SECTION: PIL

IN THE SUPREME COURT OF INDIA
(CIVIL ORIGINAL JURISDICTION)

WRIT PETITION NO. 607 OF 2021

IN THE MATTER OF:

DR. JACOB PULIYEL ....PETITIONERS

VERSUS

UNION OF INDIA & ORS. ....RESPODENTS

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Prashant Bhushan

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER
301, NEW LAWYERS CHAMBERS
SUPREME COURT OF INDIA
NEW DELHI 110 001
CODE NO.: 515

NEW DEHI:
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IN THE HON'BLE SUPREME COURT OF INDIA

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DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

PAPER BOOK

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COUNSEL FOR THE PETITIONER**: PRASHANT BHUSHAN**

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IN THE HON'BLE SUPREME COURT OF INDIA

(CIVIL ORGINAL WRIT JURISDICTION)

I.A. NO. _____ OF 2021

IN

WRIT PETITION (CIVIL) NO. 607 OF 2021

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DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

ADDITIONAL AFFIDAVIT ON BEHALF OF THE PETITIONER

I, Dr. Jacob Puliyel, S/o Late Mr. P M Mammen, r/o 6A, 7 Raj Narayan Marg, Delhi – 110054, do hereby solemnly affirm and state on oath as under:

1. That I am the Petitioner in the aforementioned writ petition and being familiar with the facts and circumstances of the case, I am competent and authorized to swear this Affidavit.

2. That the petitioner has filed the instant writ petition under Article 32 of the Constitution of India for the enforcement of fundamental rights under Article 14 and 21 of the Constitution of India, seeking a writ directing the respondents to make public the segregated data of the clinical trials for the vaccines that are being administered to the population in India under the Emergency Use Authorization granted by the Drugs Controller General of India (DCGI). Further the petitioner has prayed that no coercive mandates for use of these inadequately tested vaccines may be issued and that the courts reiterate that vaccine mandates are repugnant to the right of humans to autonomy and right to self-determine what may be injected into their

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bodies. It is submitted that coercing citizens directly or indirectly to get vaccinated is unconstitutional and violates the right to life of citizens. While the government has clearly stated in numerous RTIs and affidavits in court, that Covid vaccines are voluntary, there are many instances from across the country where now various authorities are mandating the vaccines for opening shops, retaining employment, entering educational and other premises, etc. which the petitioner has brought before the court in earlier applications (IA no. 71402/2021). There are been some important new developments which are very relevant to this petition which are being brought on record by way of this additional affidavit.

3. On the 8th of October 2021, the Government of NCT of Delhi issued an order mandating Covid vaccines for all employees, failing which they will not be allowed to attend their offices and places of work and will be marked as "on leave". This amounts to illegal coercion of citizens to get vaccinated when the government has repeatedly claimed that the Covid-19 vaccination programme is voluntary. Many professors/teachers at colleges at Delhi University and schools have written to advocate for the petitioner, aggrieved by this order that would deny them their right to livelihood especially in light of the various vaccine adverse events that have been reported worldwide and the lack of clinical trial data for the vaccines being administered under emergency authorisation in India.

4. Order dated 8.10.2021 issued by the Delhi Disaster Management Authority, Government of NCT of Delhi dated 8.10.2021, directed that all the employees/officers should get vaccinated (at least first dose) by 15.10.2021, failing which they will not be allowed to attend their respective offices/educational institutions with effect from 16.10.2021 till they have obtained the first dose of vaccination. Further the said period of leave shall be treated as "on leave" till the administration of the first dose of the vaccination. The relevant order states:

> "i)All Government employees working in Departments/Autonomous Bodies/ PSUs/Local Bodies/Educational Institutions under Government of NCT of Delhi, including Frontline Workers, Healthcare Workers as well as Teachers and other staff working in Schools/ Colleges should get vaccinated (at least

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first dose) by 15.10.2021 as per prevailing guidelines/ protocols prescribed for vaccination by MOH&FW, Govt of India.

ii) The aforesaid Government employees/ Frontline Workers/Healthcare Workers/ Teachers and other staff working in Schools / Colleges, who do not get vaccinated (at least first dose) by 15.10.2021 shall not be allowed to attend their respective offices/ Health care institutions/ educational institutions with effect from 16.10.2021 till they have obtained the first dose vaccination.

iii) The said period of absence from duty shall be treated as "On Leave" till the administration of the first dose of vaccination.

iv) The administration of the first dose of vaccination / complete vaccination shall be verified by the concerned HOD/office through Arogya Setu application/ certificate of vaccination produced by the concerned employee.

(A copy of the order dated 8.10.2021 issued by the Disaster Management Authority, Government of NCT of Delhi is annexed as **Annexure AA 1_____at Page** 19 **to** 20).

5. It is pertinent to note that in a petition filed before the High Court of Bombay at Goa seeking a direction that vaccination for teaching and non teaching staff in Goa be made voluntary and thereby seeking a stay on orders issued by schools on compulsory vaccination of staff, the counter affidavit dated 8th October 2021, filed by the Ministry of Health and Family Welfare through the Under Secretary Covid Vaccination Administration Cell states explicitly the stand of the Union of India with regard to vaccination. The affidavit states as follows:

"8…It is humbly submitted that vaccination for Covid-19 is a matter of social obligation and is of a larger public interest. As a responsible citizen looking to contribute in the nation and humanity's fight against the Pandemic of Covid-19 infection, it is natural that every person would get her/himself vaccination against Covid-19 so as to prevent the spread of Covid-19 infection in the community.

9. That, it is further humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and family welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that COVID-19 vaccination is completely voluntary for all citizens

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of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between citizens of India on the basis of their vaccination status.

10. That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against his/her wishes.

11. That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid vaccination on Co-WIN or visiting Covid Vaccination Centre for vaccination. If a person above the age of 18 years visits a Covid Vaccination Centre by her/his choice for vaccination and asks for the same, it implies that she/he is voluntary coming to the center to get the benefit of Covid Vaccination.

12. Therefore, it is humbly submitted that in order to prevent the transmission and spread of Covid-19 pandemic, it is expected that all responsible citizens especially the teachers who are also the role models and influencers for the society get themselves vaccinated as soon as possible against Covid-19 and meticulously follow Covid Appropriate Behaviour."

(A copy of the counter affidavit dated 8th October 2021, filed by the Ministry of Health and Family Welfare through the Under Secretary Covid Vaccination Administration Cell is annexed as **Annexure AA 2** at Page 21 to 26).

6. In an additional affidavit (IA no. 110625/2021) the petitioner had also brought on record some important aspects for consideration of this Hon'ble Court, mainly regarding the scientific evidence that has emerged regarding natural immunity which is long lasting and robust as compared to vaccine immunity, that vaccines do not prevent infection or transmission for Covid-19 and are not effective in preventing against infection from the new variants, that the clinical trials in relation to the vaccines have not been completed and the vaccines are only authorized for emergency use and further that serious adverse events are being reported in India and globally from the Covid 19 vaccinations. In light of this, any mandates for these vaccines are not only against scientific caution, cannot be in issued in public interest and are also

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against an individual's right to free and complete informed consent and the right to self-determination. The petitioner submits through this application some new material related to these aspects.

Vaccination rates and Covid cases are not correlated

7. In a recently published study (30th September 2021) in the European Journal of Epidemiology, the authors looked at statistical correlation between vaccination level in a population and the weekly average of Covid cases in that population. They found no significant correlation; in fact the correlation was a weak positive, i.e. higher vaccination level resulted in a slightly higher level of Covid cases. The study looked at data from 68 countries as well as nearly 3000 counties in the USA.

> "**Findings**
>
> At the country-level, there appears to be no discernible relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 1). In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days. The lack of a meaningful association between percentage population fully vaccinated and new COVID-19 cases is further exemplified, for instance, by comparison of Iceland and Portugal. Both countries have over 75% of their population fully vaccinated and have more COVID-19 cases per 1 million people than countries such as Vietnam and South Africa that have around 10% of their population fully vaccinated.

(A copy of the Paper titled "Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States", published 30 Sep 2021 is annexed as **Annexure AA3** at Page 27 to 30)

8. The United Kingdom releases weekly reports on vaccine efficacy. The report released in week 40 (04 Oct 2021) shows that the vaccine shows *negative efficacy* against infection among all ages above 30 years. More importantly, the efficacy against

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infection has been steadily declining with each passing week for all age groups above 18. In the week 41 report (11 Oct 2021), the efficacy for the 40-49 age group is as low as -109% (minus 109%). AstraZeneca vaccine widely used in the UK is the same as CoviShield used widely in India.

(A copy of the relevant page showing table 2. Covid 19 cases by vaccination status between week 36 and week 39 2021 from the "COVID-19 vaccine surveillance report Week 40" dated 04 Oct 2021, is annexed as **Annexure AA4** at Page 31 to 32)

9. A recent study published in the MedRxiv, found no significant difference in viral load between vaccinated and unvaccinated, asymptomatic and symptomatic groups when Infected with SARS-CoV-2 Delta Variant. The study states:

> "In our study, mean viral loads as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge, regardless of vaccine status, age, or gender. This contrasts with a large ongoing UK community cohort in which the median Ct-value was higher for vaccinated individuals (27.6) than for unvaccinated individuals (23.1) [5]. Also, a study from San Francisco reported that 10 fully vaccinated asymptomatic individuals had significantly lower viral loads than 28 symptomatic, vaccinated individuals [6]. Our study is consistent with other recent reports showing similar viral loads among vaccinated and unvaccinated individuals in settings with transmission of the Delta variant. In a Wisconsin study, Ct-values were similar and culture positivity was not different in a subset of analyses between 11 vaccinated and 24 unvaccinated cases [4]. In both Massachusetts and Singapore, individuals with vaccination breakthroughs caused by the Delta variant had similar Ct-values as unvaccinated individuals [3, 10]. Our findings are supported by consistency across large sample sets using different assays from two distinct locations.
>
> A substantial proportion of asymptomatic, fully vaccinated individuals in our study had low Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of high levels of virus, culture positivity, and increased transmission [11], our detection of low Ct-values in asymptomatic, fully

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vaccinated individuals is consistent with the potential for transmission from breakthrough infections prior to any emergence of symptoms."

A copy of the study titled "No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant" posted on 5th October 2021 is annexed as **Annexure AA5** at Page 33 to 41)

10. Another recent study compared the amount of infectious virus shed by vaccinated versus unvaccinated individuals. Excerpt from the study abstract and main text states:

"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 via self-reporting and state immunization records (Supplemental Figure 1).

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)."

(A copy of the study "Shedding of Infectious SARS-CoV-2 Despite Vaccination", preprint posted 24 Aug 2021 is annexed as **Annexure AA6** at page 42 to 46).

11. There have been several instances of covid outbreaks in highly vaccinated college populations in the USA:

a) Harvard University had an outbreak of Covid cases in early September despite having over 90% of its staff and students fully vaccinated: https://www.thecrimson.com/article/2021/9/3/harvard-hikes-testing-requirements/

b) In the same week, Cornell University had nearly 400 Covid cases although nearly all students were fully vaccinated on campus: https://cornellsun.com/2021/09/06/as-cornell-reports-record-cases-students-miss-first-classes-bear-burdens-of-covid-policies/

c) Brown University had a similar outbreak in mid September in spite of having nearly 100% of its students and staff fully vaccinated: https://boston.cbslocal.com/2021/09/15/brown-university-covid-dining-stduents-gathering/

(A copy of the news articles related to these university outbreaks is annexed as Annexure **AA7** at Page 47 to 55)

12. Even at the level of a country, vaccination does not reduce Covid cases. Israel had a huge surge in mid September despite leading most countries in vaccination levels.

"Health Ministry Director-General Nachman Ash said Tuesday that the current wave of coronavirus infections is surpassing anything seen in previous outbreaks and that he is disappointed that a recent downward trend appeared to be reversing…Pointing out that there is an average of 8,000 new infections each day, with occasional peaks over 10,000, he said, "That is a record that did not exist in the previous waves," including the massive third wave at the end of last year."

(A copy of the article in The Times of Israel titled "Health Ministry chief says coronavirus spread reaching record heights" dated 14 Sep 2021 is annexed as **Annexure AA8** At Page 56 to 58)

13. In an interview with journalist Girijesh Vashistha on Knocking News, Dr. Sanjay Rai, Professor at Department of Community Medicine at AIIMS, Delhi states that the best protection and possibly life time immunity only comes from Natural immunity/natural infection i.e. those who have recovered from COVID-19. He further stated that death

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due to Covid-19, among those who acquired Natural Immunity is nearly zero and possibility of re-infection is rare. Further that vaccines could cause harm or result in adverse effects if administered to those who have already acquired natural immunity and are also non-susceptible.

(A copy of excerpt of comments of Dr. Sanjay K Rai, Professor at Department of Community Medicine at AIIMS, Delhi in Conversation with Girijesh Vashistha of Knocking News is annexed as **Annexure AA 9** at Page 59 to _____) https://www.youtube.com/watch?v=-btDk0eSi5U

Tracking Side-Effects and Correcting Course

14. Various countries have been meticulously tracking vaccine side-effects and correcting course during their vaccination campaign, after noticing adverse side-effects. An article published in the American Thinker states:

> "This vast Phase 3 clinical trial of mRNA vaccines in which Americans are participating mostly out of fear is not going well. It is abundantly clear for anyone advocating for public health that the vaccination program should be stopped. Iceland has just stopped giving the Moderna vaccine to anyone which is a good step in the right direction. Sweden, Denmark, and Finland have banned the Moderna vaccine for anyone under the age of 30.
>
> VAERS, our vaccine adverse effect reporting system, showed at the beginning of this week 16,000 deaths, 23,000 disabilities, 10,000 MI/myocarditis, 87,000 urgent care visits, 75,000 hospital stays, and 775,000 total adverse events. The VAERS system is widely known to under-report events, with an estimated 90 to 99% of events going unreported there.
>
> Eudravigilance, the European reporting system now associates 26,000 deaths in close proximity to administration of the vaccine. Whistleblower data from the CMS system (Medicare charts) showed close to 50,000 deaths in the Medicare group shortly after the vaccine.
>
> An AI-powered tracking program called Project Salus also follows the Medicare population and shows vaccinated Medicare recipients are having worse outcomes week by week of the type consistent with Antibody

> Dependent Enhancement. This occurs when the vaccine antibodies actually accelerate the infection leading to worsening COVID-19 infection outcomes. Antibody Dependent Enhancement has occurred previously with trials of other coronavirus vaccines in animals. The CDC and the FDA are suppressing this data and no one who receives the vaccine has true informed consent."

(A copy of the article published in the American Thinker titled, "The Unvaccinated Are Looking Smarter Every Week" dated 16th October 2021 is annexed as **Annexure AA 10** at Page 60 to 63)

15. AstraZeneca (Covishield) related risks:

a) The UK's yellow card system has reported adverse events at the rate of about 1 in 106 doses for the AstraZeneca vaccine (Covishield). https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#yellow-card-reports

b) In March 2021 about 16 European countries banned the use of Astra Zeneca's Covid Vaccine over concerns of blood clotting among receipts of the vaccine. In Apr 2021, various European countries such as Spain, Belgium, Italy, restricted the AstraZeneca vaccine to older people:

> "Italy, Spain and Belgium have joined other European countries in limiting the use of the Oxford/AstraZeneca vaccine to older age groups as the EU struggles to agree common guidelines to counter expected public hesitancy.
>
> The European Medicines Agency (EMA) on Wednesday found a possible link between the vaccine and very rare cases of blood clots, although it said its benefits far outweighed the risks and did not announce any restrictions.
>
> In Britain, the government's joint committee on vaccines and immunisation said healthy people aged 18 to 24 who were not at high risk of Covid should have the option of a different jab if one was available in their area."

(A copy of the article in The Guardian titled "Spain, Belgium and Italy restrict AstraZeneca Covid vaccine to older people" dated 8th April 2021 is annexed as Annexure **AA11** At page 64 to 65)

c) As recently as last month, the NIH (USA) ordered a study on the Covid-19 vaccines impact menstrual cycle.

(A copy of an article in the New York Post titled "NIH orders $1.67M study on how COVID-19 vaccine impacts menstrual cycle" dated 7th September 2021 is annexed sa **Annexure AA12** at Page 66 to 67)

16. Moderna related risks:

d) Toward the end of Sep 2021, based on an understanding of myocarditis (heart inflammation) risk among young people, Ontario (Canada) restricted the Moderna vaccine to only those above age 24.

(A copy of the article in the Toronto Sun tiled "Ontario now recommending against Moderna vaccine for men 18-24 years old" dated 29th September 2021, is annexed as **Annexure AA13** at Page 68 to _____)

e) In the first week of October 2021, various European countries followed suit with Sweden and Denmark pausing Moderna COVID-19 vaccine for younger age groups after reports of rare cardiovascular side effects.

(A copy of an article in Reuters titled "Sweden, Denmark pause Moderna Covid-19 vaccine for younger age groups" dated 6th October 2021 is annexed as **Annexure AA14** at Page 69 to 71)

f) Following this Finland limited the use of the Moderna vaccine.

(A copy of the article titled "Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine" dated 07 Oct 2021 is annexed as **Annexure AA 15** At Page 72 to 73)

g) The Chief Epidemiologist in Iceland decided to stop the use of Moderna vaccine against Covid 19 while further information is obtained on safety of the vaccine during booster vaccinations.

(A copy of the report titled "Stop the use of the Moderna vaccine in Iceland in the light of new data" dated 08 Oct 2021 is Annexed as **Annexure AA16** at Page 74 to _____)

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17. Johnson & Johnson vaccine

h) Slovenia has temporarily suspended use of the Johnson & Johnson (Janssen) Covid-19 vaccine after a 20-year-old woman died of a brain hemorrhage and blood clots just days after getting the jab.

> "The health ministry has called on the Public Health Institute to temporarily suspend vaccinations with the Janssen vaccine until all details related to this case are cleared up," Health Minister Janez Poklukar told a news conference in Ljubljana."

(A copy of the article titled "Slovenia suspends Johnson & Johnson vaccine after death" dated 29 Sep 2021 is annexed as **Annexure AA17** at Page 75 to 77)

18. In sharp contrast, the Indian government has not shown any seriousness in tracking adverse events and taking corrective action. Senior Virologist Dr Jacob John told the Times of India that the overall methodology of reporting Adverse Events Following Immunisation after the rollout of Covid-19 vaccines in India lacked professionalism and seriousness to know the reality.

> "There is a state mechanism for AEFI (Adverse Events Following Immunisation) monitoring under the Universal Immunisation Programme (UIP) and it seems to be the 'active' part in AEFI monitoring. By its own admission the Central AEFI Committee announced that the state AEFI monitoring system was not functioning satisfactorily," Dr. John told TOI, against the backdrop of alleged under-reporting of adverse events by many states.
>
> The AEFI committee relies on adverse event reports received on the CoWIN web platform. Dr. John said this was a passive system as it might represent a very small but unknown proportion of all serious AEFI. The AEFI Committee released its last report on July 18. Earlier, it had come out with reports on April 2, May 17 and July 12. Dr. John said the committee apparently made its own assessments as to what was serious among the reported cases, what was vaccine related and what was the cause of death.

> ...Dr. John said of the 498 serious AEFI in a review, a total of 26 cases of blood clotting were reported, none associated with death. "Blood clotting and no death suggests poor follow-up or outright hiding of death. All these were reported after administering one particular vaccine. But that was not followed up with detailed instructions to all vaccination centres on how to diagnose clotting very early so that it can be properly treated to save lives," said Dr. John, the former head of clinical virology department of Christian Medical College."

(A copy of the report in The Times of India titled "AEFI reporting lacks seriousness: Sr virologist" dated 24 Aug 2021 is annexed as **Annexure AA18** At Page 78 to 79)

Recent order and reports from around the world against vaccine mandates

19. The governor of Texas has barred all Covid-19 vaccine mandates in state and termed the vaccine mandates as bullying by the administration. The order states:

> "WHEREAS, I issued Executive Orders GA-35, GA-38, and GA-39 to prohibit governmental entities and certain others from imposing COVID- 19 vaccine mandates or requiring vaccine passports; and
>
> WHEREAS, in yet another instance of federal overreach, the Biden Administration is now bullying many private entities into imposing COVID-19 vaccine mandates, causing workforce disruptions that threaten Texas' s continued recovery from the COVID- 19 disaster; and
>
> WHEREAS, countless Texans fear losing their livelihoods because they object to receiving a COVID- 1 9 vaccination for reasons of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19; and
>
> ...
>
> WHEREAS, the legislature has taken care to provide exemptions that allow people to opt out of being forced to take a vaccine for reasons of conscience or medical reasons; and
>
> ...

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NOW, THEREFORE, I, Greg Abbott, Governor of Texas, by virtue of the power and authority vested in me by the Constitution and laws of the State of Texas, do hereby order the following on a statewide basis effective immediately:

1. No entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19. I hereby suspend all relevant statutes to the extent necessary to enforce this prohibition.

2. The maximum fine allowed under Section 4 1 8. 173 of the Texas Government Code and the State' s emergency management plan shall apply to any "failure to comply with" this executive order. Confinement in jail is not an available penalty for violating this executive order.

(A copy of the executive order of the Governor of Texas, USA dated 11th October 2021 is annexed as **Annexure AA19** At Page 80 to 82)

20. The Slovenia Constitutional Court has blocked the government plan to make coronavirus vaccines mandatory for public employees, hours before it was due to come into force.

"In its decision the court said that "despite the very serious epidemic situation", it considered that "implementing the potentially unconstitutional (measure) ... would have worse consequences than delaying implementation".

(A copy of the article titled "Vaccine mandate for public employees in Slovenia blocked", dated 30 Sep 2021 is annexed as **Annexure AA20** at Page 83 to 87).

21. In New York, a federal appeals court blocked New York City's coronavirus vaccine mandate days before the mandate goes into effect.

"The 2nd Circuit Court of Appeals granted an expedited injunction on Friday blocking the city from mandating that all public school employees submit proof of their first coronavirus vaccine dose by Monday."

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(A copy of the article in The Hill titled "Federal appeals court blocks NYC teacher vaccine mandate" dated 25 Sep 2021 is annexed as **Annexure AA 21** at Page 88 to _____).

22. In Gainesville, Florida a lower court has issued an injuction against vaccine mandates for employees.

"A Circuit Court judge has issued a temporary injunction preventing the City of Gainesville from requiring a COVID-19 vaccine for employees or terminating employees that do not get the vaccine."

(A copy of the news report titled "BREAKING: Judge grants temporary injunction preventing vaccine mandates for city employees" dated 23 Sep 2021 is annexed as **Annexure AA 22** at Page 89 to _____).

23. The UK Parliamentary Committee report dated 09 Sep 2021 held that the Covid passport policy lacks scientific evidence base and must be done away with. Based on this report the government decided not to issue any vaccine mandates. The report stated:

> "the Committee's report demanded that the Government provide scientific evidence backing-up its claims that requiring Covid passports was necessary to reopening the economy and society if it pressed ahead with plans to implement them. Doing so through the publication of the public health case, cost-benefit analyses, and modelling of the potential impacts would be essential to public understanding and acceptance of the system, the report said. The Government failed to give any such evidence in its response.
>
> Added to this, the latest analysis by Public Health England (PHE) found that although being fully vaccinated protects against infection and severe symptoms, it unlikely to do much to stop the spread of the virus if people become infected. Jabbed and unjabbed individuals carry similar amounts of the virus. Researchers call this having a similar viral load.
>
> Concerns over viral load of the Delta variant appeared in Sage meeting minutes from 22 July. Sage, the Government's scientific advisory panel, warned that there is 'limited vaccine effect against onward transmission' of the variant. Given that this meeting was held before the Government responded to the Committee's report, the Committee has severe concerns

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about the way in which this policy has been developed and kept under consideration.

(A copy of the article on the report titled "Covid passport policy lacks scientific evidence base" dated 9 Sep 2021 is annexed as **Annexure AA 23** at Page 90 to 91).

24. A court in Galicia, Spain, over turned regional governments requirement for Covid passports in bars and restaurants.

(A copy of the article titled "Galicia courts overturn regional government requirement for Covid passports in bars and restaurants" dated 12 Aug 2021 is annexed as **Annexure AA 24** at Page 92 to _____)

25. In Andalusia, Spain,

"Andalusian justice rejects the requirement of the covid certificate to enter the nightclubs. The magistrates consider that the measure requested by the Board violates the right to privacy and the principle of non-discrimination and is neither suitable nor necessary."

(A copy of the article, "Andalusian justice rejects the requirement of the Covid certificate to enter the nightclubs" dated 12 Aug 2021, is annexed as **Annexure AA 25** At Page 93 to 94)

26. The Scandinavian countries of Sweden, Finland, Norway, Denmark have all done away with all Covid restrictions; Denmark had briefly considered vaccine passports but recently decided to do away with such a system.

(A copy of the article in News.com titled "Denmark ditches vaccine passports, its last remaining Covid restriction" dated 10 Sep 2021 is annexed as **Annexure AA 26** at Page 95 to 97).

