Ispettorato Nazionale del Corpo Militare Volontario C.R.I.
Ausiliario delle Forze Armate

XXIV CONVEGNO NAZIONALE
DEGLI UFFICIALI MEDICI E DEL PERSONALE SANITARIO DELLA
CROCE ROSSA ITALIANA
Siracusa - Centro Congressi del Museo Archeologico "Paolo Orsi"
29 Settembre - 2 Ottobre 2022

Il Sars-Cov-2 oggi

Prof. Fabrizio Pregliasco

UNIVERSITÀ DEGLI STUDI DI MILANO

Il sottoscritto Fabrizio Pregliasco *ai sensi dell'art. 3.3 sul Conflitto di Interessi, pag. 17 del Reg. Applicativo dell'Accordo Stato-Regione del 5 novembre 2009,*

dichiara

che negli ultimi due anni ha avuto rapporti diretti di finanziamento con i seguenti soggetti portatori di interessi commerciali in campo sanitario:

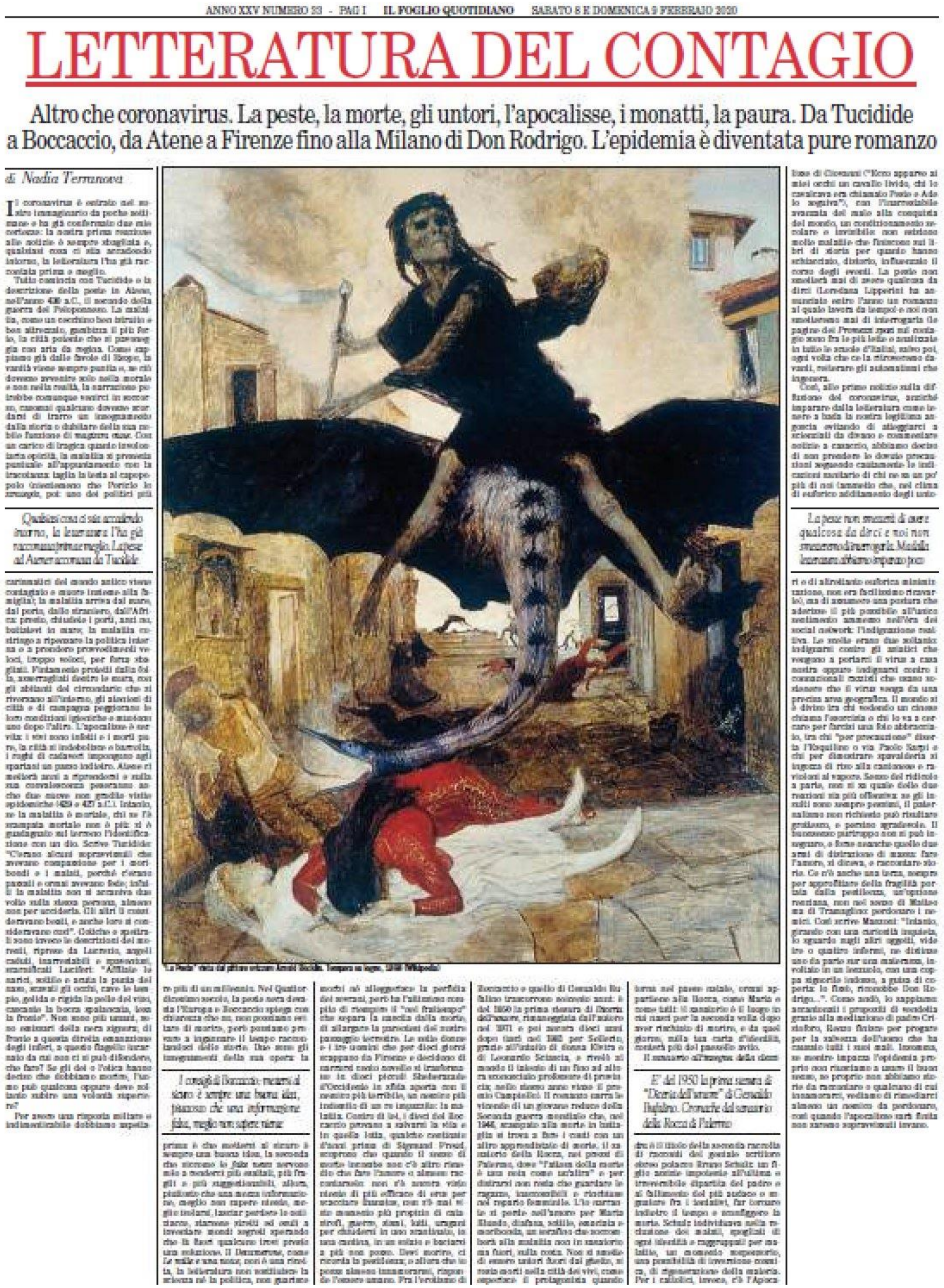
- *GSK, Sequirus, Bayer, Janssen, Sanofi, Baush & Lomb, Lilly, Pfizer*

LE GRELOT

Tout abonné à un journal de Paris peut recevoir gratuitement le GRELOT (Voir en tête de la 2e page)

TOUT LE MONDE L'A (ur) L'INFLUENZA!

La Ronde des Médecins et des Potards.



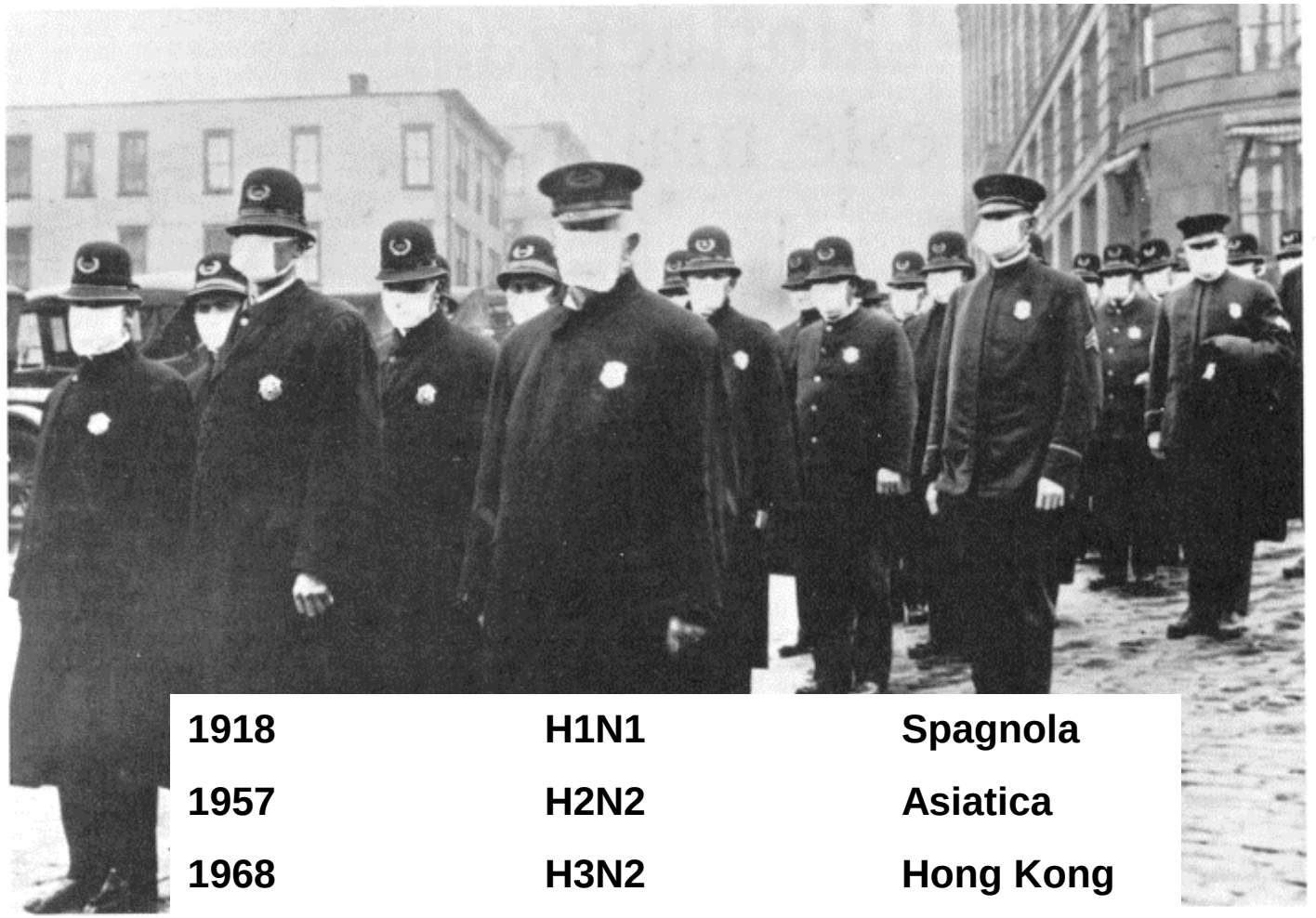
ANNO XXV NUMERO 33 - PAG I IL FOGLIO QUOTIDIANO SABATO 8 E DOMENICA 9 FEBBRAIO 2020

LETTERATURA DEL CONTAGIO

Altro che coronavirus. La peste, la morte, gli untori, l'apocalisse, i monatti, la paura. Da Tucidide a Boccaccio, da Atene a Firenze fino alla Milano di Don Rodrigo. L'epidemia è diventata pure romanzo

di Nadia Terranova

"La Peste" vista dal pittore svizzero Arnold Böcklin. Tempera su legno, 1898 (Wikipedia)



1918	H1N1	Spagnola
1957	H2N2	Asiatica
1968	H3N2	Hong Kong
1977*	H1N1	Russa

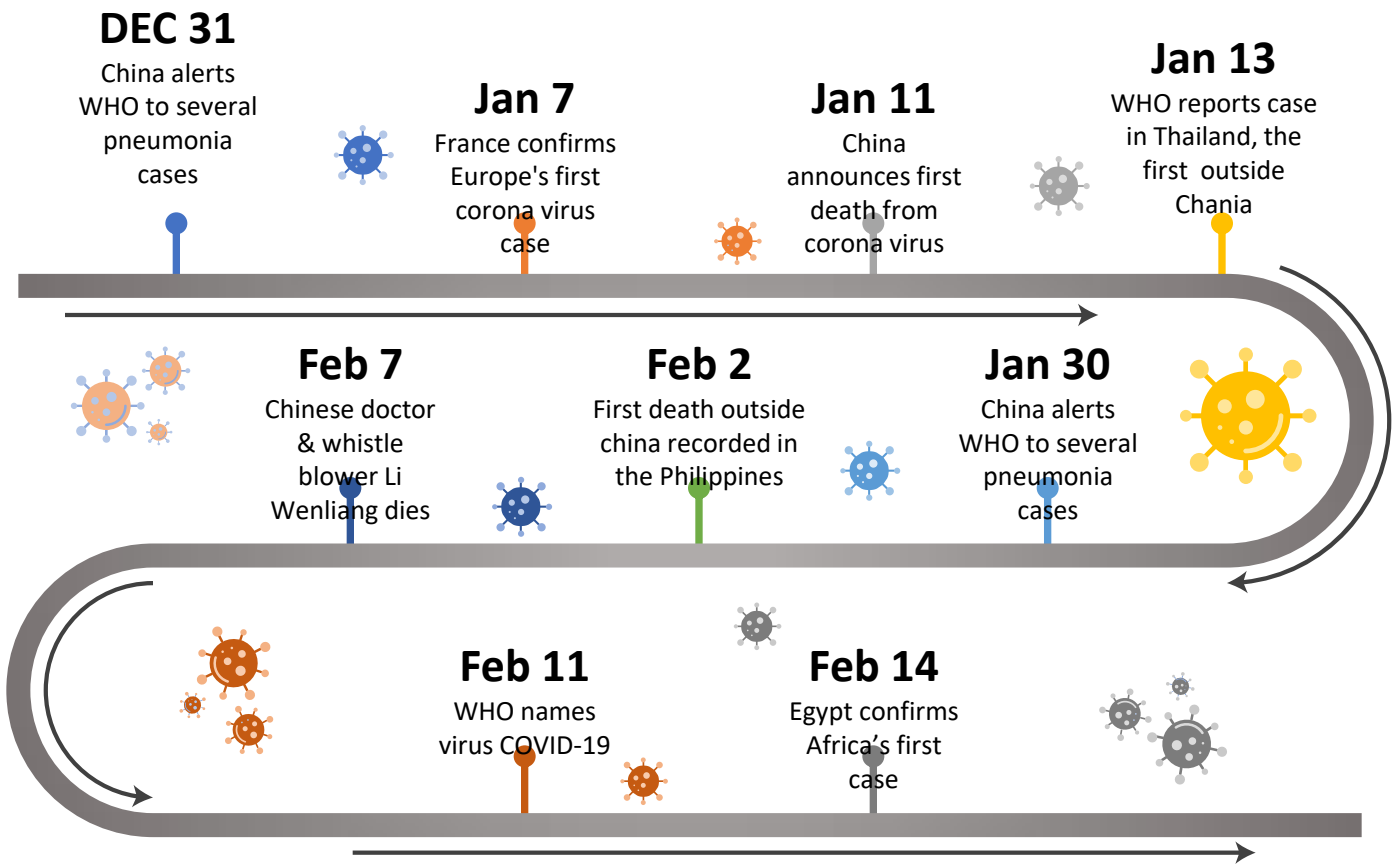
*ha colpito sopratutto soggetti nati dopo 1957.

GIANNELLI

GIANNELLI

GIANNELLI

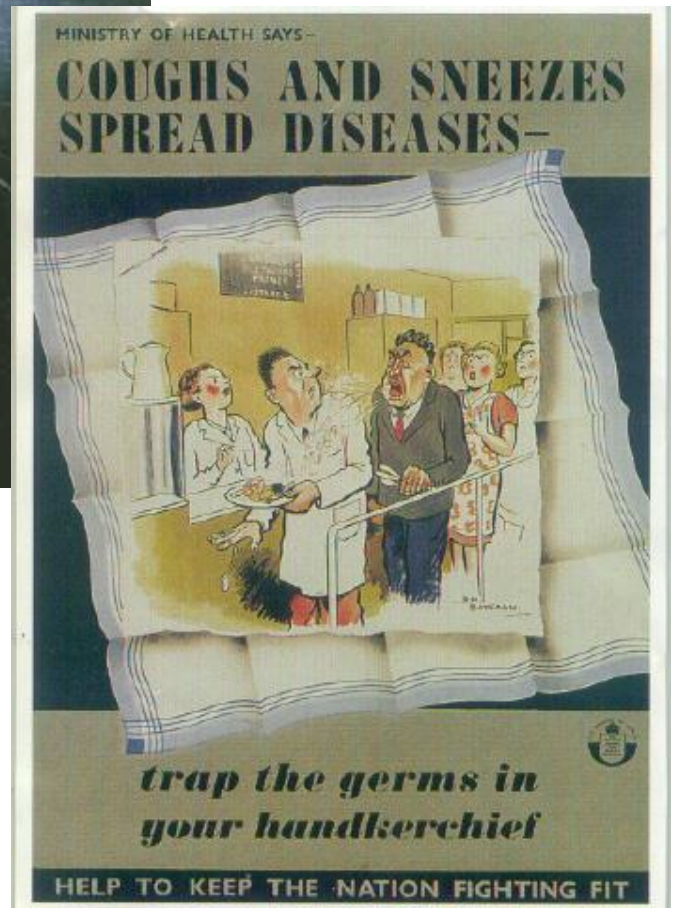
CORONA VIRUS (COVID-19)



