IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) No 1220 OF 2021

(Under Article 32 of the Constitution of India)

IN THE MATTER OF:

Rachana Gangu & Anr. …Petitioners

Versus

Union of India & Ors. …Respondents

PAPERBOOK

(FOR INDEX, PLEASE SEE INSIDE)

Rejoinder on behalf of the Petitioners

Filed on:

Advocate for the Petitioner: Satya Mitra

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Rejoinder on behalf of the Petitioner

I, Venugopalan Govindan, S/o Shri. Govindan Gopalan, aged about 52 years. R/o 'Karunyam', No. 5, EB Colony, Vadavalli, Coimbatore, Tamil Nadu- 641041, do hereby solemnly affirm and state on behalf of me and on behalf of the other applicant as under:

1. The Petitioners are filing the present rejoinder in response to the Counter Affidavit filed by Respondent No.1 in the above captioned Writ Petition No. 1220 of 2021

2. At the outset, the Petitioners appreciate the condolences from the Union of India. However, the irresponsible statements presented by Respondents in their counter affidavit are appalling to the Petitioners. The Petitioners further craves leave of this Hon'ble Court to file such other/additional rejoinder(s) as may be necessitated in order to adjudicate the matter in issue in the present case.

NOTARY ADVOCATE

3. That the present rejoinder affidavit is sub-divided in to following parts:

Sr. No.	Chapter No.	Particulars	Page No.
1.	A	Informed consent not taken	
2.	B	Serious Side effects and Death due to Covid-19 vaccines	
3.	C	Conflict of Interest of authorities who approve vaccines and in AEFI committee	
4.	D	Petitioners children aged 18 and 20 died due to vaccination of Covid-19	
5.	E	GoI says vaccine 110% safe Blatantly lied to the people of India	
6.	F	GoI says vaccines limit spread of infection	
7	G	Failure to heed early warning signals from within India	
8.	H	GoI forced citizens to take covid-19 vaccinations	
9.	I	The AEFI system implementation by	

		GOI is below international standards and standards set by Indian authorities including the Hon'ble Supreme Court	
10.	**J**	Lack of AEFI investigation in serious adverse event cases due to vaccination	
11.	**K**	Systemic under-reporting of adverse events by AEFI Non-transparency, lack of follow-up, lack of planning	
12.	**L**	Entities facing parliamentary investigation in criminal negligence, involved in AEFI management	
13.	**M**	Failure of GOI to address grievances of parents who have lost their children to covid-19 vaccine adverse events	
14	**N**	Mathematical model cited by GOI is legally inadmissible and also fatally flawed	
15	**O**	Serious lapses in regulatory process	

NOTARY ADVOCATE

Chapter A: Informed Consent Not Taken

Guidelines made information to patients about adverse events mandatory

4. The **Covid 19 Vaccines Operation Guidelines** at page no. **107,** annexed in the Affidavit by Union of India at page 227, mentions the following relevant para;

> "All beneficiaries **must be counselled about adverse events** which may occur after COVID-19 vaccine"

4.1. Further, in the affidavit dated 13.01.2022 in **Evara Foundation Vs. Union of India Writ Petition (Civil) No. 580 of 2021** filed by Dr. Veena Dhawan, it is submitted as under;

> "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."

A True Copy of the Affidavit is annexed herewith and marked as **Annexure P-1, pg no.** 167-188

4.2. NTAGI meeting dated 10.12.2020, while endorsing the STSC recommendations for the vaccination rollout clearly spelt out that informed consent component was part of EUA authorisation.

> *"The NTAGI endorsed suggestive framework on advanced purchase agreement of COVID-19 vaccines with following points:*
>
> *A report on: (i) emergency use authorization of COVID-19 vaccines,* ***including informed consent component****"*

A True Copy of the Minutes of Meetings of NTAGI dated 10.12.20 is annexed herewith and marked as **Annexure P-2, pg no.** 189- 209

4.3. V. G. Somani, DCGI, Central Licensing Authority gave permission to Serum Institute of India to produce their Covid-19 vaccine ChAdOx nCoV-19 (Covishield) with the following conditions:

> *"7. The vaccine should be supplied along with the* ***factsheet*** *for recipients and prescribing information/Package Insert (PI)*

*8. The firm should provide the **updated Package Insert**, Summary of Product Characteristics (SmPC) & Factsheet for ChAdOx1 nCov-19 Corona Virus (Recombinant) incorporating the changes as per the Subject Expert Committee (SEC) recommendations dated 01.01.2001*

*9. The firm should ensure that **factsheet for the vaccine recipient/his attendant is provided prior** to the administration of the vaccine"*

A True Copy of the Permission to Manufacture Pharmaceutical Formulation of New Drugs For Sale and For Distribution by DCGI dated 03.01.21, is annexed herewith and marked as **Annexure P-3, pg no.** 210-211

4.4. None of the above procedures were followed while vaccinating the petitioner's daughters.

UOI so bold as to say since vaccine is "voluntary", No information about adverse events will be given

4.5. Respondent in para 43 of the Affidavit by UoI on 23.11.2022, has made the following statement:

*"It is most respectfully submitted that the **concept of informed consent is <u>inapplicable</u> to***

the voluntary use of a drug such as a vaccine…"

Not a single person was informed about serious and fatal adverse events

4.6. Para 4.0 to 4.3 of this rejoinder affidavit proves that **the Vaccinating Officer was duty bound to convey messages and take written informed consent** regarding management of AEFI's and inform the vaccine beneficiary about the possible adverse events of the vaccines. Specifically, the information about serious adverse events, including death causing ones, was not available in the FAQs at the time of the vaccination of the Petitioners daughters. The Petitioners were also never given any information about serious adverse events of Covid vaccine from the vaccinator.

4.7. Respondents makes the following submissions in the Affidavit:

"29. It is pertinent to note that the Operational Guidelines, which are circulated and explained to all stakeholders in State / UTs, clearly recommend that ***all vaccine***

> ***beneficiaries should be informed*** *about the benefits as well as likely side-effects associated with the particular vaccine they choose to take...*
>
> *... Moreover,* ***posters*** *with information on COVID-19 vaccination, the risks of Covid-19 infection and benefits of vaccination along with rare complications / contraindications associated with vaccines have also been developed in English & Hindi...*
>
> *...* ***Awareness*** *has also been created through mass media and social media platforms.*

4.8. The above statements are false and misleading, as can be clearly seen from the facts presented below. In para 43 of the affidavit, the Respondent mentions the following:

> *"...As detailed earlier, all relevant information on Covid-19 vaccination is made freely available in Public domain by both the vaccine manufacturer and MoHFW."*

4.9. On the contrary, In all the communication and frequently asked questions (FAQ) issued by the Central & State Governments even after May 2021, there is a specific call to all public to get vaccinated, **without any mention of potential death causing side effects**.

4.10. In the **old FAQs, created on 4th January 2021, there was no mention of death causing side effects**, as can be seen in the reproduction of question "What about the possible side-effects from COVID-19 vaccine?", which reads thus;

> *"COVID Vaccine will be introduced only when the safety is proven. As is true for other vaccines, the common side effects in some individuals could be mild fever, pain, etc. at the site of injection. States have been asked to start making arrangements to deal with any Covid-19 vaccine-related side-effects as one of the measures towards safe vaccine delivery among masses."*

True copy of document titled "Frequently Asked Questions on COVID-19 Vaccine" published by MoHFW on 04.01.21 is annexed herewith and marked as **Annexure P-4, pg. no** 212-219

4.11. That in para 34 of the Affidavit, the Respondent mentions the following:

> *"It is also respectfully submitted that the information about TTS as an AFFI has been included in the package insert / summary of product characteristics of Covishield which is available inside the packaging of the vaccine as well as on the website of the vaccine manufacturer"*

The Respondent is misleading the Hon'ble Court as it fails to mention that the Package Insert available at the time of vaccination of the daughters of Petitioners 1 and 2 does not mention any information about TTS. The daughter of Petitioner 1 was vaccinated on 29.05.21 and died on 19.06.21. The daughter of Petitioner 2 was vaccinated on 08.06.21 and died on 10.07.21. The Product Insert was only updated on **25.10.21** to include TTS as a "Very Rare" risk of the Covishield Vaccine. Despite knowing TTS as an Adverse Event of Covishield vaccine since **17.05.2021**, as mentioned in the Affidavit, the Government failed to demand the vaccine manufacturers to update their Product Inserts.

Please find a True copy of the Product Insert created on 03.01.2021 annexed herewith and marked as Annexure P-5. (220 -221)

Please find a True copy of the Product Insert created on 25.10.2021 annexed herewith and marked as Annexure P-6. (222-223)

4.12. In the affidavit of the respondents it is mentioned in para 34 that an advisory was issued by Press Information Bureau on 17.5.21 to inform the public about TTS (Thrombosis with Thrombocytopenia Syndrome) as a potential AEFI. However, the FAQs issued by MoHFW were not updated till 31.8.2021. Moreover, none of the 2 updated versions of the FAQs dated 31.8.21 and 26.9.22 mention unequivocally that TTS can cause death, as can be seen in the case of the daughter of Petitioner 1.

True copy of the document titled "FAQs on COVID-19 Vaccines and Vaccination Program" published by MoHFW on 31.08.21 is annexed herewith and marked as **Annexure P-7, pg. no** 224- 241

True copy of the document titled "FAQs on COVID-19 Vaccines and Vaccination Program" published by MoHFW on 26.09.22 is annexed herewith and marked as **Annexure P-8, pg. no** 242-258

4.13. Moreover, the product **insert of the vaccine is not accessible to the ordinary citizen** as the vaccine is supplied by the Government and only the doctor or nurse sees the vaccine insert accompanying the vaccine. The Government

deliberately did not publicise this adverse effect of TTS and they downplayed the importance of AEFIs — by suggesting only mild side-effects occur. As a result, ordinary citizens will never know what to look for to detect potential effects of TTS following vaccination. This is a specific instance of lack of full information disclosure, resulting in the death of the Petitioners' daughters.

4.14. The **caller tune set by the Central Government** is another instance of the lack of full information disclosure. The English Translation of the caller tune is as under:

> *"Hello, the New Year has brought a new ray of hope in the form of covid-19 vaccine, the vaccine made in India* ***is safe and effective*** *and gives us immunity against Covid,* ***so trust the Indian vaccine****, take the vaccine when your turn comes. And don't believe the rumors and yes, remember medicine as well as strictness along with the vaccine, keep in mind that always wear a mask and keep a distance of two yards from others and wash your hands well again and again. For more details visit*

http://www.mohfw.gov.in/ or call the national helpline 1078"

4.15. The failure of the Government of India to disseminate the side-effect information on Covid-19 vaccines widely in the public domain is in violation Delhi High Court order in case of **Master Haridaan Kumar Vs. Union of India 2019 SCC OnLine Del 11929** which categorically states that the authorities have to place advertisements in major newspapers all across the country so that necessary information is available to parents in the public domain as a result they can take an informed decision. It has ruled as under;

> *"14. The contention that indication of the side effects and contraindications in the advertisement would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be avoided, is unmerited. The entire object of* ***issuing advertisements is to ensure that necessary information is available*** *to all parents/guardians in order that they can take an informed decision. The respondents are not only required to indicate the benefits of the MR vaccine but also indicate the side*

effects or contraindications so that the parents/guardians can take an informed decision whether the vaccine is to be administered to their wards/children.

(I) ***Directorate of Family Welfare shall issue quarter page advisements in various newspapers*** *as indicated by the respondents, namely...* ***The advertisement shall also clearly indicate the side effects and contraindications*** *as may be finalised by the Department of Preventive Medicine, All India Institute of Medical Sciences."*

4.16. According to an RTI reply received by Shri Vikrant Kadwadkar, dated 12th October 2022, it was disclosed by the MoHFW that the GoI has released 8473.73 crores to the States/UTs for fight against COVID-19 including for the IEC/BCC activities under the 'India COVID-19 emergency response and Health System Preparedness Package-I'. However, even with this money, relevant information about potential death-causing adverse events has not been provided to the public. This is an act of serious omission on part of GoI, misleading the public that the Covid-19

vaccines are completely safe, while suppressing information about the serious side-effects including death.

4.17. It is important to note that the Government of India is in contempt of the Hon'ble Supreme Court Judgement as it has failed to provide the public with details of adverse events reports. As per Hon'ble Supreme Court Judgement dated 02.05.2022, in **Jacob Puliyel v. Union of India, 2022 SCC OnLine SC 533,** it has directed Union of India to publish all adverse events without reservations. GoI also failed to advertise the online AEFI Reporting system. The relevant para of the judgement as under:

> *"93…(viii) 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."

4.18. **Many countries like Japan have warned its citizens of death causing side effects.** The Japan government made companies of Covid "vaccines" to warn of dangerous and potentially deadly side effects such as myocarditis. In addition, the country is reaffirming its commitment to adverse event reporting requirements to ensure all possible side effects are documented.

Link: https://rairfoundation.com/alert-japan-places-myocarditis-warning-on-vaccines-requires-informed-consent/

4.19. None of the advisories or communications of the MoHFW to the States/UT's instruct Health workers / Doctors / DIO's etc requires to show the package inserts to the vaccine recipients and the MoHFW has not submitted any material on record to prove that vaccine recipients were informed to check the package insert before administering the vaccines to them.

4.20. The photos of the two largest Government hospitals namely KEM and JJ hospital, located in Mumbai, have been attached. The photos clearly demonstrate that information

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regarding severe and serious AEFI's like TTS, Myocarditis have not been mentioned anywhere. The **fact that Covid vaccines are having death causing side effects have not been displayed in any of the posters all throughout the hospitals where Covid vaccination have been carried out.** It is pertinent to note that these photos were taken after the Affidavit of Union of India MoHFW dated 23rd November 2022 and still death causing side effects were not being advertised nor any kind of counselling of vaccine recipients is being done even for contraindications putting lives of citizens in danger. The posters provided by Union of India MoHFW are nowhere to be found in both the Hospitals. The posters are thus an attempt by UoI to mislead the Hon'ble court.

True copy of the Photographs are annexed herewith and marked as Annexure P-9, pg no. 259- 266

4.21. The Respondent in their Affidavit in Para 29, states as under:

> "..... *Moreover, posters with information on Covid-19 vaccination, the risks of COVID-19 infection and benefits of vaccination along with rare complications/ contraindications associated with the*

vaccines have also been developed in English and Hindi. It has been advised to the States/ UT's that these posters and other awareness materials should be prominently displayed in all vaccination centres across the country Awareness has also been created through mass media and social media platforms"

The posters attached in the affidavit are **not to be found either online on the websites of the Government of India, Social Media handles of MoHFW and neither with any vaccination center or any place where vaccination is being carried out by the State or Central government.**

4.22. We draw attention of the Hon'ble Court to the fact that UoI has provided no account or proof that advertisements of such posters were made either in oral/electronic media via videos, written in print/newspapers, digital media, social media and especially in the vaccine centres where Covid vaccines were actually administered to the people. Further, the posters never mention even one adverse event of Covid vaccines apart from mentioning that chances of death are rare.

V. VASUDEVA RAO NOTARY ADVOCATE G.O.Ms.No.2742 Dt:16-12-91 Appointed by the Govt. of A.P. India Krishnaiah, Rajahmundry

4.23. Below are examples where the government, while disseminating message about vaccination, failed to warn about the process for AEFI. **We argue that government's efforts to raise awareness about AEFI were not proportionate to the efforts & messaging around vaccination.**

i. In the below tweet, MoFHW while suggesting the vaccine is safe does not make a mention that the vaccine is restricted emergency use or that potential side effects may show up in the future.

https://twitter.com/MoHFW_INDIA/status/1350140927478624256

ii. The Ministry of Health and Family Welfare have released a document titled "Covid-19 Vaccine Communication Strategy". In the entire strategy document, the main things which are repeatedly discussed are how to promote the vaccines as safe and effective. There is no mention about how to communicate potential and newly identified side effects of the experimental Covid-19 vaccines. Nor does the document mention the need to communicate to the public regarding reporting of potential Adverse Events.

True Copy of relevant extracts of "Covid-19 Vaccine Communication Strategy" published by MoHFW is annexed herewith and marked as Annexure P-10, pg no. 267-290

Government so bold as to say find out for yourself

4.24. In placing the onus of seeking relevant information on vaccine beneficiaries (para 43 of UoI affidavit), the UoI is violating its own operational guidelines, and misleading the Hon'ble Court. In UoI Affidavit dated 23.11.2022 it is stated:

> "... ***A vaccine beneficiary always has the option to access even more information about the vaccine and its possible adverse effects from the health workers at the vaccination site or their doctor before making an informed decision on their own.*** *As such it is humbly submitted that once a vaccine beneficiary who has access to all relevant information voluntarily chooses to enter a vaccination center and receive vaccination, the question of lack of informed consent does not arise"*

When the Government promises in all media about "safe and effective vaccines" without any mention of the possibility of serious adverse effects, it is preposterous to expect the people to suspect such statements and make inquiries about the vaccine's safety.

Consent taken for other vaccinations in the past

4.25. The Union of India already has a process for taking informed consent of vaccine beneficiaries. This can be seen from RTI reply from CPIO, AIIMS Bhubhaneswar, in the context of Yellow Fever vaccination, where it has provided information about "Consent Form" and the information detailed in it. However, no such forms were provided to the Petitioners (as submitted in Para 1 of the Writ Petition) prior to administration of Covid-19 vaccines.

A True Copy of the RTI Reply from AIIMS Bhubhaneswar is annexed herewith and marked as Annexure P-11, pg no. 291

Internationally informed consent taken in writing

4.26. That, recently the Health Ministry of **Japan** has made Following declaration/orders on their website:

> ***"Consent to vaccination***
>
> *Although we encourage all citizens to receive the COVID-19 vaccination, it is not compulsory or mandatory.* ***Vaccination will be given only with the consent*** *of the person to be vaccinated after the* ***information*** *provided. Please get vaccinated of your own decision, understanding both the effectiveness in preventing infectious diseases* ***and the risk of side effects. No vaccination will be given without consent.*** *Please do not force anyone in your workplace or those who around you to be vaccinated, and do not discriminate against those who have not been vaccinated."*

Link: https://www.mhlw.go.jp/stf/covid-19/vaccine.html

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Dt:26-12-2011

The law on informed consent

4.27. The legal requirement of informed consent is very much clear from the following:

(i) Universal Declaration on Bioethics & Human Right 2005

(ii) Judgement in **Montgomery v. Lanarkshire Health Board [2015] UKSC 11**

4.28. That in **Universal Declaration on Bioethics and Human Rights, 2005 (UDBHR),** which is binding upon India since it is a signatory to the said declaration, following provisions are made:

> *"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.*

4.29. In **Montgomery's case [2015] UKSC 11**, it is ruled as under;

> **"78.** *Another current document (Consent: patients and doctors making decisions together (2008)) describes a basic model of partnership between doctor and patient:*
>
> *"The* ***doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects*** *of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one." (para 5)*
>
> *89. Three further points should be made. First, it follows from this approach that the assessment of* ***whether a risk is material***

cannot be reduced to percentages.... *The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient."*

4.30. That in the case of **Ajay Gautam vs Amritsar Eye Clinic 2010 SCC OnLine NCDRC 96**, Hon'ble Supreme Court granted compensation for failure to produce the consent form of the patient.

Chapter B: Serious Side effects and Death due to Covid-19 vaccines

5. Reactions from Covishield Covid vaccine are wide-ranging as captured by European Medical Agency Database, EudraVigilance. A summary of all such reported reactions are listed below:

Total reactions for the **vaccine AZD1222 / VAXZEVRIA (CHADOX1NCOV-19) from Oxford / Astra Zeneca**: **9,427 deaths** and **1,328,069 injuries** to 30/07/2022

- 15,427 Blood and lymphatic system disorders **incl. 335 deaths**
- 23,779 Cardiac disorders **incl. 991 deaths**
- 281 Congenital familial and genetic disorders **incl. 11 deaths**
- 14,975 Ear and labyrinth disorders **incl. 8 deaths**
- 834 Endocrine disorders **incl. 7 deaths**
- 22,260 Eye disorders **incl. 33 deaths**
- 119,238 Gastrointestinal disorders **incl. 501 deaths**
- 357,237 General disorders and administration site conditions **incl. 2,198 deaths**
- 1,202 Hepatobiliary disorders **incl. 84 deaths**
- 6,727 Immune system disorders **incl. 47 deaths**
- 58,172 Infections and infestations **incl. 800 deaths**
- 15,172 Injury poisoning and procedural complications **incl. 232 deaths**
- 32,384 Investigations **incl. 226 deaths**

- 14,713 Metabolism and nutrition disorders **incl. 150 deaths**
- 191,884 Musculoskeletal and connective tissue disorders **incl. 197 deaths**
- 915 Neoplasms benign malignant and unspecified **incl. 55 deaths**
- 263,649 Nervous system disorders **incl. 1,356 deaths**
- 718 Pregnancy puerperium and perinatal conditions **incl. 23 deaths**
- 207 Product issues **incl. 1 death**
- 23,695 Psychiatric disorders **incl. 84 deaths**
- 4,860 Renal and urinary disorders **incl. 101 deaths**
- 18,374 Reproductive system and breast disorders **incl. 3 deaths**
- 46,318 Respiratory thoracic and mediastinal disorders **incl. 1,254 deaths**
- 58,025 Skin and subcutaneous tissue disorders **incl. 77 deaths**
- 2,440 Social circumstances **incl. 11 deaths**

- 3,147 Surgical and medical procedures **incl. 43 deaths**
- 31,436 Vascular disorders **incl. 599 deaths**

Vaccine banned/suspended in 15 countries

5.1. Within weeks after the rollout of the AstraZeneca vaccine, some people died of blood clots resulting from vaccination. Following this, 15 countries restricted or suspended the AstraZeneca COVID-19 vaccine (which is the same as Covishield in India as per Government of India FAQs). The details of the status of the Suspension/Restriction of the vaccine in these countries is as under:

Sr. No.	Name of the Country	Status & Date	Link of the News Report
1	Norway	Suspended, May 12, 2021	https://www.bloomberg.com/news/articles/2021-05-12/norway-permanently-removes-astrazeneca-from-vaccine-program?leadSource=uverify%20wall

2	Sweden	Suspended, March 16, 2021	https://www.npr.org/sections/coronavirus-live-updates/2021/03/16/977731757/sweden-venezuela-latest-countries-to-question-astrazeneca-vaccine#:~:text=Sweden%20is%20the%20latest%20European,at%20%20all%20following%20those%20reports
3	Bulgaria	Suspended, March 12, 2021	https://www.reuters.com/article/us-health- coronavirus-astrazeneca-bulgar/bulgaria-suspends-rollout-of-astrazeneca-covid-19-vaccine-idUSKBN2B4196
4	Slovakia	Suspended, May 11, 2021	https://www.euronews.com/2021/05/11/slovakia-suspends-use-of-the-astrazeneca-jab-for-first-time-vaccinations

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5	Canada	Suspended, April 26, 2021	https://indianexpress.com/article/explained/explained-why- canada-has-stopped-use-of-astrazeneca-vaccine-for-those-below- 55-years-7251250/
6	Denmark	Suspended, March 11, 2021	https://www.euronews.com/2021/03/11/denmark-suspends-astrazeneca-covid-19-vaccinations-as-a-precaution-after-blood-clot-report
7	Austria	Suspended, May 18, 2021	https://medicalxpress.com/news/2021-05-austria-phase-astrazeneca-virus-vaccine.html
8	Venezuela	Suspended, March 16, 2021	https://www.france24.com/en/live-news/20210316-venezuela-will-not-authorize-astrazeneca-covid-vaccine
9	France	Suspended, March 15, 2021	https://www.reuters.com/article/us-health-coronavirus-idUSKBN2B722U

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10	Brazil	Restricted, May 11, 2021	https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-health-agency-calls-halt-astrazeneca-vaccine-pregnant-women-2021-05-11/
11	Iceland	Restricted, March 25, 2021	https://www.ndtv.com/world-news/finland-iceland-approve-astrazeneca-covid-19-vaccine-for-seniors-2398488
12	Italy	Restricted, June 12, 2021	https://www.business-standard.com/article/current-affairs/italy-suspends-use-of-astrazeneca-vaccine-for-people-under-60-year-old-121061200086_1.html
13	Portugal	Restricted, April 9, 2021	https://www.reuters.com/article/us-health-coronavirus-portugal-astrazene-idUSKBN2BV2RF

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14	Netherlands	Restricted, April 12, 2021	https://www.reuters.com/article/us-health-coronavirus-netherlands-astraz-idUSKBN2BP13Q
15	United Kingdom	Restricted, May 7, 2021	https://www.theguardian.com/world/2021/may/07/people-under-40-in-uk-to-be-offered-alternative-to-astrazeneca-jab

Extrapolating from the U.K data of deaths/AE

Using the same vaccine UOI should have declared

39,793 deaths following vaccination and 1,13,75,583 AE

as vaccine related

5.2. A comparison of Adverse Events in the United Kingdom and India is presented below:

Particulars	UK	India
Total no. of doses administered	94.5M	2.19B
Total population size	68.4M	1.4B
No. of people who have received covid 19 vaccine	53.8M	824.6M

No. of people who have received Astrazeneca vaccine	24.9M	742.1M
No. of Injuries reported post vaccination	3,81,731	90,966
No. of deaths reported post vaccination	**2362 (1 in 22777)**	**1148 (1 in 718293)**
No. of injuries reported post Az/covisheild	246866	81869
No. of deaths reported post Az/covishield	1334	1033

5.3. The data is captured from the following sources:

- RTI First Appeal Response dated 31.10.22 by Scroll regarding Serious and Severe AEFIs and Deaths reported Statewise.
- Affidavit dated 23.11.2022 on behalf of Union of India in WP (C) 1220 of 2021.
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1121458/Coronavirus_Vaccine_-_Summary_of_Yellow_Card_reporting_23.11.2022.pdf

As can be seen above, the number of people in India who have received Covishield is approximately 30 times than in UK. However, the number of deaths reported after administering Covishield in India is less than in UK. The **injury reporting rate** in India is a mere **one-sixtieth** of the rate in the UK, and the **reporting rate of death** following vaccination is **32 times lower** than the rate in the UK. This indicates the unacceptably poor standards of the AEFI system implementation by GoI.

Media reports show 17,979 adult deaths and 100 children deaths

Not one media report investigated by government

5.4. There have been thousands of cases of deaths following vaccination reported in the newspapers and social media in India till December 2022. Petitioners have made a compilation of 17,979 newspaper reports reporting deaths after administration of vaccine in the adult population in India. There are 100 media / social media reports of deaths among Children in India.

