.org/10.1101/2021.08.22.457114

Abstract | Full Text | Info/History | Metrics | Preview PDF

10

Abstract

mRNA-based vaccines provide effective protection against most common SARS-CoV-2 variants. However, identifying likely breakthrough variants is critical for future vaccine development. Here, we found that the Delta variant completely escaped from anti-N-terminal domain (NTD) neutralizing antibodies, while increasing responsiveness to anti-NTD infectivity-enhancing antibodies. Although Pfizer-BioNTech BNT162b2-immune sera neutralized the Delta variant, when four common mutations were introduced into the receptor binding domain (RBD) of the Delta variant (Delta 4+), some BNT162b2-immune sera lost neutralizing activity and enhanced the infectivity. Unique mutations in the Delta NTD were involved in the enhanced infectivity by the BNT162b2-immune sera. Sera of mice immunized by Delta spike, but not wild-type spike, consistently neutralized the Delta 4+ variant without enhancing infectivity. Given the fact that a Delta variant with three similar RBD mutations has already emerged according to the GISAID database, it is necessary to develop vaccines that protect against such complete breakthrough variants.

Competing Interest Statement

Osaka University has filed a patent application for the enhancing antibodies. HA and YL are listed as inventors. HA is a stockholder of HuLA immune Inc.

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Posted August 23, 2021.

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https://www.blacklistednews.com/article/80801/hot-mic-catches-israeli-health-minister-admitting-vaccine-passports-are-about.html

HOT MIC CATCHES ISRAELI HEALTH MINISTER ADMITTING VACCINE PASSPORTS ARE ABOUT COERCION

Published: September 14, 2021

|

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SOURCE: SUMMIT.NEWS

Unaware that he was on a hot mic and being broadcast live on a TV station, Israeli health minister Nitzan Horowitz admitted that vaccine passports were primarily about coercing skeptical people to get the vaccine.

"Imposing "green pass" rules on certain venues is needed only to pressure members of the public to get vaccinated, and not for medical reasons, Israeli Health Minister Nitzan Horowitz said on Sunday, ahead of the weekly Cabinet meeting," reports Jewish News Syndicate.

Unaware that his words were being broadcast live to the nation on Channel 12, Horowitz told Interior Minister Ayelet Shaked that not only should the green pass be removed as a requirement to dine at outdoor restaurants, but also, "For swimming pools, too, not just in restaurants."

"Epidemiologically, it's true," said Horowitz, adding, "The thing is, I'm telling you, our problem is people who don't get vaccinated. We need [to influence] them a bit; otherwise, we won't get out of this [pandemic situation]."

The health minister went on to acknowledge that the system wasn't even being enforced in most venues.

> NEW – Israeli Ministry of Health (right) recorded saying to the Minister of Interior (left) "there is no medical or epidemiological justification for the Covid passport, it is only intended to pressure the unvaccinated to vaccinate".pic.twitter.com/c3oAOpZdEE
>
> — Disclose.tv (@disclosetv) September 13, 2021

"There is a kind of universality to the 'green pass' system, other than at malls, where I think it should be imposed, [because] now it's clear that it applies nowhere," he said.

Israel was once lauded for its successful vaccine rollout and the speed with which it introduced vaccine passports.

The green pass was heralded as an "early vision of how we leave lockdown." However, the country recently reported its highest ever number of daily COVID cases, with nearly 11,000 infections being recorded.

Although the early threat that the unvaccinated would be banned from entering numerous public venues convinced many younger people to get the vaccine, once it rolled out, the 'green pass' system was rarely even enforced and was subsequently scrapped at the end of May.

But once cases started rising again later that summer, Israel's vaccine passport system was reintroduced and expanded.