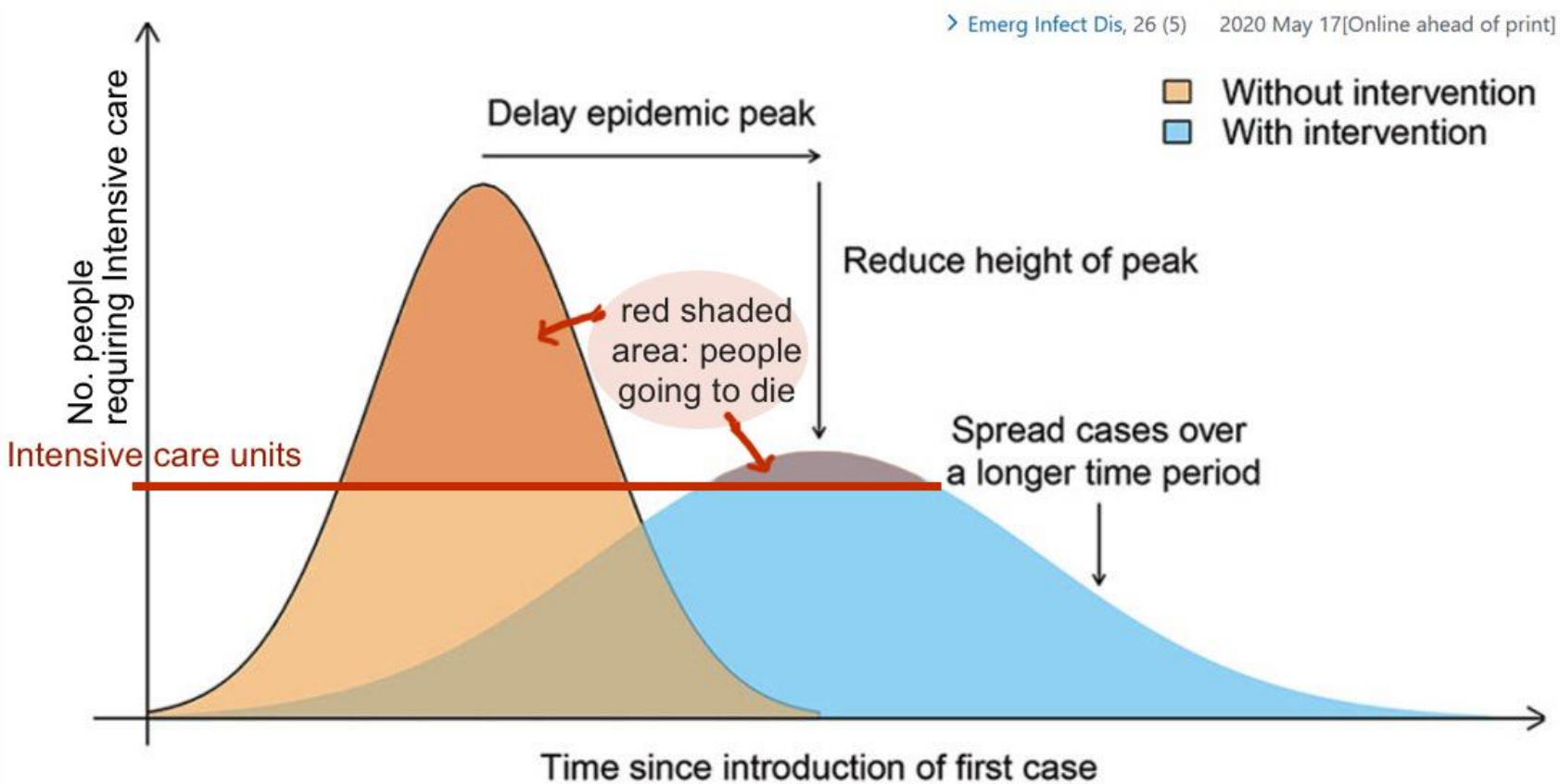

海鲜
临时停车
卸货区


CARABI

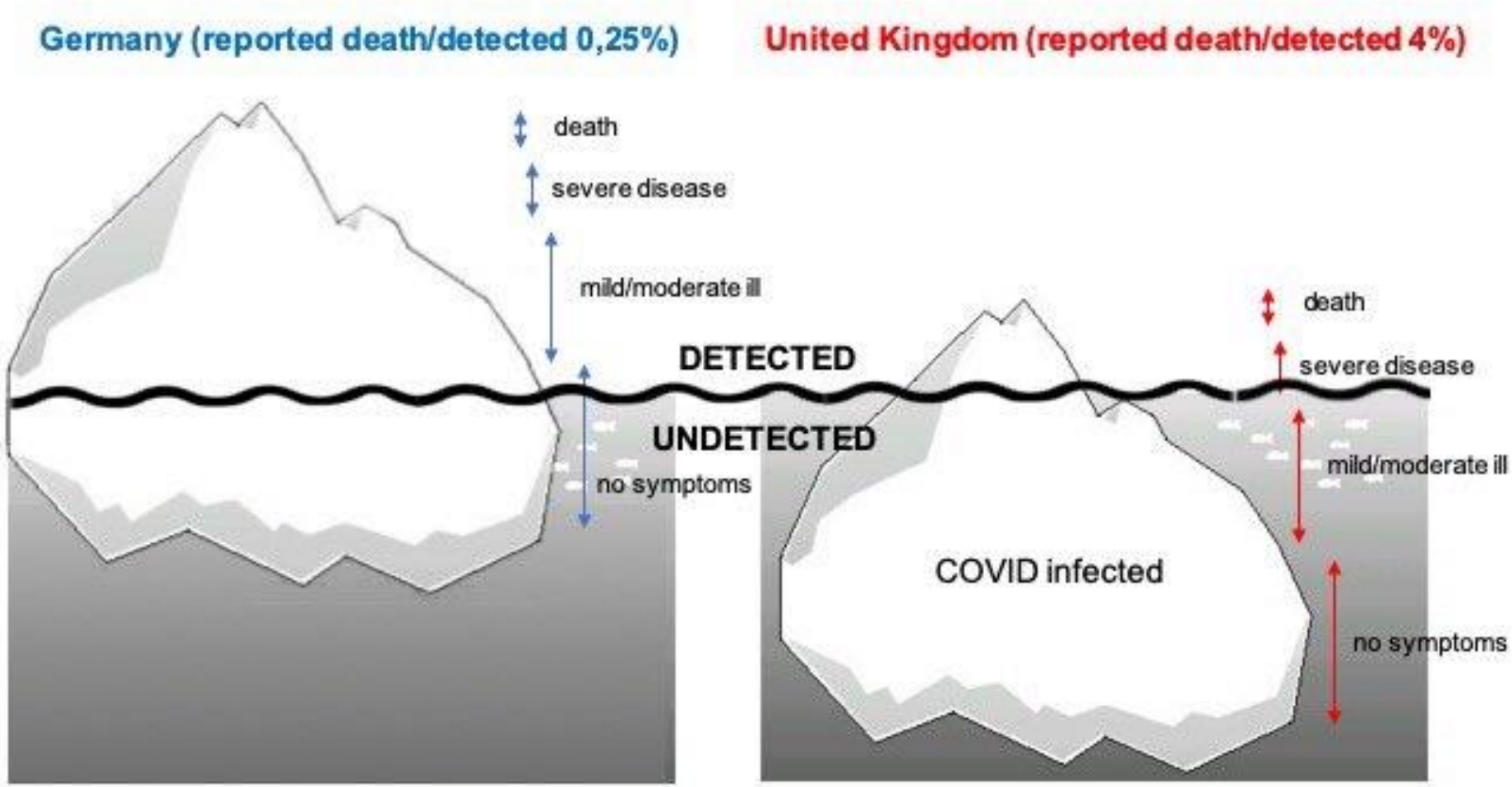

www.fermailvirus.it
Campagna contro l'influenza A
Lavati le mani spesso
con sapone o alcol
Ministero del Lavoro, della salute e delle Politiche Sociali

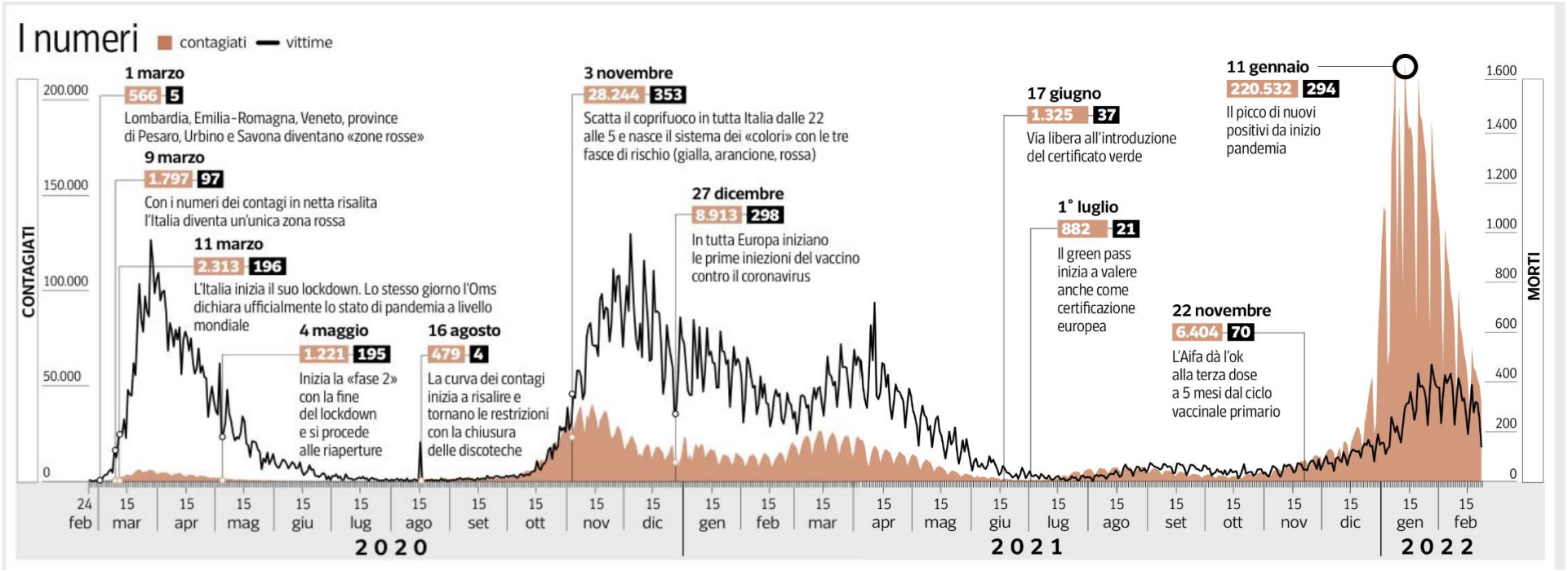

MINISTRY OF HEALTH SAYS–
COUGHS AND SNEEZES
SPREAD DISEASES–
trap the germs in
your handkerchief
HELP TO KEEP THE NATION FIGHTING FIT

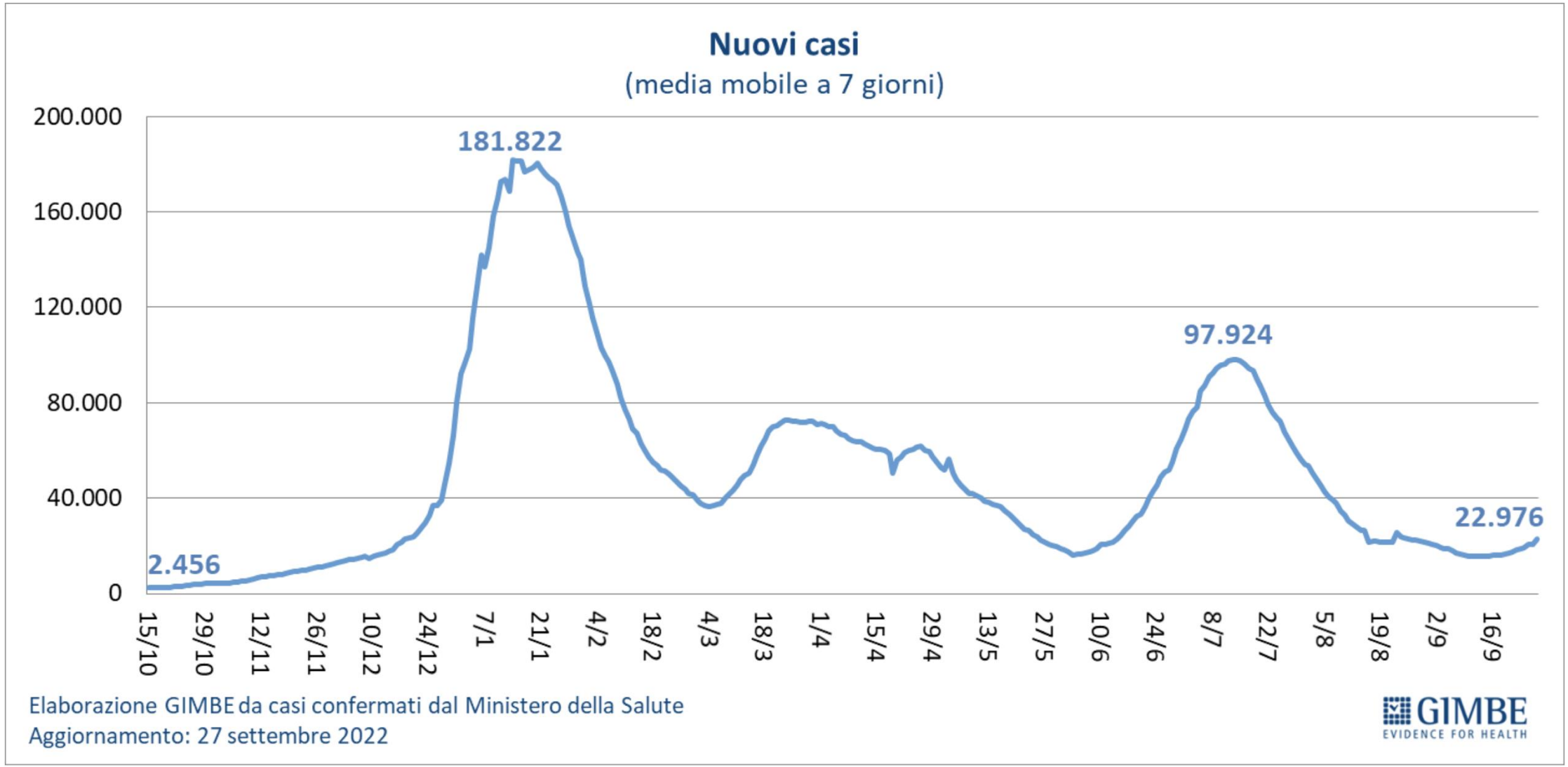
Efficacia delle misure di isolamento sociale sul contenimento delle epidemie



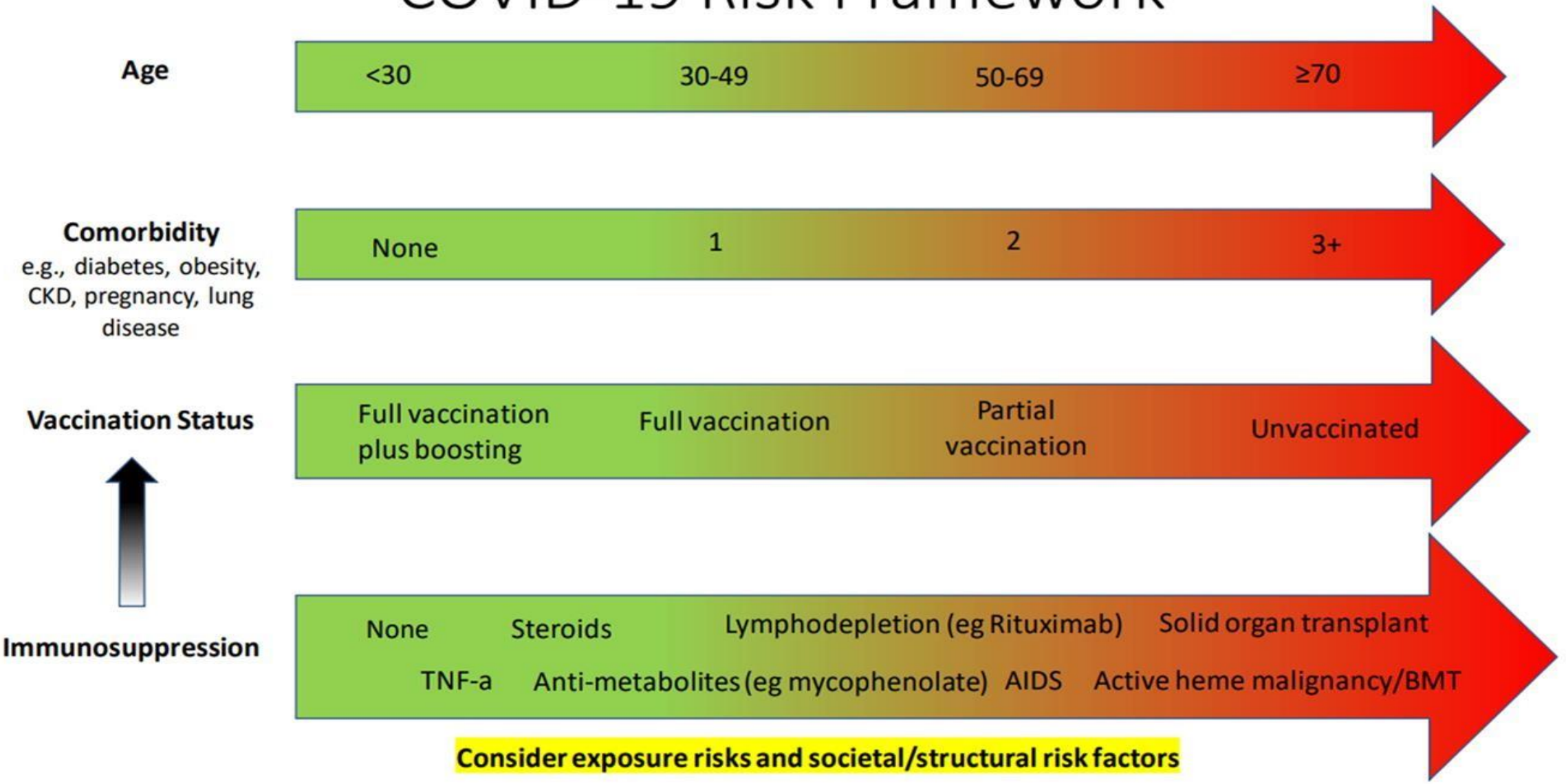
ICEBERG ANALOGY COVID19 REPORTING




I numeri
contagiati
vittime
CONTAGIATI
200.000
150.000
100.000
50.000
0
MORTI
1.600
1.400
1.200
1.000
800
600
400
200
0
1 marzo
566 5
Lombardia, Emilia-Romagna, Veneto, province di Pesaro, Urbino e Savona diventano «zone rosse»
9 marzo
1.797 97
Con i numeri dei contagi in netta risalita l'Italia diventa un'unica zona rossa
11 marzo
2.313 196
L'Italia inizia il suo lockdown. Lo stesso giorno l'Oms dichiara ufficialmente lo stato di pandemia a livello mondiale
4 maggio
1.221 195
Inizia la «fase 2» con la fine del lockdown e si procede alle riaperture
16 agosto
479 4
La curva dei contagi inizia a risalire e tornano le restrizioni con la chiusura delle discoteche
3 novembre
28.244 353
Scatta il coprifuoco in tutta Italia dalle 22 alle 5 e nasce il sistema dei «colori» con le tre fasce di rischio (gialla, arancione, rossa)
27 dicembre
8.913 298
In tutta Europa iniziano le prime iniezioni del vaccino contro il coronavirus
17 giugno
1.325 37
Via libera all'introduzione del certificato verde
1° luglio
882 21
Il green pass inizia a valere anche come certificazione europea
22 novembre
6.404 70
L'Aifa dà l'ok alla terza dose a 5 mesi dal ciclo vaccinale primario
11 gennaio
220.532 294
Il picco di nuovi positivi da inizio pandemia
24 feb
15 mar
15 apr
15 mag
15 giu
15 lug
15 ago
15 set
15 ott
15 nov
15 dic
15 gen
15 feb
15 mar
15 apr
15 mag
15 giu
15 lug
15 ago
15 set
15 ott
15 nov
15 dic
15 gen
15 feb
2020
2021
2022