27. It is therefore important for this Hon'ble Court to step in and exercise of its powers of judicial review of executive policy which is manifestly arbitrary and irrational and to set aside any vaccine mandates that have been brought in by the government or private bodies and thereby safeguard citizen's fundamental rights. This Hon'ble Court

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has held in **Distribution of Essential Supplies and Services During Pandemic, In re, 2021 SCC OnLine SC 411** vide order dated 31st May 2021, the SC held that:

> *"15.* It is trite to state that separation of powers is a part of the basic structure of the Constitution. Policy-making continues to be in the sole domain of the executive. The judiciary does not possess the authority or competence to assume the role of the executive, which is democratically accountable for its actions and has access to the resources which are instrumental to policy formulation. However, this separation of powers does not result in courts lacking jurisdiction in conducting a judicial review of these policies. Our Constitution does not envisage courts to be silent spectators when constitutional rights of citizens are infringed by executive policies. Judicial review and soliciting constitutional justification for policies formulated by the executive is an essential function, which the courts are entrusted to perform.
>
> ...
>
> 17. The Supreme Court of United States, speaking in the wake of the present COVID-19 pandemic in various instances, has overruled policies by observing, inter alia, that "Members of this Court are not public health experts, and we should respect the judgment of those with special expertise and responsibility in this area. But even in a pandemic, the Constitution cannot be put away and forgotten" 20 and "a public health emergency does not give Governors and other public officials carte blanche to disregard the Constitution for as long as the medical problem persists. As more medical and scientific evidence becomes available, and as States have time to craft policies in light of that evidence, courts should expect policies that more carefully account for constitutional rights"
>
> 18. Similarly, courts across the globe have responded to constitutional challenges to executive policies that have directly or indirectly violated rights and liberties of citizens. Courts have often reiterated the expertise of the executive in managing a public health crisis, but have also warned against arbitrary and irrational policies being excused in the garb of the "wide latitude" to the executive that is necessitated to battle a pandemic. This Court in Gujarat Mazdoor Sabha vs State of Gujarat , albeit while speaking in the context of labour rights, had noted that policies to counteract a pandemic must continue to be evaluated from a threshold of proportionality to determine if

they, inter alia, have a rational connection with the object that is sought to be achieved and are necessary to achieve them.

19. In grappling with the second wave of the pandemic, this Court does not intend to second-guess the wisdom of the executive when it chooses between two competing and efficacious policy measures. However, it continues to exercise jurisdiction to determine if the chosen policy measure conforms to the standards of reasonableness, militates against manifest arbitrariness and protects the right to life of all persons. This Court is presently assuming a dialogic jurisdiction where various stakeholders are provided a forum to raise constitutional grievances with respect to the management of the pandemic. Hence, this Court would, under the auspices of an open court judicial process, conduct deliberations with the executive where justifications for existing policies would be elicited and evaluated to assess whether they survive constitutional scrutiny."

(A copy of the **Judgement Distribution of Essential Supplies and Services During Pandemic, in re, 2021 SCC OnLine SC 411** is annexed as **Annexure AA 27** at page 98 to 116

DEPONENT

VERIFICATION:

I, the above named Deponent, do hereby verify that the contents of the above Affidavit are true and correct to my knowledge; that no part of it is false and that nothing material has been concealed therefrom.

Verified at New Delhi on 26th September 2021.

DEPONENT

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

26 OCT 2021

ATTESTED

NOTARY PUBLIC DELHI

GOVERNMENT OF NCT OF DELHI
DELHI DISASTER MANAGEMENT AUTHORITY

No. F.02/07/2020/S-1/Pt-1/479 Dated: 08.10.2021

ORDER

Whereas, the Delhi Disaster Management Authority (DDMA) is satisfied that the NCT of Delhi is threatened with the spread of COVID-19 Virus, which has already been declared as a pandemic by the World Health Organization and has considered it necessary to take effective measures to prevent its spread and issued various orders/instructions from time to time to all authorities concerned to take all required measures to appropriately deal with the situation in NCT of Delhi.

2. And whereas, in a meeting of Delhi Disaster Management Authority (DDMA) held on 29.09.2021, it was decided to ensure 100% vaccination of all Government Employees, Frontline Workers, Healthcare Workers as well as Teachers and other staff working in schools/colleges, as these categories of persons have frequent interaction with the general public/vulnerable section of the society.

3. Now, therefore, in exercise of powers conferred under section 22 of the Disaster Management Act, 2005, the undersigned, in his capacity as Chairperson, State Executive Committee, DDMA, GNCTD, hereby directs as follows:-

i) All Government employees working in Departments/Autonomous Bodies/ PSUs/Local Bodies/Educational Institutions under Government of NCT of Delhi, including Frontline Workers, Healthcare Workers as well as Teachers and other staff working in Schools / Colleges should get vaccinated (at least first dose) by 15.10.2021 as per prevailing guidelines / protocols prescribed for vaccination by MOH&FW, Govt of India.

ii) The aforesaid Government employees/ Frontline Workers/Healthcare Workers / Teachers and other staff working in Schools / Colleges, who do not get vaccinated (at least first dose) by 15.10.2021 shall not be allowed to attend their respective offices/ Health care institutions/ educational institutions with effect from 16.10.2021 till they have obtained the first dose vaccination.

iii) The said period of absence from duty shall be treated as "On Leave" till the administration of the first dose of vaccination.

iv) The administration of the first dose of vaccination / complete vaccination shall be verified by the concerned HOD/office through Arogya Setu application/ certificate of vaccination produced by the concerned employee.

4. Government of India may consider issuing similar directions in respect of its employees working in Delhi.

(Vijay Dev)
Chief Secretary, Delhi

Copy for compliance to :

1. All Addl. Chief Secretaries/ Principal Secretaries/Secretaries/HODs of all Departments/ Autonomous Bodies/PSUs/Local Bodies of Govt. of NCT of Delhi.
2. Chairman, New Delhi Municipal Council.
3. Addl. Chief Secretary (Health), GNCTD.
4. Commissioner of Police, Delhi.
5. Pr. Secretary (Revenue)-cum Divisional Commissioner, GNCTD.
6. Pr. Secretary (Education), GNCTD.
7. Commissioner (South DMC/East DMC/North DMC).
8. Secretary (I&P) for wide publicity in NCT of Delhi.
9. Secretary (Higher Education), GNCTD
10. Secretary (TTE), GNCTD.

11. CEO, Delhi Cantonment Board.
12. Director (Education), GNCTD.
13. All District Magistrates of Delhi.
14. All District DCPs of Delhi
15. Director, DGHS, GNCTD.

Copy for kind information to :

1. Secretary to Hon'ble Lt. Governor, Delhi.
2. Secretary to Hon'ble Chief Minister, GNCTD.
3. Staff Officer to Cabinet Secretary, Government of India.
4. Secretary, Department of Personnel & Training, Government of India.

Prashant Bhushan

(TRUE COPY)

ANNEXURE: AA2

IN THE HIGH COURT OF BOMBAY AT GOA

WRIT PETITION No. 1820 of 2021

IN THE MATTER OF:

Mr. Nelson Paulo Fernandes & Another

.....Petitioners

Versus

The State of Goa & Ors.

.....Respondents

COUNTER AFFIDAVIT ON BEHALF OF ANSWERING RESPONDENT NO. 6 (MINISTRY OF HEALTH & FAMILY WELFARE, GOVT. OF INDIA)

I, Satyendra Singh, S/o Sh. Phool Singh, aged about 41 years, working as Under Secretary COVID Vaccination Administration Cell in the Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi do hereby solemnly affirm and sincerely state as follows:

1. That, I am well acquainted with the facts of the case from the records. I am filing this Counter Affidavit on behalf of the Ministry of Health & Family Welfare, Govt. of India, as I am authorized to do so.

NOTARY PUBLIC
M. P. SHUKLA
Regd. No. 17817
DELHI
Expiry Date: 22.12.2024
GOVT. OF INDIA

08 OCT 2021

2. I have perused the Writ Petition of the petitioner and I deny the averments made therein, except those that are specifically admitted hereunder.

3. I humbly submit that, the Petitioner has filed this writ petition seeking directions predominantly as against the State Government. However, since we are also made a party, I am filing this counter affidavit.

4. That, it is humbly submitted by the Answering Respondent No. 6 that, instead of traversing various allegations para-wise, this respondent deems it appropriate to counter the whole set of the facts in this matter as follows:

It is submitted that in the Writ Petition the petitioner has prayed the interim prayer as follows: -

"1. *For an appropriate Writ, order or direction, thereby quashing the circular dated 13/07/2021 issued by respondent no. 2 (Director, Directorate of Education, Govt of Goa).*

2. *For an appropriate Writ, order or direction, thereby directing the respondent no. 1 and 2 (State of Goa and Director, Directorate of Education, Govt of Goa) to consider the petitioner's representations dated 30/07/2021 and 11/08/2021 and to issue a corrigendum*

NOTARY PUBLIC * M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024 * GOVT. OF INDIA

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thereby making the vaccination by the teaching and non-teaching staff voluntary.

3. *For an interim relief, staying the operation of circulars dated 16/07/2021, 28/07/2021 and 16/08/2021 thereby directing the respondent No 2 and 3 (Headmistress, Little Flower of Jesus High School) not to take any coercive measures/actions against the petitioners pending the hearing and final disposal of petition.*

4. *For ex parte relief in terms of prayer clause 3.*

5. It is further humbly submitted that the matter has been examined and from the prayer (at para 1, 2 & 3 above) and the statements of the petitioner in the writ petition, it is evidently clear that the grievances of the petitioner in the prayer is related to the Departments of State Government of Goa (Respondent No. 1 and 2).

6. That, it is further humbly submitted that the annexures as mentioned in the Writ Petition by the petitioner have been issued by the Departments under State Government of Goa.

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7. That, it is further submitted that the subject matter of the present Petition does not fall within the domain of the Answering Respondent No. 6 (Union of India).

8. That, it is further humbly submitted that however, since this matter is related to vaccination, and Union of India is the respondent no. 6; thus, it is pertinent to present the stand of Union of India with regards to vaccination. It is humbly submitted that vaccination for Covid-19 is a matter of social obligation and is of a larger public interest. As a responsible citizen looking to contribute in the nation and humanity's fight against the Pandemic of Covid-19 infection, it is natural that every person would get her/himself vaccinated against Covid-19 so as to prevent the spread of Covid-19 infection in the community.

9. That, it is further humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and family Welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that COVID-19 vaccination is completely voluntary for all citizens of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between

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citizens of India on the basis of their vaccination status.

10. That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against her/his wishes.

11. That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on Co-WIN or visiting Covid Vaccination Center for vaccination. if a person above the age of 18 years visits a Covid Vaccination Centre by her/his choice for vaccination and asks for the same, it implies that she/he is voluntarily coming to the,center to get the benefit of Covid Vaccination.

12. Therefore, it is humbly submitted that in order to prevent the transmission and spread of Covid-19 pandemic, it is expected that all responsible citizens especially the teachers who are also the role models and influencers for the society get themselves vaccinated as soon as possible against Covid-19 and meticulously follow Covid Appropriate Behaviour.

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08 OCT 2021

13. **Prayer:**

It is therefore most humbly prayed that, this Hon'ble Court may be pleased to admit this Counter Affidavit on behalf of Answering Respondent No. 6 (Union of India) on this petition for the ends of justice.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

Identified by

VERIFICATION:

Verified at New Delhi on October 08, 2021 that the contents of this affidavit are true and correct to the best of my knowledge and belief and no part of it is false thereof, and no material fact has been canceled therefrom.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

NOTARY PUBLIC
M. P. SHUKLA
Regd. No. 17817
DELHI
Expiry Date: 22.12.2024
GOVT. OF INDIA

08 OCT 2021

M. P. SHUKLA
Notary Public, Delhi

CERTIFIED THAT THE DEPONENT
Shri/Smt/Km. ..... Aged .....
S/o, W/o, D/o, Sh. .....
identified by .....
has solemnly affirmed before me
on ..... at .....
that the contents of this affidavit
have been read & explained to him/her/them.

M. P. SHUKLA
Notary Public, Delhi

Prashant Bhushan
(TRUE COPY)

European Journal of Epidemiology
https://doi.org/10.1007/s10654-021-00808-7

CORRESPONDENCE

Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States

S. V. Subramanian[1,2] · **Akhil Kumar**[3]

Received: 17 August 2021 / Accepted: 9 September 2021

Vaccines currently are the primary mitigation strategy to combat COVID-19 around the world. For instance, the narrative related to the ongoing surge of new cases in the United States (US) is argued to be driven by areas with low vaccination rates [1]. A similar narrative also has been observed in countries, such as Germany and the United Kingdom [2]. At the same time, Israel that was hailed for its swift and high rates of vaccination has also seen a substantial resurgence in COVID-19 cases [3]. We investigate the relationship between the percentage of population fully vaccinated and new COVID-19 cases across 68 countries and across 2947 counties in the US.

Methods

We used COVID-19 data provided by the Our World in Data for cross-country analysis, available as of September 3, 2021 (Supplementary Table 1) [4]. We included 68 countries that met the following criteria: had second dose vaccine data available; had COVID-19 case data available; had population data available; and the last update of data was within 3 days prior to or on September 3, 2021. For the 7 days preceding September 3, 2021 we computed the COVID-19 cases per 1 million people for each country as well as the percentage of population that is fully vaccinated.

For the county-level analysis in the US, we utilized the White House COVID-19 Team data [5], available as of September 2, 2021 (Supplementary Table 2). We excluded counties that did not report fully vaccinated population percentage data yielding 2947 counties for the analysis. We computed the number and percentages of counties that experienced an increase in COVID-19 cases by levels of the percentage of people fully vaccinated in each county. The percentage increase in COVID-19 cases was calculated based on the difference in cases from the last 7 days and the 7 days preceding them. For example, Los Angeles county in California had 18,171 cases in the last 7 days (August 26 to September 1) and 31,616 cases in the previous 7 days (August 19–25), so this county did not experience an increase of cases in our dataset. We provide a dashboard of the metrics used in this analysis that is updated automatically as new data is made available by the White House COVID-19 Team (https://tiny.cc/USDashboard).

Findings

At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 1). In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days. The lack of a meaningful association between percentage population fully vaccinated and new COVID-19 cases is further exemplified, for instance, by comparison of Iceland and Portugal. Both countries have over 75% of their population fully vaccinated and have more COVID-19 cases per 1 million people than countries such as Vietnam and South Africa that have around 10% of their population fully vaccinated.

Across the US counties too, the median new COVID-19 cases per 100,000 people in the last 7 days is largely similar across the categories of percent population fully vaccinated (Fig. 2). Notably there is also substantial county variation in

✉ S. V. Subramanian
svsubram@hsph.harvard.edu

[1] Harvard Center for Population and Development Studies, Cambridge, MA, USA

[2] Department of Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health, Boston, MA, USA

[3] Turner Fenton Secondary School, Brampton, ON, Canada

Published online: 30 September 2021

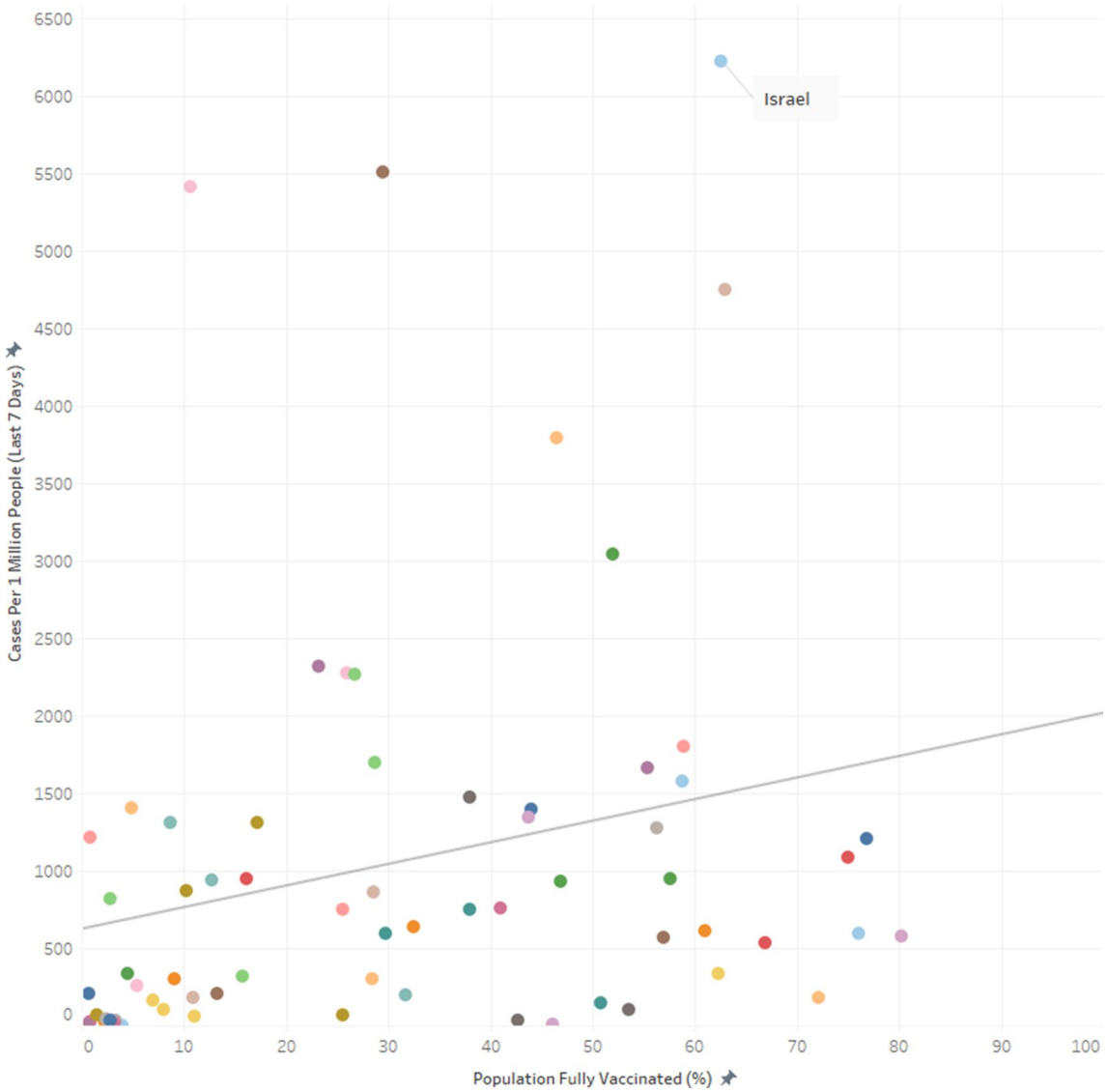

Fig. 1 Relationship between cases per 1 million people (last 7 days) and percentage of population fully vaccinated across 68 countries as of September 3, 2021 (See Table S1 for the underlying data)

new COVID-19 cases *within* categories of percentage population fully vaccinated. There also appears to be no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated (Fig. 3).

Of the top 5 counties that have the highest percentage of population fully vaccinated (99.9–84.3%), the US Centers for Disease Control and Prevention (CDC) identifies 4 of them as "High" Transmission counties. Chattahoochee (Georgia), McKinley (New Mexico), and Arecibo (Puerto Rico) counties have above 90% of their population fully vaccinated with all three being classified as "High" transmission. Conversely, of the 57 counties that have been classified as "low" transmission counties by the CDC, 26.3% (15) have percentage of population fully vaccinated below 20%.

Since full immunity from the vaccine is believed to take about 2 weeks after the second dose, we conducted sensitivity analyses by using a 1-month lag on the percentage population fully vaccinated for countries and US counties. The above findings of no discernable association between COVID-19 cases and levels of fully vaccinated was also observed when we considered a 1-month lag on the levels of fully vaccinated (Supplementary Figure 1, Supplementary Figure 2).

We should note that the COVID-19 case data is of confirmed cases, which is a function of both supply (e.g., variation in testing capacities or reporting practices) and demand-side (e.g., variation in people's decision on when to get tested) factors.

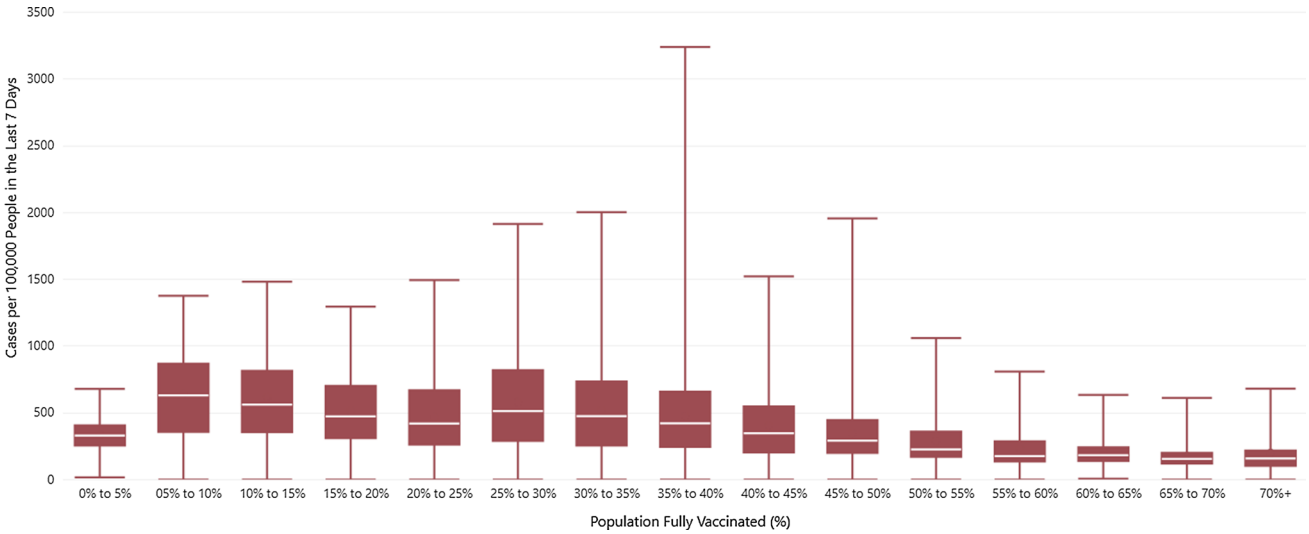

Fig. 2 Median, interquartile range and variation in cases per 100,000 people in the last 7 days across percentage of population fully vaccinated as of September 2, 2021

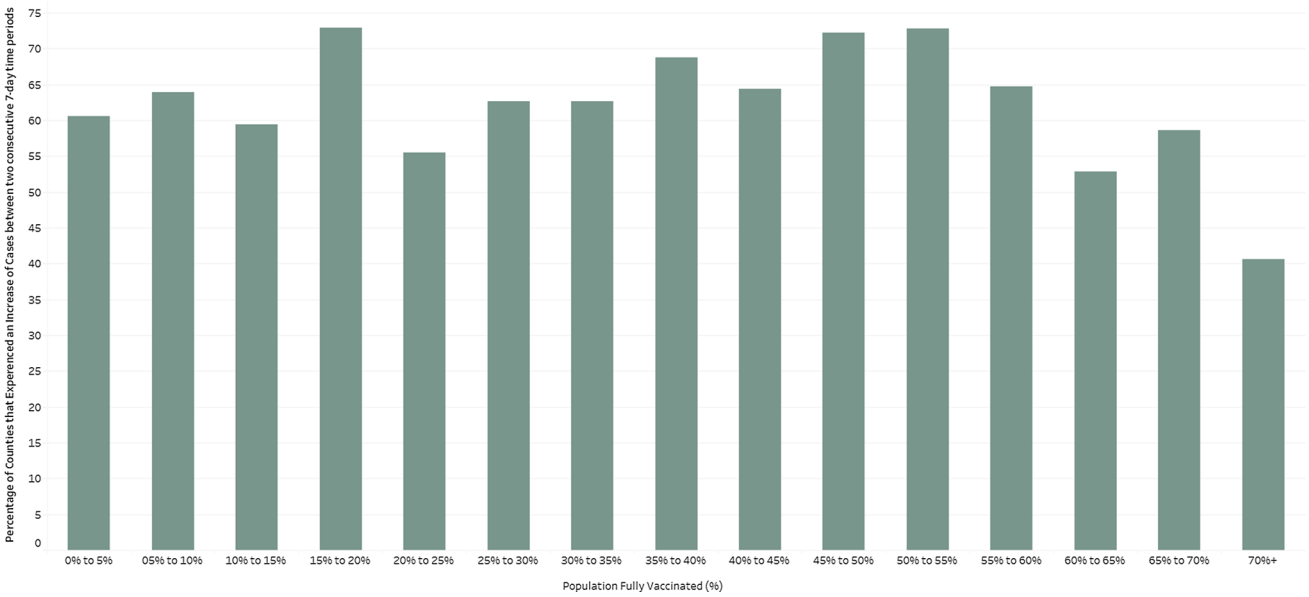

Fig. 3 Percentage of counties that experienced an increase of cases between two consecutive 7-day time periods by percentage of population fully vaccinated across 2947 counties as of September 2, 2021

Interpretation

The sole reliance on vaccination as a primary strategy to mitigate COVID-19 and its adverse consequences needs to be re-examined, especially considering the Delta (B.1.617.2) variant and the likelihood of future variants. Other pharmacological and non-pharmacological interventions may need to be put in place alongside increasing vaccination rates. Such course correction, especially with regards to the policy narrative, becomes paramount with emerging scientific evidence on real world effectiveness of the vaccines.

