"Exhibit A-1"

सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

Certificate for COVID-19 Vaccination

Partially Vaccinated : **1st Dose**

Beneficiary Details

Beneficiary Name / लाभार्थीचे नाव	**Ayush Tiwari**
Age / वय	**20**
Gender / लिंग	**Male**
ID Verified / ओळखपत्र	**Aadhaar # XXXXXXXX2929**
Unique Health ID (UHID)	
Beneficiary Reference ID	**31626077783460**

Vaccination Details

Vaccine Name / लसीचे नाव	**COVISHIELD**
Date of 1st Dose / पहिल्या डोसची तारीख	**19 Aug 2021 (Batch no. 4121Z115)**
Next due date / पुढील देय तारीख	**Between 11 Nov 2021 and 09 Dec 2021**
Vaccinated by / यांच्याद्वारे लसीकरण	**Amisha Bhoir**
Vaccination at / लसीकरणाचे स्थळ	**R/C APEX HOSPITALS, Mumbai, Maharashtra**

औषध सुद्धा आणि शिस्त सुद्धा
Together, India will defeat COVID-19"

- पंतप्रधान श्री. नरेंद्र मोदी

In case of any adverse events, kindly contact the nearest Public Health Center/ Healthcare Worker/District Immunization Officer/State **Helpline No. 1075**

कोणतेही प्रतिकूल परिणाम आढळून आल्यास कृपया जवळचे सार्वजनिक आरोग्य केंद्र/ आरोग्यसेवा कर्मचारी/ जिल्हा लसीकरण अधिकारी/ राज्य हेल्पलाइन क्रमांक १०७५ वर संपर्क साधा.

COWIN
Winning Over COVID

This certificate can be verified by scanning the QR code at http://verify.cowin.gov.in

सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

Certificate for COVID-19 Vaccination

Fully Vaccinated : **2nd Dose**

Beneficiary Details

Beneficiary Name / लाभार्थीचे नाव	**Ayush Tiwari**
Age / वय	**20**
Gender / लिंग	**Male**
ID Verified / ओळखपत्र	**Aadhaar # XXXXXXXX2929**
Unique Health ID (UHID)	
Beneficiary Reference ID	**31626077783460**

Vaccination Details

Vaccine Name / लसीचे नाव	**COVISHIELD**
Date of 1st Dose / पहिल्या डोसची तारीख	**19 Aug 2021 (Batch no. 4121Z115)**
Date of 2nd Dose / दुसऱ्या डोसची तारीख	**11 Nov 2021 (Batch no. 4121Z237)**
Vaccinated by / यांच्याद्वारे लसीकरण	**joslin**
Vaccination at / लसीकरणाचे स्थळ	**Ambedkarnagar UPHC, Palghar, Maharashtra**

औषध सुद्धा आणि शिस्त सुद्धा
Together, India will defeat COVID-19”
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COWIN
Winning Over COVID

This certificate can be verified by scanning the QR code at http://verify.cowin.gov.in

"Exhibit-A"

सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

COVID-19 VACCINES

OPERATIONAL GUIDELINES

(Updated as on 28 December 2020)

24x7 helpline no. 1075 (Tollfree)

www.mohfw.gov.in | www.cowin.gov.in

10. ADVERSE EVENTS FOLLOWING IMMUNIZATION

10.1 INTRODUCTION

COVID-19 vaccines have limited safety data. Therefore, it is important to monitor the safety of these vaccines when administered to a large population. A robust AEFI surveillance system would enable us to monitor adverse events and better understand the safety profile of the vaccines. During COVID-19 vaccinations, AEFIs must be rapidly detected and promptly responded to or else it can undermine confidence in the vaccine and immunization programme. All AEFIs should be reported as per the National AEFI Guidelines.

Programme managers should be aware of the following:

- COVID-19 vaccination will involve vaccination of large population over a short period of time. This may lead to increased reporting of AEFIs;
- During mass campaigns, there can be chances of anxiety reactions and occurrence of programme errors, especially if it involves reconstitution of vaccines using diluents; and
- Immunization errors which might lead to AEFI must be prevented at all costs through proper training, regular and intensive monitoring and supervision, and strict adherence to proper vaccine / diluent handling procedures and injection practices.

COVID 19 vaccines may be administered to persons belonging to high risk groups such as health care workers, other front line workers such as those in the police, municipal workers, etc. who are more at risk of contracting the disease and the elderly and persons with co-morbidities as they are more likely to have higher mortality and morbidity rates as compared to healthy individuals. Many of the deaths, and hospitalizations following COVID19 vaccinations in these high-risk groups may be coincidental. However, it is important that all deaths, hospitalizations, any event occurring in clusters following COVID19 vaccination, or any event felt by health workers and medical staff to be due to COVID 19 vaccines or vaccinations should be reported and investigated immediately.

10.2 AEFI SURVEILLANCE SYSTEM

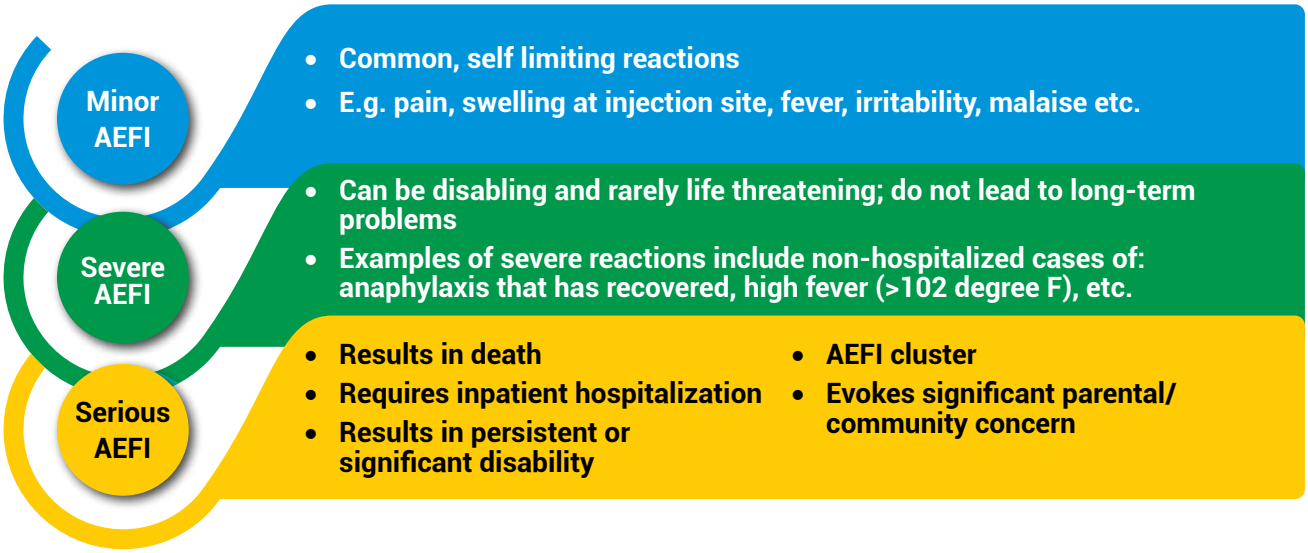
The overall goal of AEFI surveillance is to ensure that vaccines are administered safely to the recipients and the trust in vaccines is sustained. The specific objectives of AEFI surveillance are to:

- Promptly detect, report and respond to AEFIs;
- Promptly identify programmatic errors and implement corrective measures;
- Document the rates of AEFI for a specific vaccine lot / brand in a specific region/population;
- Estimate serious AEFI rates in the population and compare these with local and global data;
- Identify signals of unexpected adverse events that would need further confirmation and planned studies; and
- Sustain confidence of the public, health functionaries and professionals on the vaccines and immunization program.

10.3 ADVERSE EVENTS FOLLOWING IMMUNIZATION

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended disease, symptom, sign or abnormal laboratory finding. Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

For purposes of reporting, AEFIs can be classified as minor, severe and serious



10.3.1 PREVENTION OF AEFIs

Injectable COVID-19 vaccines are expected to be given in a campaign mode and these vaccines may have different modalities of administration. Appropriate measures need to be taken to avoid possibilities of anxiety reactions in individuals and clusters. Programme managers and implementers must plan to prevent and minimize chances of occurrence of preventable AEFIs. Beneficiaries should be observed at the session site for at least 30 minutes post-vaccination to detect, manage and treat immediate adverse reactions.

10.3.2 PREVENTING ANXIETY REACTIONS

Session sites should be planned in such a way that there is a separate area for those waiting for vaccination, site of actual vaccination and post-vaccination observation area.

- Ensure vaccinations occur in comfortable, well-ventilated and airy settings. Beneficiaries who seem anxious or nervous should be identified and made to calm down or their attention diverted from the process and the pain. After vaccination, they should be asked to remain seated for some time and observed. If they feel light-headed or giddy, they should be asked to lie down for some time.

10.3.3 PREVENTING PROGRAMME ERRORS

Ensure guidelines for safe injection practises are followed at the session site. Special attention should be on the following:

- Ensure nothing other than vaccines / diluents are stored in ILRs;
- If reconstitution is required, separate reconstitution syringes should be used for each vial and diluent;

- Proper cold chain management of the vaccines at the session site;
- Screening for contraindications of the vaccine; and
- Other specific precautions as per guidelines issued or as mentioned in the vaccine product insert.

10.4 AEFI MANAGEMENT

Vaccinators and supervisors at the vaccination site will provide primary treatment of all AEFIs. If needed, cases should be immediately referred to the nearest AEFI management centre/ health facility and reported to the appropriate authority.

COVID 19 vaccination sessions may be at fixed sites such as at government health facilities such as PHCs, urban PHCs, CHC, Sub divisional hospitals, district hospitals, medical college hospitals and identified private hospitals and nursing homes, etc. or in outreach.

- All beneficiaries must be counselled about adverse events which may occur after COVID-19 vaccine. These are expected to be minor events such as local pain and swelling and mild to moderate fever, etc. However, the list of expected events could be different based on the safety profile of the COVID19 vaccine(s) which finally gets approved for use.
- In case of any type of discomfort or illness following COVID vaccination, the vaccine recipient should visit the nearest health care facility for treatment.
- At fixed session sites, an AEFI management kit or an emergency tray should be available for use. The contents of the AEFI kit are: Inj. Adrenaline (1:1000) (3), Inj. Hydrocortisone (3), Ringer lactate/Normal saline (2), 5% dextrose (2), IV drip set (2), scalp vein sets or IV cannula (2), disposable syringes – 5 ml with 24/25G IM needle (3 sets), adhesive tape and blank Case Reporting Formats (CRF).
- Outreach session sites should have an Anaphylaxis kit
- Contents of Anaphylaxis Kits
- All vaccinators must be trained to suspect signs and symptoms of anaphylaxis and to use the contents of the anaphylaxis kit to provide a single, age-appropriate dose of injection Adrenaline and arrange transportation of the patient to the nearest AEFI management centre/hospital for further treatment. This is crucial for saving lives in case of rare but life-threatening anaphylactic reactions.

  - Job aid for recognizing anaphylaxis
  - Dose chart for adrenaline as per age
  - 1 mL ampoule of adrenaline (1:1000 aqueous solution) - 3 nos.
  - Tuberculin syringes (1 mL) OR insulin syringe (of 40 units, without fixed needle) – 3 nos.
  - 24G/25G needles (1 inch) – 3 nos.
  - Swabs – 3 nos.
  - Updated contact information of DIO, Medical Officer(s) of PHC/CHC, referral center and local ambulance services
  - Certification by Medical Officer for expiry dates of contents

- Ensure that is enough stock / supply of injection adrenaline during the campaign, keeping in mind the short expiry period of the adrenaline.
- Each outreach session site should be linked to an identified AEFI management centre to provide immediate treatment for serious AEFI cases.
- Adequate transportation should be available to transfer persons with serious adverse reactions to nearest identified AEFI management centre or health facility. The vaccinators at the session sites must be aware of all relevant contact numbers like ambulance services (108 or 102), AEFI management centres, higher health care facilities, etc.

10.4.1 AEFI MANAGEMENT CENTRES

- States and UTs should identify **at least** one AEFI management centre in each block.
- During vaccination campaign, AEFI management centres must be identified near the vaccination sites. PHCs, CHCs, UPHCs, DHs or any other fixed health facilities with medical officers and paramedical staff should be identified as AEFI management centres. Private health facilities may also be made AEFI management centres.
- Every session site should be linked to a designated AEFI management centre. Contact details of medical officer, and address of AEFI management centre should be mentioned in the micro plans and should be known to staff of the session site.
- Adequate mobility support/ambulance services (102, 108) must be available to transport any person with AEFI from session sites to AEFI management centres.
- All MOs acting as supervisors will carry an AEFI management kit.
- All AEFI management centres should have an AEFI management kit and AEFI reporting forms.
- BMO and PHC MOIC should have mobility support to respond to AEFI investigation and management.
- AEFI management centres will report the AEFI as per laid out procedures in the national guidelines.
- If required, arrangements should be made to transfer the patient to a secondary or tertiary care hospital for specialist management.

10.5 REPORTING AND RECORDING

Any adverse event following COVID-19 vaccination must be reported. There is no time limit (between vaccination and onset of symptoms) for reporting AEFIs. If the health worker or the treating physician or anyone suspects the event to be due to vaccination, it should be reported.

State and district authorities (DIO/CMO or the Block MO) should proactively reach out to all health care service providers such as medical colleges, hospitals (public, autonomous and private) and individual practitioners and sensitize them to report any adverse event following COVID-19 vaccine as per guidelines.

Doctors should ask and record history of COVID-19 vaccination in OPD prescriptions, casualty records, clinical treatment sheets, etc. Patients with history of COVID-19 vaccination (any duration) in which onset of symptoms has occurred AFTER COVID-19 vaccination should be considered as AEFIs and reported by the treating doctor to the nearest PHC doctor or District Immunization / RCH Officer in Case Reporting Format or telephonically. During investigations conducted by the DIO/district AEFI committee, all treatment records of the patient must be shared for causality assessment.

Professional bodies like IAP, IMA, IPHA, partner agencies like WHO-NPSP, UNICEF, UNDP, USAID, PATH and others should also be encouraged to support AEFI surveillance.

Blank copies of Case Reporting Formats (CRF) should be available with potential reporters to capture AEFI details. The reporter should also know whom to report and how to report. Thereafter, the case should be investigated by the district health authorities (DIO with support of the district AEFI committee members) as per national AEFI guidelines.

10.5.1 IMMEDIATE REPORTING OF SERIOUS AND SEVERE AEFIs

A serious or severe AEFI case needs to be reported immediately to the concerned Medical Officer or the appropriate health authorities. Soon after the identification / notification of a serious and severe AEFI, a two-step process must be initiated.

STEP 1 Report serious and severe AEFI to the appropriate authority (DIO or the nearest government health facility) in Case Reporting Format.

STEP 2

- Investigation of all reported serious and severe AEFI by District Immunization Officer or District AEFI Committee.
- All serious and severe AEFIs should be treated as a medical emergency and priority should be given to its management followed by its reporting and investigation on the standardized AEFI formats. All serious and severe AEFIs should be documented on a CASE REPORTING FORM (CRF).

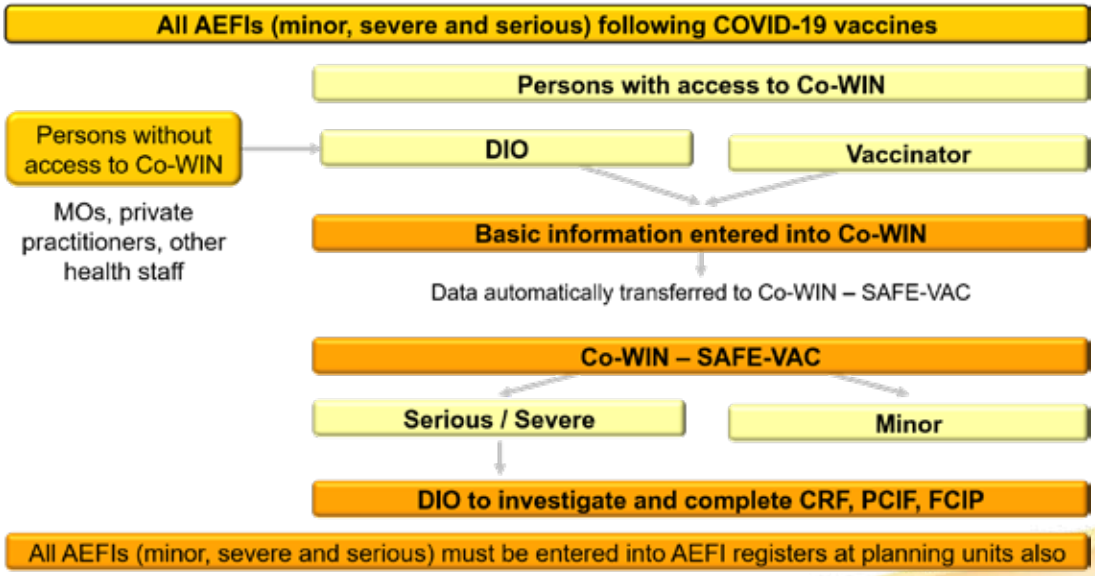
All serious and severe AEFIs should be treated as a medical emergency and priority should be given to its management followed by its reporting and investigation on the standardized AEFI formats. All serious and severe AEFIs should be documented on a CASE REPORTING FORM (CRF).

10.5.2 ROUTE OF REPORTING

Reporting through Co-WIN

Co-WIN is a web-based application developed for management of COVID-19 vaccination process including AEFI reporting. In the beneficiary module of Co-WIN, there is a provision for reporting of AEFI cases following COVID-19 vaccines.

- All adverse events (minor, severe and serious) following COVID-19 vaccination must be reported in Co-WIN by
  - The vaccinator through vaccinator's module
  - The DIO through district login in Co-WIN
- Immediately inform severe and serious AEFI cases telephonically by vaccinator to supervisor/medical officer/DIO.



- Only basic information is entered in Co-WIN, which is automatically transferred to SAFE-VAC.
- Once the basic case details are entered through Co-WIN, DIO can generate CRF for a serious / severe case. DIO, using a single sign-on through Co-WIN, can access SAFE-VAC for AEFIs related to COVID-19 vaccines and can enter information into CRF, PCIF, FCIF and can upload the documents

AEFI registers at PHC/block/planning unit levels: ANMs at block/planning unit should notify all AEFIs (serious, severe and minor) of their respective areas on weekly basis and document them in the AEFI register which is being maintained at the centre. Medical Officer In-charge of the block or planning unit (PHCs, CHCs etc.) should analyse the information regularly to look for any pattern or preventable programme errors and inform to District Immunization Officer.

Reporting and investigation of cluster AEFI cases: Cluster of AEFI cases is a specific condition which warrants immediate investigation because of its nature and seriousness. Each case of an AEFI cluster should be separately reported and investigated as per national AEFI guidelines.

For known anxiety clusters, separate CRFs should be filled for each case of a cluster. In confirmed anxiety clusters ONLY, if symptoms, clinical sequence of events, treatment and outcome are similar in all cases, a single, completely-filled PCIF and FCIF with all critical information recorded can be submitted. In addition, a summary report of the district AEFI committee certifying that this is an anxiety cluster should also be submitted along with the CRFs, PCIF, FCIF, hospital records, etc. of the cluster.

If cases of a cluster are showing different clinical pictures, separate PCIFs, FCIFs need to be filled for each case.

10.6 INVESTIGATION OF AEFI CASES

All serious and severe AEFI cases after COVID-19 vaccines must be investigated as per the National AEFI Guidelines. The process of investigation must be expedited in order to collect accurate and complete clinical and epidemiological facts so that causality assessment can be completed as soon as possible. Following actions are required in advance as preparation for investigation of cases:

- District AEFI committee meetings must be held at least one month prior to the start of COVID-19 vaccination. All members of the committee must be sensitized, and their services should be utilized, if needed, to investigate the cases.
- The district AEFI committees must include drug inspectors and ensure their support in the investigations.
- Medical Officers of government and private health care facilities, where serious AEFI cases are expected to reach for treatment, must be informed and sensitized about AEFI surveillance for immediate reporting and cooperation in investigations. Their support is also crucial for ensuring availability of medical records and clinical details of the cases which are required for causality assessment of the cases.

If a death following vaccination is reported, and the case was not hospitalised or clinical records are not available, relatives should be motivated to give consent for post mortem. Post mortems should be conducted to find the pathological cause of death. Any samples sent for laboratory tests should be followed up for obtaining results as soon as possible.

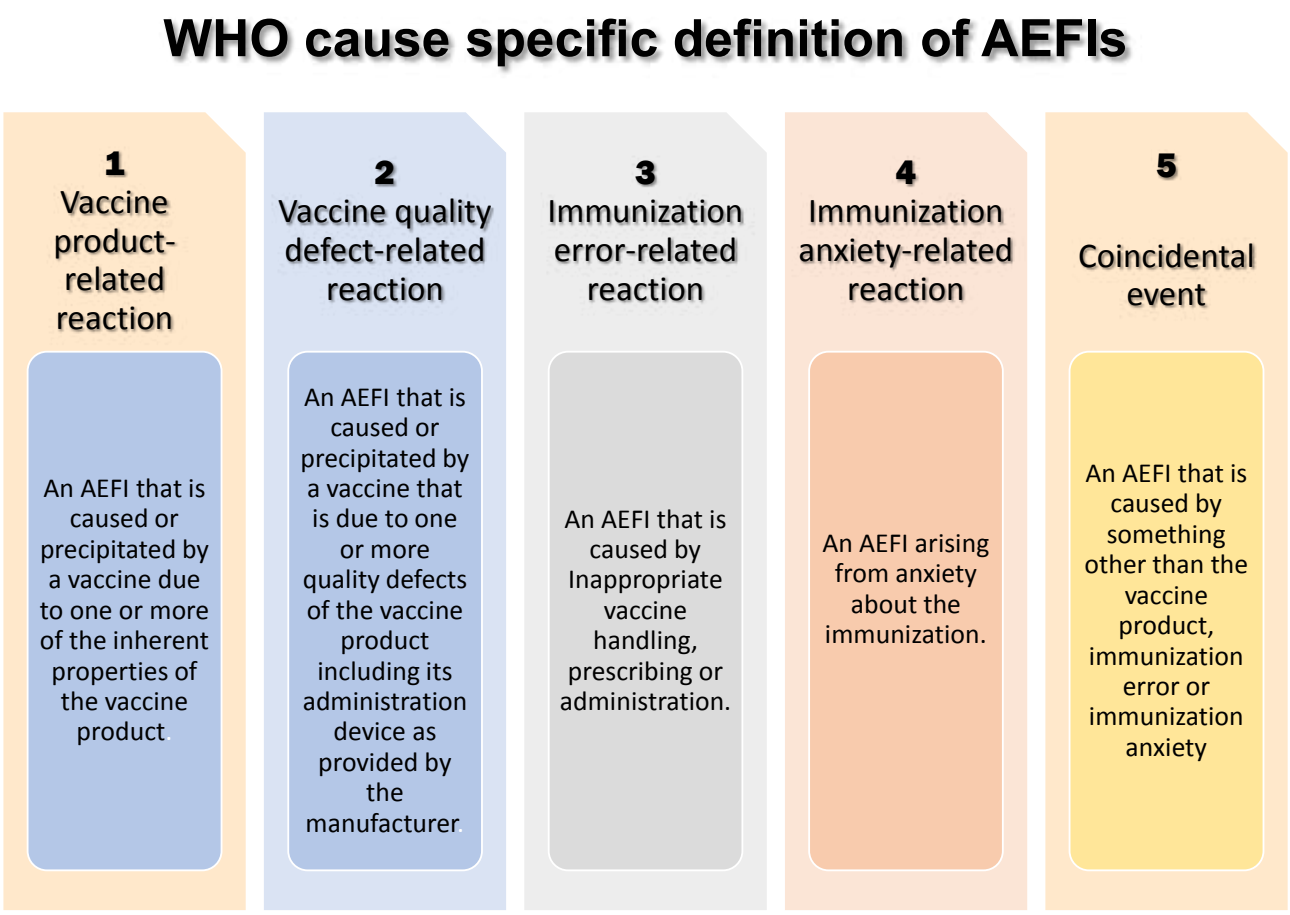
If consent for post mortem is refused, the AEFI verbal autopsy form should be administered as soon as possible.

10.7 TESTING OF VACCINE SAMPLES

The testing of vaccine samples is done very rarely. It should not be done unless there is a specific reason to doubt vaccine quality. Decision for testing will be taken by the district AEFI committee and the DIO should consult the state for this. Necessary guidelines and procedures for testing of COVID 19 vaccine samples available at that time should be followed.

10.8 CAUSALITY ASSESSMENT

Once investigations are complete for a serious/severe AEFI case and all supporting documents are available (hospital records, post mortem reports, final outcome), trained experts of the state and national AEFI committees assess the case as per globally accepted causality assessment protocol and available evidence of safety profile of the vaccine to classify it as follows:



10.9 CAPACITY BUILDING ACTIVITIES

Training on AEFI surveillance will be a part of overall training package for COVID-19 vaccine implementation. Cascaded trainings will be conducted till the level of vaccinators. The content will provide information on AEFI surveillance system in the country with roles and responsibilities and specific information on AEFIs related to COVID-19 vaccines. All personnel involved in vaccination and AEFI surveillance including those in the private sector should be sensitized for identification and reporting of AEFIs.

10.9.1 ROLES AND RESPONSIBILITIES

Session site

Vaccinator Officer–vaccinator at the session site will be responsible for administering COVID19 vaccines safely as per guidelines and conveying appropriate messages to each beneficiary regarding management of AEFIs. S/he will also be responsible for reporting all AEFIs informed to her through recommended channels.

a. Inform the beneficiaries about the possible minor adverse events following COVID-19 vaccination

b. Ask beneficiaries to wait at vaccination sites for 30 minutes after vaccination

c. If any adverse event happens at the session site, manage appropriately

   i. Primary treatment to all AEFIs

   ii. Inj. Adrenaline for suspected anaphylaxis

   iii. Inform to MO / DIO

   iv. Arrange transport to refer, if required

   v. Enter the AEFI information in beneficiary module of Co-WIN

d. If any person reports about adverse event after 30 minutes following vaccination

   i. Ask beneficiary to contact nearest health care facility for prompt management

   ii. Enter the AEFI information in beneficiary module

SUPERVISOR

Supervisor will ensure that the trained vaccinators at sessions are following all guidelines for safe administration of vaccines, conveying correct messages regarding adverse events and their management and ensure availability of anaphylaxis kits at the session site.

PHC / AEFI MANAGEMENT CENTRE

Medical Officer – The medical officer at the PHC will ensure that all session sites are tagged to an AEFI management centre with AEFI management kits. S/he should be trained in managing emergencies following COVID19 vaccination and ensures adrenaline ampoules at the session sites are within expiry dates.

DISTRICT LEVEL

a. DIO should ensure all health personnel involved in the COVID19 immunization programme are trained, cold chain is adequate, and processes are in place to manage AEFIs following vaccination.

b. DIO should network with all large hospitals and medical colleges (government, PSU, autonomous and private) and doctors to report minor, serious and severe AEFIs using the recommended processes.

c. District AEFI Committee - DIO will expand the committee to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist. These specialists will support DIOs in investigation of the case and establishing a diagnosis for causality assessment. District AEFI committee shall meet at least 15 days before the campaign to familiarise itself regarding preparations for vaccination, potential vaccine issues, is available to conduct urgent serious AEFI investigations and assesses investigation reports to give probable diagnosis.

d. If any serious/severe AEFI case is reported

- Arrange for clinical management at secondary or tertiary care hospitals
- Investigate the case
- If the case information has not already been entered in Co-WIN by vaccinator, enter the basic information through district log-in (information is automatically transferred from Co-WIN to SAFE-VAC)
- Complete CRF, PCIF and FCIF in SAFE-VAC
- Entry of all AEFIs (minor, severe and serious) reported directly to DIO by persons not having access to Co-WIN (MOs, private practitioners, other healthcare staff etc.)

Preparatory

- Expansion of District AEFI Committee
- Sensitization of District AEFI Committee members
- Expansion of reporting network – medical colleges, private practitioners

AEFI Management

- Arrange for clinical management
- Investigate the case
- Enter the basic information into Co-WIN
- Complete CRF, PCIF and FCIF in SAFE-VAC

Reporting

- Entry of all AEFIs (minor, severe and serious) reported directly to DIO by persons not having access to Co-WIN (MOs, private practitioners, other healthcare staff etc.)

STATE LEVEL

- **SEPIO**–Ensure all districts are using trained vaccinators for session sites, and they are aware of procedures for managing, reporting and investigating AEFIs as per guidelines. He/she ensures state AEFI committee and district AEFI committee members are oriented on COVID19 vaccination and are aware of their roles and responsibilities.
- **State AEFI Committee**–SEPIO will expand State AEFI Committee to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist. State AEFI committee meets at least 7 days before the campaign to familiarise itself regarding preparations for vaccination, potential vaccine issues, be available to conduct urgent serious AEFI investigations and assess causality of AEFI cases following COVID19 vaccinations within recommended timelines.

NATIONAL LEVEL

a. **MOHFW (including AEFI Secretariat)** – Coordinates with partners to ensure preparations are in place for COVID 19 vaccination. Reported and investigated AEFIs are causally assessed and database analysed for potential signals. Consultative meetings with experts are held for further management of potential signals.

b. National AEFI Committee – National AEFI Committee will be expanded to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist. The national AEFI committee monitors the progress and analysis/ assessment of AEFIs reported and investigated in the districts, conducts and approves causality assessment results, assesses causality assessment data and active surveillance data for better understanding of the safety profile of COVID19 vaccines.

10.10 ADVERSE EVENTS OF SPECIAL INTEREST (AESI) SURVEILLANCE FOR COVID 19

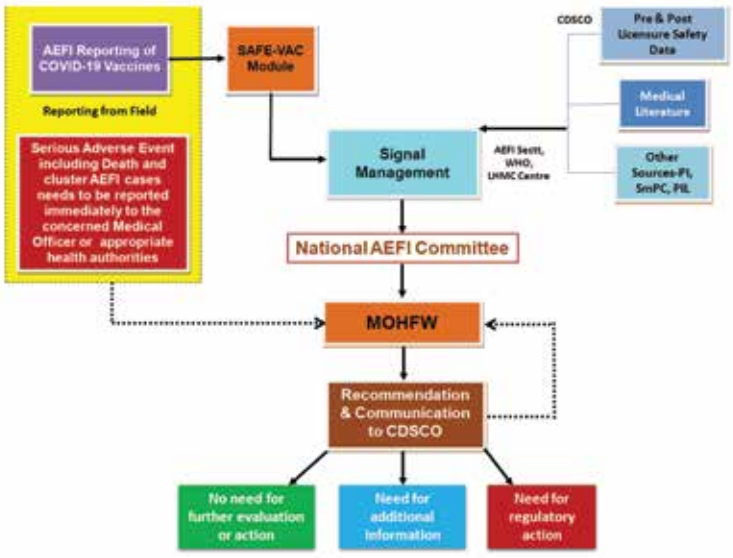
When a new vaccine is approved for use, there is a theoretical possibility of occurrence of some events based on available data for existing and new vaccines. Such Adverse Events of Special Interest (AESI) should be monitored

- To ensure these are not occurring at a rate more than the background or expected rate and
- To elicit safety issues related to these as early as possible and take appropriate action

An active AESI sentinel surveillance, which is one of the ways to assess these AESIs, will complement the regular passive AEFI surveillance system. The combined evidences from routine AEFI surveillance and active AESI surveillance will further help in generating sound evidence to characterize the safety profile of the new vaccine. A few sentinel sites across the country will be chosen for this AESI surveillance as part of separate project.

10.11 SIGNAL MANAGEMENT AND SAFETY MONITORING

The evaluation of safety signals identified through reported AEFIs is part of vaccine vigilance and is essential to ensure that regulatory authorities and immunization programme have the most up-to-date information on benefits and risks. Database of AEFI cases reported from the districts, can be analysed for safety signals by integrating automated data-mining and appropriate statistical methodologies. The evidences generated by the system will equip decision makers to take important decisions to ensure vaccines administered under the programme are safe.



KEY POINTS

1. Expand committees at various levels to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist
2. Expand reporting network through sensitizing medical colleges, private practitioners and medical officers
3. Expedite investigation and causality assessment of cases
4. Prompt case management / referral of AEFI cases
5. Vaccinators at the session sites and DIOs at district level can directly enter basic information of AEFIs following COVID-19 vaccines, which will be transferred automatically to SAFE-VAC for further processing.

"Exhibit-B"

E- FILED ON: 13/1/2022

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 580 OF 2021

IN THE MATTER OF:

EVARA FOUNDATION ... PETITIONER

VERSUS

UNION OF INDIA & ORS. ... RESPONDENTS

AFFIDAVIT DATED 13.01.2022 ON BEHALF OF THE UNION OF INDIA

PAPER-BOOK

(FOR INDEX KINDLY SEE INSIDE)

ADVOCATE FOR THE UNION OF INDIA: G S MAKKER

ADVOCATE FOR THE UNION OF INDIA: G S MAKKER

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 580 OF 2021

IN THE MATTER OF:

EVARA FOUNDATION ... PETITIONER

VERSUS

UNION OF INDIA & ORS. ... RESPONDENTS

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IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL WRIT JURISDICTION
WRIT PETITION (CIVIL) NO.580 OF 2021

EVARA FOUNDATION ...PETITIONER

VERSUS

UNION OF INDIA &ANR. ...RESPONDENTS

AFFIDAVIT DATED 13.01.2022 ON BEHALF OF THE UNION OF INDIA

I, Dr. Veena Dhawan, Wife of Dr. Puneet Dhawan, aged 56 years, working as Joint Commissioner (UIP) in the Ministry of Health & Family Welfare, Government of India, the deponent herein, do hereby solemnly affirm and state on oath as under:-

1. That I am Joint Commissioner (UIP) in the Ministry of Health & Family Welfare, Government of India ('MoHFW'). I am filing this affidavit in furtherance of this Hon'ble Court's order dated 03.12.2021 wherein this Hon'ble Court was pleased to observe as under:

"... A preliminary affidavit has been filed by the Union of India. In view of the contents of the affidavit which has been filed on behalf of

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16959 Exp. Date: 31.01.2025 GOVT. OF INDIA

(डॉ. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त आयुक्त (इम्यु.)
Joint Commissioner (Imm.)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
Govt. of India

the Union of India, we grant liberty to the Petitioner to formulate any concrete suggestions which they may have to strengthen the existing framework for facilitating the vaccination of the disabled and to ensure that they have proper access to vaccination against COVID-19.

Mr. Pankaj Sinha, Counsel appearing on behalf of the Petitioner, together with other counsel appearing for the Petitioner, would, after due consultation, prepare a set of suggestions which can be emailed to the following email id: cmvc.dyc@gmail.com. A copy of the suggestions shall also be emailed to Ms. Aishwarya Bhati, Additional Solicitor General appearing on behalf of the Union of India. Once the suggestions are emailed, they would be the subject matter of further deliberations, with a view to consider if the existing framework for vaccination of the disabled needs to be suitably strengthened by incorporating additional safeguards or facilities. Ms. Aishwarya Bhati may respond to the suggestions with proposed measures."

2. That in furtherance of the above order, the Union of India received a list of suggestions from the Petitioner on 09.12.2021, which have been duly considered and the deponent is filing the present affidavit to apprise this Hon'ble Court about the steps that have been taken to address the suggestions given by the Petitioner.

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3. India's COVID-19 vaccination programme is the largest vaccination programme in the world. As on 11.01.2022, a total of 1,52,95,43,602 doses have been administered wherein, 90.84% of eligible adult population has received their first dose of the vaccine and 61% has received their second doses. Furthermore, a total of 23678 doses have been administered to disabled persons who have voluntarily chosen to be identified as such by using their Unique Disability ID Card/Disability Certificate for registration at the time of their vaccination.

PRELIMINARY SUBMISSIONS

4. At the outset, it is most respectfully submitted that India's COVID-19 vaccination drive is being guided by scientific and domain knowledge experts through a National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). NEGVAC provides guidance on all aspect of COVID-19 vaccination including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc. The NEGVAC comprises of subject matter experts, Secretaries of all pertinent Ministries of Government of India, eminent technical experts and State Governments' representatives for

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evidence based and collaborative decision making that is adaptive to local needs. On technical aspects pertaining to COVID-19 vaccination, the NEGVAC is guided by the National Technical Advisory Group of Immunisation (NTAGI) which is India's apex advisory body on immunisation. The NTAGI examines the technical aspects like usage of different varieties of COVID-19 Vaccines, interval between vaccine doses, contraindications etc. and recommends the same to NEGVAC. NEGVAC in turn provides overall guidance and recommendations on all aspects of COVID-19 vaccination to MoHFW including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc.

RESPONSE TO SUGGESTIONS MADE BY THE PETITIONER

5. Helpline numbers: It is humbly submitted that this suggestion has already been implemented. The Government of India has a toll-free 24x7 national helpline number 1075 which caters to queries on COVID-19 vaccination from every individual, including those with disabilities. A Technical Helpline (0120-4473222) has also been established to specifically handle Co-WIN software

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related queries. The personnel administering these helplines are aware of advisories and guidance documents issued by MoHFW in regard to differently abled people. There is also a State 104 Helpline number, which is primarily intended to provide medical assistance for several minor illnesses, ailments, and mental distresses, along with details on health schemes. The GoI has also provided guidance for augmenting the capacity of 104 Helpline for addressing queries on COVID-19 vaccination including grievance redressal related to vaccination process as well as linking to concerned facilities for management of any adverse event (available at: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf).

Further guidance has been provided by Government of India by way of letter dated 11.06.2021 for orientation of 104 helpline personnel so as to facilitate the provision of requisite information to differently abled persons so as to facilitate their proper care and vaccination.

Ref: Letter dated 11.06.2021 issued by Secretary, MoHFW at page 20 of Preliminary Affidavit dated 30.09.2021.

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Furthermore, for medical query related assistance, MoHFW has established a patient to doctor telemedicine platform. Accordingly, a National Telemedicine Service by the name of eSanjeevaniOPD (https://www.esanjeevaniopd.in/) was rolled out nationally by MohFW on 13.04.2020 in the early stage of the COVID-19 pandemic. Since then, eSanjeevaniOPD (National Telemedicine Service) has been rolled out by 30 States and around 25,000 doctors have been on-boarded on eSanjeevaniOPD. Over 531 online OPDs are functional on eSanjeevaniOPD of which over 480 are specialist and super-specialist OPDs and 51 are General OPDs. Till now 63,56,743 consultations have been effected on eSanjeevaniOPD. eSanjeevaniOPD is citizen-friendly safe medium to seek health services by citizens in the confines of their homes. In many states eSanjeevaniOPD services are available round the clock and even on holidays.

6. Door to door vaccination and other measures relating to vaccination centers: It is most respectfully submitted that suggestions in this regard have already been implemented. It is humbly submitted that guidance has been provided to States/UTs to undertake meticulous, need-based micro-planning so that Near

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to Home Vaccination Centre (NHCVC) strategy is undertaken at block/urban area level and identification of NHCVC sites done as per Guidelines. The location of NHCVCs is to be done by district/urban task forces so as to ensure maximum reach of services to the eligible population.

Guidelines on NHCVC suggest utilizing of line lists already available with health or other departments (like department of Social Welfare) at state/district level. Provisions have already been made to consider scenarios where there is a group of target beneficiaries under one roof such as institutions serving differently abled people, old age homes etc; wherein the NHCVC can be organized at that site as per operational guidelines.

NHCVC Guidelines also details the steps that may be taken for making the vaccination centre friendly to the elderly and persons with special needs. The Guidelines further mention that vaccination team will facilitate on-site registration of the targeted beneficiaries in the Co-WIN portal, if they are not already registered.

States have been advised that while NHCVCs should continue to be functional, at the same time, it must also be

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ensured that other CVCs are also fully accessible to persons with disabilities as per the accessibility standards mandated under Rights of Persons with Disabilities Act 2016.

Ref: Annexure R/2 at pages 13-19 and Annexure R/4 at pages 22-23 of the Preliminary Affidavit dated 30.09.2021.

Keeping in view the need of all persons who might be bed ridden or have extremely restricted mobility or disability and/or special needs that may hamper their accessibility even to Near to Home Vaccination Centres (NHCVCs), Government of India in its letter dated 22.09.2021 has advised all States/UTs for preparing a line-list of all such potential beneficiaries and their care givers and subsequently vaccinate all such beneficiaries at their place of residence using mobile vaccination teams. Furthermore, on 03.11.2021, the Government of India launched the "Har Ghar dastak Abhiyan" campaign to ensure 100% coverage of eligible beneficiaries with first dose and vaccination of due beneficiaries with second dose of the COVID-19 vaccines. Due beneficiaries identified by the team are vaccinated on the spot or mobilized to CVC, if one is operational in close vicinity. This brings the Covid 19 vaccination to the door step of all due beneficiaries, including persons with disabilities. Spot registration of all beneficiaries and

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vaccination doses in Co-WIN in door-to-door campaigns and through mobile teams is facilitated by the vaccinators.

A true copy of letter dated 01.11.2021 for the Har Ghar Dastak Campaign is annexed herewith and marked as **ANNEXURE- R/1.**

7. **Vaccination access for persons with disabilities without ID cards**: It is most respectfully submitted that suggestions in this regard have already been implemented. Provisions have been made for persons who do not have any of the prescribed ID cards for availing Covid-19 vaccinations by following Facilitated Cohort Registration process on Co-WIN. Co-WIN system provides the facility for creation of special vaccination sessions for this purpose and these sessions will have the features of registration of as many beneficiaries as are to be covered (subject to the limit of session capacity), without mandatory capturing of Mobile Number and Photo ID Card, through facilitated cohort registration and all vaccination slots in such special sessions will be reserved for vaccination of such facilitated cohorts. It may be noted that as on 06.01.2022, a total of 58,81,979 persons without any IDs have been vaccinated under the National COVID-19 vaccination programme.

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A true copy of the SOP for COVID-19 vaccination of persons without prescribed ID cards through Co-WIN is annexed herewith and marked as **ANNEXURE – R2.**

8. **Definition of disability:** It is most respectfully submitted that the scope of the National COVID-19 vaccination programme is to vaccinate all eligible population, including all persons with different types of disabilities. For the purposes of the COVID-19 vaccination programme, the definition of disability under the Rights of Persons with Disabilities Act, 2016 and the contours thereof are immaterial.

9. **Data collection of persons with disabilities:** It is most respectfully submitted that the scope of the National COVID-19 Vaccination Programme is to facilitate self-registration and vaccination of all eligible population in the shortest possible time, taking into consideration the needs of vulnerable sections of society. The framework for data collection/recording on Co-WIN portal is decided by technical groups such as NEGVAC and NTAGI based on scientific necessity.

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10. Nodal Officers: As previously submitted in the Preliminary Affidavit dated 30.09.2021, this suggestion has already been implemented by the Government of India. It is most respectfully submitted that in its letter dated 11.06.2021, Government of India has advised that District level officer of Disability/Social Welfare department is to be considered as designated Nodal Officer for the purpose of dealing with redressal of grievances of differently abled persons in connection with COVID-19. She/he will work in close co-ordination with Chief Medical Officer of the district for the said purpose.

Ref: Annexure R/3 at pages 20-21 of Preliminary Affidavit dated 30.09.2021.

11. Information related to COVID-19 vaccination be available in accessible/disabled-friendly formats and vernacular languages: It is most respectfully submitted that the Co-WIN public interface is available in 11 regional languages in addition to English. It is also submitted that open files of awareness materials have been shared with the States for translation, publication and dissemination in any language / accessible format. It may be noted that any information pertaining

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to COVID-19 vaccination may also be sought from the multiple helplines mentioned earlier.

12. Awareness campaigns: It is most respectfully submitted that information on all aspects of COVID-19 vaccination programme is disseminated by Government of India and State/UTs through websites, print media, AV radio and television and also through other social media platforms. The Har Ghar Dastak Campaign in particular is a pan India campaign which will increase this reach even further. The Ministry has regularly promoted the National helpline number 1075 for all COVID-19 related queries.

13. Consent of persons with disabilities: It is humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and Family Welfare, do not envisage any forcible vaccination without obtaining consent of the concerned individual. It is further humbly submitted that vaccination for COVID-19 is of larger public interest in view of the ongoing pandemic situation. It is duly advised, advertised and communicated through various print and social media platforms that all citizens should get vaccinated and systems and processes

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have been designed to facilitate the same. However, no person can be forced to be vaccinated against their wishes.

14. Exemption from vaccination certificates for persons with disabilities: It is most respectfully submitted that the Government of India has not issued any SOPs which make carrying of vaccination certificate mandatory for any purpose.

15. Care providers as essential workers: It is most respectfully submitted that the National COVID-19 vaccination program endeavours to vaccinate the entire eligible population in the least amount of time. As such, Government of India in its letter dated 22.09.2021 has advised all States/UTs to vaccinate bed ridden or beneficiaries with extremely restricted mobility or disability and/or special needs along with their care givers at their place of residence using mobile vaccination teams.

Ref: Annexure R/4 at page 22 of Preliminary Affidavit dated 30.09.2021.

16. Exemption from masks/face-cover: It is humbly submitted that the practice of using masks/face cover is in line with the recommendation of the W.H.O (World Health Organization) and

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other prominent public health agencies globally and is being advocated and followed universally as one of the most important methods to prevent the spread of COVID-19 infection. Asymptomatic or pre-asymptomatic infected person who may feel well and are unaware of their infectiousness to others are also likely to transmit infections to others. Similarly, persons with disabilities are just as likely to get infected with COVID-19 and transmit the same around them as any other person. In view of the same, in larger public interest, it is advisable that use of mask/face covers be universally followed.

17. Post vaccination monitoring: It is respectfully submitted that the Adverse Event Following Immunization (AEFIs) are monitored through a well-structured & robust AEFI surveillance system which has stood the test of time. As per the AEFI surveillance guidelines for COVID-19 vaccine, any suspected adverse events, following COVID-19 vaccine may be reported by any vaccine-recipient or his/her caregiver on COWIN portal through the vaccinator or the District Immunization Officer (DIO) Ref: Covid-19 Vaccine Operational Guidelines available at MoHFW website at:

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https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf.

18. Co-WIN app and portal to be fully accessible: It is most respectfully submitted that Government of India is already implementing features in Co-WIN portal to make it more accessible to persons with disabilities as mentioned in the Preliminary Affidavit dated 30.09.2021.

19. Counselling before vaccination: It is humbly submitted that Government of India has formulated Operational Guidelines for COVID-19 vaccination. As per these Guidelines, all beneficiaries are to be informed about adverse events which may occur after COVID-19 vaccine.

Ref: Covid-19 Vaccine Operational Guidelines available at MoHFW website at: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf.

20. Accountable assessment/feedback of vaccination process: It is humbly submitted that there already exists a grievance redressal mechanism wherein all grievances received, including

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those received from persons with disabilities, are redressed in a timely manner. In addition, as mentioned earlier, nodal officers in each State have been advised to look into grievance redressal for persons with disabilities in particular.

21. The present affidavit is filed bona fide and in the interest of justice. The present affidavit is filed to apprise this Hon'ble Court on the steps taken by the Union of India in regard to issues highlighted by the Petitioner and the same may be read in conjunction with the earlier Preliminary Affidavit dated 30.09.2021 for receiving an exhaustive view on the matter.

I identify the deponent who has signed/put T.I. in my presence
MHH/433/9/2016

ATTESTED
A.N. Singh, Adv.
Notary Public
Govt. of India, Delhi
Mob.: 9718139501, 7982599115
13 JAN 2022

DEPONENT
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नई दिल्ली/New Delhi

VERIFICATION

I, the deponent above named, do hereby verify that the contents of Para 1 to 20 of my above affidavit are prepared on the basis of instructions received by me and on the basis of legal advice received and no part of it is false and nothing material has been concealed therefrom to the best of my knowledge.

Verified at New Delhi on this 13 JAN 2022

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Certified that the above Named Deponent identify by Shri/Smt. ...
Solemenly affarmed before me at Delhi
S. No. 3361
The contents of the affidavit which have been read & explained to me are true and correct
Notary
13 JAN 2022

DEPONENT
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Annexure-R/1

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सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

राजेश भूषण, आईएएस
सचिव
RAJESH BHUSHAN, IAS
SECRETARY

D.O No. 2088847/2021/Imm
1st November 2021

Dear Colleague,

Let me take this opportunity to appreciate the efforts of the States/UTs in achieving the milestone of administering 100 crore COVID-19 vaccine doses across our vast country, which is a significant feat in the fight against COVID-19 pandemic.

2. To sustain this momentum, the Hon'ble Union Minister of Health & Family Welfare had urged all States/UTs on 27th October 2021 during the meeting with Hon'ble Health Ministers of States/UTs at Delhi, to initiate '***Har Ghar Dastak Campaign***' from 3rd to 30th November, 2021 to accelerate the coverage of 1st and 2nd dose. All States/UTs were primed towards a house-to-house campaign approach vide letter of even no. dated 9th October 2021.

3. The healthcare workers are to reach out, counsel, mobilise and vaccinate all missed-out and dropped-out eligible beneficiaries to complete the vaccination schedule for adequate protection. The details for door to door vaccination has already been shared vide letter no. 2319278/2021/Imm dated 22nd September.2021.

4. For this activity, a comprehensive plan at district level should be prepared to approach the missed out and left out beneficiaries of Covid-19 vaccination & ensure they are vaccinated with the vaccine dose as due. Such district level plan has to be formulated by the District Magistrates and District Immunization Officers and then implementation has to be reviewed on a daily basis not only by the DMs but also by the State Health Department.

5. The due list for the 2nd dose can be extracted from CoWIN and can be used to reach house-to-house to identify and mobilize dropped out beneficiaries. A micro plan may be prepared and human resource from the partner agencies could be deployed to specific districts to provide support in such planning. All Panchayati Raj functionaries, NGOs may be involved for mobilization.

6. I am looking forward to your effective leadership in this massive public campaign--"***Har Ghar Dastak***".

Warm Regards.

Yours sincerely,

True Copy

(Rajesh Bhushan)

To: Additional Chief Secretary/Principal Secretary/Secretary (Health), All States/UTs

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
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Annexure-R12

18

SOPs on
COVID-19 Vaccination of Persons without prescribed Identity Cards through CoWIN

1. India's National Covid-19 Vaccination Strategy is based on scientific and epidemiological evidence and focuses on systematic end-to-end planning. Phase-I of the National Covid-19 Vaccination Strategy was launched on 16th January 2021 and focussed on protecting Health Care Workers (HCWs) and Front Line Workers (FLWs). Phase-II was initiated from 1st March 2021 and 1st April 2021 and focussed on protecting the most vulnerable i.e. population more than 45 years of age. Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy came in effect from 1st May 2021 under which COVID-19 Vaccination was opened for persons 18-44 years of age groups.

2. In all these phases, it has been prescribed that the beneficiary must either self-register or be registered in Co-WIN portal and that the identity and eligibility of the beneficiary be verified by vaccinator through one of the following seven prescribed individual Photo ID Proof prior to vaccination, namely –

    i. Aadhar Card
    ii. Electoral Photo Identity Card (EPIC) - Voter ID
    iii. Passport
    iv. Driving License
    v. PAN Card
    vi. NPR Smart Card
    vii. Pension Document with photograph.

3. Ministry is cognizant of the need for facilitating COVID-19 vaccination for all people, and especially the vulnerable groups who may not possess any of the seven prescribed Identity Cards. The Ministry has also received several representations from various state governments and agencies/organizations regarding COVID-19 Vaccination of such people who do not have any of the seven prescribed Identity Cards, required for verification before vaccination.

4. In this context, there is need to provide special consideration to vulnerable population of the country, as these beneficiaries are also at risk of exposure to COVID-19 infection and the consequent sequalae and outcomes of the disease, during the pandemic. Further they may not have any official Photo ID card like other citizens, but COVID-19 Vaccination services may not be denied in absence of Identity Proofs.

5. In view of the above, following procedure, developed in consultation with the technical experts, is hereby prescribed for providing vaccination coverage to people who do not possess any of the seven Identity Cards prescribed for availing COVID vaccination services–

    i. Such groups of people include nomads (including sadhu/saints from various religions), prison inmates, inmates in Mental Health Institutions, citizens in Old Age Homes, road side beggars, people residing in rehabilitation

True copy

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centres/camps and any other identified eligible persons, aged 18 years or more, and not having any of the seven prescribed individual Photo ID Cards.

ii. District Task Force may identify such groups of persons in respective districts not having any of the prescribed individual Photo ID Cards with assistance from concerned government department/ organisation like department of minority affairs, social justice, social welfare etc.

iii. The information regarding the identified groups and the number of beneficiaries to be covered, must be collated at the state level and the state government must issue clear instructions for implementation of these SOPs along with the district-wise estimated maximum number of doses to be administered using this special dispensation. A copy of such instructions must be displayed in public domain and should also be endorsed to the Ministry.

iv. A Key Facilitator may also be identified for each such group. The Key Facilitator must have a valid and active mobile phone and must also have at least one of the seven mandated ID cards. These could be officials of the institutions (both public or private) which normally provide care and services to people in the identified groups, e.g. Prison officials for prison inmates, Executive Officer/Superintendent of and Old Age Home etc.

v. A district nodal officer may be designated by the DTF, for identification of Key Facilitators, preparation of vaccination plan, identification of CVCs where vaccination sessions are to be organised, preparation of vaccination schedule, communication of vaccination schedule to the identified groups/beneficiaries and mobilization of beneficiaries as per vaccination plan.

vi. District Immunization Officer (DIO) will be responsible for organization of vaccination sessions at identified CVCs for providing coverage to the identified groups.

vii. The CoWIN system will provide the facility for creation of special vaccination sessions for this purpose. The session will have following features –

   i. Registration of as many beneficiaries as are to be covered (subject to the limit of session capacity), without mandatory capturing of Mobile Number and Photo ID Card, through facilitated cohort registration.
   ii. All vaccination slots in such special sessions will be reserved for vaccination of such facilitated cohorts.
   iii. This facility will only be available at government CVCs.
   iv. Information such as name, year of birth (as provided by the beneficiary) and gender will be entered in the CoWIN system for the beneficiaries.
   v. The Key Facilitator shall verify the identity of the beneficiaries.
   vi. Digital vaccination certificates are to be provided to the beneficiaries, preferably at the Vaccination Center itself.

viii. The District Nodal Officer will be personally responsible to ensure that the special dispensation provided through these instructions, is extended only to

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cover such persons who do not have any of the seven mandated Photo ID Cards.

ix. Vaccine doses made available through the Government of India channel may be used for vaccination of beneficiaries aged 45 years or more and the vaccine doses procured by the State/UT Government may be used for those aged 18 years to 44 years.

x. All technical protocols as prescribed in the Guidelines of the Ministry regarding vaccination centres and AEFI management etc., must be followed.

True Copy

"Exhibit-C"

Universal Declaration on Bioethics and Human Rights

The General Conference,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Noting the United Nations International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the General Assembly of the United Nations in 1993, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture which was adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) annexed to the Marrakech Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Also noting international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, which was adopted in 1997 and entered into force in 1999, together with its Additional Protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences, adopted in 1982 and amended in 1993 and 2002,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

Considering UNESCO's role in identifying universal principles based on shared ethical values to guide scientific and technological development and social transformation in order to identify emerging challenges in science and technology taking into account the responsibility of the present generations towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International

Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, *inter alia*, life expectancy and improving the quality of life, and *emphasizing* that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is the common heritage of humanity, but *emphasizing* that it may not be invoked at the expense of human rights and fundamental freedoms,

Also bearing in mind that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had a particular impact on indigenous and local communities,

Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity,

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations,

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and *adopts* the present Declaration.