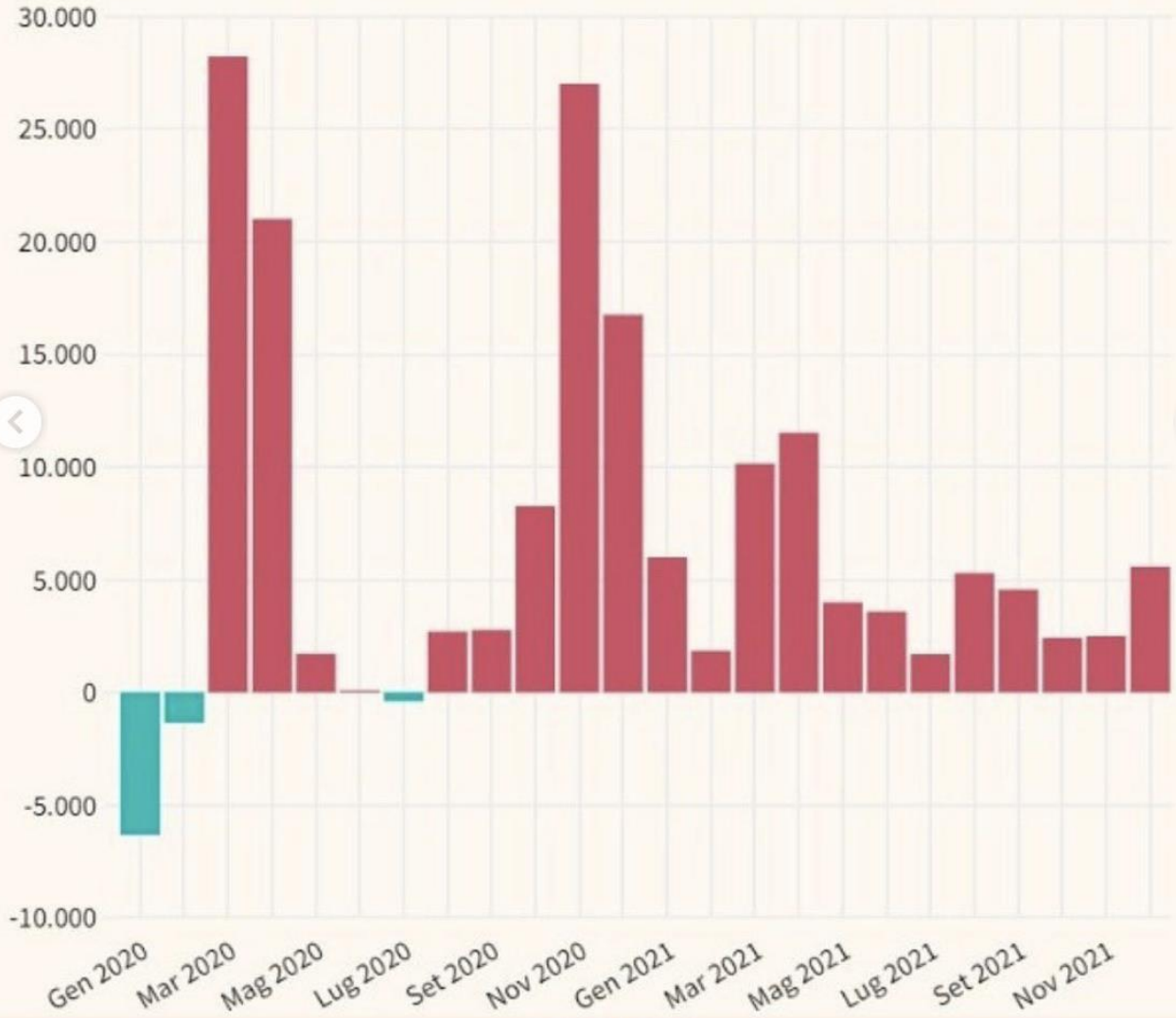

Nuovi casi
(media mobile a 7 giorni)
200.000
160.000
120.000
80.000
40.000
0
181.822
97.924
22.976
2.456
15/10
29/10
12/11
26/11
10/12
24/12
7/1
21/1
4/2
18/2
4/3
18/3
1/4
15/4
29/4
13/5
27/5
10/6
24/6
8/7
22/7
5/8
19/8
2/9
16/9
Elaborazione GIMBE da casi confermati dal Ministero della Salute
Aggiornamento: 27 settembre 2022
GIMBE
EVIDENCE FOR HEALTH

COVID-19 Risk Framework



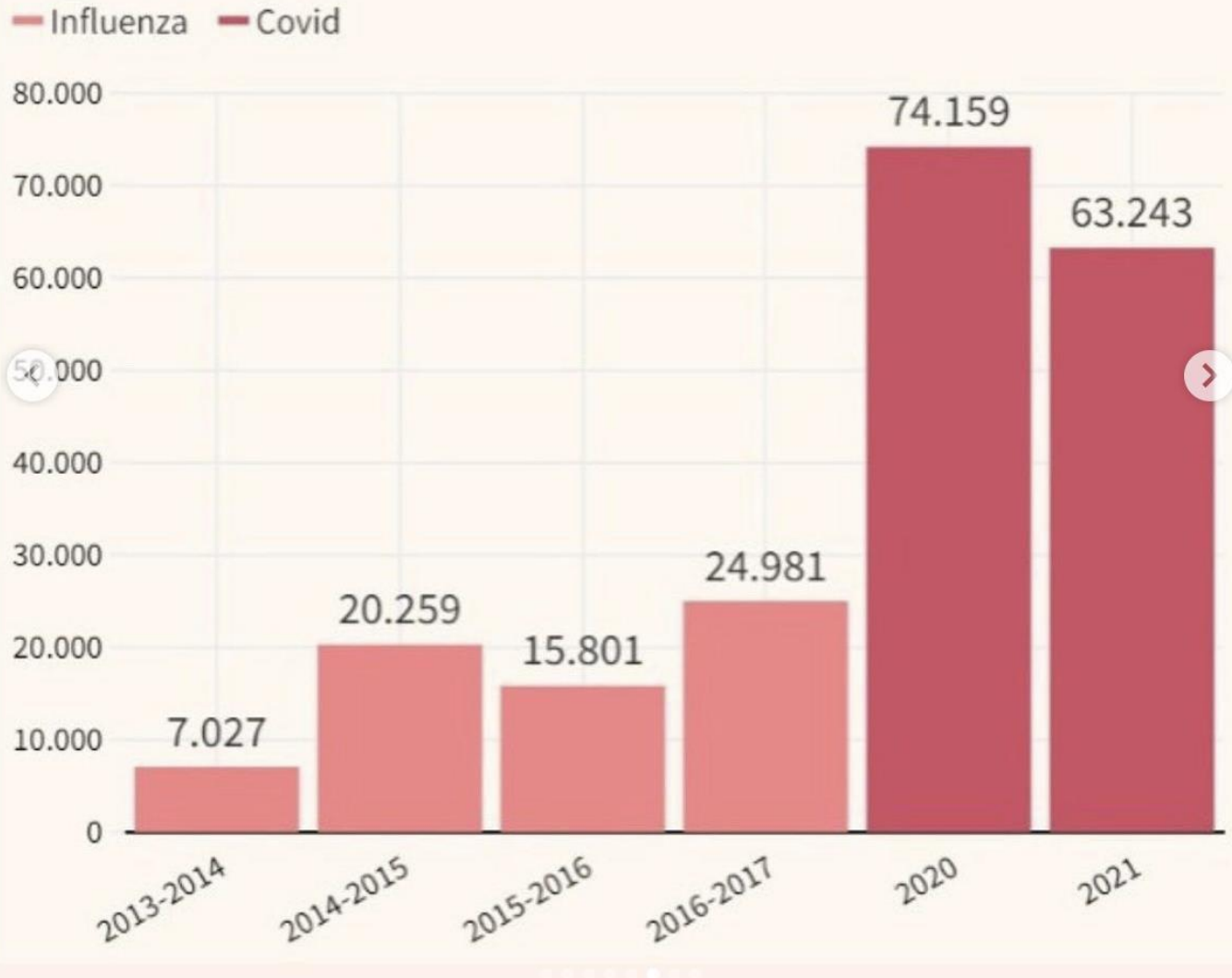
ITALIA, ANDAMENTO MENSILE DELLA MORTALITÀ IN ECCESSO

Differenza di decessi per tutte le cause rispetto alla media degli anni 2015-19. Fonte: Istat



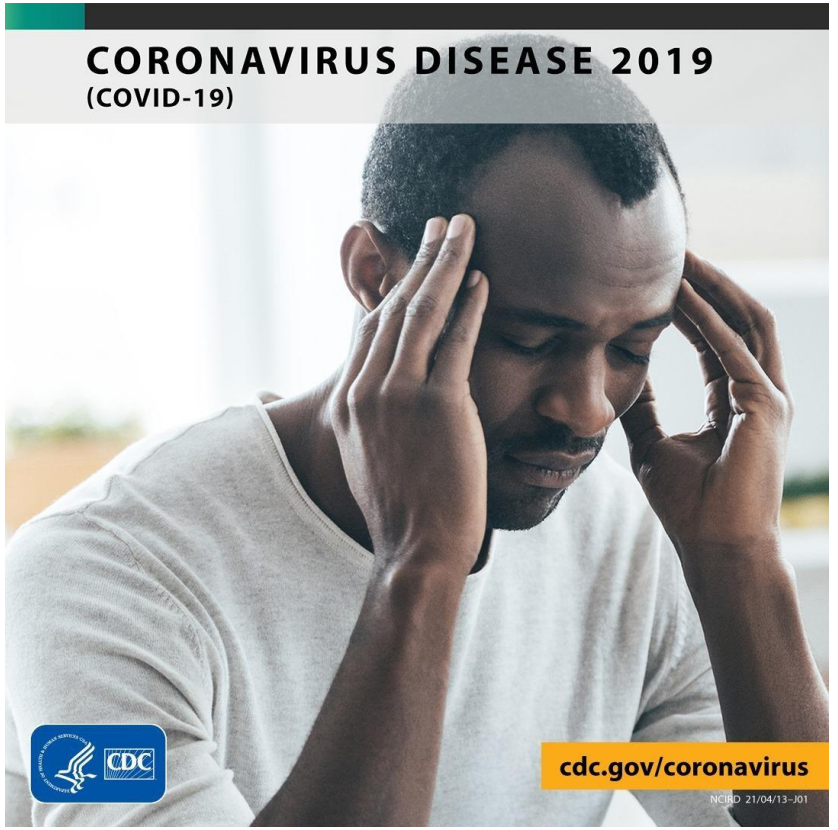
INFLUENZA VS COVID: MORTI IN ITALIA

Stima delle morti per stagioni influenzali con relative complicanzee numero cumulato di morti annuali causate dal Covid. Fonte: InfluNet



Post-COVID Conditions is an umbrella term

- "**Post-COVID conditions**" is an umbrella term for the wide range of physical and mental health consequences experienced by some patients that are present four or more weeks after SARS- CoV-2 infection, including by patients who had initial mild or asymptomatic acute infection.

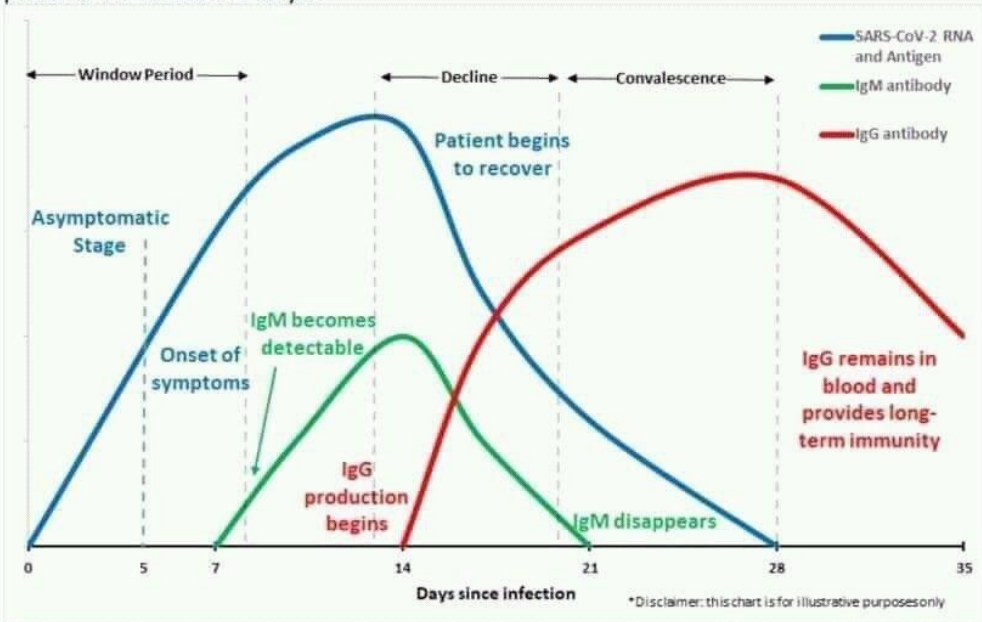


For clinical features warranting further evaluation, consider broad range of possible post-COVID conditions

Body System	Conditions (subject to change and not mutually exclusive)
Cardiovascular	Myocarditis, heart failure, pericarditis, orthostatic intolerance (e.g., postural orthostatic tachycardia syndrome [POTS])
Pulmonary	Interstitial lung disease, reactive airway disease
Renal	Chronic kidney disease
Dermatologic	Alopecia
Rheumatologic	Reactive arthritis, fibromyalgia, connective tissue disease
Endocrine	Diabetes mellitus, hypothyroidism
Neurologic	Transient ischemic attack/stroke, olfactory and gustatory dysfunction, sleep dysregulation, altered cognition, memory impairment, headache, weakness, neuropathy
Psychiatric	Depression, anxiety, post-traumatic stress disorder (PTSD), psychosis
Hematologic	Pulmonary embolism, arterial thrombosis, venous thromboembolism, other hypercoagulability
Urologic	Incontinence, sexual dysfunction
Other	Weight loss, dysautonomia, allergies and mast cell activation syndrome, reactivation of other viruses, pain syndromes, hearing loss, vertigo, and progression of comorbid conditions

Ma che fare?

Therefore, this COVID-19 Rapid Test should not be used until symptoms have been present for at least 3 days.



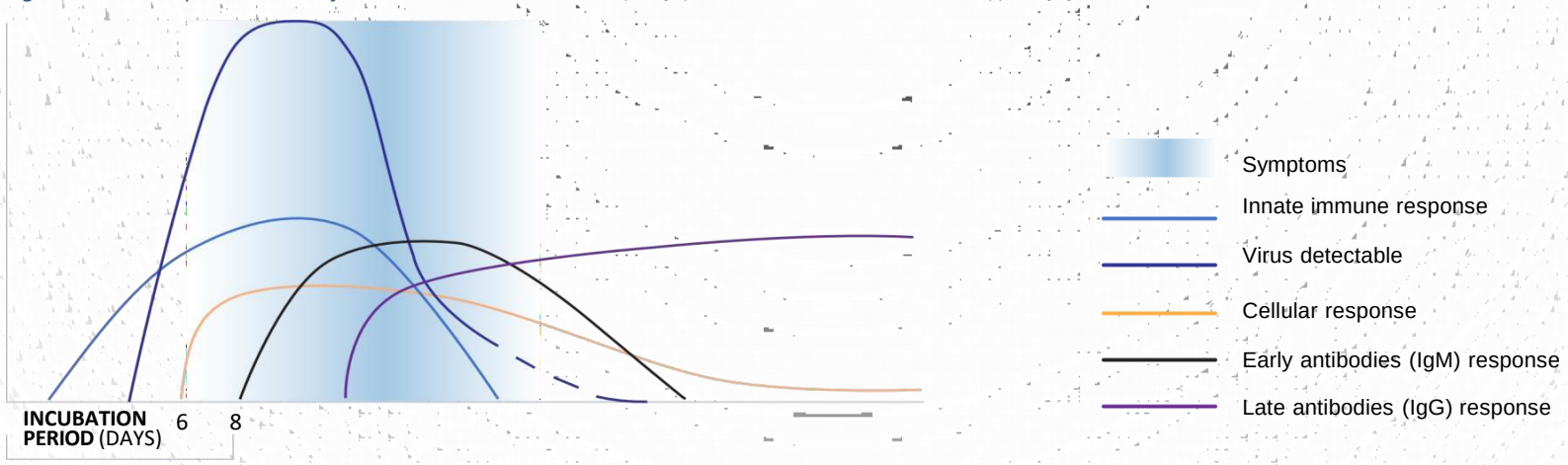
Test results			Clinical Significance
PCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. PCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the PCR result may be false-negative.