Meanwhile, Sweden, which never imposed a hard lockdown, recently banned travelers arriving from Israel from entering the country.

https://anti-empire.com/the-epidemic-of-the-unvaccinated-75-of-august-covid-deaths-in-scotland-were-among-the-double-jabbed/

“Pandemic of the Unvaccinated”? 75% of August COVID Deaths in Scotland Were Among the Double-Jabbed

Comparing Public Health Scotland datasets tells a story

12

The Rio Times 14 Sep 21 3865 15

We live in strange times, and if you think the Covid-19 vaccination program is working because the authorities on TV tell you it is, then you will maybe find it disturbing that the UK is in the midst of a ‘third wave’ in the middle of summer.

Especially when you consider that in the summer of 2020, Covid deaths were reduced to zero despite no vaccines being available.

But the bizarre does not end there, if **looking at the latest Covid-19 Statistical Report published by Public Health Scotland (PHS) on September 8, 2021, new questions must be raised.**

An official website of the European Union How do you know?

https://www.ombudsman.europa.eu/en/case/en/59918

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ISSUE

Failure to deal properly with requests for public access to documents [Article 23 ECGAB]

The European Medicines Agency's (EMA) refusal of public access to documents relating to the manufacturing of mRNA vaccines against COVID-19

CASE 1458/2021/MIG - **OPENED ON** Friday | 20 August 2021 - **INSTITUTION CONCERNED**
European Medicines Agency

The complainant sought from the European Medicines Agency (EMA) public access to documents concerning the raw materials used in manufacturing mRNA vaccines against COVID-19. In processing the request, EMA refused access to two documents, arguing that disclosure would undermine the commercial interests of the company in question.

The Ombudsman opened an inquiry and sought to inspect the two documents in question.

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The case

Friday | 20 August 2021 CASE OPENED

The European Medicines Agency's (EMA) refusal of public access to documents relating to the manufacturing of mRNA vaccines against COVID-19

Other documents

Friday | 20 August 2021 CORRESPONDENCE

Letter from the European Ombudsman to the European Medicines Agency (EMA) on its refusal of public access to documents relating to the manufacturing of mRNA vaccines against COVID-19 - EMA reference number ASK-82701

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Immunization expert: ‘Unvaccinated people are not dangerous; vaccinated people are dangerous for others’

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Immunization expert: ‘Unvaccinated people are not dangerous; vaccinated people are dangerous for others’

posted by Mordechai Sones August 17, 2021 6:43 pm

PRINT

https://streamable.com/e/h881fu

World Health Organization European Advisory Group of Experts in Immunization former Vice President Professor **Christian Perronne** yesterday said that all vaccinated people must quarantine over the winter months or risk serious illness.

Perronne specializes in tropical pathologies and emerging infectious diseases. He was Chairman of the Specialized Committee on Communicable Diseases of the High Council of Public Health.

Confirming the rapidly deteriorating situation in Israel and the UK, the infectious disease expert stated: “Vaccinated people should be put in quarantine, and should be isolated from the society.”

He went on to say: “Unvaccinated people are not dangerous; vaccinated people are dangerous for others. It’s proven in Israel now – I’m in contact with many physicians in Israel – they’re having big problems, severe cases in the hospitals are among vaccinated people, and in UK also, you have the larger vaccination program and also there are problems.”

The current working group on the COVID-19 pandemic in France was reported to be “utterly panicked” on receipt of the news, fearing pandemonium if it follows the guidance of the experts.

Israeli doctor Kobi Haviv told *Channel 13 News*: “95% of seriously ill patients are vaccinated. Fully vaccinated people account for 85-90% of hospitalizations. We are opening more and more COVID branches. The effectiveness of vaccines is declining or disappearing.”