General provisions

Article 1 – Scope

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 – Aims

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;

(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;

(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(g) to safeguard and promote the interests of the present and future generations;

(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights.

Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 – Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

(a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;

(b) access to adequate nutrition and water;

(c) improvement of living conditions and the environment;

(d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;

(e) reduction of poverty and illiteracy.

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

(b) access to quality health care;

(c) provision of new diagnostic and therapeutic modalities or products stemming from research;

(d) support for health services;

(e) access to scientific and technological knowledge;

(f) capacity-building facilities for research purposes;

(g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Application of the principles

Article 18 – Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 – Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 – Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 – Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.
4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.
5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

Promotion of the Declaration

Article 22 – Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

Article 23 – Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 24 – International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 – Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Final provisions

Article 26 – Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

"Exhibit-D"

FAQs on COVID-19 Vaccines and Vaccination Program

A. GENERAL

1. **Is vaccination for COVID-19 mandatory?**
   As per the operational guidelines issued by the GOI and disseminated to all States/ UTs the COVID-19 vaccination is totally voluntary; however, all individuals are encouraged to take vaccination for protecting themselves and their families from serious Covid-19 infection.

2. **Which COVID-19 vaccines are used in the country at present for COVID-19 Vaccination?**
   The vaccines namely **Covishield** (AstraZeneca's vaccine manufactured by Serum Institute of India), **Covaxin** (manufactured by Bharat Biotech Limited), **Sputnik V** (Manufactured by Gamaleya Research Institute, Russia and imported by Dr Reddy's Lab), **CorBEvax** (manufactured by M/s Biological E) and **Covovax** (manufactured by M/s Serum Institute of India) are being used in the country. As on August 2022, Covishield and Covaxin have received market authorization with certain conditions, where as other vaccines are permitted for restricted use in emergency situation in the country by Central Drugs Standard Control Organization (CDSCO), the National Regulator.

3. **What is Emergency Use Authorization (EUA)/ Permission for restricted use?**
   Emergency Use Authorization (EUA) is a regulatory mechanism to allow the use of vaccines and medicines to prevent and/or reduce the impact of life-threatening diseases or conditions as caused by COVID-19. However, before grant of the EUA, there are rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy. Safety is particularly critical aspect of this scrutiny and a risk-versus-benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data. EUA by Indian regulators is aligned with global guidelines.

4. **Is the EUA a new process introduced for COVID-19 Vaccine?**
   Concept of EUA always existed to save the lives of people all over the world with vaccine and medicines for life threatening diseases while companies continue to obtain additional safety and effectiveness information to enable full licensure. Previously, EUAs have been granted to vaccines for outbreaks due to Anthrax, Ebola, Enterovirus, H7N9 influenza, and Middle East Respiratory Syndrome. WHO EUL COVID-19 vaccines and their status is available on WHO website (https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjUnIHVm6L4AhWf7zgGHQ96BIIQFnoECAUQAQ&url=https%3A%2F%2Fcovid19.trackvaccines.org%2Fagency%2Fwho%2F&usg=AOvVaw2df7h7IPYNceyKBqoAVtvt)

5. Have the vaccines undergone the needed clinical trials before EUA?

All vaccines have conducted their phase I, II & III clinical trials before EUA and only after these clinical trials, they have been granted EUA by CDSCO.

6. What is Phase I, II and III of clinical trial for a vaccine?

The clinical trial phases include:

Phases of vaccine development/trial	**Purpose**
Pre-clinical	Vaccine development in laboratory animals
Phase I Clinical trial (small number of participants)	Assess vaccine safety, immune response and determine right dosage (short duration)
Phase II Clinical trial (few hundred participants)	Assess safety and the ability of the vaccine to generate an immune response (short duration)
Phase III Clinical trial (thousands of participants)	Determine vaccine effectiveness against the disease and safety in a larger group of people (duration 1-2 years)

7. Why vaccination is not provided to children who are usual target?

The general practice is to first evaluate any new vaccine in older population and then age reduction is done to assess the safety and effectiveness in paediatric population. Presently COVID-19 vaccines in India have received approval for Childrens of 12-17 years of age group among children. Therefore, COVID-19 vaccines are given to Childrens of 12-17 years age group under the National Covid-19 Vaccination Programme based on the recommendation of Domain knowledge experts.

8. What are the vaccines that have received approval for children in India?

ZyCoV D by M/s Cadila healthcare limited, Covaxin by M/s Bharat Biotech, CorBEvax by M/s Biological E Ltd. and Covovax by M/s Serum Institute of India Ltd. have received emergency used authorization by Central Drugs Standard Control Organization (CDSCO), by the National Regulator.

SN	Age group	Vaccine	Covid Vaccination Centres (CVCs)
1	12-14 year	CorBEvax	Govt and Pvt CVCs
		Covovax	Only at Pvt CVCs
		ZyCoV-D	Only at Pvt CVCs
2	15-17 years	CorBEvax	Only Pvt CVCs
		Covaxin	Govt and Pvt CVCs
		Covovax	Only at Pvt CVCs
		ZyCoV-D	Only at Pvt CVCs

B. VACCINE ATTRIBUTES

1. **What technology has been used in development of the currently available vaccines in India?**

Covishield® vaccine, manufactured by the Serum Institute of India, is a Viral Vector-based Technology which is also used to manufacture Ebola vaccine.

Covaxin® vaccine, manufactured by the Bharat Biotech, is a whole-Virion Inactivated Corona Virus Vaccine which is also used to manufacture vaccines like Influenza, Rabies and Hepatitis-A.

Sputnik V is manufactured by Gamaleya research Institute in Russia and is imported by Dr Reddy's Laboratories for Gam-COVID-Vac Combined vector vaccine (Component I & II).

CorBEvax is developed by Biological E Ltd. is a protein subunit vaccine which has receptor binding domain of SARS-CoV-2 gene.

Covovax manufactured by Serum Institute of India is a SARS-CoV-2 rS Protein COVID-19 recombinant spike protein Nanoparticle Vaccine.

ZyCoV-D manuafcured by Zydus Cadila is recombinant DNA Novel Corona Virus-2019-nCoV vaccine.

2. **What are the compositions of the above vaccines?**

Composition of Covishield® includes inactivated adenovirus with segments of Corona Virus, Aluminium Hydroxide Gel, L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, and Disodium edetate dihydrate (EDTA).

Composition of Covaxin® includes inactivated Corona Virus, Aluminium Hydroxide Gel, TLR 7/8 agonist, 2-Phenoxyethanol and Phosphate Buffered Saline

Composition of Sputnik V: Component I Active substance: replication incompetent recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene.

Component II Active substance: replication incompetent recombinant adenovirus serotype 5 particles containing SARS-CoV-2 protein S gene.

Excipients: Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, EDTA disodium salt dihydrate, polysorbate-80, ethanol 95%, and water for injection.

Composition of CorBEvax: The CorBEvax includes the following ingredients: Aluminium hydroxide gel as Al^{+++}, CpG 1018, Buffer(Tris and NaCl in WFI).

Composition of Covovax: The COVOVAX™ Vaccine includes the following ingredients: SARS-CoV-2 rS Protein, DS Adjuvant Matrix-M1 Disodium hydrogen phosphate heptahydrate, Sodium dihydrogen phosphate monohydrate, Sodium chloride Polysorbate 80.

3. **All vaccines currently used in National Covid-19 vaccination program require cold chain temperature. How is the cold chain been maintained during storage and transportation of vaccine?**

   The vaccines (Covishield, Covaxin, CorBEvax,Covovax and ZyCoV-D) need to be stored and transported at $+2^0$ to $+8^0$ Celsius. The cold chain for the vaccines is maintained through active and passive cold chain equipment available at approximately 29,000 cold chain points across India.

   Sputnik V requires storage temperature of -18^0C to -22^0C (minus eighteen degrees centigrade to minus twenty two degree centigrade) or below . This vaccine is being administered by private hospitals only.

4. **Is COVISHIELD® same as the vaccine been given by other countries like in UK by Astra Zeneca?**

   Yes, Covishield® vaccine, manufactured by the Serum Institute of India, is based on the same patent technology as the AstraZeneca vaccine administered by other countries.

5. **What is the dose schedule of the vaccines under the national Covid-19 vaccination program?**

   In the National Covid-19 vaccination programme following dose schedule is as followed:

   - Covishield®: two doses, an interval of 12-16 weeks (84-112 days)
   - Covaxin®: two doses at an interval of 4-6 weeks (28-42 days)
   - CorBEvax: two doses at an interval of 4 weeks (28 days)
   - Covovax: two doses at an interval of 3 weeks (21 Days)
   - Sputnik V: two doses at an interval of 3 weeks (21 days)
   - ZyCoV-D : two doses at an interval of 4 weeks (28 days)
   - Precaution dose (with the same vaccine or with CorBEvax following primary vaccination of Covishield & Covaxin), at an interval of 6 months (26 weeks) from the date of administration of 2nd dose.

6. **Do I have a choice of the vaccine that I will receive?**

   Yes, Co-WIN portal displays the availability of the different vaccines across the COVID Vaccination Centres, both government and private as per the age appropriate criteria. The beneficiary can choose to get vaccinated with a particular vaccine at a particular CVC of his/her choice. For more details please visit CoWIN (www.cowin.gov.in)

7. **What are the general indications for COVID-19 vaccination?:**

   a. **Co-administration with non-COVID-19 vaccines**: If required, COVID-19 vaccine and other adult vaccines should be separated by an interval of at least 14 days. However, if a person seeks emergency care due to injury/accident and had received COVID-19 vaccine in less than 14 days, tetanus toxoid injection may be provided.

   b. **Interchangeability of COVID-19 vaccines**: Till now:

      A. First & Second dose of Covid-19 vaccination should be of same vaccine and

      B. Precaution dose

I) should also be of the same COVID-19 vaccine OR

II)Heterologous Precaution Dose with CorBEvax is allowed after vaccination with second dose of Covaxin or Covishield only.

8. Who are eligible for Precaution dose?

The following types of beneficiaries who are fully vaccinated (with 2 doses) and have completed 6 months (26 weeks) after the 2nd dose, as per the records available on Co-WIN, are eligible to take precaution dose.

a. Health Care Workers (HCW)
b. Frontline Workers (FLW)
c. Citizens aged 60 years and more. It is availed at all Government CVCs free of cost and Private CVCs in all States/UTs

Under Covid Vaccination Amrit Mahostav,all Citizens aged 18 years and more are eligible **for Precaution dose** free of cost at Govt CVCs. and also eligible for precaution dose at private CVCs on a payment basis.

C. EFFICACY & PROTECTION

1. **Developing a vaccine takes years. However, this time our scientists have developed a vaccine against the novel corona virus in such a short time. How was this possible?**
   Developing a vaccine generally involves years of research. First, we need a vaccine candidate that is evaluated in animals for its safety and efficacy. After a vaccine candidate passes a pre-clinical trial, it enters the clinical trial phase. While scientists have worked round the clock in the laboratory, even regulatory approvals that used to take several months have been fast-tracked as per standard guidelines. It helped eliminate all the time lapses between the pre-clinical and clinical trial stages. Earlier, the vaccine development involved a series of steps, but in the case of the coronavirus vaccine, the scientists and regulators worked in tandem, accelerating the whole process without compromises on any protocols and any steps.

2. **What is the safety and efficacy of the vaccines used in the country?**
   To ensure that a vaccine is safe, we need to try it on a large number of people. The vaccine developers have not reduced the sample size at any stage of clinical trials rather it was bigger than what usually a vaccine is tested on.
   When a vaccine is tested, most of the adverse events or unwanted effects, if any, occur in the first four to six weeks of its administration. Therefore, in order to ensure that it is safe, a close watch is kept on the people it has been given to for the first two-three months. This data helps to decide if a vaccine is safe. All concerned in the line of vaccine development, testing and evaluation have followed these procedures. The vaccines being used are considered safe on this yardstick.
   As for the efficacy of the vaccine, we need time to tell how effective a vaccine is. All the global agencies have set the benchmark that only those vaccine candidates that show an efficacy of at least 50-60% will be considered. Most of the vaccines have shown an efficacy of 70-90% within the short period of two or three months of observation. Besides when a vaccine is given as emergency use authorization/permission for restricted use, as in the case of the COVID-19 vaccine, the trial follow-up continues for one to two years to assess the total duration of protection the vaccine will provide.
   More than 100 crore people have received at least a single dose of Covid-19 vaccine and the proportion of side effects is very low.

3. **Do I need to use mask/other COVID appropriate precautions after receiving the vaccine?**
   Yes, it is absolutely necessary that everyone who has received the COVID vaccine should continue to follow COVID appropriate behaviour i.e., mask, do gaj ki doori (physical distance of 6 feet) and hand sanitization; this is required to protect themselves and those around from spreading the infection.

4. **How long I will remain protected after vaccination?**
   The longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, maintaining physical distance and other COVID-19 appropriate behaviours is strongly recommended.

5. **Does vaccination protect me against newer strains / mutated virus of SARS-CoV2?**
   All vaccines are expected to provide reasonable amount of protection against the mutated virus also.

6. **Which vaccine is better between Covishield®/Covaxin®/Sputnik V/CorBEvax/Covovax/ZyCoV-D?**
   There is no head-to-head comparison done between the vaccines being used in India, so one cannot choose one over another. All vaccines would work well in reducing the mortality and morbidity caused by COVID-19 disease.

7. **In how many days will the vaccination create an adequate immune response and protection?**
   Adequate immune response develops approximately 2-3 weeks after completion of the Primary vaccination schedule i.e., after the second dose of Covid-19 vaccine in most of the beneficiaries.

8. **Does this vaccine provide herd immunity?**
   When an increasing number of people get vaccinated in the community, indirect protection through herd immunity develops.
   The percentage of people who need to be immune in order to achieve herd immunity varies with each disease. For example, its 95% for measles, however, the proportion of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known.

D. SIDE-EFFECTS

1. **What are expected immediate and delayed side effects of this vaccine?**

Covishield®: Some mild symptoms may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia, nausea. Very rare events of demyelinating disorders, thrombosis with thrombocytopenia syndrome (TTS) have been reported following vaccination with this vaccine. **Any specific Information for vaccine beneficiaries in relation to Covishield® vaccine?**

A vaccine beneficiary vaccinated with any of the COVID-19 vaccines, particularly Covishield® and having one or more of the symptoms mentioned below should be suspected to have Thrombosis and Thrombocytopenia Syndrome (TTS). Persons taking Covishiled should be vigilant for atleast 30 days after taking vaccine for the following symptoms:

- Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache)
- Shortness of breath
- Chest Pain
- Pain in limbs / pain on pressing the limbs or swelling in the limbs (arm or calf)
- Multiple, pinhead size red spots or bruising of skin in an area beyond the injection site
- Persistent abdominal pain with or without vomiting
- Seizures in the absence of previous history of seizures with or without vomiting
- Weakness/paralysis of limbs or any particular side or part of the body (includes cranial nerve involvements)
- Persistent vomiting without any obvious reason
- Blurred vision/ pain in eyes/Diplopia
- Mental status change / encephalopathy/ depressed level of consciousness
- Any other symptom or health condition which is of concern to the recipient or the family

Contraindications for the administration of COVISHIELD in the context of TTS:

Past history of major venous and arterial thrombosis occurring with thrombocytopenia.

Covaxin®: Some mild symptoms AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough and injection site swelling.

Sputnik V:

Short term general: Chills, fever, arthralgia, myalgia, asthenia, general discomfort, headache

➢ Local: injection site tenderness, hyperaemia, swelling

➢ Less common: nausea, dyspepsia, loss of appetite,

➢ Occasionally: enlarged regional lymph nodes

CorBEvax:
Systemic:
Common: Fever/Pyrexia, Headache, Fatigue, Body Pain, Myalgia, Nausea
Uncommon: Arthalgia, urticaria, Chills, Lethargy
Local:
Common: Injection Site Pain (Very common), Injection site erythema
Uncommon: Injection site swelling, Injection site rash, Injection site pruritis
Rare: Injection site irritation

Covovax:
Very Common: Injection site pain, Injection site tenderness, Feeling tired (fatigue) , Malaise ,Headache , Fever , Soreness of muscles , Joint pain , Nausea or vomiting
Common: Chills, Injection site redness , Injection site swelling , Injection site induration (hardness) , Pain in extremity (legs or arms) , Body ache
Uncommon: Asthenia (weakness or lack of energy), Injection site pruritus (itching) , Injection site rash , Rash , Skin redness , Itching , Hives , Enlarged lymph nodes , Back pain
Rare: Dizziness (feeling dizzy) , Sleepiness

ZyCoV-D :
Pain at injection site, redness, swelling and itching, headache, fever, muscle pain, and fatigue, Arthralgia, Back pain, Muscle spasms, Myalgia, Musculoskeletal pain, Neck pain, Vertigo, Diarrhoea, Gastritis, Gastrooesophageal reflux disease, Nausea, Vomiting, Asthenia, Chills, Eye irritation, Abdominal distension, Abdominal pain, Fatigue, Pain, Pyrexia, Nasopharyngitis, Pain in extremity, Ageusia, Anosmia, Cerebral infarction, Dizziness, Headache, Cough, Dyspnoea, Nasal dryness, Oropharyngeal pain, Rhinorrhoea, Sneezing.
Source: As per the data information provided by vaccine manufacturer

2. **What do I do if I have fever, pain or any other side-effect after vaccination?**
Post-vaccination, you must wait for at least half an hour at the center so that side-effects can be managed. If they occur afterwards, please contact the nearest health facility or the health care worker for guidance.

3. **What are the contraindications to COVID-19 vaccines?**
1. Persons with history of:
    - Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine and its ingredients.
    - A suspected or confirmed case of thromboembolic phenomenon following first dose of any of the COVID-19 vaccines
    - Immediate or delayed-onset anaphylaxis or allergic reaction requiring hospitalization to vaccines or injectable therapies, pharmaceutical products, food-items and insect sting etc.
2. The vaccination may be deferred in the following scenario

i. In case of individuals having lab test proven SARS-2 COVID-19 illness, COVID-19 vaccination to be deferred by 3 months after recovery.
ii. In case of SARS-2 COVID-19 patients who have been given anti-SARS-2 monoclonal antibodies or convalescent plasma, COVID-19 vaccination is to be deferred by 3 months from discharge from the hospital.
iii. In case of individuals who have received at least 1st dose and got COVID-19 infection before completion of the dose schedule, the 2nd dose should be deferred by 3 months from clinical recovery from COVID-19 illness.

3. An Individual can donate blood after 14 days of either receipt of COVID-19 vaccine or getting RT-PCR negative, if suffering from COVID-19 disease.

4. Which drug should be taken to minimize the adverse effects of this vaccine?

The minor adverse effects of Covid-19 vaccination such as injection site pain, tenderness, malaise, pyrexia, etc., are self-limiting. In case of no relief, Health Care Worker (HCWs) may be contacted to seek further advice.

5. Claims on social media suggested that COVID-19 vaccine could affect female fertility. Is it true?

Rumours or social media posts suggesting that COVID-19 vaccines could cause infertility are not true and totally baseless. Such rumours were floated in the past against other vaccines like e.g. polio and measles. None of the available Covid-19 vaccines affects fertility. All vaccines and their constituents are tested first on animals and later in humans to assess if they have any such side effects. Vaccines are authorized for Human use only after their safety and efficacy is assured and ascertained.

6. Should one avoid taking vaccine during and around menstruation?

The time period around menstruation is no contraindication for taking vaccines and like other vaccines, COVID-19 vaccine can be taken at any time of the monthly menstrual period.

7. Do I need to get myself tested for COVID-19 before taking the vaccine?

No, there is no requirement for screening of the vaccine recipient by Rapid Antigen Test (RAT) or RTPCR prior to COVID-19 vaccination. However, if you are symptomatic and suspected of suffering from COVID-19 infection, it is advisable to get tested yourself for Covid-19. In case of COVID-19 positive by lab test, COVID-19 vaccination can be deferred for 3 months (90 days)/12 weeks from the date of recovery of illness.

E. PRECAUTIONS

1. **What precautions do I need to take after receiving the vaccine?**
   COVID-19 vaccines are safe but in case of any bodily discomfort or complaint, the beneficiary should contact Health Care Worker (HCWs) or visit the nearest health facility, District Immunization Officer or call at 1075.

2. **If I suffer from HTN/DM/CKD/heart disease/lipid disorders etc., can I safely take this vaccine?**
   Overall, the vaccine is safe and efficacious in adults with co-morbidity. However, if you are concerned for any specific medical reason, please consult your Health Care Worker prior to Covid vaccination.

3. **What medications should be avoided before taking COVID-19 vaccine and for how long?**
   A person receiving aspirin, clopidogrel (both of these are anti-platelet agents) or other anti-coagulants; the dose of that day should be taken after the vaccination. Patients on Vitamin K antagonist (VKA) should have an International Normalized Ratio (INR) less than 3 before administration of the vaccine. In all cases, application of firm pressure at the injection site for at least 5 minutes after the injection may be done to reduce the risk of haematoma formation. The beneficiary should also inform to vaccinator about the same, prior to Covid vaccination.

4. **The Health Ministry has advised caution in vaccinating persons with a history of bleeding or coagulation disorder. How does a person know if he/she has a coagulation disorder? What tests can be conducted?**
   There are a few bleeding disorders like 'haemophilia'. These persons should take the vaccine under the supervision of their treating physician. Patients who are admitted in hospital or ICU and have bleeding problems should delay the vaccination till they are discharged. However, several people with heart and brain disorders are on blood thinners like aspirin and anti-platelet drugs. They can continue with their medicines and have the vaccines. Vaccine should be administered with caution in persons with history of any bleeding or coagulation disorder (e.g., clotting factor deficiency, coagulopathy or platelet disorder). In such persons, there is a slightly increased risk of bleeding through the intra-muscular route of administration.
   Individuals with these disorders are to be treated as those with any co-morbidity, they are an at-risk population and hence should be encouraged to get COVID-19 vaccines. COVID-19 vaccine should be administered with caution in individuals with Thalassemia and hemoglobinopathies, those who have a history of any bleeding or coagulation disorders (e.g., clotting factor deficiency, coagulopathy or platelet disorders). The vaccinator/health worker should ask these individuals and or their care providers if they have blue spots (ecchymosis), bleeding spots on the skin or prolonged oozing of blood after any injury.

In case of presence of these symptoms or any doubt about the presence of bleeding/clotting disorder, these individuals should be referred to their treating physicians for further clarification and approval for COVID-19 vaccination.

5. **The health advisory also states that those with immunity issues should be cautious about taking the vaccine. What are the markers of 'Immunity issues'?**
   Immune issues are of two types: first, immunosuppression due to any disease such as AIDS, and people on immunosuppressant drugs such as anti-cancer drugs, steroids, etc. Second, immunodeficiency in people who suffers from some defect in the body's protective system such as congenital immunodeficiency.
   Currently, available COVID vaccines do not have any live virus and therefore individuals with immune issues can have the vaccine safely. But the vaccine may not be as effective in them. One should inform the vaccinator about the medicines they consume and if they are suffering from any known immune issues. The vaccine recipient should have a record of their medical condition.
   Immuno-deficiency, HIV, patients having immune-suppression due to any condition (persons on stable immunosuppression for 12 weeks or more) should be able to safely receive the vaccine although the response to the COVID-19 vaccines may be less in these individuals.
   It is advised that such beneficiaries may seek Health Care Worker advice before taking vaccine. However, the prescription is not required for taking the vaccine.

6. **I had COVID infection and was treated, why should I receive vaccine?**
   Development of immunity or duration of protection after COVID-19 exposure is not established therefore it is recommended to receive vaccine even after COVID-19 infection.

7. **Is the vaccine contraindicated in person with chronic diseases?**
   Chronic diseases and morbidities like the Cardiac, neurological, pulmonary, , metabolic, renal and malignancies etc. are not contraindicated. In fact, the benefit of COVID vaccines to reduce the risk of severe COVID disease and death is for those who have these co-morbidities.

F. COVID-19 VACCINATION PROGRAM

1. **How are the policy decisions on COVID-19 vaccination being taken in the country?**
   - A National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) was constituted by Cabinet Secretariat on 7th August 2020 under the Chairpersonship of Member (Health) NITI Aayog and Co-Chairpersonship of Secretary (H&FW).
   - NEGVAC has representation of Secretaries from Ministry of External Affairs, Dept. of Biotechnology, Dept. of Health Research, Pharmaceuticals, MeitY, Finance and State governments and technical experts including Director General Health Services (DGHS), Directors of AIIMS, National AIDS Research Institute (NARI) and experts from National Technical Advisory Group on Immunization (NTAGI) and five state governments.
   - The NEGVAC has guided on all aspects of COVID-19 Vaccine introduction in India including Regulatory Guidance on Vaccine Trials, Vaccine selection, equitable distribution of vaccine, procurements, financing, delivery mechanisms, prioritization of population groups, vaccine Safety Surveillance, regional cooperation and assisting neighbouring countries, communication & media response etc.
   - Domain knowledge experts have continuously guided the policy decision in National Covid-19 vaccination programme.

2. **What are the principles followed for selecting the priority groups for vaccination?**
   The prioritization of beneficiaries for COVID-19 vaccination in India has been done based on the review of available scientific evidence, guidelines issued by the World Health Organization (WHO), global examples and practices followed in other countries with the primary objective to:
   - Protect the healthcare and the pandemic response system
   - Prevent deaths due to COVID-19 and protect individuals at highest risk and vulnerability of mortality due to Covid-19 disease

   The current prioritization is the most preferred approach as it follows WHO guidelines and is based on the principle of equity wherein the most vulnerable to complications and mortality from COVID-19 disease are prioritized for vaccination.

3. **Whether the Central or State Governments propose to undertake targeted vaccination drives for persons who are at the forefront of the war against COVID-19 and those that are providing on-ground assistance during the pandemic?**
   Those who are at the frontline of the fight against COVID-19 include the healthcare workers in the public and the private health care facilities involved in direct care of the COVID-19 patients and are most at risk of exposure were the first to receive the vaccination. This was followed by those who are exposing themselves to risk of exposure while carrying out the surveillance and containment measures and were included as frontline workers and were the second to be vaccinated.

4. **How has the COVID-19 vaccination been introduced and scaled up in the country?**

Based on the recommendations of NEGVAC and approval of GoI, COVID-19 vaccination programme started with the Health Care Workers (HCWs) who were directly involved in care of the COVID-19 patients w.e.f 16th January 2021 followed by Front Line Workers (FLWs) who were involved in containment and enforcement activities from 2nd February 2021.

Subsequently, the individuals above 60 years and those between 45 years and 60 years with the identified 20 comorbidities were included for COVID-19 vaccination from 1st March 2021. Since 1st April 2021, prioritized age group was expanded to cover all persons aged 45 years and above for COVID-19 vaccination.. Starting 1st May, 2021 the eligible age for vaccination was expanded to cover all adults above 18 years.

- The program has further expanded to include adolescents aged 15 to 18 years from 3rd January 2022, and administration of precaution dose to Health Care Workers, Front Line Workers and persons aged ≥60 years with co-morbidities from 10th January 2022.
- On 14th March 2022, it was announced to expand National COVID-19 vaccination program to age group of 12-14 years of age along with precaution dose to all beneficiaries above 60 years of age effective from 16th March 2022.
- From 10th April 2022, precaution dose of Covid-19 vaccines are made available to the 18+ population at Private COVID-19 Vaccination Centers (PCVCs) on completion of nine months i.e. 39 weeks/273 days from date of administration of second dose.
- From 13th May 2022, early administration of precaution dose of Covid-19 vaccine to Persons who need to undertake international travel for educational Purpose, employment opportunities, participation in sports tournaments in foreign countries, participation in bilateral, multilateral meetings as part of India's official delegation, for attending business commitments in foreign countries, etc has been approved , as required by the destination country, subject to a minimum period of 90 days between 2nd dose and the precaution dose.
- From 6th July 2022, the time interval between second dose & precaution dose was reduced to 6 months i.e. 26 weeks for all 18 years & above beneficiaries.
- From 15th July 2022 to 30th September 2022, under Azadi ka Amrut Mahotsav precaution dose of Covid-19 vaccines are made available free of cost to the 18+ population at Govt. COVID-19 Vaccination Centers on completion of six months i.e. 26 weeks from date of administration of second dose.

5. How have the other countries phased out their COVID-19 vaccination?

Prioritization criteria from WHO and other countries shows that a step-wise layered approach is advisable. For instance, the UK followed a step-wise approach for vaccination by first prioritizing those who are 80 years of age or above, followed by those above 75 years of age, next covering those over 70 years, and so on. Likewise, France first covered those above 75 years of age, followed by those between 65 – 74 years. Similarly, USA started with vaccination of Health Care Workers and higher age groups and COVID-19 vaccination is available as per the prescribed age group. A staggered approach has been taken by other countries starting with those in the higher age group.

6. **How has the citizen interest been kept in mind with the vaccination strategy?**

The vaccination program has been strategized to maximize the reach of vaccines to the citizens, keeping in mind their vulnerability, and allowing the states to use their strengths in service delivery. The Co-WIN platform, the backbone of National Covid-19 vaccination programme which is a very citizen friendly platform, was continuously upgraded to respond to the States /UTs and citizens based on the feedback received.

The vaccination can be availed at both government and private CVCs, with government CVCs providing it free of cost. Those who can afford, may approach private hospitals where vaccination would be done at a price. Vaccination through private sector would facilitate improved access and will reduce the operational stress on the government vaccination facilities thus reducing the crowd.

To promote the spirit of "Lok Kalyan", use of non-transferable Electronic Vouchers which can be redeemed at private vaccination centers, are being encouraged to enable people to financially support vaccination of Economically Weaker Sections at private vaccination centres.

Hon'ble Prime Minister has inaugurated the use of e-RUPI voucher for payment of Covid-19 vaccination at Private Covid Vaccination Centre. Efforts are being made to ensure that the e-RUPI Vaccination Vouchers are sponsored in the State/UT in sufficient numbers to facilitate better access for people to vaccination even in the private C0VID Vaccination centres. The Public sector undertaking, Industry and the Corporates are being encouraged to issue these vouchers to their employees, dependants and other beneficiaries.

7. **What will be the cost of vaccination for eligible citizens?**

Currently, vaccination is free at Government hospitals. In private facilities, vaccination is available for a price. For more details on pricing, it is advised to visit https://www.cowin.gov.in/faq.

G. COVID-19 VACCINATION IN PREGNANT AND LACTATING WOMEN

1. **Is it safe to get COVID vaccine during pregnancy?**
   The National Technical Advisory Group on Immunization (NTAGI) has recommended that "pregnant women may take any one of the two (Covishield and Covaxin) Covid-19 vaccines and lactating women are also eligible for vaccination any time before and after delivery." This recommendation is based on the emerging evidence which shows that benefits of COVID-19 vaccination during pregnancy far outweigh the risk associated with contracting COVID infection during pregnancy (like increased risk for severe illness, preterm birth). However, it is important that pregnant women make an informed choice and opt voluntarily for vaccination.

2. **Are risks of Covid vaccination more than benefits for a pregnant /lactating woman?**
   The benefits of vaccinating pregnant and lactating women seem to far outweigh the risks. Lactating women are also eligible for Covid vaccine.

3. **I am a pregnant / lactating Health worker engaged with Covid patient care. Should I take Covid vaccine?**
   Yes. Since you are at higher risk of getting infected, you should consider getting yourself vaccinated.

4. **A lady was provided Covid vaccination and now suspected of being pregnant. Should she terminate the pregnancy if found pregnant? What should she do?**
   It is not advised to delay or terminate pregnancy because of vaccination. As per the available evidence, the vaccines do not have any ill effects on the fetus or the outcome of pregnancy. Also, it is not necessary to conduct pregnancy testing prior to vaccination.

5. **I was advised by my obstetrician not to take any vaccine as some vaccines are contraindicated during pregnancy. Should I take Covid vaccine?**
   In pregnancy, there could be concerns with live attenuated vaccines. There are no live attenuated COVID-19 vaccines presently in the National COOVD-19 vaccination program Historically, vaccines are being provided to pregnant women such as tetanus and diphtheria which are safe. Therefore, presently there is no evidence of risk with COVID-19 vaccines as such. In case you are on treatment for any other pre-existing conditions then you may seek advice of your treating physician.

6. **During my lactation period, I got Covid infection, what should I do now? Should I discontinue breast feeding and stay isolated from my newborn baby?**
   Please continue with breast feeding, which is very important for the wellbeing of the newborn. A COVID positive lactating mother is unlikely to transmit SARS CoV 2 virus through breast milk. Consequently, WHO recommends that mothers continue to breastfeed their infants. At the same time, it is important to wear mask properly, wash

your hand frequently and take all precautions while taking care of baby and while breastfeeding.

7. **I am a pregnant / lactating mother. Is it mandatory to take COVID-19 vaccine?**
   As per the Operational Guidelines document and guidance note for vaccination of pregnant women, COVID-19 vaccination is voluntary; however, it is encouraged that all eligible individuals take vaccination for public health good.

8. **While in my pregnancy, I was recently diagnosed as COVID-19 positive. Should I immediately go for COVID-19 vaccination?**
   No, you should defer COVID-19 vaccination for 12 weeks/3 months after recovery.

9. **Does getting the vaccine affect my future fertility and the chances of getting pregnant?**
   No, there is no evidence or no indications so far that the COVID vaccines impact fertility.

10. **What should pregnant woman consider before getting the vaccine?**
    Expectant woman may consider to discuss the following with their /health care provider to guide them to make their decision:
    - Likelihood of exposure to COVID-19, risks of COVID-19 to them and potential risks to her and fetus
    - Benefits of getting vaccinated
    - Information about the type of vaccine and known side effects of the vaccine.

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"Exhibit-E"

Title: Which countries have stopped using AstraZeneca's COVID vaccine?

Publishers: Aljazeera

Date: **15 Mar 2021**

Link: https://www.aljazeera.com/news/2021/3/15/which-countries-have-halted-use-of-astrazenecas-covid-vaccine

Concerns grow over reports of blood clotting among some recipients, but WHO urges countries to keep using the COVID vaccine.

More than a dozen countries, mostly in Europe, have suspended the use of AstraZeneca's COVID-19 vaccine over fears the shot may have caused some recipients to develop blood clots.

Sweden and Latvia on Tuesday became the latest nations to halt the rollout, following moves by Germany, Italy, France, Spain, Denmark, Norway, and The Netherlands, among others.

list of 4 itemslist 1 of 4

Ireland temporarily suspends use of AstraZeneca vaccine

list 2 of 4

WHO backs AstraZeneca coronavirus vaccine and plays down risks

list 3 of 4

Bulgaria latest to halt AstraZeneca vaccine; WHO says no need

list 4 of 4

AstraZeneca may miss second-quarter EU vaccine deliveries: Report end of list

The World Health Organization (WHO) is meeting on Tuesday to review the available safety data on the vaccine, although it has repeatedly expressed confidence in its safety; WHO chief Tedros Adhanom Ghebreyesus has said there was no evidence of a link so far.

More than 17 million people have received the vaccine in the United Kingdom and the European Union to date, with fewer than 40 cases of blood clots reported as of last week, AstraZeneca, a British-Swedish multinational, said on Sunday.

The EMA reiterated its stance on Tuesday, that the vaccine is safe and its benefits outweigh any risks as coronavirus infections and deaths continue. The regulator will release results of its investigation into incidents of bleeding, blood clots and low platelet counts in recipients on Thursday.

But reassurances appear to have done little to calm doubts. These are the countries that have suspended use of the vaccine to date:

Sweden

Sweden's health agency on March 16 suspended the use of the AstraZeneca shot as a precautionary measure.

"The Swedish Public Health Agency has decided to suspend the use of AstraZeneca's covid-19 vaccine until the European Medicines Agency's investigation into suspected side effects is done," the agency said in a statement.

The Swedish Medical Products Agency said a day earlier it had recorded 10 cases of blood clots and one case of low levels of platelets among people who received the AstraZeneca vaccine, but not in combination.

Latvia

Latvian government health agencies on March 16 announced a “temporary suspension” of up to two weeks.

The move was taken as “an additional precaution” while the vaccine is scrutinised, and no problems have been linked to its use in Latvia, the agencies said in a statement.

France

President Emmanuel Macron on March 15 announced that France was suspending use of the AstraZeneca vaccine pending an EMA assessment of the shot.

“The decision has been made … to suspend the use of the AstraZeneca vaccine as a precaution, hoping that we can resume it quickly if the judgement of the EMA allows it,” Macron told a press conference.

Macron did not elaborate on the reasons for the decision but said he hoped France would be able to vaccinate with the AstraZeneca shots again “soon”.

Ireland temporarily suspends use of AstraZeneca vaccine

Germany

The German government on March 15 said it had halted use of AstraZeneca’s shot.

The country's health ministry said the decision was taken as a "precaution" and on the advice of Germany's national vaccine regulator, the Paul Ehrlich Institute, which called for further investigation of the cases.

Italy

Italy's medicines agency on March 15 said it had joined other European nations in blocking the use of the AstraZeneca vaccine.

The move came just days after Italy's AIFA regulator banned the use of a single batch of the shot as a precaution while insisting there was no established link to the alleged side-effects.

"AIFA has decided to extend the ban on the use of AstraZeneca's COVID-19 vaccine throughout Italy as a precautionary and temporary measure pending European Medicines Agency (EMA) rulings," AIFA said in a statement.

Spain

Spain announced on March 15 that it would suspend use of the AstraZeneca vaccine for at least two weeks to allow experts to review its safety.

"We have decided to temporarily suspend [use of the AstraZeneca vaccine] as a precaution," Health Minister Carolina Darias told reporters.

Luxembourg

Luxembourg on March 15 said it was suspending use of the AstraZeneca shot as "a precautionary measure" until the EMA report on the vaccine is available.

Cyprus

Cyprus moved to pause use of the AstraZeneca COVID-19 shots on March 15 pending an EMA review of the vaccine.

The country's health ministry said the suspension will last until March 18, when the EMA is due to issue a review of the vaccine following reports of thrombosis among some recipients in Europe.

Portugal

Portugal temporarily suspended use of the AstraZeneca shot on March 15 following the reports of possible serious side effects.

Graca Freitas, head of the health authority DGS, told a news conference that although the side effects were "extremely severe", they were "extremely rare", adding no such cases had been reported in Portugal so far.

Officials said they hoped a scientific review of the jab can be completed by the end of the week.

Slovenia

Slovenia announced on March 15 that it was joining other European nations in suspending use of the AstraZeneca jab.

Health Minister Janez Poklukar said the government had taken the decision in order to "ensure the highest possible level" of safety.

"There is no medical expertise justifying this halt" but it is a preventive measure pending an opinion from the European Medicines Agency (EMA), he said.

Indonesia

Indonesia's health minister said on March 15 the country would delay administering AstraZeneca's COVID-19 vaccine.

"To be conservative, the food and drug agency delayed implementation of AstraZeneca [vaccine] as it awaits confirmation from the WHO," said Budi Gunadi Sadikin.

Indonesia received 1.1 million doses of the AstraZeneca vaccine via the global COVAX vaccine-sharing programme this month and is set to receive some 10 million more in the next two months.

COVID-19: UK Bristol University developing nasal spray vaccine

The Netherlands

The Netherlands saw 10 cases of noteworthy adverse side effects, a Dutch drug watchdog said on March 15, hours after the government suspended the vaccine.

The Pharmacovigilance Centre Lareb said the reported incidents included cases of possible thrombosis or embolisms, but none included a lowered number of platelets, as has been reported in Denmark and Norway.

The vaccine will not be used until at least March 29 as a precaution.

Ireland

Ireland announced on March 14 that it had halted AstraZeneca "out of an abundance of caution" after reports from Norway of serious blood clotting in some recipients there.

Ireland's National Immunisation Advisory Committee (NIAC) recommended the suspension pending further information from the EMA.

"It may be nothing, we may be overreacting and I sincerely hope that in a week's time that we will have been accused of being overly-cautious," Deputy Chief Medical Officer Ronan Glynn said.

Bulgaria

Bulgaria on March 12 temporarily halted AstraZeneca after reports that a 57-year-old woman died hours after receiving a shot.

Prime Minister Boyko Borissov said the AstraZeneca rollout would be paused "until all doubts are dispelled and as long as the experts do not give guarantees that it does not pose a risk to the people".

The woman is believed to have died of heart failure; the autopsy found no blood clots.

Denmark, Norway suspend AstraZeneca vaccine over blood clot fears

The Democratic Republic of the Congo

The Democratic Republic of the Congo (DRC) announced on March 12 it was delaying the AstraZeneca vaccine, citing the European countries' moves.

The DRC received 1.7 million AstraZeneca doses via the COVAX scheme on March 2 but is yet to start its inoculation programme.

"We are going to check to know more about this problem," a spokesperson for the DRC's health ministry told Reuters news agency.

Thailand

Thailand was the first country outside Europe to delay the AstraZeneca vaccine, on March 12 – the day its political leaders were due to have the first shots.

The suspension was brief, however, and Prime Minister Prayuth Chan-ocha became the first person in Thailand to receive the vaccine on March 16.

Romania

Romania temporarily stopped vaccinating people with one batch of AstraZeneca's COVID-19 vaccine – the same one in question in Italy – on March 11. Officials described the move as an "extreme precaution" until the EMA completes an inquiry.

Iceland

Iceland on March 11 suspended jabs with the vaccine as it awaited the results of an investigation by the EMA.

Denmark suspends use of AstraZeneca vaccine over blood clot fears

Denmark

Denmark on March 11 announced it was halting the use of the AstraZeneca shot for two weeks, following reports of blood clots in some people who had been vaccinated.

The Danish Medicines Agency later said a 60-year-old Danish woman who died of a blood clot after receiving the vaccine had "highly unusual" symptoms.

The woman had a low number of blood platelets and clots in small and large vessels, as well as bleeding, it said on March 14.

A few similar cases were found in Norway and in the EMA database of drug side effects, the Danish Medicines Agency added.

Norway

Norway also said it was suspending the use of the vaccine on March 11, as a caution amid the reports of possible serious side effects.

On March 13, Norwegian health authorities revealed that three health workers – all aged below 50 – who had recently received the AstraZeneca vaccine were being treated in hospital for bleeding, blood clots and a low blood platelet count.

“We do not know if the cases are linked to the vaccine,” said Sigurd Hortemo, a senior doctor at the Norwegian Medicines Agency.

Austria

Before Denmark and Norway stopped their rollout, Austria on March 7 paused its use of a batch of AstraZeneca shots while investigating a death from coagulation disorders and an illness from a pulmonary embolism.

Estonia, Latvia, Lithuania and Luxembourg also suspended the use of the batch singled out by Austria.

"Exhibit-F"

"Ethically Unjustifiable" – Scientists from Harvard & Johns Hopkins Found Covid-19 Vaccines 98 Times Worse Than the Virus

By Jim Hoft

Publication: Gateaway Pundit

Link: https://www.thegatewaypundit.com/2022/09/ethically-unjustifiable-new-harvard-johns-hopkins-study-found-covid-19-vaccines-98-times-worse-disease/

Published September 12, 2022 at 5:10pm

A new pre-print study by nine health experts from major universities showed that the COVID-19 vaccines are 98 times worse than the virus, and mandatory booster vaccination in college is "ethically unjustifiable," as reported by **Epoch Times**.

The study was posted on The Social Science Research Network (SSRN) in September, titled, "***COVID-19 Vaccine Boosters for Young Adults: A Risk-Benefit Assessment and Five Ethical Arguments against Mandates at Universities***."

It was conducted by nine top scientists from the University of Washington, University of Oxford, University of Toronto, Harvard University – Harvard Medical School, University of California, San Francisco (UCSF), Johns Hopkins University – Department of Surgery, and others.

Using CDC and sponsor-reported adverse event data, researchers conclude that booster regulations may result in more harm than good.

According to the study, for every one COVID hospitalization prevented in previously uninfected young adults, "18 to 98 actual serious adverse events" have been caused.

"Per COVID-19 hospitalization prevented in previously uninfected young adults, we anticipate 18 to 98 serious adverse events, including 1.7 to 3.0 booster-associated

myocarditis cases in males, and 1,373 to 3,234 cases of grade ≥3 reactogenicity which interferes with daily activities," the study stated.

University booster mandates were deemed unethical by the researchers for the following reasons:

- no formal risk-benefit assessment exists for this age group;
- vaccine mandates may result in a net expected harm to individual young people;
- mandates are not proportionate: expected harms are not outweighed by public health benefits given the modest and transient effectiveness of vaccines against transmission;
- US mandates violate the reciprocity principle because rare serious vaccine-related harms will not be reliably compensated due to gaps in current vaccine injury schemes; and
- mandates create wider social harms. We consider counter-arguments such as a desire for socialization and safety and show that such arguments lack scientific and/or ethical support.

The study concludes:

Based on public data provided by the CDC, we estimate that approximately 22,000 to 30,000 previous *uninfected* young adults ages 18–29 years must be boosted with an mRNA vaccine to prevent one Covid-19 hospitalisation. Given the fact that this estimate does not take into account the protection conferred by prior infection nor a risk-adjustment for comorbidity status this should be considered a conservative and optimistic assessment of benefit.

Our estimate shows that university Covid-19 vaccine mandates are likely to cause net expected harms to young healthy adults—between 18 and 98 serious adverse events requiring hospitalisation and 1373 to 3234 disruptions of daily activities—that is not outweighed by a proportionate public health benefit.

Serious Covid-19 vaccine-associated harms are not adequately compensated for by current US vaccine injury systems. As such, these severe infringements of individual liberty are ethically unjustifiable.

Worse still, mandates are associated with wider social harms. The fact that such policies were implemented despite controversy among experts and without updating the sole publicly available risk-benefit analysis to the current Omicron variants suggests a profound lack of transparency in scientific and regulatory policy making.

These findings have implications for mandates in other settings such as schools, corporations, healthcare systems and the military. Policymakers should repeal booster mandates for young adults immediately, ensure pathways to compensation to those who have suffered negative consequences from these policies, provide open access to participant-level clinical trial data to allow risk- and age-stratified harm-benefit analyses of any new vaccines prior to issuing recommendations125, and begin what will be a long process of rebuilding trust in public health

"Exhibit-G"

Govt. Database Shows 10,000% Increase In Cancer Reports Due To Covid Vaccines

Link: https://adversereactionreport.org/research/govt-database-shows-10000-increase-in-cancer-reports-due-to-covid-vaccines/

Dated: December 3, 2022

Source: Adverse Reaction Report

LifeSite is reporting that a researcher who queried the Centers for Disease Control's (CDC) Vaccine Adverse Event Reporting System (VAERS) discovered a 10,661.4% increase in cancer reports as a result of experimental Covid-19 gene-base vaccines as compared with all FDA- approved vaccines over the last 30 years.

Brian Shilhavy, who is the editor of *Health Impact News*, traced his steps in the searchproviding links to documentation of his various findings.

Having first queried the cases of 'the most common cancers [that] had been reported following Covid-19 vaccines,' he found "837 cases of cancer, including 88 deaths, 66permanent disabilities, and 104 life threatening events.

He emphasized that even these numbers were not exhaustive, and the VAERS database could not handle the larger search of 'ALL cancers listed in VAERS' under this category of Covid inoculations. 'Using the exact same search terms for cancer,' he wrote, 'I then searched ALL FDA-approved vaccines for the **previous 30 years** and found only 140 cases of cancer reported.'

'That result is for 360 months (30 years), whereas the 837 cases following the experimental Covid-19 vaccines were reported in just 20 months, since the roll out of the Covid-19 shots beginning in December of 2020,' Shilhavy wrote. 'That is an increase of 10,661.4%!' he concluded.

Shilhavy, whose organization is located in Texas, also made note of the significant number of the cancer cases in the database that were of young people, from age 12 up through many young adults in their 20s. Last October, a Swedish lab study found that the spike protein associated with the Covid-19 illness, and its experimental vaccines, enters the nucleus of cells and significantly interferes with DNA damage-repair functions, compromising a person's adaptive immunity and perhaps encouraging the

formation of cancer cells.

In March 2021, board-certified pathologist Dr. Ryan Cole reported that he was seeing a massive ‘uptick’ in various autoimmune diseases and cancers in patients who have been Covid-vaccinated. ‘Since January 1, in the laboratory, I’m seeing a 20 times increase of endometrial cancers over what I see on an annual basis,’ he said.

In regard to overall adaptive immunity, Cole describes, ‘post-vaccine, what we are seeing is a drop in your killer T-cells’ that ‘keep all other viruses in check,’ leaving the patient susceptible to a variety of illnesses.

In January, data leaks given by three ‘decorated high-ranking soldiers who are doctors and public health officials,’ in sworn declarations under penalty of perjury, showed enormous spikes in dozens of diseases following Covid vaccine uptake in the U.S. military.

These included:

- Miscarriages — 279% increase,
- Hypertension (high blood pressure): 2,281%
- increase, Diseases of the nervous system: 1,048%
- increase, andCancer: 296% increase.

VAERS data released July 29 from the CDC reported 1,357,937 total adverse events inthe United States after injections of experimental Covid-19 gene-based vaccines, including 29,790 deaths and 247,686 serious injuries between December 14, 2020, and

July 22, 2022.

These also include 55,719 permanent disabilities, 50,739 cases of myocarditis/pericarditis, and 14,374 reported cases of shingles. As such figures are based on voluntary reports, it is important to note that they are very likely just ‘the tip ofthe iceberg’ in actual figures.

A 2010 Harvard-executed study commissioned by the Department of Health and Human Services (HHS) revealed that ‘fewer than 1% of vaccine adverse events’ are reported to VAERS, and vaccine manufacturer Connaught Laboratories calculated at least a ‘fifty-foldunderreporting of adverse events’ in a confidential study.”

"Exhibit-H"

Five Months to Kill: The horrifying relationship between Deaths, COVID Deaths & Covid-19 Vaccination

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Link: https://expose-news.com/2022/09/30/5-months-to-kill-covid-vaccination/

Source: By The Exposé

Date: September 30, 2022

A peculiar pattern has now persisted in official UK Government data for some time. Approximately five months after each dose of the Covid-19 vaccine is administered to each age group, the mortality rates per 100,000 rise significantly among the vaccinated compared to the unvaccinated in each age group.

So much so that by the end of May 2022, mortality rates were lowest among the unvaccinated in every single age group in England, and highest among the one- dose vaccinated, the two-dose vaccinated and the three-dose vaccinated.

Now, an analysis of Covid-19 data published by the UK Government has found thatnot only does the same pattern persists in Covid-19 deaths, but each dose of Covid-19 injection given causes a significant rise in Covid-19 deaths.

Between the 1st March and 31st July 2021, a period of 5 months, the vaccinated accounted for the majority of Covid-19 deaths in England, and it was the one-dose vaccinated who accounted for the majority (66%) of those deaths.

Between the 1st August and 31st December 2021, a period of 5 months, the vaccinated again accounted for the majority of Covid-19 deaths, with deaths nearly tripling compared to the previous 5 months, and it was the two-dose vaccinated who accounted for the majority (83%) of those deaths.

Finally, between the 1st January and 31st May 2022, a period of 5 months, the vaccinated once again accounted for the majority of Covid-19 deaths, with deaths again increasing compared to the previous five months, and it was the triple vaccinated who accounted for the majority (82%) of those deaths.

The following charts were created using data extracted from table 1 of the Office for National Statistics dataset on 'Deaths by vaccination status (Jan 21 to March 22)' whichcan be accessed on the ONS website here, and downloaded here.

The first chart shows the age-standardised mortality rates per 100,000 person-years by vaccination status between the 1st January 2021 and the 30th April 2021

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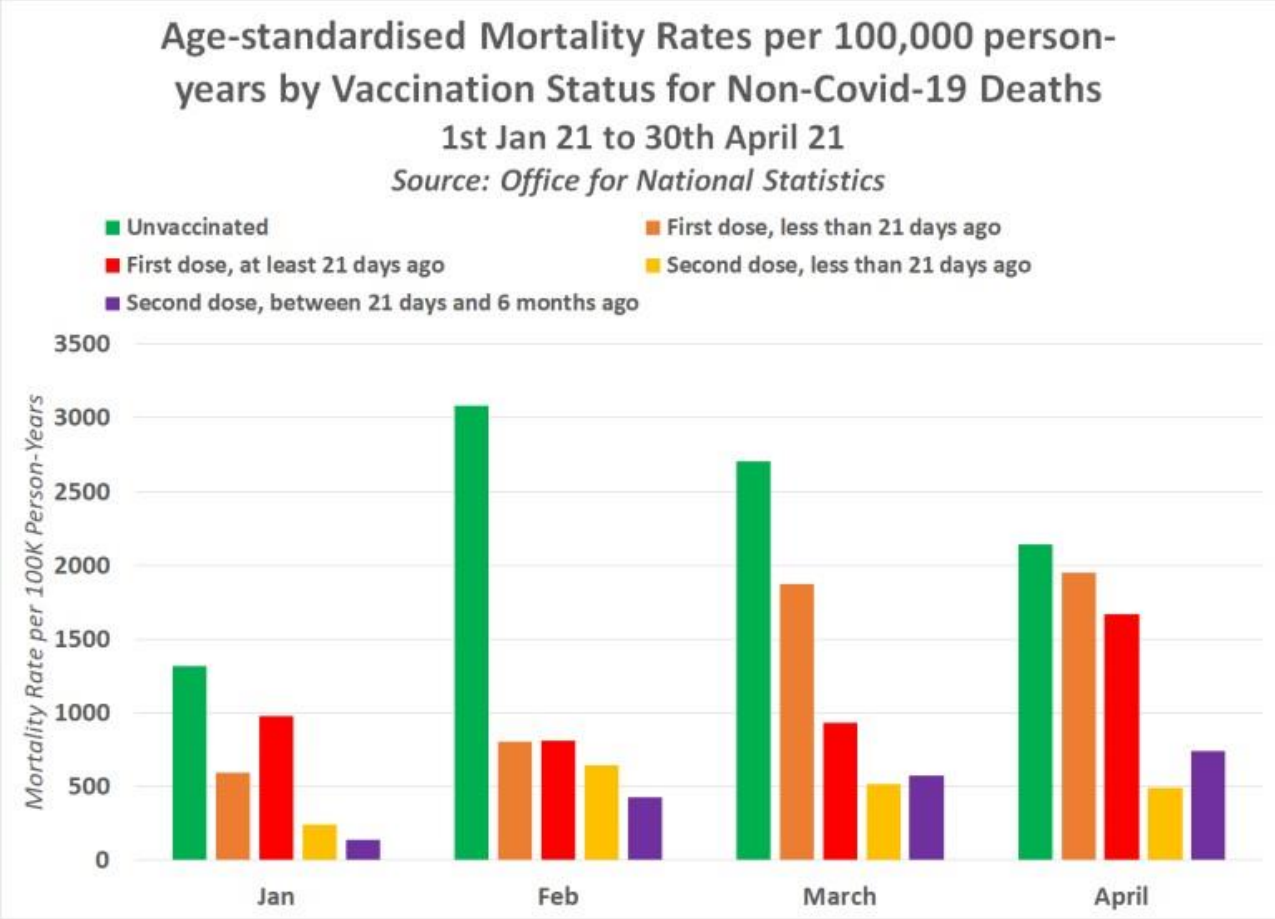


As you can see, mortality rates are highest among the unvaccinated each month.

However, by the end of April 2021, five months after the first Covid-19 injection was administered in the UK, things started to even out among each vaccination group and theunvaccinated.