For instance, in a report released from the Ministry of Health in Israel, the effectiveness of 2 doses of the BNT162b2 (Pfizer-BioNTech) vaccine against preventing COVID-19 infection was reported to be 39% [6],

substantially lower than the trial efficacy of 96% [7]. It is also emerging that immunity derived from the Pfizer-BioNTech vaccine may not be as strong as immunity acquired through recovery from the COVID-19 virus [8]. A substantial decline in immunity from mRNA vaccines 6-months post immunization has also been reported [9]. Even though vaccinations offers protection to individuals against severe hospitalization and death, the CDC reported an increase from 0.01 to 9% and 0 to 15.1% (between January to May 2021) in the rates of hospitalizations and deaths, respectively, amongst the fully vaccinated [10].

In summary, even as efforts should be made to encourage populations to get vaccinated it should be done so with humility and respect. Stigmatizing populations can do more harm than good. Importantly, other non-pharmacological prevention efforts (e.g., the importance of basic public health hygiene with regards to maintaining safe distance or handwashing, promoting better frequent and cheaper forms of testing) needs to be renewed in order to strike the balance of learning to live with COVID-19 in the same manner we continue to live a 100 years later with various seasonal alterations of the 1918 Influenza virus.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10654-021-00808-7.

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Prashant Bhushan
(TRUE COPY)

UK Health Security Agency

COVID-19 vaccine surveillance report

Week 40

Table 2. COVID-19 cases by vaccination status between week 36 and week 39 2021

Cases reported by specimen date between week 36 and week 39 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date	Rates among persons vaccinated with 2 doses (per 100,000)	Rates among persons not vaccinated (per 100,000)
Under 18	305,428	20,967	272,981	4,973	5,898	609	278.8	2,325.7
18-29	67,820	8,556	23,440	1,119	12,593	22,112	409.6	688.1
30-39	81,532	7,534	21,449	690	7,468	44,391	763.6	738.4
40-49	101,094	6,839	11,662	297	3,653	78,643	1,281.8	690.2
50-59	70,731	4,668	5,144	89	1,464	59,366	839.5	502.5
60-69	36,953	2,585	1,798	26	546	31,998	563.1	332.9
70-79	22,142	1,367	693	6	207	19,869	428.9	281.4
80+	10,581	869	403	4	199	9,106	354.4	319.5

*individuals whose NHS numbers were unavailable to link to the NIMS

** Interpretation of the case rates in vaccinated and unvaccinated population is particularly susceptible to changes in denominators and should be interpreted with extra caution.

Prashant Bhushan

(TRUE COPY)

No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant

Authored by: Charlotte B. Acharya, John Schrom, Anthea M. Mitchell, David A. Coil, Carina Marquez, Susana Rojas, Chung Yu Wang, Jamin Liu, GenayPilarowski, Leslie Solis, Elizabeth Georgian, Maya Petersen, Joseph DeRisi, Richard Michelmore, Diane Havlirdoi:

Abstract: We found no significant difference in cycle threshold values between vaccinated andunvaccinated, asymptomatic and symptomatic groups infected with SARS-CoV-2 Delta. Giventhe substantial proportion of asymptomatic vaccine breakthrough cases with high viral levels,interventions, including masking and testing, should be considered for all in settings withelevatedCOVID-19transmission.

Background

Vaccines reduce infection, severe disease, and death from SARS-CoV-2 (COVID-19)[1], yet breakthrough cases occur [2]. Several reports show no difference in cycle thresholdvalues (Ct-values) between vaccinated and unvaccinated individuals [2, 3, 4]; however, othershave suggested that breakthrough infections, particularly among asymptomatic individuals, havea lowerviralloadandthereforemaybelesslikelytoresultintransmission[5, 6].

Effective epidemic control requires contemporary data to guide public health mitigationmeasures. Here, we report on Ct-values among fully vaccinated and unvaccinated individuals,asymptomatic and symptomatic at time of testing, during a period of high transmission of theDelta variant in two distinct populations: aUnidosenSalud (UeS) community-based site in theMission District of San Francisco and Healthy Yolo Together (HYT) asymptomatic testingthroughtheUniversityofCalifornia (UC), Davis.

MaterialsandMethods

StudyPopulations

Data was collected on individuals who voluntarily sought testing for SARS-CoV-2 fromtwo demographically distinct populations in California during a two-month period from June 17toAugust31,2021, duringwhichDeltawasthepredominantvariant.

HYT: Aspartoftheresponse to theCOVID-19pandemic,UCDavisdeployedan

extensive free asymptomatic testing program that included the City of Davis and Yolo County(HealthyYoloTogether).Asymptomaticindividualsovertheageof2wereeligiblefortesting.

Asymptomatic cases were classified as individuals not reporting symptoms at the time of testing.Samples were collected through a supervised method in which individuals transferred their salivainto abarcoded tube(COVID-19 Testing |CampusReady).Smallernumbersofsymptomaticindividuals were processed using a different workflow and an antigen test; therefore, they werenotincludedinthis study.

UeS:ThestudypopulationincludedindividualswhosoughtSARS-CoV-2testingatthe

UeS walk-up site, an ongoing academic (UC San Francisco, CZ Biohub, and UC Berkeley),community organization (Latino Task Force), and government (SFDPH) partnership. Theoutdoor, free BinaxNOW™ testing site was located at a public transport and commercial hub inthe Mission District, a setting of ongoing transmission in San Francisco [7]. Individuals one yearofageandolder, withorwithoutsymptoms,wereeligiblefortesting.

Measurements

Infections were classified as breakthrough infections if the individual was

fullyvaccinated (two weeks following receipt of all vaccine doses). Individuals that had had only onedose or were tested within two weeks of the second dose, in the case of Pfizer and Modernavaccines,werenotincludedinthe analysis.

HYT: Demographicinformationwascollected from individualsat thetimeof registration. Vaccination status information was obtained at the time of contact tracing andconfirmed in the California Vaccine Registry. Only confirmed, fully vaccinated individuals wereused in the analysis; discordant samples, self-reported as vaccinated but unconfirmed, weretreated as status unknown. Saliva samples from asymptomatic individuals were tested for thepresence of the N1 and N2 regions of the viral nucleocapsid (N) gene using primers and probesdescribed in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR DiagnosticPanel, using IntelliQube high-throughput quantitative PCR instruments (LGC BiosearchTechnologies).Ct-valueswerecalculated with FastFindersoftware(UgenTec|FastFinder).

Genotypes of all N1/N2 positive samples were determined using RT-PCR SNP analysisat11 loci diagnosticforvariantsofconcern(SARS-CoV-2 Variant ValuPanelassays| LGC BiosearchTechnologies).Asubsetofsamples(39%)werealsosequencedusingtheIllumina MiSeq sequencing platform. Consensus genomes were generated with Viralrecon2 and variantscalled in Pangolin version 3.1.11 and PLEARN-v1.2.66. Sequencing confirmed the variantscalledbygenotyping.

UeS: Individualsprovided demographicdataand information onsymptomsimmediately prior to testing using BinaxNOW™ kits. COVID-19 vaccine status, including date of final shot,was obtained through the California Vaccine Registry. Anterior-nasal swab samples (iClean,Chenyang Global) collected by certified lab assistants from BinaxNOW positive individualswere placed in DNA/RNA Shield (Zymo, Inc.) and processed for qRT-PCR, genome recovery,and variant/lineage determination as previously described [8, 9]. Ct-

values for the detection of Nand E genes [8] were determined via the single threshold Cq-determination mode using Bio-RadCFX Maestro v4.1 (Bio-Rad Inc). SARS-CoV-2 genomes were sequenced using the IlluminaNovaSeq platform. Consensus genomes were generated via the COVID module of the IDseqpipeline (https://idseq.net)as described[9].

Analysis

Ct-valueswereplotted,stratifiedbysite;fullyvs.notvaccinated;andsymptom status.

Partially vaccinated samples and stratification by age and vaccine type are reported insupplementarymaterials. Ct-valuesbetweenstratawerecomparedusingatwosidedt-test.EthicsStatement

HYT: TheGenomeCenterlaboratorythatconductedCOVID-19 testingwasCLIA

approved asan extension to theStudentHealthCenter'slaboratory.TheUCDavisIRB Administration determined that the study met criteria for public health reporting and was exemptfromIRB reviewandapproval.

UeS: The UCSan Francisco CommitteeonHumanResearch determined thestudy met

criteriafor publichealthsurveillance.Allparticipantsprovidedinformedconsentfor testing.

Results

Atotal of869 samples,500from HYTand 369from UeS,wereincluded intheanalysis.

All analyzed samples from HYT were asymptomatic at the time of collection and 75% of thepositive samples were from unvaccinated individuals (N=375). Positive samples from UeS werefrom both symptomatic (N=237) and asymptomatic individuals (N=132). The frequency ofvaccine breakthroughs among the UeS samples (171 fully vaccinated, 198

unvaccinated) wasgreater than among the HYT samples, reflecting the different types of populations sampled. TheDeltavariant wasthepredominant variantdetected in bothpopulations(SupplementaryTable1).

There were no statistically significant differences in mean Ct-values of vaccinated (UeS:23.1; HYT: 25.5) vs. unvaccinated (UeS: 23.4; HYT: 25.4) samples. In both vaccinated andunvaccinated, there was great variation among individuals, with Ct-values of <15 to >30 in bothUeS and HYT data (Fig. 1A, 1B). Similarly, no statistically significant differences were found inthe mean Ct-values of asymptomatic (UeS: 24.3; HYT: 25.4) vs. symptomatic (UeS: 22.7)samples, overall or stratified by vaccine status (Fig. 1B). Similar Ct-values were also foundamong differentage groups,betweengenders,andvaccinetypes(SupplementalFigure1).

In all groups, there were individuals with low Ct-values indicative of high viral loads. Atotal of 69 fully vaccinated individuals had Ct-values <20. Of these, 24 were asymptomatic at thetime oftesting.

Discussion

In our study, mean viral loads as measured by Ct-value were similar for large numbers ofasymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge,regardless of vaccine status, age, or gender. This contrasts with a large ongoing UK communitycohort in which the median Ct-value was higher for vaccinated individuals (27.6) than forunvaccinated individuals (23.1) [5]. Also, a study from San Francisco reported that 10 fullyvaccinated asymptomatic individuals had significantly lower viral loads than 28 symptomatic,vaccinated individuals [6]. Our study is consistent with other recent reports showing similar viralloads among vaccinated and unvaccinated individuals in settings with transmission of the Deltavariant. In a Wisconsin study, Ct-values were similar and culture positivity was not different in asubset of analyses between 11 vaccinated and 24 unvaccinated cases [4]. In both Massachusettsand Singapore, individuals with vaccination breakthroughs caused by the Delta variant hadsimilar Ct-values as unvaccinated individuals [3, 10]. Our findings are supported by consistencyacrosslarge sample sets usingdifferentassaysfromtwodistinctlocations.

A substantial proportion of asymptomatic, fully vaccinated individuals in our study hadlow Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of

highlevelsof virus,culturepositivity,andincreasedtransmission[11], our detectionof lowCt-valuesin asymptomatic, fully vaccinated individuals is consistent with the potential for transmissionfrom breakthrough infections prior to any emergence of symptoms. Interestingly, the viral loadsdecreased more rapidly in vaccinated than unvaccinated individuals in Singapore [3], suggestingthat vaccinated individuals may remain infectious for shorter periods of time. Also, aretrospective observational cohort study of contacts of SARS-CoV-2-infected index cases inEngland documented reduced transmission from vaccinated individuals [12]. In our study, over20%ofpositive,vaccinatedindividualshadlow Ct-values(<20),a thirdofwhichwereasymptomatic when tested. This highlights the need for additional studies of the immunologicalstatus of such vaccine escapes and how infectious they are. If such individuals carry high loadsof active virus, asymptomatic vaccinated individuals may increasingly contribute to the ongoingpandemic as theproportionofvaccinatedindividuals grows.

Ct-values in some children under 12 who are not yet eligible for vaccination were alsolow. Twenty out of 109 (18.3%) children under 12 years of age had Ct-values <20, of which 14were asymptomatic at the time of testing. Low Ct indicates that the children had high viral loadsand were likely infectious. This emphasizes the value of regular, rapid testing for school childrento detect infection early and block chains of transmission in settings where the Delta variant iscirculating.

While vaccination remains the best protection against becoming infected and severedisease [12], the data gathered in this study during the surge of the Delta variant strongly supportthe notion that neither vaccine status nor the presence or absence of symptoms should influencethe recommendation and implementation of good public health practices, including maskwearing, testing, social distancing, and other measures, designed to mitigate the spread of SARS-CoV-2.

AuthorContributionStatement:

JD, RWM, DH, and MP conceived the project. DC, CM, SR, DH, and GP helped collect thedata. CA, AM, CYW, and JL helped perform the tests, genotyping, and sequencing. CA, JH, LS,JD, AM, CYW, JS, and JL prepared the data for publication. RM, EG, DH, MP, DC, JS, and JDcontributed tothewritingofthemanuscript.Allauthorsread and approvedthefinal manuscript.

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Acknowledgements: Many people were responsible for collecting the samples, running thetests, performing the genotyping and sequencing, and processing the data as listed inSupplementaryTable2.

Conflict of Interest: Dr. DeRisi reports being a scientific advisor to the Public Health Co. and ascientific advisor to Allen & Co. Dr. Havlir reports non-financial support from Abbott outside ofthe submittedwork.Theotherauthorsdeclarenocompetinginterests.

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LINK: https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2

Prashant Bhushan
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SheddingofInfectiousSARS-CoV-2DespiteVaccination

Authored by: Kasen K. Riemersma, Brittany E. Grogan, Amanda Kita-Yarbro, Peter J. Halfmann, Hannah E. Segaloff, Anna Kocharian, Kelsey R. Florek, Ryan Westergaard, Allen Bateman, Gunnar E. Jeppson, Yoshihiro Kawaoka, View ORCID ProfileDavid H. O'Connor, View ORCID ProfileThomas C. Friedrich, Katarina M. Grande

Abstract

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and containsmutations that confer partial immune escape [1,2]. Outbreak investigations suggest that vaccinatedpersons can spread Delta [3,4]. We compared RT-PCR cycle threshold (Ct) data from 699 swabspecimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay bya single contract laboratory. Specimens came from residents of 36 counties, most in southern andsoutheastern 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%. Vaccinationstatuswasdeterminedviaself-reportingandstateimmunizationrecords(**SupplementalFigure1**).

Maintext

WeobservedlowCtvalues(<25)in212of310fullyvaccinated(68%;**Figure1A**)and246of389(63%) unvaccinated individuals. Testing a subset of low-Ct samples revealed infectious SARS-CoV-2 in15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people(**Figure1B**).

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing(**Figure1C**).Ctvalues<25weredetectedin7of24unvaccinated(29%;CI:13-51%)and9of11fully vaccinatedasymptomaticindividuals(82%;CI:48-97%),and158of232unvaccinated(68%,CI:62-

74%)and156of225fullyvaccinated(69%;CI:63-75%)symptomaticindividuals.Timefromsymptomonset to testing did not vary by vaccination status (p=0.40; **Supplemental Figure 2**). Infectious viruswas detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Althoughfew asymptomatic individuals were sampled, these results indicate that even asymptomatic, fullyvaccinatedpeoplemightshedinfectiousvirus.

Combined with other studies [2–5], these data indicate that vaccinated and unvaccinated individualsinfectedwiththeDeltavariantmighttransmitinfection.Importantly,weshowthatinfectiousSARS-CoV-2 is frequently found even in vaccinated persons when specimen Ct values are low. The inclusion ofviruses from Pango lineages B.1.617.2, AY.2, and AY.3, and multiple counties without a linkingoutbreak, indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent withtransmissibility in fully vaccinated individuals across a range of settings. Vaccinated and unvaccinatedpersons should get tested when symptomatic or after close contact with someone with suspected orconfirmedCOVID-19.Continuedadherencetonon-pharmaceuticalinterventionsduringperiodsofhighcommunity transmission to mitigate spread of COVID-19 remain important for both vaccinated andunvaccinatedindividuals.

Figure

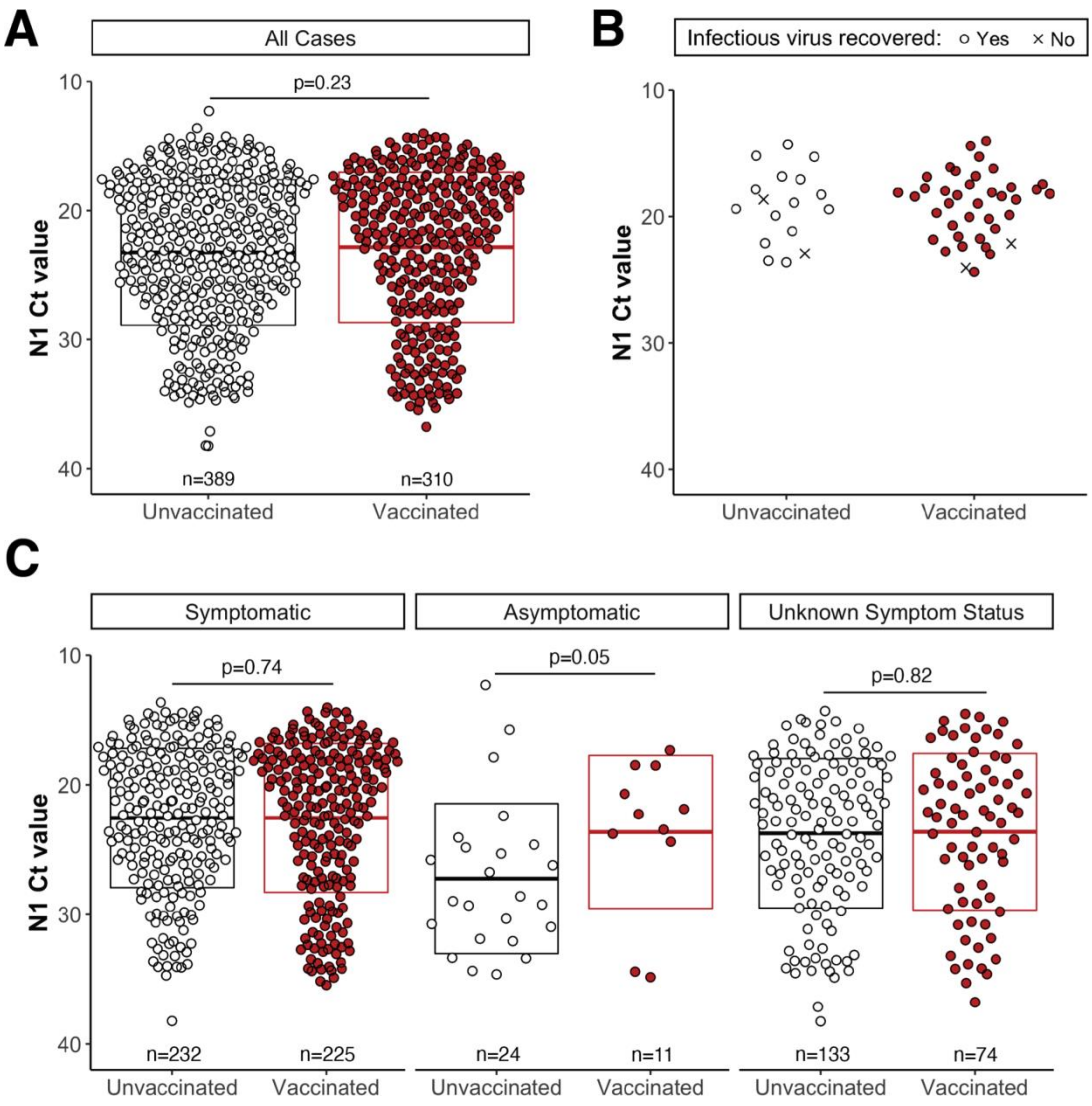
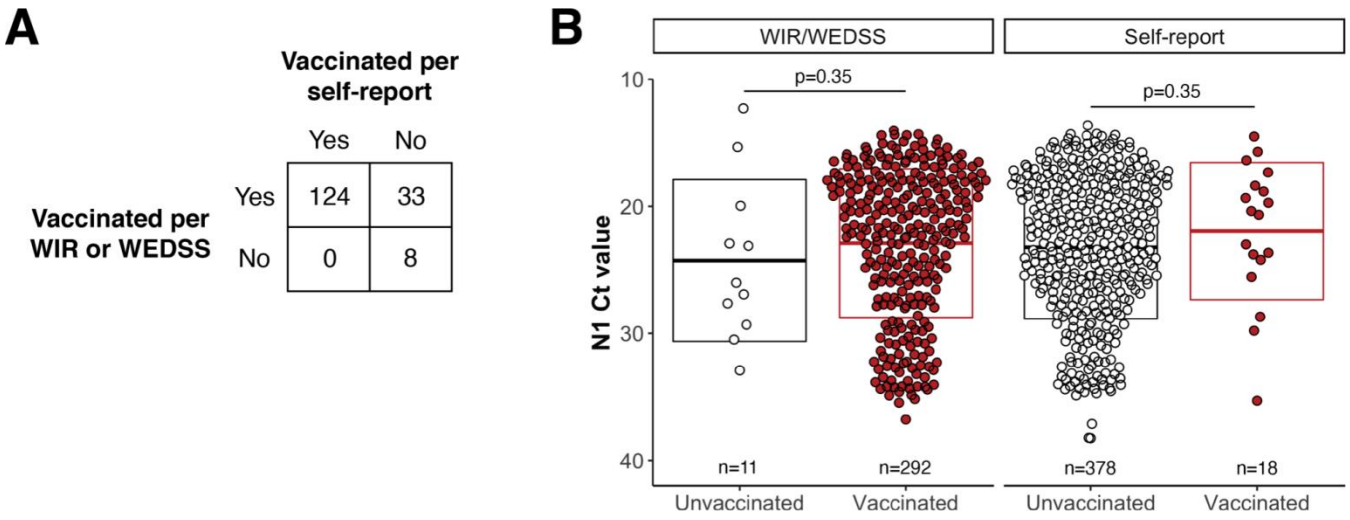


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values andshed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccinationstatus. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCRtests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 Ngene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized foremergency use by FDA (https://www.fda.gov/media/138328/download).**B.** Infectiousness wasdetermined for a subset of N1 Ct-matched specimens with Ct <25 by inoculation onto Vero E6TMPRSS2cellsanddeterminingpresenceofcytopathiceffects(CPE)after5daysinculture.
Specimenswere selected by N1 Ct-matching between fully vaccinated and not fully vaccinatedpersons, then specimens from persons with unknown vaccination status were excluded from theanalysis. Circles indicate presence of CPE; 'X' indicates no CPE detected. **C.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic orasymptomatic,orthosewhosesymptomstatuswasnotdetermined,atthetimeoftesting.In**A**and**C**,

boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated bycomparingmeanCtvaluesbyindependenttwo-groupMann-WhitneyUtests.

Supplementalmaterials

Supplementalfigure1



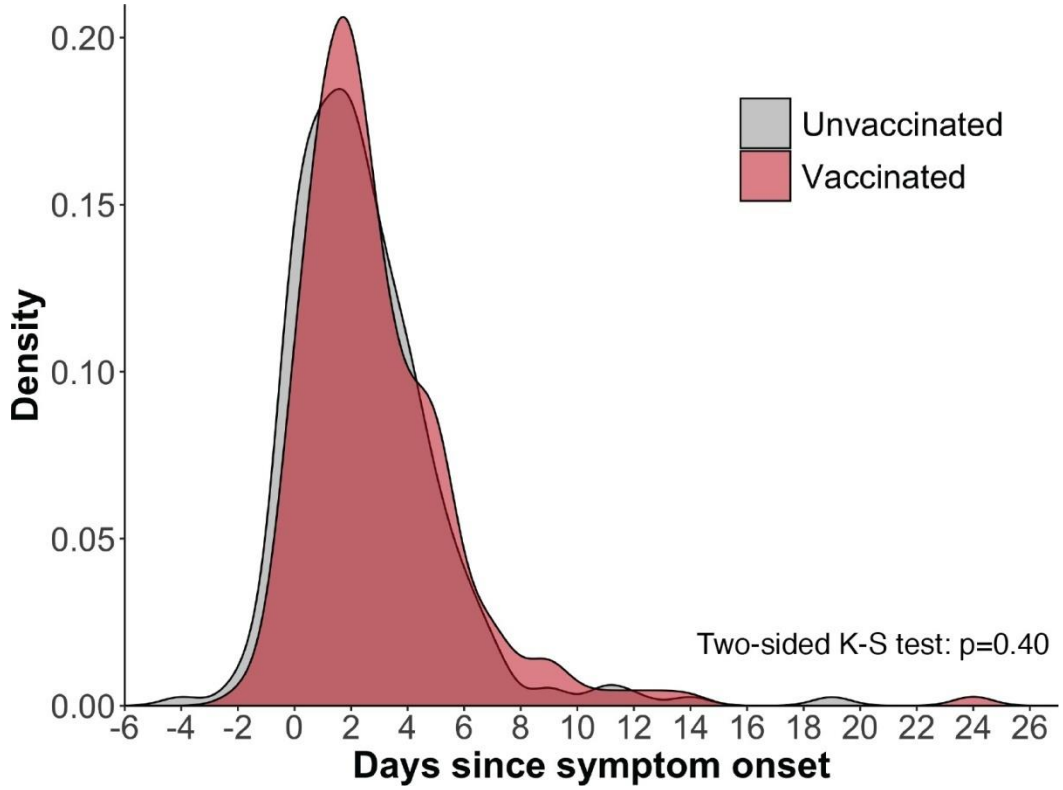
Supplemental figure 1. Concordance between self-reported vaccination status and the WisconsinImmunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For allindividuals, vaccination status was determined using WIR/WEDSS electronic registries when data wereavailable. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS dataindicatedreceiptofafirstSARS-CoV-2vaccinedoseafterthetestdate.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicatedreceiptofafinalvaccinedoseatleast14dayspriortotesting.Forindividualswhosevaccinationstatusco uldnotbeverifiedinWIR/WEDSS,self-reporteddatacollectedatthetimeoftestingwereused.
Individuals were considered unvaccinated based on self-report only if there was an explicit declarationof unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based onself-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVIDvaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported adateoflastvaccinedosethatwasatleast14dayspriortotesting.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partiallyvaccinatedindividuals(incompletevaccineseries,or<14dayspost-finaldose)werealsoexcluded.
Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported datafor18.UnvaccinatedstatuswasdeterminedbyWIR/WEDSSfor11andbyself-reporteddataby378.
A.Ofthe699specimenswithvaccinationstatusavailablefromatleastonesource,165specimenshaddata available from both sources. For self-reporting, under-reporting of full vaccination status (33/157)was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimensgroupedbyvaccinationstatusforindividualswhosevaccinationstatuswasdeterminedbyWIR/WED DSorbyself-reporteddata.BoxplotsrepresentmeanN1Ctvalues+/-onestandard

deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-WhitneyUtests.