Immune response to a viral infection

Two types of immunity are:

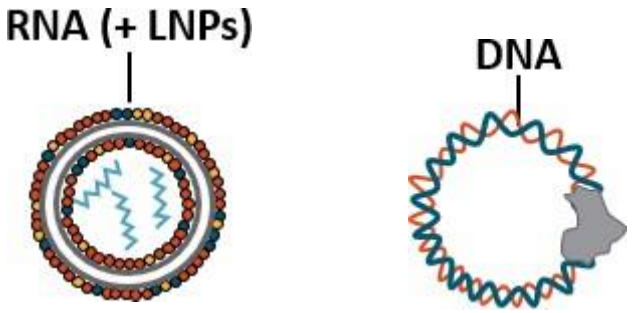
- **Innate immunity**
  - General immediate response to ANY infection
- **Adaptive immunity**
  - Specific response to an infection
  - Involves the **cellular response** (T cells) and the **antibody response** (B cells)
- Innate immune response is immediate; whereas cellular & antibody response usually starts after 6 to 8 days

Figure. *Immune response to viral infection*

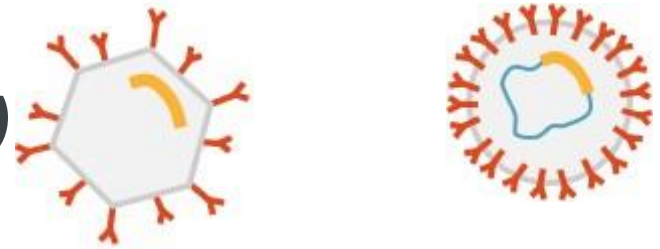


Vaccini anti-COVID: Piattaforme utilizzate

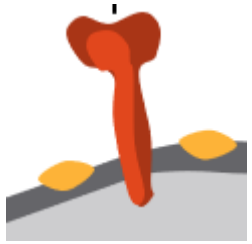
- ***Vaccini genetici***



- ***Vaccini a vettori virali (replicativi e non replicativi)***



- ***Vaccini proteici***



- ***Vaccini con virus attenuato o inattivato***

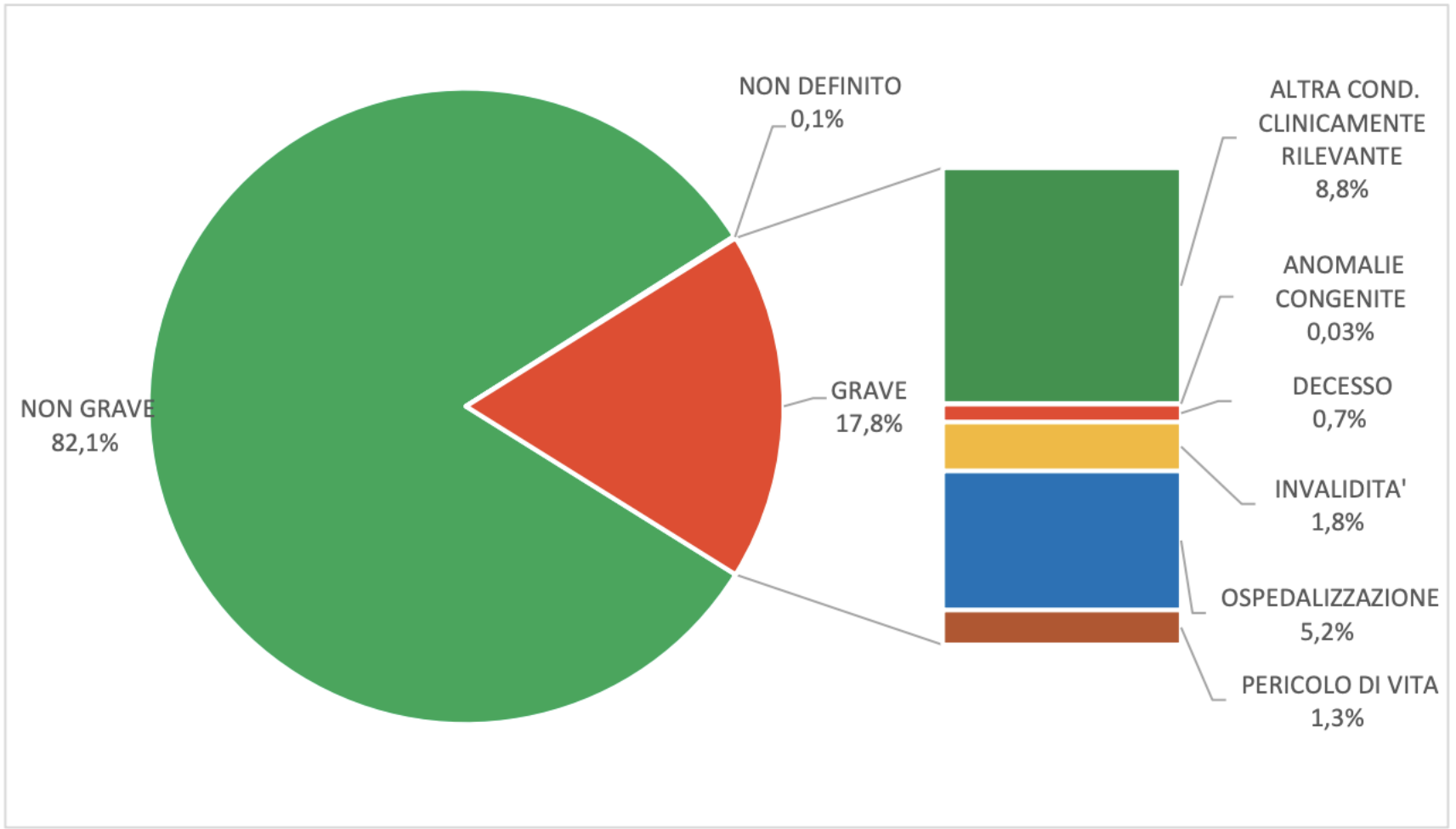
https://www.aifa.gov.it/documents/20142/1315190/Rapporto_sorveglianza_vaccini_COVID-19_11.pdf

Tabella 1 *- Segnalazioni, dosi somministrate e relativi tassi per vaccini anti-COVID-19 attualmente autorizzati*

Vaccino anti-COVID-19	Segnalazioni al 26/03/2022	Dosi somministrate al 26/03/2022	Tasso di segnalazione (per 100.000 dosi somministrate)	Intervallo di Confidenza al 95%
Comirnaty	89.315	88.552.383	101	***100-102***
Spikevax	19.472	33.592.002	58	***57-59***
Principio attivo mRNA	24			
Vaxzevria	23.826	12.170.299	196	***194-198***
Janssen	1.731	1.507.726	115	***110-120***
Nuvaxovid	47	27.578	170	***121-219***
Totale	**134.415***	**135.849.988**	**99**	***98-100***

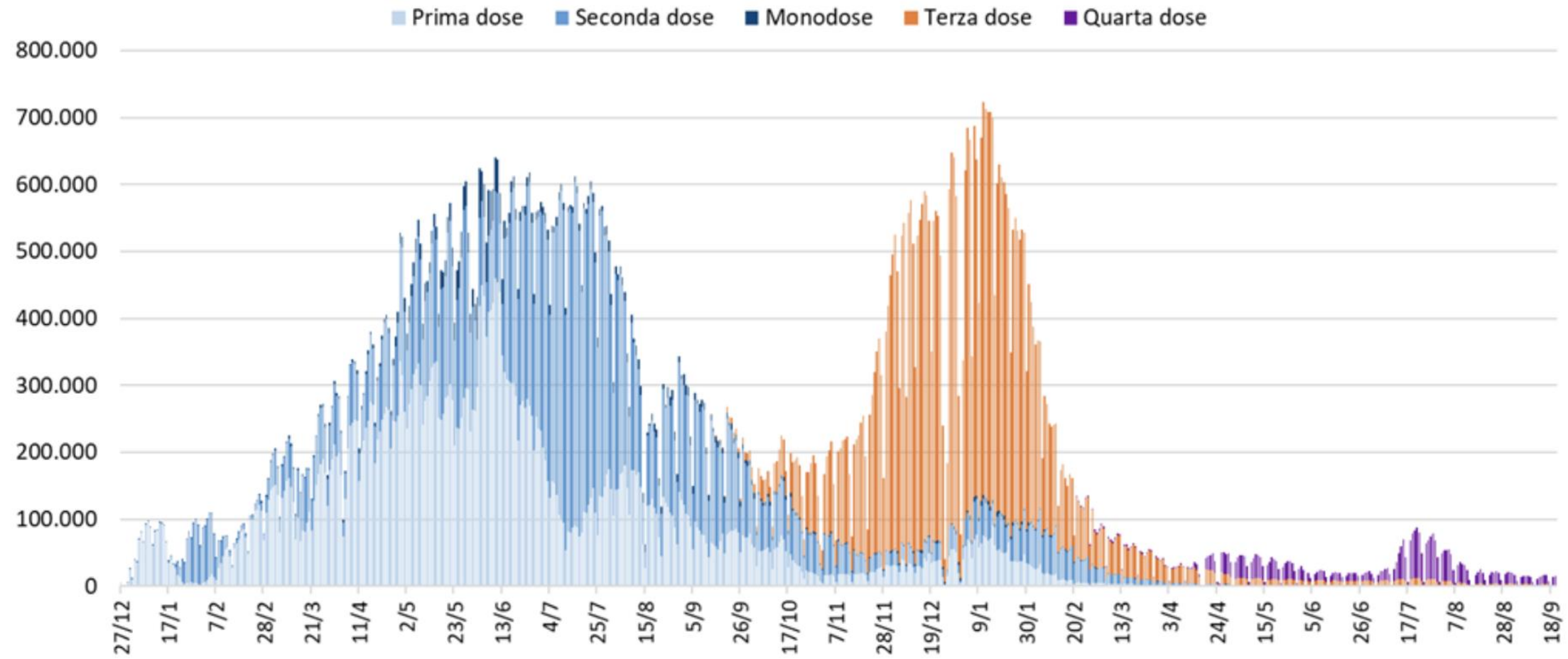
**il numero totale delle segnalazioni per vaccino commerciale non corrisponde al totale delle schede presenti nella RNF ma è maggiore in quanto in alcune schede sono indicati due vaccini sospetti (dopo vaccinazione eterologa)*

Figura 6 *- Distribuzione per criterio di gravità delle segnalazioni inserite nel periodo in esame (nello 0,1% delle segnalazioni il criterio di gravità non è indicato)*



https://www.aifa.gov.it/documents/20142/1315190/Rapporto_sorveglianza_vaccini_COVID-19_11.pdf

Dosi di vaccino somministrate



Elaborazione GIMBE su dati Ministero Salute e Unità per il completamento della campagna vaccinale
Aggiornamento: 21 settembre 2022 ore 06:16

GIMBE
EVIDENCE FOR HEALTH

SARS-CoV-2 changes over time, with the potential for new variants to emerge and impact the course of the pandemic[1,2]

BETA B.1.351

Earliest documented in: **South Africa**
VOC designation on: December 18, 2020

DELTA B.1.617.2

Earliest documented in: **India**
VOC designation on: May 11, 2021

OMICRON B.1.1.529*

Earliest documented in: **South Africa**
VOC designation on: November 26, 2021

2020 **2021** **2022**

ALPHA B.1.1.7

Earliest documented in: **United Kingdom**
VOC designation on: December 18, 2020

GAMMA P.1

Earliest documented in: **Brazil**
VOC designation on: January 11, 2021

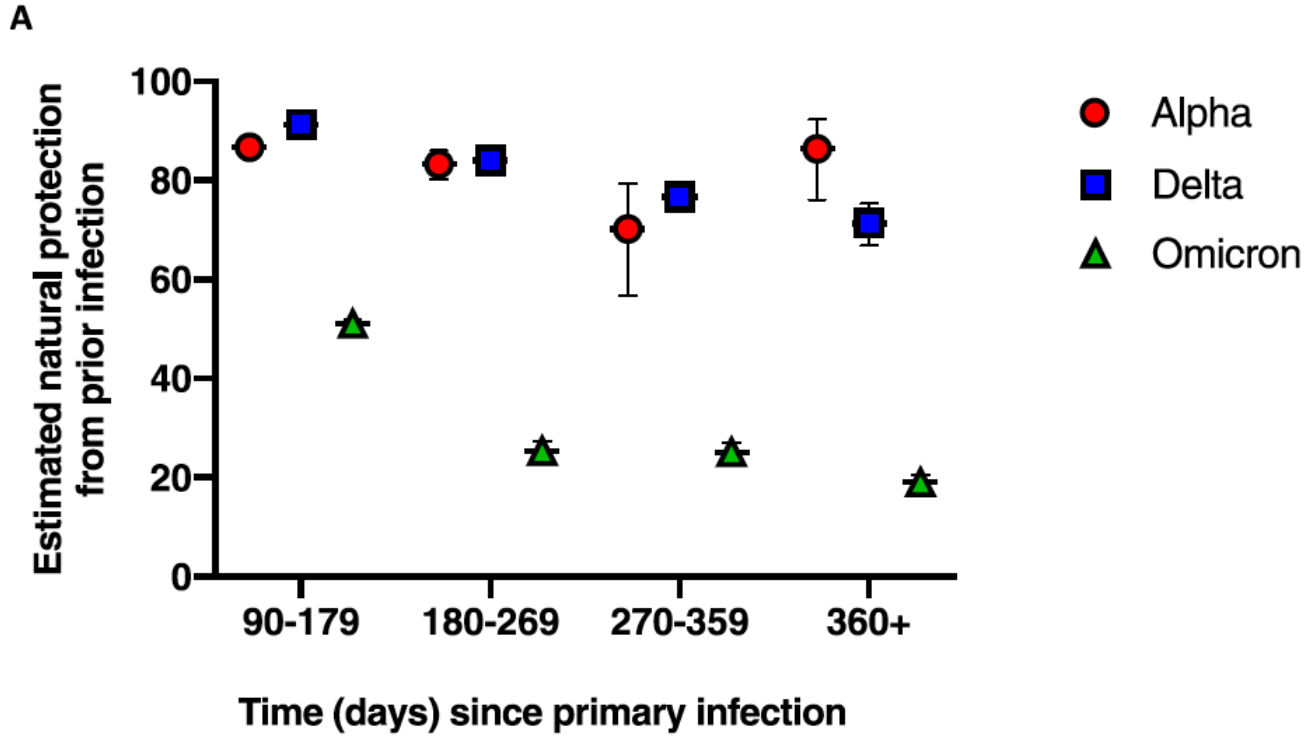
As of 12 May 2022:
BA.1, BA.2, BA.4, and BA.5 OMICRON sub-lineages have been designated VOC in EU/EEA[3]

***Includes BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages.** It also includes BA.1/BA.2 circulating recombinant forms such as XE. WHO emphasizes that these descendant lineages should be monitored as distinct lineages by public health authorities and comparative assessments of their virus characteristics should be undertaken.

VOC=variant of concern.

1. World Health Organization. Tracking variants of concern. https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (accessed May 2022). **2.** World Health Organization. Epidemiology update. https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---21-december-2021 (accessed May 2022). **3.** ECDC. May 2022. SARS-Cov2 variants of concern as of 12 May 2022. https://www.ecdc.europa.eu/en/covid-19/variants-concern (accessed May 2022).

Observed protection against SARS-CoV-2 reinfection following a primary infection among unvaccinated.



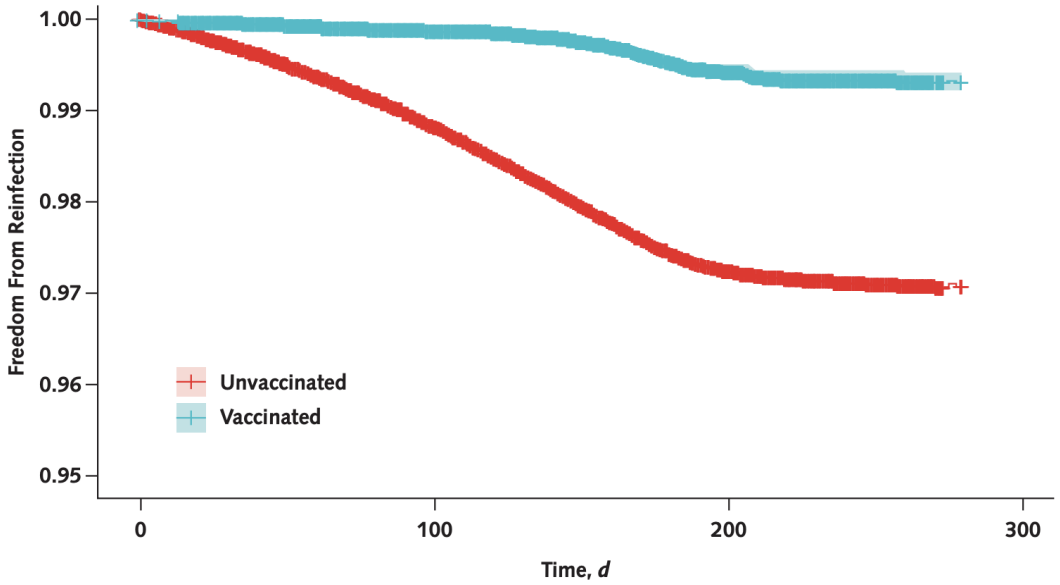
Michlmayr D, Hansen CH, Gubbels SM, Valentiner-Branth P, Bager P, Obel N, Drewes B, Møller CH, Møller FT, Legarth R, Mølbak K, Ethelberg S. Observed protection against SARS-CoV-2 reinfection following a primary infection: A Danish cohort study among unvaccinated using two years of nationwide PCR-test data. Lancet Reg Health Eur. 2022 Sep;20:100452.