But look what happened in the following four months.

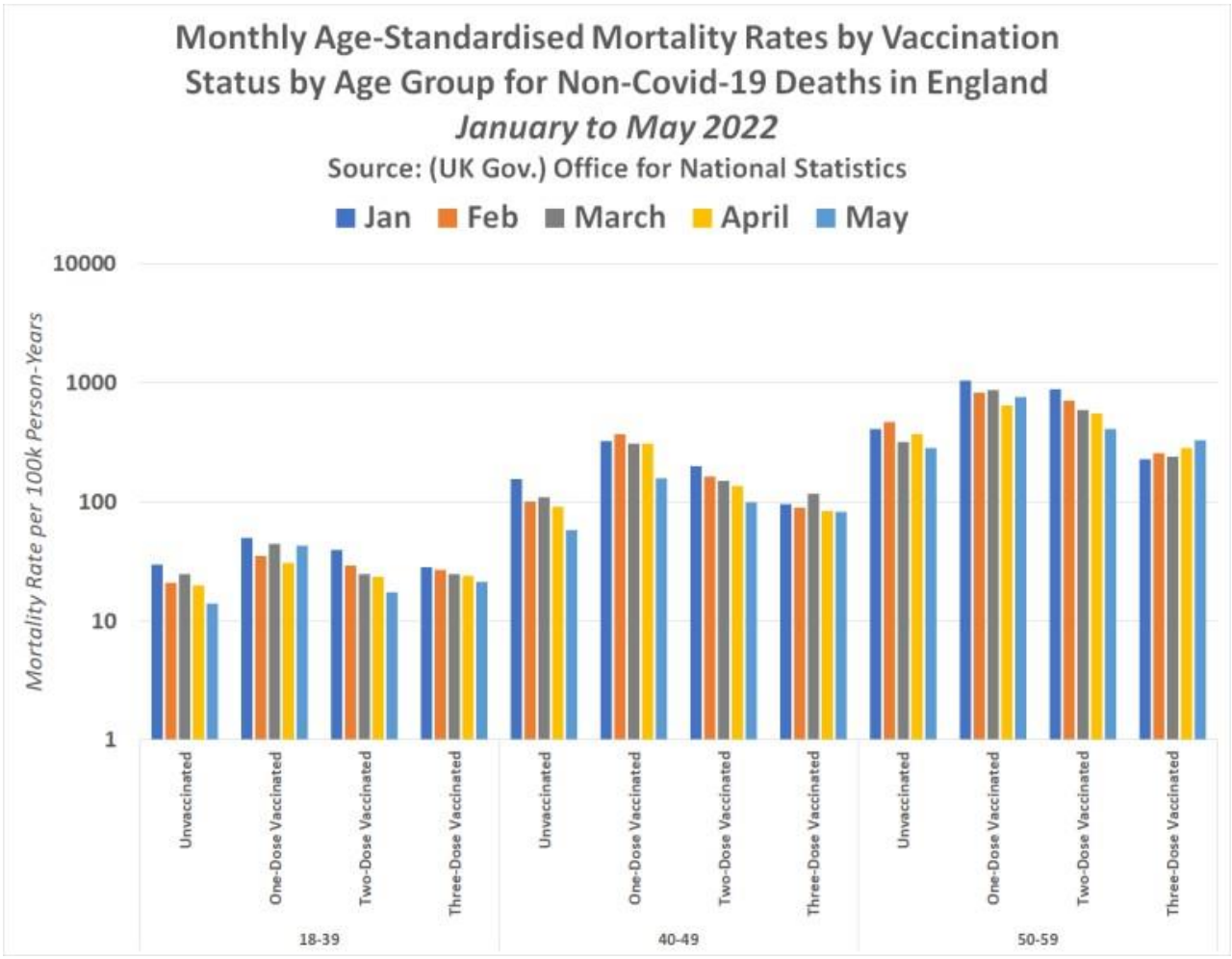
The first chart shows the age-standardised mortality rates per 100,000 person-years byvaccination status between the 1st May 2021 and the 30th August 2021 –

The mortality rate among the vaccinated began to surpass the mortality rate among the unvaccinated significantly. By the end of August 2022, the mortality rate per 100,000 among the unvaccinated was the second lowest among each vaccination group.

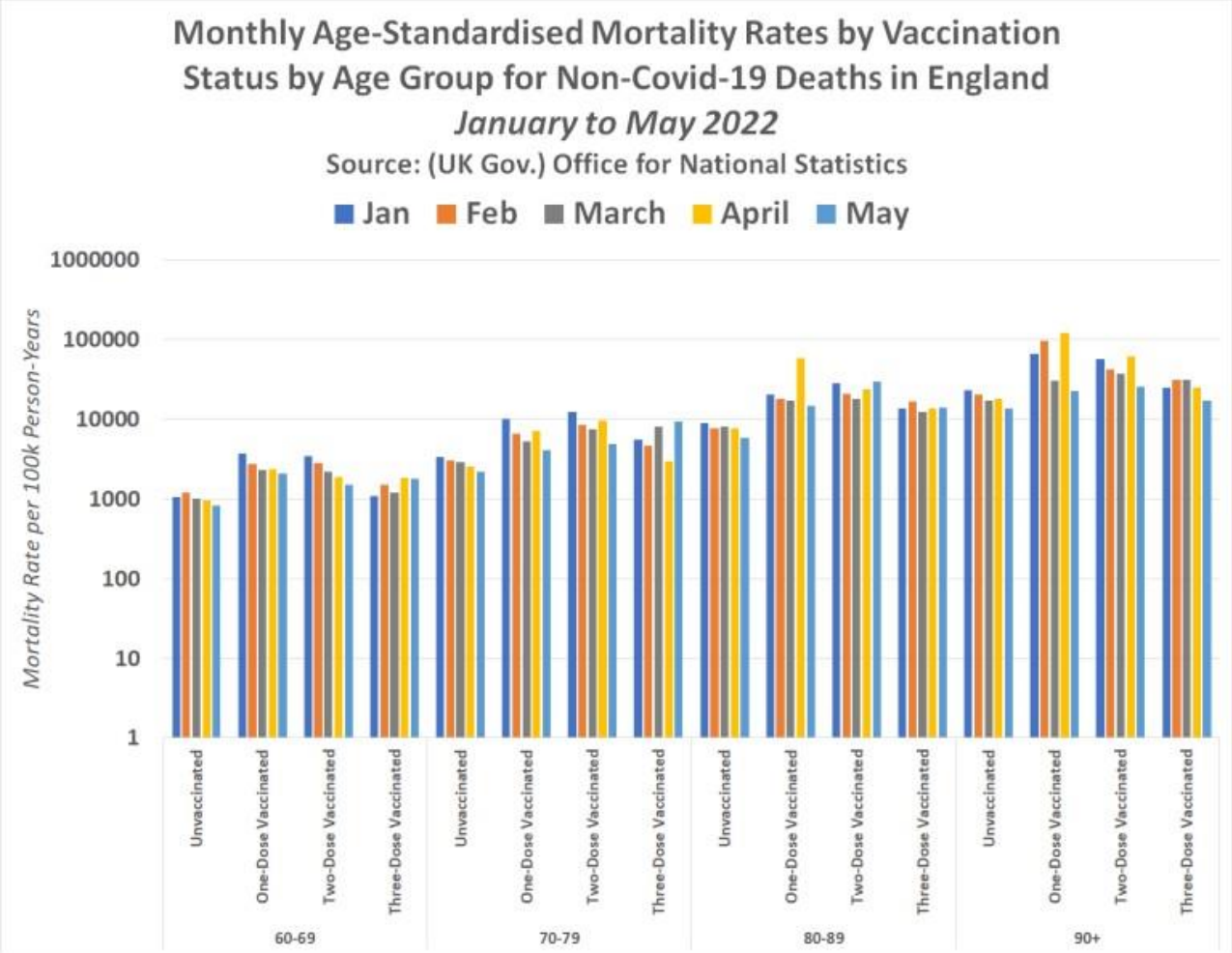
Unfortunately, a follow-up report published by the ONS on 6th July 2022, proves thatthings did not improve for the vaccinated population.

The following two charts were created using data extracted from table 2 of the latest ONS dataset on ‘Deaths by vaccination status (Jan 21 to May 22)’, which can be accessed on the ONS website here, and downloaded here.

The charts show the monthly age-standardised mortality rates by vaccination status andage group between January 2022 and May 2022 –



Click to enlarge



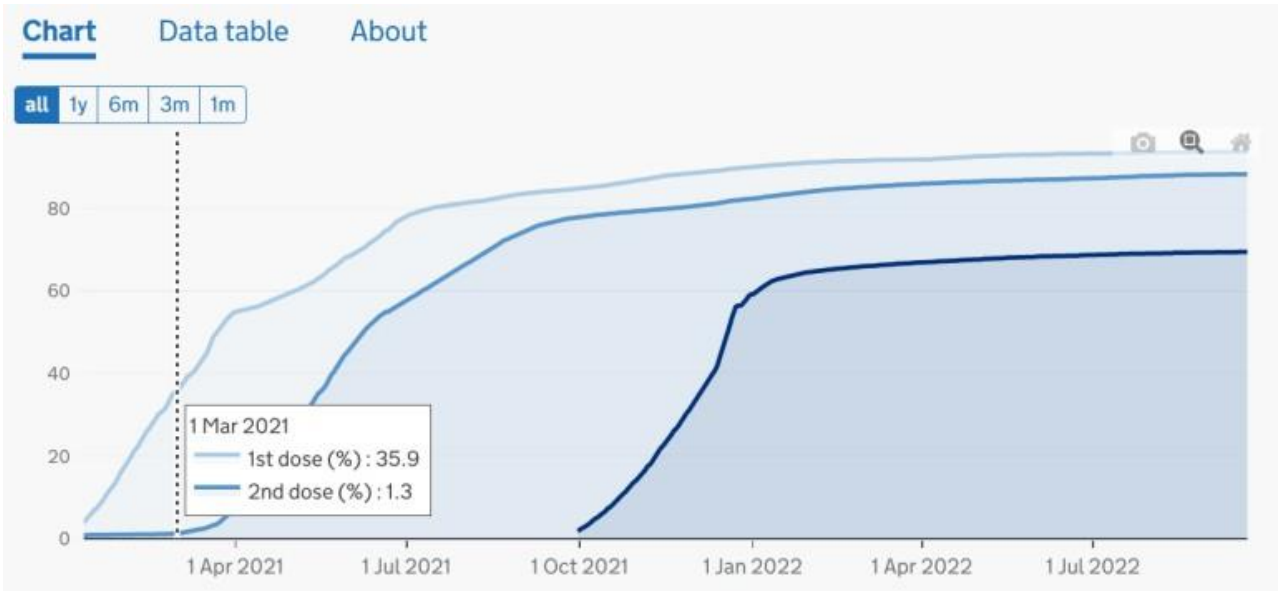
A more detailed analysis of the data contained in the above charts can be read here, but what these two charts show is that by May 2022 at the latest, mortality rates per 100,000 were the lowest among the unvaccinated in every single age group in England.

Mortality rates were already generally higher among the one-dose vaccinated and two- dose vaccinated in each group, but with a mass booster (third dose) campaign not beginning until December 2021, we did not begin to see mortality rates among the three- dose vaccinated surpass mortality rates among the unvaccinated until… you guessed it…approximately five months later.

These are age-standardised figures. There is no other conclusion that can be found for the fact mortality rates per 100,000 are the lowest among the unvaccinated other than that the Covid-19 injections are killing people.

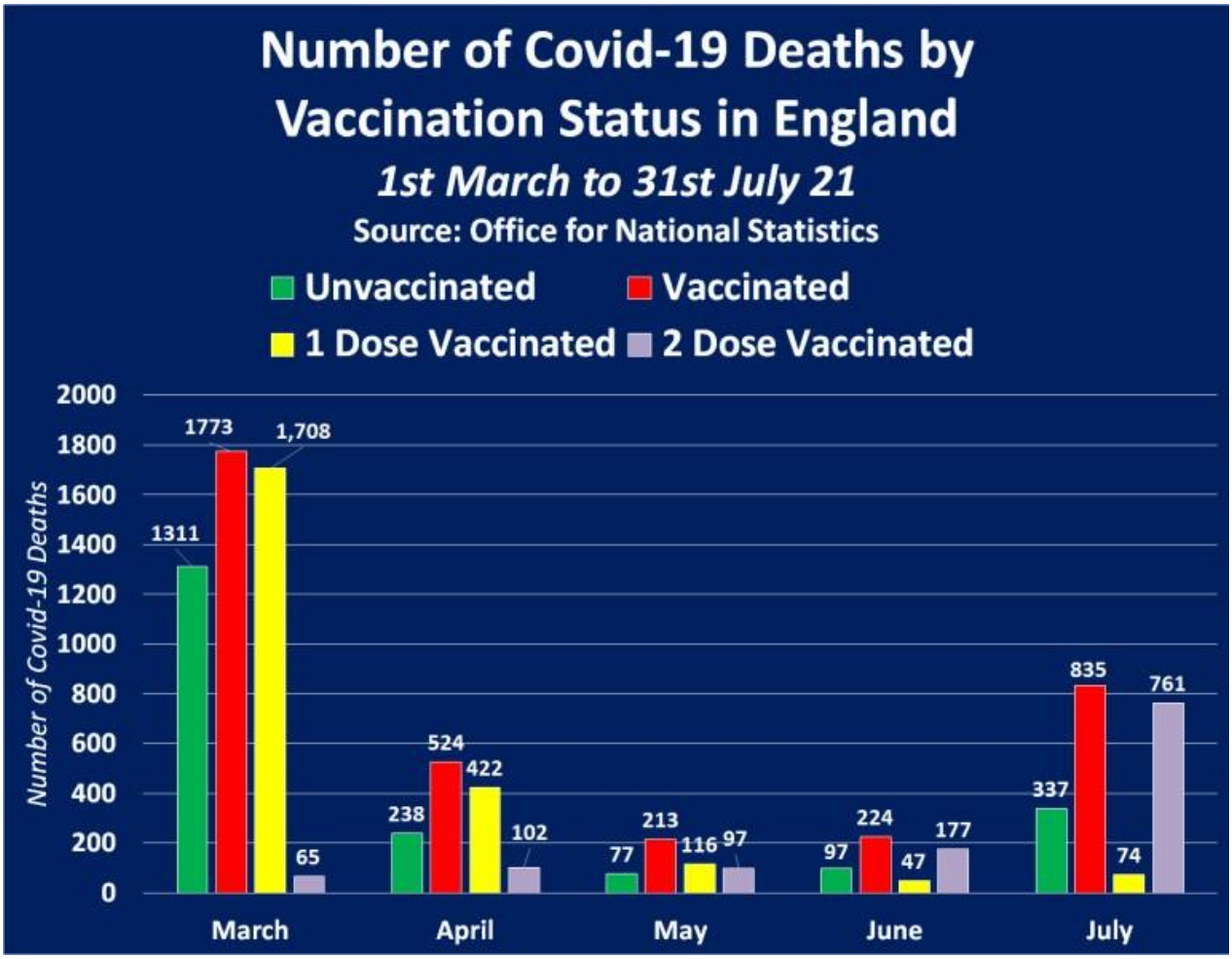
This pattern may explain why official data on Covid-19 deaths suggests that each dose of Covid-19 vaccine administered increases the number of alleged Covid-19 deaths, with those who have had the most doses accounting for the majority of those deaths.

According to the UK Governments' COVID-19 Dashboard', by the 1st March 2021, 35.9% of people in England aged 12 and over had received a single dose of the Covid-19 vaccine, and just 1.3% of people in England aged 12 and over had received two doses ofthe Covid-19 vaccine.



Source

But here's what happened in terms of Covid-19 deaths in the following five months from that point onwards according to data extracted from table 1 of the latest ONS 'Deaths byvaccination status' dataset –



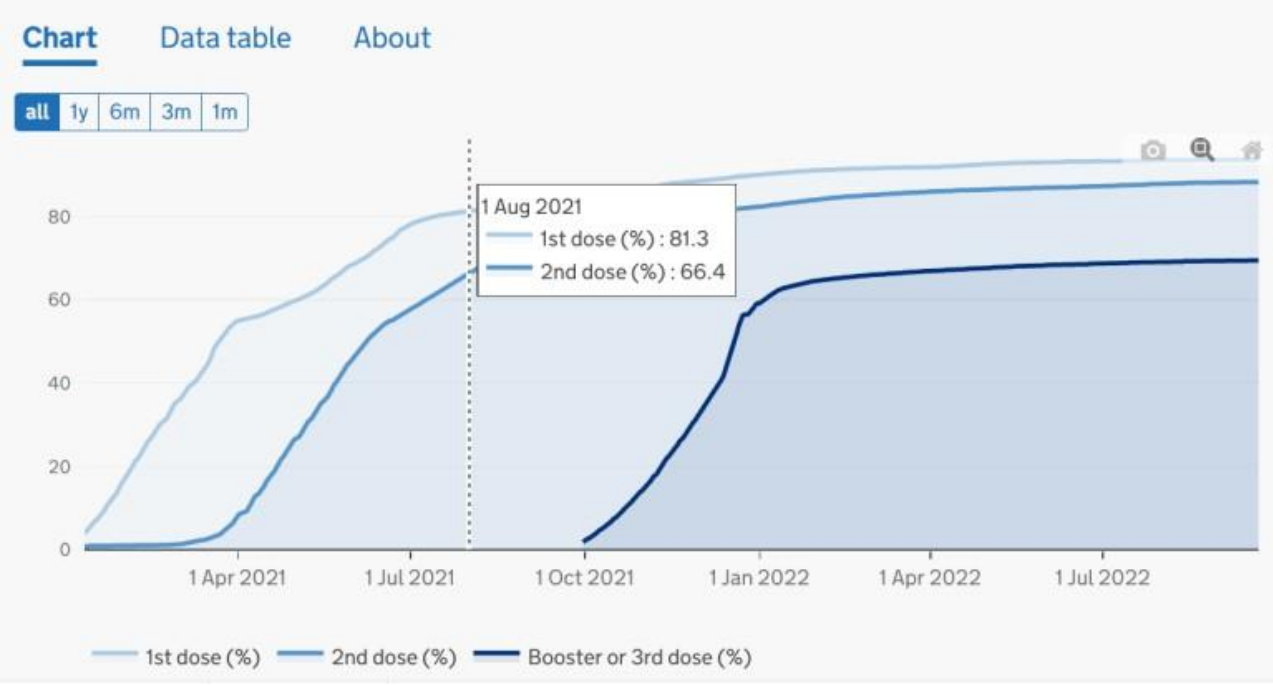
The public was told that they needed two doses of the Covid-19 vaccine for it to be fully effective. But despite only a tiny percentage of people being two-dose vaccinated by the 1st of March, Covid-19 deaths began to fall significantly by the month.

However, as you can see from the above chart, it was the vaccinated who accounted for the majority of Covid-19 deaths each month, and it was the one-dose vaccinated who accounted for the majority of those deaths over a period of five months.

In all, there were 5,629 Covid-19 deaths. The vaccinated accounted for 63% of thosedeaths, 66% of which were among the one-dose vaccinated.

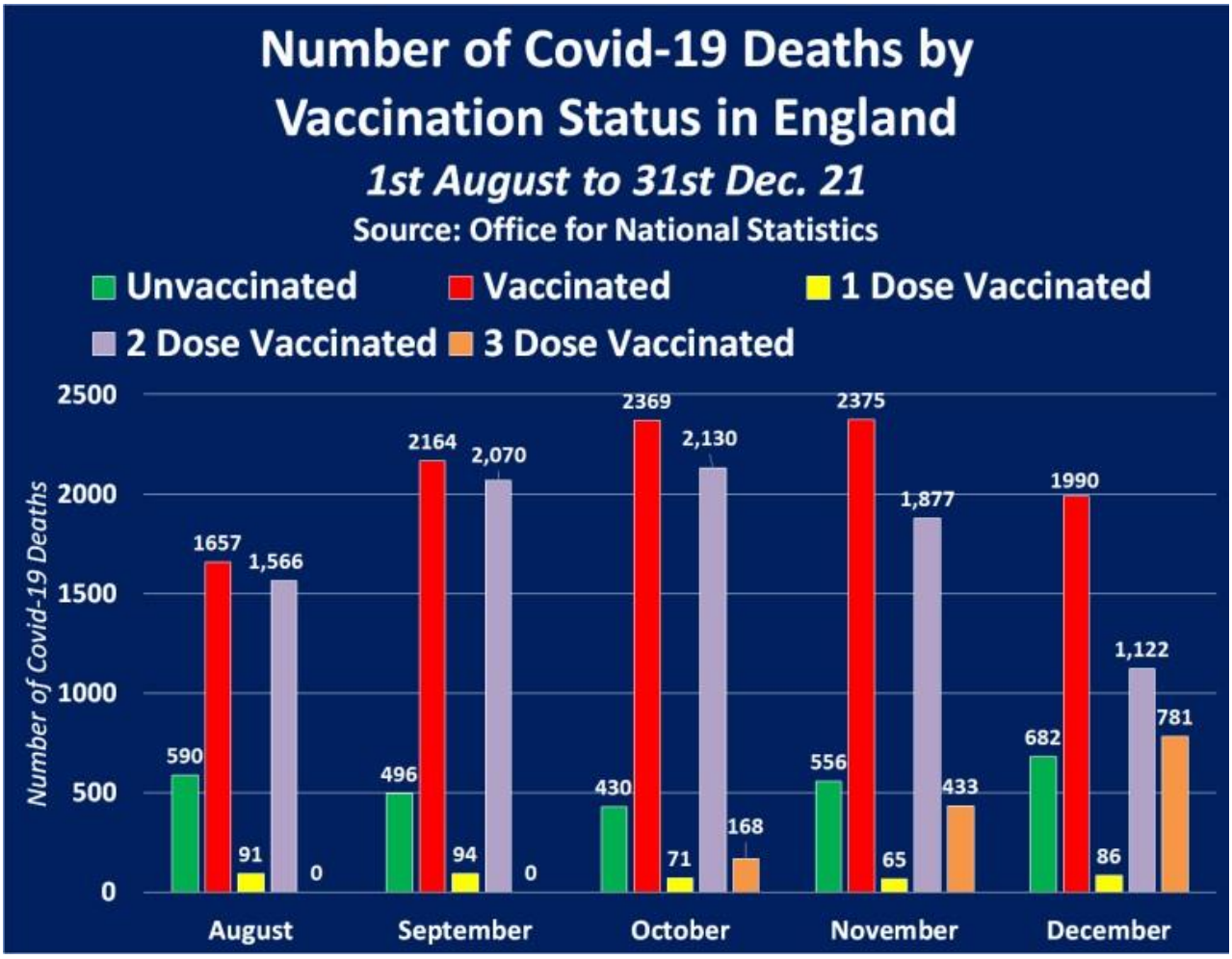
But things actually began to get worse for the double vaccinated in June, andunfortunately, by July 2021, Covid-19 deaths were on the rise again.

By the 1st of August 2021, 81.3% of people in England aged 12 and over had received a single dose of the Covid-19 vaccine, and 66.4% of people in England aged 12 and over had received two doses of the Covid-19 vaccine.



But here’s what happened in terms of Covid-19 deaths in the following five months from that point onwards according to data extracted from table 1 of the latest ONS

‘Deaths byvaccination status‘ dataset –



In the middle of this period, it was decided that vaccine effectiveness wanes and that a third dose needed to be offered to the elderly and vulnerable from the beginning of October. But the claim that vaccine effectiveness wanes is a myth.

All the vaccine allegedly does is instruct our cells to produce part of the Covid-19 virus. It’s our immune system that does the rest. Therefore, it’s the performance of the immunesystem that wanes.

Nevertheless, as you can see from the above, people given a third dose began to account for a large chunk of the people dying of Covid-19 from the very first moment itwas administered.

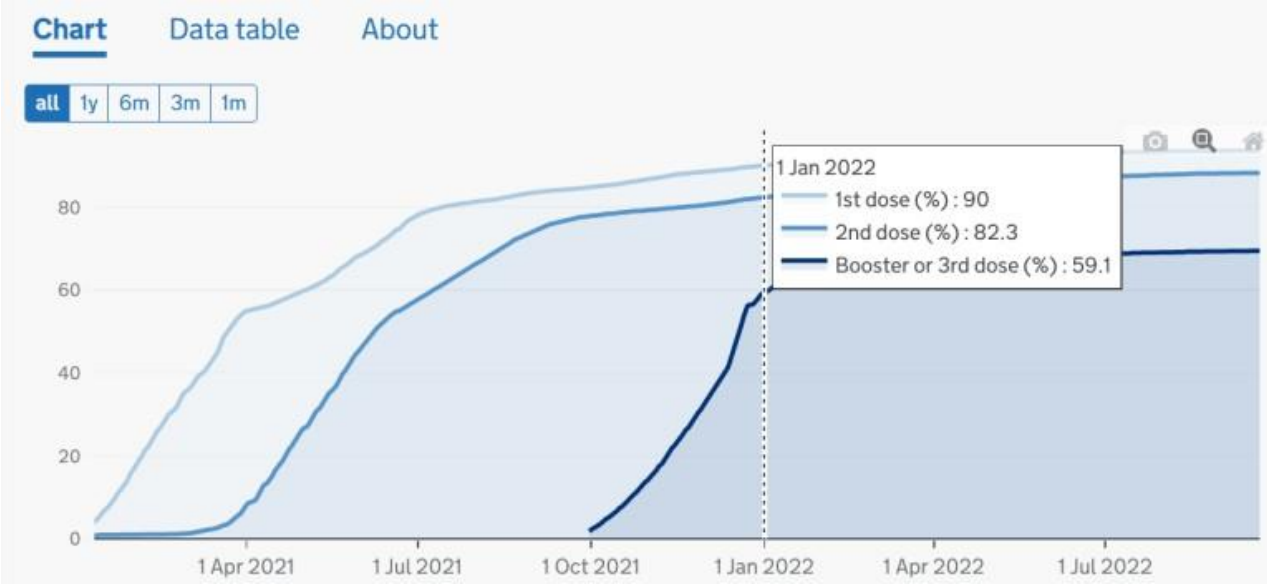
It was however the double vaccinated who accounted for the vast majority of Covid-19 deaths among the vaccinated during this period. 83% to be exact. And the vaccinated population as a whole accounted for 79% of the 13,309 alleged Covid-19

deaths betweenthe 1st of August and the 31st of December 2021.

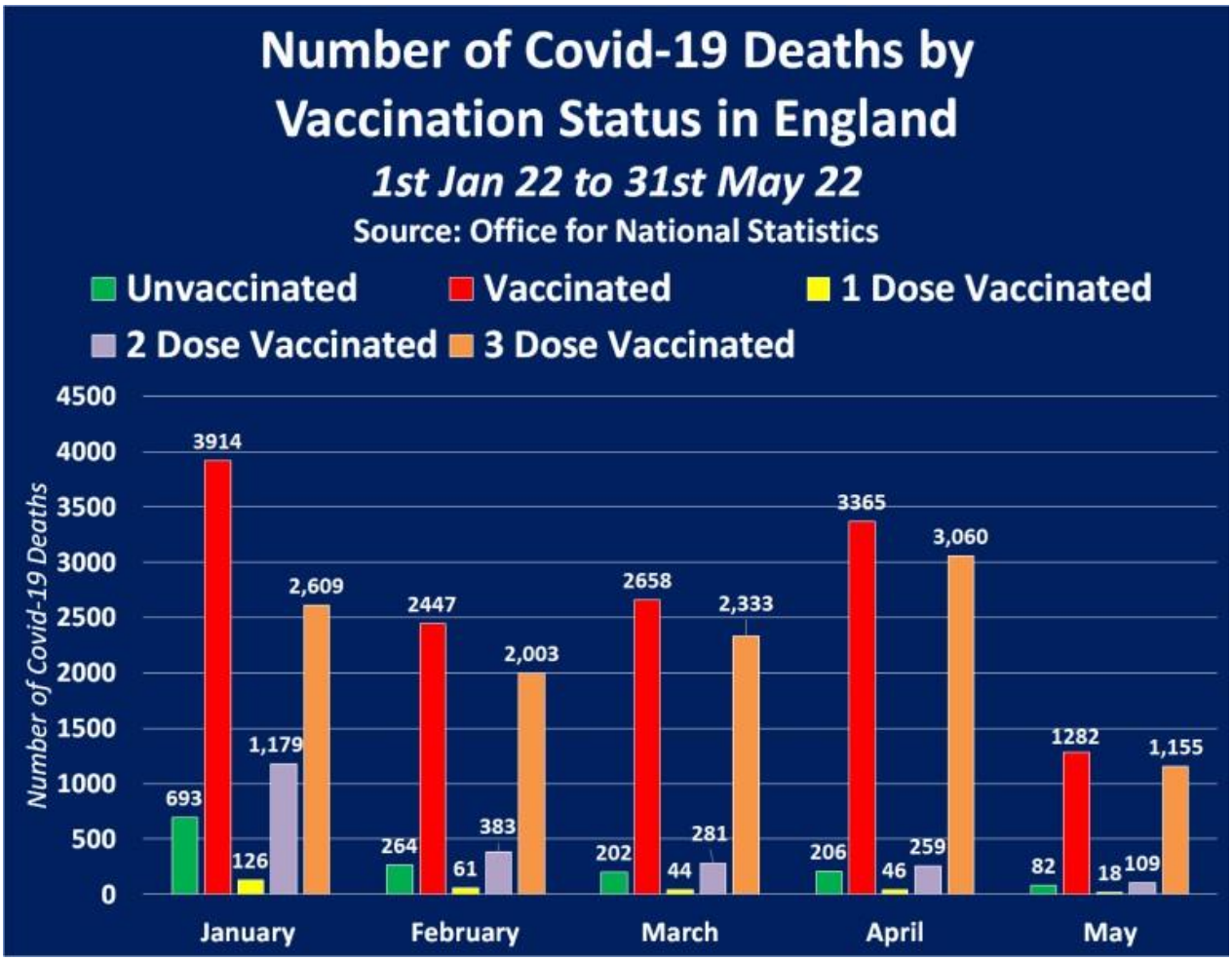
This means the overall number of Covid-19 deaths increased by 136% over this periodcompared to the previous five months.

By the 1st of January 2022, 90% of people in England aged 12 and over had received a single dose of the Covid-19 vaccine, 82.3% of people in England aged 12 and over had received two doses of the Covid-19 vaccine, and 59.1% of people in England had

received three doses of the Covid-19 vaccine.



But here's what happened in terms of Covid-19 deaths in the following five months from that point onwards according to data extracted from table 1 of the latest ONS 'Deaths byvaccination status' dataset –


Number of Covid-19 Deaths by Vaccination Status in England
1st Jan 22 to 31st May 22
Source: Office for National Statistics
Unvaccinated
Vaccinated
1 Dose Vaccinated
2 Dose Vaccinated
3 Dose Vaccinated
Number of Covid-19 Deaths
4500
4000
3500
3000
2500
2000
1500
1000
500
0
693
3914
126
1,179
2,609
264
2447
61
383
2,003
202
2658
44
281
2,333
206
3365
46
259
3,060
82
1282
18
109
1,155
January
February
March
April
May

By the end of May 2022, England had suffered 15,113 Covid-19 deaths, and the vaccinated accounted for a shocking 13,666 of them. The majority of them among thetriple vaccinated every single month.

This means that overall the vaccinated population accounted for 90% of Covid-19 deathsduring this period. 82% of which were among the triple vaccinated.

But what's perhaps most concerning in this period is the massive decline in deaths among the unvaccinated but the increase in deaths each month among the vaccinated.

In January the vaccinated accounted for 85% of Covid-19 deaths, 67% of which wereamong the triple jabbed.

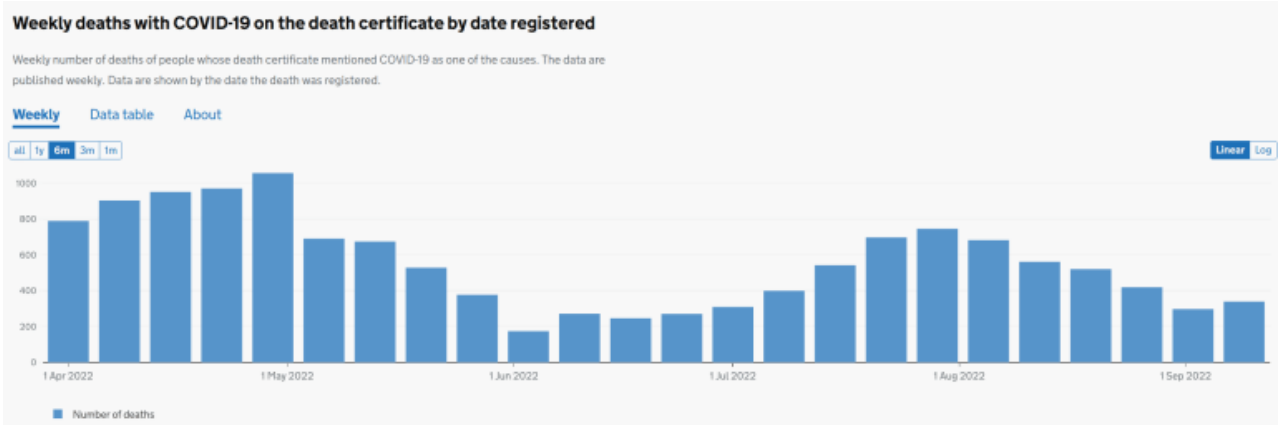
In February the vaccinated accounted for 90% of Covid-19 deaths, 74% of which wereamong the triple jabbed.

In March the vaccinated accounted for 93% of Covid-19 deaths, 82%% of which wereamong the triple jabbed.

In April the vaccinated accounted for 94%% of Covid-19 deaths, 91% of which wereamong the triple jabbed.

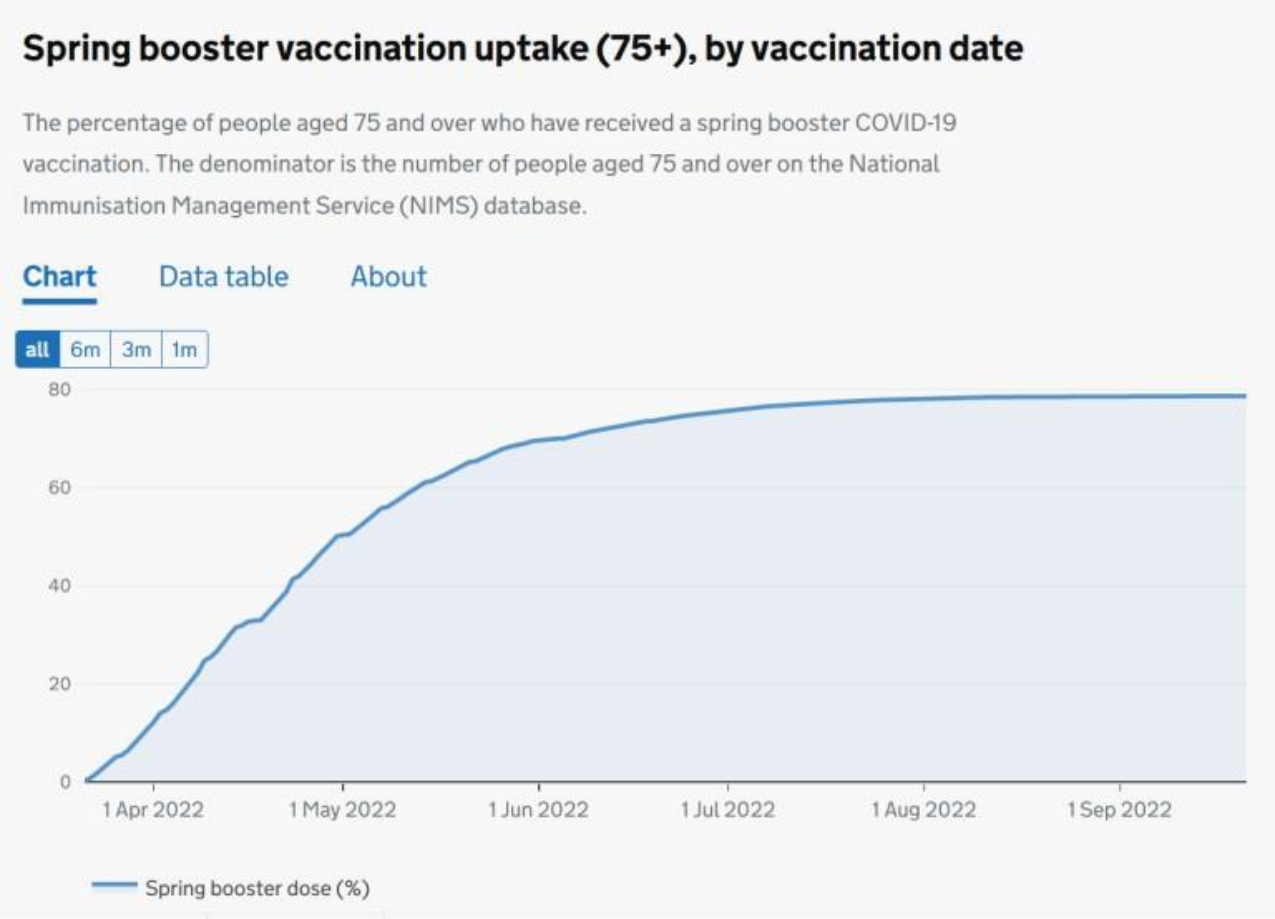
Finally, in May, a month where we would expect seasonal illness to decline, as proven by the figures, the vaccinated still accounted for 94% of Covid-19 deaths, 85% of which wereamong the triple jabbed.

We are still waiting for the official figures on deaths by vaccination status to be published for the months following, but unfortunately, we know from the UK Governments' Covid-19 dashboard that the drop in Covid-19 deaths in May was short-lived, with deaths beginningto rise again from July onwards.

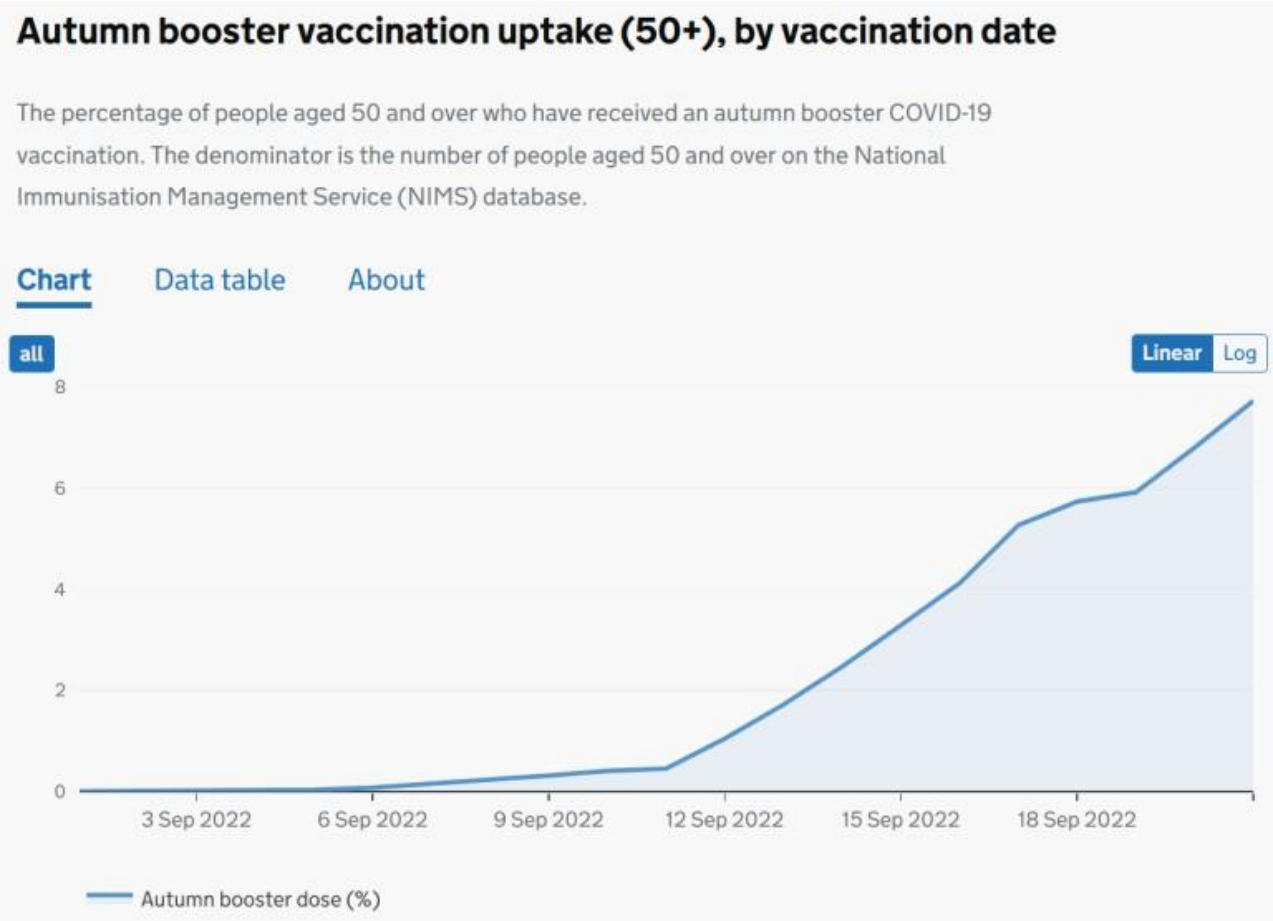


Something that doesn't make sense when it comes to the fact these deaths are supposedto be caused by a virus that thrives in winter and declines in summer.

But when we see that the elderly and vulnerable were being offered a fourth dose from April onwards, we perhaps shouldn't be so surprised that Covid-19 deaths began to risein the middle of a red hot summer.



The problem now is that they are offering a fifth dose to the over 75's and "most



vulnerable" and a fourth dose to the over 50's –

This means an already struggling National Vaccination Service, sorry, National Health Service (NHS), could be in for one hell of a winter and about to rename itself the NationalTreat Covid Only Service once again.

"Exhibit-I"

Fully Vaccinated Young Adults suffer 73% increase in Heart Attacks & Strokes and 92% higher Mortality Ratecompared to Unvaccinated

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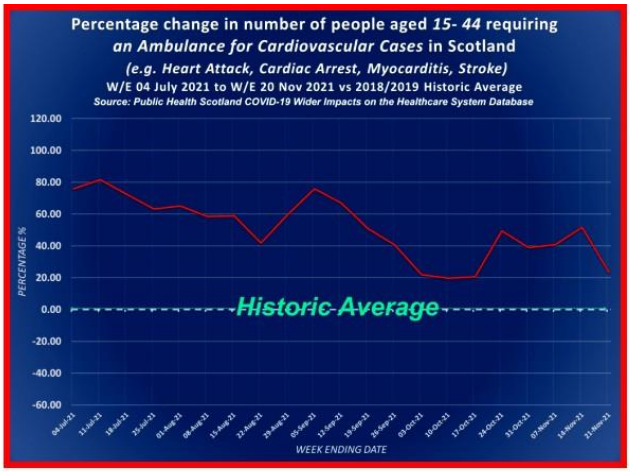
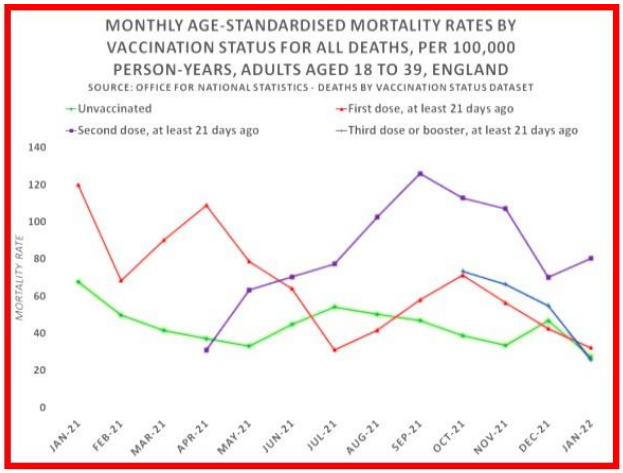
Link: https://expose-news.com/2022/05/17/covid-jabs-increase-risk-heart-attack-death-young-adults/

Source: By The Exposé

Date: May 17, 2022





Fully Vaccinated Young Adults suffer 73% increase in Heart Attacks & Strokes and 92% higher Mortality Rate compared to Unvaccinated

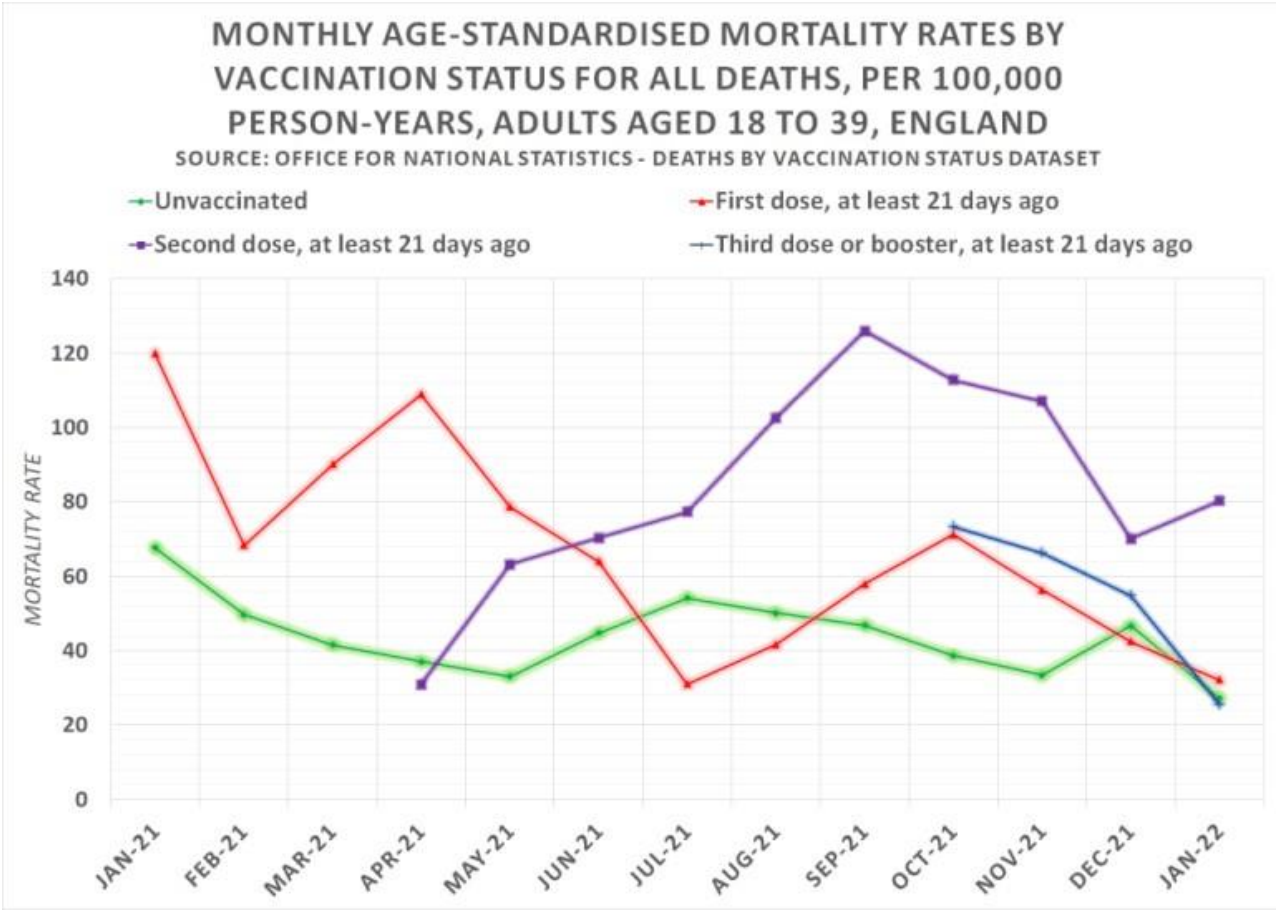
Official figures show there has been a 67% increase compared to the historical average in the number of people aged 15 to 44 suffering heart attacks, cardiac arrest, myocarditis, stroke, and other cardiovascular diseases since this age groupwas first offered the Covid-19 injection in Scotland.

And further analysis shows this issue is actually getting worse, with the numbers for 2022 so far revealing a 73% increase against the historical average.

Meanwhile, data published by the Office for National Statistics show that

between January 2021 and January 2022, double vaccinated 18 to 39-year-olds in England were on average 92% more likely to die than unvaccinated young adults of the same age.

This is either a terrible coincidence or the smoking gun that proves the damage the Covid-19 injections have done and are doing to the population.

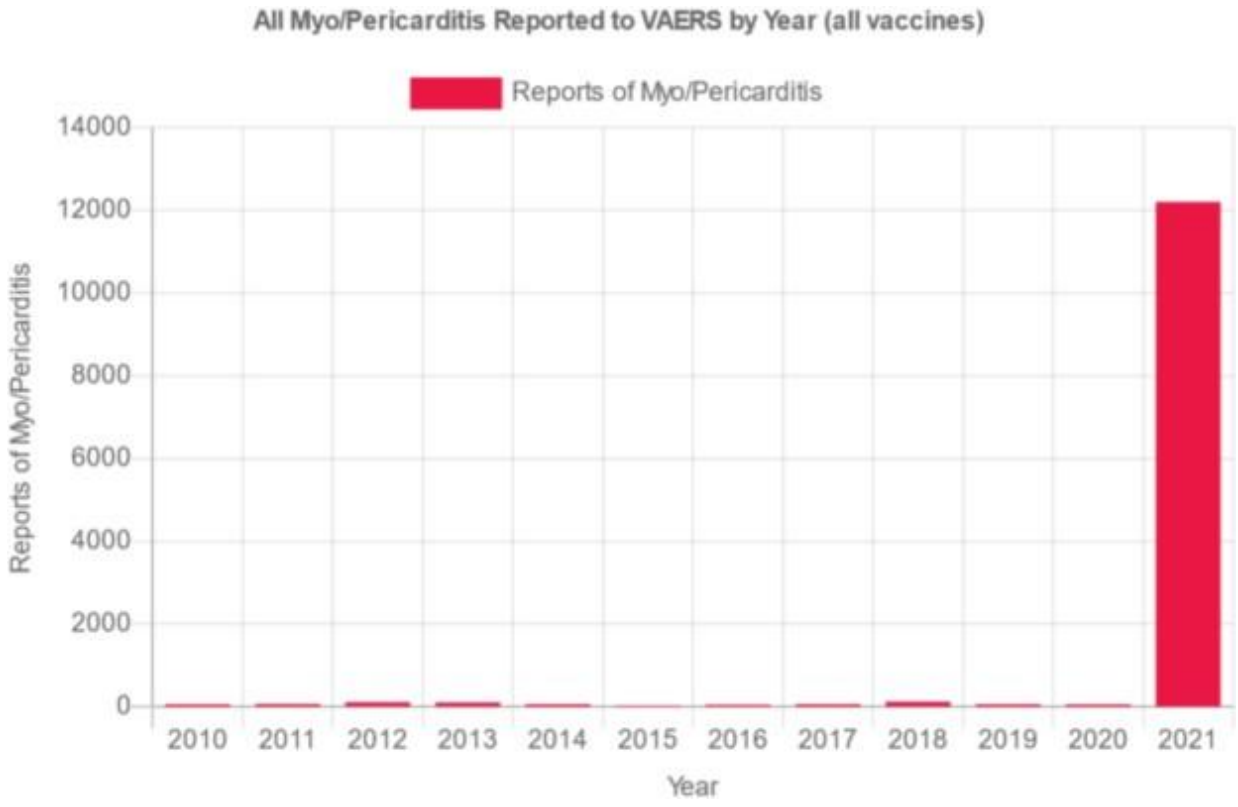


It is now well known that a possible severe consequence of getting the Covid-19 injection is that one may develop either myocarditis or pericarditis, or in some cases both. We know this because the authorities have had to admit it occurs, although as expected have downplayed it as extremely rare. This probably means it is much more common than people realise.

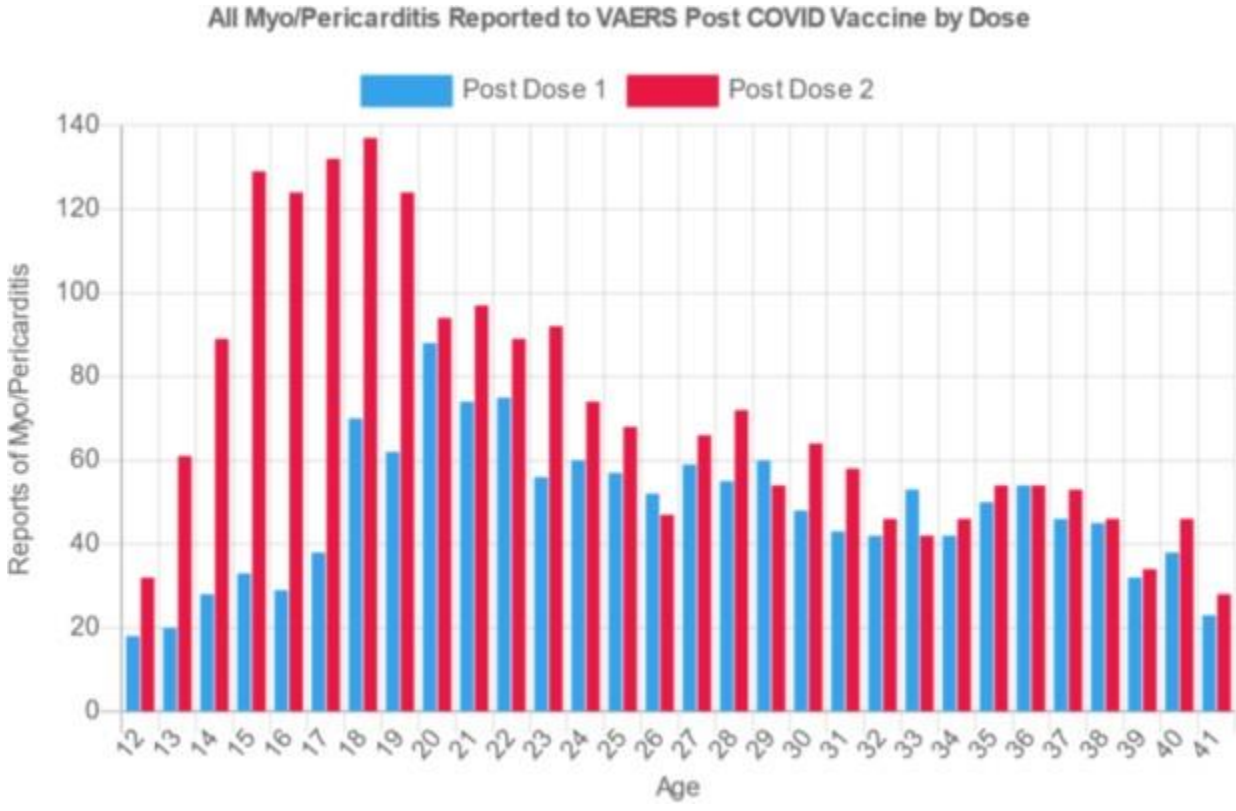
In simple terms, myocarditis is an autoimmune disease that causes inflammation of the heart muscle. This inflammation enlarges and weakens the heart, creates scar tissue and forces it to work harder to circulate blood and oxygen throughout the body. (*source*)

Whilst Pericarditis is an autoimmune disease causing inflammation of the pericardium, a sac-like structure with two thin layers of tissue that surround the heart to hold it in place and help it work.