Supplementalfigure2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection datesbydaysincesymptomonset.Day0onthex-axisdenotesself-reporteddayofsymptomonset.
Negative values for days indicate specimen collection prior to symptom onset. Symptom onset datawereavailableforn=263unvaccinatedcasesandn=232vaccinatedcases.

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Prashant Bhushan
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‘A Turning Point’: Harvard Hikes Testing Requirements Amid Campus Covid-19 Surge

By Christine Mui, Crimson Staff Writer

September 3, 2021

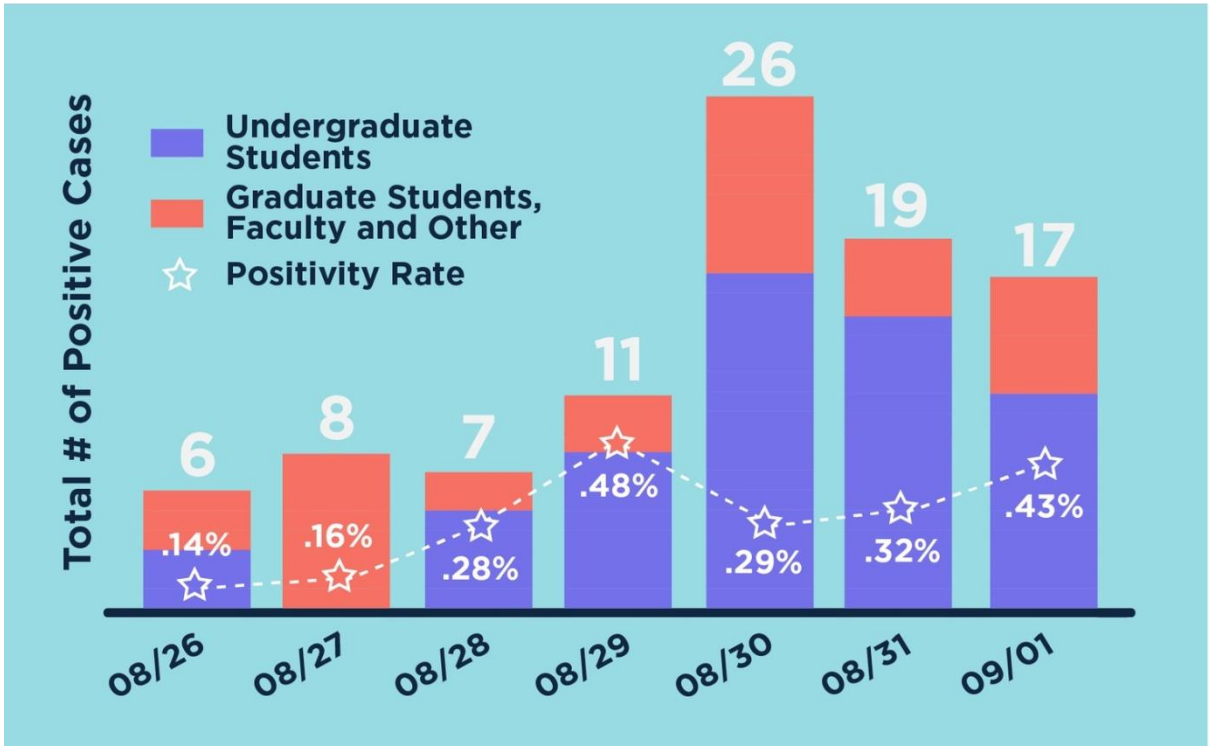
Harvard increased the frequency of coronavirus testing for affiliates living in undergraduate housing Thursday, citing a surge of new cases less than two weeks since students returned to campus and on the third day of classes.

In the last week, Harvard University Health Services counted 94 positive cases, HUHS Director Giang T. Nguyen wrote in an email to affiliates late Thursday.

As a result, Harvard will require affiliates living in undergraduate housing to test three times a week — an increase from once a week.

“Many campuses across the nation are now facing high numbers of COVID-19 infections, so I am writing to encourage that we all act with increased caution in the days and weeks ahead,” Nguyen warned. “This pandemic is not over.”

The new cases bring the campus positivity rate to nearly 0.3 percent, according to the University’s COVID-19 dashboard. As of Thursday, there are more than 100 individuals in isolation and an additional 29 in quarantine.



In his email, Nguyen touted high vaccination rates across campus — 95 percent of employees and 93 percent of students are fully vaccinated — but noted that the spread of the Delta variant makes it vital to maintain "all of our safeguards."

"If you need to interact with many people in a single day, keep your mask on, limit each interaction to under 15 minutes, and don't stand closer than necessary," Nguyen wrote, advising that students keep the number of people closer than 6 feet from them "as low as possible."

Last Friday, Cambridge announced it would reinstate its indoor mask mandate, effective Friday. The same day, Boston began to require face coverings in all indoor public settings.

Citing both orders, Nguyen recommended affiliates follow Harvard's indoor mask requirement "on and off campus."

Harvard also extended its indoor mask mandate on Thursday to include all strength and conditioning facilities, according to a Wednesday email Harvard Athletics sent student-athletes.

"With positive cases steadily increasing since all students moved onto campus and the volume of student-athletes that will be training in contained spaces for strength and conditioning sessions, we made the decision to require masks to make the activity as safe as possible," Athletics Director Erin McDermott wrote in an emailed statement.

The requirement is a reversal of a policy implemented last week that required vaccinated student athletes to test twice weekly, which McDermott said would allow them to safely train and compete maskless. Athletes living in undergraduate dorms will also increase testing to at least three times per week.

In a separate email with Nguyen on Thursday, Dean of Students Katherine G. O'Dair called the rise in new infections "a turning point."

"The Delta variant and our full-capacity residential campus has changed the landscape compared to early summer, and we need to respond as a community to the changing risk profile," they wrote.

O'Dair and Nguyen added that the number of undergraduates in isolation housing — 63 as of Thursday — is only expected "to grow."

“Let us be clear – this uptick is happening because this variant is highly transmissible, even within a vaccinated population. No one is to blame but the COVID virus itself, and it’s up to us to respond and protect each other,” O’Dair and Nguyen said.

Any undergraduates living off-campus are advised, but not required, to test three times a week, they said.

Ahead of the Labor Day long weekend, O’Dair and Nguyen asked students to modify any plans involving indoor activities and risky behaviors, such as partying or gathering with food and alcohol.

“Socializing with consistent and universal masking and minimizing the total number of close interactions you have in any 2-day window will make a big difference,” they wrote.

LINK: https://www.thecrimson.com/article/2021/9/3/harvard-hikes-testing-requirements/

As Cornell Reports Record Cases, Students Miss First Classes, Bear Burdens of COVID Policies

By Madeline Rosenberg and Anil Oza

In February 2021, Jamie ’24 was forced to quarantine hours after stepping foot on Cornell’s campus after someone on her bus from New York City tested positive for COVID-19. She never tested positive herself — but she spent seven days in quarantine at The Statler Hotel.

But on Aug. 26, after Jamie, who asked to omit her last name because of mention of personal medical history, learned the boss of her summer job tested positive, the sophomore spent two days trying to get a COVID test at Cornell before learning that she, too, had COVID-19.

“[The health department] basically said since you’re vaccinated, it’s not urgent,” Jamie said. “Between the time that I found out I was contact traced, and when I actually got my positive result back on Saturday night, I had no restrictions. I could have gone anywhere.”

Jamie is one of nearly 400 Cornell students who tested positive for COVID from Aug. 26 to Sept. 5. They’ve scrambled to get tested and find isolation arrangements during the first weeks of classes — isolating in Balch Hall, hotels or at home.

She and hundreds of other students are now keeping up with coursework with few live classes to attend. Some students will meet their professors for the first time three weeks into the school year, as faculty aren’t required to provide remote course access to those in isolation.

Most Cornell cases are linked to “informal, off-campus gatherings” among undergraduates, and the University has asked students to put off parties and wear masks as much as possible. Case levels are reaching record highs in Tompkins County — as of Monday evening, there are 442 active cases in the county.

With nearly all students vaccinated, the University suspended arrival testing and reduced surveillance testing to weekly nose swabs for vaccinated students. But now, some students are reporting long waits to get supplemental tests and test results, and some have been forced to navigate campus with the suspicion that they are positive for COVID-19.

After Jamie learned she might have been exposed, she spent two days attending classes and gathering with her friends. She minimized her time spent indoors and

wore a mask indoors and outdoors — but without specific University guidance, she was forced to calculate her own decisions while she awaited her test results. (According to the University, fully vaccinated individuals do not need to quarantine after contact with someone who tests positive unless they have symptoms.)

“It was pretty scary, because I knew that I had been in contact with a lot of people,” Jamie said. “At a certain point, I knew I should limit my indoor use, like the mask on outside when possible, but I’d already been in close contact with like 30 people.”

While Jamie said she tried to keep her distance, even avoiding crowded dining halls, she attended Trevor Wallace’s performance in Bailey Hall directly before she received a call that she had tested positive. While Jamie wasn’t breaking University policy when attending class and the event, she feared facing repercussions now that she has tested positive.

“I’m relying on the school to not only keep me from getting COVID, but also keep me from giving it to other people,” Jamie said. “It feels like neither of that is happening.”

Ekaterina Shetekauri ’24 said that finding out she had COVID was “pretty overwhelming,” but said the process of being isolated in Balch Hall was relatively seamless. A van picked her up from West Campus and dropped her off to a room furnished with a fan, various electronics chargers, bedding and three meals a day.

Justine ’24, another student in isolation at Cayuga Blu Hotel by the Shops at Ithaca Mall who also asked to omit her last name because of mention of personal medical history, waited nearly two days after her test to be isolated. After being tested on Aug. 26, she woke up to a text from the New York State Health Department notifying her she had tested positive on Saturday.

But Justine said she didn’t get a call from Cornell until the early afternoon, and was transported to the hotel around 5 p.m. Without guidance, she and her roommate — who also tested positive — isolated in their room and did not eat until getting to the hotel in fear of infecting other students in a dining hall.

As Justine and her roommate retraced their steps to tell those they had been in close contact with, she said it was difficult to know when they contracted COVID because of the lack of arrival testing.

“It was also stressful, because I went through the first two days of classes with COVID unknowingly,” Justine said. “On Friday, I ate my meals with people I just met.”

As Cornell’s isolation capacity fills — as of Monday, only 19 percent of quarantine and isolation space is available, according to the COVID dashboard — the University is giving students living off campus the option to isolate at home, as long as they have access to their own bedroom and bathroom.

Emma Grabowski ’23 — who lives in an off-campus house — said her roommates who tested negative are delivering meals to her door to stay isolated from her. Grabowski rushed to urgent care last Saturday when she learned she might have been exposed to the virus, unable to find available supplemental tests at Cornell.

Two days after testing positive, she called Cornell Health herself to report her positive test result, when Cornell Health offered her isolation space in Balch Hall. She opted to stay home until her isolation period ends Sept. 8.

“I chose to stay because by that point I was frustrated by Cornell Health and didn’t trust them,” Grabowski wrote to The Sun. “I had access to my own bathroom and room and by that point, I was already isolating in my house for a few days.”

This reality worried Clara Enders ’22, who lives in a University-owned co-op. When one of her fellow residents tested positive last week, Enders said Cornell Health asked the resident to isolate in the house alongside more than 20 students. The co-op ultimately decided to have the resident isolate outside of their home.

“Last semester and fall 2020, if we had a positive, that person would have been yanked out of the house,” Enders said. “We only have so many bathrooms and we share them all. Plus our house is so old, no AC, no real ventilation. In a house that has over 20 people living in it, to have one positive person stay was too great a risk to take.”

Enders said she received no information from Cornell Health after the resident tested positive — creating public health guidance fell on Enders and her housemates. Living with shared kitchens and bathrooms, the co-op residents decided to mask up in common spaces and get supplemental tests until cases ebb. In spring 2021, students living in group housing got tested three times a week — that requirement is now weekly.

“I had to call Cornell Health myself and say, ‘I live in this house and someone tested positive, what should we do?’” Enders said. “If there’s no alternative in terms of online classes, then your home life is really the only place where you can manage your own level of risk.”

“We were given literally zero guidance by Cornell,” she continued. “I have no idea why this house full of 20-year-olds has to make public health decisions.”

But other students living off campus are isolating at home, sharing bathrooms with their COVID-positive roommates. John Ninia ’22 said he and three of his other six roommates have tested positive — more than half of his house is in quarantine. Now, one of his roommates who tested negative is staying in a hotel off campus, and another is spending as much time in his room as possible, according to Ninia.

Ninia said he decided to self-quarantine after he lost his sense of taste and smell — emailing his professors about his absence even before he received a positive test result. But with no universal remote class option, Ninia said he worried other Cornell students might not follow suit if they feel sick.

“It just incentivizes people to keep going to class if they might feel a little sick,” Ninia said. “We’re at a competitive school. Everyone wants to get ahead, and nobody wants to fall behind. Classes are the biggest concern. I’m gonna be going to my first day of classes on the second or third week of it.”

Ninia said Cornell sent out a Student Disability Services letter to his professors after he tested positive, writing that he wouldn’t be penalized for missing class. But Ninia and other students in isolation said they worried they’re falling behind on their coursework while Cornell doesn’t require professors to offer remote classes.

Only some of Ninia’s classes are being recorded, and he said doing school remotely mostly means following along on Canvas. Grabowski said attending class now largely consists of reading textbooks and reviewing lecture slides from her bedroom.

So far, she said only one of her professors is offering Zoom lectures. Under current University policy, it is up to faculty to figure out how to support students in isolation or quarantine — from uploading lectures from previous semesters to asking students to compile class notes.

“I feel behind. I’m pretty stressed,” Grabowski said. “I just feel like I’m going to feel so out of place next week.”

While most Cornell students have found themselves back to a packed campus, hopping from 1,000-person oceanography lectures to snaking Trillium lines, the worlds of isolated Cornellians have once again narrowed to their bedrooms — or to a vacant dorm or hotel room.

Grabowski has spent her days putting up pictures on her walls in between coursework to keep herself busy — and to keep her frustrations at bay.

“It just seems like the administration is being negligent,” Grabowski said. “It annoys me because they keep on this front that everything’s fine. They’re doing outdoor mask mandates, but they’re not doing what they could for the people who are in quarantine and isolation.”

LINK: **https://cornellsun.com/2021/09/06/as-cornell-reports-record-cases-students-miss-first-classes-bear-burdens-of-covid-policies/**

Brown University Pauses Indoor Dining, Limits StudentGatherings As COVID Cases Rise

September 15, 2021 at 8:43 am

Filed Under:Brown University, Coronavirus, Rhode Island News

PROVIDENCE, R.I. (AP) — Brown University has paused in-person dining and placed a limit of five people for undergraduate social gatherings in response to a recent rise in confirmed coronavirus cases on campus.

The Ivy League school had 82 confirmed positive COVID-19 tests, primarily among undergraduate students, in the past seven days, according to a statement Monday.

“The increase in positive asymptomatic test results is a reflection of the transmissibility of the delta variant, our significant increase in the number of tests conducted at Brown, and an increase in our student population, some of whom have been engaging with other students in multiple smaller groups outside the classroom, especially indoors without masks,” the school’s statement said.

Those testing positive generally remain asymptomatic and there are no indications of serious illness and no hospitalizations, the school said.

There is no evidence of spread in classrooms, and classes will continue, the school said.

The “short-term” restrictions also include increased undergraduate student testing from once to twice per week and an indoor mask requirement.

Brown requires vaccinations for students and employees.

LINK: **https://boston.cbslocal.com/2021/09/15/brown-university-covid-dining-stduents-gathering/**

Prashant Bhushan
(TRUE COPY)

Health Ministry chief says coronavirus spread reaching record heights

As over 10,000 new cases are diagnosed, Nachman Ash tells lawmakers he had hoped recent downward trend would continue

By **STUART WINER** 14 September 2021, 2:25 pm

Health Ministry Director-General Nachman Ash said Tuesday that the current wave of coronavirus infections is surpassing anything seen in previous outbreaks and that he is disappointed that a recent downward trend appeared to be reversing.

Ash's remarks via video call to the Knesset Constitution, Law, and Justice Committee came as Health Ministry figures showed that over 10,000 new COVID-19 cases were diagnosed the day before and that the positive test rate was climbing.

Pointing out that there is an average of 8,000 new infections each day, with occasional peaks over 10,000, he said, "That is a record that did not exist in the previous waves," including the massive third wave at the end of last year.

Ash expressed some pessimism, though he observed that, belying fears, there wasn't a large spike in infections following last week's Rosh Hashanah holiday — the Jewish New Year — or the opening of the school year at the beginning of the month.

After bringing daily infections down to little more than a dozen a day in June, Israel has been battling to control a resurgence of COVID-19 in what has been its fourth wave of infections since the start of the global pandemic.

"A week ago we were in a clear downward trend; in recent days we've been seeing that decline stop, and the virus reproduction number is [again] above 1," Ash said of the so-called R number, which indicates how many people each virus carrier will infect. Values above 1 show that the outbreak is growing, below 1 that it is shrinking.

"I hoped that we would see a clearer drop, but we are still not seeing it," he said.

Ash noted the number of seriously ill ranges between 670 and 700. Every day 70-80 new patients fall seriously ill, slightly fewer than in recent weeks.

The number of patients on ventilators has climbed in the past ten days from 150 to 190, while the number of those on the more critical ECMO machines rose from 23 to 31, he said.

Despite the numbers, Ash said that the so-called Green Pass restriction would be removed from open-air swimming pools, in part to help out parents searching for activities for their children during the holiday period when schools are closed. The holiday period, including the weeklong Sukkot festival, ends September 28.

The Green Pass enables only those who have been vaccinated against COVID-19, recovered from the disease, or recently tested negative for the virus to access most indoor public places, as well as crowded outdoor attractions. Since children below the age of 12 are not eligible for vaccination, they — if they're over the age of 3 — must get rapid virus tests to attend many recreation venues.

The Knesset meeting was convened to discuss the Green Pass system.

National coronavirus czar Salman Zarka, who also participated in the meeting, said that 50 percent of confirmed cases on Monday were children. He said that the Health Ministry was working on the assumption that it will in the future need to deal with a fifth wave of virus infections.

Zarka said that the ministry will prepare by continuing to use the Green Pass system, asserting that it helps prevent the virus spread, while noting that it would be eased as morbidity drops off.

"I hope that we will pass the month of September and stabilize in October," Zarka said. "Then we will take a fresh look at the policy."

Zarka said the ministry had urged the government to restrict large gatherings and ban events such as a major student festival in Eilat, crowds at soccer matches, and an annual pilgrimage by tens of thousands of Israelis to Uman, Ukraine, to visit the grave of a venerated rabbi. Officials feared that hundreds of pilgrims would return with the virus. Dozens of infected travelers have been caught with forged paperwork declaring they tested negative for COVID-19 before boarding planes home.

"The cabinet sees things differently from us and decided that the events can be held," Zarka said.

Health Ministry figures released Tuesday showed there were 10,556 new cases diagnosed the day before and 690 patients seriously ill with COVID-19.

The positivity rate from 178,000 tests for the virus was 5.93%, up from the 5.24% recorded on Sunday.

In total there were 83,952 active virus patients in the country. With the death of 18 people on Tuesday, the toll since the start of the pandemic last year reached 7,297.

The virus reproduction number, which is calculated to show the situation ten days earlier, was given as 1.01 for September 3. After weeks of steadily dropping, the "R rate" began to tick up again two weeks ago.

On Sunday, several ministers were overheard prior to a cabinet meeting saying that some coronavirus-related restrictions were only aimed at incentivizing vaccination, rather than driving down morbidity.

LINK:

https://www.timesofisrael.com/health-ministry-chief-says-coronavirus-spread-reaching-record-heights/

Prashant Bhushan
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Excerpt Comments & Opinion of Dr. Sanjay K. Rai, Professor at Department of Community Medicine at AIIMS, Delhi in Conversation with Girijesh Vashistha of Knocking News[1]

- The Best protection &possiblylifetime immunity only comes from "*Natural Immunity/Natural Infection*" i.e those who had have Covid19& recovered
- Death due to Covid19, among those who have acquired Natural Immunity is nearly zero & possibility of re-infection is rare
- *Vaccination* can cause harm orresult in adverse effect if done to those who have already acquired Natural Immunity & are also non-susceptible

Best Protection from Covid19 is from "Natural Infection" & Lifetime. Naturally Acquired Immunity has very low re-infection probability & near zero death rates

- *Immunity Passport* if need to be given should only be given to those who have acquired Natural immunity as only in them the possibility of re-infection & transmission is very low
- *Herd immunity* can only be provided by Natural Infection & not by Covid Vaccines

Vaccination can cause harm & result in adverse effects if administered to those who have Natural Immunity & are not Susceptible

- Vaccination can neither prevent infection nor transmission e.g. Some of the countries that had large population vaccinated like Seychelles &Israel, have had high infections despite vaccines. Also, Kerela etc.
- The immunity is not quite developed as much in case of vaccination than of Natural Infection
- There is no additional benefit, rather sheer waste of Country's resources in mass vaccination especially when majority population (As per ICMR, Sero Survey indicates approx. 68%) has already acquired NaturalImmunity
- Vaccinating in areas where virus is active is not beneficial but is only at places where virus has not reached
- Vaccination is only beneficial for those who are *susceptible*, but not in preventing infection but in only reducing its severity
- Despite vaccination done at such large scale, Case mortality rate did not come down& where it has come down, is because of natural herd immunity

Immunity Passports if at all should be given to those who have Natural Immunity as Vaccinated people can still get infection & can Transmit

- Natural Immunity & its importance is being ignored & seems to be vested interests
- There is no specific evidence that booster dose will increase protection
- Only the symptomatic should be tested&RT-PCR should not be done again & again. It is harassment to patients

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- [1]Uploaded on YouTube on 10th October 2021 https://www.youtube.com/watch?v=-btDk0eSi5U.
- E&OE

Prashant Bhushan

(TRUE COPY)

The Unvaccinated Are Looking Smarter Every Week

By Thomas T. Siler, M.D.

16 October, 2016

There is a massive propaganda push against those choosing not to vaccinate against COVID-19 with the experimental mRNA vaccines. Mainstream media, the big tech corporations, and our government have combined efforts to reward compliance and to shame and marginalize non-compliance. Their mantra says that this is a pandemic of the unvaccinated. Persons who choose not to vaccinate are characterized as unintelligent, selfish, paranoid people who don't read much and live in a trailer park in Florida (or Alabama, or Texas, or name your state). Never has there been such an effort to cajole, manipulate through fear, and penalize people to take an experimental medical treatment.

However, as time has passed with this pandemic and more data accumulates about the virus and the vaccine, the unvaccinated are looking smarter and smarter with each passing week. It has been shown now that the vaccinated equally catch and spread the virus. Vaccine side effect data continues to accumulate that make the risk of taking the vaccine prohibitive as the pandemic wanes. Oral and IV medications (flccc.net) that work early in the treatment of COVID-19 are much more attractive to take now as the vaccine risks are becoming known, especially because the vaccinated will need endless boosters every six months.

First, let's address the intelligence of the unvaccinated. Vaccine hesitancy is multi-factorial and has little to do with level of education or intelligence. Carnegie Mellon University did a study assessing vaccine hesitancy across educational levels. According to the study, what's the educational level with the most vaccine hesitancy? Ph.D. level! Those can't all have been awarded to liberal arts majors. Clearly, scientists who can read the data and assess risk are among the least likely to take the mRNA vaccines.