File 1 - Deaths From 1 to 15,432

https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

File 2 - Deaths From 15,433 to 17,979

https://docs.google.com/document/d/1Ld2WHNXxMGPsJm4FPlu1DEPHzSNGzqGq/edit?usp=sharing&ouid=103856627695944525595&rtpof=true&sd=true

File 3 - CHILDREN Deaths – From 1 to 100

https://docs.google.com/document/d/1LZJDp-ub6BfVt-nnc8daISgemhkRieQG/edit?usp=sharing&ouid=103856627695944525595&rtpof=true&sd=true

India says unbelievably low 19 vaccine related deaths!

In 200 crore vaccination

Hid the truth from the public

5.5. National AEFI committee has certified A1- vaccine product related reaction i.e death due to Covid -19 vaccine in many cases till date. The following is a summary table of the deaths accepted so far as A1 Deaths.

S. No.	NATIONAL ID	Age	SEX	Status	Vaccine	Diagnosis
1	IND(CO-AEFI)MHPNA21007	33	Male	Death	COVISHIELD	THROMBOCYTOPENIA WITH INTRACEREBRAL HEMORRHAGE
2	IND(CO-AEFI)KEKNU21034	18	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME

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3	IND(CO-AEFI)KEKLM21024	28	Male	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
4	IND(CO-AEFI)KEENK21030	41	Female	Death	COVISHIELD	THROMBOCYTOPENIA WITH INTRACRANIAL HEMORRHAGE
5	IND(CO-AEFI)MPBPL21017	22	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
6	IND(CO-AEFI)TSHYD21023	28	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
7	IND(CO-AEFI)KAUDU21007	20	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
8	IND(CO-AEFI)APGTR21002	58	Male	Death	COVISHIELD	SEVERE ANAPHYLACTIC REACTION
9	IND(CO-AEFI)UPETA21004	22	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
10	IND(CO-AEFI)KEENK21015	19	Female	Death	COVISHIELD	THROMBOCYTOPENIA WITH INTRACRANIAL HEMORRAGE
11	IND(CO-AEFI)TSJOG21003	20	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
12	IND(CO-AEFI)KEKOT21008	32	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
13	IND(CO-AEFI)KEAPZ21040	28	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
14	IND(CO-AEFI)MHBMC21025	68	Male	Death	COVISHIELD	Anaphylaxis
15	IND(CO-AEFI)TSHYD21022	18	Female	Death	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME
16	IND(CO-AEFI)JKKUA21001	21	Male	Death	COVISHIELD	ANAPHYLACTIC SHOCK
17	IND(CO-AEFI)HAHSR21004	68	Female	Death	COVISHIELD	ANAPHYLAXIS
18	IND(CO-AEFI)CGRGH21006	47	Male	Death	COVAXIN	ANAPHYLAXIS
19	IND(CO-AEFI)MHNSK21001	34	Female	Death	COVISHIELD	Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia

5.6. An article featured in Scroll.in titled "*How India failed those who were harmed by the Covid-19 vaccine*" published on 02.11.22 by Tabassum Barnagarwala.

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Relevant Excerpts:

- **Across the world, countries have reported far higher AEFI rates. Argentina has reported AEFIs in 0.06% of vaccinations, ten times more than India. Canada, Brazil and Colombia's AEFI rate is 0.05%, eight times higher, while Chile and Paraguay reported AEFI in 0.03% of vaccinations, five times higher than India.**
- **There are also significant discrepancies within India. While Kerala has reported the most AEFI cases – a total of 490, including 242 deaths, the most populous state Uttar Pradesh, which has administered six times more doses of vaccine than Kerala, has reported just about a third of this number, with 159 AEFIs, including 85 deaths.**

A True Copy of the article is annexed herewith and marked as Annexure P-12, pg no. 292- 304

5.7. In Thailand, where a sizable proportion of the population was vaccinated with Astra Zeneca and Sinovac (which is a traditional vaccine like Covaxin), compensation has been provided to 0.011% of recipients. The percentage of

compensation recipients whose reactions were not mild works out to 0.003151%, which is about 24 times the rate of serious or severe AEFIs reported in paragraph 30 in GoI's affidavit. It is important to note that majority of Thai vaccine recipients were vaccinated with Covishield and Sinovac (which uses the same traditional platform as Covaxin).

Links:https://www.bangkokpost.com/thailand/general/2292514/b1-7bn-for-adverse-jab-effects

5.8. An article featured in the British Medical Journal titled *"How covid-19 vaccines exposed India's adverse events reporting system"* published on 7-Jan-2022 by Priyanka Pulla. It reports on the travails of Petitioner-2 when faced with the AEFI system. It also gives an example of Rijuta (20) who died because of brain blood clot / TTS after 1st dose of Covishield but the Bhopal hospital did not report an AEFI despite evidence, with doctors even dismissing the idea.

Key Points:-

- Hospitals are failing to report Adverse Events Following Immunisation (AEFI)
- Patients and their families don't know how to report

- Slow pace of investigation – Only 89 of 946 deaths investigated. Only 6 of 26 cases of thrombosis with thrombocytopenia syndrome (TTS) investigated.
- Non-communication of findings with families
- Many physicians have never heard of AEFIs as per Jyoti Joshi Jain, who previously worked with New Delhi's Immunisation Technical Support Unit
- For every 1,00,000 doses India's system got only 4 adverse events, while Canada's got 48 and the UK's got 300-700
- Distinguishing between causally related and coincidental adverse events often requires sophisticated medical investigations, which aren't always done by hospitals.
- Conflict in roles - Members of the national committee evaluating AEFIs were also involved in Covid policy making including recommendation for vaccination. And some of these committee members have connections to organisations that have interest in vaccine manufacturers District immunization officers have to meet high vaccination targets.

- Once reported, the system is "a black hole" with no assurance that a case will be dealt with in a time bound manner.
- A strong safety system will also allow finer calculations of a vaccine's benefit-risk ratio in specific age groups - younger people had a higher risk of TTS and a lower risk of severe covid-19.
- Article highlights the pains of Venugopalan Govindan who lost his daughter, Karunya (20) to multisystem inflammatory syndrome (an Adverse Event of Special Interest in WHO's list) after her first dose of Covishield. However, AEFI committee declared her death as "indeterminate"
- Article gives an example of Rijuta (20) who died because of brain blood clot / TTS after 1st dose of Covishield but the Bhopal hospital did not report an AEFI despite evidence.

A True Copy of the article is annexed herewith and marked as Annexure P-13, pg no. 305-307

5.9. A Letter has been sent to the Hon'ble Prime Minister dated 8.12.21 by a group of Indian Doctors on the subject: "Petition to improve and make functional, AEFI Reporting

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and it's active Monitoring in India". Relevant extracts from the letter are reproduced as under:

> *"We, Indian Doctors for Truth, are alarmed that there is practically no proper protocol to report Adverse Event Following Immunization (AEFI) in India, as mass vaccination drive for Covid vaccines is implemented."*
>
> *... "severe AEFIs were reported in less than 0.5 percent of recipients... 5 severe cases out of 1,000 vaccinations."*
>
> *"... "it is possible several cases of AEFI may be going unreported or undetected, says Vineeta Pandey, while writing about her first hand struggle to get her 21 yr old son's AEFI."*
>
> ***"It is unbelievable that a country of our size with the largest Covid Vaccination drive on this planet has only 2116 AEFIs which also includes death."***

A True Copy of the Letter by Indian Doctors for Truth is annexed herewith and marked as Annexure P-14, pg no.308 - 314

Chapter C - Conflict of Interest of authorities who approve vaccines and in AEFI committee.

Adverse events and deaths deliberately understated by UOI and vaccine manufacturers.

6. The AEFI Committee and the body governing reporting and monitoring of AEFI in India is plagued with Conflicts of Interest as shown in the details below

6.1. **Narendra Kumar Arora** is the Chairperson & Adviser to the National Adverse Events Following Immunization (AEFI) Committee in India which is tasked with the responsibility of setting out the framework for adverse event reporting in India, and performing causality assessment on reported cases. We would ideally want the person heading/advising this committee to not have any connections with vaccine/pharmaceutical companies as these companies stand to make windfall profits from the sale of vaccines, and it is in their best interest to try to underreport vaccine adverse events/deaths so that the sales are higher. The evidence shows that NK Arora's research is funded by the **Bill & Melinda Gates Foundation**. This foundation was severely indicted in the **72nd Parliamentary**

Committee Report (Rajya Sabha). He is also an advisor to Bill Gates Projects on Immunization, & a Chairperson of Scientific Advisory Committee of HPV program between India's Dept of Biotechnology & Gates Foundation. He was also involved in the drafting of the revised AEFI causality assessment guidelines, which make it very difficult to attribute deaths and new serious adverse events to vaccines. Furthermore, he is also the Chairperson of Covid-19 Working Group, NTAGI which has recommended Covid-19 vaccines in India. The following links show the conflict of interest involving Shri N.K.Arora:

1. https://timesofindia.indiatimes.com/city/pune/no-test-for-fully-vaccinated-travellers-panel/articleshow/85223745.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
2. https://www.who.int/vaccine_safety/publications/CausalityAssessmentAEFI_EN.pdf
3. https://main.icmr.nic.in/sites/default/files/upload_documents/Vol_III_1.pdf
4. http://inclentrust.org/inclen/wp-content/uploads/N-K-Arora.pdf

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6.2. **Immunization Technical Support Unit ITSU was Setup by PHFI in 2012 by a $6.9 million grant from Gates Foundation.** The Gates Foundation had funded an activity called 'evidence to policy' at the Immunization Technical Support Unit (ITSU), which in turn acted as secretariat of another key body called the National Technical Advisory Group on Immunization (NTAGI). This was a crucial panel that examines scientific evidence on the effectiveness of new vaccines and recommends their inclusion in the national vaccination programmes.

6.3. The Senior Management Team of the ITSU's key areas of focus consist of the AEFI Secretariat, Implementation of India's Immunization Program, & the Communications Strategy of the Covid-19 Vaccine Communication Program. Other Partners in deciding the communication strategy of the Covid-19 vaccine program include the Bill & Melinda Gates Foundation. Following link suggests the same: https://m.economictimes.com/news/politics-and-nation/centre-shuts-gate-on-bill-melinda-gates-foundation/articleshow/57028697.cms

6.4. The funding of the BMGF to the ITSU Secretariat was withdrawn after controversy over influence of vaccine manufacturers in India's Universal Immunization

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Programme, but funding to other parts of the ITSU by the BMGF still continues, according to WHO Chief Scientist Soumya Swaminathan.

https://www.reuters.com/article/us-india-health-bmgf-idUSKBN15N13K

6.5. Members of Senior Management Team of ITSU include :

1) Pritu Dhalaria, Director of ITSU is the Ex Director of PATH (Program for Appropriate Technology in Health) an organization funded by the Foundation.
2) Apurva Rastogi, Project Manager at ITSU, Ex Researcher at PHFI (Public Health Foundation of India) also funded by the Foundation.
3) Kishore Kumar Bajaj, Senior Operations Manager at ITSU. Has worked at PHFI & PATH in the past.
4) Dr. GK Soni , Team Lead of program implementation at ITSU. Has worked at PHFI in the past

https://itsu.org.in/about-itsu/

6.6. PHFI, a public private partnership started by Ex Prime Minister Manmohan Singh, Rajat Gupta, Bill & Melinda Gates Foundation & Srinath Reddy, has received funding from pharmaceutical companies, vaccine manufacturers. Where does philanthropy end and commercials interest dominate is a relevant question.

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6.7. Everything to do with the adverse events of the Covid-19 vaccines is handled by the ITSU, right from the drafting of the guidelines which decide which death will be considered to be caused by a vaccine and which will not.

Source: https://itsu.org.in/aefi/

6.8. The Covid-19 Pandemic Public Health Response was not just driven by Governments and International NGOs like World Health Organisation but also by many public-private partnerships involving drug companies and private foundations. The article titled "How Foundations' Investments in Drug Companies Influence COVID Research" published on 10.03.21 in the online portal The Defender outlines the role of Gates Foundation and Wellcome Trust who have financially benefited from the pandemic response. The article mentions that Gates had more than $250m invested in companies working on Covid-19.

Link:

https://childrenshealthdefense.org/defender/foundations-investments-influence-covid-research/

6.9. Another article published on online news portal lifesitenews, titled "Gates Foundation makes billions through dangerous vaccine development" dated 21.2.21

mentions the Gates Foundation has injected $384m in Oxford University's vaccine project, which has developed the widely used Covid-19 vaccine Covishield in India. Bill and Melinda Gates Foundation had invested USD300 million in Serum Institute for Covishield manufacturing. https://www.seruminstitute.com/news/press_sii_gavi_bmgf.pdf

Link: https://www.lifesitenews.com/news/gates-foundation-makes-billions-through-dangerous-vaccine-development/

Chapter D: Petitioners children aged 18 and 20 died due to vaccination of Covid-19

One had headache along with classic symptoms of TTS, the other high fever, throat pain and severe pain in legs limiting movement

Family doctors did not realize this was vaccine related

Doctors in India not told of adverse events or AESI

Case of 18 year old Ritihika

Clot in the brain was treated with headache medicine

7. This is a specific instance of GoI's failure in dissemination of important advisories on TTS (Thrombosis with

Thrombocytopenia Syndrome) to all concerned public and private health institutions.

7.1. Government of India sent a letter dated 17.5.2021 to all States and Union Territories informing about specific adverse events related to TTS. But this was not advertised in the public domain. The letter included Advisory for Healthcare Service Providers to be alert about the signs and symptoms of TTS. However, it is clearly seen from the case of Petitioner no.1 that there was no information regarding TTS in the public domain, and the treating physicians of the daughter of Petitioner 1 were completely ignorant of the signs and symptoms of TTS

7.2. At page 252 and 253 of the respondent's Affidavit, the Additional Secretary, Dr. Manohar Agnani, sent out an advisory which was to be shared with public & private health institutions and also amongst the vaccine beneficiaries, as follows:

> *"You are kindly requested to share the first advisory on TTS with all concerned public & private health institutions and professional bodies like IMA, etc, to provide guidance for Diagnosing and treating Thrombosis and Thrombocytopenia Syndrome (TTS)*

occurring after administration of Covid-19 vaccine. The second advisory to be circulated to all healthcare workers and made available at such platforms so as to create awareness amongst vaccine beneficiaries."

However, the government was negligent in passing this valuable information to the concerned public and private health institutions.

7.3. In Page 254 and 255 of the Affidavit by UoI, the first advisory dated 17.5.21 is mentioned:

> *"Reports of rare cases of thrombosis associated with thrombocytopenia have been reported globally from some countries following the use of some COVID 19 vaccinations particularly AstraZeneca vaccine [Covishield in India] and Johnson's Janssen vaccine. These cases have been reported to have occurred within two to three weeks of vaccination, mostly after the first dose; younger than 60 years and women were observed to have a higher risk of the problem."*
>
> *"Healthcare professionals should be alert to the signs and symptoms of TTS*

(Thromboembolism and thrombocytopenia syndrome), so that they can promptly investigate and treat people affected in line with available guidelines."

i. The above advisory was not disseminated. Petitioner no.1 informed her doctors that her daughter Rithiaka received the Covishield vaccine on 29.5.21. But the doctors were unaware of any connection between the vaccine and the symptoms.

ii. **All the doctors and the public in the country were told that the vaccine was "100% safe" and even told "110% safe"!". Therefore, no doctors were willing to believe that there was any connection between the adverse events and the vaccine. Because of this mass deception by the government and the vaccine manufacturers and all those pushing the vaccine, no training was done of doctors in the country to deal with adverse events. No recording of these adverse events was done anywhere in the country because all health care institutions were told that the vaccine did not have any significant side events.**

iii. Petitioner No. 1, contacted two doctors from **Apollo Hospital,** Hyderabad during 1st week of June. It is in Apollo that Rithaika died. They contacted the doctors twice. First they had an appointment with Dr. Dhanraj K. K., on 6.6. 2021, and again with Dr. Anish Anand on 8.6.2021. Both the doctors were completely unaware of any possible side-effects of the vaccine.

7.4. In the same Advisory for healthcare service providers under "Diagnosis and Management " there are guidelines on investigations for any suspected cases of thrombosis and thrombocytopenia provided as follows:

- *Blood*
- *Platelet count < 150x109 /L confirming Thrombocytopenia*
- *Coagulation screen-raised D-Dimer values (>4000 mcg/L, suspect if the D-dimer level is 2000-4000 mcg/L)*
- *Radio-imaging studies*
- *CT/MRI specifically for cerebro-vascular sinus thrombosis, haemorrhage, stroke*
- *USG-doppler of the limbs for deep vein thrombosis (DVT)*

7.5. In the case of Petitioner 1's daughter Rithaika, Dr. Anish Anand was consulted, and the report of her blood test was also shared with him, which showed her Platelet count was at 40,000 If the guidelines had reached Dr. Anish Anand, he would have realized that thrombocytopenia was happening in Rithaika, as her platelet count was way below the biological reference range and he would have ordered the required diagnostic test of D-dimer to confirm Thrombosis in her case. But instead she was **prescribed Crocin** 650mg (Paracetamol) for pain management. The doctor was also told that Rithaika was **suffering from pain in her hands** and left toe, and that she was also seeing **red spots underneath her skin**, and was having a **constant headache**. None of these mentioned symptoms triggered the doctor to further investigate the root cause or call for additional diagnostic tests as mentioned in the advisory.

7.6. In Page 257 of the Affidavit, the advisory for vaccine beneficiaries was passed on 17th May, 2021 about Thrombosis and Thrombocytopenia Syndrome (TTS) occurring after administration of Covid-19 vaccine. This advisory was to be circulated to all healthcare workers and made available at such platforms so as to create awareness

amongst vaccine beneficiaries. The advisory was as follows:

> *"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).*
>
> *Symptoms occurring within 20 days after receiving any COVID-19 vaccine*
>
> - ***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*
> - ***Severe and persistent headaches** with or without vomiting*
> - *Any other symptom or health condition which is of concern to the recipient or the family"*

7.7. As per the **advisory**, the above life-saving information about TTS and specific adverse events related to TTS should have been circulated to all healthcare workers and made available on public platforms so as to create

awareness amongst vaccine beneficiaries. It **was not at all advertised in the public domain**. Neither the doctors nor the health care workers provided this information to the Petitioners. And both the doctors at Apollo have failed to recognize those symptoms in Rithiaka's case.

7.8. Apollo Hospital is considered to be a premium hospital with doctors who are supposed to be experts in their field of study. This clearly shows how the government has failed in trickling down the valuable advisory for doctors, and healthcare service providers. In the case of Petitioner 1, GoI failed in reaching the relevant information to the treating doctors, as both the doctors did not diagnose her condition; and timely information and intervention could have saved her life.

A True Copy of the consultation with Rithaika's doctors are annexed herewith and marked as Annexure P-15, pg. no 315 -325

7.9. In cases of TTS, time is very critical. In Rithaika's case, early detection could have saved her life. Rithaika's family reached out to doctors early enough on the onset of symptoms, and they informed the doctors that she got vaccinated a few days back, but it was simply marked off as viral infection, when in reality she was a victim of the fatal side effect of the vaccine. The government has failed in

providing relevant information to safeguard the precious life of a young woman. If the government had reached information to the doctors about the early detection and treatment protocols, the Petitioner's daughter would be alive today.

7.10. In Para 36, the Respondents mention the UK reporting rate of adverse events for TTS as **39 cases**. This is totally false. There were **444 cases** of blood clots with low platelet counts. The incidence was the highest in the **18-49 age group** following the first dose (21.5 per million). For reference, the smallpox vaccine which was labelled as "the most dangerous vaccine" had a severe side effect profile of 15 per million according to vaccine researcher Paul Offit. **In the case of vaccine, just one severe side effect, namely TTS, is occurring at a rate of 21.5 per million.**

7.11. With regards to the annexure on pg. 252 in the UoI Affidavit, it is important to note that it's dated May 17th, 2021. There's no mention of age stratified risk. The document shows that the **AEFI Committee had studied cases upto 3.4.21. This is before the vaccination opened up for the 18+ age group only on 1.5.21. By this time, several countries had discontinued/suspended the**

vaccine, and the UK was already advising against vaccinating under the age of 30 with vaccine.

7.12. As per the Affidavit filed by Union of India, a letter was issued on 11.10.21 by Dr. Manohar Agnani where he mentions the following:

> *"However, it has been observed that* ***all such suspected cases of TTS are still not being reported from the districts*** *as* ***these advisories have not been disseminated widely among health care professionals in districts.*** *Clinicians might have come across such cases but are not aware of details of the District Immunization Officer/District RCHO to whom these cases need to be reported and what are the* ***standard treatment protocols*** *to manage the same."*

7.13. This shows that the information shared by the Government of India vide its letter dated 17th May 2021 was not disseminated effectively which has led to significant deaths in the country like in the case of Petitioner 1's daughter.

Case of 20 year old Karunya :W.P 1220 of 2021

High fever/throat pain:

20-year old Karunya Venugopalan dies of <MIS-C

(Multisystem inflammatory syndrome in children)

8. In Para 38 of the Affidavit by Union of India, it is stated that *"As per Brighton Collaboration, Multisystem inflammatory syndrome in children/adults (MIS C/A) is identified as an* ***Adverse Event of Special Interest (AESI)*** *following COVID-19 vaccination."*

A True Copy of List of Covid-19 AESI by Brighton Collaboration is annexed herewith and marked as Annexure P-16, pg no. 326- 327

8.1. When Karunya was hospitalized following her Covid-19 vaccination, she had **severe disability in her lower limbs.** This should have made the treating doctors to conduct the diagnostic tests for DVT **(Deep vein thrombosis) as per the advisories dated 17.5.21.** But this advisory was also never circulated to the doctors in the public and the private sector or put in the public domain. The vaccination was hardly considered as a causative factor till very late in her hospitalisation. The transfer summary from Arogya Hospital where Karunya was treated first and the death

summary from PSG hospitals where she was treated during the last three weeks are enclosed. Also enclosed is the referral letter to Royal Care Hospitals to which she was referred to on 29th June 2021, for a PET scan as part of diagnosis, showing the lack of certainty in diagnosis even after 10 days after the onset of serious adverse event.

A True Copy of Treatment Reports of Karunya are annexed herewith and marked as Annexure P-17, pg no. 328 - 334

8.2. As per "COVID-19 Vaccines: Safety Surveillance Manual, Module: Establishing **active surveillance** systems for adverse events of special interest during COVID-19 vaccine introduction" published by WHO, definition of AESI is *"...a pre-specified medically significant event that has the potential to be causally associated with a vaccine product that needs to be **carefully monitored** and confirmed by further **special studies**."*

i. It is important to note that an AESI is a significant event that needs to be captured through Active Surveillance in order to monitor and confirm its causality through further studies.

ii. In order to capture such events, they must be widely publicised and all Healthcare and Frontline

Workers must be educated and sensitised about them.

iii. In the case of Petitioner 2's daughter, the **treating physicians were unaware of MIS C being categorised as an AESI** for Covid-19 vaccines. Due to the lack of information regarding AESI, timely diagnosis and early treatment for the condition could not be administered, which led to her untimely demise. Arogya Nursing Home, the first hospital where Petitioner 2's Daughter was admitted, **despite her having the exact symptoms as per Brighton Collaboration flow chart for MIS-C,** the diagnosis given was ***"? Viral Fever / ? Vaccination".*** This clearly shows a total lack of information with Healthcare and Frontline Workers on the possible AESIs from Covid-19 Vaccines which includes MIS-C.

iv. Petitioner 2's daughter was shifted to PSG Hospitals and was treated by **Dr. Murali A, an infectious disease specialist,** who was not sure of the diagnosis of the patient, and ran multiple tests, PET scan etc to rule out Bacterial Infection, Sternal Osteomyelitis, Adult Still's disease. They

only suspected MIS-C in the final days and referred the case to a Paediatric Cardiologist.

8.3. Even more egregious is the fact that, in para 38 of the Affidavit, the Respondent has claimed the following:

> ***"However, as of now, there is no definitive evidence globally to associate MIS C/A with Covid-19 vaccines and no causal association of MIS C/A has been proven with Covid-19 vaccines."***

This claim is patently false. The Petitioners draw attention of the Hon'ble Court to the Peer Reviewed research submitted to the court vide IA No. 124527 of 2022 dated 16.11.2021.

8.4. Further the petitioners wish to submit the following Peer Reviewed studies which show causal association of MIS C with Covid-19 vaccines.

i. A true copy of Peer Reviewed research article published in Journal of Korean Medicine Science on 05.11.21 titled "**Multisystem Inflammatory Syndrome** in an Adult after **COVID-19 Vaccination**: a Case Report and Literature Review", is annexed herewith and marked as Annexure P-18. (335- 341)

ii. A true copy of Peer Reviewed research article published in Pubmed, National Library of Medicine on 12.09.21 titled "A case of **multisystem inflammatory syndrome (MIS-A)** in an adult woman **18 days after COVID-19 vaccination**", is annexed herewith and marked as Annexure P-19. (342- 348)

iii. A true copy of Peer Reviewed research article published in Pubmed, National Library of Medicine on 01.12.21 titled "**Postvaccination Multisystem Inflammatory Syndrome** in Adult with No Evidence of Prior SARS-CoV-2 Infection", is annexed herewith and marked as Annexure P-20. (349-352)

8.5. The Brighton Classification Case definition document gives a clear flowchart that can be definitively used to both diagnose MIS-C and to definitively link it to vaccine and Karunya's case fits every aspect of that and links it clearly to vaccination as evidenced from the flowchart in this document and the medical documents of Karunya's transfer summary from the first hospital, death summary from the medical college hospital and her investigative reports. Hence it was wrong to conclude Karunya's causality assessment as B1.