Here's how both autoimmune diseases have affected people in the USA according to the Vaccine Adverse Event Reporting System (VAERS), where just 1-10% of adverse reactions are actually reported –



Here's how those unprecedented amounts of cases of myo/pericarditis reported toVAERS have been distributed by age –



As you can clearly see, the two autoimmune conditions are much more likely to occur in younger age groups, and the UK Medicine Regulator has admitted this is the case –

There has also been reporting of similar cases internationally following receipt of the Pfizer/BioNTech and Moderna vaccines. These have occurred most frequently in younger men aged 40 years and younger and within 10 days after the second dose. Most of these cases were mild and individuals typically recovered within a short time and with symptomatic treatment and rest. While reports of myocarditis and pericarditis after vaccination with COVID-19 vaccine AstraZeneca have also been received, there is insufficient evidence to recommend similar warnings for this vaccine.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Confirmation of diagnosis of these conditions typically requires targeted diagnostic procedures, such as electrocardiograms, cardiac imaging, and biomarker analysis, and it is also important to exclude other potential causes for the symptoms. Treatment of more symptomatic patients will occasionally require relevant expert follow up that might need detailed cardiac imaging to determine the nature of the condition.

Advice for the public

Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, or symptoms of disturbance of cardiac rhythm.

UK MHRA Safety Data

You may have noticed how the UK Medicine Regulator, the MHRA, stated how "most of these cases [of Myocarditis] were mild". So nothing to worry about then? Unfortunately not.

A mild case of myocarditis or pericarditis does not exist. You only get one heart, and it is incapable of regenerating/ repairing once damage has been done. Ongoing cardiovascular medication or even a heart transplant may be needed.

Overall, myocarditis which can cause dilated cardiomyopathy, is thought to account

for upto 45 percent of heart transplants in the U.S. today. (*source*)

Myocarditis can permanently damage your heart muscle, possibly causing:

- **Heart failure.** Untreated, myocarditis can damage your heart's muscle so that it can't pump blood effectively. In severe cases, myocarditis-related heart failure mayrequire a ventricular assist device or a heart transplant.

- **Heart attack or stroke.** If your heart's muscle is injured and can't pump blood, the blood that collects in your heart can form clots. If a clot blocks one of your heart's arteries, you can have a heart attack. If a blood clot in your heart travels to an arteryleading to your brain, you can have a stroke.
- **Rapid or irregular heart rhythms (arrhythmias).** Damage to your heart musclecan cause an arrhythmia.
- **Sudden cardiac death.** Certain serious arrhythmias can cause your heart to stopbeating (sudden cardiac arrest). It's deadly if not treated immediately.

With all that being said the following data that has been published by Public HealthScotland should come as no surprise.

Public Health Scotland (PHS) has a not very well known database presenting figures on the wider impact to the health service due to measures imposed in the name of Covid-19. The database is called 'COVID-19 wider impacts on the health care system'.

We have previously researched the data contained within the database to reveal a huge upsurge in cases of ovarian cancer across Scotland since the introduction of the Covid-19 injections. It just so happens that a study conducted by Pfizer reveals the mRNA Covid- 19 injection accumulates in the ovaries.

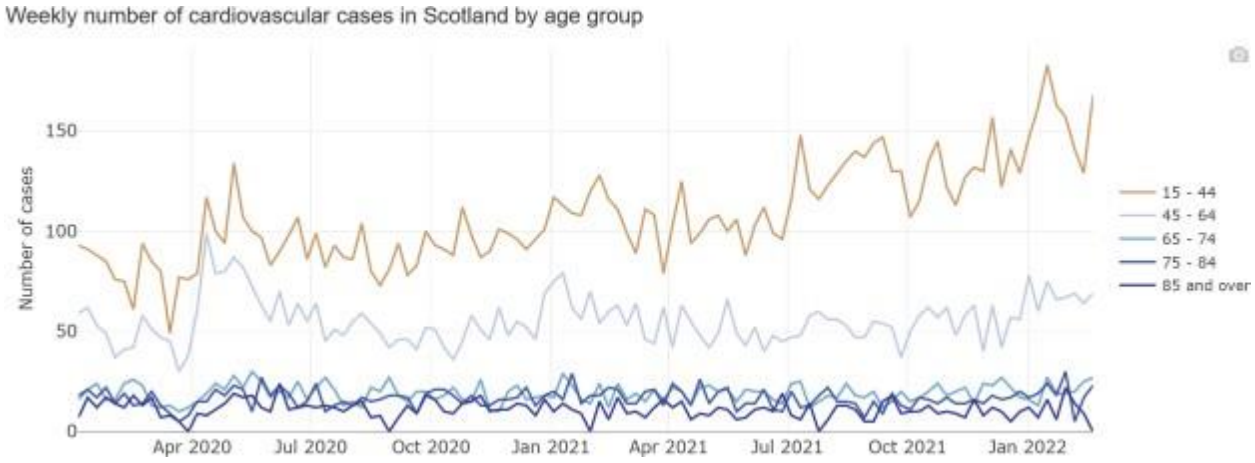
But this time we decided to analyse the data for cardiovascular cases across Scotland. Cardiovascular diseases are conditions that affect the structures or function of your heart,such as:

- Abnormal heart rhythms, or
- arrhythmias Aorta disease and Marfan syndrome
- Congenital heart disease
- Coronary artery disease (narrowing of the
- arteries) Deep vein thrombosis and pulmonary embolism

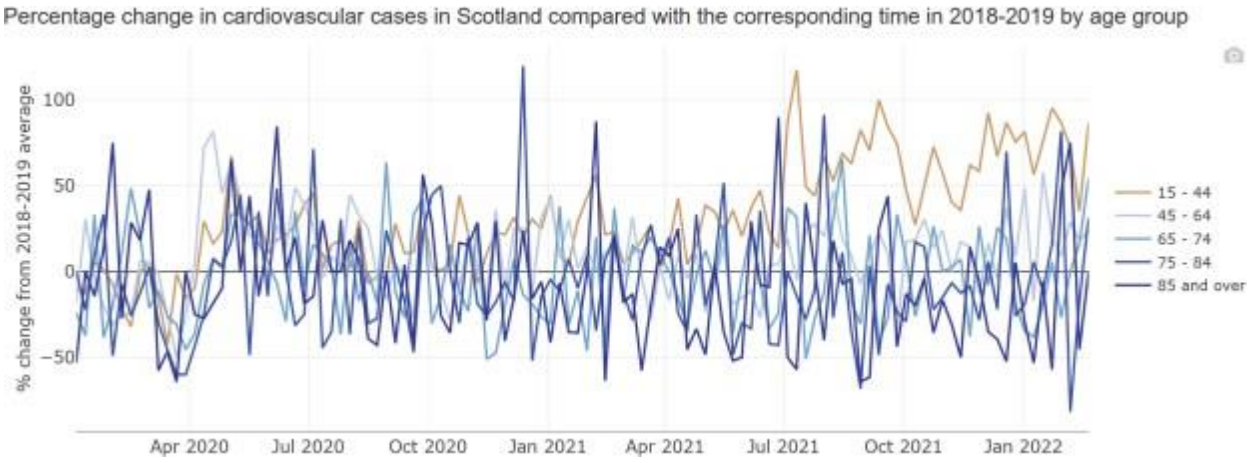
- Heart
- attack Heart failure
- Heart muscle disease (cardiomyopathy)
- Heart valve disease
- Myocarditis
- Pericardial disease
- Peripheral vascular disease
- Rheumatic heart disease
- Stroke
- Vascular disease (blood vessel disease)

For the ‘out of hours’ category, and the ‘ambulance service’ category, PHS provides a breakdown by age. Meaning we can assess the number of cardiovascular cases amongadults aged 15 to 44.

Here is how Public Health Scotland present the data on the number of cases requiringout-of-hours care across Scotland –



Source



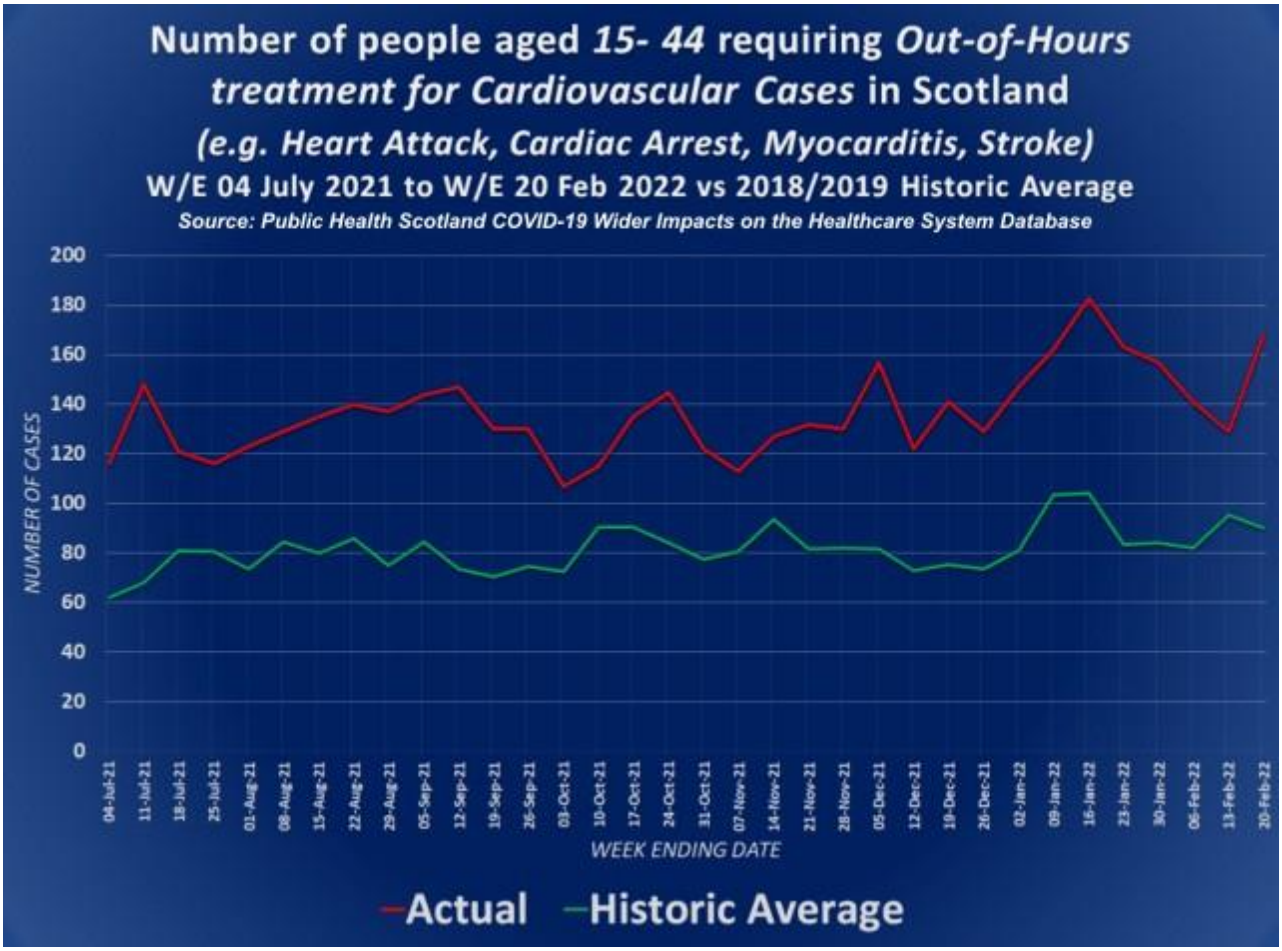
Source

As you can see from the above the weekly number of cases has been highest among 15- 44-year-olds since the beginning of the pandemic, but that gap between all other age groups suddenly got much bigger in 2021.

This is confirmed by the second graph above which shows the percentage change in cardiovascular cases against the 2018-2019 historical average. From around July 2021 there has been a huge spike in cardiovascular cases among 15-44-year-olds that should set alarm bells ringing and deserves further attention. So that's exactly what we gave it.

We extracted the data and produced a series of charts in order to present the figures provided by Public Health Scotland much more clearly and to attempt to understand the severity of what has been occurring since the introduction of the Covid-19 injections.

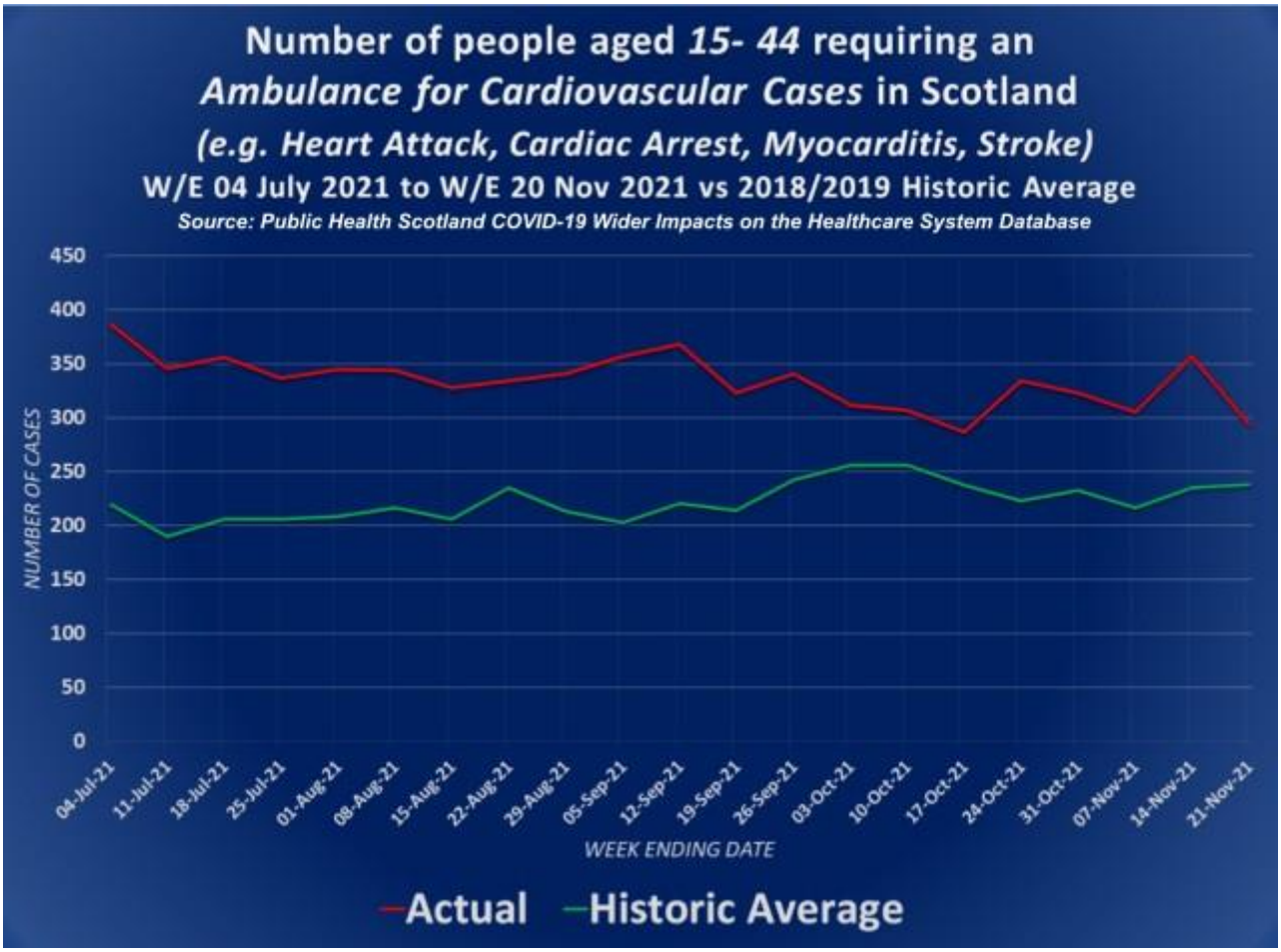
The following chart shows the number of people aged 15-44 requiring out-of-hours treatment for cardiovascular cases per week from the week ending 4th July 2021 to the week ending 20th Feb 2022, as well as the 2018-2019 historical average per week among the same age group –



The historical average shows that there have been anywhere from around 60 to just over 100 cardiovascular cases among 15 to 44-year-olds requiring out-of-hours treatment across Scotland. But the data for 2021 and 2022 shows that there have been anywhere from around 110 cases to 185 cardiovascular cases among 15 to 44-year-olds requiring out-of-hours treatment.

So the number of cases have essentially doubled.

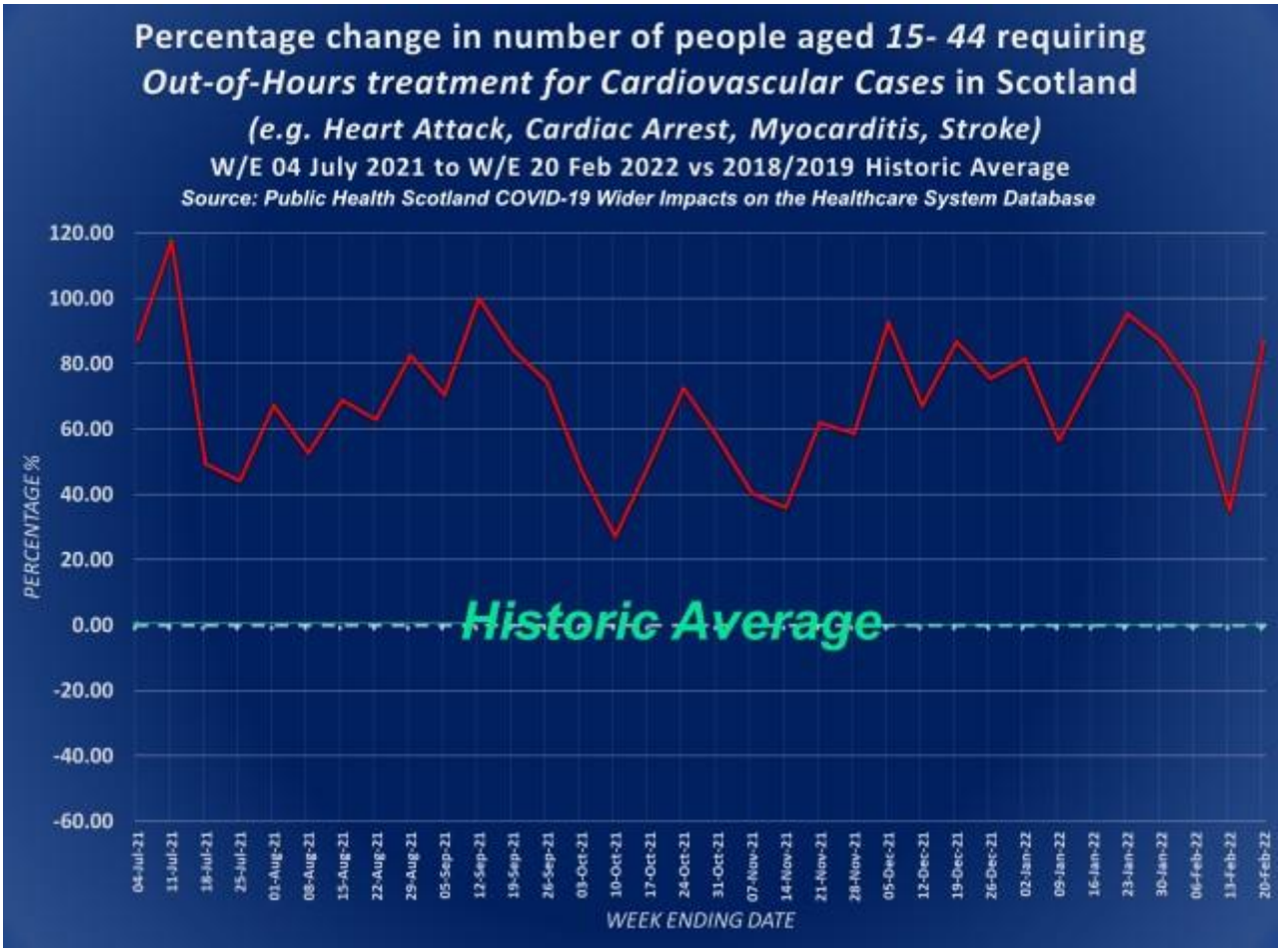
The following chart shows the number of people aged 15-44 requiring an ambulance for cardiovascular cases per week from the week ending 4th July 2021 to the week ending 21st November 2021 *(the most up to date data)*, as well as the 2018-2019 historical average per week among the same age group –



The historical average shows that there have been anywhere from around 185 to just over 250 people aged 15-44 requiring an ambulance for cardiovascular cases per week across Scotland. But the data for 2021 and 2022 shows that there have been anywhere from around 290 cases to 390 people aged 15-44 requiring an ambulance for cardiovascular cases per week.

So cases haven't quite doubled but they've still increased quite dramatically.

The following chart shows percentage change in the number of people aged 15-44 requiring out-of-hours treatment for cardiovascular cases per week from the week ending 4th July 2021 to the week ending 20th Feb 2022, compared to the 2018-2019 historical average per week among the same age group –

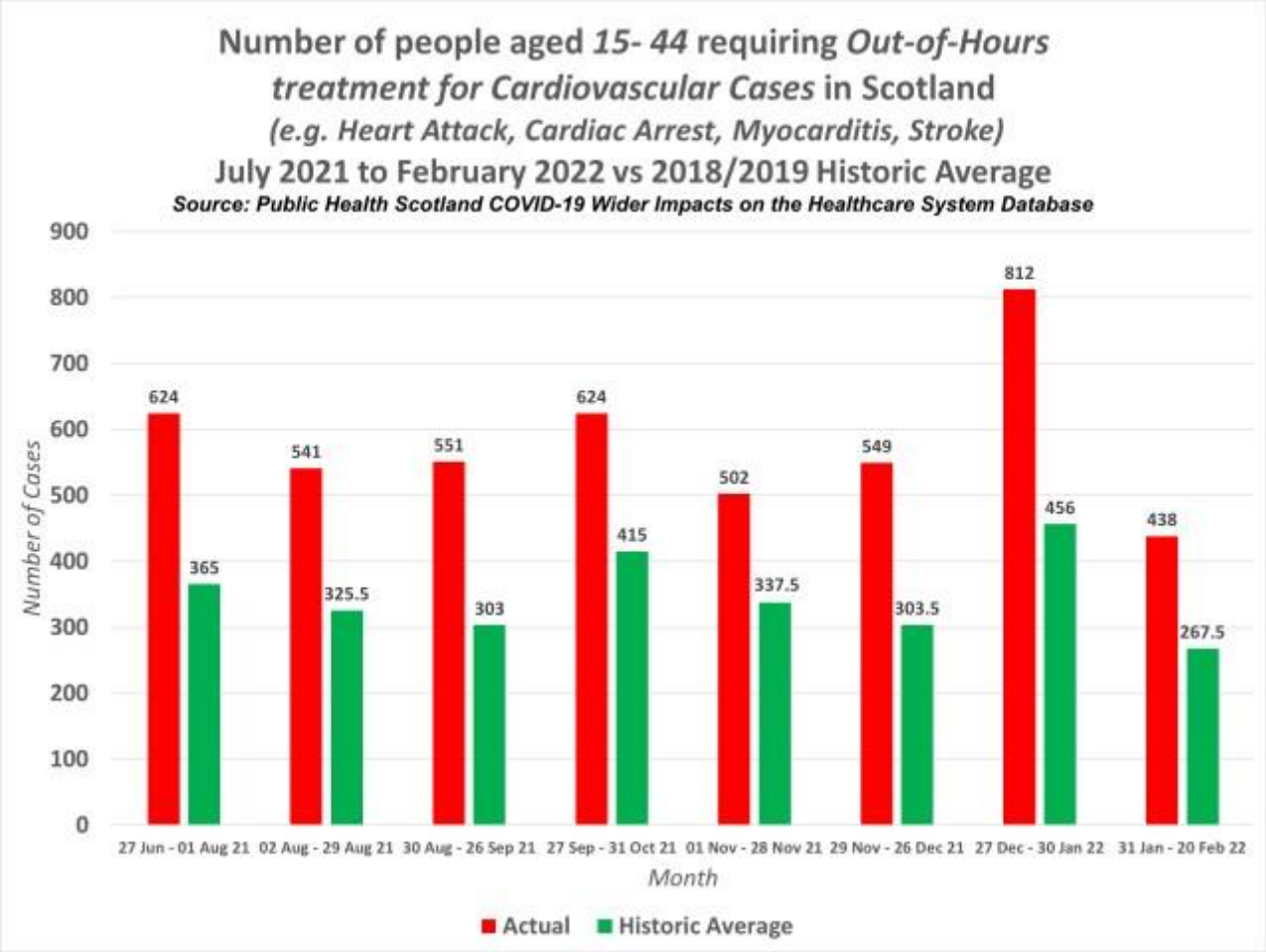


Here we can see that the number of cases requiring out-of-hours care has been higher throughout this entire period, ranging from a 35% increase in a single week to a staggering 117% increase in a single week compared to the historical average.

The following chart shows the percentage change in the number of people aged 15-44 requiring an ambulance for cardiovascular cases per week from the week ending 4th July 2021 to the week ending 21st November 2021 2018-2019 , compared to the historical average per week among the same age group –

Again we can see that the number of 15 to 44-year-olds requiring an ambulance has been higher than the historical average throughout the entire period, ranging from a 23% increase in a single week to an 82% increase compared to the historical average.

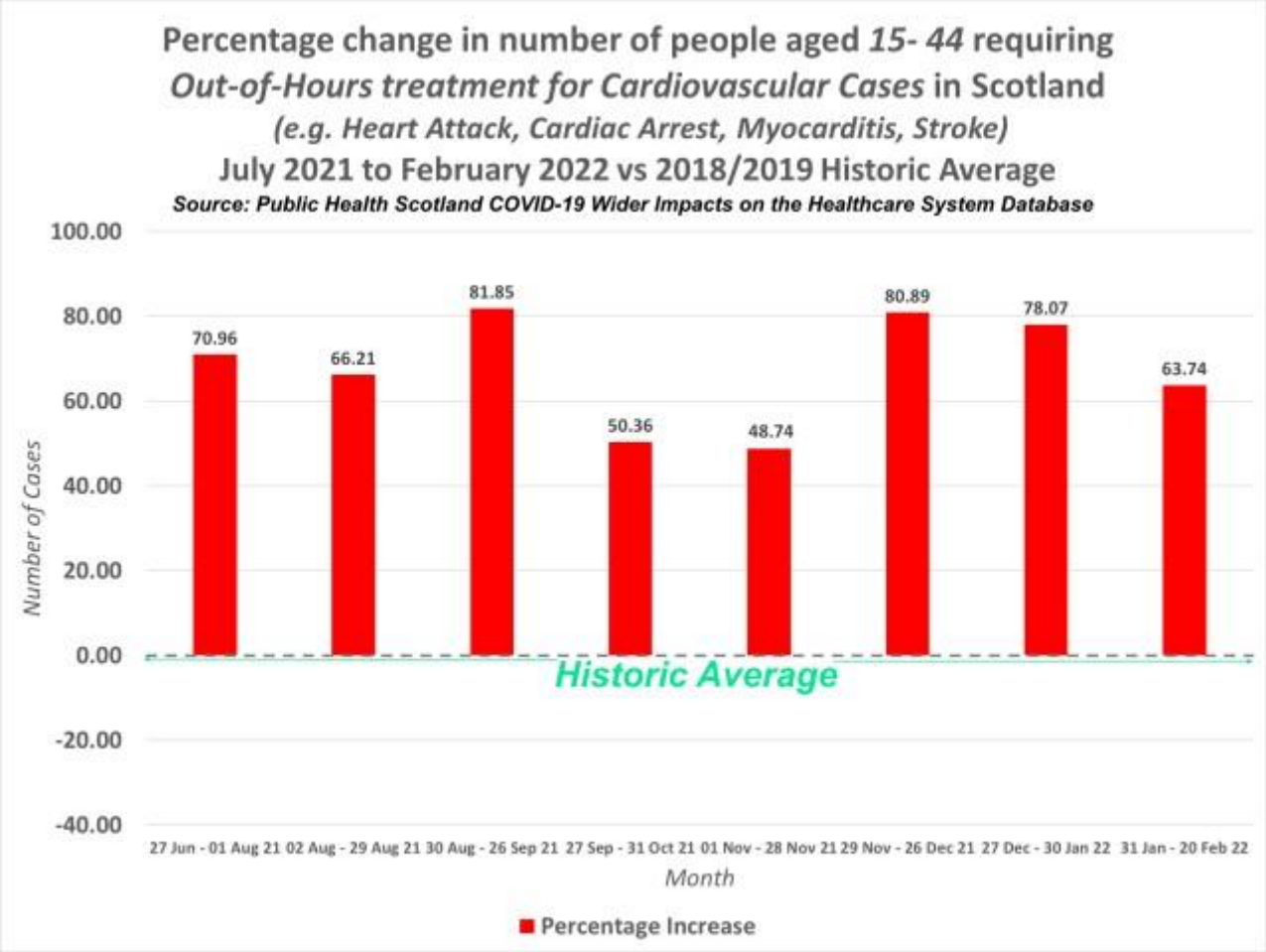
The following chart shows the number of people aged 15-44 requiring out-of-hours treatment for cardiovascular cases per month from July 2021 to February 2022, as well as the 2018-2019 historical average per month among the same age group –



January has seen the most cases both historically and in 2022, but the difference here is that 2022 saw a 78.07% increase on the historical average, this was not however the

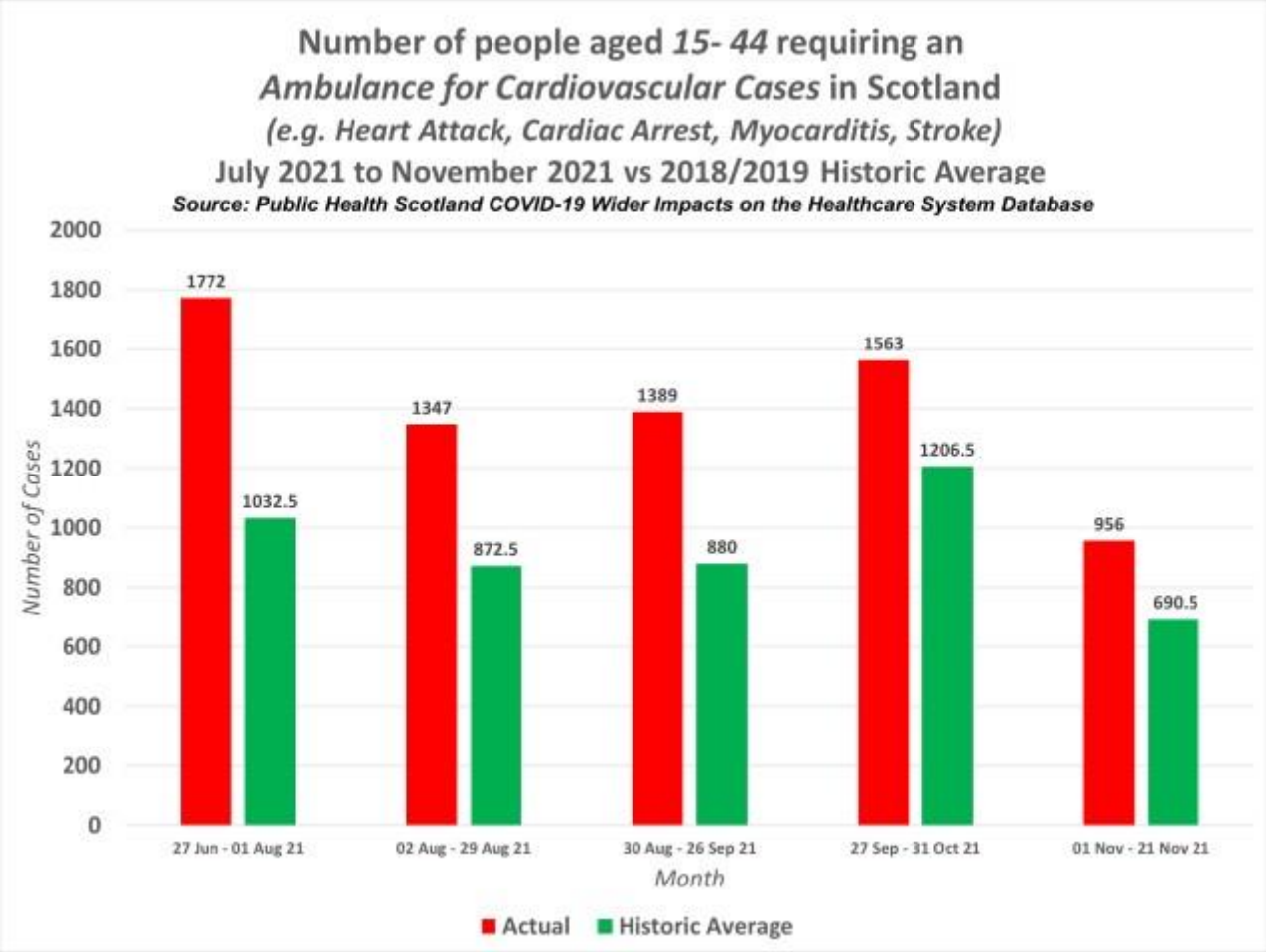
worst increase seen since July 2021.

The following chart shows the percentage change in the number of people aged 15-44 requiring out-of-hours treatment for cardiovascular cases per month from July 2021 to February 2022, as well as the 2018-2019 historical average per month among the sameage group –



The biggest increase was actually recorded in September 2021, with a 82% increase recorded against the historical average. This was closely followed by December 2021 with an 81% increase against the historical average. The smallest increases were recorded in both October and November 2021, but these months still saw a 50% and 49% increase against the historical average.

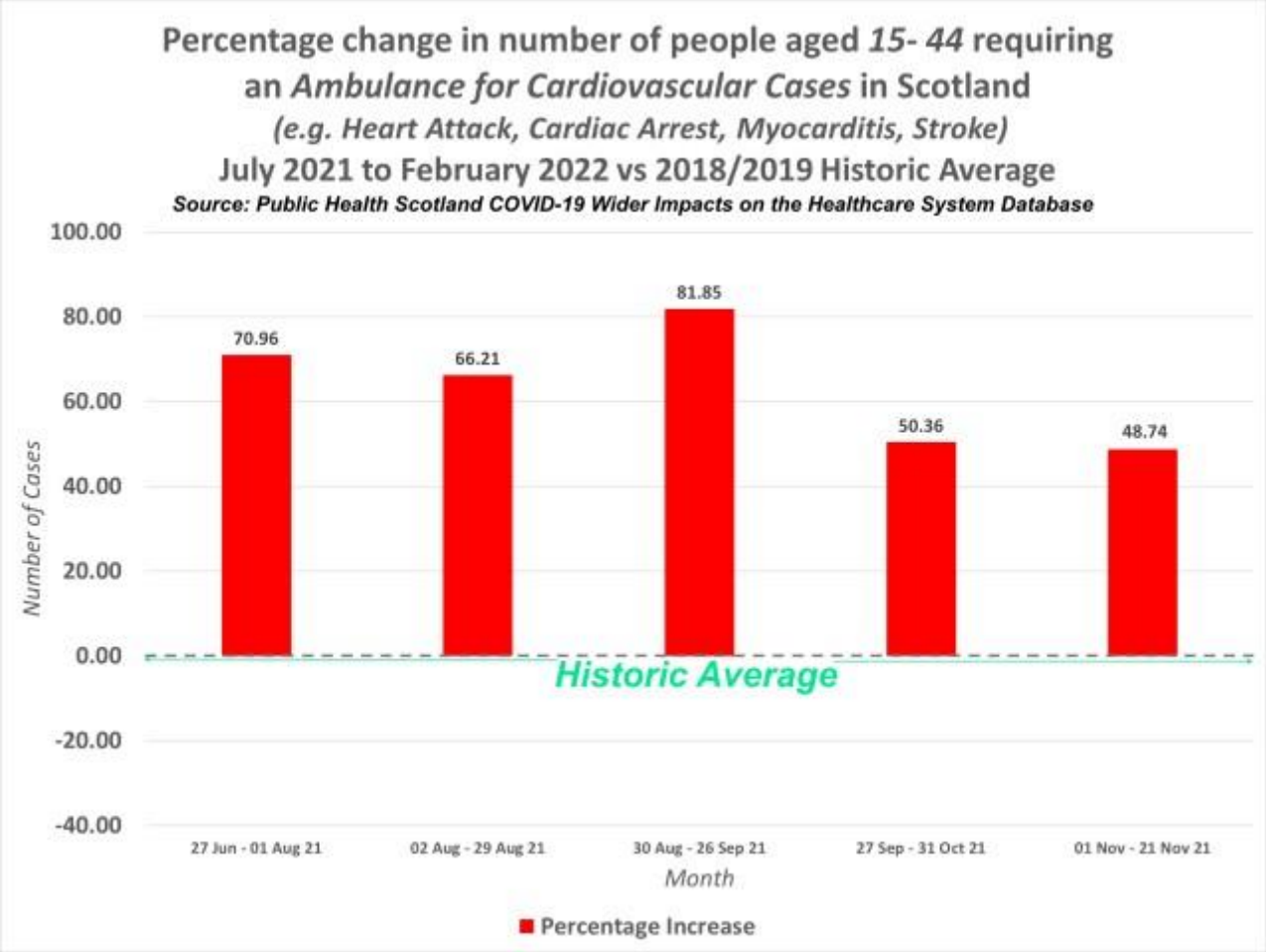
The following chart shows the number of people aged 15-44 requiring an ambulance for cardiovascular cases per month from July 2021 to February 2022, as well as the 2018- 2019 historical average per month among the same age group –



June 2021 saw the most people aged 15-44 requiring an ambulance due to an issue such as suffering a heart attack, cardiac arrest, myocarditis, or stroke with 1,772 cases. But the historical average shows that October is usually the month where the highest number of people requiring an ambulance is recorded.

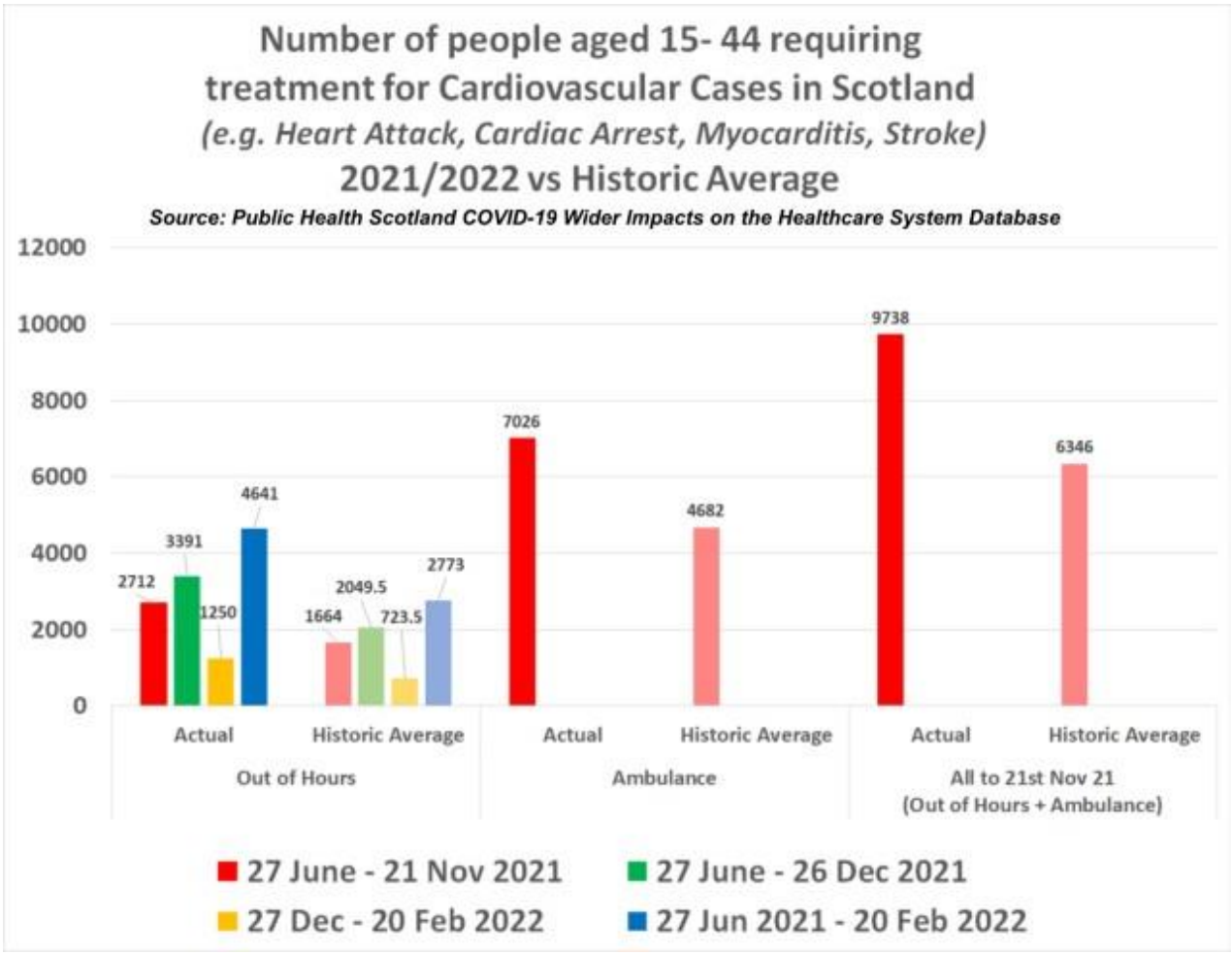
Unfortunately, Public Health Scotland are yet to publish any further data on the ambulance service past November 2021, but we will most likely find a huge jump in casesagain as was seen with people requiring out-of-hours treatment.

The following chart shows the percentage change in the number of people aged 15-44 requiring an ambulance for cardiovascular cases per month from July 2021 to February 2022, compared to the 2018-2019 historical average per month among the same age group –



The largest increase was again recorded in September 2021, with a 82% increase against the historical average. This was followed by July 2021 which saw a 71% increase and then August 2021 which saw a 66% increase. The lowest percentage change was again recorded in October and November 2021, but these months still saw a 50% and 49% increase.

The following chart shows the number of people aged 15 to 44 requiring an ambulance or out-of-hours treatment for cardiovascular cases in different time periods –



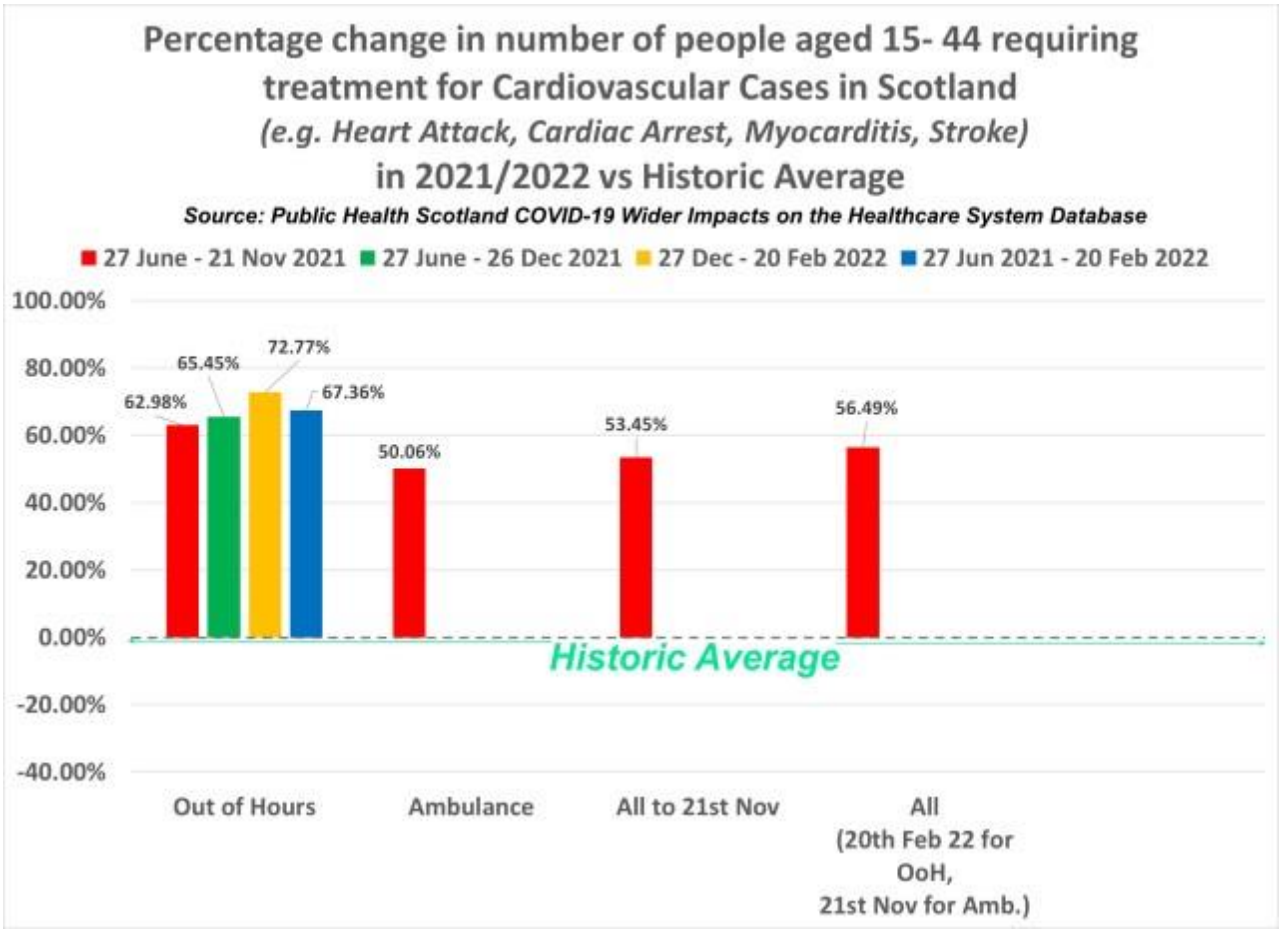
What we can clearly see above is the number of out-of-hours cases between 27th June and 21st November 2021, 27th June and 26th December 2021, 27th December and 20th February 2022, and 27th June 2021 and 20th February 2022 compared to the historic average.

As well as the number of people requiring an ambulance between 27th June and 21st November 2021 as well as the historic average. And finally the combined number of out of hours cases and ambulance cases between 27th June and 21st November 2021 compared to the combined historic average.

As you can see 2021 and 2022 has seen substantially more cardiovascular cases among 15 to 44-year-olds in all date-ranges. But what we're really interested in seeing here is thepercentage change compared to the historic average.

The following chart shows the percentage change in the number of people aged 15 to 44 requiring an ambulance or out-of-hours treatment for cardiovascular cases in

different time periods –



Because the ambulance data currently only goes as far as 21st November 2021 we'vecalculated the same time period for out-of-hours cases.

What we can see here is that between 27th June and 21st November, the number of people requiring an ambulance due to suffering a heart attack, cardiac arrest, myocarditis, stroke etc., increased by 50%, whilst the number of out-of-hours cases in the same time frame increased by 63%.

With both ambulance figures and out-of-hours figures combined up to 21st November, we can see that there was a 53.45% increase against the historic average. But when combining the ambulance figures with the full amount of out-of-hours figures up to 20th February 2022, we can see there was a 57% increase against the historic average.

The number of people aged 15-44 requiring out-of-hours treatment for cardiovascular cases between 27th June 2021 and 20th February 2022, saw a 67.36% increase against the historical average. But what we're most interested in is

how the figures for 2022 so far stack up against the figures for the second half of 2021.

The out-of-hours data shows that there was a 65.45% increase in the number of people requiring out-of-hours treatment for cardiovascular cases in the second half of 2021. But the data for 2022 so far shows that things are actually getting worse rather than
improving.

The number of people aged 15-44 requiring out-of-hours treatment for cardiovascular cases between 27th December and 20th February 2022 was 73% higher than the historical average in the same time frame.

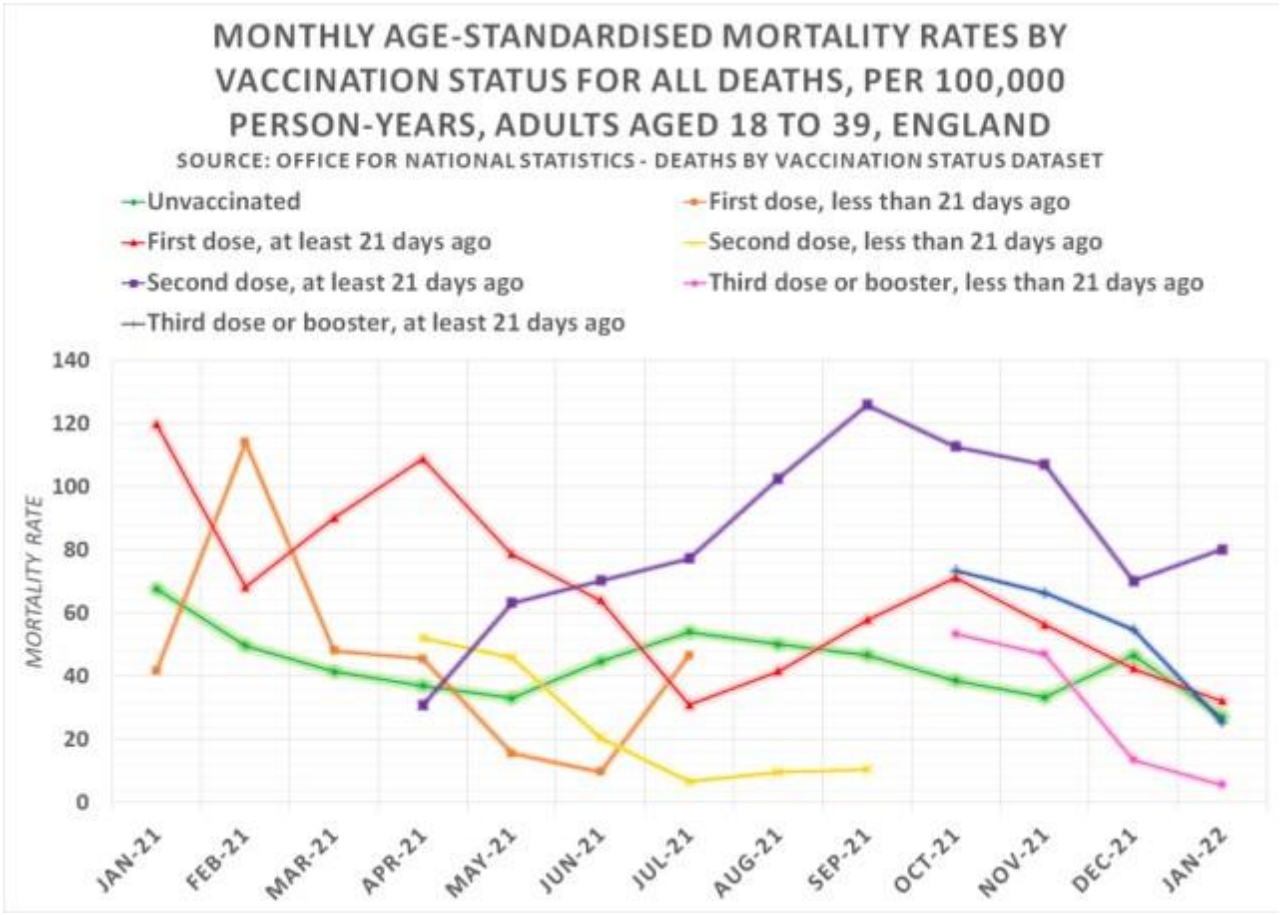
The big question of course is, why?

Official figure from the Office for National Statistics can most likely answer that question.

he Office for National Statistics is the UK's largest independent producer of official statistics and the recognised national statistical institute of the UK. It is responsible for collecting and publishing statistics related to the economy, population and society at national, regional and local levels.

Its latest dataset on deaths in England by vaccination status can be found **here**. It contains a large amount of data on age-standardised mortality rates for deaths by vaccination status between 1 January 2021 and 31 January 2022.

The following chart shows the monthly age-standardised mortality rates by vaccination status for all-cause deaths, per 100,000 person-years among adults aged 18 to 39 in England. The data has been extracted from table 2 of the ONS dataset.



The green line is the mortality rate among the unvaccinated, which while fluctuating has remained pretty stable throughout. The other lines however represent different vaccination statuses, and they are extremely concerning.

The orange, yellow, and pink lines represent mortality rates within 21 days of receiving a first, second or third dose. And they reveal that the risk of death increases significantly
immediately after vaccination.

But the most concerning figures are the mortality rates among those vaccinated at least21 days ago, which you can see more clearly in the following chart –

Around June 2021, there is a cross over from those who've received one dose to those who've received two doses in terms of the increased mortality rate against the
unvaccinated. This obviously tallies with when each injection was administered to this age group. But what's most concerning here is that the second injection seems to make thingsmuch worse in terms of the risk of death.

In January 2021 the mortality rate per 100,000 person-years among the

unvaccinated equated to 67.7. This then fell month on month to 33.1 in May, before increasing again in June to 44.8. The same however cannot be said for those who had received a single dose at least 21 days prior to their death.

In January 2021 the mortality rate per 100,000 person-years among the partly vaccinated equated to 119.9. Meaning the mortality rate was 77% higher than the mortality rate among the unvaccinated. This then fell to 68.3 deaths per 100,000 in February, before climbing to 90.1 in March, then 108.8 in April.

This means at this point the mortality rate among the partly vaccinated was 193.3% higher than the mortality rate among the unvaccinated. But not long after following thesecond dose being administered things get even worse.

The highest mortality rate among the double vaccinated (at least 21 days ago) occurred

in September 2021, with 125.9 deaths per 100,000 person-years. In the same month, the mortality rate among the unvaccinated equated to 46.8. Meaning the double vaccinated mortality rate was 169% higher than the unvaccinated mortality rate.

But the largest statistical difference occurred in November 2021. The mortality rate among the unvaccinated equated to 33.4 deaths per 100,000 person-years, whereas the mortality rate among the double vaccinated equated to 107. A difference of 220.4%.

With –

- Myocarditis; an autoimmune condition that causes inflammation of the heart, beinga known side-effect of the Covid-19 injections,
- Data showing a 73% increase in the number of people aged 15 to 44 suffering heart attacks, cardiac arrest, myocarditis, stroke, and other cardiovascular diseases sincethis age group was first offered the Covid-19 injection,
- And further data showing fully vaccinated young adults are on average 92% morelikely to die than unvaccinated young adults.

It would appear we have the smoking gun that proves the damage the Covid-19 injectionshave done and are doing to the population.

"Exhibit-J"

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPLELATE JURISDICTION

PUBLIC INTEREST LITIGATIONNO.85 OF 2021

DISTRICT:

YohanTengra ... Petitioner

V/s

The State of Maharashtra & others ... Respondents

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3	2.	The copy of FAQ.	954-969

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IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPLELATE JURISDICTION

PUBLIC INTEREST LITIGATION NO.85 OF 2021

DISTRICT:

YohanTengra ... Petitioner

V/S

1. The State of Maharashtra,
   Through Chief Secretary,
   State of Maharashtra,
   Mantralaya, Mumbai
2. Under Secretary,
   Disaster Management Unit,
   Mantralaya, Mumbai-23.
3. Shri. IqbalChahal,
   Municipal Commissioner,
   MCGM Annex Bldg. Fort, Mumbai-01.
4. Shri. ShirgangGholap,
   Under Secretary,
   Disaster Management Unit,
   Govt. of Maharashtra.
5. Shri. SitaramKunte,
   Chief Secretary, M.H State.
6. Ministry of Railways,

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Rail Bhawan, Rafi Marg, New Delhi.
7. The Union of India,
Through Chief Secretary,
To the Govt. of India, New Delhi-01.
8. Central Bureau of Investigaiton,
Lodhi Road, New Delhi-110003. ... Respondents

AFFIDAVIT IN REPLY

ON BEHALF OF RESPONDENT NO.