The claim that there's a pandemic of the unvaccinated is, therefore, patently untrue. As a retired nurse from California recently asked, "Why do the protected need to be protected from the unprotected by forcing the unprotected to use the protection that did not protect the protected in the first place?" If the vaccine works to prevent infection, then the vaccinated have nothing to worry about. If the vaccine does not prevent infection, then the vaccinated remain at some risk, and the unvaccinated would be less likely to choose a vaccine that does not work well.

The mRNA vaccine efficacy is very narrow and focused on the original alpha strain of COVID-19. By targeting one antigen group on the spike protein, it does help for the original alpha strain, but it is clear now it does not protect against Delta strain and is likely not protective against any future strains that might circulate. It also appears that the efficacy wanes in 4-6 months, leading to discussions about boosters.

Several authors have pointed out that vaccinating with a "leaky" vaccine during a pandemic is driving the virus to escape by creating variants. If the booster is just another iteration of the same vaccine, it likely won't help against the new strain but will, instead, produce evolutionary pressure on the virus to produce even more variants and expose us to more side effects. Why, then, is this booster strategy for everyone being pursued?

This vast Phase 3 clinical trial of mRNA vaccines in which Americans are participating mostly out of fear is not going well. It is abundantly clear for anyone advocating for public health that the vaccination program should be stopped. Iceland has just stopped giving the Moderna vaccine to anyone which is a good step in the right direction. Sweden, Denmark, and Finland have banned the Moderna vaccine for anyone under the age of 30.

VAERS, our vaccine adverse effect reporting system, showed at the beginning of this week 16,000 deaths, 23,000 disabilities, 10,000 MI/myocarditis, 87,000 urgent care visits, 75,000 hospital stays, and 775,000 total adverse events. The VAERS system is widely known to under-report events, with an estimated 90 to 99% of events going unreported there.

Eudravigilance, the European reporting system now associates 26,000 deaths in close proximity to administration of the vaccine. Whistleblower data from the CMS system (Medicare charts) showed close to 50,000 deaths in the Medicare group shortly after the vaccine.

An AI-powered tracking program called Project Salus also follows the Medicare population and shows vaccinated Medicare recipients are having worse outcomes week by week of the type consistent with Antibody Dependent Enhancement. This occurs when the vaccine antibodies actually accelerate the infection leading to worsening COVID-19 infection outcomes. Antibody Dependent Enhancement has occurred previously with trials of other coronavirus vaccines in animals. The CDC and the FDA are suppressing this data and no one who receives the vaccine has true informed consent.

The Rome declaration has 6,700 medical signatories attesting that the handling of the pandemic amounts to crimes against humanity for denying the best medical

treatment and continuing to advocate for harmful vaccines. The evidence is right in front of Americans to end the propaganda and mass mask psychosis.

The media narrative of perpetual fear is falling apart. Norway, Sweden, and Denmark have ended all COVID restrictions and are doing much better than the US, UK, and Israel, three countries that continue to vaccinate into the pandemic. Mexico, Guatemala, Indonesia, almost all of Africa, and parts of India have low vaccination rates and are doing much better than the US, something attributed to their managing the pandemic by using Ivermectin.

Over 500,000 people attended the Sturgis motorcycle rally in August and there was no super spread of COVID-19. Football season started in August and stadiums around the country are packed with 80,000 fans yelling and screaming with no masks. There have been no superspreader events, yet the students are forced to go back to masking in class. This makes no sense.

If the vaccine is so important why do our government leaders and illegal aliens not have to take it? Currently, 13 states that are Democratic with high vaccination rates have the highest "case" rates (using a faulty PCR test), while Republican states are all doing better. How does this happen?

It should be clear that the government has manipulated COVID to create perpetual fear, so we'll hand it our liberty. In this giant battle between our government and the unvaccinated, I hope enough people will refuse to comply so that we can unite to stop this madness.

I know this decision is very difficult for many people when it comes to losing their job. To the vaccinated, please don't take any boosters for you'll just be perpetuating the risk of side effects and new variants.

If we allow the government to decide this medical decision for us, it is a short step for the government to say it can decide other medical decisions for you, e.g., all persons over 75 never be resuscitated; people may have only three children (or two or one) with mandatory sterilization for women; or refusing the government's demands will see you denied health care.

Is this the totalitarian state you want to live in? If you are proudly vaccinated now and on the government side, what about the next government mandate, when you're on the other side, coerced into a decision you don't want, how will you feel then?

It is obvious that the government (with the Fauci subset), the media, and big tech, are trying to divide us and take away the freedoms we have enjoyed as Americans. I am praying that all who call themselves Americans can unite to end this medical

tyranny and regain a free America before it is too late. Peacefully resist and do not comply.

LINK:
https://www.americanthinker.com/articles/2021/10/the_unvaccinated_are_looking_smarter_every_week.html

Prashant Bhushan
(TRUE COPY)

Spain, Belgium and Italy restrict AstraZeneca Covid vaccine to older people
The Guardian

Thu 8 Apr 2021 11.22 BST

Italy, Spain and Belgium have joined other European countries in limiting the use of the Oxford/AstraZeneca vaccine to older age groups as the EU struggles to agree common guidelines to counter expected public hesitancy.

The European Medicines Agency (EMA) on Wednesday found a possible link between the vaccine and very rare cases of blood clots, although it said its benefits far outweighed the risks and did not announce any restrictions.

In Britain, the government's joint committee on vaccines and immunisation said healthy people aged 18 to 24 who were not at high risk of Covid should have the option of a different jab if one was available in their area.

Belgium's national and regional health ministers subsequently agreed to restrict the vaccine to the over-55s for a month, while Italy's health minister, Roberto Speranza, said late on Wednesday the shot should be offered only to those aged 60 and over.

Franco Locatelli, the head of the country's health council, said people who had already had the first dose of the AstraZeneca jab could proceed with the second, and officials stressed that while the shot was not recommended for under-60s, it was not prohibited.

After meeting regional health chiefs, Spain's health minister, Carolina Darias, also announced late on Wednesday that administration of the AstraZeneca vaccine would be temporarily suspended nationwide to people under the age of 60.

Spain's autonomous regions have given more than 2.1m first shots of the Anglo-Swedish shot under a patchwork of rules and at various paces. Authorities now have to decide whether to use a different vaccine for the second dose.

EU countries that have already imposed restrictions include Germany, which is limiting its use to under-60s and priority groups and has recommended that people under 60 who have had a first shot should receive a different second dose.

But countries are setting a range of age limits for the shot, with France restricting its use to people aged 55 and over, the Netherlands to those aged 60 and over, and Finland and Sweden to people aged 65 and over.

EU health ministers failed at an extraordinary meeting on Wednesday night to agree a coordinated approach despite a plea by Portugal, which holds the bloc's rotating presidency, to urgently seek common ground on the use of the vaccine.

"It is essential that we follow a coordinated European approach – an approach which does not confuse citizens, and that does not fuel vaccine hesitancy," the EU health commissioner, Stella Kyriakides, reportedly told ministers at the meeting.

The EMA said it received reports of 169 cases of the rare brain blood clot by early April, after 34m doses had been administered in the European Economic Area (EEA), adding that most occurred in women under 60 withintwo weeks of vaccination.

In Germany, Christian Bogdan, a member of the country's vaccine committee, said instances of the condition in women under 60 who had been given the AstraZeneca shot were 20 times higher than would normally be expected, representing what he called a "very clear risk signal".

Countries that have imposed age restrictions on the AstraZeneca vaccine now face the conundrum of what to do about younger people who have had a first dose. Some experts say different vaccines could work together to fight the virus because all target the same outer "spike" protein of the virus.

Germany has recommended that people under 60 who have had a first AstraZeneca shot should receive a different product for their second dose. Other countries are waiting for the results of a British trial launched in February to explore mixing doses of Pfizer and AstraZeneca vaccines.

France's top health advisory council is reportedly considering using mRNA vaccines such as those produced by Pfizer/BioNTech and Moderna as a second dose, but no formal decision has not been yet taken.

LINK : https://www.theguardian.com/society/2021/apr/08/spain-belgium-and-italy-restrict-astrazeneca-covid-vaccine-to-older-people

Prashant Bhushan
(TRUE COPY)

NIH orders $1.67M study on how COVID-19 vaccine impacts menstrual cycle

NY Post

September 7, 2021 5:28pm

The National Institutes of Health has announced a $1.67 million study to investigate reports that suggest the COVID 19 vaccine may come with an unexpected impact on reproductive health.

It's been a little over six months since the three COVID-19 vaccines in the US - Pfizer, Moderna and Johnson & Johnson - became widely available to all adults. But even in the early days of vaccine rollout, some women were noticing irregular periods following their shots, as reported first by the Lily in April.

Shana Clauson, 45, spoke to the Washington Post's women's news site at the time, and again this week, about her experience after getting the jab- revealing that her period arrived earlier and heavier than what she considers normal. She was one of many who gathered on social media to share what they were seeing.

"Is this not being discussed, or is it even being looked at or researched because it's a woman's issue?" Clauson speculated to the Lily last spring.

It would appear that the NIH heard Clauson and others' reports, as they announced on Aug. 30 that they intended to embark on just such research-aiming to incorporate up to half a million participants, including teens and transgender and nonbinary people.

Researchers at Boston University, Harvard Medical School, Johns Hopkins University, Michigan State University and Oregon Health and Science University have been enlisted to embark on the study, commissioned by the NIH's National Institute of Child Health and Human Development (NICHD) and the Office of Research on Women's Health.

The approximately yearlong study will follow initially unvaccinated participants to observe changes that occur following each dose. More specifically, some groups will exclude participants on birth control or gender-affirming hormones, which may have their own impact on periods.

Our goal is to provide menstruating people with information, mainly as to what to expect, because I think that was the biggest issue: Nobody expected it to affect the menstrual system, because the information wasn't being collected in the early

vaccine studies," said NICHD director Diana Bianchi in a statement to the Lily-reportedly crediting their early coverage for helping to make the NIH aware.

The NIH suggests that changes to the menstrual cycle could arise out of several of life's circumstances during a pandemic-the stress of lifestyle changes or possibly contending with illness. Moreover, the immune and reproductive systems are intrinsically linked, and the notion that the immune-boosting vaccine may disrupt the typical menstrual cycle is plausible, as demonstrated by previous studies concerning vaccine uptake.

It's also worth noting the vaccine does not cause infertility and the Centers for Disease Control and Prevention recommends the shot even for pregnant women.

As changes to the menstrual cycle are "really not a life and death issue," explained Bianchi, the Food and Drug Administration - fast-tracking their work-prioritized only the most critical risks associated with the COVID-19 vaccine.

The NIH, too, pulled together the initiative at breakneck speed. Funding for such a study would typically take years to see approval.

"We were worried this was contributing to vaccine hesitancy in reproductive-age women," said Bianchi.

LINK: **https://nypost.com/2021/09/07/nih-to-study-how-covid-19-vaccine-impacts-menstrual-cycle/**

Prashant Bhushan
(TRUE COPY)

Ontario now recommending against Moderna vaccine for men 18-24-years old

Anthony Furey, Toronto Sun

Sep 29, 2021

The Ontario government is now recommending males aged 18 to 24 take Pfizer over Moderna as their COVID-19 vaccination due to the number of young men who have experienced myocarditis after getting the vaccine.

This comes after public health officials determined there is a 1 in 5,000 risk of myocarditis — a form of heart inflammation — following a second dose of the Moderna vaccine.

For any young men in that age bracket who received Moderna as their first dose and have not yet received a second dose, the government recommends they go with Pfizer. However, if any 18 to 24 year old males still wish to receive Moderna, the government says "they can continue to do so with informed consent."

The risk of myocarditis for this demographic in Pfizer is 1 in 28,000, according to government officials.

"The majority of reported cases have been mild with individuals recovering quickly, normally with anti-inflammatory medication," explains a guidance document released by the government. "Symptoms have typically been reported to start within one week after vaccination, more commonly after the second dose."

The number of young males who have been admitted to the ICU because of this side effect is "under 10," according to a government source.

While there are reports of myocarditis in Ontario among both males and females in all age brackets, the incidence rate among young males receiving their second Moderna shot was substantially higher than other categories.

This development comes after a Public Health Ontario report released last month showed over half of the province's approximately 200 cases of hospitalizations for myocarditis following mRNA vaccination were in people under the age of 25.

Prashant Bhushan
(TRUE COPY)

Sweden, Denmark pause Moderna COVID-19 vaccine for younger age groups

Reuters
October 6, 2021, 11:45 PM IST

Sweden and Denmark said on Wednesday they are pausing the use of Moderna's (MRNA.O) COVID-19 vaccine for younger age groups after reports of possible rare cardiovascular side effects.

The Swedish health agency said it would pause using the shot for people born in 1991 and later as data pointed to an increase of myocarditis and pericarditis among youths and young adults that had been vaccinated. Those conditions involve an inflammation of the heart or its lining.

"The connection is especially clear when it comes to Moderna's vaccine Spikevax, especially after the second dose," the health agency said, adding the risk of being affected was very small.

Shares of Moderna fell 4.9%, or $16.08, to $316.11 in afternoon trading.

A Moderna spokesperson said in an email the company was aware of the decisions by regulators in Denmark and Sweden to pause the use of its vaccine in younger individuals because of the rare risk of myocarditis and or pericarditis.

"These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. The risk of myocarditis is substantially increased for those who contract COVID-19, and vaccination is the best way to protect against this."

According to one U.S. study that has yet to undergo peer review young males under 20 are up to six times more likely to develop myocarditis after contracting COVID-19 than those who have been vaccinated.

Denmark said that, while it used the Pfizer/BioNTech vaccine as its main option for people aged 12-17 years, it had decided to pause giving the Moderna vaccine to people below 18 according to a "precautionary principle".

"In the preliminary data ... there is a suspicion of an increased risk of heart inflammation, when vaccinated with Moderna," the Danish Health Authority said in a statement.

It referred to data from a yet unpublished Nordic study, which would now be sent to the European Medicines Agency (EMA) for further assessment. Final data was expected within a month, it added.

Sweden and Denmark said they now recommended the Comirnaty vaccine, from Pfizer/BioNTech (PFE.N), instead.

The Danish Health Authority said it had made the decision even as "heart inflammation is an extremely rare side effect that often has a mild course and goes away on its own".

The EMA's safety committee concluded in July that inflammatory heart conditions can occur in very rare cases following vaccination with Comirnaty or Spikevax, more often in younger men after the second dose.

The benefits of shots based on so-called mRNA technology used by both Moderna and Pfizer-BioNTech in preventing COVID-19 continue to outweigh the risks, regulators in the United States, EU and the World Health Organization have said.

Data suggests reported cases of rare heart inflammation are relatively higher after Moderna's vaccine compared with the Pfizer/BioNTech shots, Canadian health officials said last week.

Although both vaccines are based on mRNA technology, the Pfizer shot contains 30 micrograms of vaccine per dose compared with 100 micrograms in the Moderna vaccine.

Data from one of two U.S. vaccine safety monitoring databases has also suggested that Moderna's vaccine may carry a higher risk of myocarditis among young people.

The vaccine is not approved for people under age 18 in the United States.

Norway already recommends the Cominarty vaccine to minors and said on Wednesday that it was reiterating this.

"Men under the age of 30 should also consider choosing Cominarty when they get vaccinated," GeirBukholm, head of infection control at the Norwegian Institute of Public Health, said in a statement.

A Finnish health official said Finland expected to publish a decision on Thursday.

The EMA approved the use of Comirnaty in May, while Spikevax was given the nod for children over 12 in July.

LINK: **https://www.reuters.com/business/healthcare-pharmaceuticals/sweden-pauses-use-moderna-covid-vaccine-cites-rare-side-effects-2021-10-06/**

Prashant Bhushan
(TRUE COPY)

Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine
Yahoo News

EssiLehto
October 7, 2021

HELSINKI (Reuters) -Finland on Thursday paused the use of Moderna's COVID-19 vaccine for younger males due to reports of a rare cardiovascular side effect, joining Sweden and Denmark in limiting its use.

Mika Salminen, director of the Finnish health institute, said Finland would instead give Pfizer's vaccine to men born in 1991 and later. Finland offers shots to people aged 12 and over.

"A Nordic study involving Finland, Sweden, Norway and Denmark found that men under the age of 30 who received Moderna Spikevax had a slightly higher risk than others of developing myocarditis," he said.

Swedish and Danish health officials had announced on Wednesday they would pause the use of the Moderna vaccine for all young adults and children, citing the same unpublished study.

Norwegian health officials reiterated on Wednesday that they recommended men under the age of 30 opt for Pfizer's vaccine.

The Finnish institute said the Nordic study would be published within a couple of weeks and preliminary data had been sent to the European Medicines Agency (EMA) for further assessment.

The EMA's safety committee concluded in July that such inflammatory heart conditions could occur in very rare cases following vaccination with Spikevax or the Pfizer/BioNTech Comirnaty jab, more often in younger men after the second dose.

Regulators in the United States, EU and the World Health Organization have however stressed that the benefits of shots based on the mRNA technology used by Moderna and Pfizer-BioNTech in preventing COVID-19 continue to outweigh the risks.

A Moderna spokesperson said late on Wednesday it was aware of the decisions by the Swedish and Danish regulators.

"These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. The risk of myocarditis is substantially increased for those who contract COVID-19, and vaccination is the best way to protect against this."

Italy's Health Minister Roberto Speranza told reporters Italy was not planning to suspend the Moderna vaccine and said European countries should work together more closely to coordinate better.

"We have to trust international authorities, starting with EMA which is our reference agency and has expressed very clear judgments on the matter," he said.

LINK: **https://news.yahoo.com/finland-pauses-moderna-covid-19-073018651.html?guccounter=1**

Prashant Bhushan
(TRUE COPY)

Stop the use of the Moderna vaccine in Iceland in the light of new data

VISIR

October 8, 2021 2:55 PM

LINK: https://www.visir.is/g/20212167101d

The Chief Epidemiologist has decided that the Moderna vaccine against Covid-19 will not be used in Iceland while further information is obtained on the safety of the vaccine during booster vaccinations.

An announcement states that in recent days there has been data from the Nordic countries on the increased incidence of myocarditis and pericarditis after vaccination with the Moderna vaccine in addition to the Pfizer / BioNTech vaccine.

According to the epidemiologist, the Moderna vaccine has for the past two months been used almost exclusively here for stimulation vaccinations after the Janssen vaccine and after two-dose vaccinations for the elderly and immunocompromised. Very few individuals are said to have received the second dose of the basic vaccine that started with Moderna.

Sufficient supply of Pfizer

In Sweden, the use of Moderna has been restricted to individuals born before 1991. In Norway and Denmark, it has been emphasized that the Pfizer vaccine is recommended rather than Moderna for 12 to 17 year olds.

In Iceland, only the Pfizer vaccine has been recommended for primary vaccination at 12 to 17 years of age since the vaccination of the age group began.

According to the Chief Epidemiologist, the decision was made to wait with the use of Moderna as there is a sufficient supply of Pfizer vaccine for booster vaccinations of defined priority groups and basic vaccinations of those who have not yet been vaccinated.

Prashant Bhushan
(TRUE COPY)

Slovenia suspends Johnson & Johnson vaccine after death

RTE News

Wednesday, 29 Sep 2021 22:57

Slovenia has temporarily suspended use of the Johnson & Johnson (Janssen) Covid-19 vaccine after a 20-year-old woman died of a brain hemorrhage and blood clots just days after getting the jab.

"The health ministry has called on the Public Health Institute to temporarily suspend vaccinations with the Janssen vaccine until all details related to this case are cleared up," Health Minister JanezPoklukar told a news conference in Ljubljana.

Experts advising the government recommended the suspension after learning that "there could be an undesired link between the death and the vaccination," said BojanaBeovic, who heads the expert group.

Media reported the woman had been hospitalised on Monday in severe condition, only days after receiving a Johnson & Johnson jab.

One death has already been confirmed as linked to the vaccine in Slovenia, where more than 120,000 people have received it.

Some 47% of the country's two million people have been fully vaccinated, one of the lowest levels in the European Union.

In an attempt to boost numbers, the government announced earlier this month that all public employees would need to be vaccinated or recovered from Covid-19 to continue working from 1 October.

Demand for the Johnson & Johnson vaccine has increased over the last weeks because it is the only one that does not require two jabs.

The European Medicines Agency said in June that EU states must use all the vaccine options available to fight the coronavirus pandemic, and it was too early to tell if a particular type was best.

The comments came as several countries limited the use of so-called viral vector jabs such as AstraZeneca and Johnson & Johnson due to a link with rare blood clots, and opted instead for Messenger RNA vaccines like Pfizer and Moderna.

The regulator has currently approved those four vaccines for use in the EU.

France to extend state of emergency until next summer

France plans to extend its state of emergency until next year's summer to deal with the continuing coronavirus epidemic, government spokesman Gabriel Attal has said.

"What we will propose to the parliament is to maintain for several more months, until the summer, the possibility of using it", Mr Attal told reporters after a cabinet meeting when asked about the state of emergency and use of a health pass to gain access to venues such as restaurants, bars and cinemas.

This would mean that the government would keep the power to extend or reinstate restrictive measures such as lockdowns, limits on crowd movements and the health pass that currently is required until 15 November.

Singapore's health ministry has reported 2,268 new coronavirus cases, the highest since the beginning of the pandemic.

The country also recorded eight new deaths due to the disease.

A recent rise in cases after the relaxation of some Covid-19 measures has prompted Singapore to pause further reopening.

More than 80% of its population has been vaccinated against the virus.

From this week, Singapore tightened some curbs such as limiting social gatherings to two people and making work from home a default.

US CDC calls for increased vaccinations among pregnant people

The US Centers for Disease Control and Prevention have issued a health advisory to increase Covid-19 vaccinations among people who are pregnant, recently pregnant or trying to become pregnant, to prevent serious illness and deaths.

The CDC said its data showed only 31% of pregnant people have been vaccinated against the virus.

LINK: **https://www.rte.ie/news/coronavirus/2021/0929/1249718-covid-global/**

Prashant Bhushan
(TRUE COPY)

AEFI reporting lacks seriousness: Sr virologist

The Times of India

Aug 24, 2021, 04:00 IST

Pune: Virologist Dr Jacob John on Monday said the overall methodology of reporting Adverse Events Following Immunisation after the rollout of Covid-19 vaccines in India lacked professionalism and seriousness to know the reality.

"There is a state mechanism for AEFI (Adverse Events Following Immunisa monitoring under the Universal Immunisation Programme (UIP) and it seems to be the 'active' part in AEFI monitoring. By its own admission, the Central AEFI Committee announced that the state AEFI monitoring system was not functioning satisfactorily," Dr John told TOI, against the backdrop of alleged under-reporting of adverse events by many states.

The AEFI Committee relies on adverse event reports received on the COWIN web platform. Dr John said this was a passive system as it might represent a very small but unknown proportion of all serious AEFI.

The AEFI Committee released its last report on July 18. Earlier, it had come out with reports on April 2, May 17 and July 12. Dr John said the committee apparently made its own assessments as to what was serious among the reported cases, what was vaccine-related and what was the cause of death. He pointed out that one report had identified a death due to serious AEFI and diagnosed anaphylaxis. But anaphylaxis was an eminently treatable condition and death due to anaphylaxis spoke of incompetence of the vaccination centre and the local healthcare service, he stressed.

In a few other reports, a large number of serious AEFI cases were attributed to anxiety. Dr John said that was "suspect" because anxiety was not serious AEFI.

Dr John said of the 498 serious AEFI in a review, a total of 26 cases of blood clotting were reported, none associated with death. "Blood clotting and no death suggests poor follow-up or outright hiding of death. All these were reported after administering one particular vaccine. But that was not followed up with detailed instructions to all vaccination centres on how to diagnose clotting very early so that it can be properly treated to save lives," said Dr John, the former head of clinical virology department of Christian Medical College.

Public health researcher Dr AnantBhan said AEFI data collection, analysis, reporting and action being taken on them was extremely important, especially because these vaccines were still under emergency use authorisation. "It is also

critical because new vaccines to be introduced might not have any or limited local data on safety and efficacy," he said, stressing on efficient AEFI surveillance protocols.

Another public expert, R Jotkar, said AEFI data on COWIN was shown as 0.006%. "If all adverse events are being reported needs to be monitored at the state-level. It is likely people may ignore reporting in instance of minor AEFI, leaving only major AEFI being captured in the system. The collation of AEFI from secondary sources to the CoWIN system might largely be uneventful," said Jotkar.

LINK: **https://timesofindia.indiatimes.com/city/pune/aefi-reporting-lacks-seriousness-sr-virologist/articleshow/85576992.cms**

Prashant Burshan
(TRUE COPY)

ANNEXURE: AA19

GOVERNOR GREG ABBOTT

October 11, 2021

FILED IN THE OFFICE OF THE
SECRETARY OF STATE
4:30pm O'CLOCK
OCT 11 2021
Secretary of State

Mr. Joe A. Esparza
Deputy Secretary of State
State Capitol Room 1E.8
Austin, Texas 78701

Dear Deputy Secretary Esparza:

Pursuant to his powers as Governor of the State of Texas, Greg Abbott has issued the following:

> Executive Order No. GA-40 relating to prohibiting vaccine mandates, subject to legislative action.