The Incidence of SARS-CoV-2 Reinfection in Persons With Naturally Acquired Immunity With and Without Subsequent Receipt of a Single Dose of BNT162b2 Vaccine

Table 3. Hazard Ratios for SARS-CoV-2 Reinfection, Previously Infected Versus Previously Infected and Vaccinated

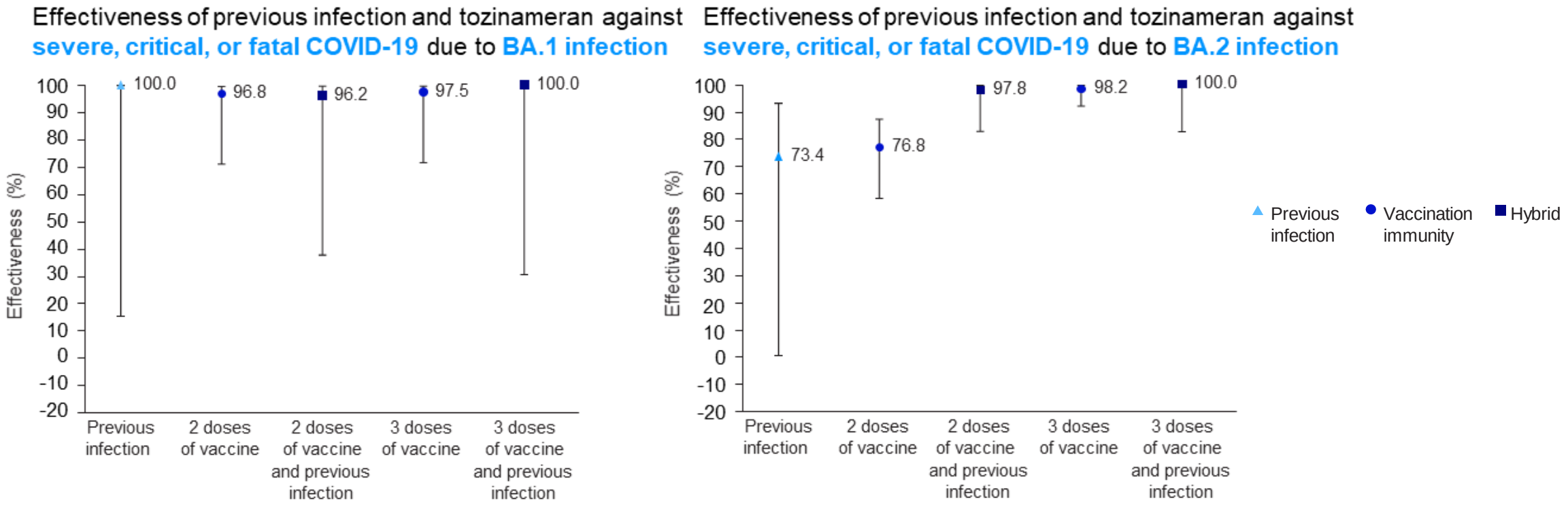
Variable and Category	Hazard Ratio	95% CI	*P* Value
Overall SARS-CoV-2 Reinfection			
Induced immunity			
Previously infected and unvaccinated	Reference	_	_
Previously infected and vaccinated	0.18	0.15-0.20	<0.001
Symptomatic Reinfection			
Previously infected and unvaccinated	Reference	_	_
Previously infected and vaccinated	0.24	0.20-0.29	<0.001

Figure 1. Standardized failure curves for SARS-CoV-2 reinfection.



Gazit S, Shlezinger R, Perez G, Lotan R, Peretz A, Ben-Tov A, Herzel E, Alapi H, Cohen D, Muhsen K, Chodick G, Patalon T. The Incidence of SARS-CoV-2 Reinfection in Persons With Naturally Acquired Immunity With and Without Subsequent Receipt of a Single Dose of BNT162b2 Vaccine : A Retrospective Cohort Study. Ann Intern Med. 2022 May;175(5):674-681.

Effects of previous infection and vaccination on symptomatic Omicron infections in a case-control test-negative study



Figures adapted from Altarawneh HN et al. *N Engl J Med* 2022.

Hybrid immunity resulting from previous infection and recent booster vaccination conferred the strongest protection against severe, critical, or fatal COVID-19 caused by Omicron BA.2 infection

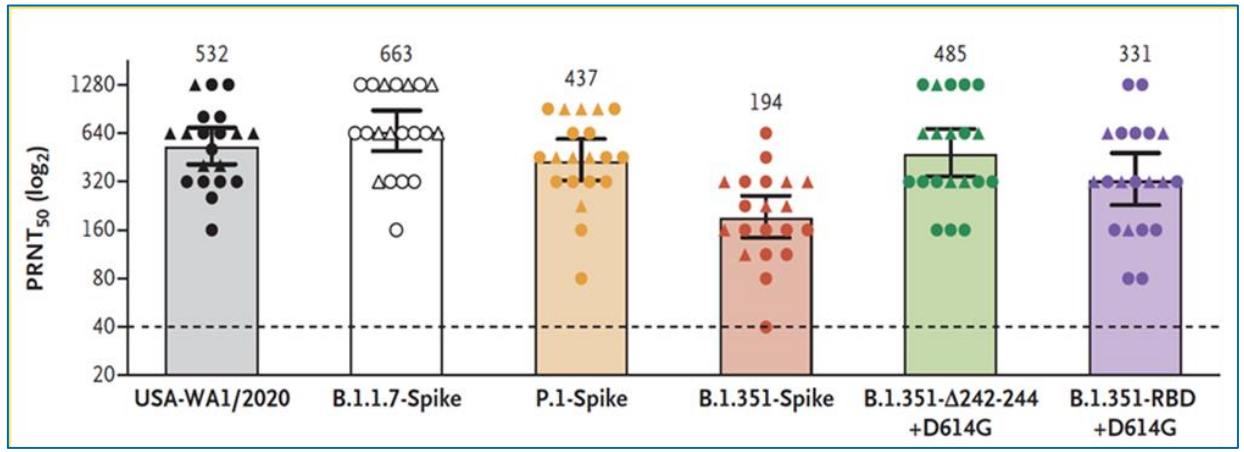
Note: A small proportion of the population of Qatar is ≥50-years-old, therefore, these findings may not be generalisable to other countries in which older adults constitute a larger proportion of the population. Participant matching was performed according to sex, age, and nationality, matching was not possible for other factors, such as coexisting conditions.
VE, vaccine effectiveness.

Altarawneh HN et al. *N Engl J Med* 2022;387:21–34.

BNT162b2-elicited sera effectively neutralize a broad range of SARS-CoV-2 spike variants after 2 doses

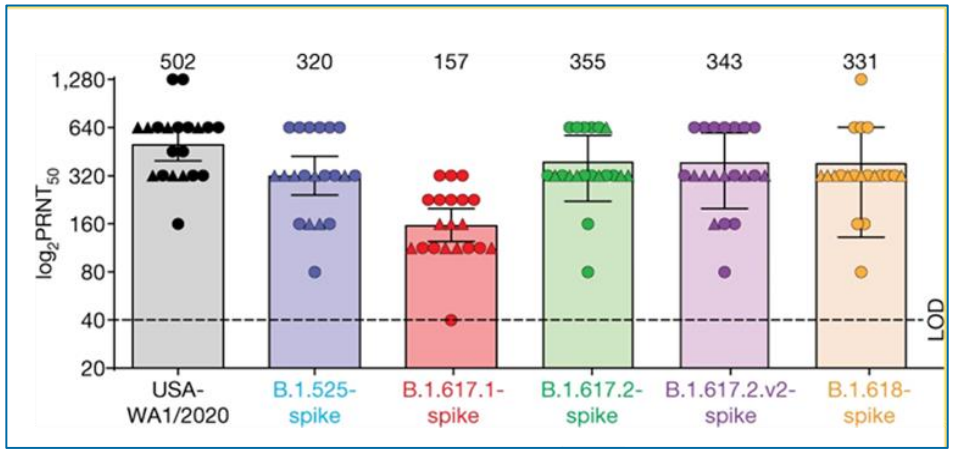
BNT162b2 mRNA vaccine-immune sera (n=15–20) tested against recombinant viruses covering key variants vs wild-type Wa-1 genetic background[1-3]

Weeks after the administration of dose 2 of BNT162b2
- ● 2 weeks (circle)
- ▲ 4 weeks (triangle)



WT **Alpha** **Gamma** **Beta**

Reproduced from reference.
Liu Y, et al. *N Engl J Med*. 2021;384:1466-1468.



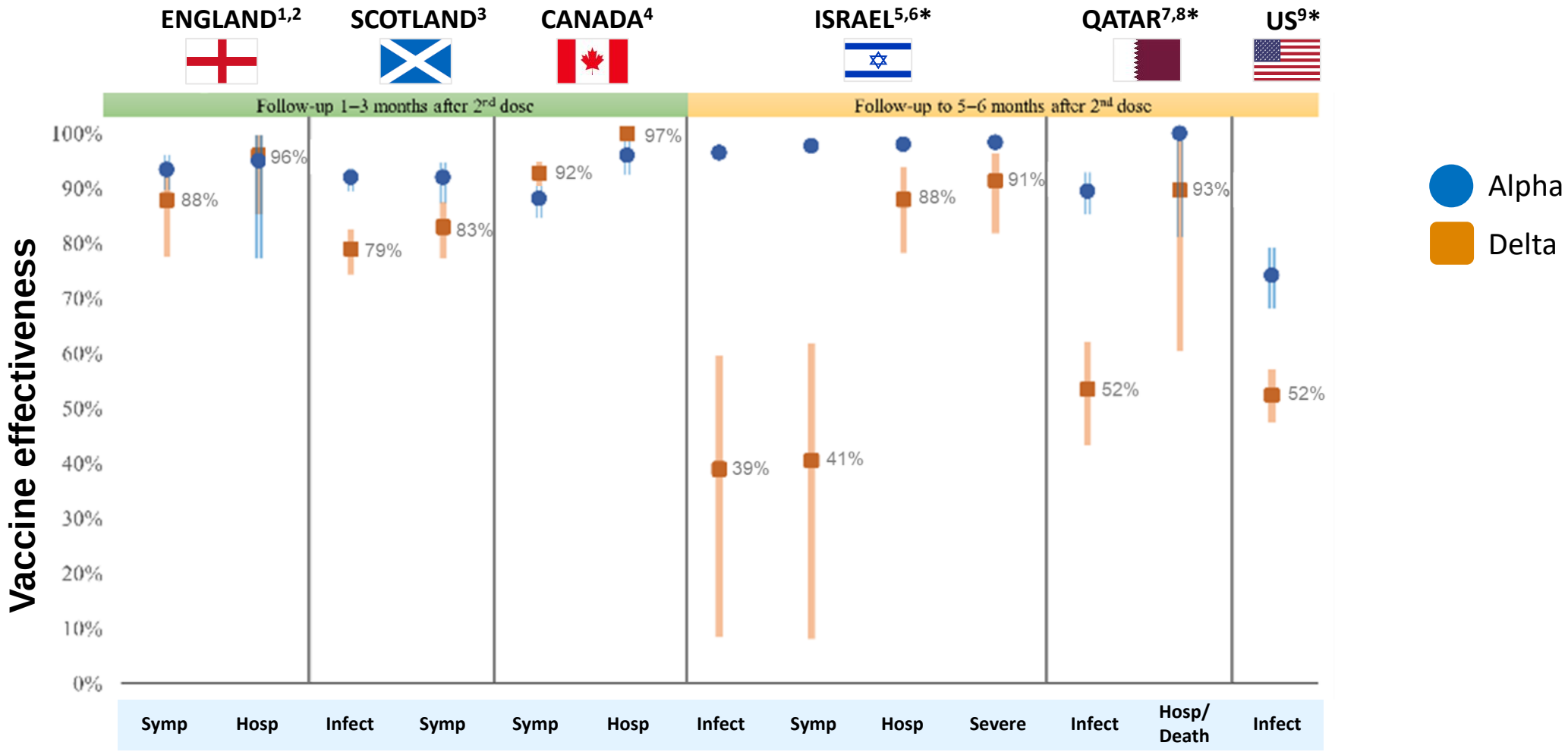
WT **Delta**

Reproduced from reference.
Liu J, et al. *Nature*. 2021;596:273-275.

To date, all variants tested have been neutralized by BNT162b2-immune sera.

Note: Because neutralization titers do not measure all potentially protective vaccine responses, they cannot substitute for studies of vaccine efficacy and real-world effectiveness of COVID-19 vaccines against variants.
$PRNT_{50}$=50% plaque reduction neutralization testing.
1. Liu Y, et al. *N Engl J Med*. 2021;384:1466-1468. **2.** Liu Y, et al. *N Engl J Med*. 2021;385:472-474. **3.** Liu J, et al. *Nature*. 2021;596:273-275.

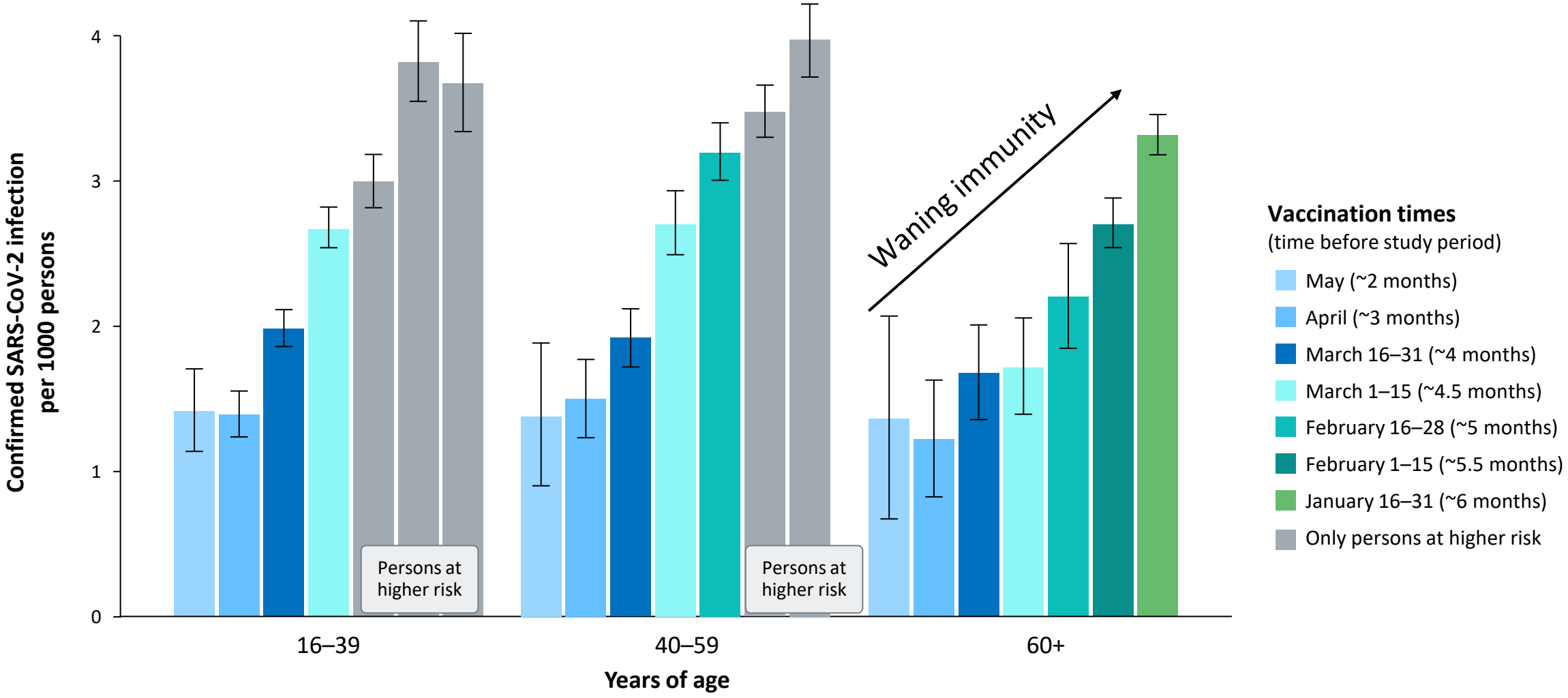
Waning of vaccine-induced immunity after 2 doses has been demonstrated in a variety of settings and against several SARS-CoV-2 outcomes (in Delta era)



*Based on analysis period rather than whole-genome sequencing.

1. Stowe J, et al. https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZlEig/view/479607266. Accessed 3 March 2022. **2.** Lopez Bernal J, et al. *N Engl J Med*. 2021;385:585-594. **3.** Sheikh A, et al. *Lancet*. 2021;397:2461-2462. **4.** Nasreen S, et al. *Nat Microbiol*. 2022;7:379-385. **5.** Haas EJ, et al. *Lancet*. 2021;397:1819-1829. **6.** Israel Ministry of Health. https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_two-dose-vaccination-data.pdf. Accessed 3 March 2022. **7.** Abu-Raddad LJ, et al. *N Engl J Med*. 2021;385:187-189. **8.** Tang P, et al. *Nat Med*. 2021;27:2136-2143. **9.** Nanduri S, et al. *MMWR Morb Mortal Wkly Rep*. 2021;70:1163-1166.