I,Dr.Sadhana M. Tayade, Age: 58, Service: presently working as Director of Health Services, Public Health Department, Mumbai, do hereby state on solemn affirmation on behalf of Respondent Nos. 1, 2, and 3 as under:-

1. I have read the copy of the present PIL along with the annexure thereto, also perused the official record pertaining to the subject matter of the case and on the basis of the information derived there from, I am filing this Affidavit-in-Reply to the above PIL. I am filing this Affidavit for the purpose of opposing the PIL. I say that the contentions, which are not specifically denied by me in this Affidavit-in-reply, should not be construed as an admission on my part. I crave leave of this Hon'ble Court to file additional affidavit, if so required. I am filing this affidavit as under:-

2. I say that present PIL has been filed by the Petitioner for directing the Respondent No.6to amend circular direction/Sop dt. 10.08.2021, 11.08.2021 and 15.07.2021 issued by the Respondent to the

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extent by permitting non vaccinated people to travel by train and they should not be treated differently than those who are vaccinated and further prayed for directing the Respondents to open Local Trains for all irrespective of their status as vaccinated or non-vaccinated and also for other prayers mentioned in the said PIL.

3. I say that, the directions, circular/sop are issued by the State Government for the benefit of the public at large. I say that the said circular/sop are issued only after consulting with the various departments of the State Government more particularly the Task Force Committee constituted by the State. I further say that, the said circular are issued after consulting the Task Force Committee and after proper and detail study of the departments.

4. I say that the contention of the Petitioner in the present PIL is that, the vaccination is voluntary and not compulsory and the Petitioner has relied upon the various Judgments. I say that, in fact due to vaccinating the people the rates of hospitalization of COVID-19 patients is gradually reduced. Hereto annexed and marked as ***Exhibit-1*** is the copy of data showing reduction of hospitalization in COVID-19 patients.

5. I say that, thevaccination is important which could save the life. COVID-19 vaccines provide strong protection against serious illness hospitalization and death. There is also some evidence that being

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vaccinated will make it less likely that you will pass the virus on to others, which means your decision to get the vaccine also protects those around you.

6. I say that, the need for emergency care/hospitalization due to breakthrough COVID-19 is an exceedingly rate even in fully vaccinated patients. As vaccination has increased regionally, emergency care visits amongst fully vaccinated individuals have remained low and occur much less frequently than unvaccinated individuals. If, hospital-based treatment is required, elderly patients with significant comorbidities are at high-risk for severe outcomes regardless of vaccination status.Hereto annexed and marked as ***Exhibit-2*** is the copy of FAQ.

7. I further say and submit that, by not allowing the non-vaccinated people to open Local Trains or other public places is only to secure the right to live of the other vaccinated people.

In view of above appropriate order may be passed.

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VERIFICATION

I,Dr.Sadhana M. Tayade, Age: 58, Service: presently working as Director of Health Services, Public Health Department, Mumbai,do hereby state on solemn affirmation that whatever sated herein above is based upon the information derived from the official records, which I believe to be true and correct.

Solemnly affirmed at Mumbai.)

This day of December, 2021)

15/12/2021

(Dr.Sadhana M. Tayade)
Director of Health Services,
Public Health Department, Mumbai.

ID ... 19/0389 by Govt of Mah.
Seen Cig. / ...

I identify the **Deponent,**

BEFORE ME

MANISH M. PABALE
B.A., LL.M.,
ADVOCATE & NOTARY (GOVT. OF INDIA)
104, Natwar Chambers,
94 Nagindas Master Road,
Fort, Mumbai - 400 001.

Clerk to the
Office of the Government Pleader,
A.S. (Writ Cell), High Court, Mumbai.

Drafted :-

NOTED & REGISTERED
Page No. 414/02 Sr. No. 308
Date 15 DEC 2021

Mrs.R. A. Salukhe
Assistant Government Pleader,
A.S. (Writ Cell), High Court, Mumbai.

Settled by:-

Mr. P. P.Kakade
Government Pleader,
A.S. (Writ Cell), High Court, Mumbai

NOTARY M. M. PABALE Mumbai Maharashtra Reg. No. 15220 Expiry Dt. 30-10-2024 GOVT. OF INDIA

NOTARIAL NOTARIAL NOTARIAL NOTARIAL

Exh-1

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No. of Admitted patient information and Covid 19 vaccination performance							
Sr. No.	On Date	No. of Admitted patient	Eligible Target Population for vaccination	1st dose Performance	%	2nd dose Performance	%
1	5/31/2021	97853	91435000	18009903	19.70	4570306	5.00
2	6/30/2021	38018	91435000	26070687	28.51	6373224	6.97
3	7/31/2021	33163	91435000	33384721	36.51	11202851	12.25
4	8/31/2021	16818	91435000	43090513	47.13	16002636	17.50
5	9/30/2021	10134	91435000	57644999	63.04	24267887	26.54
6	10/31/2021	4311	91435000	67201631	73.50	30976476	33.88
7	11/30/2021	2775	91435000	74334513	81.30	40045655	43.80
8	12/13/2021	2466	91435000	77916475	85.22	46621812	50.99

True Copy

14/12

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256-2

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World Health Organization

UNDP

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

unicef
for every child

COVID-19 Vaccination FAQs for 18-44 YEAR AGE GROUP

True Copy

19/12

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1 From when the COVID-19 vaccination for 18-44 year age group is starting?

Registrations have started on 28 April and vaccination has started on 01 May. Please check www.cowin.gov.in for available slots and vaccination centres.

2 Where can I get the Vaccine from?

You can get the vaccine from Govt Hospital in districts which are selected by State Govt.
You can also get vaccine in selected private hospital vaccination centers. Check cowin.gov.in for details after registration.

3 How to register for Vaccination?

Registration is only via CoWIN Website (www.cowin.gov.in)/Aarogya Setu App only. No other app/website/walk-in/spot registration would be allowed.
Register using mobile number and Aadhaar number. Follow the simple steps as guided by the website, register, and choose your Vaccination Centre via Pin code/District. You would get an SMS Confirmation. Keep it safe.

4 Can a person get the COVID-19 vaccine without registration with Health Department?

No, the registration of beneficiary is mandatory for vaccination for COVID-19 vaccine.

5 After registration; the beneficiaries have to book a slot for vaccination or walk into the vaccination center

For 18 to 44 age group vaccination no walk in is permitted as of now. Vaccination in this age group will only possible through scheduled appointment. Appointment can be sought on cowin.gov.in after registration. Notification and information about the vaccine session date and time will be shared with the beneficiary after scheduling the appointment.

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6 What documents are required for registration of eligible beneficiary?

Any of the below mentioned ID with Photo may be produced at the time of registration:

Aadhaar Card

Driving License

Health Insurance Smart Card issued under the scheme of Ministry of Labour

Mahatma Gandhi National Rural Employment Guarantee Act (MGNREGA) Job Card

Official identity cards issued to MPs/MLAs/MLCs

PAN Card

Passbooks issued by Bank/Post Office

Passport

Pension Document

Service Identity Card issued to employees by Central/ State Govt./ Public Limited Companies

Voter ID

7 Can I reschedule my Vaccination Appointment?

Yes. You can reschedule till the previous day.

8 What are the vaccines that would be made available?

At present, COVISHIELD (Oxford-AstraZeneca Vaccine) and COVAXIN (Bharat Biotech) would be available. In due course, many other vaccines are expected to be made available. While booking the appointment, you will be able to see both the name of the centre and the vaccine being given in private facility. Vaccine of choice among the available options at the displayed cost may be received from private facilities. At Government facilities/ sites there is no choice of vaccine.

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9 How much should I pay for the vaccine dose?

In the private sector, the price would be decided by the Private Vaccine Providers.
In the government hospitals, the vaccine will be available free of cost in Uttar Pradesh.

10 I am a young person. Is COVID-19 vaccines (COVISHIELD and COVAXINE) are safe?

Yes, Both the available vaccines are entirely safe and effective. Millions of persons have received COVISHIELD and COVAXINE in India, with extremely rare side effects. And, even in the unlikeliest scenario of a serious adverse event, there are established management protocols. There is nothing to fear.

11 Can a pregnant or lactating woman receive COVID-19 vaccine?

Studies are ongoing to prove the safety of COVID-19 vaccines in pregnant and lactating women. Currently, Government of India guidance does not include vaccination for pregnant and lactating women.

12 I am on my periods. Can I receive the vaccine?

Yes, you can. Kindly do not believe the rumours regarding the same.

13 Which of the vaccines is better for me - COVISHIELD or COVAXIN?

Both are equally efficacious in preventing mild, moderate, and severe COVID. Choose whatever is available to you, at the Vaccination Centre.

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14 I am young. I believe I have good immunity. Do I need to still take the Vaccine?

Yes. No one is safe from COVID-19, not even the fittest and healthiest of individuals. Better safe, than sorry.

15 I am hearing reports of people testing COVID-19 Positive even after receiving the first dose of Vaccine. Is it even useful?

First, the rate of infection after vaccination is much lower than the unvaccinated. And, even if such an infection occurs, by virtue of the vaccination, the body has a good titre of antibodies to limit the infection to a mild stage, thereby significantly reducing the chance of progressing to severe COVID, hospitalization and deaths. Therefore, vaccines are life-saving and effective!

16 What are the common side effects that I can expect after Vaccination?

Fever, headaches, body aches, fatigue, injection site pain are the common side effects, and they are manageable by a short course of Paracetamol. Most resolve by 2-3 days. You are observed for 30 minutes after receiving the dose, for any serious or severe effects, and even though they are rare to occur, there is definite treatment for each such serious effect.

17 I recently tested COVID-19 Positive. Should I still take the vaccine?

Yes. You should receive the vaccine 4-8 weeks after testing COVID-19 positive.

18 I received the First Dose of the Vaccine and then tested COVID-19 Positive in between the two doses? Can I take the second dose?

Yes. You should receive the vaccine 4-8 weeks after testing COVID-19 positive.

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19 **Will vaccinated beneficiaries receive information on the status of their vaccination after completion?**

Yes. On getting due dose of COVID-19 vaccine, the beneficiary will receive SMS on their registered mobile number. After all doses of vaccine are administered, a QR code-based certificate will also be sent to the registered mobile number of the beneficiary.

20 **What is the dose schedule of both the vaccines?**

The second dose of Covishield vaccine can be taken 4-8 weeks after the first dose and the second dose of Covaxin can be taken 4-6 weeks after the first dose.

21 **Is it mandatory to take the vaccine?**

Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and to limit the spread of this disease to the close contacts including family members, friends, relatives, and co-workers.

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22 If one is taking medicines for illnesses like Cancer, Diabetes, Hypertension etc, can s/he take the COVID-19 vaccine and/or If I suffer from HTN/DM/ CKD/heart disease/lipid disorders etc., can I safely take this vaccine?

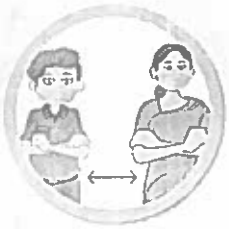
Yes, persons with one or more of these comorbid conditions are considered among the high-risk categories. They need to get COVID-19 vaccination on priority. Overall, the vaccine is safe and efficacious in adults with comorbidity. The maximum benefit of getting the COVID-19 vaccine is for those who have such co-morbidities. However, if you are concerned for any specific reason, please consult your doctor

23 Do I need to use the mask/other COVID-19 appropriate precautions after receiving the vaccine?

Yes, it is absolutely necessary that everyone who has received the COVID-19 vaccine should continue to follow the COVID-19 appropriate behaviour i.e., mask, do gaj ki doori and hand sanitization to protect themselves and those around from spreading the infection.

Use mask correctly

Wash hands with soap and water frequently and thoroughly or use hand sanitizer



Maintain 6 feet (2 gaj) physical distance

24 How long will I remain protected after vaccination?

Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, physical distancing, and other COVID-19 appropriate behaviours is strongly recommended.

961

25 **Does vaccination protect me against newer strains / mutated virus of SARS-CoV 2?**

The body responds to vaccination by making more than one type of antibodies to virus parts including spike protein. Therefore, all vaccines are expected to provide reasonable amount of protection against the mutated virus also. Based on the available data the mutations as reported are unlikely to make the vaccine ineffective.

26 **In how many days will the vaccination create an adequate immune response and protection?**

Adequate immune response takes 2-3 weeks after completion of entire vaccination schedule i.e., after the second dose of COVISHIELD® and COVAXIN®.

27 **What precautions do I need to take after receiving the vaccine?**

Both the vaccines are safe, but in case of any discomfort or complaint, ask the beneficiary to visit the nearest health facility and/or call the health worker whose phone number is given in the Co-WIN SMS received after vaccination.

28 **Is it important for me to receive the same vaccine during second dose?**

As the vaccines available are not inter-changeable, it is important to receive the second dose of the same vaccine as the first one. The Co-WIN portal is also going to help to ensure that everyone receives the same vaccine

Tome Copy

For more details, refer to
www.mohfw.gov.in
www.cowin.gov.in

24X7

Department of Health and Family Welfare
Uttar Pradesh Toll Free Number
1800-180-5145
Call Center Number
104

Frequently Asked Questions on COVID-19 Vaccination

Can people with allergies get vaccinated ?

Can pregnant women take Covid 19 vaccine? What about lactating mothers ?

Do I get enough antibodies after getting vaccinated ?

Is blood clotting common after taking the vaccine shots ?

If I have contracted Covid, after how many days can I get myself vaccinated ?

Posted On: 08 JUN 2021 10:17AM by PIB Mumbai

Mumbai / New Delhi, June 8, 2021

Can people with allergies get vaccinated ?

Can pregnant women take Covid 19 vaccine? What about lactating mothers ?

Do I get enough antibodies after getting vaccinated ?

Is blood clotting common after taking the vaccine shots ?

If I have contracted Covid, after how many days can I get myself vaccinated ?

These are some of the frequently asked questions people raise about Covid vaccination. Dr. V K Paul, Member (Health), NITI Aayog and Dr. Randeep Guleria, Director, All India Institute of Medical Sciences have addressed various doubts people have regarding COVID-19 vaccines in a special programme on DD News on Sunday the 6th June.

Read on, to be armed with the correct facts and information, and stay protected from the infection. This and other questions are also answered in the FAQs of the Union Health Ministry (https://www.mohfw.gov.in/covid_vaccination/vaccination/faqs.html)

Can people with Allergies get Vaccinated?

Dr. Paul: If someone has a significant allergy problem, then COVID vaccine should be taken only after medical advice. However, if it is only a question of minor allergies like getting common cold, skin allergies, etc., one should not hesitate to take the vaccine.

Dr. Guleria: Those on prior medication for allergies should not stop these, they should continue to take the medication regularly while getting themselves vaccinated. It is also important to understand that arrangements have been made at all vaccination sites for management of allergies arising due to vaccination. Hence, we advise that even if you happen to have a severe allergy, you keep taking the medication and go and get yourself vaccinated.

Can pregnant women take COVID-19 vaccine?

Dr. Paul: As per our current guidelines *(read PIB press release dated 19th May 2021- https://pib.gov.in/PressReleasePage.aspx?PRID=1719925)* vaccination should not be given to pregnant women. The reason for this is that a decision recommending vaccination to pregnant women could not be taken by doctors and the scientific community based on available data from vaccine trials. However, the Government of India will clarify this situation in a few days, based on new scientific inputs.

It is being found that many COVID-19 vaccines are being found safe for pregnant women; we hope the route should open for our two vaccines as well. We request the public to be a little more patient, especially considering that the vaccines have been developed in a very short span of time, and pregnant women are not usually included in the initial trials, due to safety concerns.

Dr. Guleria: Many countries have begun vaccination for pregnant women. The US FDA has given approval for Pfizer and Moderna vaccines. Data regarding COVAXIN and COVISHIELD will also come soon; some data is already available, and we hope that in a few days, we hope to get the full required data and grant approval for vaccinating pregnant women in India too.

Can breastfeeding mothers take COVID-19 Vaccine?

Dr. Paul: There is a very clear guideline regarding this the vaccine is absolutely safe for lactating mothers. There is no need for any fear. There is no need to stop or pause breastfeeding either before or after vaccination.

(https://pib.gov.in/PressReleasePage.aspx?PRID=1719925),

Do I get enough antibodies after getting vaccinated ?

Dr. Guleria: It is important to understand that we should not judge the efficacy of vaccines only by the amount of antibodies getting generated. Vaccines give many types of protection - such as through antibodies, cell-mediated immunity and memory cells (which generate more antibodies when we get infected). Moreover, the efficacy results which have come so far are based on trial studies, where the study design of each trial is somewhat different.

Data available till now shows clearly that efficacy of all vaccines - whether COVAXIN, COVISHIELD or Sputnik V - are more or less equivalent. We should not hence say take this vaccine or that vaccine, whichever vaccine is available in your area, please go ahead and get yourself vaccinated so that you and your family are safe.

Dr. Paul: Some people seem to be thinking of getting an antibody test done post vaccination. But that is not required to be done for the simple fact that antibodies alone do not indicate the immunity of a person. This is so because of T-cells or memory cells; these undergo certain changes when we receive the vaccine, they become stronger and gain resistance power. And T-Cells are not detected by antibody tests as these are found in bone marrow. Hence, our appeal is to not fall in the tendency of doing antibody tests either before or after getting vaccinated, take the vaccine which is available, take both doses at the right time and follow COVID Appropriate Behaviour. Also, people should not be under the false notion that the vaccine is not required if you have had COVID-19.

Is blood clotting common after taking the vaccine shots ?

Dr. Paul: A few cases of this complication did come to the fore, particularly with regard to Astra-Zeneca Vaccine. This complication occurred in Europe where this risk was seen to be present to some extent in their younger population due to their lifestyle, body and genetic structure. But, I would like to assure you that we have systematically examined this data in India and found that such blood-clotting incidents are almost negligible here - so negligible that one need not worry about it. In European countries, these complications were found to be almost 30 times more than that in our country.

Dr. Guleria: It has been seen earlier also that blood clotting after surgery occurs less in Indian population in comparison to that in US and European populations. This side-effect, named as Vaccine induced Thrombosis or Thrombocytopenia, is very rare in India, found to occur in a much lesser proportion than in Europe. Hence, there is no need to be scared of this. Treatments also are available for this, which can be adopted, if diagnosed early.

If I have contracted Covid, after how many days can I get myself vaccinated ?

Dr. Guleria: The latest guidelines clearly state that a person who caught COVID-19 can take the vaccine after three months from the day of recovery Doing this will help the body develop stronger immunity and the effect of the vaccine will be better. *(https://pib.gov.in/PressReleasePage.aspx?PRID=1719925).*

Both the experts – Dr. Paul and Dr Guleria also asserted and reassured that our vaccines are effective on the mutants which have been seen in India till date. They also termed as fake and unfounded the rumours circulating on social media that our immune system becomes weak after taking vaccines or people die after taking vaccines, a wrong belief held by some people in rural areas and remote blocks.

***

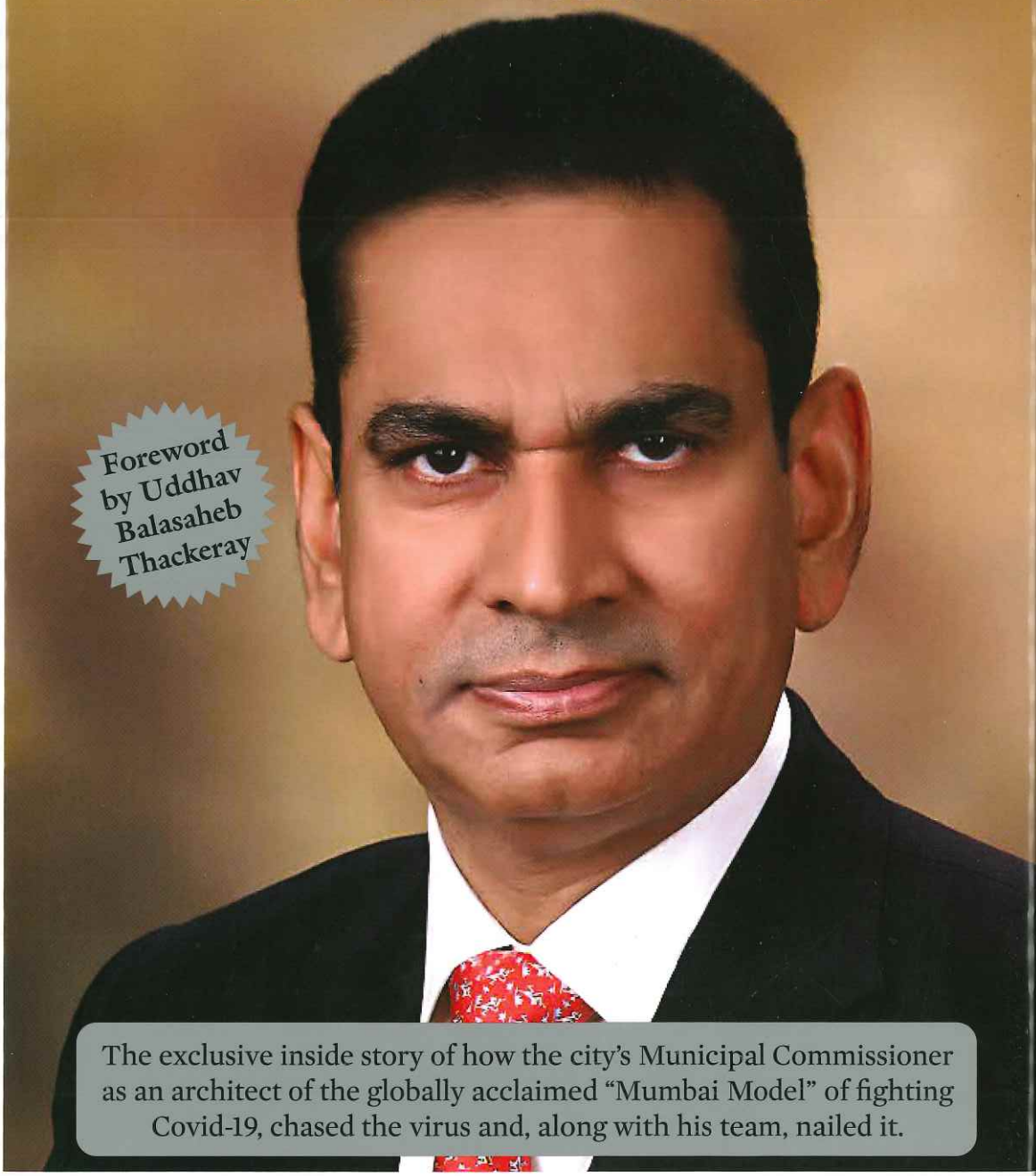
Content courtesy : DD News /PIB Mum/DJM /SC.

(Release ID: 1725244)

"Exhibit-L"

IQBAL SINGH CHAHAL

COVID WARRIOR



Foreword by Uddhav Balasaheb Thackeray

The exclusive inside story of how the city's Municipal Commissioner as an architect of the globally acclaimed "Mumbai Model" of fighting Covid-19, chased the virus and, along with his team, nailed it.

MINHAZ MERCHANT

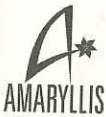
In the most devastating public health emergency in a century, the Covid-19 pandemic has killed millions around the world. As one of the world's most densely populated urban agglomerations, Mumbai was especially vulnerable to the coronavirus and its multiple mutations.

This riveting book reveals for the first time the exclusive inside story of how the Commissioner of the Municipal Corporation of Greater Mumbai (MCGM), Iqbal Singh Chahal, along with his team, tackled the Covid-19 pandemic successfully with a series of innovations acclaimed globally as the "Mumbai Model".

The MCGM's success in controlling the pandemic, including in Asia's biggest slum Dharavi where physical distancing is impossible, has drawn praise from among others, the World Bank, the World Health Organisation (WHO) and the US Congress.

Minhaz Merchant was given unrivalled access to contemporary and archival documents. The author interviewed Commissioner Chahal in more than a dozen exclusive sessions stretching to three hours each in order to distil the strategy he and his team employed to control the pandemic through the several waves that swept the city.

From setting up 24 war rooms to creating Jumbo field hospitals, Chahal's work as commissioner, which began in May 2020 at the start of the pandemic, is the story of extraordinary courage, resilience and innovation.



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Iqbal Singh Chahal: Covid Warrior by Minhaz Merchant

This edition first published in India in 2022
Third impression 2022

ISBN 978-93-5543-129-5

Printed and bound in India by Thomson Press (India) Ltd.

We had to be in the patient's house for half an hour to monitor him after vaccination. But I said we will do it. From 2 August, we started home-to-home vaccination. Again this was a first in the country. I salute my team for doing this job as it took a lot of effort and time to organise things and move door-to-door. These people are scattered in 4,500 places everywhere, in high-rise buildings and in slums. We filed an affidavit in the Bombay High Court that we are going to do this. Pune and Mumbai carried out this project in Maharashtra. Bedridden patients are not able to go to hospitals, or join vaccination camps, or mass vaccination processes. MCGM teams vaccinated 100 bedridden patients a day and completed the task in record time by the end of September 2021.'

While Mumbai found it easier than other cities to inoculate the adult population under the MCGM's jurisdiction, vaccine hesitancy was evident in small pockets of the city. After the deadly second wave though, vaccine hesitancy declined significantly. Chahal agrees: 'Vaccination hesitancy was present in a big way before the second wave. When I would tell private hospitals that they were vaccinating only 4,000 people per day instead of 45,000 in Mumbai, they would reply that people are just not coming forward for vaccination. But when the second wave hit the country, it eliminated a substantial amount of that hesitancy. People now knew that it was a choice between life and death and that the vaccine could be a saviour. Before the second wave started, the hesitancy was at a level of nearly 50 per cent. Now it has dropped significantly. We have to educate everybody that if you do not ensure 100 per cent vaccination in a city like Mumbai, non-vaccinated people can be a threat to other citizens of the city and, when they travel, to citizens in the rest of the country.

'I approached film personalities like Salman Khan to campaign in favour of vaccination. He was good enough to film a video for us.

It went viral on so many platforms. We are very grateful that he has done the video absolutely free for the MCGM. In the video he said his entire family is vaccinated. So there is no reason why anyone should not take a vaccine dose. He also said if citizens want to save their lives and the lives of their families, they must get vaccinated. This video had an impact. We also worked with more than a dozen NGOs in Dharavi to promote the vaccination drive. Together, we have motivated people and removed a large part of their vaccine hesitancy.'

Challenges, though, remained. One was safe local transportation. To get suburban trains moving again with vaccinated passengers, Chahal suggested a photo identity pass for those with two-dose certification. The CM embraced this solution as local train travel moved the city towards a semblance of normalcy. The advantage of a certified vaccine photo ID pass also encouraged train commuters to become eligible for it by getting themselves vaccinated with both doses.

'This is a weapon I used to remove vaccine hesitancy,' says Chahal, 'and to get commuters back on suburban trains as well. People know that the only way to get the railway photo ID pass is to get vaccinated. Many have got fully vaccinated just to be able to use suburban trains which are vital to their livelihoods. Further, we passed orders that shopping malls, shops, restaurants, gymnasiums, spas, etc. could open up in Mumbai provided their employees were fully vaccinated. Only fully vaccinated citizens could be their customers. This was strictly enforced over the next few months. It proved to be a game changer to crush vaccine hesitancy in Mumbai.'

What of the future? Chahal turns thoughtful as he says: 'We are building 16 new hospitals. I instructed my people to issue floating tenders for all 16 hospitals minus the equipment. New buildings will come up for all the hospitals. The infrastructure of the Jumbos, including advanced medical equipment, will be given to the 16 new

"Exhibit-M"

2022 SCC OnLine Bom 356

In the High Court of Bombay
(BEFORE DIPANKAR DATTA, C.J. AND M.S. KARNIK, J.)

Public Interest Litigation No. 84 of 2021

Feroze Mithiborwala ... Petitioner;

Versus

State of Maharashtra and Others ... Respondents.

And

Public Interest Litigation No. 85 of 2021

Yohan Tengra ... Petitioner;

Versus

State of Maharashtra and Others ... Respondents.

Public Interest Litigation No. 84 of 2021 and Public Interest Litigation No. 85 of 2021

Decided on February 22, 2022

Advocates who appeared in this case :

Mr. Nilesh Ojha i/b Adv. Abhishek N. Mishra a/w Adv Vijay Kurle, Adv Dipali N. Ojha, Adv. Awtar Singh, Adv Ishwarlal S. Aggarwal, Adv. Rajeshwar Panchal, Adv Partho Sarkar, Adv Sandeep Sheregar, Adv. Mita Rudani, Adv. Pratik Jain, Adv. Shivam Mehra, Adv. Deepika Jaiswal, Adv. Poonam Rajbhar, Adv. Nicky Pokar, Adv. Snehal Surve, Adv. Shivchand Mishra, Adv. Mangesh Mali, Adv. Siddhi Dhamnaskar, Adv. Pratik Sarkar, Adv. Vikas Pawar, Adv. Mayank Mishra, Adv Kajal Hindalekar, Adv. Aditya Parmar, Adv. Sarang Gundagwar, Adv. A.R. Kori, Adv. Mohan Rawat, Adv. Adarsh Diwani, Adv. Gopal Nirban, Adv. Mohan Rawat, adv. Aniruddh More for Petitioner in PIL No. 85/2021.

Mr. Tanveer Nizam i/b Adv. Mangesh Bhimrao Dongre a/w Adv. Vijay Kurle, Adv. Dipali N. Ojha, Adv. Awtar Singh, Adv Ishwarlal S. Aggarwal, Adv. Mayank Mishra, Adv Kajal Hindalekar, Adv. Rajeshwar Panchal, Adv. Partho Sarkar, Adv. Sandeep Sheregar, Adv. Mita Rudani, Adv. Pratik Jain, Adv. Shivam Mehra, Adv. Deepika Jaiswal, Adv. Poonam Rajbhar, Adv. Nicky Pokar, Adv. Snehal Surve, Adv. Shivchand Mishra, Adv. Mangesh Mali, Adv. Siddhi Dhamnaskar, Adv. Pratik Sarkar, Adv. Vikas Pawar, Adv. Aditya Parmar, Adv. Sarang Gundagwar, Adv. A.R. Kori, Adv. Mohan Rawat, Adv. Mita Rudani, Adv. Adarsh Diwani, Adv. Gopal Nirban, Adv. Mohan Rawat, Adv. Aniruddh More for Petitioner in PIL No. 84 of 2021.

Mr. Anil Anturkar, Senior Advocate & Special Counsel a/w Mr. P. P. Kakade, Government Pleader a/w Ms. Reena A. Salunkhe, AGP for State.

Mr. Anil C. Singh, ASG a/w Mr. Aditya Thakkar a/w Mr. D.P. Singh for Respondent - Union of India.

Mr. T.J. Pandian with Mr. T.C. Subramanian for Respondent no. 6.

Mr. Suresh Pakale a/w Mr. Om Suryawanshi for MCGM.

P.C.

1. Mr. Anturkar, learned senior counsel appearing for the State has submitted, on instructions, received from the Principal Secretary, Disaster Management, Relief & Rehabilitation, Government of Maharashtra, that a decision has been taken to withdraw the orders dated 15th July, 2021 and 11th August, 2021 as well as the Standard Operating Procedure dated 10th August, 2021. However, it is the further

contention of Mr. Anturkar that the order dated 15th July, 2021 has since been superseded by an order dated 27th August, 2021; similarly, the order dated 11th August, 2021 has since been superseded by orders dated 8th October, 2021, 19th October, 2021 and 26th October, 2021 as well as other subsequent orders dated 8th January, 2022, 9th January, 2022 and 31st January, 2022, which are now in force.

2. Mr. Anturkar also contends that having regard to the spirit of the observations that this Bench had the occasion to make in course of the proceedings in Court, it has since been decided by the State Executive Committee constituted under the Disaster Management Act, 2005 (hereafter "the Act", for short) to meet on 25th February, 2022 for reviewing all the orders in the light of the discussions in the Court as well as the factual status of Covid-19 pandemic and various directions, letters advisories, etc. received from the Government of India as well as the Task Force and to promulgate new comprehensive directives, if needed, in supersession of all the previous orders. According to Mr. Anturkar, the Principal Secretary is firmly of the belief that the fresh decision to be taken by the State Executive Committee on 25th February, 2022 would be in tune with the spirit of the observations of the Bench.

3. While we propose to adjourn hearing of these PIL petitions for a few days, it is necessary to briefly place on record what transpired in course of previous hearings. We had the occasion to consider the orders that were passed by the former Chief Secretary of the Government of Maharashtra. It was noticed and observed that the State Disaster Management Rules framed in terms of provisions contained in section 78 of the Act were observed in total breach. No decision was taken by the State Executive Committee. On the contrary, orders were issued from time to time by the former Chief Secretary, in the capacity of the Chairperson of the State Executive Committee, imposing restrictions to be adhered to during the second wave of the pandemic without there being any deliberation with the other members of the Committee, who happened to be bureaucrats having their offices in the same building where the Chief Secretary has his office. Since there were no meetings of the State Executive Committee, minutes of meetings though required to be recorded in terms of statutory rules were not recorded. Although at an earlier stage it was submitted that as the Chairperson of the Committee the former Chief Secretary had certain emergency powers and to take decisions all by himself, we have observed from the records produced yesterday by Mr. Anturkar that none of the orders recorded any emergent like situation warranting the Chairperson of the Committee to pass an order without waiting for deliberations with the other members. Satisfied that Fundamental Rights of citizens guaranteed under Article 19(1)(d) of the Constitution were abrogated without giving primacy to the rule of law, we had made certain critical oral observations in open Court wondering how an order passed by the Chairperson of the Committee, without following the relevant law, could be passed off as the decision of the State Government. Orders having been passed in clear violation of the prescribed procedure notwithstanding, we had granted time to the Government to take an informed decision on the aspect of lifting the restrictions that were illegally imposed particularly giving due regard to the declining trend of infected cases as well as bearing in mind that earning a bad name at this stage would wash away the commendable work performed by officials/staff at all levels in Maharashtra to keep the citizens safe and secure as much as possible during the second wave.

4. Be that as it may, we hope and trust that in keeping with the present situation and the observations made above, the State Executive Committee will take an appropriate decision for lifting of restrictions considering all aspects of the matter including the particular circumstance that Fundamental Rights of a section of the citizens were abrogated because of certain illegal orders passed by the Chairperson of the State Executive Committee earlier. Although it is not the function of the Court to direct the State Executive Committee to take a decision in any particular direction, it

would be eminently desirable if the State Executive Committee takes a decision on 25th February, 2022 which effectively puts a quietus to the issues raised in these PIL petitions.

5. We propose to take up these PIL petitions on Monday next (28th February, 2022) at 2.30 p.m. when the decision of the State Executive Committee shall be placed before us by Mr. Anturkar.

———

"Exhibit-N"

2022 SCC OnLine Bom 457

In the High Court of Bombay
(BEFORE DIPANKAR DATTA, C.J. AND M.S. KARNIK, J.)

Public Interest Litigation No. 84 of 2021

Feroze Mithiborwala ... Petitioner;

Versus

State of Maharashtra and Others ... Respondents.

With

Public Interest Litigation No. 85 of 2021

Yohan Tengra ... Petitioner;

Versus

State of Maharashtra and Others ... Respondents.

Public Interest Litigation No. 84 of 2021 and Public Interest Litigation No. 85 of 2021

Decided on March 2, 2022

Advocates who appeared in this case:

Mr. Tanveer Nizam i/b Adv Mangesh Bhimrao Dongre a/w Adv. Vijay Kurle, Adv. Dipali N. Ojha, Adv Mariam Nizam, Adv. Awtar Singh, Adv Ishwarlal S. Aggarwal, Adv Mayank Mishra, Adv Kajal Hindalekar, Adv Rajeshwar Panchal, Adv. Partho Sarkar, Adv. Sandeep Sheregar, Adv. Mita Rudani, Adv. Pratik Jain, Adv. Shivam Mehra, Adv. Deepika Jaiswal, Adv. Poonam Rajbhar, Adv. Nicky Pokar, Adv. Snehal Surve, Adv. Shivchand Mishra, Adv. Mangesh Mali, Adv. Siddhi Dhamnaskar, Adv. Pratik Sarkar, Adv. Vikas Pawar, Adv. Aditya Parmar, Adv. Sarang Gundagwar, Adv. A.R. Kori, Adv. Mohan Rawat, Adv Mita Rudani, Adv. Adarsh Diwani, Adv. Gopal Nirban, Adv. Mohan Rawat, Adv. Aniruddh More for Petitioner in PIL No. 84 of 2021.

Mr. Nilesh Ojha i/b Adv. Abhishek N. Mishra a/w Adv. Vijay Kurle, Adv. Dipali N. Ojha, Adv Mariam Nizam, Adv. Awtar Singh, Adv Ishwarlal S. Aggarwal, Adv Rajeshwar Panchal, Adv. Partho Sarkar, Adv. Sandeep Sheregar, Adv. Mita Rudani, Adv. Pratik Jain, Adv. Shivam Mehra, Adv. Deepika Jaiswal, Adv. Poonam Rajbhar, Adv. Nicky Pokar, Adv. Snehal Surve, Adv. Shivchand Mishra, Adv. Mangesh Mali, Adv. Siddhi Dhamnaskar, Adv. Pratik Sarkar, Adv. Vikas Pawar, Adv Mayank Mishra, Adv Kajal Hindalekar, Adv. Aditya Parmar, Adv. Sarang Gundagwar, Adv. A.R. Kori, Adv. Mohan Rawat, Adv. Adarsh Diwani, Adv. Gopal Nirban, Adv. Mohan Rawat, Adv. Aniruddh More for Petitioner in PIL No. 85/2021.

Mr. Anil Anturkar, Special Counsel a/w Mr. P. P. Kakade, Government Pleader a/w Ms. Reena A. Salunkhe, AGP for State.

Mr. Anil C. Singh, ASG a/w Mr. Aditya Thakkar a/w Mr. D P Singh for Respondent-Union of India

Mr. T.J. Pandian with Mr. T.C. Subramanian for Respondent no. 6.

Mr. Suresh Pakale a/w Mr. Om Suryawanshi for MCGM.

P.C.

1. Mr. Anturkar, learned senior advocate for the respondents, has placed before us an order dated 1st March 2022 signed by the Chief Secretary, Department of Disaster Management, Relief and Rehabilitation and Chief Executive Officer, State Executive Committee.

2. Although such order has not yet been published, as stated by Mr. Anturkar, it

reveals that the State Executive Committee has decided to maintain the impugned earlier restriction that public transport cannot be availed of by those who are not fully vaccinated. This order, according to Mr. Anturkar, is based on the minutes of the meeting of the State Executive Committee (hereafter "the Committee", for short) chaired by the Chief Secretary to the Government of Maharashtra on 25th February 2022.

3. In our order dated 22nd February 2022, we had in no uncertain terms observed that the previous orders of the State Government imposing restrictions on user of public transport had no sanction of law and that in keeping with the improving situation, it would be eminently desirable if the Committee takes a decision which would effectively put a quietus to the issues raised in the PIL petitions. The hope and trust reposed by us in the Committee that it would take a decision, which is reasonable and not in derogation of the Fundamental Rights of the citizens guaranteed by Article 19(1)(d), stand belied. We were utterly mistaken. The Committee, instead of respecting the observations that were made in the order dated 22nd February 2022, has once again insisted on only those who are vaccinated to avail public transport despite the fact that presently in Mumbai and its adjoining areas almost every activity is being performed as in the pre-pandemic days and normalcy has been restored in fair measure. In hindsight, we feel that having regard to the gross violations of the Disaster Management Act, 2005 (hereafter "the Act", for short) and the rules framed thereunder in imposing restrictions since 10th August 2021, it would have been appropriate if we had struck down the further orders passed in the name of the State Government post August, 2021 by the Chief Secretary, Government of Maharashtra in exercise of our *suo motu* powers instead of, in accordance with judicial discipline, permitting the Committee to take a fresh decision. This decision of the Committee, in the circumstances, is unexpected to say the least.

4. Be that as it may, since a new order has been issued under the Act maintaining the same restriction as before, publication of which is in contemplation, we are of the considered opinion that nothing further survives for decision on these two PIL petitions and that the petitioners herein, if they feel aggrieved by such order (as and when it is published), ought to subject such order to challenge in fresh proceedings. Granting liberty to the petitioners to pursue their remedy in accordance with law, we dispose of these PIL petitions. No costs.

5. Since we are not disposing of the PIL petitions on merit, all contentions that have been raised by the petitioners are kept open.

6. Copy of the order dated 1st March 2022 and the minutes of meeting of the Committee dated 25th February 2022 shall be retained with the records and marked 'X' for identification.

7. The respondents are granted liberty to publish the order dated 1st March 2022.

8. We direct Mr. Kakade, learned Government Pleader to supply a copy of the said minutes of the meeting of the Committee to the petitioners' advocates once the order dated 1st March 2022 is published and made available to the public.

"Exhibit-O"

SII's Chairman Cyrus Poonawalla Cautions Against Mixing Shots, Suggests Booster Doses

On meeting India's vaccination target of 45 crore doses by September, Poonawala said, "Our production of Covid-19 vaccine is 10 crore per month and producing that much quantity is not easy"

By: ABP News Bureau |

Updated at : 14 Aug 2021 11:39 AM (IST)

Link: https://news.abplive.com/health/sii-s-chairman-cyrus-poonawalla-cautions-against-mixing-shots-suggests-booster-doses-1476082

Corona vaccination drive in India/File Photo

New Delhi: The Serum Institute of India chairman Cyrus Poonawalla said he was not in favour of mixing two difference vaccines and also criticised the government for banning exports of vaccines. While talking to media after receiving the Lokmanya Tilak award, Poonawalla went on to warn against mixing of doses and insisted that booster shots may be needed for those vaccinated over six months ago, according to PTI report.

He also clearly mentioned that expectation of all Indians to be vaccinated by the end of 2021 was unlikely to be achieved. In another development, the Serum Institute of India is unlikely to be able to secure a license for its version of the highly efficacious coronavirus vaccine developed by US-based company Novavax.

What booster dose is suggested?

According to Poonawala, after six months, the antibodies go down and that is third dose is recommended. “We have given the third dose to our seven to eight thousand SII employees. For those who have completed the second dose, it is my request to take a booster dose (third dose) after six months," he said.

On increasing the gap between two doses of Covishield, he said that two months is ideal, but the Union government raised it to three months because of dose shortage.

Why mixing doses is not ideal?

On asked about the ICMR study that a cocktail of Covishield and Covaxin was found to have generated better immunity within a small group, he said "I am against the mixing of two different vaccines. There is no need to mix two different vaccines."

If such combination of doses did not work, each vaccine manufacturer will blame the other company, he said. However, he clarified later saying said such mixing can be resorted to if a particular vaccine is not available at the time of second dose.

What about achieving vaccination targets?

Poonawalla also refuted reports about "threats" to the family. His son Adar had left the country for a usual summer vacation, he claimed.

On the vaccination target, and the claim that 45 crore doses will be available by September, Poonawala said, "Our production of Covid-19 vaccine is 10 crore per month and producing that much quantity is not easy," Poonawalla added.

He specified that no company in the world can provide 10 to 12 crore doses in a month. "However, with the advance preparations by SII and investments of thousands of crores, we can produce 110 to 120 crore doses per year. As other companies are also producing the vaccines, the immunization will increase," he said.

He criticised the government's decision to ban the export of vaccines saying it’s a "very bad move". Over 150 countries are dependent on the SII for vaccines and are blaming the company for stopping the supply during a crucial period, he said.

While he also hailed the efforts of the Narendra Modi government for checking on red-tapism, and recalled how the industry used to face "hardships" in securing permissions and "harassment from bureaucrats" 50 years ago.

Speedy permissions granted by the government authorities made the development of the coronavirus vaccine within a very short time possible, he noted.

(With inputs from PTI)

"Exhibit-P"

Serum Institute Chairman Cyrus Poonawalla On Taking Third Covishield Dose

Cyrus Poonawalla said, "After six months, the antibodies go down and that is why I have taken the third dose".

India NewsPress Trust of India

Updated: August 13, 2021 11:07 pm IST

Cyrus Poonawalla said, "the ideal gap between 2 doses of Covishield is 2 months"(Representational)

Link: https://www.ndtv.com/india-news/serum-institute-chairman-cyrus-poonawalla-on-taking-third-covishield-dose-2509999

Pune:

The ideal gap between two doses of Covishield is two months and another dose of the vaccine should be taken after six months, the Serum Institute of India (SII) chairman Cyrus Poonawalla said on Friday.

Asked about a report in the medical journal Lancet that antibodies against coronavirus created by Covishield, the vaccine manufactured by the SII, decrease after some time, Mr Poonawalla told reporters that it was true that the antibodies decrease, but "memory cells" remain.

"After six months, the antibodies go down and that is why I have taken the third dose. We have given the third dose to our seven to eight thousand SII employees. For those who have completed the second dose, it is my request to take a booster dose (third dose) after six months," he said.

He was speaking at a press conference after receiving the prestigious Lokmanya Tilak award.

The ideal gap between two doses of Covishield is two months, he said.

"Since there was a shortage of vaccine, the Modi government changed it to three months, but a two-month gap is ideal," Mr Poonawalla said.

He also said that lockdown was not an effective way to deal with the virus.

"Because if there is no lockdown, the disease will be there in the beginning but later the herd immunity will prevail. Why I prefer herd immunity is because the death rate (due to coronavirus) is very low. Lockdown is a good option when the death rate is high," he said.

"Exhibit-Q"

High Percentage of COVID Deaths Had 3rd Shot, More Excess Deaths After 4th Shot

Link: https://www.theepochtimes.com/health/high-percentage-of-covid-deaths-had-3rd-shot-more-excess-deaths-after-4th-shot_4696054.html

Once people catch on to the correlation, governments stop updating the data

FEATUREDCOVID VACCINE INJURIES

Dr. Sean Lin

Currently, many countries around the world are promoting the second COVID-19 vaccine booster shots for the elderly, many of whom have already received their first booster shots. Under these circumstances, the transparency and openness of information about the safety of booster shots has become a very important issue. Amid this discussion, recently, data on the numbers of COVID-19 infections and deaths after vaccine booster injections in two Canadian provinces have been removed.

Removed Data: 76% of People Died of COVID-19 Infections Had Booster Shots?

In a Letter to the Editor published in the Prince George Citizen, a long-standing Canadian newspaper, the COVID-19 health outcomes by vaccination status data from the British Columbia Centre for Disease Control (BCCDC) in the Canadian province of British Columbia (BC) was cited in a screenshot.

The screenshot shows that in mid-April 2022, 50 percent of people in BC had already received their first booster shots, that is, their third doses of vaccines. Between March 20 and April 16, 2022, 63 percent of all people with COVID-19 infection had

received their first booster doses. But what stood out was that among those who passed away, 73 percent of them received booster shots.

Another screenshot was posted on Twitter, showing the vaccination status data from BCCDC for the period between May 15 and July 9, 2022. During this period, 52 percent of BC residents had received their first booster shots, and 76 percent of those who died from COVID-19 infection had received their first booster shots.

The author of the Letter to the Editor article commented, "If you look at the statistics from the BCCDC site, you will see that there is zero scientific evidence for keeping the vaccine passport in place."

However, on July 28, 2022, the BCCDC website indicated that their "outcomes by vaccination status" data would be removed as of that date. At present, this data is no longer available on its website.

CTV News Vancouver asked the B.C. Ministry of Health for an explanation for the data removal. The Ministry of Health responded with three points:

First, as the more transmissible Omicron variant had been spreading on a large scale, more people had chosen to do nucleic acid testing at home. Therefore, the reliability of the infection data was reduced, and the data didn't reflect the full picture of the infection.

Second, many of the hospitalized COVID-19 patients already had underlying diseases. And although they tested positive for COVID-19 infection, the reason for their hospitalization was not directly related to their infection.

Third, the temporal association between their vaccination and infection was unclear, and no accurate conclusions could be drawn from it.

However, the above official explanation was not convincing at all. Since the vaccine rolled out at the end of 2020, it is always the situation that many hospitalized COVID patients have other underlying diseases. Those who were admitted to hospital were tested with nucleic acid assays, not the at-home rapid test kits. Meanwhile, it is

always a challenge to pin down the exact infection time for a respiratory disease, so the temporal association between vaccination and infection is not always very accurately defined.

Therefore, their explanation didn't clearly explain why the number of people who received the booster shots was unusually high among those who were hospitalized and died from COVID-19 infection. In addition, the situations mentioned in the official explanation are present in all medical systems globally; why does the Canadian government take this important data down based on these excuses?

BC Situation Resembles Manitoba, UK Data

The situation in British Columbia is not an isolated case.

The provincial government of Manitoba in Canada reported (pdf) in July 2022 that the vaccine booster shot administration rate in the province was 43.8 percent in May 2022. However, people who had received booster injections accounted for more than 70 percent of COVID-related deaths.

This report (pdf) is still available on the Manitoba government website. However, in the week of July 31, the website stopped updating the chart.

Similar data are available from the UK.

On the UK Health Security Agency's COVID-19 vaccine surveillance report (pdf) published on March 31, 2022, statistics showed that 73 percent of deaths within 28 days of infection were among people who had received their third vaccine doses, before their COVID-19 infection diagnosis was confirmed.

However, on April 7, 2022, the UK Health Security Agency announced that it would stop updating the report (pdf).

Are the Second Vaccine Booster Shots Associated With an Alarming Number of Deaths?

After analyzing the data on COVID-19 vaccination status and COVID-related deaths in the Netherlands, Dr. Theo Schetters, a leading Dutch vaccinologist, discovered that there was a high temporal coincidence between the number of people who received the second booster shots (i.e. the fourth vaccine shots) and the number of excess deaths.

He stated that if more people were vaccinated, within a week there would be more excess deaths; and if fewer people were vaccinated within a week, there would be fewer deaths.

He estimated from the data that, on average, one in 800 elderly people over 60 years of age die from the COVID-19 vaccines. He also suggested that the vaccination program should be re-examined, as the current vaccination might have caused more harm than protection.

'Vaccine Dilemma': Good Versus Harm

An article published in 2021 in the British Medical Journal (BMJ) suggested that the Pfizer vaccine was "likely" to cause death in some frail elderly people.

The Norwegian Medicines Agency investigated the causes of 100 deaths of nursing home residents who received the Pfizer vaccine. About 30,000 elderly nursing home residents had received the vaccine at the time. According to the investigation, among the 100 cases, 10 deaths were "likely" to be causally related to the Pfizer vaccine; 26 were "possible" to be causally related, and 59 were "unlikely" to be related to the vaccine. The remaining 5 cases were considered "unclassifiable."

Since vaccines may bring serious side effects and even accelerate the death of some people, why do the governments still promote mandatory vaccination for the entire population?

Their rationale is that the benefits of vaccination "outweigh their harms." This theory seems to have been widely accepted.

This reminds us of the classic moral dilemma–the "trolley dilemma".

A runaway trolley is traveling on a railroad track with five people on the track. If the driver pulls the lever, the trolley will switch to another track with only one person on it.

The driver has a choice: do nothing and let the trolley run over the five people, or pull the lever and let it run over the one person on the other track.

The current vaccine policy is like choosing to pull the lever and accepting that a small number of people will die prematurely due to vaccines in order to protect more people.

However, has it ever occurred to people that instead of only two options, there is also a third way?

Maybe the driver could have chosen another way to stop the trolley, rather than having to choose to run over five people or one person.

Similarly, during this pandemic, we don't have only two options: either getting vaccinated, or getting the COVID-19 infection and becoming critically ill or dead.

We can increase our advocacy of improving the physical and mental health of the general population. We can boost everyone's immunity–both to defend themselves against the virus and to avoid the risks associated with the vaccination.

In other words, why not "mandate" people to exercise five more minutes every day, "mandate" them to eat 100 less calories of junk food every day, and "mandate" them to go into nature for an hour every month to relieve stress? In fact, there is no need to "force" people to do so. Instead, it would be enough to raise their awareness of immunity with the same intensity as vaccination promotion.

At present, the world is facing a public health crisis. Under these circumstances, it is more important to take a cautious and thoughtful approach to medical ethics than to weigh the interests of the public's life and health as a mere numerical model.

Views expressed in this article are the opinions of the author and do not necessarily reflect the views of The Epoch Times. Epoch Health welcomes professional

discussion and friendly debate. To submit an opinion piece, please follow these guidelines and submit through our form here.

"Exhibit-R"

Government of Maharashtra

DMU 2020/ CR 92/DM 1
Disaster Management, Relief & Rehabilitation
Mantralaya, Mumbai
Date: 10th August, 2021

To
The Director General of Police, Maharashtra
The General Manager, Central Railway, CSMT, Mumbai
The General Manager, Western Railway, Churchgate, Mumbai
The Municipal Commissioners (All in Mumbai Metropolitan Region)
The Collector, Thane/ Palghar
The Commissioner of Police (All in Mumbai Metropolitan Region)

Sub - Regarding Standard Operating Procedure for issue of season pass for fully vaccinated Commuters in local train in MMR region

Sir,

With reference to the above mentioned subject, the Standard Operating Procedure document for issue of season pass for fully vaccinated commuters in local trains in the MMR region is enclosed.

You are requested to direct the concerned to take all steps for the effective implementation of the same.

Disaster Management, Relief & Rehabilitation Department ★ Government of Maharashtra ★

(Shrirang Gholap)
Under Secretary
Under Secretary
Disaster Management Unit
Government of Maharashtra
Mantralaya, Mumbai 400 032

Standard Operation Procedure for issue of Railway Season Pass to Commuters in the Mumbai Metropolitan Region

The State Government is allowing people who have been fully vaccinated i.e have taken both doses of the vaccine and 14 days have lapsed since the administration of the second dose of the vaccine to travel by local trains in the Mumbai Metropolitan Region. This facility will be available to only for fully vaccinated people. It is specifically decided that such citizens shall be allowed to travel on monthly season's tickets only and not for daily commute or season's tickets of other durations.

It has been further decided that we issue Universal Pass to fully vaccinated people which has photo of the holder. This pass is to be shown like any other ID card at railway counters to buy season's ticket are per regular process of railways. Traveller is required to carry both the ticket as well as Universal Pass while travelling. This pass shall specifically mention "level 3" and travel shall be allowed on it unless MCGM/ DDMA declares levels of restrictions to be higher than level 3.