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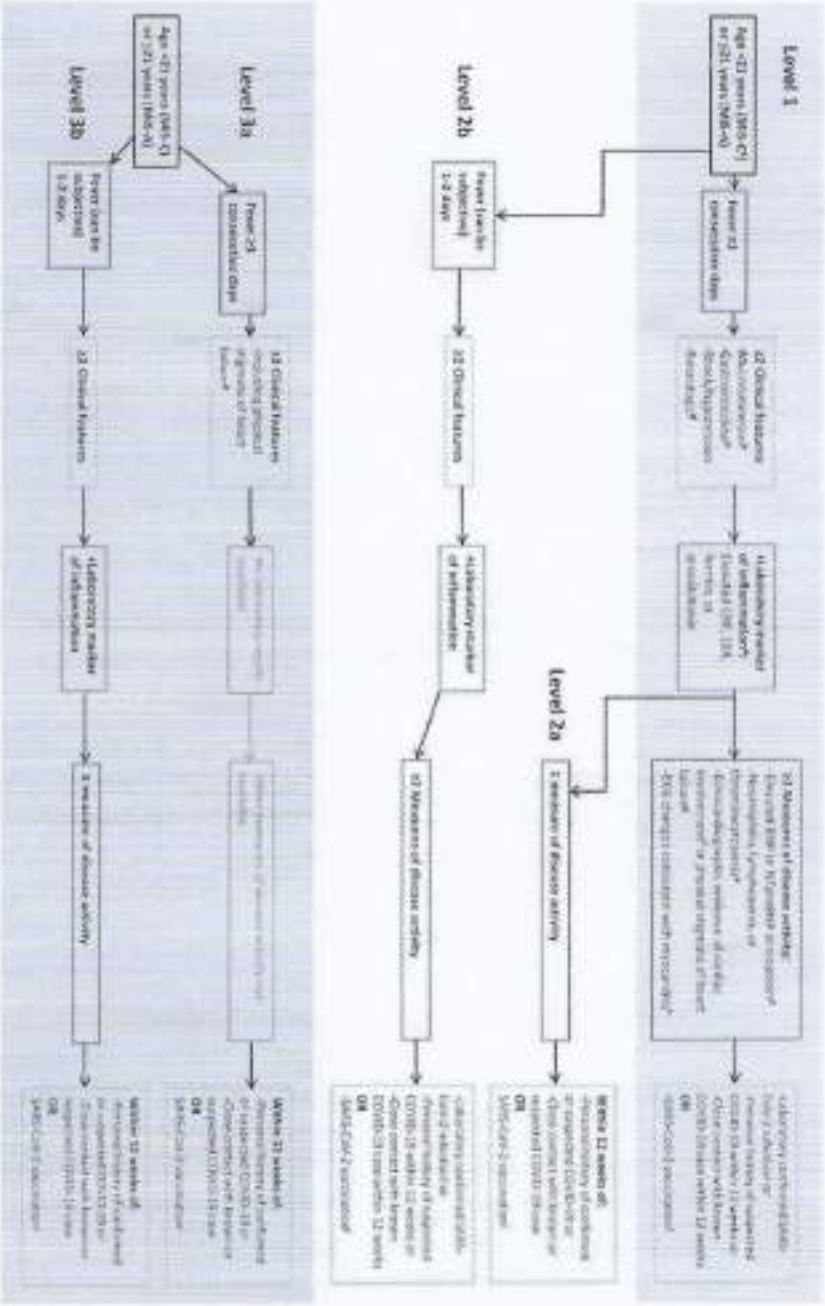
Link:

https://www.sciencedirect.com/science/article/pii/S0264410X21000931/pdfft?md5=3f57e16a2f6be88810fc8b7cf8d3d2cd&pid=1-s2.0-S0264410X21000931-main.pdf



8.6. Hence Petitioner 2 pleads that Karunya's death be correctly assigned the classification as **A1,** apart from granting the various systemic remedies sought in this prayer.

8.7. Even as per the **B1** classification of Karunya's death, there is gross negligence on part of GoI. In Para 37 of the Affidavit, GoI states that Karunya's case has been classified as **B1-Temporal Relationship is consistent but there is insufficient evidence for vaccine causing event.'** The definition for B1 in AEFI causation as per WHO is given below and clearly places the onus of further investigation on the bodies doing causative analysis

> *"B1. Temporal relationship is consistent but there is insufficient definitive evidence that vaccine caused the event* ***(it may be a new vaccine-linked event). This is a potential signal and needs to be considered for further investigation.****"*

Link:

https://apps.who.int/iris/bitstream/handle/10665/259959/9789241513654-eng.pdf

Chapter E:

GoI says vaccine 110% safe

Blatantly lied to the people of India

- Repeated claims have been made that (a) the vaccines are "safe and effective" and (b) that they "limit the spread of infection", misleading the public
- "There is no side effect that would result in death" - AIIMS director Dr. Randeep Guleria
- "The vaccines are 110 percent safe" – DCGI Dr. V. G. Somani
- Possible serious and fatal adverse events have not been mentioned by any Authority in public domain

9. In the original FAQ published by MoHFW on 4th January 2021 (Annexure P-4), the following statements were made where it is assuring that vaccines will be safe and effective.

4.	Will the vaccine be safe as it is being tested and introduced in a short span of time?	Vaccines will be introduced in the country only after the regulatory bodies clear it based on its safety and efficacy.
9.	Will the vaccine introduced in India be as effective as the ones	Yes. The COVID 19 vaccine introduced in India will be as effective as any vaccine

	introduced in other countries?	developed by other countries. Various phases of vaccine trials are undertaken to ensure its safety and efficacy.
19.	What about the possible side-effects from COVID-19 vaccine?	COVID Vaccine will be introduced only when the safety is proven. As is true for other vaccines, **the common side effects in some individuals could be mild fever, pain, etc. at the site of injection.** States have been asked to start making arrangements to deal with any Covid-19 vaccine-related side-effects as one of the measures towards safe vaccine delivery among masses.

9.1. In the FAQs published subsequently on 31.8.21 (Annexure P-5) and 26.9.22 (Annexure P-6), it is mentioned as under:

"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."*

9.2. In the interview given to NDTV on 4th January, 2021 by, **Dr. V.G. Somani**, Drug Controller General of India, it is categorically mentioned that the Covid-19 vaccines are 110% safe.

The relevant portion published in the news reads thus;

"Drug Controller General of India VG Somani said, "We'll never approve anything if there is ***slightest of safety concern. The vaccines are 110 per cent safe".***

A True Copy of article "India's Wait Over, Drug Regulator Says Covid Vaccines Cleared "110% Safe"" published by NDTV on 04.01.21 is annexed herewith and marked as Annexure P-21, pg no. 353- 354

9.3. In the news published by Hindustan Times on YouTube on 16th January 2021 titled Covid: Dr VK Paul, AIIMS director urges people to trust researchers on vaccines some excerpts from the interview are as follows;

> *"Dr V.K. Paul: **Safety is proven without doubt** on thousands and thousands of individuals.*
>
> *...Are you safe with the vaccine or not? **Safety is proven without doubt**.."*

Link: https://youtu.be/bE7vIajxZ9s

9.4. In an article published in the Journal Medical Dialogues on 19th Jan 2021 titled "There is **no side effect that would result in death**: AIIMS Director allays covid-19 vaccine fears"

> *"New Delhi: AIIMS Director Randeep Guleria on Monday allayed apprehensions about the coronavirus vaccines and assured that the side-effects **will not result in the death** of the beneficiary..."*

A True Copy of article is annexed herewith and marked as Annexure P-22, pg no. 355-357

9.5. It is important to note that as per National AEFI Committee Causality Assessment reports, **there were 6 deaths from those who were vaccinated on the first day** of the Covid vaccine roll out on 16.1.21. The AEFI details are given below:

NATIONAL ID	Age	Diagnosis
IND(CO-AEFI)RJCTG 21001	55	Presented as hypertensive emergency with systolic BP of 240mmHg. Known case of Chronic Kidney disease with underlying hypertension, getting treatment for same
IND(CO-AEFI)KABL Y21001	43	Patient had documented Myocardial infarction (clinical assessment, ECG, ECHO and post mortem finding), he had risk factors for MI including long standing diabetes mellitus and hypertension. Post

		mortem showed left ventricle wall thickening and hemorrhagic patch in heart and evidence of chronic lung infection.
IND(CO-AEFI)HAGUR21001	56	Unexplained Death
IND(CO-AEFI)UPMRD21001	52	"Sudden Cardiac Death With Underlying Left Ventricular Hypertrophy"
IND(CO-AEFI)KABLY21001	43	Acute myocardial infarction with underlying comorbidities - diabetes mellitus with hypertension with probable chronic lung infection
IND(CO-AEFI)RJCTG21001	55	Hypertensive emergency with intracranial bleed with underlying chronic kidney disease with hypertension

9.6. In the FAQs published by the PIB dated 8th June 2021 titled Frequently Asked Questions on COVID-19 Vaccination it has been stated as follows:

"Both the experts – Dr. Paul and Dr. Guleria... also termed as fake and unfounded the ***rumours*** *circulating on social media...* ***people die after taking vaccines****, a wrong belief held by some people in rural areas and remote blocks."*

A True Copy of Press Release titled "Frequently Asked Questions on COVID-19 Vaccination" published by Press Information Bureau dated 08.06.21 is annexed herewith and marked as Annexure P-23, pg no. 358-360

9.7. Adar Poonawalla, CEO of Serum Institute of India, posted the following on Twitter on 3rd Jan 2021:

"... COVISHIELD, India's first COVID-19 vaccine is approved, safe, effective and ready to roll-out in the coming weeks."

9.8. In an article published by Zee New India titled "Covishield is 'safe and immunogenic', **<u>has no side effects,</u> asserts Serum Institute of India**" dated 01 December 2020 the following was reported.

"Pune-based Serum Institute of India (SII) on Tuesday (December 01, 2020) claimed that Covishield - the anti-Covid-19 vaccine - being

developed jointly by it is ***completely "safe*** *and immunogenic". The company also* ***categorically refuted claims that the Covishield anti-Covid-19 vaccine has side-effects."***

""Covishield is safe & immunogenic," the Pune-based company said."

A True Copy article is annexed herewith and marked as Annexure P-24, pg no. 361

9.9. Due to the widely publicised statements of GoI officials such as Dr. Randeep Guleria (then Director of AIIMS), Dr. V. G. Somani (DCGI), Dr. V. K. Paul (NITI Aayog member) and others in Print, Television and Social Media news outlets, **the Petitioners daughters took the Covid vaccine under the wrong assumption that they are "safe and effective"** which resulted in their untimely death. These Government officials as well as the vaccine manufacturers **were privy to emerging information about various fatal adverse effects** of the Covid vaccine, yet time and again they kept making false assurances and claims that the Covid vaccines are safe. They have misguided the Public, including the Petitioners, due to which many lives of Indian Citizens have been lost due to the Covid vaccines while profiting the vaccine manufacturers.

Chapter F- GOI says vaccines limit spread of infection

10. Another widely publicised false and misleading information regarding the Covid vaccines was perpetrated by Central Government Authorities that the vaccines would limit the spread of infection. The FAQ for Covid vaccines where the Ministry of Health and Family Welfare states *"However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers."*

10.1. In multiple RTI replies by MoFHW regarding Mandatory Covid Vaccination where in their response they have said the following:

> *"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 also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers."*

Please find below RTI numbers where aforementioned response has been received:

1. MOHFW/R/T/21/04734 filed on 16/11/2021
2. MOHFW/R/E/21/05824 filed on 20/09/2021
3. MOHFW/R/E/21/06716 filed on 17/11/2021
4. MOHFW/R/E/21/04062 filed on 01/07/2021
5. MOHFW/R/E/21/04546 filed on 19/07/2021
6. MOHFW/R/E/21/04552 filed on 19/07/2021

10.2. Such statements have been misleading the Indian Population into believing that Vaccines were the only way out of the Pandemic. Such statements made the Public believe that taking the Covid vaccine was for greater public good, which resulted in countless unaccounted vaccine injuries and deaths.

10.3. However, it was known from early on, that the Covid-19 vaccines do not prevent infection or transmission. This was proven in Gauhati High Court and the Hon'ble Supreme Court

i. **Gauhati High Court**, in WP(C)/37/2020 of In Re Dinthar Incident versus State of Mizoram and 11 Ors, dated 2nd July 2021 whether the court ruled 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."

ii. The Hon'ble Supreme Court in **Jacob Pulivel v. Union of India, 2022 SCC OnLine SC 533,** ruled as follows:

89. In conclusion, we have summarised our findings on the various issues considered by us, below:

(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.

iii. Statement of Dr. Balram Bhargava, Director General, Indian Council of Medical Research (ICMR) on 30th December 2021:

"All COVID vaccines, whether they are from India, Israel, US, Europe, UK or China, are ***primarily disease-modifying. They don't prevent infection.*** *The precautionary dose is primarily to mitigate the severity of infection, hospitalisation, and death."*

Source: https://timesofindia.indiatimes.com/videos/news/covid-vaccines-are-disease-modifying-dont-prevent-infection-icmr/videoshow/88597995.cms

iv. Please refer to RTI reply from ICMR – National Institute of Virology for RTI number NIOVP/R/81221000A4 dated 14th January 2022, annexed herewith. Relevant response is reproduced below:

"RTI Query: Reports and evidence from scientific studies conducted to prove that if corona Covid-19 is an infectious disease then that is ***not transmitted to others by those who have been vaccinated*** *and that it is only transmitted or increasingly spread by those who have not been vaccinated."*

RTI Reply: This is ***not part of our records****. Hence, this information cannot be shared".*

Chapter G: Failure to heed early warning signals from within India

11. In a similar case of Dr. Snehal Lunawat, **who died of TTS** after taking the first dose of Covishield in early March 2021 when the vaccination drive was opened up for Health and Frontline Workers. Her death has been confirmed by the National AEFI Committee as a Vaccine Product Related Reaction – A1 death. The family had approached Serum Institute for treatment protocols, through desperate email communications with SII to save her life. It was a shocking correspondence where SII lied about its vaccine causing

TTS and denied any treatment protocol for the same. The correspondence is reproduced below:

i. First E-mail was sent by Dilip Lunawat to Serum Institute on 9th February, 2021 reads thus;

> *"Subject: Covishield vaccination and impact.*
>
> *Dear sir, my daughter Dr. Snehal Dilip Lunawat - have taken the vaccination on 27/01/2021 at SMBT College,Nasik and thereafter there was minor headache and fever on next day but on 4th of February she had again severe headache, vomitting hence after checking in college medical departments on 5th, she has been given medicine. She came to Aurangabad on 5th night and further for her certificate conference she came to Delhi by flight reached @3.30 pm, but in the same late night she had severe headache and unstoppable vomiting and due to weakness, she has to pickup by two/three people and send for hospitalisation in Gurgaon. I am enclosing the case summary in pdf for your research department. I would like to study by your research department and diagnosis the case. Similar cases has been observed in USA. I hope you will do the needful for betterment of the society at large. If any further*

information required you can contact me. Please note this is not a complaint but whatever corrective actions required should be taken. With regards.

Dilip k Lunawat 9225752831

Sent from RediffmailNG on Android"

ii. The reply dated 10th February, 2021 given by Dr. Chetanraj Bhamare of Serum Institute, Pune reads thus;

"Dear Mr. Lunawat,

We acknowledge the receipt of your report of adverse event.

For the assessment of the case kindly provide the batch details of vaccine administered.

Kindly note that, Covishield does not cause transverse sinus thrombosis or infarcts.

Please refer the details of COVISHIELD available online at

https://www.seruminstitute.com/product_covishield.php.

Regards,

Dr. Chetanraj Bhamare, MBBS MD

Safety Physician,

Clinical Research and Pharmacovigilance Dept,

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Serum Institute of India Pvt. Ltd., Pune (India)."

iii. The email dated 13th February, 2021 sent by Dilip K. Lunawat reads thus;

> *"Dear sirs, this has reference to our earlier emails, we are enclosing the medical case summary of my daughter Dr Snehal Dilip Lunawat and given below the* ***cases links around india, which are similar to our case.***
>
> *https://www.cnbctv18.com/healthcare/16-deaths-reported-among-vaccine-recipients-govt-says-not-linked-to-vaccine-patient-groups-demand-more-data-8199491.htm*
>
> *https://timesofindia.indiatimes.com/city/bengaluru/karnataka-asha-worker-dies-12-days-after-vaccination-in-belagavi/articleshow/80712499.cms*
>
> *we again request you to find out by your research team to stop further deaths due to vaccination. If you have any research done on thrombosis due to covishield please share. Our patient is critical and suffering. It might help us. Thanks"*

Y. VASUDEVA RAO NOTARY ADVOCATE G.O.Ms.No.2742 DC:26-12-2011 Appointed by the Govt. of A.P. India

iv. The reply dated 15th February, 2021 given by Dr. Chetanraj Bhamare of Serum Institute, Pune reads thus;

"Dear Mr. Lunawat,

Thank you for sharing medical case summary of Dr. Snehal.

As we could find in the news reports, you have shared, the deaths were not caused by vaccine and were the coincidental events with vaccination. The govt. has also investigated and concluded the cases as not related to the vaccination. In any large immunization campaign such coincidental events and deaths do occur, they are not caused by the vaccine but are actually a part of background rate of events.

As informed to you earlier, ***Covishield do not cause thrombosis or any other cardiovascular events.***

The known adverse reactions are injection site reactions, fever, headache, malaise, fatigue, etc. The majority of adverse reactions are mild to moderate in severity and usually resolved within a few days of vaccination.

Please refer the details of COVISHIELD available online at

https://www.seruminstitute.com/product_covishield.php.

Kindly consult your physician for the management of the case

Dr. Chetanraj Bhamare, MBBS MD

Safety Physician,

Clinical Research and Pharmacovigilance Dept,

Serum Institute of India Pvt. Ltd., Pune (India)."

11.1. Following Snehal Lunawat's death caused by the vaccine on 1st March 2021, if the AEFI committee and the Serum Institute had done their due diligence, many young lives could have been saved. Snehal's case was one of the first rounds of vaccine deaths that happened when the vaccines were rolled out for the front line workers and doctors. If the AEFI was efficient and carried out the investigation immediately, and the Union of India followed the guidelines set by other countries with restricted use of Covishield vaccine for women only above the age of 50, then our Petitioners' daughters would still be living today. It has caused not only the death of both the Petitioner's daughters, but many more innocent young valuable lives.

11.2. It is clear from the above communication that there was first a denial that TTS is caused by the Covid Vaccine but later

it was accepted. Similarly, in the case of Petitioner 2, the Government is not accepting that MIS-C is not caused by the Covid vaccine, despite the Petitioner providing many published research showing causative link between Covid Vaccine and MIS-C.

CHAPTER H: GoI forced citizens to take covid-19 vaccines

- The statements made by the Respondents in the affidavit regarding vaccination being voluntary and there was no compulsion to any citizen to get vaccinated are prima-facie false and misleading.
- Through various direct and indirect actions (listed below), GoI forced Indian citizens to take the Covid-19 vaccines

12. That the Respondent in para 41 of the affidavit had stated as under;

> *"41. It is critical to appreciate that vaccination of eligible population under the National Covid-19 Vaccination Program is **voluntary**. The Operational guidelines issued by the Central Government to all States/UTs clearly state that vaccination is voluntary."*

12.1. The above statement is malafide and seeks to deceive this honourable court. The Central Government using its powers conferred under Disaster Management Act, 2005, ordered State Governments to ensure 100% vaccination **throughout India** which compelled States to release Orders mandating 100% Covid Vaccination. This is made clear from the following points:

i. The Disaster Management Act 2005 was in force from 24 March 2020.

ii. Under this act, the entire decision making process is controlled by the Central Government, wherein State Governments have to follow the orders without any deviation.

iii. NDMA, under the Chairmanship of the Prime Minister, issues Nationwide orders, in which the Ministry of Home acts as the Nodal Agency under the NDMA Act and enforces the orders throughout the country in exercise of its powers conferred under section 6(2)(i) of the Disaster Management Act, 2005.

iv. The Ministry of Home exercised their power as mentioned above, and Ajay Bhalla, Home

Secretary, released Order No. 40-3/2020-DM-I(A) dated 26th April 2021 and stated the following:

> *"3. I would, therefore, urge you to issue directions to district authorities in your State/UT, to take all necessary measures, as advised by MoHFW in their letter, for the implementation of the containment framework, so as to flatten the curve. I would also advise that Orders issued by the respective State Governments/UT Administrations/district authorities, for imposing restrictions, should be widely disseminated to the public and to the field functionaries for their effective implementation."*

v. The MoHFW letter DO no. Z.28015/85/2021-DM Cell dated 25th April 2021 issued by MoHFW states the following:

> *"D. Vaccination*

***100% vaccination** for the eligible age-groups shall be undertaken duly creating additional vaccination centres and optimal capacity utilization of existing Centres."*

True Copy of the Home Secretary Order dated 26.04.21 and MoHFW Letter dated 25.04.21, is Annexed herewith and marked as Annexure P-25, pg. no. 362 - 367

vi. The Ministry of Home Affairs released another order dated 27th May 2021 exercising their powers conferred under section 10(2)(l) of the DM Act 2005, addressed to all State Chief Secretaries reiterating the letter of MoHFW letter DO no. Z.28015/85/2021-DM Cell dated 25th April 2021.

True Copy of the Home Secretary Order dated 27.05.21, is Annexed herewith and marked as Annexure P-26, pg. no. 368-373

vii. Thereafter, the Ministry of Home Affairs released an **Order 40-3/2020-DM-I(A) dated 27th December 2021**, undersigned by Ajay

Bhalla (Home Secretary) in exercise of its powers conferred under section 6(2)(i) and 10(2)(l) of the Disaster Management Act, 2005 directing all State and UT Governments to consider implementation of MoHFW Advisory vide D.O. letter No.Z.28015/318/21-EMR undersigned by Rajesh Bhushan (Health Secretary) dated 21st December 2021, where MoHFW repeats its advisory on vaccination as given below:

> *"D – Vaccination:* ***ensure 100% vaccination coverage*** *of left out first and second dose eligible beneficiaries in an accelerated manner. Special focus to be given to those districts where the first & second dose coverage is less than national average. The door-to-door vaccination campaign need to be strengthened."*

True Copy of the Home Secretary Order dated 27.12.21 and MoHFW Advisory dated

21.12.21, is Annexed herewith and marked as Annexure P-27, pg. no. 374- 378

viii. Ministry of Home issued specific orders to the state under the DM act to follow the advisory issued by Rajesh Bhushan where he is asking States and UTs to "Ensure 100% vaccination coverage" as shown in the point above.

Further, para iii of the said order reads:

> "***Any person violating these measures will be liable to be proceeded against as per the provisions of Sections 51 to 60 of the DM Act, besides legal action under Section 188 of the IPC, and other legal provisions, as applicable"***

ix. Thereafter, the Ministry of Home Affairs released an Order 40-3/2020-DM-I(A) dated 25th February 2022, undersigned by Ajay Bhalla (Home Secretary) in exercise of its powers conferred under section 6(2)(i) and 10(2)(l) of the Disaster Management Act, 2005 directing all State and UT Governments to consider implementation of MoHFW Advisory

vide D.O. letter No.Z.26015/1/2022-DMCell undersigned by Rajesh Bhushan (Health Secretary) dated 18th February 2022, where MoHFW repeats its advisory on vaccination as given below:

> *"D – Vaccination:* ***ensure 100% vaccination coverage*** *of left out first and second dose eligible beneficiaries in an accelerated manner. Special focus to be given to those districts where the first & second dose coverage is less than national average. The door-to-door vaccination campaign need to be strengthened. Similarly precaution dose & adolescent vaccination shall also be taken up for all eligible people.*
>
> *As far as schools are concerned, the district administration, in collaboration with school management, may* ***ensure vaccination of all teaching and non-teaching staff****.*

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***All activities**, like restaurants, gym, spas, sports, swimming pools, etc. considered for resumption of services shall **promote 100% vaccination of the eligible staff**.*

True Copy of the Home Secretary Order dated 25.02.22 and MoHFW Advisory dated 18.02.22, is Annexed herewith and marked as Annexure P-28, pg. no. 379-383

x. MoHFW released another Advisory vide D.O. letter No.Z.26015/1/2022-DMCell undersigned by Rajesh Bhushan (Health Secretary) dated 23rd March 2022, where MoHFW repeats its advisory on vaccination as given below:

*"Vaccination is an important strategy to prevent disease, reduce hospitalization and case severity, States shall strive towards **ensuring 100% vaccination for all the eligible age-groups**. Particular focus shall be given to cover left-out first*

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*and eligible second dose beneficiaries. Similarly, administration of Precaution doses and vaccination amongst young adolescents (12 years and above) shall also be taken up for all eligible people. The **resumption of services** shall be undertaken while **promoting 100% vaccination** of the eligible staff/employees.*

True Copy of MoHFW Advisory dated 23.03.22, is Annexed herewith and marked as Annexure P-29, pg. no. 384-387

12.2. The **State of Tamil Nadu**, where the Petitioner No. 2 resides, in an Counter Affidavit dated 03.01.2022 submitted to the Hon'ble Supreme Court in the case of Jacob Puliyel vs Union of India that they were following the **directives of Central Government for <u>mandating</u> Covid Vaccines**. The appropriate point is reproduced below:

... in the letter, dated 03.12.2021, the Department of Health and Family Welfare Department, Government of India, among others, has instructed that:-

"..Please ensure that the remaining 1st and 2nd dose gaps in Covid Vaccination in respect of your State are addressed and filled up through proactive measures."

... in the letter dated 21.12.2021, the Department of Health and Family Welfare Department, Government of India, among others has instructed that:-

Ensure cent per cent coverage of left out first and second dose eligible beneficiaries in an accelerated manner."

True Copy of the Counter Affidavit by the State of Tamil Nadu dated 03.01.21 filed in the Hon'ble Supreme Court of India, is Annexed herewith and marked as Annexure P-30, pg. no. 388 - 403

12.3. We draw attention of the Hon'ble Court to note that **nowhere in the above referenced Orders and Advisories, the Government of India has communicated to the States that vaccine recipients <u>should be given informed consent</u>, or duly <u>informed about all potential adverse effects</u> of the Covid vaccines. While on the other hand it has ordered to ensure 100% vaccination from the age of 12 and above.**

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12.4. That almost all states, employers and Public institutions had brought the mandates to prohibit the movement, business and livelihood of the citizens who had not taken the vaccines. The people were deprived of travel and movements. All such mandates were challenged before Hon'ble Supreme Court and various High Courts & this Hon'ble Court had declared as illegal and disproportional as well as violative of fundamental rights of the citizens.

i. Jacob Puliyel v. Union of India, 2022 SCC OnLine SC 533

ii. Re: Dinthar Incident Vs. State of Mizoram and Others 2021 SCC OnLine Gau 1313

iii. Madan Mili Vs. Union of India 20201 SCC OnLine Gau 1503

iv. Registrar General Vs. State of Meghalaya 2021 SCC OnLine Megh 130.

v. Dr. Aniruddha Babar Vs. State of Nagaland 2021 SCC OnLine Gau 1504.

vi. Osbert Khaling Vs. State of Manipur 2021 SCC OnLine Mani 234.

vii. Feroze Mithiborwala Vs. The state of Maharashtra and Others 2022 SCC OnLine Bom 457

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12.5. That on **12th December 2021**, the Puducherry LG ordered forced and compulsory vaccination.

True Copy of the article "Puducherry LG Mandates Covid-19 Vaccination, "**Punishment For Those Who Refuse**" published on 12.12.21 by Outlook India is Annexed herewith and marked as Annexure P-31, pg. no. 404

12.6. The Director to the Government of India, Ministry Women and Child Development, Navendra Singh, in a letter to Principal Secretaries / Secretaries, WCD /SJE (All States & UTs) had mandated vaccination for children falling in 15-18 age group in Child Care Institutions in all states through a circular dated 04.01.2022.