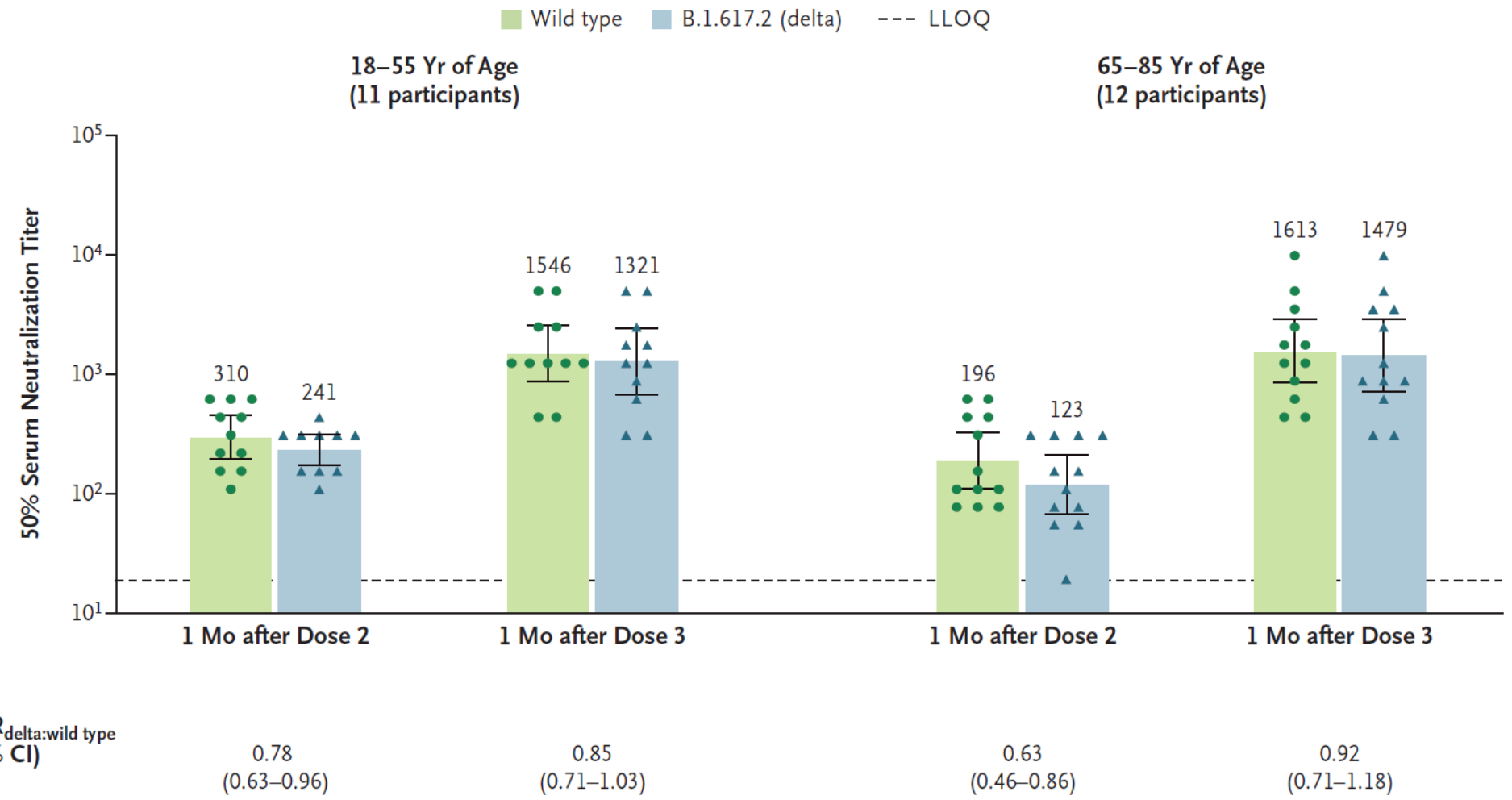
Waning immunity has also been observed across age groups as stratified by timing since second vaccine dose (in the Delta era)



Study period from 11–31 July 2021.
Goldberg Y, et al. *N Engl J Med*. 2021;385:e85. doi:10.1056/NEJMoa2114228.

NCT04368728: PHASE 1/2/3 IN HEALTHY INDIVIDUALS

Post–dose 3 BNT162b2 GMTs indicate a substantial boost to the Delta variant similar to wild type1*



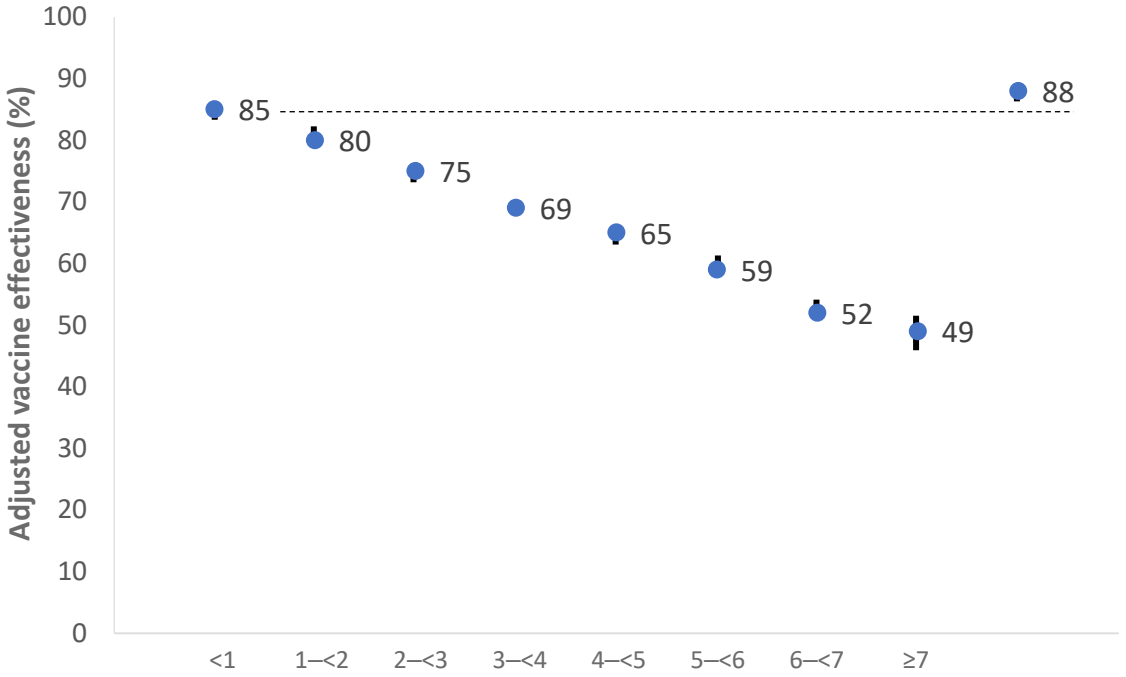
BNT162b2 booster (third dose) administered in C4591001: phase 1.[2]
*A third dose of BNT162b2 30 µg administered 7.9–8.8 months after the initial 2-dose series in adults 18–55 and 65–85 years of age from US sites in the phase 1 part of the ongoing pivotal study. GMR=geometric mean ratio; GMT=geometric mean titer; LLOQ=lower limit of quantitation.

1. Falsey AR, et al. *N Engl J Med*. 2021;385:1627-1629. **2**. Vaccines and Related Biological Products Advisory Committee Meeting. https://www.fda.gov/media/152161/download. Accessed 3 March 2022.

A booster (third) dose of BNT162b2 restored high levels of protection against SARS-CoV-2 infections and hospitalizations in individuals aged ≥18 years

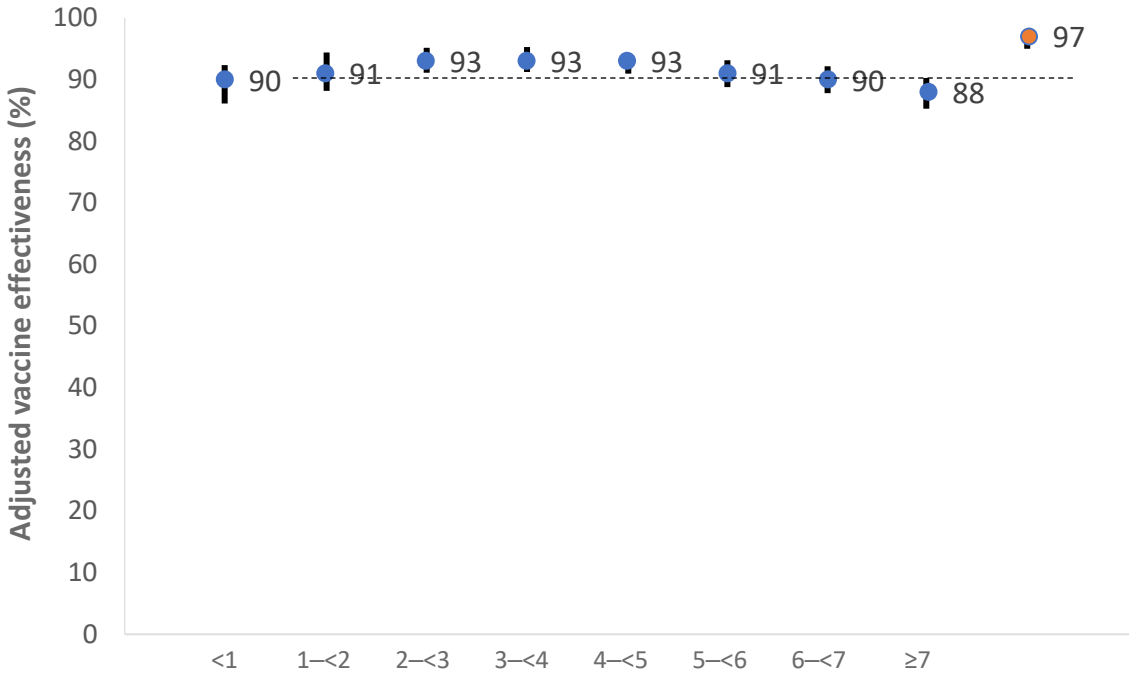
*(US, retrospective cohort, Delta predominant study)**

Vaccine effectiveness against SARS-CoV-2 infections, 14 December 2020 to 5 December 2021



Infections	403	542	1102	1935	2443	2440	2124	1946	183
Person-years	80,860	78,697	75,444	71,502	68,622	65,198	53,723	53,284	26,406

Vaccine effectiveness against SARS-CoV-2 hospital admissions, 14 December 2020 to 5 December 2021



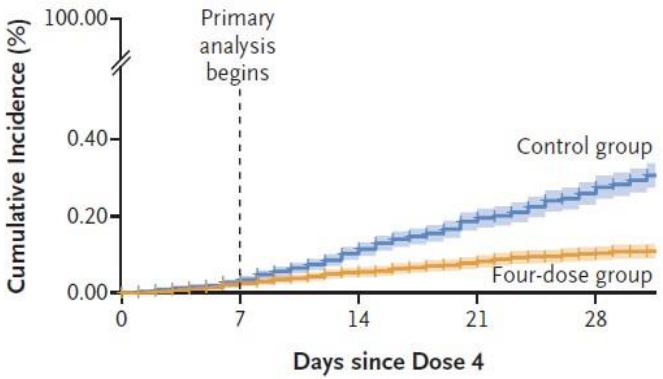
Admissions	44	38	41	61	97	131	92	80	14
Person-years	84,708	82,344	78,814	74,637	71,707	68,216	56,226	55,731	27,163

*Retrospective analysis of health records from a large integrated healthcare system in southern California among individuals aged ≥18 years (N=3,133,075).
Tartof SY, et al. *Lancet Reg Health Am.* 2022;00:100198. https://doi.org/10.1016/j.lana.2022.100198.

Lower rates of hospitalization, severe illness, and death were observed with a 4th dose of BNT162b2 during Omicron in older adults[1,2]

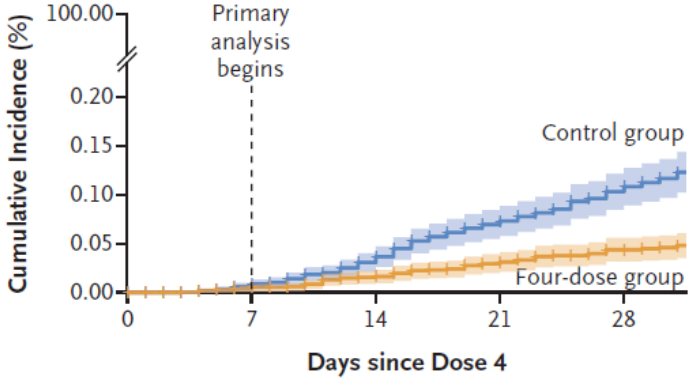
Real world data from Israel

COVID-19-Related Hospitalization[1]



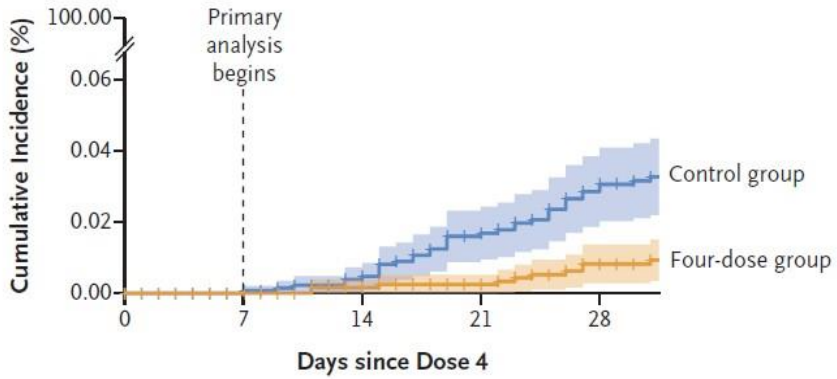
68% reduction in hospitalization after 4th dose compared to 3rd dose

Severe COVID-19[1,2]*



62% reduction in severe COVID-19 after 4th dose compared to 3rd dose

Death from COVID-19[1]



74% reduction in death after 4th dose compared to 3rd dose

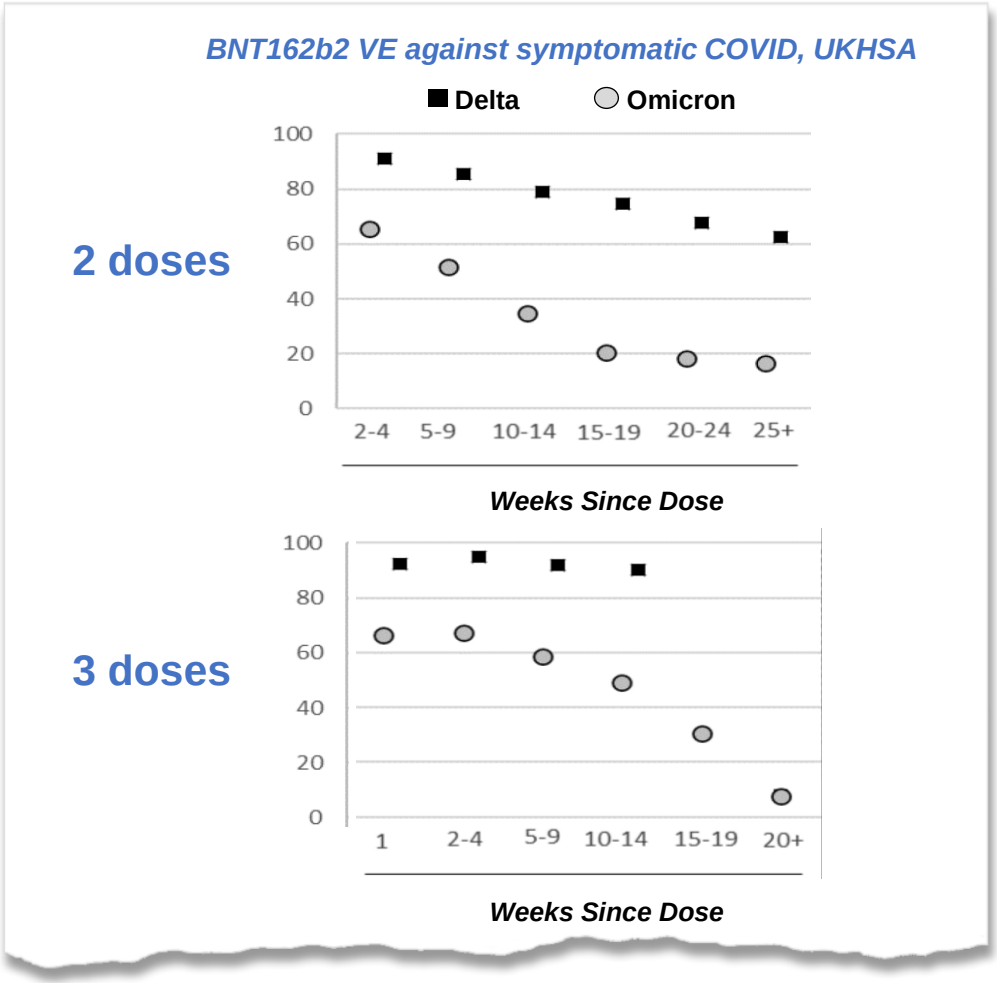
*Patients with COVID-19 are considered to have severe illness if they have SpO_2 <94% on room air at sea level; PaO_2/FiO_2 <300 mm Hg; a respiratory rate >30 breaths/min; or lung infiltrates >50% (as defined according to National Institutes of Health criteria).

†As of March 29, 2022.