While Government has taken up development of system of issuance of Universal Pass, given the number of commuters that are like to avail of this facility and the short time period available till 15th of August for issuance of passes to these many citizens, following SOP is to be rolled out to ensure that all eligible commuters get to travel local trains.

a) There shall be special help desks in railway stations decided by MCGM/ DDMA in consultation with railway authorities that shall be manned by personnel from MCGM/ Municipal Corporations/ Local authorities or anyone so directed by concerned DDMA. These help desks shall operate in two shifts, first starting at 7 AM to 3 PM and second from 3 PM to 11 PM, and will begin operations from 11th August onwards.

b) Railways will ensure that all the ticket counters are opened and fully functional. The respective Municipal Corporations/ local bodies will set up the enough number of help desks as per the number of commuters that may require this service so that these services can be provided within reasonable time.

c) The fully vaccinated persons wishing to avail the monthly season pass will first approach these help desks and show their fully vaccinated certificate along with a Government issued photo ID (preferably Aadhar Card). They should carry a photocopy of the photo ID also for stamping purpose.

d) The personnel at the help desks shall verify the authenticity of the vaccination certificate by scanning the QR code followed by due diligence like matching of names on documents, dates of both doses, passage of minimum 14 days since second dose of vaccination etc. If found to be authentic, they shall put special stamp on certificate of vaccination submitted as well as on the photocopy of I-Card.

e) With these stamped documents, commuter will proceed to the railway counter for purchasing the monthly season's ticket. They shall be given these tickets on the basis of stamping on the documents. Railway counter will issue the monthly season's ticket, with certification number of vaccination certificate mentioned thereon.

f) Traveller is to carry all three -

1. the ticket
2. vaccination certificate as well as
3. I-Card while travelling.

g) After State Government's system of Universal Pass over internet becomes operational, citizens. Such pass holders will not require going to help desks for purposes of authentication of documents at any railway station and may directly approach the counter can go to the relevant website and submit documents there at, and may print on their own Universal Pass receiving payments and issuing monthly season's tickets. Such travellers are to carry two documents –

1. the ticket as well as
2. Universal Pass while travelling.

h) Given the possibility of crowd at these help desks as well as requiring disciplining crowd to ensure convenient and safe travel for all travellers, State Police/ Police Commissioners/ SP/ RPF and others shall provide adequate Bandobast at various locations from 11th August onwards. It is expected that post 15th August, at least till 31st August, police will let only Universal Pass holders or Vaccination certificate

holders along with their I-Cards enter the railway premises by checking 100% commuters. After 31st August, with due assessment of the need, police may decide on random checks or other means to ensure that only authorised travellers are moving in the railway station. Inside the railway stations, railway authorities shall ensure maintenance of proper order and discipline.

i) The persons who already have Universal Pass issued to them can procure monthly season tickets directly at the window of the railway stations.

j) It is also emphasised that this SOP is for issuance of monthly season's tickets for the fully vaccinated citizens. Categories of the citizens that are already allowed to travel due to their profession like medical or other essential services are not affected by this SOP at all. These are already being provided Universal Passes and they are also allowed to travel on their respective I-Cards and are allowed for a daily commute also.

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महाराष्ट्र शासन
सार्वजनिक आरोग्य विभाग
गो.ते. रुग्णालय संकुल इमारत,
१० मजला, मुंबई - ४०००००१.
क्रमांक : कोरोना-२०२१/प्र.क्र.३६६/आ-५,
दिनांक : ११ ऑगस्ट, २०२१.

संदर्भ :-

१) साथरोग अधिनियम, १८९७.
२) आपत्ती निवारण कायदा, २००५.
३) भारतीय दंडसंहिता, १८६०.
४) महसूल व वन, आपत्ती निवारण मदत व पुनर्वसन विभाग आदेश क्र. डीएमयू-२०२०/ प्र.क्र.९२/आपत्ती-१, दि. ४ जून, १७ जून व २५ जून, २०२१.
५) सार्वजनिक आरोग्य विभाग, शासन समक्रमांक दिनांक २ ऑगस्ट, २०२१ चे आदेश.

आदेश

ब्रेक द चेन - सुधारित मार्गदर्शक सूचना

ज्याअर्थी, राज्यात कोविड-१९ च्या प्रादुर्भावामुळे साथरोग कायदा, १८९७ ची अंमलबजावणी सुरु आहे. ज्याअर्थी, राज्यात कोविड-१९ साथरोगामुळे आपत्ती व्यवस्थापन कायद्याची अंमलबजावणी सुरु आहे,

ज्याअर्थी, राज्यात कोविड-१९ ची दुसरी ल़ाट आटोक्यात येत आहे. परंतु अद्यापही कोविड रुग्ण आढळून येत असल्याने राज्यात कोविड प्रतिबंधक उपाययोजना करण्याची आवश्यकता भासत आहे.

त्याअर्थी, आता साथरोग अधिनियम, १८९७ च्या खंड-२ नुसार प्राप्त अधिकार व आपत्ती निवारण कायदा, २००५ नुसार सक्षम प्राधिकारी म्हणून अध्यक्ष, राज्य व्यवस्थापन समिती या आदेशाद्वारे उपरोक्त संदर्भ क्रमांक ४ व ५ मध्ये नमुद आदेश अधिक्रमित करून संपूर्ण राज्यासाठी खालील निर्देश पारित करीत आहे :-

१) <u>लोकलट्रेन सुविधा सुरु करणेबाबत</u> -

लोकलट्रेन सुविधा वापरासाठी खालील अटी व शर्तींचे पालन करणे आवश्यक राहिल :-

अ) आरोग्य सेवा देणारे अधिकारी / कर्मचारी / अत्यावश्यक सेवेतील कर्मचारी तसेच कोविड प्रतिबंधात्मक लसीकरणाच्या दोन मात्रा व दुसरी मात्रा (डोस) घेऊन १४ दिवस पूर्ण झालेल्या नागरिकांनाच लोकलट्रेन प्रवास अनुज्ञेय करण्यात येत आहे.

पृष्ठ६पैकी१

ब) ज्या कर्मचारी अथवा नागरिक यांचे कोविड प्रतिबंधात्मक लसीकरणाचे दोन मात्रा आणि दुसरी मात्रा घेतल्यानंतर १४ दिवस पुर्ण झाले आहे त्यांना लसीकरणाच्या अंतिम प्रमाणपत्राच्या आधारे लसीकरण प्रमाणपत्र व आस्थापनांच्या ओळखपत्रासह स्वतंत्रपणे राज्यशासनाने ठरवून दिलेल्या यंत्रणेमार्फत विहीत कार्यपध्दतीने (ऑनलाईन/ऑफलाईन) प्रमाणित केलेल्या ओळखपत्र धारकानांच लोकलट्रेन प्रवासासाठी मासिक/त्रैमासिक पास देण्यात यावेत. (असे प्रमाणित ओळखपत्र प्राप्त करण्याबाबतच्या तपशीलवार व स्वयंस्पष्ट सूचना प्राधिकाऱ्यांकडून स्वतंत्रपणे प्रसारीत करण्यात येत आहे.)

क) रेल्वे तिकिट तपासनीस यांना लसीकरण पूर्ण झाल्याचे नमूद केलेले ओळखपत्र तपासण्याचा अधिकार असेल. ज्या प्रवाशांकडे असे ओळखपत्र नसेल किंवा प्रवाशांकडून ओळखपत्र खोटे आढळल्यास त्यांच्याकडून तसेच ज्यानी खोटे प्रमाणपत्र प्रमाणीत केले असेल त्यांचेकडून रु. ५००/- इतका दंड तसेच भारतीय दंड संहिता १८६० नुसार कारवाई करण्यात यावी.

२) <u>उपहारगृहे</u> -

खुली अथवा बंदिस्त उपहारगृहे आसन व्यवस्थेच्या ५० टक्के क्षमतेने खालील अटींच्या पूर्ततेच्या अधीन राहून सुरु करण्याची मुभा देण्यात येत आहे.

अ) उपहारगृह/बारमध्ये प्रवेश करताना, प्रतिक्षा कक्षात अथवा जेवण मिळेपर्यंतच्या कालावधीत मास्कचा वापर अनिवार्य राहिल व याबाबतच्या स्पष्ट सूचना उपहारगृह आस्थापनांनी उपहारगृहात लावणे आवश्यक राहिल.

फ) उपहारगृह/बारमध्ये काम करणारे आचारी, वाढपे, व्यवस्थापक व स्वच्छता कर्मचाऱ्यांसह सर्व कर्मचाऱ्यांचे कोविड प्रतिबंधक लसीकरण करणे आवश्यक राहिल व ज्या कर्मचाऱ्यांच्या लसीकरणाच्या दोन मात्रा आणि दुसरी मात्रा घेतल्यानंतर १४ दिवस पुर्ण झाले आहे **असेच** कर्मचारी व व्यवस्थापक उपहारगृह/बारमध्ये काम करु शकतील तसेच या सर्व कर्मचारी व व्यवस्थापनाने उपहारगृहात मास्कचा वापर करणे अनिवार्य राहिल.

क) वातानुकुलित उपहारगृह/बार असल्यास, वायुवीजनासाठी खिडक्या असल्यास कमीत कमी दोन खिडक्या किंवा दरवाजा उघडा ठेवून आतील हवा खेळती राहण्यासाठी पंखे लावणे आवश्यक राहिल.

ड) प्रसाधनगृहातही उच्च क्षमतेचा एक्झॉस्ट फॅन असणे आवश्यक राहिल.

इ) उपहारगृह/बारमध्ये विहित शारिरीक अंतराचे पालन होईल यानुसारच आसन व्यवस्था करण्यात यावी.

फ) उपहारगृह/बारमध्ये निर्जंतुकीकरणाची तसेच सॅनिटायझरची व्यवस्था असणे आवश्यक राहिल.

उपरोक्तनुसार उपहारगृहे/बार सुरु ठेवण्यास सर्व दिवस रात्री १०.०० वा. पर्यंत मुभा देण्यात येत आहे. उपहारगृह/बारमधील भोजनासाठी ग्राहकांकडून शेवटची मागणी जास्तीत जास्त रात्री ९.०० वाजेपर्यंत घ्यावी. मात्र पार्सल सेवा २४ तास सुरु ठेवण्याची मुभा देण्यात येत आहे.

पृष्ठ६पैकी२

३) दुकाने :-

राज्यातील सर्व व्यापारी दुकाने सर्व दिवस रात्री १०.०० वा. पर्यंत सुरु ठेवण्याची मुभा देण्यात येत आहे. दुकानात काम करणाऱ्या सर्व व्यवस्थापन व कर्मचाऱ्यांचे कोविड प्रतिबंधात्मक लसीकरणाचे दोन मात्रा पूर्ण व दुसरी मात्रा झाल्यानंतर १४ दिवसाचा कालावधी पूर्ण होणे आवश्यक राहिल.

४) शॉपिंग मॉल्स :-

राज्यातील सर्व शॉपिंग मॉल्स सर्व दिवस रात्री १०.०० वा. पर्यंत सुरु ठेवण्याची मुभा देण्यात येत आहे. तथापि, शॉपिंग मॉलमध्ये काम करणाऱ्या सर्व व्यवस्थापन व कर्मचारी आणि प्रवेश करणाऱ्या सर्व नागरिकांचेही कोविड प्रतिबंधात्मक लसीकरणाच्या दोन मात्रा पूर्ण व दुसरी मात्रा घेऊन १४ दिवस पूर्ण झालेले असणे आवश्यक राहिल व तसे लसीकरण प्रमाणपत्र व त्यासमवेत फोटोसहीत ओळखपत्र प्रवेशद्वारावर दाखविणे आवश्यक राहील.

५) जिम्नॅशिअम, योगसेंटर, सलून-स्पा :-

अ) वातानुकुलित तसेच विनावातानुकुलित जिम्नॅशिअम, योगसेंटर, सलून-स्पा ५० टक्के क्षमतेने सर्व दिवस रात्री १०.०० वा. पर्यंत सुरु ठेवण्याची मुभा देण्यात येत आहे. तथापि, उक्त संस्था वातानुकूलीत असल्यास, वायुविजनासाठी फॅन व वातानुकूलनासह खिडकी अथवा दरवाजा उघडा ठेवणे आवश्यक राहील.

६) इनडोअर स्पोर्टस :-

इनडोअर स्पोर्ट्स असलेल्या ठिकाणी खेळाडूंचे व तेथील कर्मचारी व व्यवस्थापन यांच्या कोविड प्रतिबंधात्मक लसीकरणाच्या दोन मात्रा पूर्ण व दुसरी मात्रा झाल्यानंतर १४ दिवस झालेले असणे आवश्यक राहील. तसेच, या ठिकाणी हवा खेळती राहण्यासाठी योग्य वायुविजन व्यवस्था असणे आवश्यक राहील. या ठिकाणी खेळाडूना बॅडमिंटन,टेबलटेनिस, स्क्वॅश, पॅरलल बार, मलखांब अशाच खेळांसाठी केवळ दोन खेळाडू या मर्यादेत सुरु करण्याची मुभा देण्यात येत आहे.

७) कार्यालय / औद्योगिक / सेवाविषयक आस्थापना :-

अ) सर्व शासकीय / निमशासकीय आस्थापनांचे कर्मचारी, बँक कर्मचारी, रेल्वे व म्युनिसिपल कर्मचारी व व्यवस्थापन यांचे कोविड प्रतिबंधात्मक लसीकरण प्राथम्याने पुर्ण करण्यात यावे

ब) ज्या खाजगी व औद्योगिक आस्थापनांच्या कर्मचाऱ्यांचे व व्यवस्थापनांचे कोविड प्रतिबंधात्मक लसीकरण पुर्ण झालेले असेल त्या आस्थापनांना पुर्ण क्षमतेने सुरू ठेवण्याची मुभा देण्यात येत आहे.

क) सर्व आस्थापनांनी गर्दी टाळण्यासाठी शक्यतो विविध सत्रात कर्मचाऱ्यांना बोलावून कामाचे व्यवस्थापन करावे ज्या आस्थापना वरील कर्मचाऱ्यांना घरून काम करणे शक्य आहे अशा सर्व आस्थापनांच्या व्यवस्थापनांनी कर्मचाऱ्यांना घरून काम करण्याची मुभा द्यावी कार्यालयात काम करणे आवश्यक असल्यास

पृष्ठ६पैकी३

कर्मचाऱ्यांचा गर्दीच्या वेळी प्रवास टाळणे शक्य होईल अशा प्रकारे कार्यालयीन वेळेचे व्यवस्थापन करण्यात यावे.

ड) तसेच खाजगी कार्यालयाना वेळेचे व्यवस्थापन करण्यासाठी कार्यालये २४ तास सूरु ठेवण्याची मुभा देण्यात येत आहे. मात्र अशा सत्र व्यवस्थापनांतर्गत कार्यालयांना एका सत्रात कार्यालयातील एकूण कर्मचारी संख्येच्या २५ टक्के उपस्थिती मर्यादित करणे आवश्यक राहील.

८) राज्यातील सर्व मैदाने, उद्याने, चौपाटया, समुद्रकिनारे स्थानिक प्राधिकरणाने विहित केल्यानुसार त्यांच्या नियमित वेळेत सुरु राहतील.

९) विवाह सोहळे:-

अ) खुल्या प्रांगणातील /लॉन वरील किंवा बंदिस्त मंगल कार्यालयातील विवाह सोहळे संबंधित प्रांगण/लॉन/ मंगल कार्यालय/ हॉटेल मधील आसन व्यवस्थेच्या ५० टक्के क्षमतेने व कोविड प्रतिबंधात्मक उपाययोजनांचे संपूर्ण पालन होईल या अटीवर मंगल कार्यालयाच्या प्रयोजनार्थ सुरु ठेवण्याची मुभा देण्यात येत आहे.

ब) खुल्या प्रांगण/लॉन मध्ये होणाऱ्या विवाह सोहळ्यास उपस्थितांची संख्या प्रांगण किंवा लॉन क्षमतेच्या ५० टक्के परंतु जास्तीत जास्त २०० व्यक्ती या मर्यादेत असेल.

क) बंदिस्त मंगल कार्यालय /हॉटेलमध्ये उपस्थितांची संख्या क्षमतेच्या ५० टक्के परंतु जास्तीत जास्त १०० व्यक्ती या मर्यादित असेल.

ड) मात्र कोणत्याही परिस्थीतीत कोविड प्रतिबंधात्मक उपाययोजनांचे पालन केले जात आहे याची खातरजमा करण्यासाठी व्हिडिओ रेकॉर्डिंग करणे व आवश्यकतेनुसार सक्षम प्राधिकाऱ्याला तपासणीसाठी उपलब्ध करुन देणे आवश्यक राहिल. या निर्बंधांचे उल्लंघन करणाऱ्यांवर तसेच संबंधित हॉटेल/ कार्यालयांवर दंडनीय कारवाई तसेच संबंधित हॉटेल / मंगल कार्यालयाचा परवाना रद्द करण्याची कार्यवाही करण्यात येईल.

इ) तसेच मंगल कार्यालय/हॉटेल/लॉन व्यवस्थापन/भोजन व्यवस्थापन/बँडपथक/भटजी/फोटोग्राफर्स अशा विवाह व्यवस्थेशी संबंधीत सर्व संलग्न संस्था यामधील व्यवस्थापक व कर्मचारी यांचेही कोविड प्रतिबंधात्मक लसीकरण पुर्ण होऊन दुसरी मात्रा घेतल्यानंतर १४ दिवस पुर्ण होणे अनिवार्य राहील व त्यानुसार ओळखपत्रासह लसीकरण प्रमाणपत्र सोबत असणे आवश्यक राहील.

१०) सिनेमागृहे व मल्टिप्लेक्स :-

राज्यात सिनेमागृह/नाट्यगृह, मल्टिप्लेक्स (स्वतंत्र तसेच शॉपिंग मॉलमधील) पुढील आदेशापर्यंत बंद राहतील.

११) **धार्मिक स्थळे :-**

राज्यातील सर्व धार्मिक स्थळे पुढील आदेशापर्यंत नागरिकांसाठी बंद राहतील.

१२) **आंतरराज्य प्रवास :-**

ज्या नागरिकांचे कोविड प्रतिबंधात्मक लसीकरण पूर्ण झाले आहे त्या नागरिकांना, बाहेरच्या राज्यातून महाराष्ट्र राज्यात प्रवेश करण्यासाठी आरटीपीसीआर चाचणीची आवश्यकता नसेल. अन्य प्रवाशांसाठी ७२ तास पुर्वीची आरटीपीसीआर चाचणी निगेटीव्ह किंवा १४ दिवस विलगीकरण आवश्यक राहिल.

१३) कोविड प्रतिबंधात्मक उपाययोजना म्हणून राज्यात गर्दी व्यवस्थापन करण्याबाबत केंद्र शासनाने तसेच मा. सर्वोच्च न्यायालयाने निर्देशित केले आहे. यास्तव गर्दी / जमाव टाळण्यासाठी वाढदिवस, राजकीय, धार्मिक, सामाजिक व सांस्कृतिक कार्यक्रम, निवडणूक प्रचार सभा, रॅली, मोर्चे, इ. वरील निर्बंध कायम राहतील.

१४) मेडीकल ऑक्सीजनची उपलब्धता मर्यादीत असल्याने, जर राज्यातील रुग्णसंख्या वाढल्यास व कोविड रुग्णांच्या उपचारासाठी प्रतिदिन ७०० मे. टन किंवा व त्यापेक्षा जास्त ऑक्सीजन लागत असल्यास संपूर्ण राज्यात तात्काळ पूर्णपणे लॉकडाऊन घोषित करुन त्यानुसार कठोर निर्बंध लागू करण्यात येतील.

१५) राज्यातील सर्व नागरिकांना कोविड प्रतिबंधात्मक उपाययोजना जसे की, मास्कचा वापर, हातांची स्वच्छता, शारिरीक अंतराचे पालन, इतरत्र थुंकण्यास प्रतिबंध, इ. सर्व निर्बंधांचे पालन करणे अनिवार्य राहिल.

१६) सर्व दुकाने, कार्यालये, औद्योगिक आस्थापना, उपहारगृहे, बार व मॉल मालक/ व्यवस्थापनाने त्यांचे आस्थापनेवर कार्यरत असलेल्या व्यवस्थापक तसेच कर्मचाऱ्यांचे कोविड प्रतिबंधात्मक लसीकरणाचे दोन मात्रा पुर्ण होऊन १४ दिवस झाल्याची खातरजमा करावी व या कर्मचाऱ्यांची यादी (लसीकरण माहिती/प्रमाणपत्रासह) तयार ठेवावी व सक्षमप्राधिकाऱ्यांनी तपासणी साठी मागणी केल्यास त्यांना उपलब्ध करुन द्यावी.

१७) दुकाने/उपहारगृहे/बार/मॉल्सचे/कार्यालये/औद्योगिक आस्थापना यांचे नियतकालीक निर्जंतूकीकरण व सॅनीटायझेशन करण्याची जबाबदारी संबंधीत मालकाची व व्यवस्थापनाची असेल. तसेच, यामध्ये कर्मचारी तसेच ग्राहकांचे तापमान घेण्यासाठी इन्फ्रारेड/ कॉन्टॅक्टलेस थर्मामिटर याची व्यवस्था करण्यात यावी. तसेच यामध्ये मास्क डिस्पेंसर व बायोमेडीकल वेस्ट (वापरलेले मास्क व टिशु पेपर्स इत्यादीची विल्हेवाट) जमा करण्याची व विहित कार्यपध्दतीने विल्हेवाटीसाठी देण्याची जबाबदारी संबंधीत आस्थापनांची असेल.

१८) उपरोक्त आदेशाची अंमलबजावणी करण्यास टाळाटाळ केल्यास अथवा उल्लंघन केल्यास संबंधितांविरुध्द आपत्ती व्यवस्थापन अधिनियम, साथरोग अधिनियम आणि भारतीय दंडसंहिता, १८६० मधील तरतूदीनुसार कायदेशीर कारवाई करण्यात येईल.

१९) सदर आदेश दि. १५ ऑगस्ट, २०२१ पासून अंमलात येतील.

राज्यपालांचे नावाने व आदेशानुसार.

11/8/21

(सीताराम कुंटे)
मुख्य सचिव, महाराष्ट्र शासन

प्रत :-

१) मा. राज्यपाल यांचे प्रधान सचिव, राजभवन, मुंबई.
२) मा. मुख्यमंत्री यांचे प्रधान सचिव, मंत्रालय, मुंबई.
३) मा. उप मुख्यमंत्री यांचे प्रधान सचिव, मंत्रालय, मुंबई.
४) मा. मंत्री (आरोग्य व कुटुंब कल्याण), मंत्रालय, मुंबई.
५) मा. राज्यमंत्री (आरोग्य व कुटुंब कल्याण), मंत्रालय, मुंबई.
६) मुख्य सचिव, मंत्रालय, मुंबई.
७) अप्पर मुख्य सचिव / प्रधान सचिव / सचिव, मंत्रालय, मुंबई. (सर्व)
८) सचिव, महाराष्ट्र विधानमंडळ सचिवालय, विधान भवन, मुंबई.
९) मुख्य सचिव यांचे उप सचिव, मंत्रालय, मुंबई.
१०) सर्व सह सचिव / उप सचिव, सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई.
११) प्रधान सचिव यांचे स्वीय सहाय्यक, सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई.
१२) सर्व अवर सचिव / कक्ष अधिकारी, सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई.
१३) आयुक्त (आरोग्य सेवा) व अभियान संचालक, एनएचएम, मुंबई.
१४) धर्मदाय आयुक्त, एम.एस. मुंबई.
१५) मुख्य कार्यकारी अधिकारी, राज्य आरोग्य विमा संस्था, वरळी, मुंबई.
१६) सर्व विभागीय आयुक्त.
१७) सर्व जिल्हाधिकारी.
१८) सर्व महानगरपालिका आयुक्त.
१९) सर्व मुख्य कार्यकारी अधिकारी, जिल्हा परिषद.
२०) संचालक, आरोग्य सेवा मुंबई / पुणे.
२१) अतिरिक्त संचालक, आरोग्य सेवा
२२) सहसंचालक, आरोग्य सेवा (सर्व).
२३) उपसंचालक, आरोग्य सेवा (सर्व).
२४) जिल्हा शल्य चिकित्सक (सर्व).
२५) जिल्हा आरोग्य अधिकारी (सर्व).
२६) जिल्हा हिवताप अधिकारी (सर्व).
२७) निवड नस्ती (आ-५).

"Exhibit-S"

2021 SCC OnLine Gau 1503

In the High Court of Gauhati[†]
(BEFORE NANI TAGIA, J.)

Madan Mili

Versus

Union of India, Represented by the Honble Home Secretary and Others

Case No.: PIL 13/2021
Decided on July 19, 2021

Advocates who appeared in this case :

Advocate for the Petitioner: Debasmita Ghosh, Ebo Mili, Chanya Bangsia, S. Dey

Advocate for the Respondent: Marto Kato, ASG R. H. Nabam, Addl. Adv. General, A.P.

The Order of the Court was delivered by

NANI TAGIA, J.:— Heard Ms. D. Ghosh, learned counsel for the petitioner. Also heard Mr. R. Karga, learned counsel appearing on behalf of Mr. M. Kato, learned ASG for the respondent No. 1 and Mr. R. H. Nabam, learned Additional Advocate General representing respondent Nos. 2 & 3.

2. By means of this Public Interest Litigation, the petitioner has put to challenge Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, to the extent it provides that for developmental works in both public and private sector, temporary permits may be issued provided such persons are vaccinated for Covid-19.

3. The petitioner contends that as per the RTI Information furnished by the Ministry of Health & Family Welfare, which is available in the website of the Ministry of Health and Family Welfare, Government of India, Covid-19 vaccination is not a mandatory but a voluntary. A copy of the RTI Information available in the website of the Ministry of Health & Family Welfare, Government of India, has been annexed by the petitioner as Annexure 3 to the petition. The petitioner also refers to an answer given on 19.03.2021 in the Lok Sabha to an Unstarred Question No. 3976 by the Minister of State in the Ministry of Health & Family Welfare, Government of India (Annexure 4 to the petition) stating that there is no provision of compensation for recipients of Covid-19 Vaccination against any kind of side effects or medical complication that may arise due to inoculation. The Covid-19 Vaccination is entirely voluntary for the beneficiaries.

4. By referring to the fact that the Covid-19 Vaccination is entirely a voluntary exercise at the choice of an individual as indicated in the RTI answer and the answer given in the Lok Sabha by the Minister of State in the Ministry of Health and Family Welfare, Government of India, as referred to hereinabove, the learned counsel for the petitioner has contended that provision under Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, allowing temporary permits to be issued for developmental works in both public and private sector to only those persons who are vaccinated for Covid-19, have interfered with the rights of the citizens provided under Article 19 (1) (d) of the Constitution of India to move freely throughout the territory of India. The learned counsel for the petitioner, therefore, has argued that since the Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum

Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, by allowing to issue temporary permits for developmental works in both public and private sector only to persons who have vaccinated for Covid-19 Virus, have interfered with the fundamental rights granted under Article 19 (1) (d) of the Constitution of India and the same may be struck down by this Court in exercise of power under Article 226 of the Constitution of India.

5. Mr. R. H. Nabam, learned Additional Advocate General, on the other hand, has submitted that due to the rising cases of Covid-19 positive in the State of Arunachal Pradesh, the restrictions provided in Clause 11 vide Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, are reasonable restriction as the same has been issued with the sole objective of containing the Covid -19 pandemic and its further spread in the State of Arunachal Pradesh.

6. Issue notice, returnable on 28.07.2021.

7. As Mr. R. Karga, learned counsel appearing on behalf of Mr. M. Kato, learned ASG for the respondent No. 1 and Mr. R. H. Nabam, learned Additional Advocate General representing respondent Nos. 2 & 3, have entered appearance and accepted notices on behalf of their respective respondents, no formal notice need be issued to them. However, they shall be provided with requisite extra-copies of the petition along with relevant annexure appended thereto during the course of the day.

8. Heard on the prayer for interim relief.

9. Ms. D. Ghosh, learned counsel for the petitioner, has prayed for an interim order as the Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far as it discriminates between persons vaccinated and unvaccinated for Covid-19 Virus in so far as issuance of temporary permits for developmental works in both public and private sector, have violated the fundamental rights granted under Article 19 (1) (d) of the Constitution of India to those unvaccinated persons and the order being valid on and from 30.06.2021 to 01.08.2021, the said Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, may be suspended in the meanwhile.

10. The Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, appears to have been issued in exercise of powers conferred under Section 22 (2) (H) of the Disaster Management Act, 2005, setting out various directives to be followed in the management of Covid-19 pandemic to remain in force w.e.f. 6.00 p.m. of 30.06.2021 till 5.00 a.m. of 01.08.2021. The object of issuing the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, appears to be to contain Covid-19 pandemic and its further spread in the State of Arunachal Pradesh. It is in that light, vide Clause 11 of the Order dated 30.06.2021, it appears, that vaccinated and unvaccinated persons for Covid-19 virus have been discriminated/classified into 2 (two) groups for the purpose of issuing temporary permits for developmental works in both public and private sector. Clause 11 of the Order dated 30.06.2021 reads as under:

> *"11. Tourist ILPs shall remain suspended during the period of this order, however for developmental works in both public and private sector, temporary permits may be issued provided such persons are vaccinated for COVID 19."*

11. While persons who are vaccinated for Covid-19 have been allowed to be issued with a permit to visit Arunachal Pradesh, persons who are not vaccinated with Covid-

19 vaccine have not been allowed to be issued with a temporary permit to visit Arunachal Pradesh for developmental works in both public and private sector.

12. The right granted under Article 19 (1) (d) of the Constitution of India to move freely throughout the territory of India, however, is not absolute and the State may impose a reasonable restrictions on the exercise of the rights under Article 19 (1) (d) of the Constitution of India either in the interest of the general public or for the protection of the interest of the Schedule Tribe. While putting any restrictions, as above, such restrictions, however, must be a reasonable one conforming to the requirement of Article 14 of the Constitution of India as well. Article 14 of the Constitution of India guarantees to every persons the right not to be denied equality before the law or the equal protection of laws. "Equality before the law" means that amongst equals the law should be equal and should be equally administered and that like should be treated alike. Classification of persons into groups for different treatment of such groups is permissible if there is a reasonable basis for such difference. Article 14 of the Constitution of India forbids class legislation, but does not forbid classification or differentiation which rests upon reasonable grounds of distinction. The power of making classification, however, is not without limit. A classification to be valid must be reasonable. It must always rest upon some real and substantial distinction bearing reasonable and just needs in respect of which the classification is made. In order to pass the test of permissible classification, 2 (two) conditions must be fulfilled, namely, (i) the classification must be founded on an intelligible differentiation which distinguishes persons or things that are grouped together from others left out of the group; and (ii) the differentia must have a rational relation to the object sought to be achieved by such classification.

13. In the instant case, the classification sought to be made between the vaccinated and unvaccinated persons for Covid-19 by Clause 11 of the Order dated 30.06.2021 for the purpose of issuing a temporary permit for developmental works in both public and private sector in the State of Arunachal Pradesh is undoubtedly to contain Covid-19 pandemic and its further spread in the State of Arunachal Pradesh. There is no evidence available either in the record or in the public domain that Covid-19 vaccinated persons cannot be infected with Covid-19 virus, or he/she cannot be a carrier of a Covid-19 virus and consequently, a spreader of Covid-19 virus. In so far as the spread of Covid-19 Virus to others is concerned, the Covid-19 vaccinated and unvaccinated person or persons are the same. Both can equally be a potential spreader if they are infected with Covid-19 Virus in them. This aspect of the matter came up for consideration by this Court in WP(C)/37/2020 (*In Re Dinthar Incident Aizawl* v. *State of Mizoram* Aizawl; in which case, this Court vide Order dated 02.07.2021, in paragraph 14 thereof, had observed as follows -

> *"14. It has been brought to our notice that even persons who have been vaccinated can still be infected with the covid virus, which would in turn imply that vaccinated persons who are covid positive, can also spread the said virus to others. It is not the case of the State respondents that vaccinated persons cannot be infected with the covid virus or are incapable of spreading the virus. Thus, even a vaccinated infected covid person can be a super-spreader. If vaccinated and un-vaccinated persons can be infected by the covid virus and if they can both be spreaders of the virus, the restriction placed only upon the un-vaccinated persons, debarring them from earning their livelihood or leaving their houses to obtain essential items is unjustified, grossly unreasonable and arbitrary. As such, the submission made by the learned Additional Advocate General that the restrictions made against the un-vaccinated persons vis-à-vis the vaccinated persons is reasonable does not hold any water. As the vaccinated and un-vaccinated persons would have to follow the covid proper behavior protocols as per the SOP, there is no justification for discrimination."*

14. Thus, if the sole object of issuing the Order dated 30.06.2021, by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, is for containment of the Covid-19 pandemic and its further spread in the State of Arunachal Pradesh, the classification sought to be made between vaccinated and unvaccinated persons for Covid-19 virus for the purpose of issuing temporary permits for developmental works in both public and private sector, vide Clause 11 thereof, *prima facie*, appears to be a classification not founded on intelligible differentia nor it is found to have a rational relation/nexus to the object sought to be achieved by such classification, namely, containment and further spread of Covid-19 pandemic.

15. For the reasons stated hereinabove, it *prima facie* appears to this Court that Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far it makes a classification of persons who are Covid-19 vaccinated and persons who are Covid-19 unvaccinated for the purpose of issuance of temporary permits for developmental works in both public and private sector in the State of Arunachal Pradesh violates Articles 14, 19 (1) (d) & 21 of the Constitution of India calling for an interim order in the case. Accordingly, till the returnable date, Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far it discriminates between Covid-19 vaccinated persons and Covid-19 unvaccinated persons for issuance of temporary permits for developmental works in both public and private sector in the State of Arunachal Pradesh, shall remain stayed.

16. List it on 28.07.2021.

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† Itanagar Bench

"Exhibit-T"

2022 SCC OnLine SC 533

In the Supreme Court of India
(BEFORE L. NAGESWARA RAO AND B.R. GAVAI, JJ.)

Jacob Puliyel ... Petitioner;

Versus

Union of India and Others ... Respondents.

Writ Petition (Civil) No. 607 of 2021
Decided on May 2, 2022

The Judgment of the Court was delivered by

L. NAGESWARA RAO, J.:— The Petitioner was a member of the National Technical Advisory Group on Immunization (NTAGI) and was advising the Government of India on vaccines. He has filed this Writ Petition in public interest seeking the following reliefs:

> *"(a) Direct the respondents to release the entire segregated trial data for each of the phases of trials that have been undertaken with respect to the vaccines being administered in India; and*
>
> *(b) Direct the respondent No 2 to disclose the detailed minutes of the meetings of the Subject Expert Committee and the NTGAI with regard to the vaccines as directed by the 59th Parliamentary Standing Committee Report and the members who constituted the committee for the purpose of each approval meeting; and*
>
> *(c) Direct the respondent No. 2 to disclose the reasoned decision of the DCGI granting approval or rejecting an application for emergency use authorization of vaccines and the documents and reports submitted to the DCGI in support of such application; and*
>
> *(d) Direct the respondents to disclose the post vaccination data regarding adverse events, vaccinees who got infected with Covid, those who needed hospitalization and those who died after such infection post vaccination and direct the respondents to widely publicize the data collection of such adverse event through the advertisement of toll free telephone numbers where such complaints can be registered; and*
>
> *(e) Declare that vaccine mandates, in any manner whatsoever, even by way of making it a precondition for accessing any benefits or services, is a violation of rights of citizens and unconstitutional; and*
>
> *(f) Pass any other orders as this Hon'ble Court deems fit."*

2. In the Writ Petition, the Petitioner highlighted the adverse consequences of emergency approval of vaccines in India, the need for transparency in publishing segregated clinical trial data of vaccines, the need for disclosure of clinical data, lack of transparency in regulatory approvals, minutes and constitution of the expert bodies, imperfect evaluation of Adverse Events Following Immunisation (AEFIs) and vaccine mandates in the absence of informed consent being unconstitutional. The Petitioner further stated in the Writ Petition that coercive vaccination would result in interfering with the principle of informed self-determination of individuals, protected by Article 21 of the Constitution of India.

3. Notice was issued in the Writ Petition on 09.08.2021. An additional affidavit was filed by the Petitioner on 03.09.2021 raising additional grounds. It was averred in the additional affidavit that natural immunity is long-lasting and robust in comparison to vaccine immunity and that vaccines do not prevent infection or transmission of COVID

-19. The Petitioner further stated that vaccines are not effective in preventing against infection from new variants of COVID-19. The Petitioner relied on news articles on the fourth nationwide serological survey conducted by Indian Council of Medical Research (ICMR) in June and July, 2021, according to which up to two-thirds of the Indian population above the age of 6 years had already been infected with COVID-19 and had antibodies specific to the SARS-CoV-2 virus. The Petitioner relied upon other news articles and research studies conducted to state that there had been breakthrough infections even amongst vaccinated people. Urging that research has shown that vaccinated people also transmit the virus, the Petitioner contended that vaccine mandates are meaningless.

4. The Petitioner filed an Interlocutory Application seeking a direction to restrain all authorities and institutions, public and private, from mandating the vaccine in any manner whatsoever, on a precondition of accessing any service or on pain of any penalty. The Petitioner has drawn the attention of this Court to various restrictions that were placed by State Governments, other employers and educational institutions on unvaccinated individuals. The Petitioner contended that mandating vaccination for access to resources, public places and means of earning livelihood would be in violation of their fundamental rights, especially so, when scientific studies have shown that unvaccinated persons do not pose more danger of transmission of the virus when compared to vaccinated persons.

5. Respondent No. 1, the Union of India, has raised a preliminary objection regarding the maintainability of the Writ Petition. The Union of India has further contended that the serious threat posed by the unprecedented pandemic which had devastating effects on the entire world called for emergency measures. It is accepted world over that vaccination for COVID-19 is necessary to avoid infection. India was one of the few countries in the world which succeeded in manufacturing vaccines for protection from COVID-19, one of which was COVAXIN, India's indigenous vaccine and the other being COVISHIELD, which was manufactured by Serum Institute of India with technology transfer from AstraZeneca/Oxford University. The country started one of the largest inoculation programmes in the world in larger public interest, while tackling challenges of vaccine hesitancy, effect of the second wave of the pandemic and other such adverse circumstances. The Union of India expressed serious doubts about the intention of the Petitioner in filing this Writ Petition. As we have not seen the end of the pandemic caused due to the COVID-19 virus, any interference with the steps taken by the Union on the basis of the advice given by the NTAGI and other expert bodies would provide impetus to the already prevailing vaccine hesitancy in certain sections of the society. In their counter-affidavit, the Union of India reminded us that decisions of domain experts should not normally be interfered with in judicial review and that this Court should not sit in appeal over a scientific process undertaken by domain experts on a subject which is not the expertise of any judicial forum. The long-drawn procedure for making applications for issuance of licenses for manufacturing vaccines and the statutory regime governing the same have been referred to in the counter-affidavit to emphasize that the Union of India has not been remiss in grant of emergency licences. There is a detailed procedure for approval with checks at every stage which has been followed for grant of emergency approval. In so far as disclosure of clinical trial data is concerned, the Union of India referred to the National Ethical Guidelines for Biomedical and Health Research involving Human Participants published by the ICMR, which require privacy and confidentiality of human participants to be maintained. Accordingly, the Union of India contended that such details pertaining to identity and records of the participants in the clinical trial data cannot be disclosed to the public as per the prevailing statutory regime. It was asserted by the Union of India that the remaining data has already been made available in the public domain.

6. On the subject of monitoring of AEFIs, the Union of India brought to our attention established procedures and protocols in place for surveillance of AEFIs established under the National Adverse Event Following Immunisation Surveillance Guideline. Further, the multi-tier structure comprising AEFI Committees at the state and national levels, providing guidance, carrying out investigation and causality assessment was elaborated upon. Details of the procedures followed in accordance with globally accepted practices were highlighted in the counter-affidavit. According to the Union of India, all cases of serious and severe AEFI, including reported deaths, are subjected to scientific and technical review process with causality assessments done at the state and national levels by trained experts to ascertain whether a particular AEFI can be attributed to the vaccine. In the counter-affidavit, it was also made clear that COVID-19 vaccination is voluntary and that the Government of India encourages all individuals to take vaccination in the interest of public health, as the individual's ill health has a direct effect on the society. It was also made clear that COVID-19 vaccination is not linked to any benefits or services.

7. Counter-affidavits have been filed by other Respondents as well. The vaccine manufacturers, i.e., Respondents Nos. 4 and 5, have brought to the notice of this Court that approval to their vaccines was granted after strict compliance of the procedure prescribed. The States of Tamil Nadu, Maharashtra, Delhi and Madhya Pradesh have also filed counter-affidavits, justifying the restrictions that were placed on unvaccinated persons in public interest. The details of the restrictions have been discussed later.

8. We have heard Mr. Prashant Bhushan, learned counsel for the Petitioner, Mr. Tushar Mehta, learned Solicitor General of the Union of India, Mr. S. Guru Krishnakumar, learned Senior Counsel for Respondent No. 4, Mr. Amit Anand Tiwari, learned Additional Advocate General for the State of Tamil Nadu, Mr. Rahul Chitnis, learned counsel for the State of Maharashtra, Ms. Mrinal Gopal Elker, learned counsel for the State of Madhya Pradesh and Ms. Shyel Trehan, learned counsel for Respondent No. 5.

Preliminary Issues

I. *Maintainability*

9. The learned Solicitor General raised a preliminary objection as to the maintainability of the Writ Petition which is filed in public interest. He stated that this Writ Petition, if entertained, would harm public interest, as any observation made by this Court against vaccination would result in potential threat of vaccine hesitancy.

10. The Petitioner is a paediatrician, who was a member of the NTAGI earlier. It has been stated in the Writ Petition that he has a number of publications in internationally peer-reviewed medical journals to his credit. The Petitioner strongly believes that there cannot be coercive vaccination, especially of inadequately tested vaccines, which amounts to an intrusion into the individual's personal autonomy. He is also of the firm opinion that an individual is deprived of the opportunity to give informed consent in the absence of availability of segregated data of clinical trials of the vaccines. He has also aired further grievances pertaining to poor evaluation and reporting of AEFIs.

11. This Court is entitled to entertain a public interest litigation moved by a person having knowledge in the subject-matter of the lis and, thus, having an interest therein, as contradistinguished from a busybody, in the welfare of people[1]. The Union of India has objected to the maintainability of the Writ Petition on the ground that the questions raised by the Petitioner may result in raising doubts in the minds of the citizenry about the vaccination, adding to the already existing vaccine hesitancy in the country. The consequence would be a debilitating effect on public health and therefore, the petition cannot be said to be in public interest. In other words, the maintainability of the Writ Petition is raised on the ground that the sensitive issue of

vaccination should not be dealt with by this Court, as it has the propensity of fuelling doubts about the efficacy of the vaccines.

12. From the rejoinder affidavit submitted by the Petitioner, we note that a petition had been filed by the Petitioner earlier, during his tenure as a member of the NTAGI, with respect to the Rotavac vaccine claiming that adequate data from the clinical trials had not been provided to the NTAGI. The rejoinder affidavit further states that the petition was dismissed by this Court, on the ground that the Petitioner could not have filed the said petition while being a member of the NTAGI. The enthusiasm of the Petitioner in approaching this Court has not gone unobserved. However, as the issues raised by the Petitioner have a bearing on public health and pertain to the fundamental rights of the country's populace, we are of the opinion that they warrant due consideration by this Court. Therefore, we are not inclined to entertain the challenge mounted by the Union of India to the maintainability of the Writ Petition.

II. *Judicial review of executive decisions based on expert opinion*

13. Yet another ground taken by the Union of India is that this Court has to yield to executive decision and action in the matter of administration of drugs/vaccines. The existence of any other possible view cannot enable this Court to interfere in matters relating to opinion of domain experts by sitting in appeal over such decisions, while adjudicating a writ petition filed under Article 32 of the Constitution. The learned Solicitor General supported the stand of the Union of India with reference to the law laid down by this Court in *Academy of Nutrition Improvement* v. *Union of India*[2], *G. Sundarrajan* v. *Union of India*[3] and *Shri Sitaram Sugar Company Ltd.* v. *Union of India*[4]. Further, the learned Solicitor General relied upon the judgments of the Supreme Court of the United States (hereinafter, the "US Supreme Court") in *Henning Jacobson* v. *Commonwealth of Massachusetts*[5], *Zucht* v. *King*[6] and in Docket No. 21A240 titled *Joseph R. Biden* v. *Missouri* dated 13.01.2022 and the judgment of the Supreme Court of New South Wales (hereinafter, the "NSW Supreme Court") in *Kassam* v. *Hazzard*; *Henry* v. *Hazzard*[7] to bolster his submissions that courts should not lightly interfere with matters of policy concerning the safety and health of the people and it is not the court's function to determine the merits of the exercise of power by the executive. The learned Solicitor General was joined by Mr. Amit Anand Tiwari, learned Additional Advocate General for the State of Tamil Nadu, in emphasising the limited scope of judicial review in matters of policy framed on the basis of expert opinion.

14. In opposition, the Petitioner argued that matters of public importance involving invasion of fundamental rights of individuals cannot be brushed aside by this Court on the ground that they are beyond the jurisdiction of this Court. This Court has a duty to safeguard the fundamental rights of individuals and issues raised herein are of seminal importance which ought to be decided after assessing the relevant material placed before this Court by both sides. Mr. Bhushan referred to the judgment of the High Court of New Zealand in *Ryan Yardley* v. *Minister for Workplace Relations and Safety*[8] in support of his submission that the scientific data and evidence that was produced before the High Court of New Zealand was assessed to adjudge the efficacy of vaccines in preventing transmission of the COVID-19 virus.

15. It was further argued by Mr. Bhushan that the judgments relied upon by the Union of India are not applicable to the facts of this case. He relied upon the judgments of this Court in *Delhi Development Authority* v. *Joint Action Committee, Allottee of SFS Flats*[9], *Directorate of Film Festivals* v. *Gaurav Ashwin Jain*[10] and an order of this Court in *Distribution of Essential Supplies and Services During Pandemic, In re*[11] and submitted that policy decisions taken by the executive are not beyond the scope of judicial review, if they are manifestly arbitrary or unreasonable.

16. Before examining the parameters of judicial review in this case, it is profitable

to refer to judgments from beyond our borders which have dealt with the scope of judicial review in matters relating to public health and vaccinations, in particular. Compulsory vaccination against small pox was the subject-matter of *Jacobson* (supra) decided in 1905. The US Supreme Court was of the opinion that the mandate of the local government for compulsory vaccination was binding on every individual. The safety and health of the people has to be protected by the government and the judiciary is not competent to interfere with decisions taken in the interest of public health. The Court can interfere by way of judicial review of legislative action in matters of public health only when there is no real or substantial relation to the object of the legislation or when there is plain, palpable invasion of rights secured by fundamental law and thereby, give effect to the Constitution.

17. In the wake of the COVID-19 pandemic, restrictions on attendance at religious services in areas classified as 'red' or 'orange' zones were imposed by an executive order issued by the Governor of New York. The said restrictions were challenged on the ground that they violate the free exercise clause of the First Amendment of the Constitution of the United States. By a majority of 6 : 3, the US Supreme Court in *Roman Catholic Diocese* v. *Cuomo*[12] granted injunctive relief on being satisfied that the executive order struck at the very heart of the First Amendment's guarantee of religious liberty. While doing so, the US Supreme Court observed that the members of the Court are not public health experts and they should respect the judgment of those with special expertise and responsibility in this area. However, the Constitution cannot be put away and forgotten even in a pandemic. Gorsuch, J., who wrote a concurring opinion, observed that *Jacobson* (supra) hardly supports cutting the Constitution loose during a pandemic. *Jacobson* (supra) was distinguished by Gorsuch, J., who held that the Court did not interfere with the challenged law in *Jacobson* (supra) only because it did not "*contravene the Constitution of the United States*" or "*infringe any right granted or secured by*" it. A word of caution sounded by Gorsuch, J. is to the effect that the Court cannot stay out of the way in times of crisis, when the Constitution is under attack. In his dissent, Roberts, C.J. held that the injunction sought would not be in public interest, especially when it concerns public health and safety needs which calls for swift government action in everchanging circumstances. He relied upon the earlier order passed by the US Supreme Court in *South Bay United Pentecostal Church* v. *Newsom*[13] wherein it was recognised that courts must grant elected representatives broad discretion when they undertake to act in areas fraught with medical and scientific uncertainties.

18. *Biden* v. *Missouri* (supra) related to vaccine mandates for healthcare providers. The Secretary of Health and Human Services issued a rule on being convinced that vaccination of healthcare workers in facilities in the Medicare and Medicaid Programs against COVID-19 was "*necessary for the health and safety of individuals to whom care and services are furnished*". The said rule was challenged and the US District Courts for the Western District of Louisiana and the Eastern District of Missouri each entered preliminary injunctions against its enforcement. The appeals filed against the said injunction were rejected by the Fifth Circuit in Louisiana and the Eighth Circuit in Missouri. Aggrieved thereby, the Government moved the US Supreme Court seeking for a stay on the preliminary injunctions passed by the US District Courts. While granting stay of the preliminary injunctions, by its plural opinion the US Supreme Court held that the role of courts in reviewing decisions taken by the executive should be to ensure that the executive "*has acted within a zone of reasonableness*".

19. Having been aggrieved by certain orders of the Minister for Health and Medical Research that required people working in the construction, aged care and education sectors to be compulsorily vaccinated, Al-Munir Kassam and three others, along with Natasha Henry and five others, approached the NSW Supreme Court challenging the constitutional validity of the decision. While considering the grounds of challenge, the

NSW Supreme Court in *Kassam* v. *Hazzard* (supra) was of the view that "*it is not the Court's function to determine the merits of the exercise of the power by the Minister to make the impugned orders, much less for the court to choose between plausible responses to the risks to the public health posed by the Delta variant*". The NSW Supreme Court further observed that it is not the court's function to conclusively determine the effectiveness of some of the alleged treatments for those infected or the effectiveness of COVID-19 vaccines, especially their capacity to inhibit the spread of the disease, which are all matters of merits, policy and fact for the decision maker and not the court. The NSW Supreme Court emphasised that its only function is to determine the legal validity of the impugned orders. The said view of the NSW Supreme Court was approved by the New South Wales Court of Appeal in *Kassam* v. *Hazzard*; *Henry* v. *Hazzard*[14].

20. The Minister for Workplace Relations and Safety passed COVID-19 Public Health Response (Specified Work Vaccinations) Order 2021, by which it was determined that work carried out by certain police and defence force personnel could only be undertaken by workers who have been vaccinated. Three police and defence force workers who did not wish to be vaccinated sought judicial review of the said order before the High Court of New Zealand (hereinafter, the "NZ High Court"). While adjudicating the dispute, the NZ High Court in *Ryan Yardley* (supra) expressed its opinion that the choices made by governments on their response to COVID-19 involve wide policy questions, including decisions on the use of border closures, lockdowns, isolation requirements, vaccine mandates and many other measures, which are decisions for the elected representatives to make. The NZ High Court made it clear that the Court addresses narrower legal questions and the Court's function is not to address the wider policy questions. While referring to the evidence of experts, the NZ High Court stressed on the institutional limitations on the Court's ability to reach definitive conclusions but clarified that the Court must exercise its constitutional responsibility to ensure that decisions are made lawfully. While relying upon a judgment of the Court of Appeal of New Zealand in *Ministry of Health* v. *Atkinson*[15], the NZ High Court held that the Crown has the burden to demonstrate that a limitation of a fundamental right is demonstrably justified. We have come to know that in the time since the judgment in this matter was reserved, the decision of the NZ High Court in *Ryan Yardley* (supra) has been appealed by the Government of New Zealand before the New Zealand Court of Appeal.

21. We shall now proceed to analyse the precedents of this Court on the ambit of judicial review of public policies relating to health. It is well settled that the Courts, in exercise of their power of judicial review, do not ordinarily interfere with the policy decisions of the executive unless the policy can be faulted on grounds of mala fide, unreasonableness, arbitrariness or unfairness etc. Indeed, arbitrariness, irrationality, perversity and mala fide will render the policy unconstitutional[16]. It is neither within the domain of the courts nor the scope of judicial review to embark upon an enquiry as to whether a particular public policy is wise or whether better public policy can be evolved. Nor are the courts inclined to strike down a policy at the behest of a petitioner merely because it has been urged that a different policy would have been fairer or wiser or more scientific or more logical[17]. Courts do not and cannot act as appellate authorities examining the correctness, suitability and appropriateness of a policy, nor are courts advisors to the executive on matters of policy which the executive is entitled to formulate. The scope of judicial review when examining a policy of the Government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary[18].

22. This Court in a series of decisions has reiterated that courts should not rush in where even scientists and medical experts are careful to tread. The rule of prudence is

that courts will be reluctant to interfere with policy decisions taken by the Government, in matters of public health, after collecting and analysing inputs from surveys and research. Nor will courts attempt to substitute their own views as to what is wise, safe, prudent or proper, in relation to technical issues relating to public health in preference to those formulated by persons said to possess technical expertise and rich experience[19]. Where expertise of a complex nature is expected of the State in framing rules, the exercise of that power not demonstrated as arbitrary must be presumed to be valid as a reasonable restriction on the fundamental right of the citizen and judicial review must halt at the frontiers. The Court cannot re-weigh and substitute its notion of expedient solution. Within the wide judge-proof areas of policy and judgment open to the government, if they make mistakes, correction is not in court but elsewhere. That is the comity of constitutional jurisdictions in our jurisprudence. We cannot evolve a judicial policy on medical issues. All judicial thought, Indian and Anglo-American, on the judicial review power where rules under challenge relate to a specialised field and involve sensitive facets of public welfare, has warned courts of easy assumption of unreasonableness of subordinate legislation on the strength of half-baked studies of judicial generalists aided by the adhoc learning of counsel. However, the Court certainly is the constitutional invigilator and must act to defend the citizen in the assertion of his fundamental rights against executive tyranny draped in disciplinary power.[20]

23. There is no doubt that this Court has held in more than one judgment that where the decision of the authority is in regard to a policy matter, this Court will not ordinarily interfere since decisions on policy matters are taken based on expert knowledge of the persons concerned and courts are normally not equipped to question the correctness of a policy decision. However, this does not mean that courts have to abdicate their right to scrutinise whether the policy in question is formulated keeping in mind all the relevant facts and the said policy can be held to be beyond the pale of discrimination or unreasonableness, bearing in mind the material on record.[21] In *Delhi Development Authority* (supra), this Court held that an executive order termed as a policy decision is not beyond the pale of judicial review. Whereas the superior courts may not interfere with the nitty-gritty of the policy, or substitute one by the other but it will not be correct to contend that the court shall lay its judicial hands off, when a plea is raised that the impugned decision is a policy decision. Interference therewith on the part of the superior court would not be without jurisdiction as it is subject to judicial review. It was further held therein that the policy decision is subject to judicial review on the following grounds:

a) if it is unconstitutional;

b) if it is dehors the provisions of the Act and the regulations;

c) if the delegatee has acted beyond its power of delegation;

d) if the executive policy is contrary to the statutory or a larger policy.

24. During the second wave of COVID-19 pandemic, this Court in *Distribution of Essential Supplies & Services during Pandemic* (supra), to which one of us was a party (L Nageswara Rao, J.), dealt with issues of vaccination policy, pricing and other connected issues. While doing so, this Court held that policy-making continues to be the sole domain of the executive and the judiciary does not possess the authority or competence to assume the role of the executive. It was made clear that the Court cannot 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.

25. There can be no ambiguity in the principles of law relating to judicial review laid

down by this Court. A perusal of the judgments referred to above would clearly show that this Court would be slow in interfering with matters of policy, especially those connected to public health. There is also no doubt that wide latitude is given to executive opinion which is based on expert advice. However, it does not mean that this Court will not look into cases where violation of fundamental rights is involved and the decision of the executive is manifestly arbitrary or unreasonable. It is true that this Court lacks the expertise to arrive at conclusions from divergent opinions of scientific issues but that does not prevent this Court from examining the issues raised in this Writ Petition, especially those that concern violation of Article 21 of the Constitution of India.