The original executive order is attached to this letter of transmittal.

Respectfully submitted,

Gregory S. Davidson
Executive Clerk to the Governor

GSD/gsd

Attachment

Executive Order

BY THE
GOVERNOR OF THE STATE OF TEXAS

Executive Department
Austin, Texas
October 11, 2021

EXECUTIVE ORDER
GA 40

Relating to prohibiting vaccine mandates, subject to legislative action.

WHEREAS, I, Greg Abbott, Governor of Texas, issued a disaster proclamation on March 13, 2020, certifying under Section 418.014 of the Texas Government Code that the novel coronavirus (COVID-19) poses an imminent threat of disaster for all Texas counties; and

WHEREAS, in each subsequent month effective through today, I have renewed the COVID-19 disaster declaration for all Texas counties; and

WHEREAS, I have issued a series of executive orders aimed at protecting the health and safety of Texans, ensuring uniformity throughout Texas, and achieving the least restrictive means of combatting the evolving threat to public health; and

WHEREAS, COVID-19 vaccines are strongly encouraged for those eligible to receive one, but must always be voluntary for Texans; and

WHEREAS, I issued Executive Orders GA-35, GA-38, and GA-39 to prohibit governmental entities and certain others from imposing COVID-19 vaccine mandates or requiring vaccine passports; and

WHEREAS, in yet another instance of federal overreach, the Biden Administration is now bullying many private entities into imposing COVID-19 vaccine mandates, causing workforce disruptions that threaten Texas's continued recovery from the COVID-19 disaster; and

WHEREAS, countless Texans fear losing their livelihoods because they object to receiving a COVID-19 vaccination for reasons of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19; and

WHEREAS, through Chapter 161 of the Texas Health and Safety Code, as well as other laws including Chapters 38 and 51 of the Texas Education Code, the legislature has established its primary role over immunizations, and all immunization laws and regulations in Texas stem from the laws established by the legislature; and

WHEREAS, the legislature has taken care to provide exemptions that allow people to opt out of being forced to take a vaccine for reasons of conscience or medical reasons; and

WHEREAS, I am adding this issue to the agenda for the Third Called Session of the legislature that is currently convened so that the legislature has the opportunity to consider this issue through legislation; and

WHEREAS, I will rescind this executive order upon the effective date of such legislation;

NOW, THEREFORE, I, Greg Abbott, Governor of Texas, by virtue of the power and authority vested in me by the Constitution and laws of the State of Texas, do hereby order the following on a statewide basis effective immediately:

1. No entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19. I hereby suspend all relevant statutes to the extent necessary to enforce this prohibition.

2. The maximum fine allowed under Section 418.173 of the Texas Government Code and the State's emergency management plan shall apply to any "failure to comply with" this executive order. Confinement in jail is not an available penalty for violating this executive order.

3. This executive order shall supersede any conflicting order issued by local officials in response to the COVID-19 disaster. Pursuant to Section 418.016(a) of the Texas Government Code, I hereby suspend Sections 418.1015(b) and 418.108 of the Texas Government Code, Chapter 81, Subchapter E of the Texas Health and Safety Code, and any other relevant statutes, to the extent necessary to ensure that local officials do not impose restrictions in response to the COVID-19 disaster that are inconsistent with this executive order.

This executive order does not supersede Executive Orders GA-13, GA-37, GA-38, or GA-39. This executive order shall remain in effect and in full force unless it is modified, amended, rescinded, or superseded by the governor. This executive order may also be amended by proclamation of the governor.

Given under my hand this the 11th day of October, 2021.

Greg Abbott

GREG ABBOTT
Governor

ATTESTED BY:

JOE A. ESPARZA
Deputy Secretary of State

FILED IN THE OFFICE OF THE SECRETARY OF STATE
4:30pm O'CLOCK
OCT 11 2021

Prashant Bhushan
(TRUE COPY)

Vaccine mandate for public employees in Slovenia blocked

RTE News

Thursday, 30 Sep 2021 18:15

Slovenia's Constitutional Court has blocked a government plan to make coronavirus vaccines mandatory for public employees, hours before it was due to come into force.

The government had planned to require around 31,000 people including civil servants, policemen and soldiers to either be vaccinated or to have recovered from Covid-19 in order to continue working.

The mandate was due to come into effect tomorrow, but in response to a complaint against the measure brought by the police officers' union the court decided to block its implementation.

In its decision the court said that "despite the very serious epidemic situation", it considered that "implementing the potentially unconstitutional (measure) ... would have worse consequences than delaying implementation".

The block on the mandate will remain in place until the court rules definitively on the complaint brought by the police union, but no date has been fixed for this.

Public Administration Minister BostjanKoritnik told reporters that he "regrets the court's decision but will absolutely carry it out".

He insisted the vaccine mandate was aimed at "ensuring safer working conditions in the premises under the government's responsibility".

Under the measure employees had faced losing their jobs if they rejected vaccination and their position did not allow them to work from home.

Slovenia has vaccinated just 45% of its two million people, one of the lowest levels in the European Union.

Rising case numbers have pushed officials to introduce new measures, including a form of health pass that must be shown in workplaces and shops.

Health authorities say those measures have contributed to a steep increase in vaccinations.

An increasing number of countries have taken steps to boost their vaccination rates, including France and Italy where health workers have to be inoculated.

A Covid-19 outbreak within Disney's stage show Aladdin prompted an 11th-hour cancellation of last night's performance in New York.

The production had opened just 24 hours earlier, joining the return of Broadway's biggest musicals from a pandemic-induced hiatus.

In a notice posted on Twitter shortly before the curtain was due to go up, producers said testing protocols had detected an unspecified number of "breakthrough" infections among vaccinated members of the Aladdin company at The New York Amsterdam Theatre.

"Because the wellness and safety of our guests, cast, and crew are our top priority, tonight's performance, Wednesday, 29 September, is cancelled," the tweet said, adding that tickets would be refunded at their points of purchase.

It added that the status of future performances of Aladdin, based on Disney's 1992 animated hit film, would be announced today.

A number of Broadway's leading shows, among them Hamilton and The Lion King, reopened earlier this month, 18 months after the Covid-19 crisis forced an unprecedented shutdown of New York City's theatre community. Aladdin had just joined the fray on Tuesday.

Under health and safety rules agreed between theatre unions and producers, cast and crew members for shows are required to provide proof of vaccination or a valid exemption in order to work, and must be tested for the coronavirus every three days.

According to the New York Times, yesterday's cancellation was the first and only one confirmed for a reopened Broadway production since Springsteen on Broadway kicked off the industry's return in June.

Covid-19 cases in Australia's Victoria state have surged to record levels despite Melbourne, the state capital, being stuck in a hard lockdown for nearly two months as officials race to vaccinate the population before easing restrictions.

A total of 1,438 new infections were reported, the majority in Melbourne, eclipsing the previous daily high of 950. Five new deaths were also recorded in the state.

Australia's largest cities, Sydney and Melbourne, and the capital Canberra are in a weeks-long lockdown to combat a third wave of infections fuelled by the fast-moving Delta variant.

Authorities have ditched a Covid-zero strategy and are looking at higher vaccination rates as their exit strategy from lockdowns.

The record cases in Victoria come as the federal government decided to phase out its emergency financial support for businesses impacted by the lockdowns, in line with its plan to end support to virus-impacted employees.

Treasurer Josh Frydenberg said the temporary payments will stop once 80% of the adult population in states and territories becomes fully vaccinated.

But Victoria's businesses will receive a fresh €1 billion support from the federal government through the next six weeks at which point the state should hit that dosage target, from around 50% now.

"We can't eliminate the virus, we need to learn to live with it in a Covid-safe way", Mr Frydenberg said in a statement.

Australian Prime Minister Scott Morrison has been pressing all states and territories to begin living with the virus once full inoculations reach 70%-80% but Queensland and Western Australia, largely Covid-free, flagged they may delay their reopening.

Despite the latest Delta outbreaks, total cases in Australia stand at around 104,000 and deaths at 1,283, well below other comparable nations.

Egypt has received 1.6 million doses of the Covid-19 vaccine produced by Pfizer as a gift from the United States as part of the COVAX initiative, the first batch of a total of five million doses, the country's health ministry said in a statement.

Egypt has been quickly accumulating a stock of vaccines for its population of over 100 million, having already received vaccines produced by AstraZeneca, Sinopharm, Sputnik and Johnson & Johnson, as well as Sinovac, which it is also producing locally.

Germany supplied a total of 2.3 million doses to Egypt over two days last week, the Egyptian health ministry said.

The COVAX facility, backed by the World Health Organization and the Global Alliance for Vaccines and Immunization (GAVI), has delivered over 301 million doses to 142 countries.

The Beijing Winter Olympics in February next year will be held without overseas spectators and athletes must be fully vaccinated against coronavirus or face 21 days' quarantine, the International Olympic Committee said.

The measures, which do allow spectators who are living in mainland China, were revealed with the Games just four months away and after the Tokyo 2020 Olympics similarly juggled with how to go ahead safely during the pandemic.

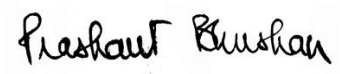
The Tokyo Games, which were postponed by a year because of the health crisis, mostly took place without any spectators to prevent infections.

Another difference from Tokyo will be that all participants must be vaccinated or will need to do a 21-day quarantine on arrival in the Chinese capital.

Athletes who can provide a "justified medical exemption" will have their cases considered.

All attendees will enter a strict "bubble" as soon as they land that covers Games-related areas and stadiums as well as accommodation, transport, catering and the opening and closing ceremonies.

LINK: **https://www.rte.ie/news/world/2021/0930/1249811-global-virus-latest/**



(TRUE COPY)

Federal appeals court blocks NYC teacher vaccine mandate

The Hill

BY JORDAN WILLIAMS - 09/25/21 03:53 PM EDT

A federal appeals court blocked New York City's coronavirus vaccine mandate late Friday evening, dealing a blow to the city days before the mandate goes into effect.

The 2nd Circuit Court of Appeals granted an expedited injunction on Friday blocking the city from mandating that all public school employees submit proof of their first coronavirus vaccine dose by Monday.

The court referred the case to a three-judge panel on an expedited basis.

New York City Mayor Bill de Blasio (D) said in late August that all of the city's public school teachers and staff would need to have their first dose by Sept. 27. There was no alternative option for regular testing.

A group of New York City public school employees sued earlier this month to block the mandate, arguing that their rights to due process and equal protection were violated. The complaint specifically alleged that the order violated their right to pursue their profession.

On Thursday, U.S. District Judge Brian Cogan upheld the mandate, prompting the plaintiffs to quickly appeal the decision.

About 82 percent of the city's roughly 149,000 public school employees are vaccinated, the agency told The Hill, including 88 percent of roughly 78,000 teachers and 95 percent of roughly 1,600 principals.

Danielle Filson, press secretary for the New York City Department of Education [DOE], said in a statement to The Hill that the agency is "confident our vaccine mandate will continue to be upheld once all the facts have been presented, because that is the level of protection our students and staff deserve."

"Over 82 percent of DOE employees have been vaccinated and we continue to urge all employees to get their shot by September 27," Filson said.

Prashant Bhushan

(TRUE COPY)

BREAKING: Judge grants temporary injunction preventing vaccine mandates for city employees

By WCJB Staff

Published: Sep. 23, 2021 at 12:17 AM GMT+5:30

GAINESVILLE, Fla. (WCJB) - A Circuit Court judge has issued a temporary injunction preventing the City of Gainesville from requiring a COVID-19 vaccine for employees or terminating employees that do not get the vaccine.

Judge Monica Brasington of the Eighth Judicial Circuit Court issued the ruling.

In her ruling, Judge Brasington stated the city did not present any evidence that the vaccine mandate serves "a compelling interest through the least restrictive means," and that the burden is on the city to prove the mandate is in the best interest of the public.

This injunction is a temporary measure until the courts are able to reach a decision on the vaccine mandate enacted by the city.

Attorney Jeff Childers is representing 200 city employees in a lawsuit who are in opposition to the mandate.

Governor Ron DeSantis previously announced a $5000 fine for any government entity requiring vaccines for its employees.

A date has not been set for the next court hearing about the mandate.

LINK: **https://www.wcjb.com/2021/09/22/breaking-judge-grants-temporary-injunction-preventing-vaccine-mandates-city-employees/**

Prashant Bhushan
(TRUE COPY)

Covid passport policy lacks scientific evidence base

UK Parliament

9 September 2021

The Public Administration and Constitutional Affairs Committee publishes the Government's response to the Committee's report on Covid-status certification released on 12 June.

Covid passports are being introduced for entry to some venues, including nightclubs and live sporting events, to control the spread of the virus according to the Government. However, new analysis and a lack of evidence provided by the Government in its response to the Committee's report casts doubt on whether this will work in practice.

Citing the diminishing benefits of a certification system as more and more people get vaccinated, the Committee's report demanded that the Government provide scientific evidence backing-up its claims that requiring Covid passports was necessary to reopening the economy and society if it pressed ahead with plans to implement them. Doing so through the publication of the public health case, cost-benefit analyses, and modelling of the potential impacts would be essential to public understanding and acceptance of the system, the report said.

The Government failed to give any such evidence in its response.

Added to this, the latest analysis by Public Health England (PHE) found that although being fully vaccinated protects against infection and severe symptoms, it unlikely to do much to stop the spread of the virus if people become infected. Jabbed and unjabbed individuals carry similar amounts of the virus. Researchers call this having a similar viral load.

Concerns over viral load of the Delta variant appeared in Sage meeting minutes from 22 July. Sage, the Government's scientific advisory panel, warned that there is 'limited vaccine effect against onward transmission' of the variant. Given that this meeting was held before the Government responded to the Committee's report, the Committee has severe concerns about the way in which this policy has been developed and kept under consideration.

Chair's comments

Reacting to the Government's response, Committee Chair William Wragg said,

"We have often heard throughout the pandemic that the Government will follow the science, but when afforded the opportunity to provide it on Covid passports, it has failed to do so. All we have is a flimsy claim that there is a public health case, but without any foundation for the claim to stand on."

"With recent analysis suggesting that vaccinated people carry as much of the virus as the unvaccinated into any setting, the disappointing lack of any scientific basis for the Government's decision to go ahead could reasonably lead people to conclude that there is in fact no such basis. If the real goal is to drive vaccine uptake, then it is a deeply cynical approach that will be counterproductive."

"Following through on such a costly, discriminatory and, potentially, ineffective policy will have consequences for trust in and acceptance of the Government's measures to tackle the pandemic. It's surely either time to prove how this'll work or to put an end to it."

LINK: **https://committees.parliament.uk/committee/327/public-administration-and-constitutional-affairs-committee/news/157355/covid-passport-policy-lacks-scientific-evidence-base/**

Prashant Bhushan

(TRUE COPY)

Galicia courts overturn regional government requirement for Covid passports in bars and restaurants

Spanish News Today

Published on: 12:08:2021

Galicia courts overturn regional government requirement for Covid passports in bars and restaurants Covid certificates are no longer required for entry into hostelries and nightlife venues in Galicia as the regional government falls foul of the courts for the first time. The High Court in the north-western Spanish region of Galicia has overturned regional government measures to make Covid passports obligatory for entry into bars, restaurants and nightlife venues, renewing the debate over the uses for which the health and vaccination certificates should be used.

The Spanish government has already resisted pressure to introduce such measures on the grounds that this is not the purpose for which the EU passport scheme was devised, and instead prioritizes vaccination as the key strategy in combating the coronavirus pandemic. The reason given by the court for overturning the requirement in Galicia, though, is that no approval was ever given by the court in the first place, and that the regulation therefore lacks validity.

It seems that the Galicia government only requested approval for other measures presented on July 21, but not for the Order issued on July 22 in which the obligation to present Covid passports was contained. This "anomaly" effectively nullifies the second Order, according to the ruling. Since then various groups have expressed their opposition to policy, including Lugo Monumental in the city of Lugo and the hostelries association of Santiago de Compostela.

It had been the regional government's intention to drop the requirement in any case on August 14 in both Santiago and Orense due to decreasing Covid incidence rates, but the measure was to be maintained in the cities of A Coruña, Ferrol, Lugo, Pontevedra and Vigo as well as other municipalities. This will now no longer be possible as the regional government has fallen foul of the High Court for the first time in its management of the pandemic in Galicia.

LINK: https://spanishnewstoday.com/galicia-courts-overturn-regional-government-requirement-for-covid-passports-in-bars-and-restaurants_1631248-a.html

Prashant Bhushan
(TRUE COPY)

Andalusian justice rejects the requirement of the covid certificate to enter the nightclubs
El Pais

07 AUG 2021 - 22:17 CEST

The Contentious-Administrative Chamber of the TSJA, based in Granada, in the wake of the high courts of the Canary Islands and Cantabria, has rejected the obligation to present the covid certificate or a negative antigen test to enter nightlife venues that the Junta de Andalucía had proposed last Monday. The magistrates understand that the measure affects the right to privacy and non-discrimination and that it does not meet the criteria of suitability or necessity.

The Chamber considers that this requirement could affect the right to privacy "insofar as it implies the need to show data related to health, considered, in accordance with European regulations, as sensitive" and with the principle of non-discrimination because "establishes a differentiated treatment for access to such premises, based on the possession or not of the aforementioned certificate "

The magistrates understand, however, that these fundamental rights affected "are not of great importance" because the accreditation of being vaccinated or having passed the disease "does not seem to seriously condition the right to personal privacy" and as there is a greater percentage of the population that is vaccinated, the requirement "affects a much lower percentage of people than could benefit from being already vaccinated." However, the court does understand that the measure would affect the "suitability and necessity" of its application.

In this sense, the TSJA maintains that "it is not an ideal measure to the required degree", because it establishes the compatibility of the requirement of the COVID certificate with that of a PCR test or antigen test. For the judges, if the people who have been vaccinated or have passed the covid, despite having developed immunity may be potential transmitters, "it is not possible to understand how the possible contagion of those who have accessed the premises covered by the presentation of a receipt for the performance of a PCR or an antigen test, which only proves that at the time of its performance they were not carriers of the active virus, but not that they had any immunization against it".

Regarding the need, the magistrates consider that it is not sufficiently proven that "the greatest number of infections of the so-called fifth wave has its origin

precisely in nightlife venues", an argument similar to that used by businessmen in the sector when on Monday they learned of the Board's intention to apply this measure only to access the interior of their premises. The ruling also warns that the Board has not stipulated an effective term for this requirement, "without knowing what criteria will be followed to render it ineffective or modify it . "

The meaning of this ruling contradicts, in terms of the argument of proportionality, necessity and suitability to the resolutions issued by the same court, although by rooms of Seville, this morning, in which the request for confinement was ratified for eight municipalities of the Andalusian territory, having exceeded 1,000 cases per 100,000 inhabitants.

It is not the first time that the Granada room contradicts the criteria established by the Seville rooms. After the end of the confinement, the same court based in Seville endorsed the perimeter closure for several municipalities of Córdoba and Cádiz, while the magistrates of Granada denied it on two occasions in the case of Montefrío (Granada).

The Junta de Andalucía announced this Monday, after the meeting of the expert committee, that it would impose the measure requiring the covid passport to enter the clubs and that it would come into effect this Thursday. A day later, he backed off and decided to suspend it until the TSJA ruled. For the Andalusian Government, the endorsement of justice was essential to continue with the extension of this measure in other areas such as restoration. The nightlife entrepreneurs themselves were willing to apply this measure, but always in exchange for keeping their hours and lifting restrictions on capacity.

LINK: **https://elpais.com/sociedad/2021-08-06/la-justicia-andaluza-rechaza-la-exigencia-del-certificado-covid-para-entrar-en-las-discotecas.html**

Prashant Bhushan
(TRUE COPY)

Denmark ditches vaccine passports, its last remaining Covid restriction

News.au.com

September 10, 2021 - 8:15PM

Offices are buzzing, concerts are full and there are no masks in sights. This country with no restrictions says it is “on the other side of the pandemic”

With no masks in sight, buzzing offices and concerts drawing tens of thousands, Denmark on Friday ditched vaccine passports in nightclubs, ending its last Covid curb.

The vaccine passports were introduced in March 2021 when Copenhagen slowly started easing restrictions.

They were abolished at all venues on September 1, except in nightclubs, where they will be no longer necessary from Friday.

“We are definitely at the forefront in Denmark as we have no restrictions, and we are now on the other side of the pandemic thanks to the vaccination rollout,” UlrikOrum-Petersen, a promoter at event organiser Live Nation, told AFP.

On Saturday, a sold-out concert in Copenhagen will welcome 50,000 people, a first in Europe.

Already on September 4, Live Nation organised a first open-air festival, aptly named “Back to Live”, which gathered 15,000 people in Copenhagen.

“Being in the crowd, singing like before, it almost made me forget Covid and everything we’ve been through these past months,” said Emilie Bendix, 26, a concert-goer.

Denmark’s vaccination campaign has gone swiftly, with 73 per cent of the 5.8 million population fully vaccinated, and 96 per cent of those 65 and older.

“We’re aiming for free movement … What will happen now is that the virus will circulate and it will find the ones who are not vaccinated,” epidemiologist Lone Simonsen told AFP.

“Now the virus is no longer a societal threat, thanks to the vaccine,” said Simonsen, who works at the University of Roskilde.

According to the World Health Organisation, the Scandinavian country has benefited from public compliance with government guidelines and the Covid strategy adopted.

“Like many countries, Denmark has, throughout the pandemic, implemented public health and social measures to reduce transmission. But at the same time it has greatly relied on individuals and communities to comply voluntarily,” said Catherine Smallwood, WHO Europe’s emergency officer.

With around 500 daily Covid cases and a reproduction rate of 0.7, Danish authorities say they have the virus under control.

Health Minister Magnus Heunicke has however vowed that the government would not hesitate to swiftly reimpose restrictions if necessary.

Authorities insist that the return to normal life must be coupled with strict hygiene measures and the isolation of sick people.

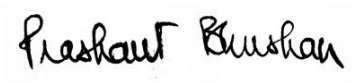
The WHO still considers the global situation critical and has urged caution. “Every country needs to remain vigilant as and when the epidemiological situation changes,” Smallwood said.

Denmark has said it will keep a close eye on the number of hospitalisations — just under 130 at the moment — and conduct meticulous sequencing to follow the virus.

A third dose has also been available to risk groups since Thursday. Simonsen said the vaccines have so far provided immunity from variants “but if escape variants (resistant to the vaccine) were to appear, we will have to rethink our strategy.” Christian Nedergaard, who owns several restaurants and wine bars in Copenhagen, said that while everyone is happy about the return to normal life, “the situation is still complicated.” “The memory of coronavirus will fade very quickly from some people’s minds but not for everyone, and for restaurants this period has for sure been a game-changer,” he said.

“The industry needs to think about how to become more resilient.” Travellers entering Denmark must still present either a vaccine passport or a negative PCR test, and masks are mandatory in airports.

LINK: **https://www.news.com.au/world/europe/denmark-ditches-vaccine-passports-its-last-remaining-covid-restriction/news-story/7a66cd2404693934cc1ddde0671bd970**



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2021 SCC OnLine SC 411

In the Supreme Court of India

(BEFORE D.Y. CHANDRACHUD, L. NAGESWARA RAO AND S. RAVINDRA BHAT, JJ.)

In Re: Distribution of Essential Supplies and Services During Pandemic

Suo Motu Writ Petition (Civil) No. 3 of 2021

Decided on May 31, 2021

ORDER

1. This order has been divided into the following sections to facilitate analysis:

A Introduction

2. Proceedings in the present *suo motu* writ petition were initiated on 22 April 2021, when this Court took cognizance of the management of the COVID-19 pandemic during the second wave. Subsequently, hearings were conducted on 23 April 2021, 27 April 2021 and 30 April 2021 when submissions were heard on behalf of the *Union of India*[1], *States/Union Territories*[2], learned *Amici* appointed by this Court and some of the intervenors.

3. On 30 April 2021, this Court passed a detailed order in relation, *inter alia*, to the following issues : vaccination policy, supply of essential drugs, supply of medical oxygen, medical infrastructure, augmentation of healthcare workforce and the issues faced by them, and issues of freedom of speech and expression during the COVID-19 pandemic. In its order, this Court had noted that its observations and directions were in consonance with a bounded-deliberative approach[3] and hence, the UoI was directed to re-consider its policies on the above issues, taking into account this Court's observations.

4. Following the order dated 30 April 2021, another two judge Bench of this Court heard a Special Leave Petition[4] against an order of the High Court of Delhi in relation to the supply of medical oxygen to the National Capital Territory[5] of Delhi. During the course of the proceedings in that matter, the Bench primarily issued directions in relation to the supply of medical oxygen to the NCT of Delhi. However, through its order dated 6 May 2021, it also constituted a National Task Force to provide a public heath response to the COVID-19 pandemic on the basis of a scientific approach. The terms of reference of this National Task Force included, *inter alia*, assessing and making recommendations for the need, availability and distribution of medical oxygen; devising a methodology for allocation of medical oxygen and periodical review of the

allocation based on the stage of the pandemic; providing recommendations for augmenting the supplies of oxygen; facilitating audits in each State/UT to determine whether oxygen supplies had reached its destination; efficacy, transparency and efficiency of the distribution networks within the State/UT; providing recommendations for ensuring availability of essential drugs, augmentation of medical and paramedical staff, management of the pandemic and treatment of cases.