1. Magen O, et al. *N Engl J Med.* 2022;386:1603-1614. **2.** Bar-On YM, et al. *N Engl J Med.* 2022;386:1712-1720.

Effectiveness and Duration of Protection against Omicron Lineages and Emerging Variants Unknown

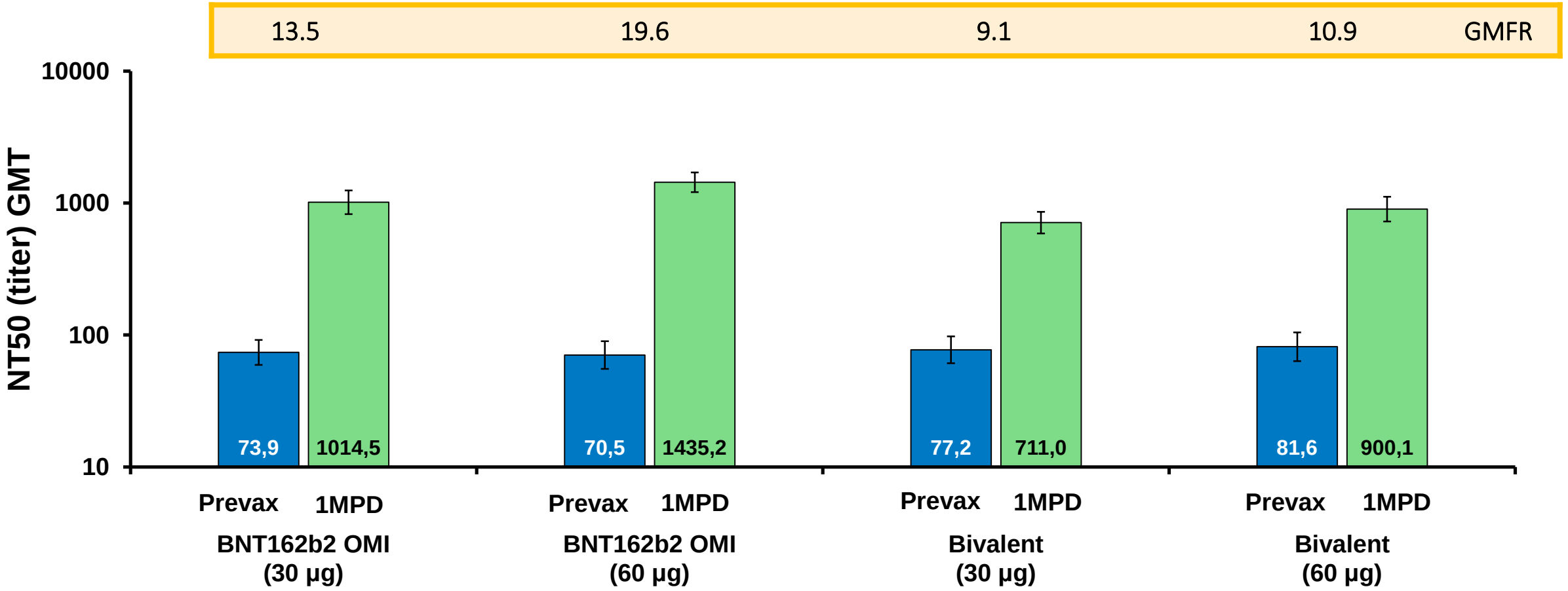
- Vaccine efficacy against COVID-19 is lower and wanes faster for Omicron (figure)[1]
  - Adapted vaccines can help slow virus circulation and emergence of VOCs
- Vaccines have been effective against severe Omicron illness,[1,2] however…
  - Waning against Omicron hospitalization observed >9m after second dose[3]
  - Duration of protection >6m post-boost is unknown



Swanson KA. Presented at: Vaccines and Related Biological Products Advisory Committee Meeting; 28 June 2022. https://www.fda.gov/media/159496/download. Accessed 28 June 2022.
1. UK Health Security Agency. COVID-19 vaccine surveillance report: week 24. 16 June 2022. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1083443/Vaccine-surveillance-report-week-24.pdf. Accessed June 20, 2022.
2. Tartof S, et al. *Lancet Respir Med*. 2022 May 6:S2213-2600(22)00170-9. doi: 10.1016/S2213-2600(22)00170-9. **3.** Tartof S, et al. *Lancet Respir Med*. 2022 Apr 22:S2213-2600(22)00101-1. doi: 10.1016/S2213-2600(22)00101-1.

Omicron BA.1 Neutralization Activity Substantially Increased with Omicron-Modified Vaccines as 4th Dose Booster

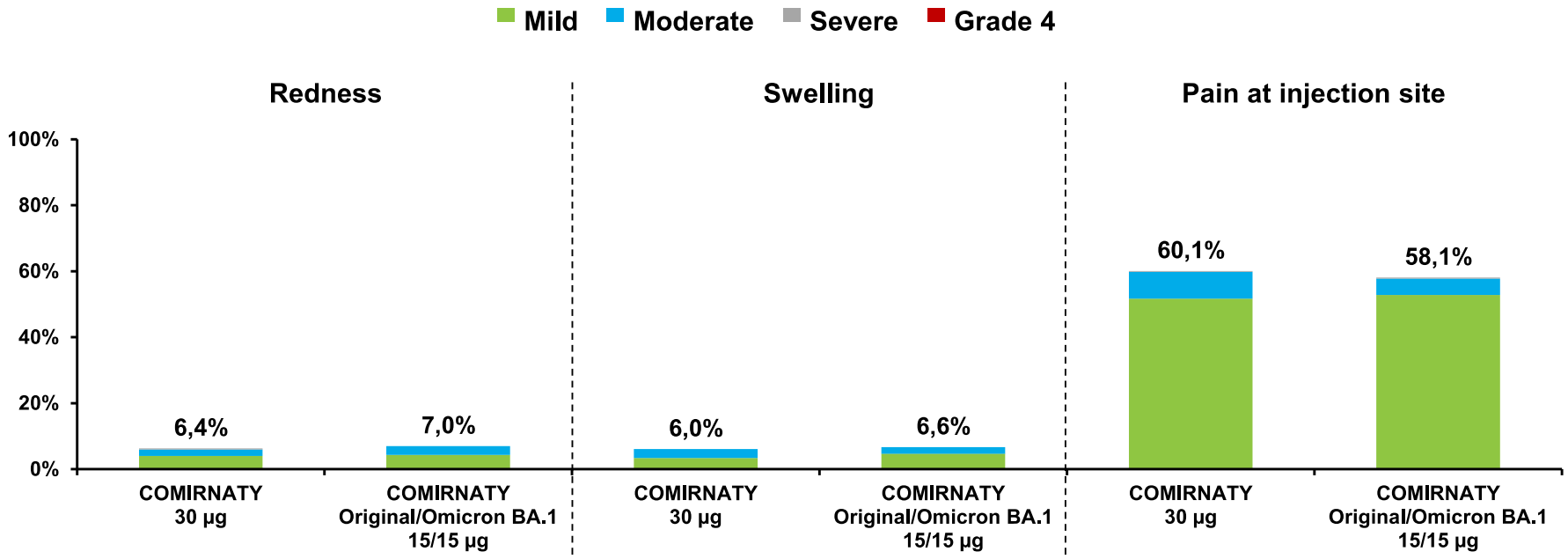
>55 Year Olds Without Evidence of Prior Infection
Median Time from Dose 3 to Study Vaccination: 6.3 Months (4.7, 12.9)



Omicron BA.1 NT50 measured using validated 384-well assay.
Swanson KA. Presented at: Vaccines and Related Biological Products Advisory Committee Meeting; 28 June 2022. https://www.fda.gov/media/159496/download. Accessed 28 June 2022.

Reactogenicity Profile of Variant Vaccines Overall Similar to Prototype BNT162b2 Vaccine

Substudy E: Received 3 prior doses of COMIRNATY 30 µg – Local reactions within 7 days after study vaccination – Participants aged >55 years[1]

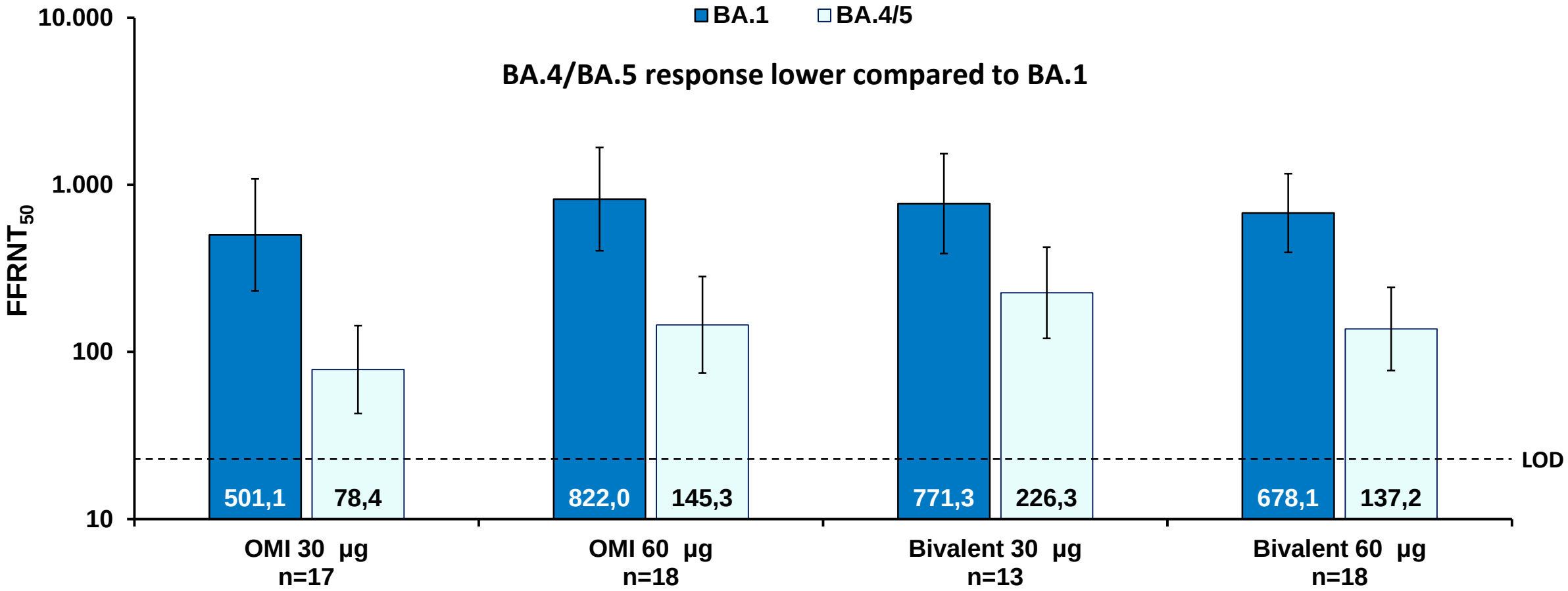


1. Pfizer, Inc. Data on file.

Omicron-containing Modified Variant Vaccines as 4th Dose Elicit Improved Omicron Neutralization Response

>55y Participants Sentinel Cohort, 30 and 60 µg Dose

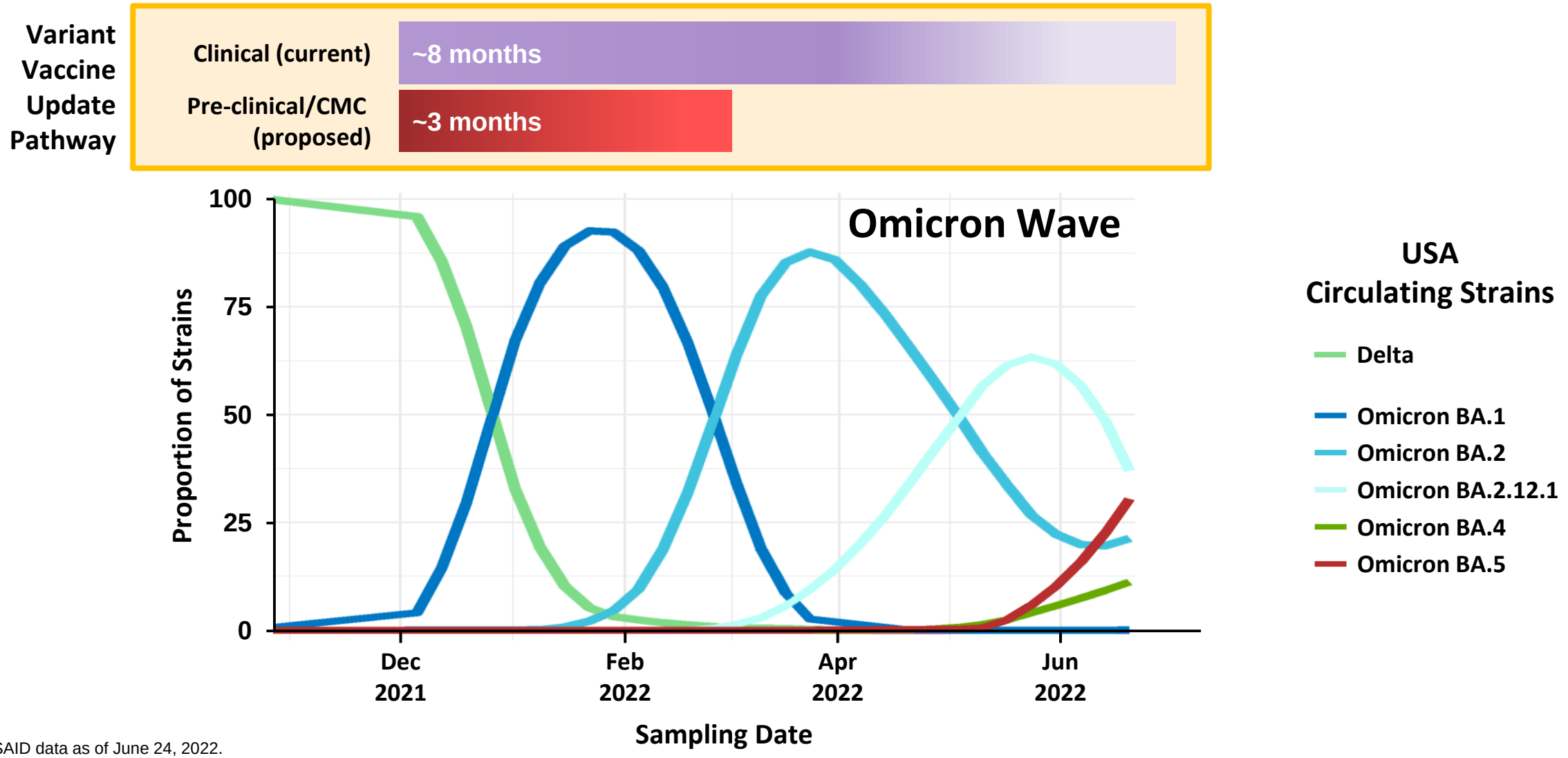
Participants WITHOUT Evidence of Infection up to 1 Month After First Study Vaccination



FFRNT, fluorescent foci reduction neutralization test; LOD, Limit of Detection.

Swanson KA. Presented at: Vaccines and Related Biological Products Advisory Committee Meeting; 28 June 2022. https://www.fda.gov/media/159496/download. Accessed 28 June 2022.

SARS-CoV-2 Epidemiology Changes Quickly – Vaccine Updates Need to Adapt with the Pace of the Virus

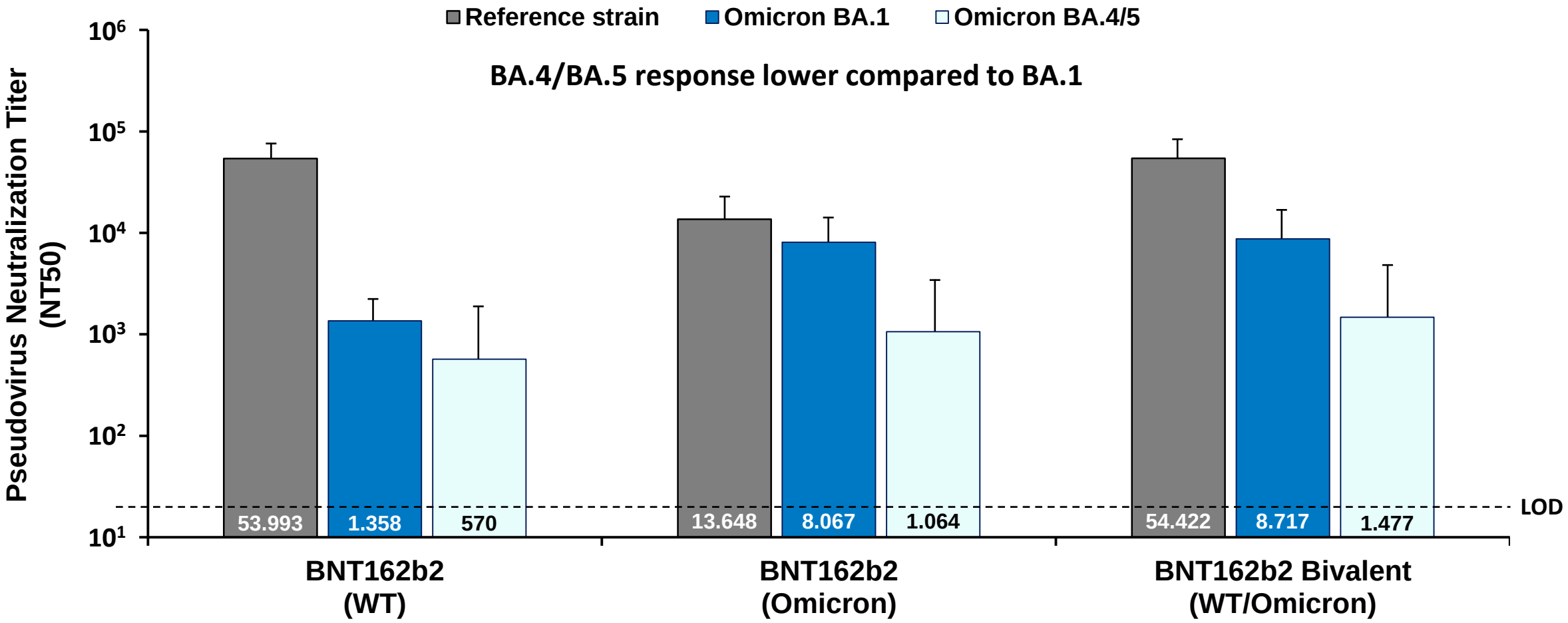


GISAID data as of June 24, 2022.