26. Identifying the issues in the present matter, they can be divided as follows:

I. Vaccine mandates being violative of Article 21 of the Constitution of India.

II. Non-disclosure of segregated clinical trial data in public domain.

III. Improper collection and reporting of AEFIs.

IV. Vaccination of children.

I. Vaccine Mandates

A. *Submissions*

27. Mr. Bhushan submitted that there is nothing wrong in the Government encouraging the people to get vaccinated. However, coercive vaccination from the pain of denial of essential services is plainly unconstitutional, being violative of the principle of bodily autonomy and the right to access one's means of livelihood. Though the Union of India has made a categorical submission that vaccines are voluntary, the State Governments have been placing restrictions on unvaccinated people by denying them access to public places and services. He referred to : (i) an order passed by the Government of NCT of Delhi on 08.10.2021 by which government employees, including frontline workers and healthcare workers, as well as teachers and staff working in schools and colleges were not to be allowed to attend their respective offices and institutions without the first dose of vaccination with effect from 16.10.2021; (ii) a directive issued by the Government of Madhya Pradesh on 08.11.2021 stating that it was mandatory to be vaccinated with two doses of the vaccine to get food grains at fair price shops; (iii) an order passed by the Government of Maharashtra dated 27.11.2021 requiring persons to be fully vaccinated if they are connected with any program, event, shop, establishment, mall and for utilising public transport; (iv) an order issued by the Government of Tamil Nadu dated 18.11.2021 permitting only vaccinated people into open, public places, schools, colleges, hostels, boarding houses, factories and shops; and other instances where students in the age group of 15 to 18 years were not permitted to appear for their examinations without being vaccinated.

28. Mr. Bhushan contended that there is need to balance individuals' rights with public interest concerning health. According to him, vaccine mandates can be on the basis of efficacy and safety of vaccination and prevention of transmission. He submitted that there is sufficient evidence to the effect that natural immunity acquired from a COVID-19 infection is long-lasting and robust in comparison to vaccine immunity. Studies also indicate that vaccines do not prevent infection from the virus or transmission amongst people. Vaccines are also ineffective in preventing infection from new variants. According to serological studies, 75 per cent of the Indian population has already been infected and is seropositive and, therefore, they have better immunity to infection than what is provided by the vaccines. The vaccines which are being administered in this country are only authorised for emergency use and the procedure for clinical trials of such vaccines has not been fully complied with. In view of the lack of transparency in disclosure of trial data resulting in absence of informed consent, any vaccine mandate would be unconstitutional. Mr. Bhushan

contended that every individual has personal autonomy and cannot be forced to be vaccinated against his will. For the said proposition, he relied on the judgments of *Common Cause (A Registered Society)* v. *Union of India*[22], *Aruna Ramachandra Shanbaug* v. *Union of India*[23] and *K.S. Puttaswamy* v. *Union of India*[24]. Imposing restrictions on the rights of persons who are unvaccinated is totally unwarranted as there is no basis for discriminating against unvaccinated persons. He relied upon scientific studies, opinions of experts and news articles to contend that vaccinated people are also prone to infection and there is no difference between a vaccinated individual and an unvaccinated person with respect to transmission of the virus. As there is no serious threat of spread of the virus by an unvaccinated person in comparison to a vaccinated person, placing restrictions on unvaccinated persons is meaningless.

29. *Per contra*, the learned Solicitor General of India contended that more than 180 crore doses had been administered, resulting in a substantial number of individuals in the country being vaccinated. He submitted that the vaccines have proved to be effective and safe and any indulgence by this Court would result in vaccine hesitancy. The Government had taken extra care to appoint various committees to examine the efficacy, safety, immunogenicity, pharmacodynamics of the vaccines before granting approvals. Some of the material placed before this Court to bolster the Union of India's submissions have been listed below:

(a) 'Science Brief : SARS-CoV-2 Infection-induced and Vaccine-induced immunity' of the United States Centers for Disease Control and Prevention (CDC) updated as on 29.10.2021, which in its conclusion states that : *"Numerous immunologic studies and a growing number of epidemiologic studies have shown that vaccinating previously infected individuals significantly enhances their immune response and effectively reduces the risk of subsequent infection, including in the setting of increased circulation of more infectious variants. Although the Delta variant and some other variants have shown increased resistance to neutralization by both post-infection and post-vaccination sera in laboratory studies, observed reduction in effectiveness has been modest, with continued strong protection against hospitalization, severe disease and death."*

(b) A study conducted by researchers of *Christian Medical College, Vellore*[25], wherein it has been concluded as follows:"*Among symptomatic COVID-19 patients, prior vaccination with either Covishield™ or Covaxin® impacted the severity of illness and reduced mortality when compared with unvaccinated patients. Full vaccination conferred a substantially higher protective effect over partial vaccination.*" The results of the study also indicate that compared with unvaccinated patients, partially vaccinated patients had milder disease, reduced requirement of oxygen, hospital admission, ICU admission and mortality. Again, when fully vaccinated patients were compared with unvaccinated individuals, full vaccination was associated with significantly less disease severity, requirement of respiratory supports, hospital admission, ICU admission and mortality. The study further showed that majority of the patients screened who required hospitalisation were unvaccinated.

(c) A study conducted by researchers of *All India Institute of Medical Sciences (AIIMS), New Delhi*[26], which states that:"*We evaluated the association between COVID-19 vaccination status (the number of vaccine shots received and time interval since the last dose) and the vaccines' clinical efficacy in India in preventing the disease and its severity. This study has several noteworthy findings. Firstly, both the Indian vaccines provided a significant protective role in preventing the disease among people who had a clinical suspicion of COVID-19. Secondly, These vaccines protected from progression to a severe form of the disease among the patients who turned RTPCR positive despite getting*

vaccinated. The probability of hospitalisation was about eight times less, and ICU admission/death was about fourteen times lesser among fully vaccinated patients in comparison to unvaccinated RT-PCR positive patients. Thirdly, the protective efficacy of the vaccines had a dose-dependent effect. The effectiveness is maximum among individuals who received both doses of vaccination at least two weeks before the onset of their symptoms."

(d) A study conducted by researchers of *AIIMS, Patna*[27], which concludes as follows:"*COVID-19 vaccination was found to be effective in infection prevention. One out of two and four out of five individuals were found to be protected against SARS-CoV-2 infection following partial and full vaccination, respectively. The vaccinated individuals had lesser LOS compared to unvaccinated ones. Additionally, the fully vaccinated individuals were less likely to develop severe disease.*" LOS herein refers to the length of hospital stays.

30. On behalf of the State of Tamil Nadu, Mr. Amit Anand Tiwari, learned Additional Advocate General, submitted that the restrictions placed by way of the circular dated 18.11.2021 are within the competence of the State in exercise of its powers under the Disaster Management Act, 2005 (hereinafter, the "DM Act") and the Tamil Nadu Public Health Act, 1939. Section 76(2)(b) thereof empowers the State Government to make vaccinations compulsory, in the event of a declaration by the Government of an outbreak of a notified disease. He submitted that the restrictions placed by the circular dated 18.11.2021 are in larger public interest and cannot be said to be unreasonable restrictions, as these were an essential facet of the precautionary approach adopted by the State of Tamil Nadu in dealing with the unprecedented pandemic. According to Mr. Tiwari, these restrictions were in furtherance of the State realising the importance of curtailing the spread of COVID-19. The unchecked spread of the virus could lead to further dangerous mutations. While referring to opinions of experts in the field of health, including that of the World Health Organization (WHO), the United Nations International Children's Emergency Fund (UNICEF) and the Oxford Vaccine group, as well as scientific studies published in the New England Journal of Medicine, the Lancet and the International Journal of Scientific Studies, it was submitted on behalf of the State of Tamil Nadu that vaccination prevents severe disease and significantly reduces hospitalisation and mortality and that vaccines continued to be highly effective in preventing severe disease and death. The measures were justified on the ground that they were not only aimed for the safety of a particular individual but also served a greater purpose of ensuring safety of the community at large.

31. Mr. Rahul Chitnis, learned counsel appearing for the State of Maharashtra, referred to the information provided by the WHO to contend that vaccines save infected individuals from "*life threatening complications, … and consequential untimely death*" and therefore, vaccine mandate issued by the State of Maharashtra is in the interest of general public. The restrictions that are imposed are reasonable and cannot be said to "manifestly arbitrary" as they are issued only for a temporary period with exclusions and are reviewed periodically by the State to assess if relaxations can be granted. He submitted that there is no compulsion to get vaccinated, however, in view of the serious threat that not being vaccinated poses to the right of life and personal liberty of the larger population, certain unavoidable restrictions have been imposed, especially given that strict adherence to social distancing and masking is significantly compromised in bigger cities.

32. The complaint of the Petitioner in relation to prevention of access to essential resources in the State of Madhya Pradesh pertains to ration not being provided to unvaccinated persons through the public distribution system. We were informed by the learned counsel for the State of Madhya Pradesh that the order dated 08.11.2021, by which vaccination was made mandatory for receiving ration from fair price shops,

was not implemented and was eventually withdrawn on 07.01.2022.

33. In the counter-affidavit filed on behalf of the Government of NCT of Delhi, it was submitted that the order dated 08.10.2021 was issued by the Delhi Disaster Management Authority after due application of mind, to control the spread of COVID-19 and mitigate its effects. Under Section 6(2)(i) of the DM Act, the National Disaster Management Authority has been issuing orders from time to time directing State Governments and Union Territories, amongst other authorities, to take effective measures to prevent the spread of COVID-19, and in furtherance of this, also permitted States to impose further local restrictions. The Delhi Disaster Management Authority, in a meeting held on 29.09.2021, decided to ensure 100 per cent vaccination of all Government employees, frontline workers, healthcare workers as well as teachers and staff working in schools and colleges, on the advice of medical and other experts. It was considered necessary as these individuals have frequent interaction with the general public and vulnerable sections of the society and therefore, pose greater risk of spreading the virus. While an individual may have a right to decide against getting vaccinated, the State, however, has a statutory duty to regulate the interaction of unvaccinated persons within the society in the interest of public health.

34. In his rejoinder, Mr. Bhushan, while reiterating his submissions, took exception to the contradictory stand taken by the Union of India on COVID-19 vaccination being voluntary and not mandatory. On one hand, the Union of India made it clear in the counter-affidavit that vaccination is voluntary and on the other, a series of advisories and material had been filed by the Union of India, supporting the claim of vaccination being mandatory. Mr. Bhushan submitted that the Union of India has not provided any material to the Court contrary to what has been supplied by the Petitioner furthering his scientific and legal contention that unvaccinated people pose no greater danger than vaccinated individuals in the matter of transmission of the COVID-19 virus, and therefore, there is no public health rationale in vaccine mandates. In addition to the various points raised in his submissions, the learned counsel for the Petitioner relied upon the opinion of Dr. Aditi Bhargava, who is a professor at University of California, San Francisco and a molecular biologist with 33 years of research experience, from her presentation made before the US Senate on 02.11.2021. Her opinion is to the effect that vaccines do not prevent infection and transmission. She is of the further belief that natural immunity is the gold standard. According to Dr. Bhargava, there has been no documented case of a naturally immune person getting reinfected with severe disease or hospitalised, despite the first case reported nearly two years ago, whereas, there have been thousands of cases of severe infection, hospitalisation, and deaths in fully vaccinated people. Mr. Bhushan concluded by submitting that any restrictions placed on personal autonomy of individuals would be violative of Article 21, unless the criteria laid down in *K.S. Puttaswamy* (supra) is met.

B. *Evolution of COVID-19 and vaccines*

35. COVID-19 emerged in late 2019. The WHO officially declared the novel coronavirus outbreak as a pandemic on 11.03.2020. The virus was detected in the country in the last week of January, 2020 and spread rapidly. As the threat of infections from the virus loomed large, an unprecedented national lockdown was announced on 24.03.2020, which extended for a few months, with restrictions being removed thereafter in a phased manner. India was not alone in this; several countries imposed lockdowns to arrest the spread of the deadly disease, which has led to a drastic loss of human life worldwide and presented a threat of extraordinary proportions to public health, food systems, economic and social conditions. Scientific studies and research for manufacture of vaccines to prevent severe infections were undertaken on an emergency basis. Towards the end of 2020, emergency vaccines came to be administered in the western part of the world. However, by then, the

spread of COVID-19 around the globe was considerable. Around the same period, a variant called B.1.1.7 was found in the United Kingdom. The said variant was renamed as Alpha, as per the naming scheme recommended by the expert group convened by the WHO, which also includes scientists from the WHO's Technical Advisory Group on Virus Evolution (TAGVE). Another variant, called B.1.351 and later renamed as Beta, was found to be linked to a second wave of infections in South Africa. Both these variants were identified as Variants of Concern (VOC) by the WHO on 18.12.2020, meaning that they were variants with genetic changes that would affect virus characteristics such as transmissibility, disease severity or immune escape and through a comparative assessment, are found to be associated with an increase of transmission or increase in virulence or decrease in effectiveness of public health measures such as vaccines, therapeutics etc. Soon thereafter, the highly transmissible variant called Gamma was found in Brazil and was identified as a VOC by the WHO on 11.01.2021.[28]

36. In the first half of 2021, the Delta variant was identified as the predominant variant in India and was believed to be 60 per cent more transmissible than the Alpha variant. Thereafter, Delta rapidly spread beyond the borders to other countries. Another variant, Omicron, surfaced in November, 2021, whose spread was much more accelerated than earlier variants, including that of Delta. On the basis of the evidence available as on 21.01.2022, the WHO was of the opinion that the Omicron has a significant growth advantage over Delta, leading to rapid spread in the community with higher levels of incidence than previously seen in the pandemic. It was further observed that despite a lower risk of severe disease and death following infection, the very high levels of transmission nevertheless have resulted in significant increases in hospitalisation and continue to pose overwhelming demands on health care systems in most countries. It was found that because of the 26-32 mutations that it has in the spike protein, Omicron has infected even those who have been previously infected or vaccinated.[29] Though the infections and transmission from Omicron at present within the country are not as serious as they were in the first two months of 2022, expert opinion is to the effect that Omicron might not be the last of the variants, as we have since witnessed.

37. The WHO established the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) in September, 2021. According to the statement made by the said group on 11.01.2022 in the context of circulation of the Omicron variant, the group reviews and assesses the public health implications of emerging VOCs on the performance of COVID-19 vaccines and provides recommendations on COVID-19 vaccine composition. The said group is developing a framework to analyse the evidence on emerging VOCs in the context of criteria that would trigger a recommendation to change COVID-19 vaccine strain composition and will advise the WHO on updated vaccine compositions, as required. The group has spelt out in their statement that at present, with the available COVID-19 vaccines, the focus is on reducing severe disease and death, as well as protecting health systems. According to the TAG-CO-VAC, vaccines, which have received WHO Emergency Use Listing across several vaccine platforms, provide a high level of protection against severe disease and death caused by VOCs. The group takes note of data which indicates that vaccine effectiveness will be reduced against symptomatic disease caused by the Omicron variant but at the same time, it was of the opinion that protection against severe disease is more likely to be preserved. Along with the Strategic Advisory Group of Experts on Immunization (SAGE) and its Working Group on COVID-19 vaccines, TAG-CO-VAC has recommended COVID-19 vaccines for priority populations worldwide to provide protection against severe disease and death globally and, in the longer term, to mitigate the emergence and impact of new VOCs by reducing the burden of infection.[30]

38. With the outbreak of the devastating pandemic, as many as 5,23,843 lives have been lost in this country, as per the latest data available on the website of the Ministry of Health and Family Welfare (MoHFW). Initially, efforts made by the Government of India were to protect people by arresting serious infection. With treatment protocol and clinical management protocol for COVID-19 being revised periodically as more and more data and research on the virus came to be known, persons affected by the virus were treated with the information that was available at the point. Using whatever little was known about the virus in the initial stages, dedicated efforts have been made to save countless lives in this country. With the approval of vaccines on an emergency basis in January, 2021, there was some hope about preventing infections from the virus. Inoculation, which commenced slowly in view of the non-availability of sufficient doses of vaccines, gained pace with the increase in manufacture by Respondent Nos. 4 and 5. With the Government embarking upon extensive awareness drives encouraging vaccination, more than 189 crore doses of vaccine have been administered within the country till date, as per the data available on the website of the MoHFW.

39. With the introduction of vaccines, it was understood that vaccines would aid in preventing infections. To protect their populace from infection, countries worldwide promoted vaccination as, needless to say, an uninfected person will not transmit the disease. Thereafter, with the mutation of the virus eventually resulting in multiple VOCs, breakthrough infections were noticed. Vaccinated people were found to be infected with the virus and could also act as carriers, transmitting the virus to others. Even in such a situation, there is no question of whether vaccination for COVID-19 should be continued. The recommendations of the WHO's TAG-CO-VAC and SAGE make it amply clear that vaccines, which have received emergency use approvals, provide strong protection against serious illness, hospitalisation and death and getting vaccinated is one of the most crucial steps towards protecting oneself from COVID-19, stopping new variants from emerging and helping end the pandemic. It should be noted that the advice of the WHO with respect to COVID-19 has been consistent since the time vaccines became available, even after recognising that it was still possible to get infected and spread the infection to others despite being vaccinated, as is evident from the latest version of the WHO's 'COVID-19 advice for the public : Getting vaccinated' as of 13.04.2022[31]. The Union of India has placed considerable material on record in terms of scientific briefs and published studies which stand testimony to the significance of vaccination as a crucial public health intervention in this pandemic and its continued benefits to individual health as well as public health infrastructure. Vaccination of a majority of the population of this country has undoubtedly been instrumental in preventing severe disease, hospitalisation and deaths, and benefited the community at large, especially those members with co-morbidities, the elderly and sick persons. Even the Petitioner is not opposed to the vaccination programme and does not challenge the vaccination drive of the Government of India, as has been reiterated by him during the course of his arguments. Exception to the vaccination programme taken by the Petitioner is only to coercive vaccination through vaccine mandates, which place unjustifiable restrictions on those who wish to not be vaccinated.

40. In light of the virulent mutations of the COVID-19 virus and advice of experts from the WHO as well as common findings of several studies on this subject, the vaccination drive that is being undertaken by the Government of India in the interest of public health cannot be faulted with.

C. Personal autonomy and public health

41. Before dealing with the issue of coercive vaccination, it is necessary to consider whether the right of privacy of individuals can override public health, more so, when the submission on behalf of the Respondents is that steps taken to restrict the rights

of individuals are in the larger interest of public health. It is true that to be vaccinated or not is entirely the choice of the individual. Nobody can be forcefully vaccinated as it would result in bodily intrusion and violation of the individual's right to privacy, protected under Article 21 of the Constitution of India. Personal autonomy was read into Article 21 by this Court in *Common Cause* (supra), by placing reliance on *National Legal Services Authority* v. *Union of India*[32], and *Aruna Ramachandra Shanbaug* (supra). This Court, in *Common Cause* (supra), emphasized the right of an individual to choose how he should live his own life, without any control or interference by others. It recognised the right of an individual to refuse unwanted medical treatment and to not be forced to take any medical treatment that is not desired. In view of the categoric statement of the Union of India that vaccination of COVID-19 is voluntary, the question of any intrusion into bodily integrity does not arise for consideration in this case. However, the Petitioner has asserted that limitations placed on access to public places and public resources for unvaccinated persons result in coercive vaccination, and therefore, limit the right of unvaccinated persons to refuse medical treatment.

42. Disclosure of data of a patient suffering from AIDS was the subject matter of a decision of this Court in *X* v. *Hospital 'Z'*[33]. Placing reliance on *Kharak Singh* v. *State of U.P.*[34], *Gobind* v. *State of M.P.*[35] and a judgment of the US Supreme Court in *Jane Roe* v. *Henry Wade*[36], this Court held that though non-disclosure of medical information of an individual can be traced to the right to privacy protected under Article 21, it is not absolute and is subject to action lawfully taken for protection of health or morals or protection of rights and freedoms of others.

43. In *Association of Medical Super Speciality Aspirants and Residents* v. *Union of India*[37], to which one of us was a party (L Nageswara Rao, J.), this Court, while considering validity of service bonds to be executed at the time of admission to postgraduate and superspeciality courses in medical science, held as follows:

> *"33. The above discussion leads us to the conclusion that right to life guaranteed by Article 21 means right to life with human dignity. Communitarian dignity has been recognised by this Court. While balancing communitarian dignity vis-à-vis the dignity of private individuals, the scales must tilt in favour of communitarian dignity. The laudable objective with which the State Governments have introduced compulsory service bonds is to protect the fundamental right of the deprived sections of the society guaranteed to them under Article 21 of the Constitution of India. The contention of the appellants that their rights guaranteed under Article 21 of the Constitution of India have been violated is rejected."*

44. Strong reliance was placed by the Petitioner on the judgment of the High Court of New Zealand in *Ryan Yardley* (supra). The principal contention of the applicants therein was that the impugned order, requiring police and defence force personnel to be vaccinated, placed unjustified limitation on the rights protected by the New Zealand Bill of Rights Act 1990 (hereinafter, the "NZ Bill of Rights"), particularly the right to refuse to undergo medical treatment, the right to manifest religion, the right to be free from discrimination and other rights under Section 28 of the said Act (including the right to work, and of minority groups to enjoy their culture and practice their religion). The purpose of the order, as clarified by the Minister by way of an amendment order in February, 2022 is as below:

> *"(a) avoid, mitigate, or remedy the actual or potential adverse effects of the COVID-19 outbreak (whether direct or indirect); and*
>
> *(b) ensure continuity of services that are essential for public safety, national defence, or crisis response; and*
>
> *(c) maintain trust in public services."*

45. Considering the submissions of the applicants therein that the order placed

unjustified limitations on fundamental rights protected by the NZ Bill of Rights, the NZ High Court held that the impugned order limits the right of affected workers to refuse to undergo a medical treatment as well as the right (or significant interest) to retain employment. While examining the question of whether the limitation of the said rights was justified, the NZ High Court noted that the order mandating vaccinations for the police and defence personnel was imposed to ensure the continuity of services that are essential for public safety, national defence, or crisis response, and to promote public confidence in those services, rather than to stop the spread of COVID-19. The NZ High Court further took note of the fact that by October, 2021, 83.1 per cent of police personnel had received at least one or more doses of the vaccination, and 70.1 per cent had received both doses. By the time the order took effect on 17.01.2022, there were only 164 unvaccinated staff members in an overall workforce of 15,682 staff. It was found that the position within the New Zealand Defence Forces (NZDF) was similar. From a total of 15,480 NZDF personnel, 3,048 are civil staff. As on 01.02.2022, 99.2 per cent of the regular forces were fully vaccinated, leaving aside 75 members and 98.7 per cent of the civil staff were fully vaccinated, leaving 40 who were not. The NZ High Court was of the view that the relatively low number of unvaccinated police and NZDF personnel impacted by the order may not, by itself, mean that the order was not a reasonable limit on rights that can be demonstrably justified, if there was evidence to establish that the presence of unvaccinated personnel, even in small numbers, created a materially higher risk to the remaining workforce. While observing that the evidence on this issue is sparse, the NZ High Court referred to the evidence of Dr. Petrovsky, who deposed that vaccination has potential benefit in reducing the severity of disease, even with the Omicron variant. However, in his view, mandatory vaccination did not assist in preventing workers in affected roles from contracting COVID-19, or transmitting it to others. The NZ High Court further considered the evidence of Dr. Town, the Ministry's Chief Science Adviser, who, according to the NZ High Court, did not directly respond to Dr. Petrovsky's analysis of the effectiveness of the vaccine to inhibit the spread of COVID-19 in a workforce, but instead provided his more generalised opinions. In his evidence, Dr. Town stated that vaccines show reduced effectiveness compared with Delta in terms of becoming infected with and transmitting Omicron.

46. After weighing the evidence, the NZ High Court was of the view that vaccination may still be effective in limiting infection and transmission, but at a significantly lower level than was the case with the earlier variants. It was further concluded that vaccination does not prevent persons contracting and spreading COVID -19, particularly with the Omicron variant. The NZ High Court referred to an earlier judgment in *Four Aviation Security Service Employees* v. *Minister of COVID-19 Response*[38], where the precautionary principle had been applied, to make the point that even a modest vaccination protection on a modest number of personnel needs to be considered in the context of potential effects of a pandemic. The NZ High Court referred to a judgment of the Federal Court of Ontario in *Spencer* v. *Attorney General of Canada*[39] to elaborate on the precautionary principle, as "*a foundational approach to decision-making under uncertainty, that points to the importance of acting on the best available information to protect the health of*" the citizens. In *Four Aviation Security Service Employees* (supra), which dealt with restrictions placed on aviation security workers, the NZ High Court held that even though the applicants therein were not being forcibly treated, they were required to be vaccinated as a condition of their employment, refusal of which led to termination. Observing that a right does not need to be taken away in its entirety before it is regarded as having been limited, the NZ High Court opined that the level of pressure in that case was significant and amounted to coercion, and therefore, the applicants' right to refuse to undergo medical treatment was limited. However, the said limitation was held to be justified. From the evidence

adduced before the NZ High Court, it concluded that the vaccine was effective at reducing the transmission of the earlier variants of the virus and that it was also effective at reducing symptomatic infection and detrimental effects of the Delta variant. As the applicants were border workers interacting with international travellers who may be carrying the virus and given the likelihood of vaccines contributing to preventing the risk of transmission, the NZ High Court held that a precautionary approach, in doing everything that can be reasonably done to minimise risk of the outbreak or spread in strong public interest, is justified. Further, the curtailment of the right to refuse to undergo medical treatment was found to be proportionate to the objective, as the applicants, who worked as aviation workers, were situated in a key location where COVID-19 might enter New Zealand.

47. In *Ryan Yardley* (supra), the NZ High Court held that the principle in *Four Aviation Security Service Employees* (supra) is not directly applicable as the order was not promulgated to contain the spread of the virus but for the purpose of ensuring continuity of, and confidence in, essential services. Additionally, there was no evidence of a threat to the continuity of the police and NZDF services, which would enable the NZ High Court to give the benefit of the doubt to the New Zealand Crown in imposing measures to address that risk. Placing reliance on the evidence adduced as well as the public health advice which was to the effect that vaccine mandates were not considered necessary for addressing the risk of the outbreak or spread of COVID-19, the High Court made it clear that while vaccination significantly improved the prospects of avoiding illness and death even with the Omicron variant, given the variant's propensity to break through vaccination barriers, it concluded that there was no real threat to the continuity of these essential services that the impugned order sought to address. Further, finding that suspension of the unvaccinated would address any potential problems, the terminations arising from the order in light of the temporary, albeit significant, period of peak impact of the infection, were found to be disproportionate and unjustified. While the Petitioner has sought support from this judgment to demonstrate how courts in other jurisdictions have struck down vaccine mandates taking into account Omicron's impact on the effectiveness of vaccines in addressing spread, we believe that this judgment may not be of much assistance to us for determining the issue at hand for two reasons. First, the judgment expressly recognised that the impugned vaccine mandate was not brought about to suppress the spread of the virus but to ensure continuity of, and confidence in, essential services, such as the police and the defence personnel, which we are not concerned with in the present case. Second, while the NZ High Court looked into depositions of expert witnesses to come to its own conclusion on efficacy of vaccines vis-à-vis the Omicron variant, the scope of our review does not entail assessment of competing scientific opinions, as the judiciary is not equipped to decide issues of medical expertise and epidemiology.

48. The crucial point that requires to be considered by us is whether limitations placed by the Government on personal autonomy of an individual can be justified in the interest of public health in the wake of the devastating COVID-19 pandemic. As stated, personal autonomy has been recognized as a critical facet of the right to life and right to self-determination under Article 21 of the Constitution, by this Court in *Common Cause* (supra). In *K.S. Puttaswamy* (supra), this Court laid down three requirements to be fulfilled by the State while placing restraints on the right to privacy to protect legitimate State interests. It was held:

> *"310. ... The first requirement that there must be a law in existence to justify an encroachment on privacy is an express requirement of Article 21. For, no person can be deprived of his life or personal liberty except in accordance with the procedure established by law. The existence of law is an essential requirement. Second, the requirement of a need, in terms of a legitimate State aim, ensures that the nature*

and content of the law which imposes the restriction falls within the zone of reasonableness mandated by Article 14, which is a guarantee against arbitrary State action. The pursuit of a legitimate State aim ensures that the law does not suffer from manifest arbitrariness. Legitimacy, as a postulate, involves a value judgment. Judicial review does not reappreciate or second guess the value judgment of the legislature but is for deciding whether the aim which is sought to be pursued suffers from palpable or manifest arbitrariness. The third requirement ensures that the means which are adopted by the legislature are proportional to the object and needs sought to be fulfilled by the law. Proportionality is an essential facet of the guarantee against arbitrary State action because it ensures that the nature and quality of the encroachment on the right is not disproportionate to the purpose of the law. Hence, the threefold requirement for a valid law arises out of the mutual interdependence between the fundamental guarantees against arbitrariness on the one hand and the protection of life and personal liberty, on the other. The right to privacy, which is an intrinsic part of the right to life and liberty, and the freedoms embodied in Part III is subject to the same restraints which apply to those freedoms."

49. While the judgment is in context of the right to privacy, the analysis with respect to the threefold requirement for curtailment of such right is on the anvil of the protection guaranteed to fundamental freedoms under Article 21, and therefore, would also be the litmus test for invasion of an individual's bodily autonomy under Article 21.

50. The upshot of the above discussion leads to the following conclusions:

a) Bodily integrity is protected under Article 21 of the Constitution of India and no individual can be forced to be vaccinated.

b) Personal autonomy of an individual involves the right of an individual to determine how they should live their own life, which consequently encompasses the right to refuse to undergo any medical treatment in the sphere of individual health.

c) Persons who are keen to not be vaccinated on account of personal beliefs or preferences, can avoid vaccination, without anyone physically compelling them to be vaccinated. However, if there is a likelihood of such individuals spreading the infection to other people or contributing to mutation of the virus or burdening of the public health infrastructure, thereby affecting communitarian health at large, protection of which is undoubtedly a legitimate State aim of paramount significance in this collective battle against the pandemic, the Government can regulate such public health concerns by imposing certain limitations on individual rights that are reasonable and proportionate to the object sought to be fulfilled.

51. The submission made on behalf of the Petitioner is that the Delta and Omicron variants have shown breakthrough infections and it is clear from the scientific data that, an unvaccinated person does not pose a greater risk than a vaccinated person in terms of transmission of the infection. While this submission has been dealt with subsequently, we believe that as long as there is a risk of spreading the disease, there can be restrictions placed on individuals' rights in larger public interest. Further, extensive material from experts has been placed before this Court, which extol the benefits of vaccination in tackling the severe and life-threatening impact of the infection, specifically in terms of reduction in oxygen requirement, hospitalisation, ICU admissions and mortality, thereby easing the disproportionate burden from the upsurge of severe cases on the health infrastructure, which has already been witnessed by the country during the second wave of the pandemic where resources were woefully inadequate to stem the impact of the Delta variant on a then scarcely vaccinated population. We hasten to add that restrictions that are placed by the

Government should not be unreasonable and are open to scrutiny by constitutional courts. It is difficult for us to envisage the myriad situations in dealing with the evolving pandemic that may call for restraint on individual rights in larger public interest and therefore, as and when such limitations are challenged, they can be assessed by constitutional courts to see whether they meet the threefold requirement laid down in *K.S. Puttaswamy* (supra).

D. *Assessment of the vaccine mandates imposed by State Governments*

52. The grievance of the Petitioner pertains to the vaccine mandates imposed by various State Governments and private organisations, resulting in restrictions on fundamental freedoms of persons who have chosen not to be vaccinated. The Petitioner has alleged duality in the stand of the Respondents, as on one hand, the Union of India has categorically stated that vaccines are voluntary and on the other, the State Governments have imposed and defended restrictions on access to public places and resources for persons who are unvaccinated. The Petitioner contested the vaccine mandates on the following grounds:

(a) Natural immunity acquired from COVID-19 infection is more long-lasting and robust as compared to vaccine immunity.

(b) Serological studies show that more than 75 per cent of the Indian population has already been infected and is seropositive and therefore, has better immunity to the infection than that which can be provided by the vaccine.

(c) Vaccines do not prevent infection from or transmission of COVID-19 and are especially ineffective in preventing against infection from new variants.

53. In support of the above grounds, other than on the aspect of transmission of the virus, the Petitioner has relied on individual opinions of doctors and other advisors, news articles and findings from research studies, some of which are preprints meaning they have not been peer-reviewed and report new medical research which has yet to be evaluated and therefore, should not be used to guide clinical practice, as explained by medRxiv, a platform where several preprint articles in the field of health sciences are published. Some of the material relied on by the Petitioner has been listed below:

(a) An article in the scientific journal *Nature*[40], which states that "*studies have shown that memory plasma cells secreted antibody specific for the spike protein encoded in SARS-CoV-2 even 11 months after the infection and further that, immune memory to many viruses is stable over decades, if not for a lifetime".*

(b) A study published in the *European Journal of Epidemiology*[41], which has analysed data from 68 countries available as of 03.09.2021 and has found that "*at the country level, there appears to be no discernible relationship between percentage of population fully vaccinated and new COVID-19 cases*". It is further stated therein that in fact higher percentage of population fully vaccinated have higher COVID-19 per 1 million people.

(c) The United Kingdom's COVID-19 vaccine surveillance report, Week 40, which appears to indicate negative efficacy against infection amongst all ages above 30 years, on the basis of data between week 36 and week 39 in 2021.

54. While we are aware that courts cannot decide whether natural immunity is more resilient as compared to vaccine-acquired immunity and we do not seek to substitute our own views in matters of differences in scientific opinion, we cannot help but notice that in the first article referred to above, published in *Nature*, it has been noted that immunity in convalescent individuals (i.e., those who have recovered from COVID-19) can be boosted further by vaccinating them after a year. According to the said article, this results in the generation of more plasma cells, together with an increase in the level of SARS-CoV-2 antibodies that was up to 50 times greater than before vaccination. In the second article referred to above, published in the European Journal of Epidemiology, it has been mentioned therein that the interpretation of the

findings should be as follows:"*The sole reliance on vaccination as a primary strategy to mitigate COVID-19 and its adverse consequences needs to be reexamined, 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.*" We do not see how these conclusions and interpretations are in favour of an argument that natural immunity has proven to be better in protection against COVID-19 infection, as compared to vaccine-acquired immunity.

55. In any event, what we have to assess, in accordance with the law laid down by this Court, is whether the Union of India has taken note of scientific and medical inputs and research findings in putting together its policy advocating vaccination for the entire eligible population. Article 47 of the Constitution of India imposes an obligation on the Union of India to improve public health. It is the obligation of the State to ensure the creation and the sustaining of conditions congenial to good health. From the several obligations of the State enshrined in Part IV of the Constitution, maintenance and improvement of public health rank high as these are indispensable to the very physical existence of the community.[42]

56. It should be noted that the submission made on behalf of the Petitioner championing natural immunity is from the perspective of a healthy person. Even the Petitioner does not dispute the fact that the same standard is not applicable to persons with co-morbidities, the sick and elderly people. A cursory glance at the data recorded in the India Fact Sheet on the basis of the National Family Health Survey - 5 (2019-21) shows that (i) in the age group of 15-49 years, 57 per cent of women and 25 per cent of men are anaemic, (ii) amongst individuals aged above 15 years, 13.5 per cent of women and 15.6 per cent of men have high or very high blood sugar level or take medicines to control blood sugar level, (iii) amongst individuals aged above 15 years, 21.3 per cent of women and 24 per cent of men have hypertension or elevated blood pressure or take medicines to control blood pressure. Further, as per the 75th Round National Sample Survey (NSS), conducted from July 2017 to June 2018, the average age of the elderly population in India was 67.5 years, with 67.1 per cent of India's elderly living in rural areas. A study was conducted[43] on the basis of the data from the NSS, aiming to highlight the vulnerability of the aged amidst the COVID-19 pandemic. According to the study, out of every 100 elderly, 27.7 persons reported ailments during the previous 15 days, with cardiovascular conditions including hypertension (32.0%), endocrine conditions including diabetes (22.5%), musculoskeletal conditions (13.9%), infectious diseases (10.0%), and respiratory ailments (7.3%) being the top five conditions for seeking outpatient care among the elderly in the preceding 15 days. The Constitution, through Article 41, mandates the State to make available to the elderly the right to live with dignity and to provide the elderly, ill and disabled with assistance, medical facilities and geriatric care[44].

57. Surely, the Union of India is justified in centering its vaccination policy around the health of the population at large, with emphasis on insulating the weaker and more vulnerable sections from the risk of severe infection and its consequences, as opposed to basing its decision keeping in mind the interests of a healthy few. Given the considerable material filed before this Court reflecting the near-unanimous views of experts on the benefits of vaccination in dealing with severe disease, reduction in oxygen requirement, hospital and ICU admissions and mortality and stopping new variants from emerging, this Court is satisfied that the current vaccination policy of the Union of India, formulated in the interest of public health, is informed by relevant considerations and cannot be said to be unreasonable. Whether there is contrasting scientific opinion supporting the argument of natural immunity offering better protection against infection from COVID-19 and whether these scientific opinions can be substantiated are not pertinent for determination of the issue before this Court.

58. We now come to the crux of the challenge against coercive vaccine mandates, with respect to which the Petitioner has argued that they amount to restrictions on the fundamental rights of unvaccinated individuals and cannot be said to be proportionate, as according to the Petitioner, with the prevalence of the Omicron variant, unvaccinated people pose no greater danger to the transmission of the virus in comparison to vaccinated persons. It was claimed by the Petitioner that even if the vaccines reduced the severity of the disease, it was up to the individual to decide whether they wanted to be the beneficiary of vaccines. The State's lookout was the protection of larger public health and with both the vaccinated and unvaccinated posing nearly equal risks in transmission of the infection to others around them, the State cannot impose restrictions targeting only the unvaccinated and impeding their right to access public resources. The Petitioner has thus, alleged discrimination against the unvaccinated, who in the present situation, are placed more or less on the same footing as vaccinated individuals with respect to the transmission of the virus. In support of his submissions, the Petitioner has relied on scientific studies and reports, some of which are listed below:

(a) A letter published in the Lancet, *Regional Health*[45], which states:"*In the UK it was described that secondary attack rates among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% for vaccinated versus 23% for unvaccinated). 12 of 31 infections in fully vaccinated household contacts (39%) arose from fully vaccinated epidemiologically linked index cases. Peak viral load did not differ by vaccination status or variant type….The US Centres for Disease Control and Prevention (CDC) identifies four of the top five counties with the highest percentage of fully vaccinated population (99.9-84.3%) as "high" transmission counties. Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures.*"

(b) A study conducted on breakthrough infection in Massachusetts in July, 2021 and reported in the *Morbidity and Mortality Weekly Report*[46], which investigated 469 COVID-19 cases that had been identified among the Massachusetts residents who had travelled to a town where multiple large public events had been held and 346 cases, i.e., 74 per cent of the infections occurred in fully vaccinated individuals. Findings from the investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

59. The Petitioner has also cited various news articles reporting instances of breakthrough infections in fully vaccinated people, carrying as much virus as those who were unvaccinated, abroad as well as within India.

60. We have already referred to the material placed by the Union of India and the States appearing before this Court. While there is abundant data to show that getting vaccinated continues to be the dominant expert advice even in the face of new variants, no submission nor any data has been put forth to justify restrictions only on unvaccinated individuals when emerging scientific evidence appears to indicate that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons. To put it differently, neither the Union of India nor the State Governments have produced any material before this Court to justify the discriminatory treatment of unvaccinated individuals in public places by imposition of

vaccine mandates. No doubt that when COVID-19 vaccines came into the picture, they were expected to address, and were indeed found to be successful in dealing with, the risk of infection from the variants in circulation at the time. However, with the virus mutating, we have seen more potent variants surface which have broken through the vaccination barrier to some extent. While vaccination mandates in the era of prevalence of the variants prior to the Delta variant may have withstood constitutional scrutiny, in light of the data presented by the Petitioner, which has not been controverted by the Union of India as well as the State Governments, we are of the opinion that the restrictions on unvaccinated individuals imposed through vaccine mandates cannot be considered to be proportionate, especially since both vaccinated and unvaccinated individuals presently appear to be susceptible to transmission of the virus at similar levels.

61. Details of the vaccine mandates passed by the States of Maharashtra, Tamil Nadu, Madhya Pradesh and Delhi have been discussed earlier. It has come to our knowledge that since the judgment in this matter was reserved, the National Disaster Management Authority took a decision that there may not be any further need to invoke provisions of the DM Act for COVID-19 containment measures, taking into consideration the overall improvement in the situation. Further, the States of Maharashtra and Tamil Nadu, taking into account the present situation in which near-normalcy has been restored, have rolled back the restrictions placed on unvaccinated persons. The State of Madhya Pradesh had withdrawn the restrictions imposed on unvaccinated individuals in terms of withholding distribution of food grains from fair price shops and had notified this Court of the same during the hearing. Till the infection rate and spread remains low, as it is currently, and any new development or research finding comes to light which provides the Government due justification to impose reasonable and proportionate restrictions on the rights of unvaccinated individuals in furtherance of the continuing efforts to combat this pandemic, we suggest that all authorities in this country, including private organisations and educational institutions, review the relevant orders and instructions imposing restrictions on unvaccinated individuals in terms of access to public places, services and resources.

62. While we appreciate that it is the domain of the executive to determine how best to encourage vaccination without unduly encroaching into the fundamental rights of unvaccinated individuals, we wish to highlight the mechanism of the “health pass” employed in France, as an apt example of a proportionate measure intended to cope with the perils of the spread of the virus. We understand that a “health pass” may take the form of either the results of a viral screening test not concluding that a person has been infected with COVID-19, or proof of vaccination status, or a certificate of recovery following an infection. In a referral by the Prime Minister to review the law on managing the public health state of emergency, the Constitutional Council in France, in Decision no. 2021-824 DC dated 05.08.2021, determined that the “health pass” did not infringe the right to personal privacy guaranteed by Article 2 of the Declaration of Human and Civic Rights of 1789 as the requirement did not introduce an obligation to vaccinate.

63. Having expressed our opinion on the vaccine mandates in the prevailing context, we reiterate that vaccines effectively address severe disease arising from COVID-19 infections, are instrumental in reducing oxygen requirement, hospital and ICU admissions and mortality and continue to be the solution to stopping new variants from emerging, as per the advice of the WHO. Since the time arguments were heard in the matter, we have come to know of more variants that have now come into circulation. Given the rapidly-changing nature of the virus and the clear purpose served by the approved vaccines in terms of restoration and protection of public health, our suggestions with respect to review of vaccine mandates are limited to the

present situation alone. This judgment is not to be construed as impeding, in any manner, the lawful exercise of power by the executive to take suitable measures for prevention of infection and transmission of the virus in public interest, which may also take the form of restrictions on unvaccinated people in the future, if the situation so warrants. Such restrictions will be subject to constitutional scrutiny to examine if they meet the threefold requirement for intrusion into rights of individuals, as discussed earlier.

II. Non-disclosure of segregated clinical trial data in public domain

64. It is the complaint of the Petitioner that the COVID-19 vaccines, manufactured by Respondent Nos. 4 and 5, have been given restricted emergency approval by the Drugs Controller General of India (DCGI) in a hurried and opaque manner. Mr. Bhushan argued that clinical trials in respect of the vaccines had not been completed and at present, the vaccines are only authorised for emergency use. According to the Petitioner, while clinical trials are scheduled to be completed in the year 2023, even the full dataset from the interim analysis conducted has not been made public. The disclosure of segregated data of clinical trials is essential to determine the adverse effects, if any, across various age groups and diverse populations and accordingly, enable individuals to make more informed decisions on whether to be vaccinated. Reliance was placed on an order of this Court in *Aruna Rodrigues (4)* v. *Union of India*[47] and a judgment of the Delhi High Court dated 15.01.2019 in W.P. (C) No. 343 of 2019 titled *Master Hridaan Kumar (minor)* v. *Union of India* with respect to the importance of disclosure of relevant technical data and informed consent. Additionally, the last amended version of the Declaration of Helsinki - Ethical principles from medical research involving human subjects (hereinafter, the "Declaration of Helsinki") and a statement by the WHO dated 09.04.2015 on 'public disclosure of clinical trial results' (hereinafter, the "WHO Statement on Clinical Trials") were pressed into service to establish the significance of disclosure of data of clinical trials, so as to enable the data to be assessed independently, and not only by the vaccine manufacturer who has a commercial interest in production of the vaccines. Mr. Bhushan submitted that there would be no invasion of privacy of individuals, if personal identification data and past medical history of the trial participants was redacted and the raw data pertaining to clinical trials is made public. The further grievance of the Petitioner pertained to lack of transparency in regulatory approvals, minutes of meetings and constitution of expert bodies. The Petitioner has sought for clear detailing of the information furnished before, and evidence relied on by, the expert bodies such as the NTAGI and the Subject Expert Committee (SEC), the body which sends recommendations to the Central Drugs Standard Control Organisation, while deliberating on the applications and data of the vaccine manufacturers, and the names and institutional relationships of the experts who participated in each of these meetings. Mr. Bhushan relied on the 59th Report of the Parliamentary Standing Committee on Health and Family Welfare, in support of his submission on a need for transparency in the decision-making of the CDSCO and other regulatory authorities.

65. In response, the Union of India submitted that the procedure prescribed under the statutory regime was scrupulously followed before granting emergency approval of the vaccines manufactured by Respondent Nos. 4 and 5. As per the extant statutory regime, permission to import or manufacture new drugs including vaccines or to undertake clinical trials is granted by the Central Drugs Standard Control Organisation (CDSCO). The CDSCO, in consultation with the SEC, evaluates the applications for grant of such permission, which are to be accompanied with data as required under the Second Schedule to the New Drugs and Clinical Trials Rules, 2019 (hereinafter, the "2019 Rules") framed under the Drugs and Cosmetics Act, 1940. The SEC is a statutory body, constituted by the CDSCO under Rule 100 of the 2019 Rules, comprising group of experts with specialisation in relevant fields. According to the

Union of India, the SEC looks into the details of trials and results presented before it and examines them, interacts with the developers of the vaccines and gives them appropriate directions and eventually makes recommendations in writing, by way of a resolution, reflecting the collective opinion of all the domain experts. We were informed that the trials have been registered on the database of the Clinical Trials Registry - India, which is hosted at the ICMR's National Institute of Medical Statistics. The provisions in relation to 'Accelerated Approval Process' under the Second Schedule to the 2019 Rules were pointed out to this Court, which stipulate that "*accelerated approval process may be allowed to a new drug for a disease or condition taking into account its severity, rarity, or prevalence and the availability or lack of alternative treatments, provided that there is a prima facie case of the product being of meaningful therapeutic benefit over the existing treatment". It is further stated that "After granting accelerated approval for such drug, the post marketing trials shall be required to validate the anticipated clinical benefit*." It was submitted that applying these provisions on Accelerated Approval Process, the CDSCO, in detailed consultation with the SEC and after examining the efficacy of the vaccine and its effects, granted permission for restricted emergency use of COVAXIN and COVISHIELD, as manufactured by Respondent Nos. 4 and 5, respectively.

66. As regards COVAXIN (Whole Virion Inactivated Corona Virus Vaccine), the Union of India stated that application for permission to manufacture the vaccine was made by Bharat Biotech on 23.04.2020. The CDSCO, in consultation with the SEC, granted permission to Bharat Biotech for conducting Phase I/II clinical trials on 29.06.2020 and Phase III clinical trials on 23.10.2020. Respondent No. 4 submitted interim safety and immunogenicity data of Phase I and Phase II clinical trials carried out in the country, along with safety data, including Serious Adverse Events data, of the ongoing Phase III clinical trial in the country. The data provided by Respondent No. 4 from the various phases were evaluated and analysed by the SEC, which consisted of eminent experts from the fields of microbiology, medicine, pulmonary medicine, paediatrics and immunology and immunogenetics. The resolutions of the various meetings of the SEC, which also required the presence of the developer/manufacturer with the necessary information, have been put up on the website of the MoHFW at every stage. In its meeting dated 02.01.2021, observing that on receiving further updated data, justification and request for consideration of the proposal in the wake of a new mutation of the COVID-19 virus, and on recognising that the data generated till then showed that the vaccine had the potential to target mutated coronavirus strains, the SEC recommended for grant of permission for restricted use in emergency situation in public interest in clinical trial mode, as an abundant precaution. While granting such permission, Respondent No. 4 was directed to continue the ongoing Phase III clinical trial and submit data from the trial, as and when available. Approval for restricted use in emergency situation in clinical trial mode with various conditions/restrictions was granted by the CDSCO to Respondent No. 4 to manufacture COVAXIN on 03.01.2021.

67. Thereafter, Respondent No. 4 submitted the interim safety and efficacy data of Phase III clinical trial, which was reviewed by the SEC in meetings held periodically. In its meeting conducted on 10.03.2021, the SEC, after detailed deliberation on the updated interim safety and efficacy data of the phase III clinical trial, recommended omission of the condition of the use of the vaccine in clinical trial mode. However, it was recommended that the vaccine be continued to be used under restricted use in emergency situation condition. Following expansion of the Government's vaccination drive to include individuals in the age group of 18-45 years, in its meeting held on 23.04.2021, the SEC considered Bharat Biotech's proposal to unblind the trial participants in the said age group. After detailed deliberations, the SEC recommended the unblinding of the participants in the said age group, upon the request of the

participants or the principal investigator after completion of two months from the second dose. Eventually, on consideration of relevant data of Phase I and Phase II clinical trials along with safety data of 6 months' Phase III clinical trial, including data of serious adverse events till the date, the SEC in its meeting dated 19.01.2022 noted that there had been no safety issues and the vaccine maintained its efficacy, specially to avoid hospitalisation and severe infections in the existing situation as well. Accordingly, the SEC recommended that the status of approval of COVAXIN from the restricted use in emergency situation to the New Drug permission be updated, along with the condition that the firm shall continue to submit data of ongoing clinical trial and monitor AEFIs. The Union of India pointed out that Phase I and Phase II clinical trial reports were published in the Lancet Infectious Diseases Journal, which was publicly available. Further, to the knowledge of the Union of India, Phase III trial publication had been submitted to the Lancet journal by Respondent No. 4 on 02.07.2021, a copy of the manuscript of which has been provided to this Court.

68. COVISHIELD (ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)) manufactured by Respondent No. 5 was developed by the Serum Institute of India in collaboration with Oxford University and AstraZeneca under technology transfer. As the clinical development of the said vaccine, including Phase I clinical trial, was conducted in other countries, Phase II/III clinical trials were conducted by Respondent No. 5 in the country. Application for permission to manufacture COVISHIELD for test, examination and analysis was first made by Respondent No. 5 on 03.05.2020. The safety, immunogenicity and efficacy data of Phase II/III clinical trials of the AstraZeneca vaccine carried out in the United Kingdom, Brazil and South Africa were submitted to the SEC, along with the safety and immunogenicity data from the ongoing Phase II/III clinical trials in India. On reviewing this data as well as the approval dated 30.12.2020 granted by the United Kingdom's Medicines and Healthcare Products Regulatory Authority (hereinafter, the “UK-MHRA”) for the AstraZeneca vaccine along with its conditions/restrictions, the SEC, in its meeting dated 01.01.2021, noted that the safety and immunogenicity data from the Indian study was comparable with that of the overseas clinical trial data. After detailed deliberation and taking into account the emerging situation, the SEC recommended grant of permission for restricted emergency use of the vaccine, subject to various regulatory provisions and conditions, including requirement to submit relevant data from the ongoing clinical trials nationally and internationally at its earliest. Eventually, in its meeting dated 19.01.2022, the SEC considered the request of Respondent No. 5 to grant permission to manufacture the vaccine, excluding the conditions for restricted use in emergency situation and other conditions, on the lines of Marketing Authorisation by the UK-MHRA for the parent vaccine. After detailed deliberation and consideration of safety, immunogenicity and efficacy data from Indian and overseas clinical trials, amongst other data, the SEC recommended grant of New Drug permission or regular approval, with conditions that data of ongoing clinical trials and vaccine shall continue to be supplied and AEFIs shall continue to be monitored.

69. We were directed to Rule 25 of the 2019 Rules, framed under the Drugs and Cosmetics Act, 1940, which provides that the clinical trial shall be conducted in accordance with approved clinical trial protocol and other related documents as per the requirements of Good Clinical Practices (GCP) guidelines and the other rules. The expert committee set up by the CDSCO under Rule 25(vi) in consultation with clinical experts formulated the GCP guidelines for generation of data on drugs. The ‘Ethical Principles’, which are part of the said guidelines, protect principles of privacy and confidentiality of human subjects of research. The learned Solicitor General also relied upon para 2.4.4 of the GCP guidelines, which require safeguarding of the confidentiality of research data that might lead to identification of individual subjects. He further referred to the important role played by the Ethics Committee under Rule

11 of the 2019 Rules, which includes safeguarding the rights, safety and well-being of trial subjects in accordance with the said rules. The 2019 Rules also empower the Ethics Committee to discontinue or suspend the clinical trial in case it concludes that the trial is likely to compromise the right, safety or well-being of the trial subject. As per the ICMR's National Ethical Guidelines for Biomedical and Health Research involving Human Participants, the four basic ethical principles for conducting biomedical and health research are (i) respect for persons (autonomy), (ii) beneficence, (iii) non-malfeasance and (iv) justice. These four basic principles have been expanded into 12 general principles, including the 'principle of ensuring privacy and confidentiality' which requires maintaining the privacy of potential participants, her/his identity and records, with access given to only those authorised. As regards transparency of functioning of expert bodies, it was submitted by the Union of India that recommendations of the SEC in all its meetings are uploaded on the website of the CDSCO. Additionally, the detailed minutes of NTAGI meetings were already available in public domain, which can be downloaded from both the ICMR and the MoHFW websites.

70. The contention of Respondent No. 4 is that COVAXIN has undergone all clinical trials. In Phase III, trials revealed a 77.8% efficacy against symptomatic COVID-19 disease. The findings of the clinical trials have been published in reputed peer-reviewed journals and are readily available on the website of Respondent No. 4. A reference was made by Respondent No. 4 to the WHO Statement on Clinical Trials, to submit that it is only the key outcomes and findings which are required to be made publicly available. It was contended that Respondent No. 4 is in compliance with the WHO Statement on Clinical Trials as the key outcomes and results of the Phase III clinical trial have been published in the Lancet. On behalf of Respondent No. 5, it was submitted that the clinical data generated during the trials had been submitted to the regulatory authorities for obtaining permissions/licences etc. Further, the peer-reviewed study of the partial clinical data of Phase II/III trials had already been published in reputed scientific journals, which included all the information necessary for safeguarding the public as well as informing them of the credibility and efficacy of the vaccine. According to Respondent No. 5, the raw data of the clinical trials served no greater public purpose than the data which was already available in the public domain. All applicable medico-legal, scientific and ethical requirements had been strictly adhered to by Respondent No. 5.

71. In rejoinder, the learned counsel for the Petitioner argued that there is no transparency in the process of approvals of vaccines and relevant data is not always placed before the NTAGI. He referred to a news article in The Wire, according to which Jayaprakash Muliyil, a member of the NTAGI had stated that the NTAGI had not recommended vaccination of children in the age group of 12-14 years. He also drew the attention of this Court to non-supply of relevant data to the NTAGI at the time of approval of the Rotavac vaccine against rotavirus. The Petitioner further complained of the haste shown in grant of emergency approval to Respondent No. 4. The Petitioner has sought support of a decision of the United States District Court for the Northern District of Texas dated 06.01.2022 in *Public Health and Medical Professionals for Transparency* v. *Food and Drug Administration*, which highlighted the need for transparency in disclosure of clinical trial data. It was reiterated by the Petitioner that privacy of individuals would not be at risk as their personal identification data can be redacted before disclosing segregated data of clinical trials.