> *"Further it is brought to the notice that in light of the* ***compulsory vaccination of children against COVID-19*** *falling in the 15-18 age group, it is requested that all District Magistrates may be directed to make appropriate arrangements on for vaccination of the Children living in CCIs as well, on priority basis."*

True Copy of the Letter by Navendra Singh, dated 04.01.22 is Annexed herewith and marked as Annexure P-32, pg. no. 405-406

12.7. Vaccine mandate was issued for Indian Railways Chitranjan Locomotive Works, Chitranjan which is directly under the management of Ministry of Railways. The following was ordered by CPCO/CLW:

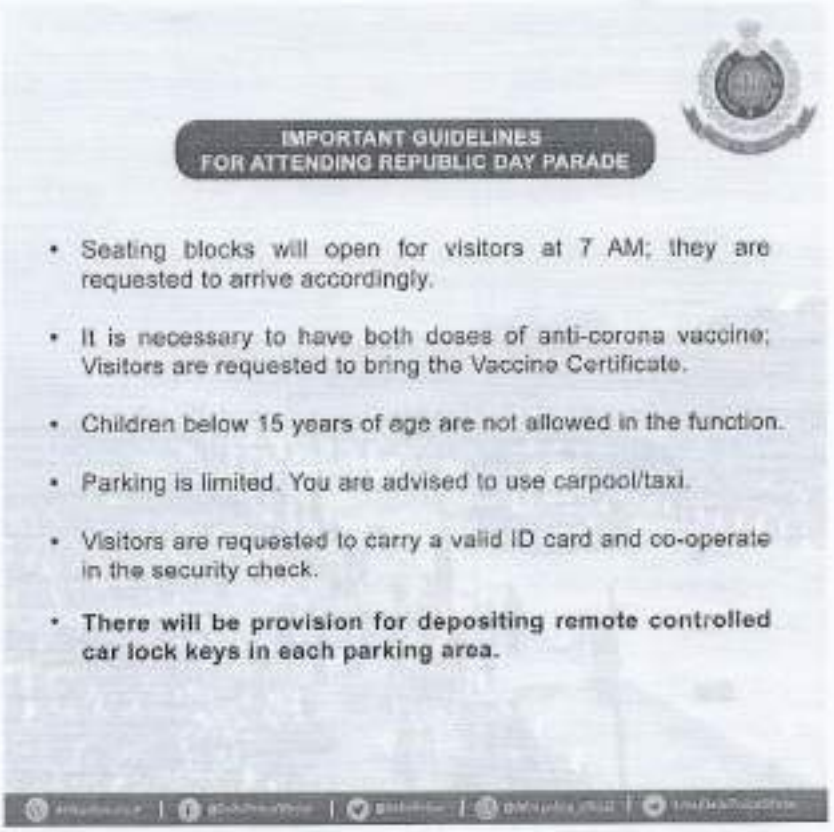
> *"Further it was advised that, staff, who were not yet vaccinated, were* ***not to be allowed to join duty*** *w.e.f. 10.1.2022 till such time they get themselves vaccinated by first dose...*
>
> *The above instructions were issued* ***to ensure 100% vaccination*** *of the staff working in workshops and offices keeping in mind the condition prevalent at the particular time."*

True Copy of Circular by Chittaranjan Locomotive Works, Indian Railways, dated 28.2.22, is Annexed herewith and marked as Annexure P-33, pg. no. 407

12.8. In a letter issued by Dy. Chief Personnel Officer (W), For Chief Works Manager, Eastern Railway, Kanchrapara dated 30.6.21 mentions, *"9. All staff should invariably get themselves* ***vaccinated on priority and mandatory basis****. Respective BOs shall monitor and impress upon staff under their control for their immediate to their producing supportive documents and vaccination."*

True Copy of Circular by Eastern Railways, Indian Railways, dated 30.6.21, is Annexed herewith and marked as Annexure P-34, pg. no. 408-409

12.9. On 23rd Jan 2022, Delhi Police, under the jurisdiction of Ministry of Home Affairs, Government of India, shared an image on Twitter with important guidelines for Republic Day 2022 Parade celebrations. The guidelines mention *"It is necessary to have both doses of anti-corona vaccine;"*



IMPORTANT GUIDELINES
FOR ATTENDING REPUBLIC DAY PARADE

- Seating blocks will open for visitors at 7 AM; they are requested to arrive accordingly.
- It is necessary to have both doses of anti-corona vaccine; Visitors are requested to bring the Vaccine Certificate.
- Children below 15 years of age are not allowed in the function.
- Parking is limited. You are advised to use carpool/taxi.
- Visitors are requested to carry a valid ID card and co-operate in the security check.
- **There will be provision for depositing remote controlled car lock keys in each parking area.**

12.10. The Agniveer Recruitment Rally Notification also mentions pre-requisite for vaccination of candidates

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*"38. Vaccination Certificate. All candidates appearing for rally should be **fully vaccinated for Covid-19**. The certificate to be produced to auth upon asking"*

True Copy of Relevant Extracts of Agniveer Recruitment Rally Notification by Indian Army is Annexed herewith and marked as Annexure P-35, pg. no. 410- 413

12.11. Air Force Officer was dismissed from Service for not taking the Covid vaccine. The case, Yogender Kumar vs Indian Airforce, R/SCA/14964/2021, is pending in the Hon'ble Gujarat High Court.

12.12. The Office of Dy. Inspector General NZ-II, Central Industrial Security Force, Ministry of Home Affairs has released a circular dated 18.02.2023 requiring all personnel to get their precautionary dose of Covid vaccine. This clearly shows that despite Court orders, the Government is pressing citizens to get the Covid vaccine. They mention the following in the circular:

"It is pertinent to mention that the MHA is pressing hard to get administered the precautionary dose at the earliest to all vaccine due personnel."

*"...submit a compliance report of **100% vaccination** (except personnel with medical issue CISF Booster dose mandate*

True Copy of Circular by CISF, MHA is Annexed herewith and marked as Annexure P-36, pg. no. 414 -415

12.13. There have been repeated orders from GoI to **"ensure 100% coverage"** and also threats of legal action on any violation. Various basic services such food rations, employment, education, transportation, government services, etc. had been made conditional on taking the Covid-19 vaccine. In light of this, the claim that there was no legal compulsion to take the vaccine in UoI's affidavit is tantamount to prevarication to mislead the Hon'ble Court and Indian Citizens.

12.14. Various High Courts have taken note of deaths of citizens due to Covid vaccines and passed orders.

Sr Nos	Party Name & Case Nos	Name of the Court	Detail brief of prayers	Status and Date of Order

1	**Dilip Lunawat** v. Serum Institute of India (P) Ltd. [Writ Petition (C) No. 2739/2022] Link:	Bombay High Court	Action against guilty and compensation and interim compensation of Rs. 1000 Crores from Serum Institute, Institute, Adar Poonawala Bill Gates	Notice issued to: **1.** Bill Gates **2.** Adar Poonawalla **3.** Randeep Guleria **4.** Dr. V.G. Somani **5.** Union of India **6.** State of Maharashtra **7.** Drug Controller General of India **[Citation]** Dilip Lunawat v. Serum Institute of India (P) Ltd., **2022 SCC OnLine Bom 1773**

2	**Jean George** & Anr v. Serum Institute Of India & Ors. [Writ Petition (C) No. 13573/2022]	Kerala High Court	Action against guilty and compensation and interim compensation of Rs. 10 Crores from Serum Institute, Institute, Adar Poonawala Bill Gates.	Court asked UOI to file reply. **Title:** Vaccination: Kerala High Court Seeks Centre's Response On Parents' Plea **Link:** https://www.livelaw.in/news-updates/19-year-old-dies-post-covishield-vaccination-kerala-high-court-seeks-centres-response-on-parents-plea-196742?from-login=672554

3	**Sayeeda** Vs Union of India [WP (C) No. 17628 of 2022]	Kerala High Court	Compensation to widow of a person died due to vaccine.	Court issued directions to the Central Government to immediately formulate guidelines for giving compensation to the victims of deaths or other side effects of vaccines. **Citations: -** **(i)** Sayeeda K.A. v. Union of India,**2022 SCC OnLine Ker 4531** **(ii)** Sayeeda K.A. v. Union of India,**2022 SCC OnLine Ker 4514**

Compensation paid world-wide in vaccine injuries

13. Compensation suit 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 death is 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 haemorrhage, a complication caused by the syndrome, according to the panel's findings. Link: https://focustaiwan.tw/society/202203290026)

13.1. As per article titled "Government to pay out NT$ 2 Million in Covid-19 Vaccine Case", published in online portal Focus Taiwan dated 3rd December 2022, reports that *"The Ministry of Health and Welfare has agreed to pay NT$2 million (US$65,460) under the Vaccine Injury Compensation Program (VICP) to a Nantou County man who had a stroke after receiving the AstraZeneca (AZ) COVID-19 vaccine."*

True Copy of the article is Annexed herewith and marked as Annexure P-37, pg. no. 416

13.2. 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

13.3. 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 £110million. Vikki Spit, from Alston, Cumbria, hopes to qualify for financial support after her fiancé Zion, 48, died of a brain haemorrhage 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

13.4. In a recent case of vaccine injury the Government of Singapore granted a compensation of Rs. 1 Crore 78 Las to the victim as vaccine cause increase in heart beats.

Link: https://greatgameindia.com/pfizer-heart-attack-compensation/

13.5. Thailand Government till now gave Rs. 1.71 Billion (around 400 Crores) to 14,034 people as a compensation for side effects of Corona Vaccine. In them 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

13.6. 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 (7,50,34,31,400 Crores).

Link: https://www.mctlaw.com/101-million-dollar-vaccine-injury-mmr/

13.7. SINGAPORE - A financial assistance programme will be introduced for those suffering from serious side effects related to the Covid-19 vaccine, said the Ministry of Health (MOH) on Thursday (Jan 28).

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Link:

https://www.straitstimes.com/singapore/health/financial-help-for-those-suffering-from-serious-side-effects-related-to-vaccine

13.8. In an article published in Korean Times titled **"Court orders gov't to compensate man for coronavirus vaccine side effects"** on 20th September 2022, relevant paras are reproduced below:

> *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.*

True Copy of the article is Annexed herewith and marked as Annexure P-38, pg. no 417- 418

13.9. So, a compensation mechanism exists in most of the countries and many of the vaccine adverse events injuries have been compensated appropriately.

Chapter I:

The AEFI system implementation by GOI is below international standards and standards set by Indian authorities including the Hon'ble Supreme Court

14. Even looking at India's own AEFI data, published till January 2023, we see that the AEFI recorded is very skewed and when vaccination coverage increased the AEFI counts started decreasing.

Year & month of vaccination	AEFI cases recorded	Covered people
2021-01	331	from Jan 16th. Healthcare +frontline
2021-02	191	
2021-03	429	Also 60+ aged

2021-04	307	Also 45+ aged
2021-05	67	Also 18+ aged
2021-06	159	
2021-07	155	
2021-08	156	
2021-09	132	
2021-10	43	100 crore vaccine doses completed
2021-11	55	
2021-12	45	
2022-01	117	
2022-02	31	
2022-03	57	
2022-04	20	
2022-05	24	
2022-06	10	
2022-07	59	200 crore vaccine doses completed
2022-08	2	
Total	2390	

We have 1970 cases in the first 100 crore vaccine doses and just 420 (about 25%) in the next 100 crore vaccine doses. This indicates callousness on part of GoI in the AEFI reporting process.

14.1. If we look at the AEFI deaths, this anomaly becomes even more stark:

Year & month of vaccination	AEFI deaths	Covered people
2021-01	40	from Jan 16th. Healthcare +frontline
2021-02	38	
2021-03	253	Also 60+ aged
2021-04	189	Also 45+ aged
2021-05	29	Also 18+ aged
2021-06	80	
2021-07	64	
2021-08	66	
2021-09	71	
2021-10	26	100 crore vaccine doses completed
2021-11	26	
2021-12	21	
2022-01	35	
2022-02	4	
2022-03	3	
2022-04	1	
2022-05	3	

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2022-07	3	200 crore vaccine doses completed

While 856 deaths are reported in the AEFI system in the first 100 crore vaccine doses, but just 96 in the next 100 crore vaccine doses! The AEFI implementation by GoI is thus clearly dysfunctional, and shows the disregard for Indian citizens' lives on part of GoI.

Chapter J: Lack of AEFI investigation in serious adverse event cases due to vaccination

15. **Case of Aarya Bhanushali, Aged 15 years, Ghatkopar, Mumbai, Maharashtra**

Aarya had taken Covid vaccine on 8th January 2022 as reported in article published in Midday, Mumbai. On 12th January 2022, Aarya complained of chest pain and acidity. She was given soda and cold water but the pain had increased. She suddenly fell unconscious. She was taken to a nearby hospital but upon examination by the Doctor, she was declared dead.

This death was brought to public notice by Delhi based Dr. Tarun Kothari who had used Twitter, a social media platform, to inform the public of potential risks of Death

after Covid Vaccination. Brihanmumbai Municipal Corporation (BMC) responded to his tweet, threatening legal action against the doctor. Furthermore, without due investigation, they have declared the death as "Natural death due to cardiac arrest."

iv. AEFI Surveillance and Response Operational Guidelines – 2015 on page 25 under para "4.2 Channels for reporting AEFI" and sub para "4.2.2 Immediate serious AEFI notification (by the first person who identifies the event)" mentions that AEFI reports in the local media are to be investigated.

v. The guidelines mention that the investigation of reported AEFI death and cluster (two or more cases of the same adverse event related in time, place or vaccine administration) should be conducted without any delay. It is recommended that an autopsy in a death suspected to be due to an AEFI be performed as soon as possible (within 72 hours) to avoid tissue damage, development of postmortem artifacts and lysis of the adrenal glands, which can alter diagnosis.

vi. Use of Verbal Autopsy form in case of unexplained death/home death/inadequate information/insufficient medical records is a new addition in the guidelines.

vii. Far from following the guidelines, Brihanmumbai Municipal Corporation was instead engaging in defamation of people who are bringing an adverse event following vaccination to public attention.

15.1. The following is an exchange between family members of 2 victims who suffered Fatal Adverse Events after taking the Covid Vaccine. The Government Official refuses to register an AEFI and demands proof from the family members for the Causality of the Adverse Event, and only after which she is willing to register the AEFI.

Nikita Patel – Government Official

Aarogya Vibhaag, Opp. Fire Station, Vesu, Surat

By: Minal Madhwani, Dharmesh, Kirit Bhalani

https://u.pcloud.link/publink/show?code=XZsK2eXZ4zobpIVuQGy38iFyCCMezfORj9ky

Nikita Patel: In this there is nothing which shows that the death is caused by the vaccine.

Unknown: So then what is the cause?

Nikita: ***Death due to vaccine has not been proven here and vaccines have no such side effects that***

cause death after 20 days. *After taking the vaccine, you can get Covid positive. Who are you? (someone asking the videographer)*

Is he your father (someone asking the victim family members).

Who are you (someone asking Kirit Bhalani)

Minal: His father also went through the same problem

Nikita: I told her the same thing and I am telling you also the same thing., Both doses of the vaccine including 1st dose and 2nd dose takes a total of 45 days. 14 days after the 2nd vaccine, we find out the effectiveness of the vaccine. Whenever we get a vaccine, if within 30 minutes there is some allergic reaction then it is a serious side effect, only if there is a known allergy to one of the ingredients of the vaccine. Only then, there is a chance of serious side effect for 1 individual out of 10 lacs. If we give proper treatment to them, there is a chance to save their life. The other side effects of vaccines like headaches, slight fever or anything else stays for 2-3 days and it is minor. That we can call AEFI but that is also very minor. There are no known cases of death after

vaccine. I am still trying to explain to you that effectiveness of vaccines starts only after 45 days. From your father's report it looks like he took the vaccine on the 20th and then he tested positive, that doesn't mean it was because of the vaccine. I have explained the same thing to this lady as well. Please wear your mask (to the videographer). You ask me your questions because I don't want to repeat the same thing again and again.

Kirit: My father's age was 60 years. He had no other type of disease, no pressure or nothing else. So then why this happened only after the vaccine?

Nikita: It is not like that. We cannot prove that it happened because of the vaccine, whatever you have written is not proof.

Kiritbhai: We don't have any proof

Minal: In other states such cases are being registered, we are with an organization and we are going to file a case in the Supreme Court.

Nikita: Which states? It is important for us to register.

Kirit: Every state is doing it in AEFI

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Nikita: We are also doing. But until YOU prove that this death is caused by the vaccine we will not register.

Kirit: But what proof I can find for it? How to give that proof?

Minal: Post Mortems are not happening

Nikita: When did the death happen?

Kirit: He had no other illness, otherwise we could have thought its because of that.

Nikita: In this there is no proof that they came positive because of the vaccine.

Cross Talk between Nikita, Minal and Kirit

Minal: We are not coming here because we are enjoying this. My mother has died

Nikita: Covid is not happening because of the vaccine. It is happening after the vaccine.

Another Official: We empathise with the death in your family. It is a very sad experience. But how the vaccine works and how disease happens, we should understand that first.

Minal: Are you a doctor? Did you go to the Lab to make the vaccine?

Unknown: Yes I am a doctor.

15.2. The article featured in Scroll.in titled "How India failed those who were harmed by the Covid-19 vaccine" published on 02.11.22 by Tabassum Barnagarwala (Annexure -P12). Relevant Excerpts:

- *Chandra told Scroll.in that after vaccination, his brother-in-law, K Sarvottam, suffered* ***thrombosis****, and then a brain haemorrhage, and died in Bengaluru in March 2021. "I reached out to top decision makers in the health ministry when he was on a ventilator," he said. "Till date there is no response."*
- *Chandra reported the case to the district AEFI committee. Sarvottam's treating doctor, Gurucharan Adoor, even made a presentation to the committee, showing members evidence of vaccine-induced haemorrhage. "We showed them records and recommended this be categorised as AEFI," Adoor told Scroll.in. But, Chandra said, after that* ***they heard nothing from the government****.*
- *Chandra said that he later learnt that vaccine-induced thrombosis can be treated with intravenous immunoglobulin. "Our intention to report this was to bring it in records," he said. "But the* ***local AEFI***

committee did not bother *to visit the hospital or family to gather evidence."*

- *Government officials told Scroll.in that the Central government had assured free treatment to those who suffered adverse events – but on the ground, patients have received* ***little support from government*** *hospitals.*
- *Sudhir Waghmare, who is 40, and who lives in Pune, is a case in point... He was hospitalised for 13 days, then required home-rest for six months to recuperate.*
- *Waghmare owns a tea stall in a busy timber market in the city, and earlier managed to earn between Rs 2,000 and Rs 3,000 per day. But his visits to numerous doctors, and his various treatments, ate up Rs 6 lakh. He exhausted his savings, and borrowed money from friends and family.*
- *Waghmare suffered Guillain-Barré syndrome, an adverse event well documented in some recipients of the AstraZeneca vaccine.*
- *Waghmare said that after he began experiencing these symptoms, he returned to the vaccination site and informed the nurse. The nurse asked him to visit a municipal hospital but did not report it on CoWIN.*

Even as he struggles to get make ends meet again, Waghmare believes that he should be provided "compensation for the medical bills I incurred and the months I could not work due to treatment".

15.3. The Petitioners have come across multiple potential severe AEFI cases where the victims have died however there is no information with the family of the victims regarding whether the cases have been investigated by AEFI committee.

i. **Arya Satheesan**

Arya Satheesan, R/o. Thekkinath House, Kaipathoor PO, Pathanamthitta, Kerala, Aged 28, took COVISHIELD vaccine on 3rd August 2021, serious adverse events commenced on 5th August and after 3 weeks of hospitalisation died on 23rd August 2021. Rakshana, her daughter was 8 year old then. Vaccine connection was highlighted by the family and autopsy was conducted. Autopsy opinion was reserved pending laboratory examination results. Till date they have not received the laboratory exam results. Also her record is not seen in the AEFI causality analysis results updated till September 30th 2022 in MoHFW website. Her family have done all that they can (Her husband

has filed police complaint, approached the human rights commission and her death and its link to vaccine were reported in a newspaper also) but there is no justice for them so far.

ii. **Amita Netam D/o Balram Netam, village-Kutulnar, Block- Geedam, Police Station- Faraspal, District- Dantewada, Chhattisgarh**

The deceased girl Amita Netam had gone to school on 4-1-2022 and she was vaccinated in the school situated at village Bade Tumnar. On 5-1-2022 she had gone to school and when, she returned home in the evening, she complained about fever and body ache to her mother. On 6-1-2022, she again went to school for submitting leave application to the teacher. She died on 7-1-2022 at about 12 pm at home. The family members said their daughter used to cycle for 15 km for reaching school. The family said the teachers should have brought their daughter by some vehicle after vaccination considering the distance of 15 km between school and the village of the deceased girl. The family and prominent persons of the village had made a complaint to the police station Faraspal on 7-1-2022 at 6 pm. Post mortem has been conducted on the body but

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they don't have faith that the report would say she died of vaccination because all the doctors and police are working for government.

iii. **Anuradha Makvana D/o Bhagwan Singh, aged 16 years, Makadone (Bisankhedi),Tehsil-Tarana, Ujjain, Madhya Pradesh**

Anuradha, was a 16-year-old and studied in 9th Grade. Her health was also perfectly fine and faced no health issues. She got vaccinated under a vaccination programme organised by government in her school, Girls Government Higher Secondary School, itself. This vaccination programme was available to all and every child was vaccinated under the same. Registration of the programme was to be done on Wednesday (05.01.22) and vaccination was given on Thursday i.e., 06.01.22. at 1 PM. After getting vaccinated, she sat in the bus to go back home. It took her approximately 30 minutes to reach her stop. Her stop was a few miles away from her house, so she used to walk the distance after reaching the stop. When finally reached the stop, she walked out of the bus, walked a few steps and then felt some sort of pressure in her stomach so she went inside a farm to defecate

after which she fell unconscious. Her uncle found her lying near the farm and took her to Tarana Government Hospital.

There, she got admitted and was given a glucose drip within 10 minutes. The doctors of the Tarana Government Hospital referred her to a hospital of Ujjain, Patidar Hospital for better treatment. While she was being taken to Ujjain on bike, she had another drip attached to her. But after some point her health deteriorated and died en route to Ujjain itself. Her death took within 2-3 hours of vaccination.

Chapter K:

Systemic under-reporting of adverse events by AEFI

Non-transparency, lack of follow-up, lack of planning

16. The Hon'ble Supreme Court Judgement in **Jacob Puliyel v. Union of India, 2022 SCC OnLine SC 533** has noted the following:

> *"84... 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."*

A facility for voluntary reporting of Adverse Events by individuals was created by the Government of India and made available on the Cowin online portal after this judgement. However this system is still dysfunctional for all practical purposes. While the public has no facility to query the registered AEFIs and see the anonymised data, even the victims who registered their complaints do not get any reply for their queries, and there is no follow up inquiry from the authorities to know more about the AEFI and to investigate it.

Petitioner 2 has personal experience with it as he had registered his Graves disease and hyperthyroidism (whose onset followed soon after his first dose of vaccination, but unfortunately after his daughter got vaccinated) in the COWIN portal as soon as this facility opened up. The AEFI

number allotted was (CO-AEFI)TNCBE21000025. The system does not have any facility to explain the difficulty/adverse event faced. Also till date there has been no inquiry or follow-up regarding the report, and no facility exists in COWIN to seek any status update. In short this facility for self-reporting makes a mockery of the clear guidelines set out in the Hon'ble Supreme Court judgement which clearly ordered a functioning, publicly accessible platform that also includes self-reporting of AEFI.

Also, till date there has been no efforts by the Government to widely advertise the platform and explain its functioning. More importantly the reporting system does not offer the **instructions/information in any local language including Hindi**. Moreover, it is **in contempt of the Hon'ble Supreme Court Order** to "create awareness of, and to navigate, this platform for self-reporting".

16.1. "AEFI: Surveillance and Response Operational Guidelines 2015", published by Ministry of Health and Family Welfare, Government of India provides that all the persons vaccinated must be followed up and all the cases of death/serious adverse events must be reported immediately. A True Copy of relevant extracts of the Guidelines is annexed herewith as Annexure P-39, pg no. 419- 433

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16.2. Clause 4.2.2 of the above 2015 Guidelines requires that an immediate notification be made of a serious AEFI by the first person who identifies the event. This is followed by reporting, investigation and documentation. Clause 4.3 requires a post mortem to be conducted. Clause 5.3 sets out the role of the health worker, ASHA (Accredited Social Health Activists), Anganwadi Worker, community and media in doing prompt reporting and investigation. Clause 6.2 says "autopsy must ideally be performed in every case of AEFI death". Clause 10.3.1 specifically requires the AW's and ASHA's to **"follow up with beneficiaries to identify AEFI after vaccination session"** and to **"pass information of any adverse events immediately by telephone"**. Clause 11.1.3 requires frontline workers and others to interact with the families and communities where the deaths and serious adverse events take place. Clause 11.4 requires that the names and contact details of the officers involved in vaccinations, the members of the AEFI committee etc. be made public.

16.3. However, there is malafide in GoI's Covid-19 vaccine AEFI reporting system, suppressing the original 2015 AEFI guidelines and instead publishing a "Revised AEFI Guidelines: Executive Summary".

A True Copy of the revised guidelines dated 01.03.2017, is annexed herewith as Annexure P-40, pg no 434- 454

16.4. The critical manipulation by GoI lies in leaving out those parts in the AEFI guidelines, which specifically require the frontline workers of government to follow up with each person vaccinated and report all AEFI's. This is replaced by the phrase "Getting the information of the case". This phrase left it open for the government to take the stand which it does now that the officials are only required to record, report and investigate if the vaccinated person makes a complaint. This is how the government has manipulated and suppressed the requirement for frontline workers (ASHA's and AW's) who are available in villages and slums to carry out active follow up and to suo motu report AEFI.

16.5. In 2020, WHO published a document titled "2020 WHO Covid-19 Vaccines: Safety Surveillance Manual", emphasizing the need for active surveillance system to follow up adverse events following immunization. The relevant extracts of the 2020 WHO document is as under:

> *"However, routine* ***passive reporting systems will not be sufficient*** *to allow the rapid assessment and appropriate public health response that will be*

needed during COVID-19 vaccine introduction. Routine systems will need to be enhanced with ***active surveillance*** *to improve detection of AEFIs.*

...

COVID-19 vaccine manufacturers are also responsible for monitoring the safety of their COVID-19 vaccines introduced and for addressing any safety issues that occur. Additional safety surveillance activities should be carried out by vaccine manufacturers to continue collecting information on safety beyond that collected during prelicensure COVID-19 vaccine trials.

Deaths following COVID-19 immunization

Individuals who die following COVID-19 vaccination, including those with any related diagnosis that is an AESI, should be included in the ***protocol for investigating deaths following COVID-19 vaccination****.*

Specific protocols for autopsies of people with a suspected cause of death given as COVID-19 have been developed, and these could be used for the ***autopsy of COVID-19 vaccinated individuals*** *who die. If indicated, tissue samples should be collected*

for in-depth pathologic, virologic and genetic testing."