Swanson KA. Presented at: Vaccines and Related Biological Products Advisory Committee Meeting; 28 June 2022. https://www.fda.gov/media/159496/download. Accessed 28 June 2022.

Similar to Clinical Data, Omicron Monovalent and Bivalent Booster in Mice Increases Omicron Neutralization Response; Continued Trend for Reduced BA.4/BA.5 Neutralization Compared to BA.1

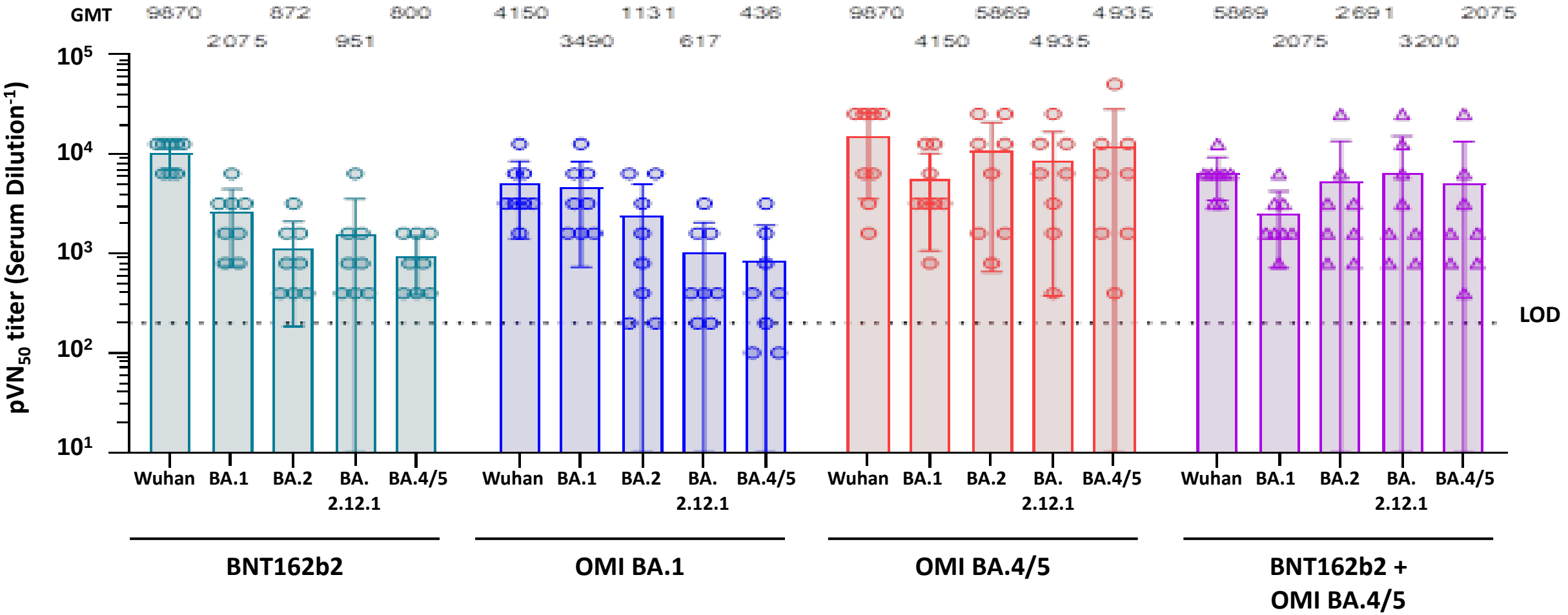
1M Post 3rd Dose Booster Following 2 Doses of BNT162b2



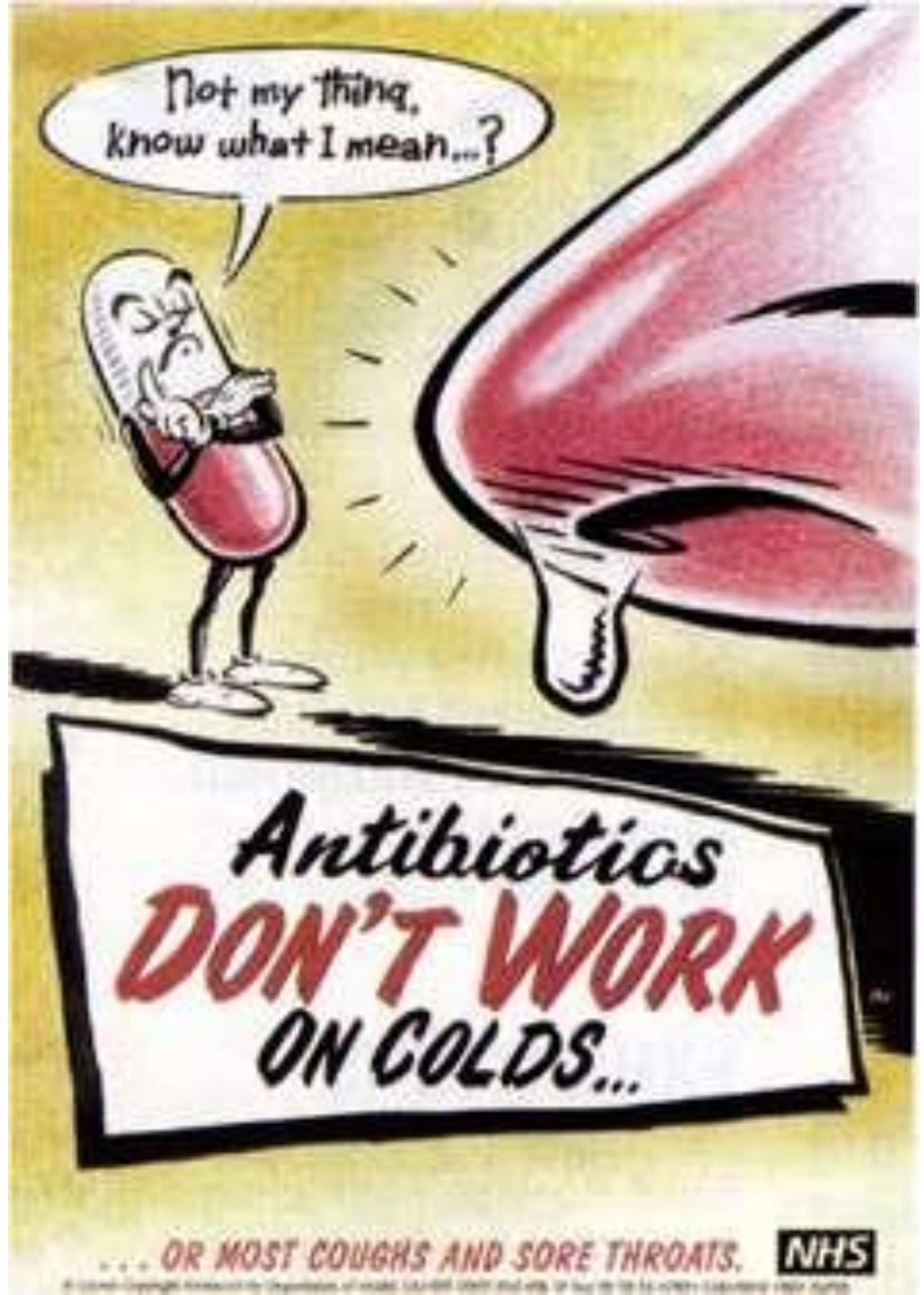
Pseudovirus neutralization assay; LOD, Limit of Detection; Reference strain, Wuhan-Hu-1.

Swanson KA. Presented at: Vaccines and Related Biological Products Advisory Committee Meeting; 28 June 2022. https://www.fda.gov/media/159496/download. Accessed 28 June 2022.

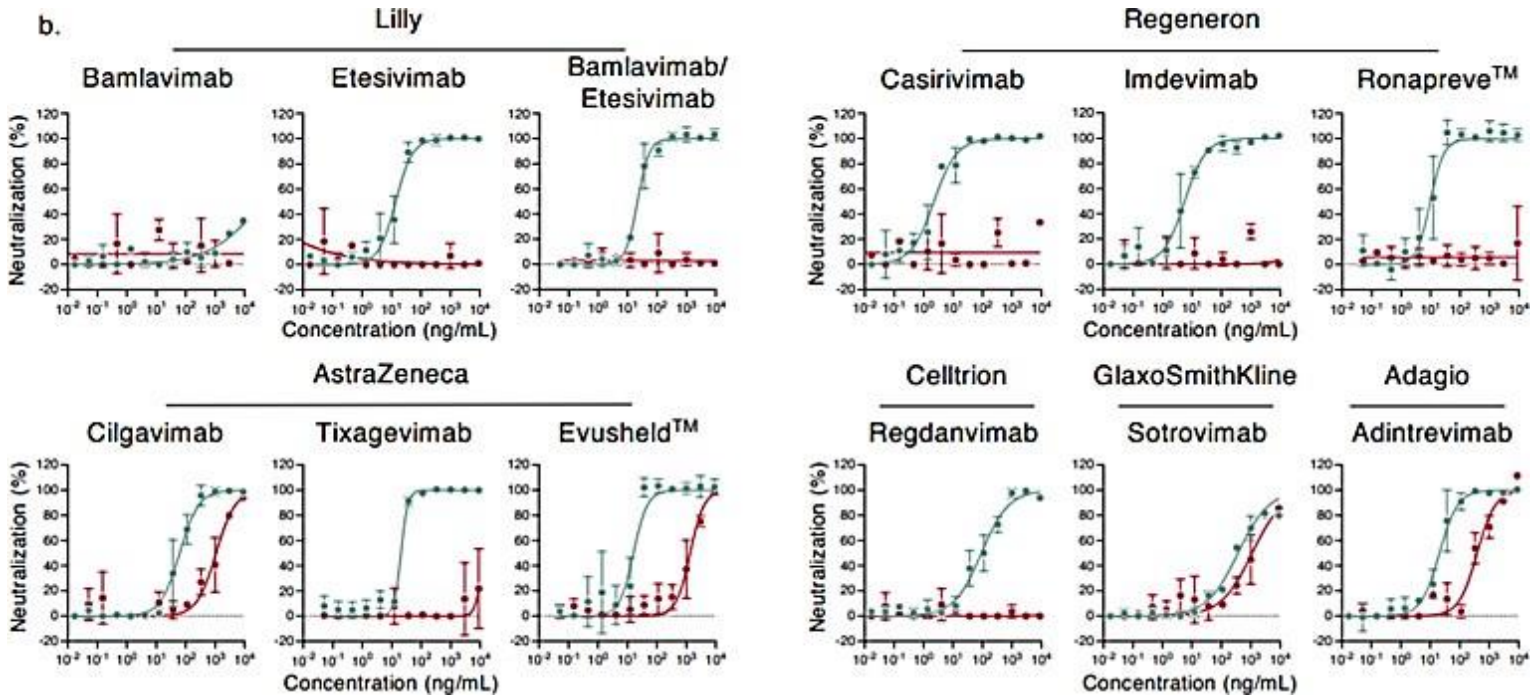
MICE: Neutralization Responses by Vaccine / Construct



N=8 mice Balb/c mice. Mice preimmunized with 2 doses of BNT162b2; boosters given at day 104.
Pseudovirus neutralization assay; LOD, Limit of Detection.
Swanson KA. Presented at: Vaccines and Related Biological Products Advisory Committee Meeting; 28 June 2022. https://www.youtube.com/watch?v=BFdzNUus_CE. Accessed 28 June 2022.


Not my thing, know what I mean...?
Antibiotics
DON'T WORK
ON COLDS...
. . . OR MOST COUGHS AND SORE THROATS.
NHS

Susceptibility to monoclonal antibodies appears to be lower for Omicron compared to Delta



Considerable escape of SARS-CoV-2 variant Omicron to antibody neutralization: https://www.biorxiv.org/content/10.1101/2021.12.14.472630v1.full.pdf

Activity of COVID 19 Therapeutics

	Pseudovirus Neutralization FOLD Reduction in Susceptibility		Prevention of Hospitalization/Death in trial data Assuming 100% Efficacy		
	Delta	Omicron	Treatment Arm	Placebo Arm	RR Reduction
Bam/Ete	No change	>2938 fold	4/511	15/258	87%×
Regen CoV	No change	>1013 fold	7/736	24/748	70%×
Sotrovimab	No change	No change	6/528	30/529	79%
Evusheld (pre exposure)	No change	132-183 fold Live virus 12-30	8/3441	17/1731	77%
Evusheld* (treatment, not EUA)			18/407	37/415	50%
Paxlovid	No change	No data	8/1039	66/1046	88%
Molnupiravir	No change	No data	49/709	77/699	30%
Remdesivir	No data	No data	2/279	15/283	87%

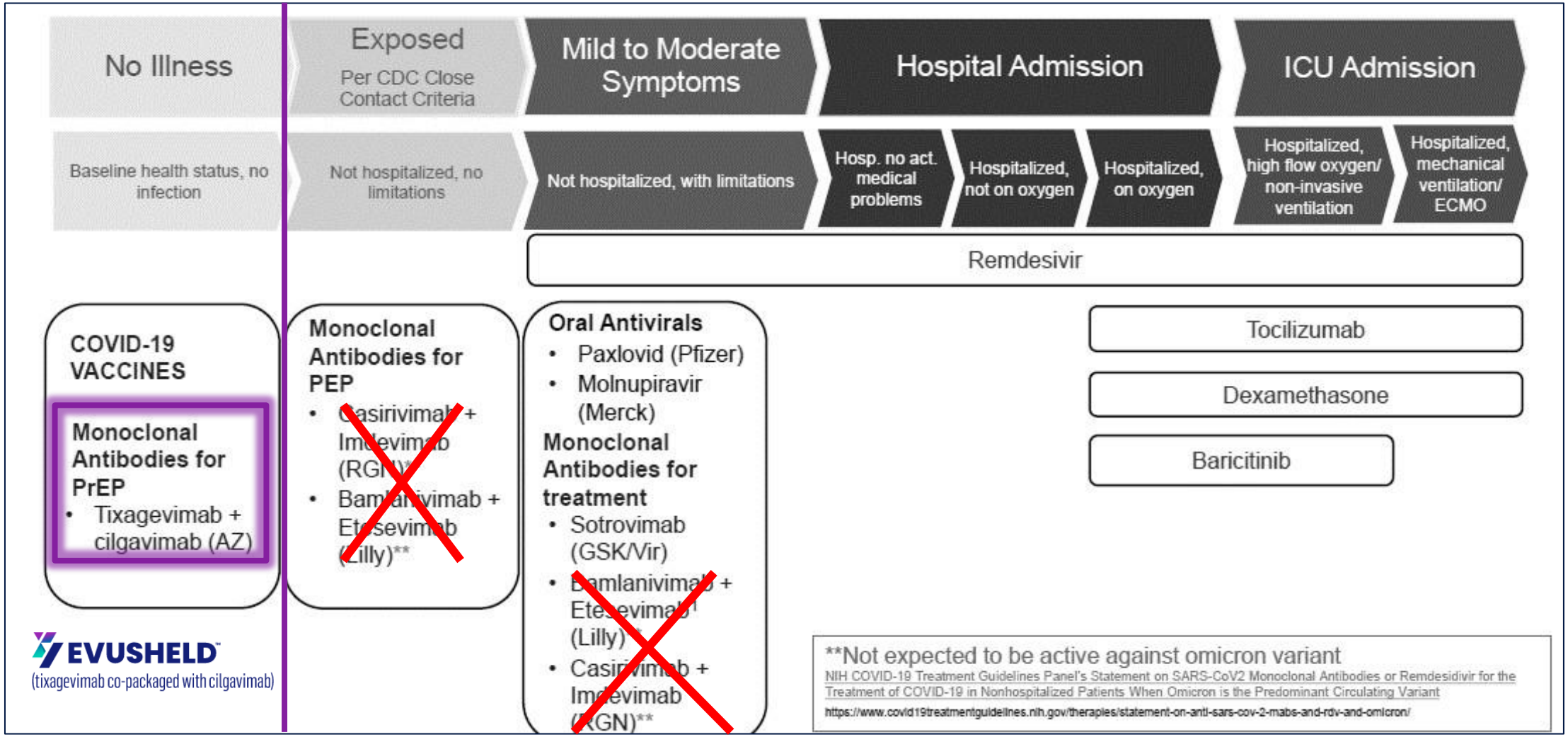
Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis

Emergency Authorized Use

- **Evusheld** (tixagevimab and cilgavimab) is indicated for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric individuals (12 years of age and older and weighing at least 40kg / 88lbs).
- It is **only** authorized for those individuals:
  - who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **AND**
  - who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **OR**
  - for whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and /or COVID-19 vaccine component(s)

Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab c - packaged with cilgavimab (https://www.fda.gov/media/154701/download)

Summary of COVID -19 Preventative Agents & Therapeutics



Source: https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/USG-COVID19-Tx-Playbook.pdf

Pensieri finali