https://rumble.com/embed/vip78g/?pub=ogg5j

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COVID YEARLY COMPARISON UK
12TH SEPTEMBER 2021:
CASES: 29,173
DEATHS: 56
HOSPITAL ADMISSIONS 7TH SEPTEMBER:
1,073
12TH SEPTEMBER 2020:
CASES: 2,656
DEATHS: 18
HOSPITAL ADMISSIONS:
218
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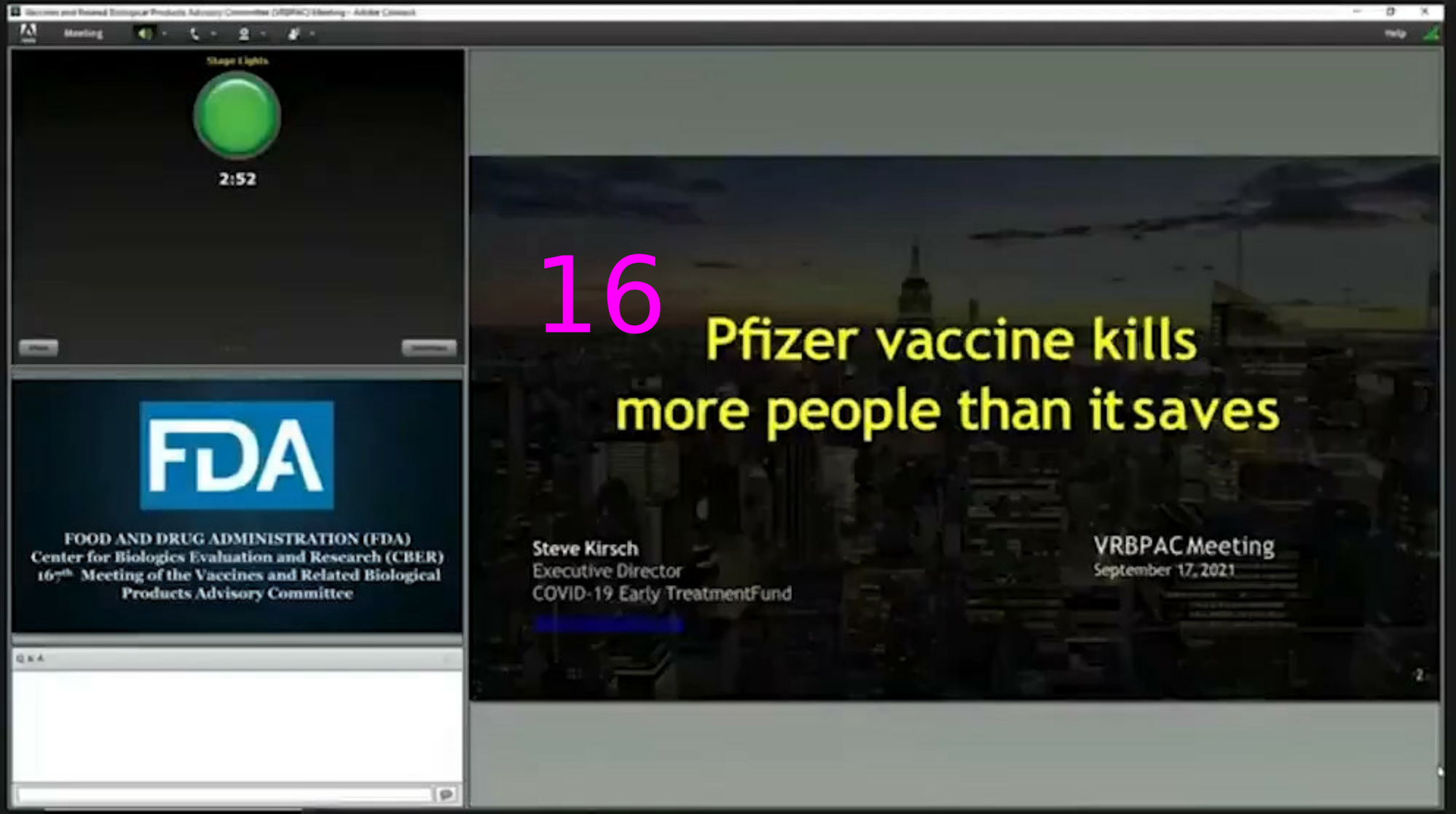

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