True Copy of relevant extracts of the "2020 WHO Covid-19 Vaccines: Safety Surveillance Manual", is Annexed herewith and marked as Annexure P-41, pg. no. 455-483

16.6. The recommendation for the rollout for the COVID-19 vaccination by **NTAGI**, during their meeting on 10th December 2020 (Annexure P-2), has the below text in the minutes.

*"It was mentioned that **safety and adverse event monitoring** in the 4-6 weeks after completing the immunization schedule among pre-specified sample size is critical in making a decision on EUA of a particular vaccine as it is accepted globally."*

16.7. The AEFI committee decided on reported cases **just twice in the first 3 months** of vaccination rollout i.e. between 16th January to 31st March, and gave decision only on 13 cases. 5 cases on 5th Feb (report published one month later on 5th March) and 8 cases on 9th March (report published on 17th March), even though there are 526 cases in AEFI, who were vaccinated before Feb 28th of which 83 had an outcome of DEATH.

16.8. Even prior to Covid-19 vaccination program, India's AEFI system was quite weak.

i. It was reported as far back as 2017 that India's AEFI is underreported. One of the reasons outlined by Gagandeep Kang, member of NTAGI was due to the AEFI committee met **only 4 times a year** and cited only 100 cases at a time.

Link: https://www.thehindu.com/sci-tech/health/heath-ministry-to-study-2017-spike-in-vaccine-related-adverse-events/article22537462.ece/amp/

ii. Following the alarming number of pickup in vaccination deaths, there were several reports about how the government in India was not able to explain why this was happening. In fact, in 2013, a team of doctors had expressed discontinuing the pentavalent vaccine, but to this day the pentavalent vaccine continues to be administered to children.

Link: (i) https://timesofindia.indiatimes.com/india/128-kids-died-after-vaccine-in-2010-govt-cant-say-why/articleshow/8641123.cms

(ii) https://timesofindia.indiatimes.com/city/pune/pentavalent-vaccine-unsafe-say-experts/articleshow/18067307.cms?from=mdr

16.9. In summary, there has been **gross negligence and criminal violation of all norms**, both established international norms and the specific terms on which the Covid-19 vaccination go ahead was given.

Chapter L: Entities facing parliamentary investigation in criminal negligence, involved in AEFI management

17. Department-Related Parliamentary Standing Committee on Health and Family Welfare released the 72nd report titled "Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine by Path in India (Department of Health Research, Ministry of Health and Family Welfare)" dated 30th August 2013. The report has concluded that the program was to serve the ulterior, commercial interests of vaccine manufacturer to include the said vaccine in universal immunization programme which would have generated windfall profit for the

manufacturer(s) by way of automatic sale year after year, without any promotional or marketing expenses.

17.1. The committee also concluded that the officers of Indian Council of Medical Research (ICMR), in an unauthorized manner, had signed Memorandum of Understanding (MoU) in 2007 even before the vaccines were approved for use in the country, which actually happened in the year 2008. The decision of ICMR of committing itself to promote the drug for inclusion in the Universal Immunization Programme (UIP) without an independent study regarding its utility was strongly objected. It was suggested that the investigation should be done by the premier investigation agency i.e. C.B.I. and appropriate legal action be taken against them.

17.2. Important recommendations of the Parliamentary Committee asking for investigation and legal action against, PATH, Bill Gates and officials of ICMR are as under;

> *"2.5 The Committee finds the entire matter very intriguing and fishy. The choice of countries and population groups; the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunization progammes of the respective countries are all pointers to a well planned scheme to*

commercially exploit a situation. Had PATH been successful in getting the HPV 4 vaccine included in the universal immunization programme of the concerned countries, this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year, without any promotional or marketing expenses. It is well known that once introduced into the immunization programme it becomes politically impossible to stop any vaccination. To achieve this end effortlessly without going through the arduous and strictly regulated route of clinical trials, PATH resorted to an element of subterfuge by calling the clinical trials as "Observational Studies" or "Demonstration Project" and various such expressions. Thus, the interest, safety and well being of subjects were completely jeopardized by PATH by using self-determined and self-servicing nomenclature which is not only highly deplorable but a serious breach of law of the land. The Committee is not aware about the strategy followed by PATH in the remaining three countries viz. Uganda, Vietnam and Peru. The Government should take up the matter with the

Governments of these countries through diplomatic channels to know the truth of the matter and take appropriate necessary action, accordingly. The Committee would also like to be apprised of the responses of these countries in the matter.

3.18. ***The Committee feels that there was serious dereliction of duty by many of the Institutions and individuals involved. The Committee observes that ICMR representatives, instead of ensuring highest levels of ethical standards in research studies, apparently acted at the behest of the PATH in promoting the interests of manufacturers of the HPV Vaccine.*** *7 3.19 It was unwise on the part of ICMR to go in the PPP mode with PATH, as such an involvement gives rise to grave Conflict of Interest. The Committee takes a serious view of the role of ICMR in the entire episode and is constrained to observe that ICMR should have been more responsible in the matter. The Committee strongly recommends that the Ministry may review the activities of ICMR functionaries involved in PATH project.*

4.6 The Committee's examination has proved that DCGI has also played a very questionable role in the entire matter. Initially, it took a call that since human subjects, as part of the studies, were receiving invasive intervention like immunization, clinical trial rules must be enforced. However, it remained as a silent spectator thereafter, even when its own rules and regulations were being so flagrantly violated. ***The approvals of clinical trials, marketing approval and import licenses by DCGI appear to be irregular. Therefore, the role of DCGI in this entire matter should also be inquired into.***

6.17. The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role, usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the consent and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends ***that on the basis of the above facts, PATH should be made***

accountable and the Ministry should take appropriate action in the matter including taking legal action against it for breach of various laws of the land and possible violations of laws of the Country of its origin.

6.26 The Committee observes that the wrongful use of the NRHM logo for a project implemented by a private, foreign agency as well as the identification of this project with the UIP has adversely affected and damaged the credibility of the programme as well as that of the NRHM. ***The Committee, therefore, recommends that such practices of diverting public funds for advancing interests of a private agency should never be allowed in future. The Committee strongly recommends that strict action should be taken against those officials responsible for such lapses."***

6.27. Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding

financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization. The Committee, accordingly, observes that it might have been more prudent if the National Technical Advisory group on Immunization (NTAGI) had been brought into the picture right in the beginning to review and give its views on the study prior to its approval and implementation."

6.36 The Committee not being convinced with the action taken by the Department or DCGI, feels that the whole issue has been diluted and no accountability has been fixed on the erring Officials/Departments for the gross violations committed in the conduct of Study. The Committee also feels that a very casual approach has been taken by the Department in the matter and their replies lack any concrete action to protect and safeguard the health of our people.

6.37 The Committee also noticed lack of firm action on the part of DCGI, to avoid such irregularities in future. One of the actions proposed by the DCGI to check any recurrence of such gross violations was

'proposal to amend the definition of New Drug during the next meeting'. The same assurance was given by DCGI in December, 2012. The Committee, accordingly, observes that response of the Department and DCGI is very casual, bureaucratic and lacks any sense of urgency. The Committee feels that DCGI is not very serious in bringing improvements in the system. It, therefore, desires the Ministry to ensure compliance by DCGI.

7.11. The Committee is concerned that if PATH can set up an office in India so easily without getting the required mandatory approvals/permissions, then individuals and entities inimical to the interest of the country can do the same. The Committee expresses its concern that paper and shell companies can be easily registered in many jurisdictions and then set up a place of business in India as "Liaison offices" with no questions being asked. ***It is surprising that security and intelligence agencies did not raise an eyebrow on the way a foreign entity entered India virtually incognito through the backdoor.*** *The Committee desires that such incidents should not be allowed in future. The Government should tighten the*

rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in anti-national and/or unlawful activities.

*"7.13 Coming to the instant case, it is established that PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/**demonstration project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the Country. This is a serious breach of trust by any entity as the project involved life and safety of girl children and adolescents who were mostly unaware of the implications of vaccination. The violation is also a serious breach of medical ethics. This act of PATH is a clear cut violation of the human rights of these girl children and adolescents.** It also deems it an established case of child abuse. The Committee, therefore, recommends*

action by the Government against PATH. The Committee also desires that the National Human Rights Commission and National Commission for Protection of Children Rights may take up this matter from the point of view of the violation of human rights and child abuse. The National Commission for Women should also suo motu take cognizance of this case as all the poor and hapless subjects are females."

Link:

https://sansad.in/getFile/rsnew/Committee_site/Committee_File/ReportFile/14/14/72_2016_6_15.pdf?source=rajyasabha

17.3. The Constitution Bench of the Supreme Court in the case between **Kalpana Mehta Vs. Union of India (2018) 75 SCC 1**, has clarified that the Parliamentary report is admissible in evidence under Section 74 of Evidence Act.

17.4. Despite there being sufficient evidence and report which disclose the commission of cognizable offence against the accused as stated above, **no action has been taken yet**. The one question is arising in the mind of every citizen of this country that, even after 9 years of the clear instructions of the parliamentary committee as per the 72nd Report about

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the death of the 8 girls, the Union Government has not filed an FIR against those culprits. **Hence, it raises doubts in mind of poor girls in this country that is there a lack of political will to take action against the mafias responsible for the death or our system is so steeped into corruption.**

Chapter M: Failure of GOI to address grievances of parents who have lost their children to covid-19 vaccine adverse events

18. Timeline of Grievance Correspondence of Petitioner 1

Sr. No.	Event	Date
1	Petitoner 1 suffers loss of her daughter, Rithaika Omtri	19.06.21
2	Petitoner 1 files grievance with PMO (PMOPG/E/2021/0440276)	14.07.21
3	Petitioner 1, after failing to receive any reply, files a new grievance with PMO. (DHLTH/E/2021/17091)	29.9.21

4	Petitioner 1 original grievance was marked as "Fully Resolved" in the PMO portal. There was no action taken or reply provided to Petitioner 1 for the grievance for a sensitive and a priority matter involving the death of a young adult for over 8 months. The grievance was marked as "Fully Resolved" by the Deputy Secretary without ever reaching out or hearing the petitioner. The reply given has factual errors and counterpoints, but the petitioner was not heard at all. The Officer responded to the detailed grievance by the petitioner without addressing any of the issues raised in it. True Copy of the details of the case is annexed in the Affidavit filed by Union of India and marked as Annexure A-1	31.3.22

18.1. Timeline of Grievance Correspondence of Petitioner 2

Sr. No.	Event	Date
1	Petitoner 2 suffers loss of his daughter, Karunya Govindan	10.07.21
2	Petitioner 2 files grievance with PMO, selecting the department as "Prime Ministers Office" (PMOPG/E/2021/0442378)	16.07.21
3	Petitioner 2 sends an email to the designated officer Ms Sarita Nair (as seen in PMO Portal) referring his complaint.	16.07.21
4	Petitioner 2 sends a reminder to the same officer, this time also adding the District collector in the copy	23.07.21
5	Petitioner 2 sends an email to the Minister of Health with copy to the Secretary of Health giving the full details of the case and seeking redressal	02.10.21

6	Petitioner 2 files another grievance in PMO portal (this time selecting Dept as Health & Family Welfare >> Policy Matters >> Central Government Health Scheme, just in case last time if it landed in the wrong place). Ref. DHLTH/E/2021/17254	02.10.21
6	Petitioner 2 sends another reminder – on the news of Har Ghar Dastak programme announcement - to the Minister of health with copy to the Secretary of Health	30.10.21
7	Petitioner 2 along with Petitioner 1 files WP in the Hon'ble Supreme Court	28.10.21
8	PMO Portal case closed with the remark "Petition accepted and the solution for the grievance is given	10.12.21

	in the attachment" The 'solution' given is so flawed as to be laughable, but for the seriousness of the matter. This is described after this table.	
9	Grievance DHLTH/E/2021/17254 closed with a stock reply that vaccines are safe and effective and there is a robust AEFI mechanism to monitor issues. We were advised to contact the vaccination center for further advice.	16.09.22
10	Petitioner 2 appealed giving reasons for rejecting the given solution. The status of the appeal is seen as Under process.	20.09.22

18.2. In the case of petitioner 2, below is the 'Details of Action taken' given by the Govt (through the reply affidavit dated 27th Nov 2022, and not conveyed in any other means earlier)

"Presently, Coimbatore Municipal Corporation provides for Covid-19 vaccination services and vaccination for 1st and 2nd dose is going on intensively. So, inquire to get vaccinated in nearby centre' (emphasis added to highlight that they haven't even read the representation and have understood the details of the request).

18.3. More shockingly the 2nd page of the solution given as per PM's grievance portal is not even concerning our grievance and pertains to another petitioner. The affidavit reply by Dr. Veena Dhawan gives a translation of this 2nd page which is totally unrelated to the petitioner but then gives the name and address of the petitioner in the translation.

18.4. This reflects the callous attitude of the Government on matters dealing with life and health of citizens. And it has had disastrous consequences as suffered by the petitioners and countless others.

18.5. Aside from seeking justice for their own daughter's deaths, the petitioners filed the grievances with the motive that this information should trigger immediate action in the form of a comprehensive review of the vaccination programme with necessary course corrections so that no more lives will be lost. In spite of the ,continuous follow-ups from the

petitioners till October 2021, i.e. up to 5 months after the sad demise of our daughters added with news of more deaths trickling in and causing anguish and untold sorrow to the petitioners at the helplessness in stopping this tragedy from befalling more families. The Government of India not only callously ignored our grievance petitions but in spite of the facts presented about the deaths happening in India, and evidence of harms and suspension from many countries, went ahead with the vaccination programme aggressively pushing it to even lower age-groups. Letter to Chief Secretaries and Secretaries of Health of all States and Union Territories dated 17.05.2022, informing about TTS and specific adverse events related to TTS was not advertised in the public domain. The letter included an Advisory for Healthcare Service Providers to be alert about the signs and symptoms of TTS. However it is clearly seen from the case of Petitioner 1 that there was no information regarding TTS with the treating physicians of the daughter of Petitioner 1.

CHAPTER N: Mathematical model cited by GOI is legally inadmissible and also fatally flawed

19. GoI in its affidavit has cited a mathematical model which claims that 20 millions lives have been saved worldwide, by the Covid-19 vaccines. This has multiple problems. First, the mathematical model was published on the basis of sponsorship of BMGF which is a direct interested party having stakes in the vaccine companies. Therefore, it is **inadmissible due to conflict of interest** and as per binding precedents of the constitution Benches of this Hon'ble Court in Mineral Development LTD v. State of Bihar and Others (1960) 2 SCR 609, Gullapalli Nageswara Rao and Others v. Andhra Pradesh State Road Transport Corporation and Others 1959 Supp (1) SCR 319 , State Of Punjab v. Davinder Pal Singh Bhullar (2011) 14 SCC 770.

19.1. The Respondent has submitted a false and misleading claim based on a Lancet Study that Covid vaccines saved 4 million lives in India as it is not based upon any actual data but an algorithm/mathematical calculation. This study is funded by the World Health Organisation (WHO), GAVI Vaccine alliance, Bill and Melinda Gates Foundation among other stakeholder. It's falsity and inadmissibility is proved from

the Central Government policy and detailed analysis by IIT Mumbai's professor Dr. Bhaskaran Raman.

19.2. That Dr. Veena Dhawan in para 6 of the affidavit had made following statement:

> *"6. At the outset it is humbly submitted that the COVID-19 pandemic was an unprecedented challenge for mankind and timely development, manufacturing and administration of vaccines was critical to end the pandemic. In a noted scientific paper in the scientific journal The Lancet, it is estimated that vaccines have globally prevented roughly 20 million deaths and in India alone, at least 4 million were estimated to have been prevented with timely access to COVID-19 vaccines."*

19.3. The Petitioner requests the Honourable court to take note of evidence presented below and argues that COVID-19 was made out to look like an unprecedented challenge to mankind. Vaccines were touted as the only way out of it by Governments backed by 'experts' without necessary evidence. The eventual rollout of these 'vaccines' while resulted in windfall profits to vaccine companies at the expense of taxpayer money did not deliver on any of the

promised benefits. Hence this premise itself is wrong or at best debatable.

19.4. It is important to note, that the Affidavit fails to mention that this study, under the section Declaration of Interests, shows that it has been funded by Schmidt Science Fellowship in partnership with the Rhodes Trust; WHO; UK Medical Research Council; **Gavi, the Vaccine Alliance; Bill & Melinda Gates Foundation**; National Institute for Health Research; and Community Jameel. **All these organizations have been involved in actively promoting COVID-19 vaccination and some are directly associated with Covid vaccine manufacturing as well as its rollout.** Hence, said paper is itself inadmissible in view of law of conflict of interest Relied on:

i) Gullapalli Nageswara Rao Vs. A.P.S.R.T.C, AIR 1959 SC 308;

ii) Supreme Court Advocates-on-Record Vs. Union of India (2016) 5 SCC 808.

19.5. Furthermore, the said paper is only a mathematical projection and only a possibility and not real world data. It's frivolity is exposed by Prof. Bhaskaran Raman of IIT Bombay in the Article titled "More Flaws in the Vaccine Model Claiming 20 Million Lives Saved" was published in

online portal Brownstone Institute on 27th June 2022. Relevant excerpt below:

> ***"Flawed assumptions in the jab impact modeling study:*** *The modeling study necessarily incorporates various important parameters. A close look reveals that much of the critical parameters are based on assumptions which are* known *in the literature to be wrong. The table below summarizes this.*

Aspect	Assumption in modeling study	Critique, Reality check of the assumption
Immunity after natural infection	"loss of infection-derived immunity.. follows an Erlang distribution with a **mean duration of one year**" (see study supplement).	Immunity after natural infection is **robust and long-lasting**; protection against infection lasts much longer than for the jabbed; protection from severe disease is likely lifelong.
Immune evasion to	"**Immune evasion** for	The study cited for this 27% number is interpreted

new variants after exposure to earlier variants	infection-derived immunity occurs for 27% of the previously infected population."	incorrectly. In the cohort study, 27% of the participants showed a decline in antibodies followed by an increase. Rather than meaning that these individuals became susceptible again, it means that these individuals were re-exposed and their **immune system worked** exactly as it was supposed to.
Vaccine efficacy against infection with Delta variant	Adenovirus: **67%**, mRNA: **88%**(see Table 1 of supplement)	Efficacy wanes in 6 months: Adenovirus: **44%**, mRNA: **63%**Such waning efficacy is not modeled.

Vaccine efficacy against mortality	Adenovirus: **92%**, mRNA: **93%**(see Table 1 of supplement)	Efficacy against mortality must be calculated considering *all-cause* mortality; a preprint study shows a more modest **73%** for the adenovirus jabs, and a *negative* efficacy of **–3%** for the mRNA jabs; so the modeled numbers are way too optimistic and incorrect; protection against hospitalization and mortality is also known to be waning and this is not modeled.
Vaccine efficacy against transmission	"We assume that all vaccinated individuals have a **50% reduction** in	The study cited for this 50% reduction clearly says that efficacy against transmission **nears zero after 12 weeks** of the jab;

	infectiousness for breakthrough infections."	other studies have also shown that efficacy against onward transmission is near nil; hence the modeled number is wrong.

All of the above erroneous assumptions are in the direction of amplifying the possible impact of the jabs, while at the same time diminishing the role of immunity after natural infection. Hence it is likely that the modeling study overestimates the lives saved by the Covid-19 jab rollout. Aside from the above parameters, there is yet another technical flaw, as explained below."

A True Copy of the article is annexed herewith and marked as Annexure P-42, pg no. 484 - 486

19.6. The commentary by honest domain experts exposes the inaccuracies, fabrication and distortion of the Lancet Study, in the article titled **"Commentary on "Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. The Lancet Infectious Diseases. 2022,**

Jun 23" dated June 2022 by Spiro Pantazatos (Columbia University) and Herve Seligmann.

"Summary

"While generative models are a useful tool to simulate scenarios that have not occurred, not accounting properly for relevant variables in the model may lead to model misspecification. *In such cases, counterfactuals may grossly inflate estimates of deaths averted due to mass vaccinations. Rather than rely on simulations which may be sensitive to input parameters, prone to overfitting, and that are difficult, if not impossible to validate, more accurate and reliable approaches to inform public health vaccination policies are quantitative risk-benefit ratio analyses for specific outcomes using clinical trial or real-world data [7,11,12]."*

A True Copy of the article is annexed herewith and marked as Annexure P-43, pg no. 487-490

19.7. The commentary rightly observes *"The models in Watson et al. rely on unrealistic assumptions about vaccine-derived immunity."* We have seen empirically that even the Government agencies and vaccine manufacturers admit to

the waning of the vaccine induced immunity and their 'solution' only revolves around giving another dose (named variously as 'protection dose' / 'booster' etc.)

19.8. This study goes into many technicalities of the assumptions behind this study. Even a quick math without getting into those details shows the absurdity of the claim. The claim is vaccines saved 20 millions deaths worldwide with 4 million in India alone.

19.9. Population of Africa (122 Crores) is relatively quite close to the number of India (139 crores). If vaccines saved 4 million lives in India, the relatively unvaccinated Africa (less than 6% of the population) should have seen nearly 4 million COVID deaths. The reality is quite different, where not only did most of Africa live a near normal life during the COVID period, but their death figures are far lower than the vaccinated world. **Africa had approximately just one sixteenth of the deaths as predicted by the model thus invalidating that study totally**.

Link: https://childrenshealthdefense.org/defender/africa-covid-pandemic-cola/

19.10. While the Study claiming vaccines saved lives has been debunked in the paras above, the following paras show the

counterproductive-ness of the vaccination policy resulting in more serious illnesses and deaths.

19.11. **"Ethically Unjustifiable"** – Scientists from Harvard & Johns Hopkins Found Covid-19 Vaccines 98 Times Worse Than the Virus. 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, we find that booster mandates may cause a net expected harm:* ***per COVID-19 hospitalisation 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."*

Links:

i. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4206070

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

19.12. Dr. Amitav Banerjee, Professor & Head, Community Medicine and Clinical Epidemiologist at Dr DY Patil Vidyapeeth, Pune, has clearly outlined the blunder of *"spending Rs. 35,000 crores for mass vaccination for a disease which has more than 99% survival across all age groups."*

Table 2: Agewise survival rates of Covid-19 [Negligible Threat to young people & Children]

(Source: https://opentheword.org/2021/09/30/survival-rates-after-contracting-covid/, https://www.medrxiv.org/content/10.1101/2021.07.08.21260710v1)

Age in Years	Survival Rate (%)
0 - 19	99.9973
20 - 29	99.986
30 - 39	99.969
40 - 49	99.928
50 - 59	99.73
60 - 69	99.41
70+	97.6
70+ (in care homes)	94.5%

"Futile chase of the coronavirus which kills a minuscule proportion of our population will divert resources and attention from our major public health challenges and compromise further our population health."

A True Copy of the article titled is annexed herewith and marked as Annexure P-44, pg no. 491-495

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CHAPTER O: Serious lapses in regulatory process

20. In Para 13 of the Affidavit by UoI, the Respondent states that India's apex advisory body on Immunization, the NTAGI provides guidance and advice to MoHFW on provision of vaccination and immunization services.

20.1. Below is an excerpt from the minutes of NTAGI's meeting held on 10th December 2020, annexed herewith as **Annexure P-2**:

> *"It was mentioned that safety and **adverse event monitoring in the 4-6 weeks** after completing the immunization schedule among pre-specified sample size is critical in making a decision on EUA of a particular vaccine as it is accepted globally."*

20.2. This guideline from NTAGI was clearly not followed, as the nation did not learn from the death of Dr Snehal Lunawat, who was vaccinated in the very first round of vaccinations for healthcare staff and died soon after. (See details in para 11).

20.3. In the same NTAGI minutes we see the below also:

> *"The Chairperson mentioned that **exceptional transparency is critically important** and all facts will be shared with priority group as well as with the*

public at large. Further, it was mentioned that serology testing prior to vaccination is an open question and evidence is being reviewed by the COVID-19 WG."

20.4. What we instead saw is lack of transparency and lack of relevant information regarding the adverse effects and about the voluntary nature of the vaccines.

20.5. The NTAGI minutes also mentions, *"It was also remarked that MoHFW is actively working with State governments,* ***databases are getting created*** *and uploaded on digital platform which will enable a real time* ***tracking of every individual beneficiary****."* Such databases do not exist in the Public Domain even today nearly two years after the vaccine rollout.

20.6. In an article titled "Exclusive: Centre Approved Corbevax for 12-14 Year Olds Without NTAGI Clearance", The Wire, 15 Mar 2022, it is reported as to how GoI went ahead with Corbevax for 12-14 year old children.

"A press release issued by the Union health ministry on March 14 said the government had taken the call after "due deliberations with scientific bodies".

However, the government did not specify which were those "bodies", and the reason for the ambiguity in the health ministry release wasn't clear.

But The Wire Science has since learnt that the National Technical Advisory Group on Immunisation (NTAGI) wasn't one of these bodies."

This is another instance of serious lapse, lack of scientific input, and lack of transparency in the Covid-19 vaccine regulatory process.

True Copy of the article is Annexed herewith and marked as Annexure P-45, pg. no 496 – 498

20.7. In Para 12 of the UoI Affidavit, it states that Covishield went through a rigorous review for safety and efficacy by independent experts in the SEC and was granted 'restricted use in emergency situation' permission on 2nd January 2021.

20.8. Recommendations of the SEC meeting to examine COVID-19 related proposal and accelerated approval process made in its 130th Meeting held on 09.12.2020 at CDSCO, HQ, New Delhi:

"The firm presented their proposal for grant of Emergency Use Authorization (EUA) of ChAdOxl nCoV-19 vaccine (COVISHIELD) ...

*..., **the firm has submitted the safety data till 14.11.2020 only.** After detailed deliberation, the committee recommended that the firm should submit the following data/information for further review:*

1. Updated safety data of the Phase II/III clinical trial in the country.

2. Immunogenicity data from the clinical trial in UK and India.

3. The outcome of the assessment of UK-MHRA for grant of EUA."

True Copy of the Recommendations of the SEC's 130th Meeting dated 9th December 2020, is Annexed herewith and marked as Annexure P-46, pg. no 499-500

20.9. So SEC seeks the data from UK and also the details of assessment of UK-MHRA for grant of EUA as local data is insufficient and then bases its recommendation on these.

20.10. There are no provisions or rules in the NDCT Rules to base SEC's decision on the trials and assessment conducted outside the country and outside the controls and trials of the SEC/CDSCO. Further, H.6.G.13. **If the SEC was basing the decision based on trial data in the UK, they should have also suspended or age restricted Covishield as it**

was done in the UK and many other countries as shown earlier in Para 5.1.