72. It is settled law that courts cannot take judicial notice of facts stated in a news item published in a newspaper. A statement of fact contained in a newspaper is merely hearsay and therefore, inadmissible in evidence, unless proved by the maker of the statement appearing in court and deposing to have perceived the fact reported.[48] In the absence of anything on record in the present case to substantiate the statement

made by Mr. Jayaprakash Muliyil, member of the NTAGI, we are not inclined to take judicial notice of the news article reported in The Wire, even more so in light of the affidavit filed on behalf of the Union of India stating that the relevant data was examined by the expert bodies at all stages before granting emergency use approval to the vaccines. We are also of the opinion that the evidence relating to the approval process of the Rotavac vaccine has no relevance to the dispute in this case. On the basis of the said two incidents, it cannot be concluded that the emergency use approval to COVISHIELD and COVAXIN recommended by the SEC are not in accordance with the statutory regime.

73. At this stage, it is worthwhile to refer to the statutory regime in place. According to Rule 19 of the 2019 Rules, no person, institution or organisation shall conduct clinical trial of a new drug or investigational new drug, except in accordance with the permission granted by the Central Licensing Authority (i.e., the CDSCO) and without following the protocol approved by the Ethics Committee for clinical trial, registered in accordance with the provisions of Rule 8. Rule 19(2) of the 2019 Rules provides that every person associated with the conduct of clinical trial of a new drug or investigational new drug shall follow the general principles and practices as specified in the First Schedule. The methodology to be adopted in a clinical trial is provided for in the First Schedule to the 2019 Rules, relevant clauses of which are as under:—

"GENERAL PRINCIPLES AND PRACTICES FOR CLINICAL TRIAL

1. General Principles. " (1) The principles and guidelines for protection of trial subjects as described in Third Schedule as well as Good Clinical Practices guidelines shall be followed in conduct of any clinical trial.

xxx

4. Conduct of Clinical Trial. " Clinical trial should be conducted in accordance with the principles as specified in Third Schedule. Adherence to the clinical trial protocol is essential and if amendment of the protocol becomes necessary the rationale for the amendment shall be provided in the form of a protocol amendment. Serious adverse events shall be reported during clinical trial in accordance with these Rules.

xxx

6. Reporting. "Report of clinical trial shall be documented in accordance with the approaches specified in Table 6 of the Third Schedule. The report shall be certified by the principal investigator or if no principal investigator is designated then by each of the participating investigators of the study."

74. It is clear from the above, that there are stringent statutory requirements which have to be complied with by the manufacturers of vaccines and other participants, during different stages of clinical trials of vaccines. Further, we also note that the GCP guidelines are statutorily required to be followed.

75. The GCP guidelines further elaborate on the role of the Ethics Committee. According to the GCP guidelines, the Ethics Committee is an independent review board or a committee comprising of medical/scientific and non-medical/non-scientific members, whose responsibility it is to verify the protection of the rights, safety and well-being of human subjects involved in a study. The independent review provides public reassurance by objectively, independently and impartially reviewing and approving the "Protocol", the suitability of the investigator(s), facilities, methods and material to be used for obtaining and documenting "Informed Consent" of the study subjects and adequacy of confidentiality safeguards. Para 2.4 of the GCP guidelines deal with ethical and safety considerations, which provide that all research involving human subjects should be conducted in accordance with the ethical principles contained in the current version of the Declaration of Helsinki, as annexed to the guidelines. Amongst the principles to be followed, the GCP guidelines require adherence to the "principles of accountability and transparency" and "principles of

public domain":

"Principles of accountability and transparency, whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner, after full disclosure is made by those associated with the Study of each aspect of their interest in the Study, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality and the rights of the researcher, full and complete records of the research inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary.

xxx

Principles of public domain, whereby the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time."

76. The GCP guidelines have been formulated following the Declaration of Helsinki. The relevant portion of the said Declaration is as follows:

"Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Research Registration and Publication and Dissemination of Results

...

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication."

77. It is profitable to refer to the relevant portion of the WHO Statement on Clinical Trials, which is as under:

"Reporting timeframes for clinical trials

Clinical trial results are to be reported according to the timeframes outlined below. Reporting is to occur in BOTH of the following two modalities.

1. *The main findings of clinical trials are to be submitted for publication in a peer reviewed journal within 12 months of study completion and are to be published through an open access mechanism unless there is a specific reason why open access cannot be used, or otherwise made available publicly at most within 24 months of study completion.*
2. *In addition, the key outcomes are to be made publicly available within 12 months of study completion by posting to the results section of the primary clinical trial registry. Where a registry is used without a results database available, the results should be posted on a free-to-access, publicly available, searchable institutional website of the Regulatory Sponsor, Funder or Principal*

Investigator."

78. The GCP guidelines are being scrupulously followed, according to the Union of India. The principles of "public domain" in the GCP guidelines provide for research, experimentation or evaluation in response to the research to be brought into the public domain. The results of the clinical trials are generally to be made known through scientific and other publications. The requirement of publication, according to the WHO, also relates to the main findings of clinical trials to be published in a peer-reviewed journal and the key outcomes to be made publicly available, within 12 months of study completion. The Petitioner complains of opaqueness in clinical trials as the general public do not have access to, and the opportunity to be aware of, all the necessary details by segregated clinical trial data (primary datasets) not being available. There is no challenge by the Petitioner to the GCP guidelines. As required by the WHO Statement on Clinical Trials and the GCP guidelines, findings of the clinical trials and the key outcomes of the trials have been published. In light of the existing statutory regime, we do not see it fit to mandate the disclosure of primary clinical trial data, when the results and key findings of such clinical trials have already been published.

79. After examining the judgment of the United States District Court for the Northern District of Texas (hereinafter, the "US District Court"), we are afraid that the said decision cannot be said to be relevant for adjudication of the dispute in the present case. The grievance of the plaintiff in the said case pertained to all data and information for the Pfizer vaccine, enumerated under the relevant provisions of the Freedom of Information Act, not being provided by the United States Food and Drug Administration. The US District Court referred to the Freedom of Information Act to hold that the citizenry has a right to be provided with the relevant information pertaining to the Pfizer vaccine and that such 'information is often useful only if it is timely'. The US District Court directed expeditious completion of the plaintiff's request after concluding that the request under the Freedom of Information Act was of paramount importance. We note that with respect to COVAXIN and COVISHIELD, results of clinical trials have been published in accordance with our statutory regime in place. Reliance placed by the Petitioner on European Medicines Agency policy on publication of clinical data for medicinal products for human use is also not relevant as the GCP guidelines relating to the disclosure of clinical trial data, framed under the 2019 Rules, currently govern the field of disclosure of clinical trial data in India.

80. An analysis of the submissions made by the learned counsel appearing for the parties and a close scrutiny of the material placed on record would show that there is a strict statutory regime in force for grant of approvals to vaccines. Specialist bodies established under the provisions of the Drugs and Cosmetics Act, 1940 and the rules framed thereunder comprise of domain experts in the relevant field, who conduct a thorough scrutiny of the material produced by the manufacturers before granting approval. The information provided on behalf of the Union of India substantiates that the data provided by the vaccine manufacturers was considered by the SEC over a period of time and several conditions were imposed at the time of recommending approvals, which have been modified or lifted subsequently on availability of further data arising from the clinical trials before the SEC, as can be seen from the minutes of the meetings of the SEC, available on the website of the MoHFW. We do not agree with the submission on behalf of the Petitioner that emergency approvals to the vaccines were given in haste, without properly reviewing the data from clinical trials. We are also of the opinion that the Parliamentary Standing Committee report relied upon by Mr. Bhushan is not relevant and the lapses pointed out therein pertain to the year 2011, which have no obvious connection to the grant of approval to Respondent Nos. 4 and 5 for the restricted emergency use of their respective vaccines. As long as the relevant information relating to the minutes of the meetings of the regulatory bodies

and the key outcomes and findings of the trials are available in public domain, the Petitioner cannot contend that every minute detail relating to clinical trials be placed in public domain to enable an individual to take an informed, conscious decision to be vaccinated or not. Given the widespread affliction caused by the virus, there was an imminent need of manufacturing vaccines which would keep the infection at bay. We would like to highlight that both the vaccines have been approved by the WHO as well. A perusal of the material placed on record would show that there is material compliance with the procedure prescribed under the Drugs and Cosmetics Act, 1940 and the 2019 Rules, before grant of approval for the emergency use of the two vaccines. However, it is made clear that subject to the protection of privacy of individual subjects and to the extent permissible by the 2019 Rules, the relevant data which is required to be published under the statutory regime and the WHO Statement on Clinical Trials shall be made available to the public without undue delay, with respect to the ongoing post-marketing trials of COVAXIN and COVISHIELD as well as ongoing clinical trials or trials that may be conducted subsequently for approval of other COVID-19 vaccines/vaccine candidates.

III. Improper collection and reporting of AEFIs

81. The contention of the Petitioner is that there have been several adverse effects from vaccines, including deaths. The Petitioner has sought to fault the Government's mechanisms in place for handling of the adverse events. According to the Petitioner, during Phase III trials, where small controlled trials of a limited number of participants are conducted, a significant increase in adverse events may not be seen. But after licensure, when the vaccines are administered to the masses, rare reactions show up, which is why Phase IV post-marketing trials are legally mandated. It was pointed out by the Petitioner that there has been a revision of the rules by the WHO for classifying AEFIs in 2018. As per the revised mechanism, only reactions that are previously acknowledged to be caused by the vaccine are classified as vaccine-related reactions. Reactions observed during post-marketing surveillance are not considered as 'consistent with causal association with vaccine', if a significant increase in such reactions during Phase III trials had not been recorded. According to the Petitioner, this acquires significance in the context of trials conducted in this country, as the control trial in Phase III did not go on in the manner intended, with several members of the original control group prematurely unblinded and offered the vaccine. The Petitioner contends that owing to 'dilution of Phase III control trials prematurely', there are no controls to compare against, making it difficult to ascertain which adverse events are caused by the vaccine. Therefore, reactions which are not "known reactions" to the vaccine are not considered AEFIs. In light of this, it is necessary for the authorities to carefully monitor all vaccine recipients and publicly record all adverse events.

82. Taking this argument further, the Petitioner contended that the adverse events reporting system in India is not transparent, with obscure investigation and follow-up of deaths and other serious adverse events after COVID-19 vaccination. The Petitioner relied on a letter published in The Hindu on 17.03.2021, written by a group of experts in public health, ethics, medicine, law, and journalism to the Minister for Health & Family Welfare and the DCGI, appealing for "time-bound and transparent investigation" following deaths and serious adverse effects after COVID-19 vaccination. A presentation made by the National AEFI Committee in a meeting held on 31.03.2021 was referred to by the Petitioner to claim that complete documentation was not available for all the severe and serious adverse events (including deaths) that had occurred till the time. Additionally, it was contended that no data pertaining to the AEFIs already classified nor any analysis of the same had been published publicly till date. The Petitioner also drew the attention of this Court to the Vaccine Adverse Event Reporting System (VAERS) in place in the United States, which published all vaccine

injury reports every Friday, received till about a week prior to the release date. It was brought to the notice of this Court that 77,314 adverse events have been reported in India as on 12.03.2022, amounting to 0.004% of the total vaccination. The Petitioner has pointed out that the percentage of adverse events reported in Europe is much larger than the percentage identified in India, which would show that correct figures are not being published by the Government.

83. On behalf of the Union of India, the procedures and protocols for monitoring of adverse event following immunisation under the National Adverse Event Following Immunisation Surveillance Guideline were elaborated upon. The National Adverse Event Following Immunisation Surveillance Secretariat, established in the Immunisation Technical Support Unit in 2012, had staff dedicated for managing Adverse Event Following Immunisation surveillance system. It was further strengthened by the National Adverse Event Following Immunisation Surveillance Technical Collaborating Centre, comprising of experts from Lady Hardinge Medical College and Allied Hospitals in New Delhi. Adverse Event Following Immunisation Committees were formed at the national and state levels to provide guidance to the National AEFI Surveillance and carry out documentation, investigation and causality assessment, besides training and orientation of health care workers and others involved in AEFI. According to the Union of India, a foolproof protocol for reporting and causality assessment for any AEFI with Universal Immunisation Program (UIP) and Non-UIP vaccines has been established. The National AEFI Committee gets periodical reports regarding 'minor AEFIs', 'severe AEFIs' and 'serious AEFIs'. Online reporting of all serious and severe AEFIs at the district level to be communicated to relevant authorities at the state/national level is done on a web-based portal, SAFEVAC (Surveillance and Action for Events Following Vaccination). All serious and severe adverse events following vaccination even at district level are uploaded online on SAFEVAC. It was submitted on behalf of the Union of India that case details, scanned copies of reports are uploaded on SAFEVAC, which also has facilities for generating dashboards and line-lists at different levels.

84. Further, a similar feature of reporting of all AEFIs (including minor) by the vaccinator was made available on the Co-WIN portal. District Immunisation Officers (DIOs) were given the facility to report *AEFI cases* about which they have information from such individuals who do not have access to Co-WIN. Departmental orders and standard operating procedures have been issued for further investigations and sharing of hospital records by the DIOs through Co-WIN. The Union of India has brought to the notice of this Court that an alignment with the Pharmacovigilance Programme of India (PvPI) under Indian Pharmacopoeia Commission has been developed for receipt of information regarding *AEFI cases* from around 300 Adverse Drug Reaction Monitoring Centers in medical colleges and large hospitals. The Union of India has highlighted that information from the PvPI and the CDSCO are collated and studied, in case of any new, previously unknown events identified through AEFI surveillance. A press release of the MoHFW dated 17.02.2017 titled 'Maximum Possible Marks to Indian NRA in WHO Assessment' has been placed before this Court to state that the AEFI Surveillance System in India (which is in use for COVID-19 vaccination) has been approved by global experts in an assessment conducted by the WHO in 2017. Given the novel nature of the virus, membership of the National AEFI Committee has been expanded to include neurologists, cardiologists, respiratory medicine specialists and medical specialists, with even States/Union Territories requested to expand their AEFI Committees on a similar scale to strengthen AEFI surveillance for COVID-19 vaccines. Causality assessment of *AEFI cases* is conducted at the state and the national levels by experts trained as per the causality assessment checklist, based on the definition and algorithm developed by the WHO. Once approved by experts of the National AEFI Committee, results of causality assessment of *AEFI cases* are made available in the

public domain and are shared with the CDSCO, amongst other authorities, for appropriate regulatory action.

85. As regards the present status of AEFI surveillance for COVID-19 vaccination, it was submitted that as the causality assessment of reported *AEFI cases* is a time-consuming process, a method of rapid review and assessment had been initiated at the national level to quickly review available information in each case and look for trends in reporting of specific events or unusual cases requiring further early investigation and assessment. All cases of serious and severe AEFIs, including reported deaths, are subjected to rapid reviews, analysis and causality assessment done by a team of trained subject experts. It was clarified that mere reporting of *AEFI case* should not be attributed to the vaccine unless proved by the causality assessment analysis. The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), an additional body of experts, is also involved in providing guidance on vaccine safety and surveillance, thus, aiding in the prompt identification of AEFIs for the purpose of identifying and understanding evolving trends in the disease and taking prompt action. 2,116 serious and severe AEFIs have been reported from 1,19,38,44,741 doses of COVID-19 vaccine administered till 24.11.2021. While a report of rapid review and analysis completed for 495 cases had been submitted, a further report of 1,356 serious and severe *AEFI cases* had been presented to the NEGVAC and the rapid review and analysis of balance cases was underway. Press releases around a report on bleeding and clotting events following COVID-19 vaccination being submitted to the MoHFW by the National AEFI Committee and on clarification on deaths following vaccination and process of causality assessment were placed before this Court. Therefore, the Union of India submitted that there was continuous monitoring and examination of *AEFI cases* in India and there is no basis for the allegations around AEFIs not being properly collected and lack of transparency in their investigation.

86. From the material placed before us, we note that the National AEFI Surveillance Secretariat has been functioning for 10 years and as has been pointed out, there is a well-established protocol in place for identification and monitoring of AEFIs. The website of the MoHFW carries the results of causality assessment of *AEFI cases*, from which the public can obtain relevant information pertaining to AEFIs. We have been informed that a thorough causality assessment analysis of AEFIs is carried out by experts and not every severe disease and death can be attributed to vaccination. Reactions are examined by experts specifically trained to undertake causality analysis before notifying such reactions as adverse events arising from vaccination. There is a well-defined mechanism for collection of data relating to adverse events that occur due to COVID-19 vaccines and the Government of India has taken steps to direct all concerned medical professionals at the ground level to report adverse events. Even medical practitioners at private hospitals are associated with reporting of adverse events. Therefore, we are not inclined to accept the broad-strokes challenge mounted by the Petitioner that the surveillance system of AEFIs in this country is faulty and the correct figures of those who have suffered any side effects, severe reactions or deaths post-inoculation have not been disclosed.

87. As regards the contention of the Petitioner on abandoning of Phase III trials, we note that unblinding of participants during the Phase III trial was done on the recommendation of the SEC. The Union of India has emphasized that at every stage, the deliberations of domain experts, which involved discussions with the manufacturers, focused on safety and immunogenicity of the vaccines and it was only when there was consensus among domain experts that it was safe to extend the immunisation drive beyond the category of 'healthcare workers/frontline workers', the appropriate decisions were taken. In doing so, the available trial data, trajectory of the pandemic, evidence, future contingencies and several other factors have always been

heeded. There is no challenge to the decision of the SEC, a body of domain experts, as being unreasonable or arbitrary, nor have we been called upon to determine whether adequate time was devoted to recognise all relevant reactions as vaccine-related reactions prior to such unblinding. What the Petitioner seeks is the monitoring of all adverse events and publication of the results of investigation. The Union of India has painstakingly taken this Court through the details of the procedure followed to closely monitor, review and escalate the incidence of AEFIs to appropriate authorities. As regards previously unknown/unidentified reactions seen during the monitoring of AEFIs at the time of vaccine administration, the Union of India has elaborated on the role of the PvPI and the CDSCO, which collate and study such reactions. We believe this adequately addresses the Petitioner's concerns, as this Court has been informed that previously unidentified events are also being taken into consideration and investigated. We trust the Union of India to have the appropriate authorities ensure that this leg of the AEFI surveillance system is not compromised with while meeting the requirements of the rapid review and assessment system followed at the national level.

88. The Petitioner had taken issue with the present system to the extent it allows only DIOs or the vaccinators to report AEFIs. According to the Petitioner, the repository of AEFIs should be as detailed as the VAERS in the United State of America. The Petitioner further submitted that individuals and doctors must be able to report adverse events, with the reporter being given a unique identification number and the reports being openly accessible. The response of the Union of India on this issue is that the DIOs have been instructed to set up a network with private hospitals to report AEFIs. Training has been provided to state officers, medical officers, private practitioners and frontline health workers on their role in AEFI surveillance. Even auxiliary nurse midwives have been instructed to notify all AEFIs. However, we are in agreement with the suggestion made by the Petitioner that there should be a mechanism by which individuals and private doctors should be permitted to report suspected adverse events. Information relating to adverse effects following immunisation is crucial for the purpose of understanding the safety of the vaccines that are being administered, apart from being instrumental in further scientific studies around the pandemic. There is an imminent need for collection of requisite data of adverse events and wider participation of people in reporting the adverse events is necessary for the purpose of gathering correct information. Thus, the Union of India is directed to facilitate the reporting of suspected adverse events by individuals and private doctors on a virtual platform and the reports so made shall be publicly accessible after being given unique identification numbers, without listing any personal or confidential data of the persons reporting. All necessary steps to create awareness of, and to navigate, this platform for self-reporting shall be effectuated by the Government, roping in and training relevant participants right from the ground level of vaccine administration.

IV. Vaccination of Children

89. The opinion of the Petitioner is that children are at almost no risk from COVID-19 and instances of previously healthy children requiring hospitalisation due to COVID -19 are exceedingly rare. While referring to articles in the Nature and the Lancet, the Petitioner contended that scientific evidence shows that risk of administering vaccines to children outweigh the benefits offered by the vaccine in children. The Petitioner further submitted that serological studies would show that a large number of children have already acquired antibodies to COVID-19. The Petitioner has highlighted the risk of myocarditis associated with the mRNA vaccines, on the basis of which, several European countries have recently stopped the use of Moderna vaccines for those under the age of 30. He has also pointed out that these risks had not been identified in the initial vaccine trials as the trial size was too small to uncover rare risks, which were

discovered after mass vaccination. The Petitioner has sought for results as well as the primary data of clinical trials conducted on the paediatric population to be made public.

90. In response thereto, the Union of India contended that paediatric vaccination is advised by global agencies such as the WHO, the UNICEF and the CDC. Expert opinion in India is in tune with global consensus in favour of vaccination of children. We are informed that 8,91,39,455 doses of COVAXIN have been administered to individuals in the age group of 15 to 18 years as on 12.03.2022. The AEFIs reported are 1,739 minor complaints, 81 serious complaints and 6 severe. According to the Union of India, the said data would show that the vaccine does not pose threat to the safety of children. As regards the clinical trials, para 2.4.6.2 of the GCP guidelines were relied on to show that children are not required to be involved in research that could be carried out equally well with adults and further that, for the clinical evaluation of a new drug, study in children should be carried out after the Phase III clinical trials in adults. It has been stated that paediatric vaccination was considered at a stage where more than substantial data on safety and immunogenicity of COVAXIN in adults was available. To avoid any risks, clinical trials were also conducted on a limited number of children as per the protocol approved by domain experts. Having found no serious adverse event in the said trials, paediatric vaccination was initiated in a phased manner, starting from the eldest paediatric age group of 15 to 18 years. On 12.05.2021, on the basis of recommendations of the SEC, the CDSCO granted permission to Respondent No. 4 to conduct Phase II/Phase III clinical trials of COVAXIN for the age group of 2 to 18 years. Thereafter, Respondent No. 4 had submitted an application for grant of permission to manufacture COVAXIN paediatric vaccines for emergency use, which was subsequently granted by the CDSCO. It was argued on behalf of the Union of India that expert opinion is to the effect that paediatric vaccinations are always preventive in nature and are administered to avoid any risk of infection and of prolonged clinical symptoms.

91. This Court cannot sit in judgment of leading scientific analysis relating to the safety of paediatric vaccination. Experts in science may themselves differ in their opinions while taking decisions on matters related to safety and allied aspects, but that does not entitle the Court to second-guess expert opinion, on the basis of which the Government has drawn up its policies. The decision taken by the Union of India to vaccinate paediatric population in this country is in tune with global scientific consensus and expert bodies like the WHO, the UNICEF and the CDC have also advised paediatric vaccination. It would not only be beyond our jurisdiction but also hazardous if this Court were to examine the accuracy of such expert opinion, based on competing medical opinions. As already stated, the scope of judicial review does not entail the Court embarking upon such misadventures. Therefore, we reject the contention of the Petitioner that this Court has to intervene in paediatric vaccination on the ground that it is unscientific.

92. With respect to results of clinical trials, we note that the Union of India has stated that the results of clinical trials of COVAXIN for paediatric population have already been published. We also note that for the age group of 12 to 14 years, Biological E's Corbevax is being administered. Keeping in line with the WHO Statement on Clinical Trials, the Declaration of Helsinki and the GCP guidelines, we direct the Union of India to ensure that key findings and results of the clinical trials of Corbevax be published at the earliest, if not already done. Neither vaccine is an mRNA vaccine and to this extent, the apprehensions of the Petitioner with respect to the associated risks of mRNA vaccines are unfounded in the present situation.

Conclusion

93. In conclusion, we have summarised our findings on the various issues

considered by us, below:

(i) Given the issues urged by the Petitioner have a bearing on public health and concern the fundamental rights of individuals in this country, we are not inclined to entertain any challenge to the maintainability of the Writ Petition.

(ii) As far as judicial review of policy decisions based on expert opinion is concerned, there is no doubt that wide latitude is provided to the executive in such matters and the Court does not have the expertise to appreciate and decide on merits of scientific issues on the basis of divergent medical opinion. However, this does not bar the Court from scrutinising whether the policy in question can be held to be beyond the pale of unreasonableness and manifest arbitrariness and to be in furtherance of the right to life of all persons, bearing in mind the material on record.

(iii) With respect to the infringement of bodily integrity and personal autonomy of an individual considered in the light of vaccines and other public health measures introduced to deal with the COVID-19 pandemic, we are of the opinion that bodily integrity is protected under Article 21 of the Constitution and no individual can be forced to be vaccinated. Further, personal autonomy of an individual, which is a recognised facet of the protections guaranteed under Article 21, encompasses the right to refuse to undergo any medical treatment in the sphere of individual health. However, in the interest of protection of communitarian health, the Government is entitled to regulate issues of public health concern by imposing certain limitations on individual rights, which are open to scrutiny by constitutional courts to assess whether such invasion into an individual's right to personal autonomy and right to access means of livelihood meets the threefold requirement as laid down in *K.S. Puttaswamy* (supra), i.e., (i) legality, which presupposes the existence of law; (ii) need, defined in terms of a legitimate State aim; and (iii) proportionality, which ensures a rational nexus between the objects and the means adopted to achieve them.

(iv) On the basis of substantial material filed before this Court reflecting the near-unanimous views of experts on the benefits of vaccination in addressing severe disease from the infection, reduction in oxygen requirement, hospital and ICU admissions, mortality and stopping new variants from emerging, this Court is satisfied that the current vaccination policy of the Union of India is informed by relevant considerations and cannot be said to be unreasonable or manifestly arbitrary. Contrasting scientific opinion coming forth from certain quarters to the effect that natural immunity offers better protection against COVID-19 is not pertinent for determination of the issue before us.

(v) However, no data has been placed by the Union of India or the States appearing before us, controverting the material placed by the Petitioner in the form of emerging scientific opinion which appears to indicate that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons. In light of this, restrictions on unvaccinated individuals imposed through various vaccine mandates by State Governments/Union Territories cannot be said to be proportionate. Till the infection rate remains low and any new development or research finding emerges which provides due justification to impose reasonable and proportionate restrictions on the rights of unvaccinated individuals, we suggest that all authorities in this country, including private organisations and educational institutions, review the relevant orders and instructions imposing restrictions on unvaccinated individuals in terms of access to public places, services and resources, if not already recalled. It is clarified that in the context of the rapidly-evolving situation presented by the COVID-19 pandemic, our suggestion to

review the vaccine mandates imposed by States/Union Territories, is limited to the present situation alone and is not to be construed as interfering with the lawful exercise of power by the executive to take suitable measures for prevention of infection and transmission of the virus. Our suggestion also does not extend to any other directions requiring maintenance of COVID-appropriate behaviour issued by the Union or the State Governments.

(vi) As regards non-disclosure of segregated clinical data, we find that the results of Phase III clinical trials of the vaccines in question have been published, in line with the requirement under the statutory regime in place, the GCP guidelines and the WHO Statement on Clinical Trials. The material provided by the Union of India, comprising of minutes of the meetings of the SEC, do not warrant the conclusion that restricted emergency use approvals had been granted to COVISHIELD and COVAXIN in haste, without thorough review of the relevant data. Relevant information relating to the meetings of the SEC and the NTAGI are available in public domain and therefore, challenge to the procedures adopted by the expert bodies while granting regulatory approval to the vaccines on the ground of lack of transparency cannot be entertained. However, we reiterate that subject to the protection of privacy of individual subjects, with respect to ongoing clinical trials and trials that may be conducted subsequently for COVID-19 vaccines, all relevant data required to be published under the extant statutory regime must be made available to the public without undue delay.

(vii) We do not accept the sweeping challenge to the monitoring system of AEFIs being faulty and not reflecting accurate figures of those with severe reactions or deaths from vaccines. We note that the role of the Pharmacovigilance Programme of India and the CDSCO, as elaborated upon by the Union of India, collates and studies previously unknown reactions seen during monitoring of AEFIs at the time of vaccine administration and we trust the Union of India to ensure that this leg of the AEFI surveillance system is not compromised with, while meeting the requirements of the rapid review and assessment system followed at the national level for AEFIs.

(viii) We are also of the opinion that information relating to adverse effects following immunisation is crucial for creating awareness around vaccines and their efficacy, apart from being instrumental in further scientific studies around the pandemic. Recognising the imperative need for collection of requisite data of adverse events and wider participation in terms of reporting, the Union of India is directed to facilitate reporting of suspected adverse events by individuals and private doctors on an accessible virtual platform. These reports shall be made publicly accessible, without compromising on protecting the confidentiality of the persons reporting, with all necessary steps to create awareness of the existence of such a platform and of the information required to navigate the platform to be undertaken by the Union of India at the earliest.

(ix) On paediatric vaccination, we recognise that the decision taken by the Union of India to vaccinate children in this country is in tune with global scientific consensus and expert bodies like the WHO, the UNICEF and the CDC and it is beyond the scope of review for this Court to second-guess expert opinion, on the basis of which the Government has drawn up its policy. Keeping in line with the WHO Statement on Clinical Trials and the extant statutory regime, we direct the Union of India to ensure that key findings and results of the relevant phases of clinical trials of vaccines already approved by the regulatory authorities for administration to children, be made public at the earliest, if not already done.

94. We express our gratitude to the learned counsel on either side for their able

assistance in enabling this Court to reach the above conclusion.

95. The Writ Petition is disposed of accordingly.

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[1] *Indian Banks' Association, Bombay* v. *Devkala Consultancy Service*, (2004) 11 SCC 1

[2] (2011) 8 SCC 274

[3] (2013) 6 SCC 620

[4] (1990) 3 SCC 223

[5] 197 US 11 (1905)

[6] 260 US 174 (1922)

[7] [2021] NSWSC 1320

[8] [2022] NZHC 291

[9] (2008) 2 SCC 672

[10] (2007) 4 SCC 737

[11] (2021) 7 SCC 772

[12] 141 S.Ct. 63 (2020)

[13] 140 S.Ct. 1613 (2020)

[14] [2021] NSWCA 299

[15] [2012] NZCA 184

[16] *Ugar Sugar Works Ltd.* v. *Delhi Administration*, (2001) 3 SCC 635

[17] *Villianur Iyarkkai Padukappu Maiyam* v. *Union of India*, (2009) 7 SCC 561

[18] *Directorate of Film Festivals* v. *Gaurav Ashwin Jain*, (2007) 4 SCC 737

[19] *Academy of Nutrition Improvement* v. *Union of India*, (2011) 8 SCC 274

[20] *Pyarali K. Tejani* v. *Mahadeo Ramchandra Dange*, (1974) 1 SCC 167

[21] *Union of India* v. *Dinesh Engineering Corporation*, (2001) 8 SCC 491

[22] (2018) 5 SCC 1

[23] (2011) 4 SCC 454

[24] (2017) 10 SCC 1

[25] Abhilash, Kundavaram Paul Prabhakar et al. "Impact of prior vaccination with CovishieldTM and Covaxin® on mortality among symptomatic COVID-19 patients during the second wave of the pandemic in South India during April and May 2021 : a cohort study." Vaccine vol. 40, 13 (2022) : 2107-2113

[26] Aakashneel Bhattacharya, Piyush Ranjan, Tamoghna Ghosh, Harsh Agarwal, Sukriti Seth, Ganesh Tarachand Maher, Ashish Datt Upadhyay, Arvind Kumar, Upendra Baitha, Gaurav Gupta, Bindu Prakash, Sada Nand Dwivedi, Naveet Wig "Evaluation of the dose-effect association between the number of doses and duration since the last dose of COVID-19 vaccine, and its efficacy in preventing the disease and reducing disease severity : A single centre, cross-sectional analytical study from India" Diabetes & Metabolic Syndrome : Clinical Research & Reviews Volume 15, Issue 5 (2021), 102238

[27] Singh C, Naik BN, Pandey S, et al. "Effectiveness of COVID-19 vaccine in preventing infection and disease severity : a case-control study from an Eastern State of India." *Epidemiology and Infection*. 2021;149 : e224

[28] Tracking SARS-CoV-2 variants, World Health Organization, available at https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (last accessed on 01.05.2022)

[29] Statement by Dr. Hans Henri P. Kluge, WHO Regional Director for Europe, 11.01.2011, available at

https://www.euro.who.int/en/media-centre/sections/statements/2022/statement-update-on-covid-19-omicron-wave-threatening-to-overcome-health-workforce (last accessed on 01.05.2022)

[30] Interim Statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant from the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC), 11.01.2022, available at https://www.who.int/news/item/11-01-2022-interim-statement-on-covid-19-vaccines-inthe-context-of-the-circulation-of-the-omicron-sars-cov-2-variant-from-the-who-technical-advisory-group-on-covid-19-vaccine-composition (last accessed on 01.05.2022)

[31] Available at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice (last accessed on 01.05.2022)

[32] (2014) 5 SCC 438

[33] (1998) 8 SCC 296

[34] (1964) 1 SCR 332

[35] (1975) 2 SCC 148

[36] 410 US 113 (1973)

[37] (2019) 8 SCC 607

[38] [2021] NZHC 3012

[39] [2021] FC 361

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[41] Subramanian, S.V., Kumar, A. "Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States" Eur J Epidemiol 36, 1237-1240 (2021)

[42] *Vincent Panikurlangara* v. *Union of India*, (1987) 2 SCC 165

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[44] *Ashwani Kumar* v. *Union of India*, (2019) 2 SCC 636

[45] Gunter Kampf, Letter titled "The Epidemiological relevance of the COVID-19 vaccinated population is increasing" Lancet Regional Health Vol. 11, 100272, December 01, 2021

[46] Brown CM, Vostok J, Johnson H, et al. "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021". MMWR Morb Mortal Wkly Rep 2021;70 : 1059-1062

[47] (2011) 12 SCC 481

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"Exhibit-U"

[Big Breaking] Court orders government to compensate man for coronavirus AstraZeneca (Covishield) vaccine side effects.

Publication: SC NEWS

Link: https://rashidkhanpathan.com/big-breaking-court-orders-government-to-compensate-man-for-coronavirus-astrazeneca-covishield-vaccine-side-effects/

Author: Rashid Khan Pathan

Date: January 8, 2023

Court ordered 3.62 million won as compensation amount.

The state agency had refused to recognize a causal relationship between his diseases and vaccination. But court rejected states submission and observed that before vaccination, the plaintiff was very healthy and had no medical history and therefore it is reasonable to consider that there is a causal relationship between the diseases and vaccination.

Source: The Korea Times Dt. 20.09.2022

https://www.koreatimes.co.kr/www/nation/2022/10/113_336369.html

Similar law is laid down by the Indian High Court in the case of **Devilal Vs M.P State Through Chief Secretary 2017 SCC OnLine MP 2322, had also taken the same view and ordered a compensation with intrest of around Rs. 30 Lakhs.**

The High Court observed as under;

> **"11.** The research conducted by WHO also establishes that the paralysis can be one of the side effects of Oral Polio Vaccine. The Doctor examined before the trial Court has also supported the aforesaid view and, therefore,

the appeal filed by the plaintiff, keeping in view the facts and circumstances of the case, deserves to be allowed.

12. This Court is of the considered opinion that once the factum of side effect of Polio drops was established on the basis of statement given by the defence witness, in all fairness, the proper compensation towards treatment and mental sufferings should have been granted in the peculiar facts and circumstances of the case.

13. …… The plaintiff shall be entitled for a sum of Rs. 10,00,000/- (Rs. Ten lacs) along with interest @ 12% p.a., w.e.f. 20/11/1996, towards the treatment and the mental sufferings and the amount shall be paid by the State of Madhya Pradesh within a period of 90 days from the date of receipt of certified copy of this order. In case the amount is not paid within a period of 90 days, it shall carry interest @ 15% p.a., w.e.f. 20/11/1996."

Supreme Court of India in the case of **Balram Prasad v. Kunal Saha, (2014) 1 SCC 384** granted Rs. **11 Crore compensation for medical negligence.**

Summary of worldwide cases of compensation claims by victims of side effects of Corona Vaccine: –

Source: Biotech express Magazine

Compensation suits are not only restricted to India. In Taiwan, a panel of experts appointed by the Ministry of Health and Welfare agreed that the government should pay NT$6 million (US$209,025) in the case of a woman, whose deathis the first to be classified as directly related to receiving a COVID-19 vaccine shot in Taiwan. Because the woman did not have any chronic ailments, nor other conditions that could explain a very rare blood-clotting disorder called "thrombosis with thrombocytopenia syndrome," a known side effect of the AstraZeneca vaccine she received, the panel determined that her death was linked

to the vaccine, Chuang said. The woman was a Taipei resident in her 50s, who was identified only by her surname Yu. She died of a brain hemorrhage, a complication caused by the syndrome, according to the panel's findings.

Link: https://focustaiwan.tw/society/202203290026

As per data with Australian government, 37.8 million vaccine doses had been administered till November 7, 2021 and 78,880 adverse events linked to vaccination were recorded. A portal was being made to enable people to claim damages. At least 10,000 people have registered interest to make a claim, till the report came on news portal.

Link: https://www.wionews.com/world/thousands-of-australians-want-compensation-for-covid-vaccine-side-effects-report-429883

In UK, up to 920 compensation applications have been filed by people who were left seriously injured after getting the Covid-19 vaccine as claims could hit £110 million. Vikki Spit, from Alston, Cumbria, hopes to qualify for financial support after her fiancé Zion, 48, died of a brain hemorrhage two weeks after getting the AstraZeneca vaccine in May 2021. She claimed his death certificate named the AstraZeneca vaccine but said she has been left in 'limbo' after applying for the scheme in June.

Link: https://www.dailymail.co.uk/news/article-10556213/Covid-vaccine-claims-hit-110m-920-compensation-applications-filed.html

So, the compensation mechanism exists in most developed countries and many of the vaccine adverse events injuries have been compensated appropriately.

Additional Data:

Singapore

In a recent case of vaccine injury the Government of Singapore granted a compensation of Rs. 1.78Crore (SGD 225000) to the victim as vaccine had caused increase in heart beats.

Link: https://greatgameindia.com/pfizer-heart-attack-compensation/

Thailand – Bangkok Post

Thailand Government till now gave **1.71 Billion baht (around Rs. 400 Crores)** to 14,034 people as a compensation for side effects of Corona Vaccine. Of these, 3670 people were compensated for death due to Covid-19 vaccine.

Link: https://www.bangkokpost.com/thailand/general/2292514/b1-7bn-for- adverse-jab-effects

United States – America: -

In a case of side effects of vaccines, the United States Government has set up the **'National Vaccine Injury Compensation Program'**. In a case of side effects of MMR vaccines, the court granted a settlement of 101 Million U.S Dollars (Rs. 805 crores).

Link: https://www.mctlaw.com/101-million-dollar-vaccine-injury-mmr/

The companies' failure to report certain safety data was also taken into consider ation. The investigating agency of US on its own investigated and recovered an amount **10.2 Billion** U.S. around **812**crore Rupees. The excerpts from the news published on **July 2, 2012** in The United State' Department of Justice:

GLAXOSMITHKLINE TO PLEAD GUILTY AND PAY $3 BILLION TO RESOLVE FRAUD ALLEGATIONS AND FAILURE TO REPORT SAFETY DATA

Link: https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3- billion-resolve-fraud-allegations-and-failure-report

Largest Health Care Fraud Settlement in U.S. History

-

"1. The United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA- approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the **CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.**

Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E.

McFarland, Inspector General of the U.S. Office of Personnel Management.

Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

The company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices.

GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended.

Between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug.

The missing information included data regarding certain post- marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack).

GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million."

News in detail : – A Seoul court has recently ordered the government to compensate a man who was diagnosed with brain diseases after receiving coronavirus vaccines, officials said Tuesday.

It is the nation's first known suit won by a plaintiff claiming compensation for COVID-19 vaccine injury.

The man in his 30s claimed he had a fever one day after he got an AstraZeneca shot in April last year, and felt dizziness and numbness in his legs on the second day.

He went to a university hospital and was diagnosed with intracerebral hemorrhage, cerebral cavernous malformation and mononeuropathy.

His family applied for compensation of 3.62 million won ($2,607) with the Korea Disease Control and Prevention Agency (KDCA) but was denied payment.

The state agency refused to recognize a causal relationship between his diseases and vaccination, saying numbness in the legs is the main symptom of cerebral cavernous malformation.

The patient filed a lawsuit against the KDCA's decision with the Seoul Administrative Court, and the court sided with him.

"It is reasonable to consider there is a causal relationship between the diseases and vaccination," the court said.

“Before vaccination, the plaintiff was very healthy and had no neurological symptoms or medical history,” it added.

The court said it is not known when he developed cerebral cavernous malformation and that he showed no related symptoms before he got vaccinated.

Currently, eight other lawsuits are proceeding over compensation for COVID-19 vaccine adverse events, according to the agency. (Yonhap)

Source: **The Korea Times** Dt. 20.09.2022

https://www.koreatimes.co.kr/www/nation/2022/10/113_336369.html

"Exhibit-V"

2017 SCC OnLine MP 2322

In the High Court of Madhya Pradesh†
(BEFORE S.C. SHARMA, J.)

First Appeal No. 768/2000

Devilal

Versus

M.P. State Through Chief Secretary and Others

And

First Appeal No. 82/2000

State of Madhya Pradesh Through Chief Secretary and Others

Versus

Devilal

First Appeal No. 768/2000 and First Appeal No. 82/2000
Decided on June 29, 2017

The Order of the Court was delivered by

S.C. SHARMA, J.:— Regard being had to the similitude in the controversy involved in the present cases, both the appeals were analogously heard and by a common order, they are being disposed of by this Court. Facts of F.A. No. 768/2000 are narrated hereunder.

2. The present First Appeal is arising out of judgment and decree passed in Civil Suit No. 4A/1997.

3. Facts of the case reveal that plaintiff Devilal, through his father Bhagirath, who belongs to Scheduled Caste, has filed a Civil Suit against the State of Madhya Pradesh claiming damages to the tune of Rs. 10.00 lacs. It was stated in the plaint that on 9/12/1995 his minor child was administered Polio drops and on 10/12/1995 ie., the next day the child suffered a Polio attack and thereafter the child became permanently disabled. It was further stated in the plaint that father of Devilal incurred an expenditure of Rs. 40,000/- towards treatment of his child after he was infected by Polio virus and as the child became permanently crippled, a demand of Rs. 10.00 lacs was made in the relief clause. The trial Court has examined various witnesses. Defence witnesses were also produced during the trial and thereafter the trial Court has decreed the suit and by judgment and decree dt. 29/11/1999 and has held the plaintiff to be entitled for a sum of Rs. 25,000/- towards suffering. Interest @ 12% p.a., w.e.f. 20/11/1996 has also been awarded.

4. It has also been mentioned in the judgment and decree that the defendants No. 1 and 2 shall be free to take appropriate steps for grant of compensation from the State Government. The judgment and decree passed by the trial Court is the subject matter of challenge in these appeals by the plaintiff as well as by the State of Madhya Pradesh.

5. Mr. Suresh S. Garg, learned counsel for the appellant - Devilal has vehemently argued before this Court that the child in question was a healthy child and belongs to a poor family. The family does not have sufficient financial resources and now the child is aged about 26 years and is a totally crippled person who is not able to walk and he can walk only with the help of all the four limbs. Learned counsel for the appellant has drawn attention of this Court towardsthe statement of plaintiff Bhagirath (PW 1), Narendra Singh (PW 2)and Hazari (PW 3) and the factum of administering the Polio drops has been established. The factum of the child getting infected on the next day

on account of administering Polio drops is also admitted.

6. The respondents in their defence got one Dr. O.P. Tripathi examined who was the Chief Vaccination Officer and he has also admitted that the Polio drops were administered upon the child. The most important aspect of the case is that the Doctor who was produced by the State Government has stated that there can be adverse effect of the Polio drops, however, he has stated that it can take 7 to 14 days. Not only this, the plaintiff has stated that on 9/12/1995 the Drops were administered and on the next day the child fell ill and after about 8 days he was taken to one Dr. Punjabi and thereafter treatment was given, meaning thereby, the factum of giving Polio drops by the Doctor on behalf of the Government is not in dispute.

7. The first Issue framed by the trial Court in respect of the incident of administering Polio drops dt. 9/12/1995 was established. The Issue framed by the trial Court holding the defendants guilty for the loss caused to the child was also decided in favour of the plaintiff. However, the trial Court after the plaintiff was successfully able to prove his case, has awarded a meager amount of Rs. 25,000/- only. The statement of the Doctor Tripathi establishes that the vaccination can cause adverse effect also and once the Doctor himself has given a statement that adverse effect can be caused because of Polio drops, there appears to be no justification in not awarding proper compensation to the plaintiff. The trial Court on the one hand has held the defendants responsible for the loss caused and for the suffering and on the other hand, has confined payment of compensation towards treatment and mental suffering to a meager amount of Rs. 25,000/- only. The amount awarded has already been withdrawn by the plaintiff.

8. Polio vaccines are vaccines to prevent Poliomyetitis. They are of two types:

(A) The one that uses Inactivated Polio Virus (IPV);

(B) The one that uses weakened polio virus and is given by mouth.

9. The first vaccine which uses Inactivated Virus was developed by John Salk in 1955 and the oral Polio Vaccine was developed by Albert Sabin in 1961.

10. Administration of OPV is associated with a low incidence of paralytic polymyetitis in vaccinees. Also individuals in close contact with recently inoculated vaccinees may be at a small risk of developing paralytic poliomyetitis because polio virus can be shed in the feces (and possibly from the pharynx) for 6-8 weeks after OPV administration. Immuno compromised patients are also susceptible to this adverse reaction. The incidence of poliomyetitis is approximately 1 case per 2.6 - 5 million of OPV administered. The World Health Organisation has published position paper on Polio Vaccine on 25th March, 2016, NO.-12, 145-168 Weekly epidemiological record and as per the research paper, the polio vaccine can cause paralytic poliomyetitis. Relevant extracts of the WHO report are reproduced as under:

A. In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combinations of vaccines against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale immunization programmes. They summarize essential background information on diseases and vaccines and conclude with the current WHO position on the use of vaccines worldwide.

The position papers are designed to be used mainly by national public health officials and managers of immunization programmes. They may also be of interest to international funding agencies, vaccine advisory groups, vaccine manufactures, the medical community, the scientific media, and the public. The papers have been reviewed by external experts and WHO staff, and are reviewed and endorsed by the WHO strategic Advisory Group of Experts on immunization (SAGE)

B-Background

Epidemiology

Polimyelitis is an acute communicable disease caused by any of 3 poliovirus serotypes (types 1, 2 or 3). In the pre-vaccine era when poliovirus was the leading cause of permanent disability in children, almost all children became infected by polioviruses, with on average 1 in 200 susceptible individuals developing paralytic poliomyelitis. Polioviruses are spread by faecal to oral and oral to oral transmission. Where sanitation is poor, faecal to lral transmission predominates whereas oral to lral transmission may be more common where standards of sanitation are high. In most settings, mixed patterns of transmission are likely to occur.

C-Safety of OPV

The only serious adverse events associated with OPV are rare cases of vaccine associated paralytic poliomyelitis, which can occur in vaccinated individuals or their contacts, and the emergency of vaccine derived polio viruses. All available evidence indicates that OPV is non-teratogenic and safe to administer to pregnant women and HIV infected persons. Since bOPV contains only 2 of the 3 components of tOPV, its safety profile is assumed to be better than that of tOPV, because 26% - 31% of VAPP cases are caused by Sabin type 2 viruses.

11. The research conducted by WHO also establishes that the paralysis can be one of the side effects of Oral Polio Vaccine. The Doctor examined before the trial Court has also supported the aforesaid view and, therefore, the appeal filed by the plaintiff, keeping in view the facts and circumstances of the case, deserves to be allowed.

12. This Court is of the considered opinion that once the factum of side effect of Polio drops was established on the basis of statement given by the defence witness, in all fairness, the proper compensation towards treatment and mental sufferings should have been granted in the peculiar facts and circumstances of the case.

13. Accordingly, the judgment and decree dated 29/11/1995 deserves to be modified. In the year 1999 a claim was made for grant of a sum of Rs. 10.00 lacs towards compensation and we are in the year 2017. The child in question is now a grown up man, totally crippled, does not have any source of income and the trial Court at the time the suit was decreed has awarded Rs. 25,000/- (Rs. Twenty five thousand only) along with interest @ 12% p.a, and, therefore, this Court is of the considered opinion that the plaintiff is entitled for an amount of Rs. 10.00 lacs so prayed for in the year 1999 along with interest at the rate of 12% p.a., in the peculiar facts and circumstances of the case. The plaintiff shall be entitled for a sum of Rs. 10,00,000/- (Rs. Ten lacs) along with interest @ 12% p.a., w.e.f. 20/11/1996, towards the treatment and the mental sufferings and the amount shall be paid by the State of Madhya Pradesh within a period of 90 days from the date of receipt of certified copy of this order. In case the amount is not paid within a period of 90 days, it shall carry interest @ 15% p.a., w.e.f. 20/11/1996.

14. Out of the amount awarded, Rs. 20.00 lacs shall be kept in the Fixed Deposit for a period of 10 years, however, the plaintiff shall be free to withdraw the interest of the amount deposited in the Fixed Deposit every month in order to meet his day to day expenses and for his survival. He shall be free to withdraw the amount in excess to Rs. 20,00,000/- immediately.

15. In the light of the judgment delivered in F.A. No. 768/2000, the appeal of the State Government (F.A. No. 82/2000) which was against the award of a meager amount of Rs. 25,000/- to Devilal, is dismissed. The appeal filed by the plaintiff stands allowed with a cost of Rs. 1,00,000/- (Rs. One lac) which is also to be paid within a period of 90 days and in case the cost is not paid within 90 days, it shall bear interest at the rate of 15% p.a., from the date the amount became due till it is paid to the

plaintiff.

† Indore Bench

"Exhibit-W"

Publication: Mctlaw

Link: https://www.mctlaw.com/101-million-dollar-vaccine-injury-mmr/

Author: SARASOTA, FL

Date: July 17, 2018

mctlaw attorneys negotiated a $101 million settlement for an infant who suffered a severe reaction to the MMR vaccine.

O.R.* was a one-year-old healthy baby girl who was already walking and climbing. On February 13, 2013, she received vaccinations for Measles Mumps Rubella (MMR), Hepatitis A, Haemophilus Influenzae type B (Hib), Prevnar (pneumonia), and Varicella (chickenpox).

That evening, the mother noticed baby O.R. was irritable and feverish. After a call to the pediatrician, the doctor advised Mom to give her Tylenol and Benadryl. The fever continued for several days and on the evening before her scheduled pediatrician visit, O.R. began having severe seizures.

She was rushed to the emergency room. Baby O.R. went into cardiac and respiratory arrest and doctors placed her on a ventilator.

The seizures and cardiac arrest left O.R. with a severe brain injury, encephalopathy, cortical vision impairment, truncal hypotonia (low muscle tone), and kidney failure. After months of treatment at the hospital, baby O.R. finally went home, but her disabilities require specialized medical care and supervision around the clock for the rest of her life.

The $101 million-dollar settlement pays for the child's constant high-level medical care needed for the rest of her life. The family received a lump sum of $1 million

dollars to cover the immediate costs of medical bills and expenses. The rest will be paid out through an annuity over the child's lifetime.

FILING THE VACCINE INJURY CLAIM IN FEDERAL COURT

Attorney Diana Stadelnikas represented the child and her parents in the National Vaccine Injury Compensation Program. Ms. Stadelnikas is an experienced Vaccine Injury Attorney and also a former Registered Nurse.
She filed a claim with the Vaccine Court on behalf of O.R. alleging the MMR immunization triggered the severe, but rare, reaction.

Stadelnikas filed the case in the U.S. Court of Claims against the Secretary of the Department of Health and Human Services (HHS). Upon reviewing the records and evidence, HHS conceded the case and agreed that O.R. was entitled to compensation for her vaccine-related injuries.

$101 MILLION VACCINE INJURY SETTLEMENT

The family received a lump sum of $1 million dollars to cover the immediate costs of medical bills and expenses from when the injury first happened.

The rest will be paid out through an annuity over the child's lifetime. Attorney's fees and costs are paid by the Vaccine Injury Compensation Program separately from the money awarded to the child.

You can read the actual decision on the Court of Federal Claims website: Case Number 16-119V: MMR Vaccine; Encephalopathy. Thankfully, this family reached out to our vaccine injury team and we were able to help them, says attorney Diana Stadelnikas. Vaccine injury cases are medically and legally complex; I cannot stress

enough how important it is to work with an attorney who has experience representing injured families in the Vaccine Program to successfully navigate the complexities, urges Stadelnikas. The outcome here was a result of hard work, devotion, and the collaborative efforts of our experienced team.

OUR ATTORNEYS HAVE WON MILLIONS OF DOLLARS FOR OUR VACCINE INJURED CLIENTS

SEE CASE RESULTS

The attorneys at **mctlaw** have extensive experience representing people in the National Vaccine Injury Compensation Program (NVICP).

For almost 20 years the lawyers at our firm have helped people in all 50 states file vaccine injury claims. We have offices located in Washington, DC, Sarasota, FL, and Seattle, WA. Our DC office is located two blocks from the Vaccine Court.

Vaccine injuries are not personal injury cases, they are a unique part of the Federal Court system. There are a small number of attorneys across the US who regularly practice in this court. **Mctlaw** represents our clients in vaccine injury cases at no cost to them.

The NVICP pays attorney's fees separately from the victim's claim. This way, the victim keeps 100% of their award and never shares any part of it with their attorney.

You can review a list of over 500 of our case results here: https://www.mctlaw.com/vaccine-injury/cases/

In 1986 the federal government set up the National Vaccine Injury Compensation Program. This way, the government may compensate the small percentage of people who experience rare and severe vaccine reactions. As of June 2018, the program trust contains over $3.75 billion dollars to compensate patients who experience adverse vaccine reactions.

"Exhibit-X"

GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data

Largest Health Care Fraud Settlement in U.S. History

Link: https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

Criminal Plea Agreement

Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label uses" – renders the product "misbranded."

Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Wellbutrin: The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wllbutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and

Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of $757,387,200.

Avandia: The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack). GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

"This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

"Patients rely on their physicians to prescribe the drugs they need," said John Walsh, U.S. Attorney for Colorado. "The pharmaceutical industries' drive for profits can distort the information provided to physicians concerning drugs. This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry."

Civil Settlement Agreement

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

Off-Label Promotion and Kickbacks: The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approvedor medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered

psychiatric uses, neuropathic pain and pain management. It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

Avandia: In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

Price Reporting: GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under theMedicaid Drug Rebate Program. By law, GSK was required to report the lowest, or "best" price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as "bundles," the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as "nominal" pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay $300 million to resolve these allegations, including $160,972,069 to the federal government, $118,792,931 to thestates, and $20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

"This landmark settlement demonstrates the Department's commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks. By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective. Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way."

Non-monetary Provisions and Corporate Integrity Agreement

In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets."

"The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public's health," said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. "We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA."

"The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government," said Kevin Perkins, Acting Executive Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system."

"Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Today's announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation's veterans by the Department of Veterans Affairs," said George J. Opfer, Inspector General of the Department of Veterans Affairs. "The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans' continued care."

"This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try," said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. "The U.S. Postal Service pays more than one billion dollars a year in workers' compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost."

A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney's Office for the District of Massachusetts and the Civil Division's Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney's Office for the District of Massachusetts, the U.S. Attorney's Office for the District of Colorado and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA's Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

Court documents related to today's settlement can be viewed online at www.justice.gov/opa/gsk-docs.html .