5. During the course of the proceedings on 31 May 2021, we had the benefit of perusing the details provided in the affidavit filed by the UoI on 9 May 2021. The submissions contained in the affidavit were supplemented and updated in the hearing by Mr. Tushar Mehta, learned Solicitor General of India, appearing on behalf of the Central Government. We have further heard the learned *Amici*, Mr. Jaideep Gupta and Ms. Meenakshi Arora, learned Senior counsel.

6. Since the last hearing in this matter, the second wave of the COVID-19 pandemic has started receding across the nation and the situation appears to have become more manageable. Hence, some of the issues discussed in the previous orders can await further deliberation. However, the issue of vaccination is absolutely crucial, since health experts globally agree that vaccination of the nation's entire eligible population is the singular most important task in effectively combating the COVID-19 pandemic in the long run. Hence, during the course of the proceedings on 31 May 2021, this Court has limited itself to hearing submissions on the UoI's vaccination policy and its roadmap for the future. By way of abundant clarification, we note that all of the issues contained in this Court's previous orders still retain their overall importance, and this Court shall continue to monitor them alongside the National Task Force and intervene whenever necessary.

7. It is also important to note that numerous interlocutory applications and affidavits by individual State/UT Governments and members of civil society have been filed before us in this matter. We have perused them to understand the key issues being raised there, along with the helpful notes provided by the *Amici*.

B Submission by Counsel

8. Mr. Tushar Mehta, learned Solicitor General, relying on the UoI's affidavit dated 9 May 2021, has made the following submissions to supplement it, in view of the recent updates:

(i) The vaccination drive will be complete by the end of December 2021, and the Central Government is in active talks with foreign vaccine manufacturers at the highest political and diplomatic levels, to ensure the adequate supply of vaccines;

(ii) It would be incorrect to state that a consequence of the UoI's updated policy on vaccination of those in the 18-44 age group is that there will be competition amongst the States/UTs; and

(iii) Everyone above the age of 45 years can continue to get vaccinated at a facility through on-site registration, without previously having to book an appointment through CoWIN.

9. Mr. Jaideep Gupta and Ms. Meenakshi Arora, learned Senior counsel and *Amici*, have raised the following issues relating to vaccination distribution, augmentation of vaccine production and differential pricing of vaccines and the future preparedness for dealing with the COVID-19 pandemic:

(i) With respect to the procurement of vaccines, reports suggest that foreign vaccine manufacturers are generally not receptive or open to a dialogue with State/UT Governments on the basis that, as a matter of corporate policy, they only deal with federal governments of different nations;

(ii) Since 1978 till 1 May 2021, the UoI has implemented the Universal Immunization Programme[6] under which essential vaccines were procured by the

UoI and were distributed to States/UTs free of cost for administering them to the end beneficiary. The said policy has held the test of times. Even during the vaccination drive for COVID-19 in phases 1 and 2 for vaccination of healthcare workers[7], frontline workers[8] and persons above the age of 45 years, the UoI procured all the vaccines and distributed them to State/UT Governments for administration. The single procurement model has also been followed by other nations for ensuring fast and effective administration of vaccines against COVID-19;

(iii) The UIP has been replaced by the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy[9] from 1 May 2021 in phase 3 of the vaccination drive, whereby State/UT Governments or private hospitals are required to procure vaccines for persons between the age group of 18-44 years from the private manufacturers on the basis of a *pro rata* quota set by the UoI;

(iv) The Liberalized Vaccination Policy leaves the State/UT Governments to fend for themselves, rather than the Central Government acting on behalf of the entire nation. As a consequence, the vaccine manufacturers are free to implement a differential procurement price for the UoI for vaccinating persons above 45 years of age, and for the State/UT Governments and private hospitals for vaccinating the persons between 18-44 years of age;

(v) While the Liberalized Vaccination Policy has been introduced to spur competitive prices, there are multiple States/UTs competing to purchase a scarce commodity from a few vaccine manufacturers. Consequently, the manufacturers have the advantage of creating a monopoly and selling it at any price that they desire to private healthcare institutions. The State/UT Governments do not enjoy the unique position of the UoI, which has the advantage of being a monopolistic buyer and can negotiate an appropriate price for the vaccines on behalf of the entire population of India;

(vi) The Liberalized Vaccination Policy puts an undue burden on persons between the age group of 18-44 years, specifically persons belonging to a poor socioeconomic background, who have to purchase two doses of vaccines either from the State/UT Governments or private hospitals;

(vii) In the alternative, the UoI has stated that all State/UT Governments have agreed to vaccinate their population free of cost and have undertaken to bear the burden of the vaccines which are available at a higher purchase price than the one available to the UoI. Thus, the end beneficiary is not impacted by the differential pricing in the Liberalized Vaccination Policy. With regard to this submission, the *Amici* have raised the following concerns:

(a) While some States/UTs have announced that they will vaccinate their population for free, this policy statement must be confirmed by the State/UT Governments on affidavit before this Court. The Liberalized Vaccination Policy as it stands today, does not incorporate a condition whereby the cost of vaccination is imposed on the State/UT Governments. Instead, the end beneficiary is liable to pay the cost. There is a necessity for the State/UT Governments to place their decisions on record and for it to be part of the formal policy, such that persons can enforce their right to free vaccination, including before the courts;

(b) Although the State/UT Governments may have announced free vaccination for their population, some of them are contesting the Liberalized Vaccination Policy before this Court and have advanced submissions for universal vaccination by the Central Government. Thus, it cannot conclusively be stated that State/UT Governments have agreed to the policy decision taken by the Central Government of deviating from the single procurement model;

(c) The Liberalized Vaccination Policy, as a consequence of its differential pricing, treats individuals living across India residing in different States/UTs unequally, as States/UTs that are financially distressed may not be able to afford to purchase the vaccines at the prices set by the vaccine manufacturers or to lift the quantity allocated to them; and

(d) The end result of the Liberalized Vaccination Policy is that the UoI can purchase vaccines at Rs. 150 per dose for Covishield and Covaxin, while the State/UT Governments have to pay Rs. 300 and Rs. 400 per dose respectively. If the UoI were to be the single procurement agency for all vaccines at a fixed cost, then the cost of vaccination to the public exchequer would be substantially lower. Thus, it is incorrect to suggest that the end beneficiary, who contributes to the public exchequer, will not be unduly impacted;

(viii) Although public health is a subject under Entry 6 of List II (State List) of the Seventh Schedule to the Constitution, Entry 81 of List I (Union List) deals with inter-State migration and inter-State quarantine and Entry 29 of List III (Concurrent List) deals with prevention of extension from one State to another of infectious or contagious diseases. Thus, the management of the pandemic, control of the spread of COVID-19, vaccination policy and pricing, are the responsibility of the Central Government, which must work in tandem with the State/UT Governments. The Liberalized Vaccination Policy, by putting the burden of vaccination of persons between 18-44 years of age on the State/UT Governments, conflicts with this constitutional balance of responsibilities between the Centre and States/UTs;

(ix) With regard to the vaccine distribution, the Liberalized Vaccination Policy has created a quota of 50 : 25 : 25 for the 18-44 age group. The quota of 25% that is available to State/UT Governments, which is equivalent to the private hospitals, is extremely disproportionate and not in touch with societal realities, as a large number of persons may not be able to afford two doses of a vaccine from a private hospital. Thus, if State/UT Governments are to bear the burden of vaccinating a majority of the persons in their States/UTs, the quota available to the private hospitals must be reduced;

(x) The Liberalized Vaccination Policy does not provide any clarity on the basis of the *pro rata* allotment of the doses to each State/UT (available for purchase by the State/UT Government and private hospitals). The Policy does not indicate whether such apportionment will be on the basis of population; state of the pandemic in each State/UT; or the number of persons with comorbidities between 18-44 years of age, among others. Further, the Policy does not indicate whether the *pro rata* allotment will be made by the UoI or the private vaccine manufacturer;

(xi) It is reported that UoI on certain occasions has stated that it will refrain from interfering in the issue of vaccine distribution. Contrarily, UoI has also been stated that it may decide to redistribute the vaccines procured by it among State/UT Governments. The basis on which the re-distribution of vaccines will take place among States/UTs has not been provided in the policy document;

(xii) The Liberalized Vaccination Policy does not provide for prioritizing of persons with co-morbidities; persons with disabilities or suffering from other illnesses; care-givers for the elderly and sick; teachers and others in the age group of 18-44 years. Further, the CoWIN application is not built with functions which prioritize a certain category of persons, as it only books appointments on a first-cum-first-served basis;

(xiii) News reports indicate that crematorium workers have either not been vaccinated, or are unaware that they are eligible for vaccination in phases 1 and

2;

(xiv) With regard to preparedness, the UoI has claimed that it will be able to vaccinate a substantial number of persons (around 100 crore persons requiring 200 crore doses) by December 2021. However, no projections have been shared with this Court regarding how this target would be achieved. Based on reports, it appears that the UoI has factored a number of vaccines that are currently in their development stages to reach its projected number of 200 crore doses. This approach would be misguided as the success and efficacy of vaccines that are currently in the stage of clinical trials is uncertain and cannot be guaranteed;

(xv) There is material to suggest that the augmentation of vaccine production will be inadequate to vaccinate the population between 18-44 years of age. The total population of this age group is 59 crores, which would require around 122 crore doses. Based on reports, the existing manufacturers (Serum Institute of India[10] and Bharat Biotech India Limited[11]) will be able to produce less than 10 crore doses per month. Optimistically, around 15-20 crores doses of Sputnik V will be available per month. At this rate, it would take around 12 months for the population in this age group to be inoculated, by which time the virus may have mutated, causing further waves of the pandemic;

(xvi) Meanwhile, there is a necessity to ensure that guidelines regarding standardization of masks are formulated and publicized. Thus, medical guidance is necessary to ensure that masks of appropriate quality are produced and distributed free of cost to curb the spread of the infection; and

(xvii) It has been reported that due to dearth of electric crematoria, persons who have succumbed to COVID-19 are not dignified with a proper cremation and are cremated without any rituals. The UoI and State/UT Governments may consider forming appropriate guidelines which augment the creation of infrastructure for electric crematoria and a protocol for cremation of the dead.

C National Vaccination Policy

10. Phase 1 of the National COVID-19 Vaccination Strategy was launched on 16 January 2021 and 1 February 2021 and was targeted towards protecting HCWs and FLWs. Phase 2 was initiated on 1 March 2021 and 1 April 2021, and was directed towards protecting the most vulnerable population in the age group of persons above 45 years of age. In phase 1 and 2, the UoI was procuring the vaccines and distributing them to the States/UTs free of cost for disbursal through government and private COVID-19 vaccination centres. The private facilities were not allowed to charge a sum above Rs. 250 per person per dose (Rs 150 for vaccines and Rs. 100 as operational charges) from a beneficiary.

11. During phase 2, eligible beneficiaries could register and book appointments for vaccination on the CoWIN 2.0 portal or other IT applications such as Aarogya Setu. From 1 March 2021 onwards, the population aged 60 years or which would attain the age of 60 years or more as on 1 January 2022 was eligible to register on the CoWIN platform. Further, persons who were aged 45 years or would attain the age of 45 years to 59 years as on 1 January 2022 and had any of the 20 specified co-morbidities were also eligible to register on the CoWIN platform. From 1 April 2021 onwards, all persons who were aged 45 years or would attain the age of 45 years to 59 years as on 1 January 2022 were eligible to register on the CoWIN platform. On-site registration facility was also made available at vaccination centres in this phase.

12. In phase 3, a Liberalized Vaccination Policy was introduced by the UoI, which came into effect on 1 May 2021. We have perused the documents available in the public domain (guidance note[12], press releases[13] and policy document[14]) issued by the Central Government to understand the written policy of the Central Government with regard to phase 3. Based on such documents, the main elements of the Liberalized

Vaccination Policy can be identified as:

(i) Vaccine manufacturers are required to supply 50% of their monthly Central Drugs Laboratory[15] doses to the UoI and would be free to supply the remaining 50% doses to State/UT Governments and in 'other than Government of India channel'[16];

(ii) Manufacturers were required to make a declaration of the price of the 50% supply that would be available to State/UT Governments and in the 'other than GoI channel' before 1 May 2021. Based on this price, States/UTs, private hospitals and industrial establishments through their hospitals may procure vaccines from the manufacturers. Private hospitals would be able to procure their supplies only from the 50% supply earmarked for 'other than GoI channel';

(iii) The prices charged for vaccination by private hospitals would be monitored. As a result, the earlier dispensation where private COVID-19 vaccination centres which received doses from the UoI could charge up to Rs. 250 per dose ceased to exist;

(iv) The population which is now eligible to obtain vaccines at UoI's vaccination centres is limited to HCWs, FLWs and those above 45 years of age. The population between 18-44 years is eligible to obtain vaccines from 'other than GoI channel';

(v) The vaccination would continue to be available for free for eligible population groups in those vaccination centres which receive their vaccine doses from UoI;

(vi) The vaccination would continue to be a part of the National Vaccination Programme and would follow all existing guidelines. The CoWIN platform would capture the vaccination, stocks and price per vaccination applicable in all vaccination centres. The vaccination drive would comply with 'Adverse Event Following Immunization' management and reporting, digital vaccination certificate and all other prescribed norms;

(vii) The division of 50% supply to UoI and 50% to 'other than GoI channel' would be applicable uniformly across all the vaccine manufactures in the country;

(viii) The fully ready to use imported vaccines are allowed to be utilized entirely in the 'other than GoI channel'; and

(ix) The UoI from its share will allocate vaccines to States/UTs based on criteria of performance (speed of administration, average consumption) and extent of infection (number of COVID-19 cases). Wastage of vaccines would also be considered in the criteria and would affect the allocation negatively. Based on the above criteria, a State-wise quota would be decided and communicated to the States/UTs in advance.

13. The facility of only online appointment on the CoWIN portal was initially introduced for the entirety of the population between the ages of 18-44 years. Later, on 24 May 2021[17], the UoI announced that on-site registration will be made available for the 18-44 years age group. However, this is contingent on : (i) the State/UT Government enabling this policy; and (ii) only in cases of wastage at a particular government COVID-19 vaccination centre due to a no-show by an online appointee. Further, this facility has not been expanded to private COVID-19 vaccination centres.

D Separation of Powers

14. At the outset, we seek to clarify the nature of this Court's jurisdiction in the exercise of the power of judicial review over the management of the COVID-19 pandemic in India. In its affidavit dated 9 May 2021, the UoI has highlighted a few concerns which are detailed below:

(i) The executive is battling an unprecedented crisis and the government needs discretion to formulate policy in larger interest and its wisdom should be trusted;

(ii) The current vaccine policy conforms to Articles 14 and 21 of the Constitution, and requires no interference from the courts as the executive has "room for free play in the joints" while dealing with a pandemic of this magnitude;

(iii) The current steps are thoughtfully undertaken to tide over an imminent crisis, which may turn out to be imprudent in the long run. However, they need to be appreciated from a short-term and holistic perspective;

(iv) Judicial review over executive policies is permissible only on account of manifest arbitrariness. No interference from judicial proceedings is called for when the executive is operating on expert medical and scientific opinion to tackle a medical crisis; and

(v) Any over-zealous judicial intervention, though well-meaning, in the absence of expert advice or administrative experience may lead to unintended circumstances where the executive is left with little room to explore innovative solutions.

15. It is trite to state that separation of powers is a part of the basic structure of the Constitution. Policy-making continues to be in the sole domain of the executive. The judiciary does not possess the authority or competence to assume the role of the executive, which is democratically accountable for its actions and has access to the resources which are instrumental to policy formulation. However, this separation of powers does not result in courts lacking jurisdiction in conducting a judicial review of these policies[18]. Our Constitution does not envisage courts to be silent spectators when constitutional rights of citizens are infringed by executive policies. Judicial review and soliciting constitutional justification for policies formulated by the executive is an essential function, which the courts are entrusted to perform.

16. We had clarified in our order dated 30 April 2021, that in the context of the public health emergency with which the country is currently grappling, this Court appreciates the dynamic nature of the measures. Across the globe, the executive has been given a wider margin in enacting measures which ordinarily may have violated the liberty of individuals, but are now incumbent to curb the pandemic. Historically, the judiciary has also recognized that constitutional scrutiny is transformed during such public health emergencies, where the executive functions in rapid consultation with scientists and other experts. In 1905, the Supreme Court of the United States in *Jacobson* v. *Massachusetts*[19] considered a constitutional liberty challenge to a compulsory vaccination law that was enacted to combat the smallpox epidemic. Justice Harlan had noted the complex role of the government in battling public health emergencies in the following terms:

> "..the State may invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and the public safety... While this court should guard with firmness every right appertaining to life, liberty or property as secured to the individual by the Supreme Law of the Land, it is of the last importance that it should not invade the domain of local authority except when it is plainly necessary to do so in order to enforce that law. The safety and the health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect.....So far as they can be reached by any government, they depend, primarily, upon such action as the State in its wisdom may take, and we do not perceive that this legislation has invaded any right secured by the Federal Constitution."

17. The Supreme Court of United States, speaking in the wake of the present COVID-19 pandemic in various instances, has overruled policies by observing, *inter alia*, that "*Members of this Court are not public health experts, and we should respect the judgment of those with special expertise and responsibility in this area. But even in a pandemic, the Constitution cannot be put away and forgotten*"[20] and "*a public*

health emergency does not give Governors and other public officials carte blanche to disregard the Constitution for as long as the medical problem persists. As more medical and scientific evidence becomes available, and as States have time to craft policies in light of that evidence, courts should expect policies that more carefully account for constitutional rights"[21].

18. Similarly, courts across the globe have responded to constitutional challenges to executive policies that have directly or indirectly violated rights and liberties of citizens. Courts have often reiterated the expertise of the executive in managing a public health crisis, but have also warned against arbitrary and irrational policies being excused in the garb of the "wide latitude" to the executive that is necessitated to battle a pandemic. This Court in *Gujarat Mazdoor Sabha* v. *State of Gujarat*[22], albeit while speaking in the context of labour rights, had noted that policies to counteract a pandemic must continue to be evaluated from a threshold of proportionality to determine if they, *inter alia*, have a rational connection with the object that is sought to be achieved and are necessary to achieve them.

19. In grappling with the second wave of the pandemic, this Court does not intend to second-guess the wisdom of the executive when it chooses between two competing and efficacious policy measures. However, it continues to exercise jurisdiction to determine if the chosen policy measure conforms to the standards of reasonableness, militates against manifest arbitrariness and protects the right to life of all persons. This Court is presently assuming a dialogic jurisdiction where various stakeholders are provided a forum to raise constitutional grievances with respect to the management of the pandemic. Hence, this Court would, under the auspices of an open court judicial process, conduct deliberations with the executive where justifications for existing policies would be elicited and evaluated to assess whether they survive constitutional scrutiny.

E Issues with the Liberalized Vaccination Policy

E.1 Vaccine Procurement and Distribution among Different Categories of the Population

20. In our order dated 30 April 2021, the UoI was directed to clarify its vaccination procurement and distribution policy, especially after the introduction of the Liberalized Vaccination Policy. We had also directed the UoI to apprise this Court regarding the projected numbers of vaccinations that would be made available in the coming months to the public and the efforts being taken to augment vaccine production. In its affidavit dated 9 May 2021, UoI has made the following submissions:

(i) The vaccination policy for COVID-19 that was adopted prior to 1 May 2021 in phases 1 and 2, was designed as a system of prioritization. After vaccinating the HCWs and FLWs, vaccination was opened up for age groups on account of their heightened vulnerability and mortality to COVID-19, in consonance with the WHO guidelines and international practice;

(ii) In phase 1, HCWs (starting from 16 January 2021) and FLWs (starting from 2 February 2021) were vaccinated. In phase 2, persons above 60 years of age and persons over 45 years of age with certain co-morbidities (starting from 1 March 2021) and all persons over 45 years of age (starting from 1 April 2021) were eligible for vaccination. This priority was accorded in view of the fact that COVID-19 deaths across the world demonstrate that over 85% of all deaths occurred in the age group over 45 years;

(iii) FLWs such as municipal workers (including crematorium workers) and panchayat workers were also vaccinated in phase 1 of the vaccination drive;

(iv) With effect from 1 May 2021, the Liberalized Vaccination Policy was implemented as a response to repeated requests by State/UT Governments, and after detailed deliberations with domain experts. The parallel decentralized policy

aims to achieve higher efficiency and reach;

(v) Currently, vaccine manufacturers are obligated to supply 50% of their monthly CDL released doses to the UoI and the remaining 50% doses to the "other than GoI channel" which can be procured by State/UT Governments, private hospitals and hospitals of industrial establishments to vaccinate persons in the age group of 18-44 years;

(vi) The priority of the UoI remains vaccinating persons aged 45 years and above for free since they are more vulnerable. The simultaneous vaccinations for persons aged between 18-44 years has been introduced to respect the wishes of the State/UT Governments. In view of the differential vulnerability and mortality rates, the Liberalized Vaccination Policy conforms to the mandate of Articles 14 and 21 of the Constitution;

(vii) In order to eliminate disparity in bargaining powers, "*the Central Government has, in consultation with the vaccine manufacturers determined the pro-rata population of each State in the age group of 18-44 and each State will procure only that quantity*";

(viii) The Central Government will notify States/UTs, every fortnight, on the quantity of vaccines that will be distributed for vaccinating persons aged 45 years and above;

(ix) With regard to the augmentation of production of vaccines, it is stated that the National Expert Group on Vaccine Administration for COVID-19[23] had procured 6.6 crore doses for the initial phases. Support for other vaccine candidates under clinical development is being provided by the 'Mission COVID Suraksha the Indian COVID-19 Vaccine Development Mission';

(x) The Central Government is in talks with several vaccine developers/manufacturers outside India and is seeking to facilitate imports. The Drugs Controller General of India[24] has already approved import of 1.5 lakh doses of the Sputnik V vaccine by Dr Reddy's Laboratories';

(xi) The availability of vaccines for the next 6 months would be difficult to project as it is dynamic and contingent on foreign procurement and successful ramping of production by the two existing manufacturers;

(xii) However, it is also stated that manufacturing capacity is being increased in the following terms:

(a) SII : from 5 crore doses/month to 6.5 crore doses/month by July 2021;

(b) BBIL : from 90 lakh doses/month to 2 crore doses/month, and further increase to 5.5 crore doses/month by July 2021; and

(c) Sputnik V : from 30 lakh doses to 1.2 crore doses/month by July 2021; and

(xiii) The regulatory and testing process for foreign vaccines has been simplified by the NEGVAC which now allows bridging trials (a nearly 4-month long process) of foreign vaccines to occur simultaneously with market development.

21. Based on the response of the UoI and the submissions made by the *Amici*, we understand that there are three broad issues that are of concern : (i) vaccine distribution between different age groups; (ii) vaccine procurement process; and (iii) the augmentation of the vaccine availability in India.

22. The affidavit of the UoI sufficiently clarifies the prioritization of the groups in phases 1 and 2 for obtaining the COVID-19 vaccines. These include HCWs, FLWs and persons above the age of 45 years. The prioritization of these groups was based on the experience of India and other countries during the first wave of the pandemic in 2020. It was largely observed that these groups faced a higher risk of infection and thus, it was necessary to inoculate them free of cost and on a priority basis by the Central Government. During the vaccination for these groups, the Central Government had

allowed on-site registration and there was no prior requirement for booking an appointment on CoWIN. Having said that, the vaccination policy has been substantially changed for persons between 18-44 years of age. The Liberalized Vaccination Policy requires some of these persons to pay for the vaccines; limited vaccines are made available for this category with the State/UT Governments/private hospitals and an additional requirement of mandatory digital registration and booking an appointment through CoWIN has been imposed, among others. Unlike the prior policy, the Liberalized Vaccination Policy does not prioritize persons with comorbidities and other diseases, persons with disabilities, or any other vulnerable groups. This is especially at issue because the experience of the second wave of the pandemic has provided an experiential learning that the COVID-19 virus is capable of mutation and now poses a threat to persons in this age group as well. Reports indicate that persons between 18-44 years of age have not only been infected by COVID-19, but have also suffered from severe effects of the infection, including prolonged hospitalization and, in unfortunate cases, death. Due to the changing nature of the pandemic, we are now faced with a situation where the 18-44 age group also needs to be vaccinated, although priority may be retained between different age groups on a scientific basis. Hence, due to the importance of vaccinating individuals in the 18-44 age group, the policy of the Central Government for conducting free vaccination themselves for groups under the first 2 phases, and replacing it with paid vaccination by the State/UT Governments and private hospitals for the persons between 18-44 years is, *prima facie*, arbitrary and irrational.