20.11. Para 16 of the UoI affidavit introduces one more expert body, NEGVAC, for COVID management which we understand is a layer over and above NTAGI. On 19 May 2021, NEGVAC had recommended and MoHFW had accepted the below

> *"COVID-19 vaccination is recommended for all lactating women.*
>
> *Regarding COVID-19 Vaccination of pregnant women, the matter is under discussion and further deliberation by the National Technical Advisory Group on Immunization (NTAGI)."*

True Copy of the Press Release titled "New Recommendations of NEGVAC accepted by Union Ministry of Health" published by Press Information Bureau, Government of India dated 19th May 2021, is Annexed herewith and marked as Annexure P-47, pg. no 501

20.12. It is important to note that no trials have been conducted for Covid vaccines in pregnant women and lactating mothers in India as of September 2022. Despite that, the Government of India recommended Covid Vaccines for Pregnant

Women and Lactating Mothers from 2nd July 2021. The First Appeal Reply states that,

> *"As per reply received from concerned division, this office has not received application from M/s Serum and M/s Cadila for the grant of permission to conduct such clinical trial. Further, M/s Bharat Biotech had submitted application for grant of permission to conduct clinical trial of Covaxin in pregnant women. Subsequently, however, the said firm has withdrawn the application."*

True Copy of the RTI CDSO/R/E/22/00241 and First Appeal CDSCO/A/E/22/00091, is Annexed herewith and marked as Annexure P-48, pg. no 502- 507

20.13. On May 11th Brazil had suspended nationally AstraZeneca vaccine for pregnant women. A pregnant lady had died on May 10th after getting admitted into a hospital 5 days earlier, after her Covid-19 vaccination. The national suspension happened the next day after she died, pending a detailed investigation.

Below points from the article are also noteworthy.

> *"The AstraZeneca vaccine is produced and distributed in Brazil via a partnership with public health institute Fiocruz. Fiocruz President Nisia*

Trindade told reporters that the suspension was necessary."

Link: https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-health-agency-calls-halt-astrazeneca-vaccine-pregnant-women-2021-05-11/

20.14. NTAGI then meets on 28th May 2021 virtually. It is noteworthy that this is the first meeting of NTAGI after COVID vaccination drive was started on January 16th, 2021 nationally for health workers and further expanded to frontline and elderly on March 1st 2021 and for 45+ from April 1st 2021 and 18+ from May 1st 2021. So after meeting on December 10th 2020 to approve the recommendations of STSC to rollout COVID Vaccine, NTAGI didn't deem it necessary to convene and deliberate the programme and it's monitoring in the interim 6 months entrusting all to the COVID-19 WG.

A True Copy of the Minutes of Meetings of NTAGI dated 28th May 2021, is annexed herewith and marked as Annexure P-49, pg no. 508 - 519

20.15. In this interim period **15 countries had suspended Astrazeneca** COVID vaccine to all, **Brazil had suspended it for pregnant women**, and some countries had age-limited it as it caused more harm in certain age groups. In

India too, Dr. Snehal Lunawat had died (Para 11) on 01/03/2021. But even in the meeting on 28 May 2021, there was no discussion of any of these significant events.

20.16. In the minutes we see "Regarding young women who are at stage of pregnancy, overall COVID-19 exposure risk is three to eight times higher as compared to the risks of clotting and bleeding which can occur after receiving Covishield vaccine."

20.17. However, this is contradicted by the document published by European Medical Agency titled "Annex to Vaxzevria Art.5.3 - Visual risk contextualisation" dated 23.04.21. The picture clearly shows that for those under 50, with low exposure (defined as 55 cases per 100,000 population), the **risk outweighs the benefit**. The highest India had was 28.5 cases per 100,000.

Link: https://www.ema.europa.eu/en/documents/chmp-annex/annex-vaxzevria-art53-visual-risk-contextualisation_en.pdf

20.18. NTAGI recommends vaccination to pregnant women with the text below.

> *"As far as pregnant women are concerned, it was presented that initial experiences from mRNA vaccines are encouraging and these have been*

approved by WHO for pregnant women. These vaccine manufacturers have done DART studies, which didn't show any safety issues, further post marketing surveillance data did not show any safety signals in pregnancy. Considering the current situation of pandemic, the NTAGI-STSC recommended pregnant women should not be excluded from vaccination because exposure probability is very high and therefore the benefit far outweighs the risk."

20.19. Mrs Mahima Mathew, who was pregnant with twin foetuses and took COVISHIELD on 6th August 2021 after assurance from her Gynaecologist, died on 16th August 2021 from its complications. Her death was classified as A1 on 4th Jan 2022, after four months. Given the poor AEFI reporting, it is only likely that several such unfortunate deaths went unreported.

20.20. Further, while NTAGI had recommended that *"However, before vaccination, pregnant women should be fully informed that the long-term adverse reactions, and the safety of the vaccine for fetus and child is not yet established."*, the reality on the ground was different. Mrs. Mahima's husband who accompanied her to the

consultation with Gynaecologist and subsequently to the vaccination center upon her advice has testified that not only were they not advised of any such thing, they were told it was completely safe and necessary.

In its affidavit para 5, GoI '*seeks the indulgence of this Honourable Court to set out in detail the background of the COVID-19 vaccination program, the decision making process for administration of vaccines and the system of monitoring adverse events following immunisation (AEFI) throughout the nation.*' The petitioners entirely second this request and urge this Honourable Court to go into all aspects which have been presented in detail in this Rejoinder and provide a comprehensive judgment that will protect the health, life, livelihood and liberty of the citizens of this country.

DEPONENT

ATTESTED
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8/6/2023

Y. Vasudeva Rao, B.Sc., LL.B.
ADVOCATE & NOTARY
MY COMMISSION EXPIRES ON
25-12-2026

VERIFICATION

I, the above named deponent, do hereby verify that the contents of the above affidavit are true and correct to my knowledge and belief, no part of it is false and nothing material has been concealed there from.

Verified at Hyderabad on this 8th day of June, 2023.

DEPONENT

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MY COMMISSION EXPIRES ON
25-12-2026

Annexure P-1

1

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

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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 [illegible] 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

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Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi

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: cmoc.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.

NOTARY A.N. SINGH Supreme Court of India Regn. No. 10953 Exp. Date: 31.01.2025 GOVT. OF INDIA

(डॉ. वीणा धवन)
(Dr. VEENA DHAWAN)

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

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16599 Exp. Date: 31.01.2025 GOVT. OF INDIA

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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

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.

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16559 Exp. Date: 31.01.2025 GOVT. OF INDIA

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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

NOTARY A.N. SINGH Supreme Court of India Regn. No. 15657 Exp. Date : 31.01.2023 GOVT. OF INDIA

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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

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16833 Exp. Date 31.01.2027 GOVT. OF INDIA

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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 18-19 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

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

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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.

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

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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.

NOTARY A.N. SINGH Supreme Court of India Regn. No. 14073 Exp. Date: 31.01.2025 GOVT. OF INDIA

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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 12 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

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

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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

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16060 Exp. Date: 31.01.2025 GOVT. OF INDIA

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नई दिल्ली, New Delhi

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

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

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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 the 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:

NOTARY S.K. SINGH Saket, New Delhi Regd. No. 16959 Exp. Date 31012025 INDIA

(डॉ. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त कमिश्नर (टीका)
Joint Commissioner (Immu.)
भारत सरकार स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi

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

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

(डा. वीणा चावन)
(Dr. VEENA CHAWAN)
संयुक्त आयुक्त (टेलि.)
Joint Commissioner (Tele.)
दूरसंचार एवं संचार, विकास मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi

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.

Notary Public, Govt. of India, Delhi

DEPONENT
(डॉ. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त आयुक्त (प्रशा.)
Joint Commissioner (Adm.)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
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

NOTARY A.N. SINGH Supreme Court of India Regd. No. 1693 Exp. Date: 31.01.2025 GOVT. OF INDIA

Certified that the above Named Deponent identify by Shri/Smt. ..... Solemnly affirmed before me at Delhi S. No. ..... The contents of the affidavit which have been read & explained to me are true and correct

Notary

DEPONENT
(डॉ. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त आयुक्त (प्रशा.)
Joint Commissioner (Adm.)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India

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Annexure-R/1

17

राजेश भूषण, आइएएस
सचिव
RAJESH BHUSHAN, IAS
SECRETARY

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

D.O. No. 2058847/2021-Immu
1st November 2021

Dear Chief Secretary,

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-Immu 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 their 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"*.

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
Tel.: (011)-23061863, 23063327, Fax: (011) 23063969, E-mail: secyhfw@nic.in

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 come 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

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

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.

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Annexure P-2

T.13013/01/2018-Imm
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Dated: 20th January, 2021

To,

All NTAGI members/Participants
(As per list enclosed)

Subject: Minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI), held on 10th December, 2020 under the Chairpersonship of Secretary (Health & Family Welfare) at Nirman Bhawan, New Delhi.

Sir/Madam,

Please find enclosed herewith the minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI), held on 10th December, 2020 at Nirman Bhawan, New Delhi, under the Chairpersonship of Secretary (Health & Family Welfare), for kind perusal.

Yours faithfully,

Enclosure: as above

20/01/21

(Dr MK Aggarwal)
Additional Commissioner (UIP)
011- 23062728

Copy to:

1. PPS to Secretary (H&FW), MoHFW
2. PPS to DGHS, MoHFW
3. PPS to Secretary (Department of Health Research), MoHFW
4. PPS to Secretary (Department of Bio-technology), MoS&T
5. PPS to AS&MD (NHM), MoHFW
6. PPS to JS (RCH), MoHFW
7. Office copy

15th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
December 10, 2020, Thursday, 12:00 PM to 2:00 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Minutes of the Meeting

Welcome & Introduction

The 15th NTAGI meeting was held on 10th December, 2020 at MoHFW, New Delhi under the Chairpersonship of Shri Rajesh Bhushan, Secretary Health and Family Welfare, and Co-chairpersonship of Dr Renu Swarup, Secretary, Department of Biotechnology. The Joint Secretary (RCH) welcomed Shri Rajesh Bhushan, Chairperson and Dr Renu Swarup, Co-chairperson, and informed the members that due to health issues Dr Balram Bhargava, Secretary Department of Health Research (DHR) and DG-ICMR and one of the Co-Chairperson could not attend the meeting. The list of attendees is Annexed as Annexure-1 and agenda as Annexure-2.

All participating NTAGI members and invited attendees had duly filled and signed the confidentiality agreement, and declared conflict of interests (if any), and shared these with the NTAGI Secretariat. No conflict of interest was noted.

Participants were welcomed by the Chairperson. Following a brief round of introduction, the meeting was called to order. The following items were discussed:

Agenda Item 1: Action Taken Report on previous NTAGI meeting held on December 17, 2018

The Joint Secretary (RCH) informed the Chairperson that the last meeting of NTAGI was held on December 17, 2018. In 2019, the meeting could not be convened due to unavoidable circumstances.

Agenda Item 1.1: Action taken report on the minutes of previous meeting of the NTAGI

The Joint Secretary (RCH) presented the action taken report (ATR) based on four recommendations made in previous NTAGI meeting (held on December 17, 2018), which is as follows: -

Japanese Encephalitis (JE) Vaccines: It was apprised that the matter on number of doses and recommended schedule for the Universal Immunization Program (UIP) was referred to Standing Technical Sub-Committee (STSC). In addition, STSC was requested to generate evidence on interchangeability of three JE vaccines (SA-14-14-2, Jeev and Jenvac). It was informed that the position on recommendations will be presented in the meeting.

Rotavirus Vaccines: It was apprised that the STSC was requested to examine the available evidence on program implementation review (PIR) reports of Rotavac & Rotasiil, and vaccine wastage study reports of both the vaccines. It was informed that the position on actionable points will be presented in the meeting.

Human Vaccines Interchangeability SOP: During the last NTAGI meeting, it was recommended that the Drugs Controller General of India (DCGI) should develop a document on standard operating procedures for all vaccine manufacturers which should include interchangeability studies to address the requirement of immunization program. It was shared that a report on the same will be presented by the DCGI.

Global Experience on Human Vaccines Interchangeability: The members were apprised that the country office of World Health Organization (WHO) was requested to provide evidence on international experiences on interchangeability of vaccines, especially JE, rotavirus, pneumococcal conjugate vaccine. In this regard, a

report was shared by the country office of WHO which is part of the dossier (Page#94). It was reported that at present there is no published data on interchangeability of both indigenous vaccines i.e., Rotavac & Rotasiil. There is no safety concern for mixed RotaTeq & Rotarix schedule, another two available Rotavirus vaccines. In case of Pneumococcal Conjugate Vaccines (PCV), product switching is not recommended, however in case of unavailability of same type of vaccine, available product can be used. Further, it was informed that there is no peer reviewed published information on JE vaccine interchangeability.
It was informed that the minutes of the NTAGI meeting held on December 17, 2018, were shared with the members and no comments were received.

The minutes were formally confirmed by the NTAGI.

Agenda Item 1.2: Summary of action taken by the STSC on the NTAGI recommendations (Rotavirus and JE vaccines)

In absence of Dr Balram Bhargava, DG ICMR and Co-chairperson NTAGI, Dr Samiran Panda, from ICMR made a presentation on summary of action taken by STSC on the recommendations of NTAGI, concerning the Rotavirus vaccines and JE vaccines. Members/invited attendees were informed about the existing 8 working groups [(i) Standing Working Group (SWG) on Immunization and Vaccine Research & Capacity Building (IVRCB), (ii) SWG on Vaccine Preventable Disease (VPD) Surveillance, (iii) Leprosy Working Group (WG), (iv) Cholera WG, (v) Influenza WG, (vi) JE WG, (vii) Vaccine Cost-Effectiveness WG, and (viii) COVID-19 WG)] and 2 sub-groups [(i) Vaccine Confidence sub-group and (ii) Maternal immunization sub-group)] under the STSC.
Rotavirus Vaccines: STSC examined the Program Implementation Reports (PIRs) and vaccine wastage studies of Rotavac and Rotasiil vaccines. It was informed that Both the vaccines have some advantages and challenges in terms of vaccine delivery, however, efficacy of both the vaccines is not significantly different. An update on Rotavirus vaccines Interchangeability study was provided. The study was conducted at two sites: KEM, Pune and NICED, Kolkata. Results of the study will be shared in the next STSC meeting.
JE Vaccines: It was informed that interim recommendation on dosage and schedule of JE vaccines in Routine Immunization (RI) and Campaigns has already been provided, which is as follows: -

- For RI, two doses of any of the three available JE vaccine formulations [LAJEV (SA-14-14-2), Jenvac, or Jeev (3 µg per dose)], administered at 9-12 months and 16-24 months, may be used.
- For campaigns in children (1-15 years of age) as well as in adults (above 15 years), one dose of any of the three vaccines (for Jeev, 6-µg dose) may be used.
- The NTAGI-STSC will monitor and review the evidence on implementation of the three JE vaccines formulations and see whether there is a need for changing or adopting the interim recommendation on dosage and schedule of JE vaccines in RI.

ICMR was requested to conduct a study on interchangeability and head-to-head comparison of the three JE vaccines available in India. The available data on efficacy of three JE vaccines were reviewed, which revealed that –

- An unpublished study showed highest GMT titers after 2 doses of the vaccine from Bharat Biotech India Limited (BBIL), followed by a mixed regimen with BBIL vaccine as prime (first dose) and SA-14-14-2 as boost (second dose), SA-14-14-2 prime and BBIL vaccine boost, and two doses of SA-14-14-2, in that order. However, this study included very few subjects.

A study outside India in adult subjects with IXIARO vaccine [6 µg doses; with technology transfer to Biological E Limited (Jeev) in India] showed only 26% sero-conversion on day 56 and only 9% seroconversion by end of 6 months. Due to ethical concerns, JE vaccine from M/s Biological E Limited (BEL) was dropped from interchangeability study protocol. JE vaccine interchangeability study protocol was presented in 25th NTAGI-STSC Meeting. The STSC opined that without JE vaccine from M/s BEL, the purpose of the study will be diluted.

STSC recommendations:

- The study can start with the two vaccines other than JE vaccine from M/s BEL to avert further delay.
- JE Working Group should re-discuss and decide on exclusion or inclusion of JE vaccine from M/s BEL (possibly with a different dose or schedule) in the study.

The Chairperson requested the NTAGI members to share their observations on the presentations.

The Chairperson, JE Working Group (JE WG), Dr Rakesh Aggarwal shared that three vaccines -- one live-attenuated (SA-14-14-2) vaccine from China and two killed vaccines which are made in India (Jenvac by BBIL and Jeev by BEL) – are available. The JE vaccine from BBIL has good long-term immunogenicity following a single dose. Some data suggest that the JE vaccine from BEL has a low immunogenicity following a single-dose, and that it requires 2 doses at an interval of 4 weeks. In the program, the first dose is administered at 9-12 months and the second dose at 16-24 months after a gap of almost 7 months. For the interchangeability study, this has led to a concern that the children receiving this vaccine may not be fully protected in the intervening period. For this, the WG had discussed whether the JE vaccine could be introduced at an earlier age to align with the existing RI program.

Some members felt that moving the JE vaccine to an earlier age may lead to an overcrowding of vaccines at early age (1.5, 2.5 and 3.5 months), and an additional injectable vaccine at this age might trigger vaccine hesitancy among parents. Another view was that a new time window for immunization as well as other health interventions could be opened up.

It was highlighted that the Jeev vaccine (BEL) is being used in the immunization programme (in two states) and its expansion in the program will be considered based on the final technical recommendations of the

STSC. Therefore, STSC should provide its recommendations on the concerned issue for taking immediate programmatic decisions.

One of the members expressed that the ICMR should be consulted to share its learnings from the work on adult JE vaccination in North-East region, JE vaccine coverage in central India, and at Gorakhpur region. It was suggested that the JE WG should also look at program implementation issues.

The Co-chairperson mentioned that interim recommendations were made on grounds of urgency and limited supply of SA-14-14-2 JE vaccine. The JE WG was requested to relook at the issue and submit an early report. A special meeting of the STSC will be held to come up with recommendations and send it to the Chairperson, and a special NTAGI meeting could be convened if required. It was mentioned that a timeline of maximum 6 weeks for providing recommendations should be considered.

Decision:

Based on the discussions the NTAGI endorsed STSC recommendations on JE interchangeability study with following points:

- There is a need for immediate recommendations from STSC for taking urgent programmatic decision on account of a study showing low efficacy of single dose JE vaccine from M/s BEL. The JE WG is required to deliberate on the issue in consultation with all stakeholders including Immunization Division, National Vector Borne Disease Control Program (NVBDCP) and subject matter experts within 2 weeks of time. A report of the deliberations and specific recommendations may be presented to NTAGI Chairperson and Co-chairpersons in 6 weeks of time.

(JE Working Group and NTAGI Secretariat)

Agenda Item 1.3: Human Vaccines Interchangeability SOP at the time of licensure

The DCGI, informed that in this regard, CDSCO has prepared a SOP no. BIV-P-23 on 09.12.2019 for review of Clinical Trial applications including assessment of issue of Interchangeability of Human Vaccines used under National Immunization Programme. It was explained that subject expert committee (SEC) of vaccines reviews study design, primary and secondary endpoints, population details, result assessment criterion, study objective, Inclusion/exclusion criteria, sample size, study assessment, statistical analysis, study endpoints along with surrogate markers for vaccines used and assessment of interchangeability for vaccine in National Immunization Programme at the time of approval. Based on the evaluation recommendations are finalized as mentioned in the New Drugs and Clinical Trials Rules, 2019.

The Co-chairperson conveyed that the SOP will help in ensuring interchangeability aspect when a second candidate vaccine targeting same vaccine preventable disease goes for review of SEC of DCGI. The SOP will have implications on future vaccines, it should be accepted by the NTAGI.

The Chairperson noted that since the SOP has been devised by the regulator, so regulator is now bound to comply with the SOP as and when Indian version of different vaccines come up.

The members were informed that, it may not be applicable to trials already been completed, with regards to particular vaccine, if it fits interchangeability, a post approval or parallel recommendation is granted.

It was emphasized that COVID-19 vaccines are developed on different platforms and many of these platforms will be used for first time in humans. Interchangeability between different platforms need to be looked carefully. This will be a work in a progress as new information arises with time. Addition of type of study designs in the SOP of interchangeability of human vaccines was suggested. This may become relevant to COVID-19 and other vaccines which may come up in future.

Decision:

The NTAGI accepted the SOP on human vaccines interchangeability, with an advice to carefully examine feasibility of interchangeability of vaccines developed on different platforms. Further it was advised to include possible types of study designs in the SOP of human vaccine interchangeability.

(DCGI, CDSCO)

Agenda Item 2: Follow-up actions by MoHFW on carrying out 2 recommendations made by STSC

The Joint Secretary-RCH apprised the NTAGI on STSC's recommendations on JE vaccines and Rotavirus vaccines.

JE Vaccines: The interim recommendations of the STSC on dosing and schedule of the three JE vaccine in immunization program were shared with concerned stake holders- states, procurement division, and partner agencies. Training of trainers (ToT) on recommendations on JE vaccine interchangeability have been conducted in Orissa, Bihar, MP, Chhattisgarh, Meghalaya, and West Bengal which are undertaking JE vaccination campaign.

Rotavirus Vaccines: Globally there are 4 manufacturers of Rotavirus vaccine- 2 offshore and 2 indigenous. Rotavirus Vaccines in UIP: Rotavac: 25 states/UTs (covering 60% of the birth cohort); Rotasiil: 11 states/UTs (covering 40% of the birth cohort). Due to programmatic challenges, as recognized by NTAGI-STSC, these two vaccines are not being interchangeably used in the UIP.

Agenda Item 3: STSC Meeting Discussion and Recommendations

The Co-chairperson, Secretary, Department of Biotechnology (DBT) presented to the NTAGI, a detailed overview of the work undertaken by the STSC over past two years. In the past two years, the STSC met seven times and had deliberated on nine key issues: Five standing items as part of annual review [(i) VPD Surveillance, (i) IVRCB, (iii) UIP monitoring report for South-East Asia Region-Immunization Technical Advisory

Group (SEAR-ITAG), (iv) progress made by UIP and AEFI surveillance program, and (v) review of National certification committee polio eradication report] and four new topics identified for discussion by stakeholders [(i) leprosy, (ii) influenza, (iii) JE vaccines and (iv) COVID-19. Among new identified topics, work on influenza is delayed due to COVID-19 pandemic.

Tenth SEAR-ITAG Meeting Recommendations: MR-IEAG (Measles and Rubella-Indian Expert Advisory Group) recommendations should be fully implemented, which are as follows: -

- An evaluation of Mission Indradhanush (MI) and Intensified MI should be conducted.
- Lessons learned from urban immunization strengthening pilots and best practices should be implemented.
- Multi-antigen sero-surveys should be considered to help with: (i) identification of rubella immunity gaps in women of child-bearing age, (ii) decision-making and vaccine scheduling of Td booster doses, (iii) monitoring the progress for achieving the hepatitis B control goal.
- Reasons for outbreaks in areas that have introduced JE vaccination should be identified and corrected.

The Members were informed that MR campaigns have been conducted in 34 states/UTs and case-based surveillance has been implemented in all 36 states/UTs. Evaluation of MI had been conducted and the report shows that there is increase in coverage also there is decline in deaths due to measles. Detailed report will be shared with NTAGI-STSC once it gets approved in MoHFW. Urban immunization strengthening pilots are undergoing in 14 cities, its report is under review, based on the learnings, interventions will be scaled up in other cities. A sero-survey on rubella among pregnant women, recruited from six sentinel surveillance sites in India, showed 83.4% seropositivity. Td is part of RI at 10 years and 16 years as recommended by the NTAGI. Hepatitis-B vaccine birth dose is regularly being monitored by the program. A very high vector density and less than 50% JE vaccine coverage were two main reasons for outbreak in areas where JE vaccine has been introduced.

SWG-VPD Surveillance: Existing outbreak-based, case-based surveillance data, and sentinel surveillance data from different organizations should be integrated to get meaningful inferences.

The members were apprised that the SWG-VPD surveillance is working on framework of three vaccine preventable diseases. Based on review, recommendations for all VPDs will be developed. This process may take 8-12 weeks.

STSC recommendations

- Draft a report explaining the details of mechanism, methodologies, necessary systems, data points, manpower and support require for developing a platform/data warehouse which will help in harmonizing data from various agencies, relevant for NTAGI.
- Capacity building of NTAGI Secretariat in terms of additional human resources & trainings.

SWG-IVRCB: Identification of gaps & priorities in vaccine related research and programme & maintaining a database of ongoing vaccine related research and track their progress, & mapping of capacity building opportunities. Key areas identified: (i) Maternal Immunization, (ii) Vaccine Confidence and (iii) Life course Immunization.

STSC recommendations

- Review and Identification of the best fit for maternal Immunization into the existing ANC schedule (4+1 visits) and WHO recommended ANC schedule (8 visits).
- Effect of maternal Tdap vaccination on the whole cell pertussis containing vaccine administered in RI.
- A PhD Program in Vaccinology, under institutions like PGI, Chandigarh & JIPMER or AIIMS, New Delhi. Program will involve training from various mentors with a clear curriculum & outcomes. The Program will be funded by DBT and ICMR in the form of an award or fellowship.

Leprosy WG: A working group was formed under the Chairpersonship of Dr J P Muliyil. The WG was comprised of members from the STSC and independent subject matter experts for undertaking detailed technical review. A report of the WG was submitted in 21st and 23rd STSC meetings. The report of the WG is going to be presented

Vaccine Cost Effectiveness Analysis (VCEA) WG: The need to have a group which will look into SOPs for adopting CEA for vaccines was highlighted in 23rd NTAGI-STSC Meeting. A note on convening of a working group to consider socio-economic impact and economic cost analysis was circulated among members. A working group on CEA of vaccine was formed under the Chairpersonship of Dr Indrani Gupta. 1st meeting of the WG was convened on Oct 5, 2020. Overview of relevance of economic evaluation and general steps involved in CEA were discussed.

The members were informed that CEA WG will identify best methodologies and protocol for doing CEA of vaccines. The VCEA WG will also help in vaccine economics analysis capacity building, under the leadership of the NTAGI. Along with vaccine CEA, risk benefit assessment was also suggested.

COVID-19 WG: The need was felt to discuss development of COVID-19 vaccines, disease burden, program preparedness and other technical aspects in the 24th NTAGI-STSC Meeting. A working group on COVID-19 was formed under the Chairpersonship of Dr N K Arora. Eleven WG meetings have been convened from Aug-24 to Dec 09, 2020. Part-1 of the preliminary guidance report of the WG has been shared with the MoHFW and NEGVAC, NITI Aayog.

Co-chairperson, Secretary-DBT, summarized that the STSC meets almost once in a quarter of a year, proactively looks at issues which may concern the vaccine development and the uptake in the immunization program. Working Groups have been constituted so that they can supplement and support the data which is coming from vaccine development so that it can facilitate program implementation. She reiterated that STSC strongly recommends capacity building of critical human resources both in terms of vaccine research aspects and more importantly within the secretariat. As lots of research and analysis is needed for NTAGI-STSC work.