23. With regard to the procurement process for vaccinations which is to be followed in view of the Liberalized Vaccination Policy, there are a number of issues that need to be addressed. The *Amici* have indicated that many State/UT Governments and local municipal bodies have issued tenders and attempted to negotiate with foreign manufacturers but they have largely been unsuccessful, as foreign manufacturers are not inclined to negotiate with individual State/UT Governments and prefer negotiating with federal governments of countries. Additionally, it has been urged that Central Government is also better placed to use its monopoly as a buyer (India being the second most populous country) to bargain for higher quantities of vaccines at reasonable prices. We find that the submissions urged by the *Amici* are extremely pertinent and have indicated that in practice, the Liberalized Vaccination Policy may not be able to yield the desired results of spurring competitive prices and higher quantities of vaccines.

24. Additionally, the Liberalized Vaccination Policy seeks to remove the issue of bargaining disparities by stating that each State/UT would have a prefixed *pro rata* quota based on their population in the 18-44 age group, 50% of which will be available to the State/UT Governments and 50% to the private hospitals. The *Amici* have raised concerns that there is a lack of clarity regarding whether the UoI will intervene in the distribution process. Given that inter-State barriers in India are porous and persons are free to migrate and work in different parts of the country, it is essential to understand if the *pro rata* allotment will take into account such migration to more densely populated industrial and urban States/UTs. Other concerns, such as the stage of the pandemic, the healthcare infrastructure and existing capacities of a State/UT, the literacy rate, age and overall health condition of its population, may also be relevant factors in making such a *pro rata* determination. The UoI should thus specify whether it seeks to address these concerns within the vaccination policy such that the State/UT Governments have a realistic assessment of the assistance they can anticipate from the UoI.

25. We shall now address the issue related to augmentation of vaccine production/availability. We have noted the submissions of the UoI in its affidavit dated 9 May 2021, that it is difficult to predict the projections for vaccines given that it

depends on variable factors such as introduction of new foreign vaccines, capability of increased production by existing manufacturers, among others. Mr. Tushar Mehta has during the course of his oral submissions stated that he is in a position to address these concerns of this Court and that the UoI aims to vaccinate approximately 100 crore persons by the end of December 2021. Mr. Mehta has agreed to provide a detailed roadmap regarding projected availability of vaccines from the various vaccine manufacturers. It has also been highlighted that the Central Government is in active negotiations with various private foreign manufacturers to augment the availability of vaccines in the near future.

26. In view of the above, we direct the UoI to undertake a fresh review of its vaccination policy addressing the concerns raised. Further, we direct the UoI to provide the following clarifications:

- As noted above, the UoI is directed to place on record a roadmap of projected availability of vaccines till 31 December 2021;
- The preparedness with respect to specific needs of children in the event of a third wave of the pandemic in terms of medical infrastructure, vaccination trials and regulatory approval, and compatible drugs;
- Whether under the policy of the UoI, it is permissible for State/UT Governments or individual local bodies to access vaccine supplies of foreign manufacturers;
- The number of crematorium workers vaccinated in phase 1. A targeted drive can be conducted for vaccination of the remaining crematorium workers;
- The State/UT Governments are diverting the vaccines (procured by them at a higher price than Central Government) for the persons in the age group of 18-44 years to vaccinate persons above 45 years of age, due to a shortage of vaccines being supplied by the Central Government. The manner in which the Central Government will factor this quantity and price differential into their subsequent allocation and disbursal of vaccines to States/UTs for the persons above 45 years of age; and
- The mechanism for redistribution, if the 25 : 25 quota in a particular State/UT is not picked up by the State/UT Government or the private hospitals.

E.2 Effects of Vaccination by Private Hospitals under the Liberalized Vaccination Policy

27. Under the Liberalized Vaccination Policy covering persons in the age group of 18 -44 years, the total vaccines produced will be divided in a ratio of 50 : 25 : 25 between the Central Government, State/UT Governments and private hospitals. In its affidavit dated 9 May 2021, the UoI notes the following salient features of this Liberalized Vaccination Policy, in relation to vaccination by private hospitals:

(i) Out of the 50% quota allocated for the 'other than GoI channel', 50% will go to the State/UT Governments, calculated on a *pro rata* basis as per the population. The balance 50% would be open for private hospitals' procurement, based on contracts with the manufacturers. As such, the State/UT Governments and private hospitals would each end up with 25% of the total CDL doses;

(ii) Vaccination through the private sector of 25% of the total CDL quantity would reduce the operational stress on government facilities and help with issues of crowding at vaccination centres; and

(iii) Paid vaccination through private hospitals has been introduced for persons who can afford to pay, thereby reducing the operational stress on the Government. However, it has also been submitted that this policy may undergo a change based on performance and future availability of vaccines.

28. As a consequence of this Liberalized Vaccination Policy, 50% of the population of any State/UT in the 18-44 age group is expected to pay for its vaccination. From the

UoI's affidavit, we understand that this has been done while taking into account the ability of a certain section of the population to pay for their vaccination. However, the present system of allowing only digital registration and booking of appointment on CoWIN, coupled with the current scarcity of vaccines, will ultimately ensure that initially all vaccines, whether free or paid, are first availed by the economically privileged sections of the society. As such, even those who may have been able to afford a vaccine, may opt for a free vaccine simply because of issues of availability, even if it would entail travelling to far-flung rural areas. Hence, any calculations of the economic ability of a given individual may not directly correspond to the vaccination route (paid/unpaid) they opt for. Consequently, it is plausible that private hospitals may have vaccine doses left over with them because everyone who could afford them has either already bought it or availed of a free vaccine, while those who need it may not have the ability to pay for it.

29. Further consequences of the vaccination by private hospitals under the Liberalized Vaccination Policy relate to a simple issue at the core of their existence : that while they provide a public health service, they still remain private, for-profit entities. Consequently, they may sell the vaccine doses procured at a higher price, unless regulated stringently. Private hospitals also may not sell all their vaccine doses publicly through appointments on CoWIN, but rather sell them for lucrative deals directly to private corporations who wish to vaccinate their employees. Finally, private hospitals are not equally spread out across a State/UT and are often limited to bigger cities with large populations. As such, a larger quantity will be available in such cities, as opposed to the rural areas.

30. It is pertinent to clarify here that we are not opposed to the involvement of private hospitals in the vaccination drive. Private health care institutions have an important role as well. The UoI has correctly noted in its affidavit that these hospitals will reduce the burden on government facilities. This was also happening earlier for the vaccination of those above 45 years of age, where the Central Government was providing these hospitals with vaccines and they were allowed to charge patients a nominal fee (Rs 250). However, the issue is about the effect of privatizing 50% of all vaccines available for the 18-44 age group. In view of the above concerns, we direct the UoI to provide the following clarifications:

- The manner in which Central Government will monitor the disbursal of vaccines to private hospitals, specifically those who have hospital chains pan India. Further, whether (i) private hospitals are liable to disburse vaccines *pro rata* the population of States/UTs; and (ii) the mechanism to determine if private players are genuinely administering the lifted quota in that State/UT alone. The UoI shall place on record any written policy in relation to this.
- Whether the Central Government conducted a "means-test" of the demographic of a State/UT to assert that 50% of the population in the 18-44 age group would be able to afford the vaccine. If not, the rationale for private hospitals being provided an equal quota for procurement as the State/UT Governments.
- The manner in which the Centre and States/UTs shall ensure an equitable distribution of vaccines across sections of the society, and how this factors into the rationale of equal apportionment between State/UT Governments and private hospitals.
- The nature of the intervention with respect to the final, end-user price that is being charged by private hospitals, especially when a cap on procurement by the private hospitals has been set.

E.3 Basis and Impact of Differential Pricing

Impact of differential pricing

31. In our order dated 30 April 2021, we had elicited the UoI's justification for

enabling decentralized procurement where a pre-fixed and differential price was set for the Central Government, States/UTs and private hospitals. The UoI through its affidavit dated 9 May 2021, has submitted the following:

(i) The Liberalized Vaccination Policy was introduced to incentivize existing manufacturers and invite more manufacturers, which will ensure fastest vaccination of the majority of the population. Differential pricing has been introduced in order to instill a competitive market which would drive the market towards affordability and attract offshore vaccine manufacturers;

(ii) Vaccine manufacturers are mandated to transparently declare the price in advance for procurement by State/UT Governments and private hospitals. The price for the Central Government is pre-fixed and declared;

(iii) Extensive consultations with the manufacturers were held to ensure that pricing is uniform and reasonable. The UoI stated that these were "due to consultations and persuasion" by the Central Government;

(iv) On the differential pricing of the vaccines, it is stated that "*the Central Government by nature of its large vaccination programme, places large purchase orders for vaccines as opposed to the State Governments and/or Private Hospitals and therefore, this reality has some reflection in the prices negotiated*"; and

(v) In any event, all persons of all age groups will get free vaccination throughout the country since all State/UT Governments have announced free vaccination for persons aged 18-44 years, in addition to the Central Government vaccinating persons over 45 years for free.

32. The current Liberalized Vaccination Policy enables State/UT Governments and private hospitals to procure 50% of the monthly CDL approved doses in the country at a pre-fixed price. The justification for this Policy has been adduced in a bid to spur competition which would attract more private manufacturers that could eventually drive down prices. *Prima facie*, the only room for negotiation with the two vaccine manufacturers was on price and quantity, both of which have been pre-fixed by the Central Government. This casts serious doubts on UoI's justification for enabling higher prices as a competitive measure. Furthermore, the Central Government justifying its lower prices on account of its ability to place large purchase orders for vaccines, raises the issue as to why this rationale is not being employed for acquiring 100% of the monthly CDL doses. The Union Budget for Financial Year 2021-2022 had earmarked Rs. 35000 crores for procuring vaccines[25]. In light of the Liberalized Vaccination Policy, the Central Government is directed to clarify how these funds have been spent so far and why they cannot be utilized for vaccinating persons aged 18-44 years.

33. In response to our questions on the poor and marginalized suffering on account of the vaccine prices, the Central Government in its affidavit stated that the eventual beneficiary of the vaccine would not be affected by the Liberalized Vaccination Policy since every State/UT has promised to vaccinate its residents free of cost. Nevertheless, it is reiterated that the UoI should consider utilizing its position as the monopolistic buyer in the market and pass down the benefit to all persons. Even if the States/UTs were to fund the higher-priced vaccines, a burden they were not discharging before the Liberalized Vaccination Policy was introduced and potentially may not have planned in advance for, these funds are expended at the behest of the public exchequer. The Centre and States/UTs, both operate in the service of the Indian population, and raise and disburse funds in their name. The additional funds expended on procuring vaccines against a deadly pandemic are necessary expenditure for any State/UT Government which has battled the public health emergency for over 15 months now. However, an avoidable expense would eventually hurt the welfare of

individuals residing within those States/UTs, who may potentially be benefitted by the differential funds being utilized for ramping up the health infrastructure in the State/UT, which is equally important to combat the pandemic. If the Central Government's unique monopolistic buyer position is the only reason for it receiving vaccines at a much lower rate from manufacturers, it is important for us to examine the rationality of the existing Liberalized Vaccination Policy against Article 14 of the Constitution, since it could place severe burdens, particularly on States/UTs suffering from financial distress.

Basis of pricing

34. In our order dated 30 April 2021, we had requested for data on government funding and support, direct or indirect, into the two vaccines that are currently authorized for public use - SII's Covishield and BBIL's Covaxin. Additionally, in order to evaluate the bottlenecks in vaccine scarcity, we had sought the UoI's stance on invoking its powers of compulsory licensing under the Patents Act, 1970 in order to ramp up manufacturing and other statutory provisions to drive down costs. The UoI has adduced the following justifications in its affidavit dated 9 May 2021:

(i) SII and BBIL have taken a financial risk in developing and manufacturing these vaccines and prudence dictates pricing through a transparent and consultative negotiation, and statutory provisions must be invoked in the last resort;

(ii) Covaxin is developed under a public-private partnership through a formal MoU between Indian Council of Medical Research[26] and BBIL. ICMR would receive a 5% royalty on net sales, the intellectual property is shared between ICMR and BBIL and clauses such as prioritization of in-country supplies have been included. Phase 3 trials of Covaxin have been funded by the ICMR to the tune of Rs. 35 crores;

(iii) Covishield is manufactured by SII. The Central Government has directly transferred Rs. 11 crores to 14 clinical trials sites for conducting phase 3 trials of over 1600 participants; and

(iv) Covaxin production is being augmented with government support to the tune of Rs. 200 crores to one private manufacturer and 3 public sector manufacturing facilities - Bharat Biotech, Hyderabad; Indian Immunologicals, Hyderabad; Haffkine Biopharmaceuticals, Mumbai; and Bharat Immunologicals and Biologicals, Bulandshar. This is projected to enhance Covaxin's current manufacturing of 1 crore doses/month to nearly 10 crore doses/month in the next 8-10 months. Grant-in-aids have been recommended, but the disbursements are yet to be made.

35. We commend the co-operative efforts of the UoI and the private manufacturers in developing and distributing vaccines which are critical to mitigate the pandemic. The import of our further line of questioning is to facilitate a better understanding of the process of development and augmentation of vaccine production and its pricing for States/UTs and private hospitals. Hence, we direct that the UoI to provide the following clarifications:

- Since the Central Government has financed (officially, Rs. 35 crores to BBIL and Rs. 11 crore to SII for phase 3 clinical trials) and facilitated the production (or augmentation of production) of these vaccines through concessions or otherwise, it may not be accurate to state that the private entities have alone borne the risk and cost of manufacture. Additionally, the Central Government would have minimized the risks of the manufacturers by granting Emergency Use Authorization to the vaccines, which should factor into its pricing.
- The manner in which public financing is reflected in the procurement price for the Central Government, which is significantly lower than price for the State/UT Governments and private hospitals. Given that the R&D cost and IP have either

been shared between the Central Government and the private manufacturer (in case of *Covaxin*) or the manufacturer has not invested in R&D of the vaccine (in case of *Covishield*), the manner in which the pricing of vaccines has been arrived at, with the Central Government refusing to intervene statutorily. The justification for intervening in pre-fixing procurement prices and quantities for States/UTs and private hospitals, but not imposing statutory price ceilings.

- Comparison between the prices of vaccines being made available in India, to their prices internationally.
- Whether ICMR/BBIL formally invited contracts for voluntary licensing and if so, whether they have they received viable offers. The manner in which the UoI is independently trying to assist manufacturers for developing BSL3 labs which are essential for Covaxin production.

E.4 Vaccine Logistics

36. We have already noted that as a consequence of the Liberalized Vaccination Policy, the responsibility for the vaccination in phase 3 is being divided between the Central Government (for those above 45 years of age, HCWs and FLWs) and the State/UT Government along with the private hospitals (for the age group of 18-44 years). This would mean that the limited vaccine logistics available in a State/UT would have to be shared between the State/UT Government and the Central Government. This is different from the situation under the UIP, where the Central Government buys and allocates vaccines to States/UTs, in order to ensure that their cold storage facilities are not overwhelmed. Hence, we direct the UoI to provide the following clarifications:

- The manner in which cold storage equipment capacity is being balanced between the Central and State/UT Governments. The manner in which the States/UTs are managing the logistical burden for vaccinating persons aged between 18-44 years, along with persons aged over 45 years.
- Whether cold storage facilities in India have increased for the COVID-19 vaccination drive; the present numbers, and comparison with the numbers prior to March 2020;
- Whether the cold storage equipment is indigenously manufactured or is imported. If it is imported, the steps which have been taken to start indigenous manufacturing.
- The steps being taken to improve the cold storage management for vaccines which may require lower temperature to be stored, compared to the ones which currently have approval in India.

E.5 Digital Divide

37. In our order dated 30 April 2021, we had highlighted the concerns relating to the ability of the marginalized members of society to avail of vaccination, exclusively through a digital portal in the face of a digital divide. The UoI's affidavit made the following submissions in relation to the accessibility of the CoWIN portal:

(i) The CoWIN portal enables one person to register 4 persons using the same mobile number;

(ii) All gram panchayats in the country have Common Service Centres[27] which can effectively enable people residing in rural areas to register online for the vaccination;

(iii) Citizens who do not have access to digital resources could take help from family, friends, NGOs and CSCs;

(iv) Walk-ins cannot be permitted due to the scarcity of vaccines and fears of over-crowding at centres. The online registration requirement counters this fear and also effectively monitors the administration of the second dose. The policy may

be re-considered subsequently when more vaccines are available;

(v) Identity proofs are required for the purpose of determining age and keeping a track of persons who are due for the second dose. However, in recognizing the issues arising with the insistence of one of the seven prescribed photo-ID proofs, the Central Government issued an SoP dated 23 April 2021 which enables bulk registration of certain identifiable groups, such as homeless persons, who would be identified and registered by the District Immunization Task Force; and

(vi) It is clarified that walk-in vaccination facilities will continue for persons over the age of 45 years in separate, designated vaccination centres. This is because vaccinations have been underway for this age group for a while and overcrowding has not been experienced so far.

38. A survey on 'Household Social Consumption : Education' was conducted by National Statistics Office (July 2017-June 2018)[28] which revealed the following:

(i) Around 4% of the rural households and 23% of the urban households possessed a computer. In the age group of 15-29 years, around 24% in rural households and 56% in urban areas were able to operate a computer; and

(ii) Nearly 24% of the households in the country had internet access during the survey year 2017-18. The proportion was 15% in rural households and 42% in urban households. Around 35% of persons in the age group of 15-29 years reported use of internet during the 30 days prior to the date of survey. The proportions were 25% in rural areas and 58% in urban areas.

39. The Telecom Regulatory Authority of India in its report titled 'Wireless Data Services in India'[29] noted that:

(i) Out of the total population of 1.3 billion, only 578 million people in India (less than 50%) have subscription to wireless data services. The wireless tele density in rural areas is 57.13% as compared to 155.49% in urban areas as on 31 March 2019. The report stated that:

> "[this] reflects the rural-urban divide in terms of telecom services' penetration. Since, the number of wireless data subscribers are less than 50% of the total wireless access subscribers, the number of wireless data subscribers in rural areas would be much lower".

(ii) The report also noted that in a few Indian States like Bihar, Uttar Pradesh and Assam the tele density is less than 75%; and

(iii) The monthly income of persons living below the poverty line in urban areas and rural areas is Rs. 1316 and Rs. 896, respectively. However, to access internet data services, a minimum tariff plan would cost around Rs. 49, which includes 1 GB data every 28 days. This would constitute 4-5% of the month's income of such persons accessing data. As such, the report notes that this would bear a considerable cost for persons living below the poverty line.

40. According to the Annual Report of CSC for 2019-20, published by the Ministry of Electronics and Information Technology, while there are 2,53,134 Gram Panchayats in India, as on 31 March 2020 only 2,40,792 Gram Panchayats are covered with at least one registered CSC[30]. Hence, approximately 13,000 Gram Panchayats in India do not have a CSC.

41. It is clear from the above statistics that there exists a digital divide in India, particularly between the rural and urban areas. The extent of the advances made in improving digital literacy and digital access falls short of penetrating the majority of the population in the country. Serious issues of the availability of bandwidth and connectivity pose further challenges to digital penetration. A vaccination policy exclusively relying on a digital portal for vaccinating a significant population of this country between the ages of 18-44 years would be unable to meet its target of

universal immunization owing to such a digital divide. It is the marginalized sections of the society who would bear the brunt of this accessibility barrier. This could have serious implications on the fundamental right to equality and the right to health of persons within the above age group. In this regard, we direct that the UoI to provide the following clarifications:

- It may not be feasible to require the majority of our population to rely on friends/NGOs for digital registrations over CoWIN, when even the digitally literate are finding it hard to procure vaccination slots.
- The issue of over-crowding may also arise at CSCs in rural areas where people would have to visit constantly in hope of a vaccine slot opening up.
- Certain vaccination centres may be earmarked for on-site registrations for the population aged between 18-44 years without the existing conditions prescribed in the circular dated 24 May 2021, potentially with a view to prioritize those with co-morbidities/disabilities/other socio-economic vulnerabilities. Alternatively, whether specific daily quotas may be introduced for on-site registration at each centre or specific centres.
- This policy may not allay the issue of hesitancy which may arise from approaching a State authority (such as the District Immunization Task Force) to obtain registration for the vaccination. Whether on-site registration with self-attestation of age to ensure widespread vaccination can be provided.
- The CoWIN platform and other IT applications like Aarogya Setu should be made available in regional languages. The timeline for ensuring the availability of the platform in multiple regional languages.
- Conducting a disability audit for the CoWIN website and other IT application like Aarogya Setu to ensure that they are accessible to persons with disabilities.

42. It has been brought to our notice that the CoWIN platform is not accessible to persons with visual disabilities. The website suffers from certain accessibility barriers which should be addressed. These include:

(i) Audio or text *captcha* is not available;

(ii) The seven filters, which *inter alia*, include age group, name of vaccine and whether the vaccine is paid or free, are not designed accessibly. This issue can be addressed by creation of a drop-down list;

(iii) While visually challenged persons can determine the number of available vaccine slots, one cannot find out the day those slots correspond to. This can be resolved by ensuring that table headers correspond to associated cells;

(iv) Keyboard support for navigating the website is absent;

(v) Adequate time should be given to disabled users to schedule their appointment without the possibility of being automatically logged off; and

(vi) Accessibility protocols, such as use of appropriate colour contrasts, should be adhered to.

F Conclusion

43. We direct the UoI to file an affidavit, which shall address the issues and questions raised in Section E, wherein it shall ensure that each issue is responded to individually and no issue is missed out. We also direct that the affidavit should provide the following information:

- The data on the percentage of population that has been vaccinated (with one dose and both doses), as against eligible persons in the first three phases of the vaccination drive. This shall include data pertaining to the percentage of rural population as well as the percentage of urban population so vaccinated;
- The complete data on the Central Government's purchase history of all the COVID -19 vaccines till date (Covaxin, Covishield and Sputnik V). The data should

clarify : (a) the dates of all procurement orders placed by the Central Government for all 3 vaccines; (b) the quantity of vaccines ordered as on each date; and (c) the projected date of supply; and

- An outline for how and when the Central Government seeks to vaccinate the remaining population in phases 1, 2 and 3.
- The steps being taken by the Central Government to ensure drug availability for mucormycosis.

44. While filing its affidavit, UoI shall also ensure that copies of all the relevant documents and file notings reflecting its thinking and culminating in the vaccination policy are also annexed on the vaccination policy. Hence, we direct the UoI to file its affidavit within 2 weeks.

45. We also note that UoI's stated position in its affidavit dated 9 May 2021 is that every State/UT Government shall provide vaccination free of cost to its population. It is important that individual State/UT Governments confirm/deny this position before this Court. Further, if they have decided to vaccinate their population for free then, as a matter of principle, it is important that this policy is annexed to their affidavit, so that the population within their territories can be assured of their right to be vaccinated for free at a State vaccination centre. Hence, we direct each of the State/UT Governments to also file an affidavit within 2 weeks, where they shall clarify their position and put on record their individual policies.

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[1] "UoI"/interchangeably referred to as the "Central Government"

[2] "UTs"

[3] Sandra Fredman, "Adjudication as Accountability : A Deliberative Approach" in Nicholas Bamforth and Peter Leyland (eds), Accountability in the Contemporary Constitution (Oxford University Press, 2013)

[4] *Union of India* v. *Rakesh Malhotra*, SLP (Civil) (Diary) No 11622 of 2021

[5] "NCT"

[6] "UIP"

[7] "HCWs"

[8] "FLWs"

[9] "Liberalized Vaccination Policy"

[10] "SII"

[11] "BBIL"

[12] Guidance Note For COWIN 2.0 dated 28 February 2021, available at <https : //www.mohfw.gov.in/pdf/GuidancedocCOWIN2.pdf>

[13] Press releases dated 28 February 2021 and 19 April 2021, available at <https : //pib.gov.in/PressReleseDetail.aspx?PRID=1701549> and <https : //pib.gov.in/PressReleseDetail.aspx?PRID=1712710>

[14] Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy dated 24 April 2021, available at <https : //www.mohfw.gov.in/pdf/LiberalisedPricingandAcceleratedNationalCovid19VaccinationStrategy2042021.pdf>

[15] "CDL"

[16] "other than GoI channel"

[17] Available at <https : //www.pib.gov.in/PressReleasePage.aspx?PRID=1721225>

[18] *DDA* v. *Joint Action Committee*, (2008) 2 SCC 672

[19] 197 U.S. 11 (1905)

[20] *Roman Catholic Diocese of Brooklyn, New York* v. *Cuomo*, 592 U.S., 141 S. Ct. 63

[21] *Calvary Chapel Dayton Valley* v. *Steve Sisolak, Governor of Nevada*, et al, 140 S.Ct. 2603 (Mem) (Justice Alito Dissenting Opinion)

[22] (2020) 10 SCC 459 : AIR 2020 SC 4601, para 9

[23] "NEGVAC"

[24] "DCGI"

[25] Available at <https : //www.indiabudget.gov.in/doc/Budget_Speech.pdf>, page 7

[26] "ICMR"

[27] "CSC"

[28] Available at <http : //mospi.nic.in/sites/default/files/publication_reports/Report_585_75th_round_Education_final_1507_0.pdf>

[29] Available at <https : //www.trai.gov.in/sites/default/files/Wireless_Data_Service_Report_21082019_0.pdf>

[30] Available at <https : //csc.gov.in/assets/events-report/Annual-Report-2019-20.pdf>, at page 8

Prashant Bhushan
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