The Members felt that over a period of time the NTAGI secretariat is doing exceptional quality work under the guidance of both the Co-chairpersons of the NTAGI-STSC. There has been substantial increase in number of working groups. The secretariat provides techno-managerial support to all working groups, STSC and NTAGI. Now with COVID-19, there is a clear need for strengthening of the NTAGI Secretariat in terms of extra technical human resources and advanced trainings.

Most of the members welcomed idea of PhD in vaccinology with constructive feedback from a few other members on research and trainings. It was explained that the idea of PhD in vaccinology program evolved from the idea of young leaders training program, during the discussions in various STSC. It was felt that young leaders invited for few months training may not be worth to fulfil the long-term capacity building goal of developing future champions of vaccinology. Therefore, the idea started from young leaders and then converted to PhD. It was also felt that in addition to PhD in vaccinology there is need of leaders in immunization program operation, for that context internship position at NTAGI secretariat could be opened for public health professional, who are pursuing MPH or MD for a period of 3-6 months. This will give them operational hands.

It was mentioned that there is a need of modeling capacity building at NTAGI Secretariat. It would be multidisciplinary and interdisciplinary training and research involving medical school, statistics, and business school.

One of the members mentioned that IIPH has a program on MSc-PhD in health informatics. Modeling expertise can be developed there as well. It was emphasized that the capacity building should be done utilizing all the opportunities provided.

Suggestions were made to build capacity by conducting training and research while incorporating multidisciplinary areas including biology of vaccination, epidemiology, mathematical modeling, and social acceptance. It was also suggested to create research professor position for vaccine research and training of

PhD students as it is seen in Oxford and Harvard Universities. At the end of the year, research professor can demonstrate what research they have guided.

Emphasis was made on applied research, and alliance between the SWG-IVRCB and program divisions. As program divisions regularly monitor the data which is collected from the field. A suggestion was made to include a representative of NCDC in the SWG-IVRCB.

The members were informed that an external evaluation of all 11 NITAGs in WHO-SEAR countries was conducted and It is a matter of pride that Indian NITAG and Srilanka NITAG were found one of the best ones. It was mentioned that, these capacity building inputs will help India in becoming one of the global leaders in field of vaccinology.

The Co-chairperson thanked the members for suggestions and mentioned that SWG-IVRCB will consider them. Further, it was mentioned that regarding PhD in Vaccinology, DBT will proactively work with premier institutions to come up with the program and present the progress to STSC and NTAGI.

The Chairperson thanked, Co-chairperson for comprehensive presentation and showcasing work undertaken by different WGs.

Decisions

The NTAGI endorsed STSC recommendations on VPD surveillance and IVRCB:

- A report on mechanism, methodologies, necessary systems, data points, manpower and support require for developing a platform/data warehouse for harmonizing data from various vaccine preventable disease surveillance agencies may be developed in 12 weeks' time.

  (SWG-VPD Surveillance and NTAGI Secretariat)

- In view of surge in the work of NTAGI secretariat and requirements of NTAGI-STSC, a proposal for strengthening of the NTAGI Secretariat in terms of additional human resources and advanced trainings will be processed. Additionally, efforts will be made to establish national capacity to model disease burden and the impact of vaccination.

  (MoHFW)

- Conducting two research studies on maternal immunization: (i) Review and Identification of the best fit for maternal Immunization into the existing ANC schedule (4+1 visits) and WHO recommended ANC schedule (8 visits) and (ii) Effect of maternal Tdap vaccination on the whole cell pertussis containing vaccine administered in RI.

  (SWG-IVRCB, DBT, ICMR and NTAGI Secretariat)

- A PhD Program in Vaccinology, under premier institutes offering multidisciplinary and interdisciplinary research pertaining to the domain of vaccinology is to be established. An effort must be made to

consider capacity building of MPH & MD students on operational aspects of immunization in form of internships at the NTAGI Secretariat.

(SWG-IVRCB, DBT, ICMR, MoHFW and NTAGI Secretariat)

Agenda 4: Report of Leprosy Working Group

The Chairperson, Leprosy WG, made a detailed presentation on work carried out by the working group.

Cardinal Observations of Leprosy Disease: Majority of the individuals heal on their own, and if there is a lesion early on, then it is a good sign of protection. On the other hand, those with unstable immunity would have more serious forms of the disease which leads to deformities which is the basis of the public health burden.

Burden of Disease: Trends in new case detection top 17 countries, who were using multi drug therapy as an attempt to eradicate leprosy, was presented. It was observed that there was not significant difference in case of new case detection annually till 2005 in all countries, except India. In India, a sharp decline in new case detection was observed between 2002-2005. Now at least 200,000 new cases are detected annually and almost 5,000 cases become deformed because of leprosy.

Safety and Efficacy of MIP Leprosy Vaccine: The public health importance of leprosy rests solely on the risk of disability and consequent physical & social handicaps**.** Role of a candidate vaccine can be viewed from the following angles: a) Does the vaccine reduce disease transmission in the community? b) Does the vaccine reduce the incidence of deformity causing types of disease? Major question is whether the MIP vaccine prevents deformities, or at least can it prevent the more serious forms of the disease. Unfortunately, the disease has long incubation period, usually 25 years and no study has gone that long to demonstrate protection. No evidence supporting protection against borderline disease emanated from these studies on MIP vaccine. Increased incidence of cases happens early on, among vaccinated, showing immunogenic potential. When administered to borderline cases as therapy, it surprisingly showed reduction in granuloma, redness, and other cardinal signs of leprosy disease, which implies its immunosuppressing action. It is the opposite of what is expected from a vaccine. **Based on leprosy working group deliberations and view on the economic analysis. The working group felt that the available evidence is inconclusive to recommend introduction of MIP vaccine in public health program.**

One of the members informed about 2 major leprosy vaccine trials in India, one was along with TB and second one was conducted in 300,000 subjects in South India. It was informed that in all leprosy vaccine trials around the world, new cases were non-lepromatous, single patch cases were around 70-80%, multibacillary cases were negligible.

It was mentioned that MIP vaccine is not preventing borderline or lepromatous cases. In general population, MIP vaccine had efficacy equal or less than BCG. It was observed that MIP vaccine prevents more cases in

contacts of leprosy patients. However, it is important to consider that less than 10% of new cases of leprosy come from the contacts. It was highlighted that use of MIP vaccine in the program will not reduce the incidence of leprosy cases significantly.

Decision:

- The NTAGI endorsed the findings of the STSC on MIP Leprosy vaccine and did not recommend its inclusion in the national immunization program at this time, as the existing evidence is inconclusive for a large-scale adoption of the MIP vaccine in the public health program.

Agenda Item 5: Preliminary Report of COVID-19 Working Group

The Chairperson, COVID-19 WG, presented a brief timeline of activities of the COVID-19 working group. The NTAGI was informed that WG had deliberations on epidemiology of COVID-19 disease, sero-survey studies, at risk population characteristics, sensitivity and specificity of COVID-19 testing kits, different vaccine development platforms, immediate expectations from the COVID-19 vaccines, vaccination delivery, logistics, data management and recipient tracking system, cold chain requirement, regulatory guidelines for vaccines, prioritization of vaccine recipients, program preparedness for rolling out COVID-19 vaccines, preparedness of National AEFI surveillance program for post-licensure surveillance of COVID-19 vaccines, challenges in preparation of AEFI surveillance program, strategy for strengthening or modifying existing vaccine safety surveillance, a framework on active AEFI/AESI surveillance system. It was informed that the COVID-19 working group had presentations from 4 manufacturers on vaccine development and trials. Discussions were also held on serology testing kits specificity, and emergency use authorization of candidate COVID-19 vaccines.

STSC Recommendations:

- Development of new facilities having international standard bioassay assessment capacity.

Prioritization of vaccine Recipients: The NTAGI was apprised that globally accepted principles of human wellbeing (Equal respect, National equity, Reciprocity, and Legitimacy) were used in development of priority recipient list which has been shared with MoHFW and NITI Aayog.

STSC Recommendations on priority recipients list:

- **High Risk of Exposure (Stage I)**

  First Responders: Health providers; Security personnel; Municipal workers

  Next line of responders: Pre-school and Primary school teachers and caregivers; Maintaining other essential services

- **High Risk of Poor Outcome (Stage II):** Persons with age > 60 years; age > 50 years; Younger individuals with co-morbidities

Framework for an advanced procurement agreement of COVID-19 vaccines: A suggested generic guidance framework for advanced procurement agreement for COVID-19 vaccines by Government of India was developed.

STSC Recommendations:

- Suggestions were made to consider vaccines that are currently under different phases of clinical trials in India.
- A close scrutiny of pre-clinical and available clinical data indicating promising serological responses with appropriate neutralizing vis-à-vis total antibody response to vaccine was advised.
- Consider vaccines if there were no safety signals in the early clinical data or in animal studies.
- It was suggested that the vaccines that fulfil the programmatic feasibility considerations based on the existing immunization infrastructure (e.g., storage, transport and administration) may be considered.
- It was mentioned that manufacturer's capacity and delivery schedule versus the country's/program's requirements also need to considered.

The Part 1 of preliminary guidance document on COVID-19 vaccine use has been shared with MoHFW and NITI Aayog.

Discussions on Emergency Use Authorization, Compassionate Use and Other Options: The following are important to consider: -

- Current state of the COVID-19 pandemic & associated mortality, burden on the health system and impact on the economy.
- Country's prowess to manufacture COVID-19 vaccines in quantities required for the India.
- Development in vaccine R&D, evaluation and readiness to enter the market.

Current state of different vaccines either developed in India or under manufacturing license (as on 7th December 2020). *COVISHIELD (SII)***:** Bridging study (1575 received 2nd dose. *COVAXIN (BBL)***:** Phase I (375); Phase II (390); Phase III (5000 received 1st dose). Both the manufactures had submitted their dossiers for EUA.

The NTAGI was informed that deliberations were held on EUA versus compassionate use versus MEURI (monitoring emergency use of unregistered & experimental interventions aligned with ICMR Ethics guideline 2017). It was informed that compassionate use and MEURI are for serious illness in an individual. There were certain concerns while considering them for vaccination program for a large population. It was felt that balance between the principals of science and accelerated vaccine rollout should be seen with lenses of public health benefits. As vaccines will be administered to a large apparently healthy population. It was also highlighted that at present, correlates of protection are not yet confirmed.

Concern were raised in handling of vaccine candidates that are later on found to be ineffective or significantly less effective or have safety concerns as they might give rise to challenges for health system as well as at regulatory level. Concern over public trust on vaccines and immunization in general were shared. Therefore, it is important that all regulatory guidelines are followed for EUA of a candidate COVID-19 vaccine.

It was shared that DCGI expects sufficiency of data from sufficient number of subjects (Phase III or bridging trial); assessment of risk-benefit ratio; durability of protection and overall discernment of Subject Expert Committee (SEC) of DCGI.

It was mentioned that safety and adverse event monitoring in the 4-6 weeks after completing the immunization schedule among pre-specified sample size is critical in making decision on EUA of a particular vaccine as it is accepted globally.

Further it was informed that credibility and standing of Indian regulatory authorities are very high particularly in context of vaccines as India has emerged as a vaccine-manufacturing hub.

Agenda of forthcoming meetings of the COVID 19 WG: A brief information on forthcoming work to be undertaken by COVID-19 WG was presented. It included a) Finalization on approaches to: i) Emergency Use Authorization and ii) Compassionate use or MEURI, b) vaccine specific contraindications of use of the COVID-19 Vaccine(s), and c) Decisions on the vaccination of COVID-19 antigen and serology positive individuals.

These recommendations may change with availability of new information and change in course of SARS-CoV2 pandemic.

The following discussions were held:

- The members raised concern over considering use of COVID-19 vaccines on compassionate ground. It was mentioned that compassionate criteria should not be used for COVID-19 disease, as it is not a severe life-threatening illness which is looked at compassionate use of drugs. Further, it was mentioned that vaccines will be administered in healthy people, compassionate clause is for individual drug treatment, it should not be brought to vaccine domain. Further evidence would be needed with time on the issue of prevention of transmission by COVID-19 vaccines.

- Some of the members suggested to consider people with high risk of severe illness like elderly and comorbidity should be kept bit higher in priority order above primary school teachers.

- It was suggested that COVID-19 WG should also look into community level perspective, e.g., areas with high prevalence, how infection behaves in community group what vaccination strategy would be needed to reduce high burden and transmission. One of the members suggested expedited guidance on EUA as the pandemic is still ongoing.

- Information on identification and tracking of individual beneficiaries was solicited by members. As lot of disinformation is floating around. It was suggested that public could be informed that it is a complicated exercise and concisely designed, and vaccine will be freely available once it comes in the program. It will avoid issues of disinformation. Suggestion was made for exceptional transparency to tell everything to all the communities to every beneficiary by various channels.

Chairperson Remarks:

The Chairperson mentioned that exceptional transparency is critically important and all facts will be shared with priority group as well as with the public at large. Further, it was mentioned that serology testing prior to vaccination is an open question and evidence is being reviewed by the COVID-19 WG.

It was also remarked that MoHFW is actively working with State governments, databases are getting created and uploaded on digital platform which will enable a real time tracking of every individual beneficiary. Further, it was informed that MoHFW has formulated a communication strategy, focusing on COVID-19 vaccination in collaboration with all stakeholders and this communication strategy will be shared with State governments in next few days. Trainings for field level functionaries, have been scheduled on communication. It included training on how, whom and when to communicate, and how to counter disinformation and rumors. The members were apprised that a COVID- 19 vaccine communication dashboard is being planned and pertinent information will be placed on website as well. The work presented by the COVID-19 WG is work in progress, an account of all the suggestions shared by the members will be undertaken.

Recommendations:

Decision:

The NTAGI endorsed the STSC recommendations on development of bioassay assessment capacity, suggestions on the prioritization of the vaccine recipients and suggestive framework on advanced purchase agreement of COVID-19 vaccines with following points:

- A report on (i) emergency use authorization of COVID-19 vaccines, including informed consent component (ii) literature review findings on conducting a serology testing prior to vaccination, and (iii) product specific contraindications of COVID-19 vaccines may be shared with the Chairperson and Co-chairperson in a time-bound deadline.

(COVID-19 WG and NTAGI Secretariat)

Agenda Item 6: Annual Work Plan of NTAGI 2021

The Joint Secretary RCH, shared annual work plan of the NTAGI for the year of 2021. The annual work plan was developed in consultation with the Co-chairpersons (Secretary DBT and Secretary DHR & DG-ICMR). Following additional activities were suggested to be included in the annual work plan of 2021:

- A discussion on Controlled Human Infection Model (CHIM) studies human by STSC.
- Six-monthly NTAGI meeting for expedited decisions.
- Formal documentation, presentation and publication of the experience of COVID-19 vaccine rollout.
- Discussion on safety signals which emerge during the course of population vaccination.
- Ascertain the effectiveness of communication strategy, in terms of sustaining the demand and debunking the vaccine rumors and disinformation.
- Vaccine hesitancy: Review the strategies to counter misinformation related to adverse events effectively.

An updated annual work plan of 2021 has been annexed as Annexure-3.

Chairperson Remarks and Vote of Thanks

The Chairperson thanked all the participants for their invaluable contribution to all the six agenda items considered in the meeting. He also thanked the members for approving the annual work plan (AWP) for 2021 with significant suggestions which would be incorporated in the AWP-2021 to enrich overall interventions. Further, he mentioned that in future more frequent NTAGI meetings will be conducted and concluded the meeting.

JS (RCH) finally proposed vote of thanks.

15th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
December 10, 2020, Thursday, 12:00 PM to 2:00 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Annexure -1

List of Participants

S.No.	Name	Designation
Chairperson		
1	Shri Rajesh Bhushan	Secretary, Department of Health & Family Welfare
Co-chairperson		
2	Dr Renu Swarup	Secretary, Department of Biotechnology
Core Members, Ex-officio		
3	Dr Sunil Kumar	Director General of Health Services
4	Ms Vandana Gurnani	Additional Secretary & Mission Director, NHM
5	Dr Sujeet Singh	Director, National Centre of Disease Control
6	Dr Priya Abraham	Director, National Institute of Virology
Core Members, Independent Experts		
7	Dr J P Muliyil	Professor, CMC Vellore
8	Dr Gagandeep Kang	Professor, CMC, Vellore
9	Dr Indrani Gupta	Professor, Institute for Economic Growth, Delhi
10	Dr Rakesh Aggarwal	Director, JIPMER, Puducherry
11	Dr Mathew Varghese	Head of the Dept, Orthopedics, St. Stephan's Hospital, New Delhi
12	Dr Satinder Aneja	Professor and Head, Dept. of Pediatrics, Sharda University
13	Dr Neerja Bhatla	Professor, AIIMS, New Delhi
14	Dr M D Gupte	Former Director, NIE, Chennai
15	Dr Arun Kumar Agarwal	Professor, PGI, Chandigarh
16	Dr Lalit Dar	Professor, AIIMS, New Delhi
17	Dr Dilip Kumar Das	Professor, Burdwan Medical College, Burdwan
18	Dr Parvaiz Koul	Professor, Sher-i-Kashmir Institute of Medical Sciences, Srinagar
19	Dr Surinder Jaswal	Professor, Tata Institute of Social Sciences
20	Dr F U Ahmed	Pro-Vice Chancellor, Khaja Bandanawaz University, Gulbarga
Liaison Members		
21	Dr Manohar Agnani	Additional Secretary, MoHFW
22	Ms Preeti Pant	Joint Secretary-RCH, MoHFW
23	Dr Pradeep Haldar	Advisor-RCH, MoHFW
24	Dr M K Aggarwal	Additional Commissioner-UIP, MoHFW
25	Dr V G Somani	Drugs Controller General of India, CDSCO, MoHFW
Professional Organization Representatives		
26	Dr Bakul Jayant Parekh	President, Indian Association of Paediatrics
27	Dr Rajan Sharma	President, Indian Medical Association
28	Dr K Srinath Reddy	President, Public Health Foundation of India
International Partners Representatives		

29	Dr Roderico Ofrin	Country Representative, WHO, India
30	Dr Pankaj Bhatnagar	National Professional Officer & Deputy Team Lead, WHO, India
31	Mr Lugi D Aquino	Chief of Health, UNICEF
32	Dr Rija Andriamihantanirina	Immunization specialist, UNICEF
33	Dr Bhrigu Kapuria	Health Specialist (Immunization), UNICEF
State Representatives		
34	Dr Arundhati Chandrashekhar	MD-NHM, Karnataka
35	Dr B N Rajani	Deputy Director, Karnataka
36	Mr Amit Singla	Secretary, Delhi
37	Dr Monika Rana	Director, Govt of NCT of Delhi
Indian Council of Medical Research		
38	Dr Samiran Panda	Scientist 'G', ICMR, New Delhi
39	Dr Nivedita Gupta	Scientist 'F', ICMR, New Delhi
Department of Biotechnology		
40	Dr Alka Sharma	Adviser / Scientist 'G', Department of Biotechnology, New Delhi
41	Dr Jyoti Logani	Scientist 'E', Department of Biotechnology, New Delhi
Immunization Division, MoHFW		
42	Dr Indu Grewal	Joint Commissioner-UIP, MoHFW
Special Invitees		
43	Ms Rekha Sharma	Joint Secretary, MoHFW
44	Dr N K Arora	Chair COVID-19 Working Group, Executive Director, INCLEN International
45	Dr Rajat Ranjan	Lead Consultant, MoHFW
NTAGI Secretariat		
46	Dr Dinesh Paul	Advisor-cum-Manager
47	Dr Awnish Kumar Singh	Research Analyst
Co-chairperson Apologized		
48	Dr Balram Bhargava	Secretary, Department of Health Research & DG-ICMR
Member Apologized		
49	Dr Y K Gupta	Principle Adviser THSTI-DBT
50	Dr Veena Dhawan	Joint Commissioner-Immunization, MoHFW

15th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
December 10, 2020, Thursday, 12:00 PM to 2:00 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Annexure -2

Agenda

Chairperson: Shri. Rajesh Bhushan, Secretary (H&FW), MoHFW	***Co-chairperson: Dr Renu Swarup, Secretary DBT***	***Co-chairperson: Prof Balram Bhargava, Secretary DHR & DG-ICMR***
12:00 PM-12:05 PM	General Business	NTAGI Secretariat
12:05 PM-12:10 PM	Welcome and Introduction Submission of minutes of the NTAGI meeting held on December 17, 2018	Chairperson and Co-chairpersons NTAGI
Agenda no. 1: Action Taken Report		
12:10 PM-12:15 PM	Agenda no. 1.1: Action taken report on the minutes of previous meeting of NTAGI held on December 17, 2018	JS-RCH
	Agenda no. 1.2: Summary of ATR on previous NTAGI recommendations 1.2.1: Dosage and schedule of JE Vaccines and plan of Interchangeability study of JE Vaccines 1.2.2: Indigenous Rotavirus Vaccines Program Implementation Review	Co-chairpersons
	Agenda no. 1.3: Human Vaccines Interchangeability SOP at the time of licensure	DCGI
Agenda no. 2: Follow-up Action on carrying out NTAGI-STSC Recommendations		
12:15 PM-12:20 PM	Agenda 2: Follow-up action on STSC recommendations by MoHFW 2.1: JE Vaccines 2.2: Indigenous Rotavirus Vaccines	JS-RCH
12:20 PM-12:25 PM	Discussion	NTAGI Members
Agenda no. 3: STSC Meeting Discussion and Recommendations (closed session)		
12:25 PM-12:35 PM	Agenda 3.1: Vaccine Preventable Disease Surveillance Agenda 3.2: Immunization & Vaccine Research & Capacity Building Agenda 3.3: Introduction & Background Leprosy WG Agenda 3.4: Introduction & Background Vaccine Cost Effectiveness Analysis WG Agenda 3.5: Introduction & Background COVID-19 WG	Co-chairpersons
12:35 PM-12:40 PM	Discussion	NTAGI Members
Agenda no. 4: Leprosy Vaccines (closed session)		
12:40 PM-12:50 PM	Agenda 4: Report of Leprosy Working Group	Chair, Leprosy WG
12:50 PM-01:00 PM	Discussion	NTAGI Members
Agenda no. 5: COVID-19 Vaccines (closed session)		
01:00 PM-01:20 PM	Agenda 5: Preliminary Report of COVID-19 Working Group	Chair, COVID-19 WG
01:20 PM-01:45 PM	Discussion	NTAGI Members
01:45 PM-01:50 PM	Recommendations	Chairperson and Co-chairpersons
Agenda no. 6: Annual Work Plan of NTAGI 2021 (closed session)		
01:50 PM-01:55 PM	Agenda no. 6: Annual Work Plan of NTAGI 2021	JS-RCH
01:55 PM-02:00 PM	Concluding Remarks	Chairperson and Co-chairpersons

Annexure-3

Work plan of the NTAGI 2021

This document presents the activities planned by NTAGI for the year 2021

1. Scientific production

Activity 1.1: Collate, review and grade evidence on COVID-19 disease burden, COVID-19 Vaccines efficacy, safety and immunogenicity as part of **COVID-19 WG work.**

Activity 1.2: Daft a Final guidance document for use of COVID-19 vaccines in India as part of **COVID-19 WG work.**

Activity 1.3: Develop a report explaining the details of mechanism, methodologies, necessary systems, data points, manpower and support require for developing a platform/data warehouse which will in harmonizing data from various agencies, so that it can help in NTAGI work, as part of **SWG-VPD Surveillance work**

Activity 1.4: Identifying the priority research areas pertaining to COVID-19 vaccines program implementation and policy decision-making as part of **Standing Working Group on Immunization and Vaccine Research and Capacity Building (IVRCB) and COVID-19 WG work.**

Activity 1.5: A cost-effectiveness modelling exercise to ascertain at what cutoff point pre-vaccination serology may be effective as part of **vaccine CEA WG and COVID-19 WG work.**

Activity 1.6: Starting of PhD Programme in Vaccinology in AIIMS, New Delhi, PGI, Chandigarh or JIPMER, Puducherry with financial support from ICMR, and DBT.

Activity 1.7: Review of the data of maternal seasonal influenza vaccination data in Maharashtra as part of **Influenza working group work**.

Activity 1.8: A review of seasonal Influenza infection rates during pregnancy and its impact on maternal mortality, morbidity and fetal outcomes as part of **Maternal Immunization sub-group work.**

Activity 1.9: Identifying the priority areas of capacity building relevant to vaccine research and immunization policy decision-making as part of **Standing Working Group on Immunization and Vaccine Research and Capacity Building (IVRCB) work.**

Activity 1.10: Scoping Review on the burden of Respiratory Syncytial Virus in India as part of **Standing Working Group (SWG) on Vaccine Preventable Diseases (VPD) Surveillance and Maternal Immunization sub-group work**.

Activity 1.11: Review the surveillance data on Cholera and planned research studies on Cholera disease and OCV as part of **Cholera WG work**.

Activity 1. 12: Provide guidance on research studies on program costing, cost effectiveness, cost benefit, additional cold chain space requirement, vaccine wastage, cost for vaccination, training and capacity building of healthcare workers, and pilot implementation of vaccines as part of **Cholera WG work and Vaccine CEA WG work.**

Activity 1.13: A brain storming workshop to discuss the issue of vaccine confidence with different stakeholders and subject matter experts as part of **vaccine confidence sub-group work**.
Activity 1.14: Review of Rotavirus interchangeability study data by **NTAGI-STSC**.
Activity 1.15: Review of Typhoid surveillance study and TCV implementation study data by **NTAGI-STSC**.

Activity 1.16: A discussion on Controlled Human Infection Model (CHIM) studies human by **NTAGI-STSC**.

Activity 1.17: Formal documentation, presentation and publication of the experience of COVID-19 vaccine rollout by **COVID-19 WG.**

Activity 1.18: Discussion on safety signals which emerge during the course of population wide COVID-19 vaccination by **NTAGI-STSC.**

Activity 1.19: Ascertain the effectiveness of communication strategy, in terms of sustaining the demand and debunking the vaccine rumors and disinformation. **SWG-IVRCB**

Activity 1.20: Vaccine hesitancy: Review the strategies to counter misinformation related to adverse events effectively. **SWG-IVRCB**

2. Strengthening the Secretariat and committee's technical and scientific capacities

Activity 2.1: Access to multiple scientific articles databases for systematic literature review on VPDs by Secretariat.
Activity 2.2: Recruitment of additional technical human resource for facilitation of NTAGI work.

F. No.: BIO/MA/20/000102

Permission no.: MF/BIO/21/000001 dated 03-JAN-2021

FORM CT-23

(See rules 81, 82, 83 and 84)

PERMISSION TO MANUFACTURE PHARMACEUTICAL FORMULATION OF NEW DRUG FOR SALE OR FOR DISTRIBUTION

The Central Licensing Authority hereby grant permission to M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra (India) - 411028 Telephone No.: 020-26602113, 26602378, 26602978 Fax: 020-26993945, 26993921 to manufacture for sale of pharmaceutical formulation manufactured by a manufacturer specified below.

2. Details of manufacturer and its manufacturing site under this license:

S. No	Name and address of manufacturer (full name and address with telephone and e-mail address of manufacturer).	Name and address of manufacturing site (full name and address with telephone and e-mail address of manufacturing site).
1.	M/s. Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road Hadapsar Pune, Maharashtra (India) – 411 028. Tel. No: +91-20-26993900, 26992113 Fax No: +91-20-26993921, Email: ssj@seruminstitute.com	M/s. Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra (India) – 411 028. **Component** / **Manufacturing facility** Drug substance: • Bld.14, EOU, • SEZ-6, First Floor • SEZ-7, Second Floor Drug Product: SEZ-5 Ground Floor

3. Details of pharmaceutical formulation:

Name of the New drug to be manufactured:	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)
Dosage form:	Solution for injection Presentation: Multi-dose Glass vial (10 dose- 5ml) Route of Administration: Intramuscular
Composition:	Each dose of 0.5ml of vaccine contains:

Active Ingredients	**Quantity**
Replication- deficient chimpanzee adeno virus particles encoding SARS-CoV-2 spike (S) glycoprotein*	5×10^{10} virus particles
Inactive Ingredients	**Quantity**
L-Histidine and L-Histidine Hydrochloride	10 mM
Sodium Chloride	35 mM
Magnesium Chloride	1 mM
Polysorbate 80	0.1% (w/v)
Sucrose	7.5% (w/v)
Ethanol	0.5% (w/v)
EDTA Disodium Salt	0.1 mM
Water for Injection	q.s. to 0.5 ml

* Produced in genetically human embryonic kidney (HEK) 293 cells.

Indication:	For active immunization of individuals of ≥18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.
Shelf life with storage condition:	6 months when stored at 2 to 8 °C. Once opened, multi-dose vials should be used as soon as possible and within 6 hours when kept between 2 to 8°C.

4. This is subject to the conditions prescribed in Chapter X of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act,1940.
5. This permission is for restricted use in emergency situation for COVID-19 subject to various regulatory provisions.
6. Vaccine to be supplied for immunization programme.
7. The vaccine should be supplied along with Factsheet for recipients and prescribing information/ Package Insert (PI).
8. The firm should provide the updated Package Insert, Summary of Product Characteristics (SmPC) & Factsheet for ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) incorporating the changes as per the Subject Expert Committee (SEC) recommendations dated 01.01.2021.
9. The firm should ensure that factsheet for the vaccine recipient/his attendant is provided prior to the administration of vaccine.
10. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. through their website prior marketing/supplies of the product.
11. The firm should submit safety, efficacy & immunogenicity data from the ongoing clinical trials nationally and internationally till the completion of trial.
12. The firm should submit safety data including the data on AEFI and AESI, with due analysis, every 15 days for the first two months & monthly thereafter till the completion of the ongoing clinical trial in the country. Thereafter, the firm should submit the safety data as per the provisions and Rules.
13. The firm should provide and implement India specific Risk Management Plan.
14. The firm should submit ongoing stability (real time and accelerated) of drug substance & drug product.
15. Each batch/lot of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) shall be released from Central Drugs Laboratory, Kasauli.

VENUGOPAL GIRDHARILAL SOMANI

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Place: New Delhi
Date: 03-Jan-2021

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Frequently Asked Questions on COVID-19 Vaccine

Target Group: General Public

S. No.	Question	Potential response
1.	Is a COVID vaccine scheduled anytime soon	Yes, vaccine trials are under different stages of finalization. Government of India is geared to launch a vaccine for COVID 19 soon. For more information and updates visit www.mohfw.gov.in
2.	Will COVID 19 vaccine be given to everyone simultaneously	Based on the potential availability of vaccines the Government of India has selected the priority groups who will be vaccinated on priority as they are at higher risk. The first group includes healthcare and frontline workers. The second group to receive COVID 19 vaccine will be persons over 50 years of age and persons under 50 years with comorbid conditions
3.	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 one-self against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers.
4.	Will the vaccine be safe as it is being tested and introduced in a short span of time?	Vaccines will be introduced in the country only after the regulatory bodies clear it based on its safety and efficacy.

5.	Can a person presently having COVID-19 (confirmed or suspected) infection be vaccinated?	Person with confirmed or suspected COVID-19 infection may increase the risk of spreading the same to others at vaccination site. For this reason, infected individuals should defer vaccination for 14 days after symptoms resolution.
6.	Is it necessary for a COVID recovered person to take the vaccine?	Yes, it is advisable to receive complete schedule of COVID vaccine irrespective of past history of infection with COVID-19. This will help in developing a strong immune response against the disease.
7.	Out of the multiple vaccines available, how is one or more vaccine chosen for administration?	The safety and efficacy data from clinical trials of vaccine candidates are examined by Drug regulator of our country before granting the license for the same. Hence, all the COVID-19 vaccines that receive license will have comparable safety and efficacy. However, it must be ensured that the entire schedule of vaccination is completed by only one type of vaccine as different COVID-19 vaccines are not interchangeable.
8.	Does India have the capacity to store the COVID vaccine at temperature of +2 to +8 degree Celsius and transport them at required temperature?	India runs one of the largest Immunization programme in the world, catering to the vaccination needs of more than 26 million newborns and 29 million pregnant women. The programme mechanisms are being strengthened / geared up to effectively cater to the country's large and diverse population.

9.	Will the vaccine introduced in India be as effective as the ones introduced in other countries?	Yes. The COVID 19 vaccine introduced in India will be as effective as any vaccine developed by other countries. Various phases of vaccine trials are undertaken to ensure its safety and efficacy.
10.	How will I know if I am eligible for vaccination?	In the initial phase, COVID 19 vaccine will be provided to the priority group- Health Care and Front-line workers. The 50 plus age group may also begin early based on vaccine availability. The eligible beneficiaries will be informed through their registered mobile number regarding the Health Facility where the vaccination will be provided and the scheduled time for the same. This will be done to avoid any inconvenience in registration and vaccination of beneficiaries.
11.	Can a person get the COVID-19 vaccine without registration with Health Department?	No, registration of beneficiary is mandatory for vaccination for COVID 19. Only after registration the information on the session site to visit and time will be shared with the beneficiary.

12.	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: • Aadhar 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 with photograph issued to employees by Central/ State Govt./ PSUs/Public Limited Companies • Voter ID • Smart card issued by RGI under NPR
13.	Will a Photo / ID be required at the time of registration?	The Photo ID produced at the time of registration must be produced and verified at the time of vaccination.
14.	If a person is not able to produce Photo ID at the session site, whether s/he be vaccinated or not?	Photo ID is a must for both registration and verification of beneficiary at session site to ensure that the intended person is vaccinated.
15.	How will the beneficiary receive information about due date of vaccination?	Following online registration, beneficiary will receive SMS on their registered mobile number on the due date, place and time of vaccination.

16.	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.
17.	If one is taking medicines for illnesses like Cancer, Diabetes, Hypertension etc, can s/he take the COVID-19 vaccine?	Yes. Persons with one or more of these comorbid conditions are considered high risk category. They need to get COVID -19 vaccination.
18.	Are there any preventive measures and precautions that one needs to follow at the session site?	We request you to rest at the vaccination centre for atleast half an hour after taking the COVID-19 vaccine. Inform the nearest health authorities / ANM / ASHA in case you feel any discomfort or uneasiness subsequently. Remember to continue following key COVID Appropriate Behaviours like wearing of mask, maintaining hand sanitization and physical distance (or 6 feet or Do Gaj).
19.	What about the possible side-effects from COVID-19 vaccine?	COVID Vaccine will be introduced only when the safety is proven. As is true for other vaccines, the common side effects in some individuals could be mild fever, pain, etc. at the site of injection. States have been asked to start making arrangements to deal with any Covid-19 vaccine-related side-effects as one of the measures towards safe vaccine delivery among masses.

20.	How many doses of the vaccine would have to be taken by me and at what interval?	Two doses of vaccine, 28 days apart, need to be taken by an individual to complete the vaccination schedule.
21.	When would antibodies develop? After taking first dose, after taking second dose, or much later?	Protective levels of antibodies are generally developed two weeks after receiving the 2nd dose of COVID-19 vaccine.

Frequently Asked Questions on COVID-19 Vaccine

Target Group: Healthcare providers / Frontline workers

	Question	Potential response
1.	Why am I being chosen for COVID 19 vaccine?	Government of India has prioritised the most at risk/high risk groups which will get the vaccine first. Healthcare providers have led the battle against COVID 19 from the front. The government wantsyou to be able to continue your work, without the fear of risk associated with the virus. Therefore, healthcare and frontline workers are among the first group of people to be vaccinated in the country.
2.	What are the groups to be vaccinated in the first phase?	Based on the potential availability of vaccines the Government of India has selected the priority groups who will be vaccinated on priority as they are at higher risk. The first group includes healthcare workers because they are at high risk of contracting the infection and protecting them helps to sustain essential health services. The vaccination of frontline workers will help in reducing the societal and economic impact by reducing COVID-19 mortalities. The next group to receive COVID 19 vaccine will be persons over 50 years of age and persons under 50 years with comorbid conditions because there is high mortality in this category. The reason for including more than 50 years of age group for vaccination is that it will be able to cover 78% of persons having co-morbidities and thereby reduce mortality on account of COVID-19.

		More than 50 years of age group is divided into two sub groups. One sub group is 60 years and above, they will be vaccinated first. Second sub-group is between 50 to 60 years age group, they will be vaccinated after the first sub group is covered. The vaccination may not be sequential. It can go in parallel for all beneficiaries depending on the availability of the vaccine.
3.	Will my family members also be given the vaccine?	Due to the limited vaccine supply in the initial phase, it will first be provided to people who are at higher risk of contracting COVID-19. In subsequent phases the COVID 19 vaccine will be made available to all others in need of the same.
4.	Is this vaccine safe?	Yes. Safety and efficacy of vaccine will be ensured through various phases of vaccine trials and only then a vaccine will be introduced.
5.	Does one need to follow preventive measures such as wearing a mask, hand sanitization, social distancing after receiving the COVID 19 vaccine?	Even after receiving the COVID 19 vaccine, we must continue taking all precautions like use of face cover or masks, hand sanitization and maintain distancing (6 feet or Do Gaj). These behaviours must be followed both at the session site and in general.
6.	Are there any common side-effects of this vaccine?	The COVID 19 vaccine will be safe and effective but may have minor side effects like fever, pain, etc. at the injection site. These effects can happen in any vaccine.

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant)

COVISHIELD™

1 NAME OF THE MEDICINAL PRODUCT

COVISHIELD™
ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5 ml) contains:

ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) 5×10^{10} viral particles (vp)

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.

This product contains genetically modified organisms (GMOs).

For the full list of excipients, see section 6.1.

Both **COVISHIELD™** (manufactured by Serum Institute of India Pvt Ltd) and COVID-19 Vaccine AstraZeneca (manufactured by AstraZeneca) are ChAdOx1 nCoV- 19 Corona Virus Vaccines (Recombinant).

3 PHARMACEUTICAL FORM

Solution for injection

The solution is colourless to slightly brown, clear to slightly opaque and particle free with a pH of 6.6.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

COVISHIELD™ is indicated for active immunisation of individuals ≥18 years old for the prevention of coronavirus disease 2019 (COVID-19).

4.2 Posology and method of administration

Posology

COVISHIELD™ vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies (see section 5.1).

It is recommended that individuals who receive a first dose of **COVISHIELD™** complete the vaccination course with **COVISHIELD™** (see section 4.4).

Special populations

Elderly population

Efficacy and safety data are currently limited in individuals ≥ 65 years of age (see sections 4.8 and 5.1). No dosage adjustment is required in elderly individuals ≥ 65 years of age.

Paediatric population

The safety and efficacy of **COVISHIELD™** in children and adolescents (aged <18 years old) have not yet been established. No data are available.

Method of administration

COVISHIELD™ is for intramuscular (IM) injection only, preferably in the deltoid muscle.

For instructions on administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and special precautions for use

Hypersensitivity

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Concurrent illness

As with other vaccines, administration of **COVISHIELD™** should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, **COVISHIELD™** should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen. Immunocompromised individuals may have relatively weaker immune response to the vaccine regimen.

Duration and level of protection

The duration of protection has not yet been established.

As with any vaccine, vaccination with **COVISHIELD™** may not protect all vaccine recipients (See section 5.1).

Interchangeability

No data are available on the use of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) in persons that have previously received partial vaccine series with another COVID-19 vaccine.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant administration of **COVISHIELD™** with other vaccines has not been studied (see section 5.1)

4.6 Fertility, pregnancy and lactation

Fertility

Preliminary animal studies do not indicate direct or indirect harmful effects with respect to fertility.

Pregnancy

There is a limited experience with the use of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) in pregnant women.

Preliminary animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryofetal development, parturition or postnatal development; definitive animal studies have not been completed yet. The full relevance of animal studies to human risk with vaccines for COVID-19 remains to be established.

Administration of **COVISHIELD™** in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Breastfeeding

It is unknown whether **COVISHIELD™** is excreted in human milk.

4.7 Effects on ability to drive and use machines

ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Overall summary of the safety profile from the Overseas studies:

The overall safety of COVID-19 Vaccine AstraZeneca [ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)] is based on an interim analysis of pooled data from four clinical trials conducted in the United Kingdom, Brazil, and South Africa. At the time of analysis, 23,745 participants ≥18 years old had been randomised and received either COVID-19 Vaccine AstraZeneca or control. Out of these, 12,021 received at least one dose of COVID-19 Vaccine AstraZeneca. The median duration of follow-up in the COVID-19 Vaccine AstraZeneca group was 105 days post dose 1, and 62 days post dose 2.

Demographic characteristics were generally similar among participants who received COVID-19 Vaccine AstraZeneca and those who received control. Overall, among the participants who received COVID-19 Vaccine AstraZeneca, 90.3% were aged 18 to 64 years and 9.7% were 65 years of age or older. The majority of recipients were White (75.5%), 10.1% were Black and 3.5% were Asian; 55.8% were female and 44.2% male.

The most frequently reported adverse reactions were injection site tenderness (>60%); injection site pain, headache, fatigue (>50%); myalgia, malaise (>40%); pyrexia, chills (>30%); and arthralgia, nausea (>20%). The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. By day 7 the incidence of subjects with at least one local or systemic reaction was 4% and 13%, respectively. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently.

Adverse reactions were generally milder and reported less frequently in older adults (≥65 years old).

If required, analgesic and/or anti-pyretic medicinal products (e.g. paracetamol-containing products) may be used to provide symptomatic relief from post-vaccination adverse reactions.

Adverse drug reactions

Adverse drug reactions (ADRs) are organised by MedDRA System Organ Class (SOC). Within each SOC, preferred terms are arranged by decreasing frequency and then by decreasing seriousness. Frequencies of occurrence of adverse reactions are defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000) and not known (cannot be estimated from available data).

Table 1 - Adverse drug reactions

MedDRA SOC	Frequency	Adverse reactions
Blood and lymphatic system disorders	Uncommon	Lymphadenopathy[a]
Metabolism and nutrition disorders	Uncommon	Decreased appetite[a]
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness[a]
Gastrointestinal disorders	Very common	Nausea
	Common	Vomiting
	Uncommon	Abdominal pain[a]
Skin and subcutaneous tissue disorders	Uncommon	Hyperhidrosisa[a], pruritisa[a], rash[a]
Musculoskeletal and connective tissue disorders	Very common	Myalgia, arthralgia
General disorders and administration site conditions	Very common	Injection site tenderness, injection site pain, injection site warmth, injection site erythema, injection site pruritus, injection site swelling, injection site bruising[b], fatigue, malaise, pyrexia[c], chills
	Common	Injection site induration, influenza like illness[a]

[a] Unsolicited adverse reaction
[b] Injection site bruising includes injection site haematoma (uncommon, unsolicited adverse reaction)
[c] Pyrexia includes feverishness (very common) and fever ≥38° C (common)

Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID 19 Vaccine AstraZeneca. A causal relationship has not been established.

Overall summary of the safety profile from the Indian study:

COVISHIELD™ was also safe and well tolerated in the phase II/III clinical trial in India. An interim analysis included data of all 1600 participants who received first dose [1200 in **COVISHIELD™** group, 100 in Oxford/AZ-ChAdOx1 nCoV-19 vaccine group and 300 in Placebo group]. This interim analysis includes data collected until 14 Dec 2020 of all 1600 participants who received first dose and 1577 participants who received second dose.

Demographic characteristics were generally similar among participants across the three groups. Overall, among the participants who received **COVISHIELD™**, 87.33% were aged 18 to 59 years and 12.67% were 60 years of age or older.

Overall, the incidence of solicited reactions (injection site reactions such as pain, tenderness, redness, warmth, itch, swelling and induration; and systemic reactions include fever, chills, fatigue, malaise, headache, arthralgia and myalgia), unsolicited adverse events and serious adverse events (SAEs) was comparable in the study and control groups. No causally related SAE was caused by the study vaccine.

4.9 Overdose

Experience of overdose is limited.

There is no specific treatment for an overdose with ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant). In the event of an overdose, the individual should be monitored and provided with symptomatic treatment as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

COVISHIELD™ is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV-2. Following administration, the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralizing antibody and cellular immune responses.

Efficacy and immunogenicity data from the Overseas studies:

Clinical efficacy

Interim analysis of pooled data from COV001, COV002, COV003, and COV005

COVID-19 Vaccine AstraZeneca [ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)] has been evaluated based on an interim analysis of pooled data from four on-going randomised, blinded, controlled trials: a Phase I/II Study, COV001 (NCT04324606), in healthy adults 18 to 55 years of age in the UK; a Phase II/III Study, COV002 (NCT04400838), in adults ≥18 years of age (including the elderly) in the UK; a Phase III Study, COV003 (ISRCTN89951424), in adults ≥18 years of age (including the elderly) in Brazil; and a Phase I/II study, COV005 (NCT04444674), in adults aged 18 to 65 years of age in South Africa. The studies excluded participants with history of anaphylaxis or angioedema; severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with immunosuppression. In studies COV001 and COV002, licensed seasonal influenza and pneumococcal vaccinations were permitted (at least 7 days before or after their study vaccine). All participants are planned to be followed for up to 12 months, for assessments of safety and efficacy against COVID-19 disease.

Based on the pre-defined criteria for interim efficacy analysis, COV002 and COV003 exceeded the threshold of ≥5 virologically confirmed COVID-19 cases per study and therefore contributed to the efficacy analysis; COV001 and COV005 were excluded.

In the pooled analysis for efficacy (COV002 and COV003), participants ≥18 years of age received two doses of COVID-19 Vaccine AstraZeneca (N=5,807) or control (meningococcal vaccine or saline) (N=5,829). Because of logistical constraints, the interval between dose 1 and dose 2 ranged from 4 to 26 weeks.

Baseline demographics were well balanced across COVID-19 Vaccine AstraZeneca and control treatment groups. Overall, among the participants who received COVID-19 Vaccine AstraZeneca, 94.1% of participants were 18 to 64 years old (with 5.9% aged 65 or older); 60.7% of subjects were female; 82.8% were White, 4.6% were Asian, and 4.4% were Black. A total of 2,070 (35.6%) participants had at least one pre-existing comorbidity (defined as a BMI ≥ 30 kg/m^2, cardiovascular disorder, respiratory disease or diabetes). At the time of interim analysis the median follow up time post-dose 1 and post-dose 2 was 132 days and 63 days, respectively.

Final determination of COVID-19 cases were made by an adjudication committee, who also assigned disease severity according to the WHO clinical progression scale. A total of 131 participants had SARS-CoV-2 virologically confirmed (by nucleic acid amplification tests) COVID-19 occurring ≥15 days post second dose with at least one COVID-19 symptom (objective fever (defined as ≥37.8°C), cough, shortness of breath, anosmia, or ageusia) and were without evidence of previous SARS-CoV-2 infection. COVID-19 Vaccine AstraZeneca significantly decreased the incidence of COVID-19 compared to control (see Table 2a).

Table 2a - COVID-19 Vaccine AstraZeneca efficacy against COVID-19*

Population	COVID-19 Vaccine AstraZeneca		Control		Vaccine efficacy % (95.84% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
Primary (see above)	5807		5829		
COVID-19 cases		30 (0.52)		101 (1.73)	70.42 (58.84, 80.63)[a]
Hospitalisations[b]		0		5 (0.09)	
Severe disease[c]		0		1 (0.02)	
Any dose	**10,014**		**10,000**		
COVID-19 cases after dose 1		108 (1.08)		227 (2.27)	52.69 (40.52, 62.37)[d]
Hospitalisations after dose 1[b]		2 (0.02)[e]		16 (0.16)	
Severe disease after dose 1[c]		0		2 (0.02)	

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval; * This is a pooled data of LDSD + SDSD regimen with second dose given at dose intervals ranging from 4 to 12 weeks. LD - Low Dose, SD - Standard Dose.

[a] 95.84% CI; [b] WHO severity grading ≥4; [c] WHO severity grading ≥6; [d] 95% CI; [e] Two cases of hospitalisation occurred on Days 1 and 10 post vaccination.

Table 2b - COVID-19 Vaccine AstraZeneca efficacy against COVID-19

Population	COVID-19 Vaccine AstraZeneca		Control		Vaccine efficacy % (95.84% CI)
	N	Number of COVID-19 cases, n (%)	N	Number of COVID-19 cases, n (%)	
Primary analysis population					
Overall (SDSD + LDSD)	5807	30 (0.52)	5829	101 (1.73)	70.42 (58.84, 80.63)
Licensing regimen					
SDSD	4440	27 (0.61)	4455	71 (1.59)	62.10 (39.96, 76.08)
Exploratory analysis					
LDSD	1367	3 (0.22)	1374	30 (2.18)	90.05 (65.84, 97.10)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval; LD = Low dose; SD = Standard dose

Table 2c - COVID-19 Vaccine AstraZeneca efficacy against COVID-19 by Dose Interval (SDSD)

Dose interval	Participants with events, n (%)		Vaccine efficacy %	95% CI (%)	P-value
	AZD1222 n / N (%)	Control n / N (%)			
< 6 weeks	9 / 1702 (0.53)	19 / 1698 (1.12)	53.28	(-3.21, 8.86)	0.060
6-8 weeks	5 / 562 (0.88)	9 / 521 (1.73)	51.08	(-45.57, 3.56)	0.199
9-11 weeks	9 / 1056 (0.85)	24 / 1110 (2.16)	60.55	(15.23, 81.64)	0.017
≥ 12 weeks	4 / 1120 (0.36)	19 / 1126 (1.69)	78.79	(37.63, 92.79)	0.005

The level of protection gained from single dose of COVID-19 Vaccine AstraZeneca was assessed in an exploratory analysis that included participants who had received one dose. Participants were censored from the analysis at the earliest time point of when they received a second dose or at 12 weeks post-dose 1. In this population, vaccine efficacy from 22 days post dose 1 was 73.00% (95% CI: 48.79; 85.76 [COVID-19 Vaccine AstraZeneca 12/7,998 vs control 44/7,982]).

Exploratory analyses showed that increased immunogenicity was associated with a longer dose interval (see Immunogenicity Table 3). Efficacy is currently demonstrated with more certainty for dose intervals from 8 to 12 weeks and a similar trend for efficacy. Data for intervals longer than 12 weeks are limited.

Participants who had one or more comorbidities had a vaccine efficacy of 73.43% [95% CI: 48.49; 86.29]; 11 (0.53%) vs 43 (2.02%) for COVID 19 Vaccine AstraZeneca (N=2,070) and control (N=2,113), respectively; which was similar to the vaccine efficacy observed in the overall population.

The number of COVID-19 cases (2) in 660 participants ≥ 65 years old were too few to draw conclusions on efficacy. However, in this subpopulation, immunogenicity data are available, see below.

Immunogenicity

Following vaccination with COVID-19 Vaccine AstraZeneca, in participants who were seronegative at baseline, seroconversion (as measured by a ≥4 fold increase from baseline in S-binding antibodies) was demonstrated in ≥98% of participants at 28 days after the first dose and >99% at 28 days after the second. Higher S-binding antibodies were observed with increasing dose interval (Table 3).

Generally similar trends were observed between analyses of neutralising antibodies and S-binding antibodies. An immunological correlate of protection has not been established; therefore, the level of immune response that provides protection against COVID-19 is unknown.

Table 3 - SARS CoV-2 S-binding antibody response to COVID-19 Vaccine AstraZeneca [a,b]

Population	Baseline	28 days after dose 1	28 days after dose 2
	GMT (95% CI)	GMT (95% CI)	GMT (95% CI)
Overall	(N=882) 57.18 (52.8, 62.0)	(N=817) 8386.46 (7758.6, 9065.1)	(N=819) 29034.74 (27118.2, 31086.7)
Dose Interval			
< 6 weeks	(N=481) 60.51 (54.1, 67.7)	(N=479) 8734.08 (7883.1, 9676.9)	(N=443) 22222.73 (20360.50, 24255.3)
6-8 weeks	(N=137) 58.02 (46.3, 72.6)	(N=99) 7295.54 (5857.4, 9086.7)	(N=116) 24363.10 (20088.5, 29547.3)
9-11 weeks	(N=110) 48.79 (39.6, 60.1)	(N=87) 7492.98 (5885.1, 9540.2)	(N=106) 34754.10 (30287.2, 39879.8)
≥ 12 weeks	(N=154) 52.98 (44.4, 63.2)	(N=152) 8618.17 (7195.4, 10322.3)	(N=154) 63181.59 (55180.1, 72343.4)

N = Number of subjects included in each group; GMT = Geometric mean titre; CI = Confidence interval; S = Spike
[a] Immune response evaluated using a multiplex immunoassay. [b] in individuals who received two recommended doses of vaccine.

The immune response observed in participants with one or more comorbidities was consistent with the overall population.

High seroconversion rates were observed in older adults (≥65 years) after the first (97.8% [N=136, 95% CI: 93.7; 99.5]) and the second recommended dose (100.0% [N=111, 95% CI: 96.7; NE]). The increase in S-binding antibodies was numerically lower for participants ≥65 years old (28 days after second dose: GMT=20,727.02 [N=116, 95% CI: 17,646.6; 24,345.2]) when compared to participants aged 18-64 years (28 days after second dose: GMT=30,695.30 [N=703, 95% CI: 28,496.2; 33,064.1]). The majority of participants ≥65 years old had a dose interval of <6 weeks, which may have contributed to the numerically lower titres observed.

In participants with serological evidence of prior SARS-CoV-2 infection at baseline (GMT=13,137.97 [N=29; 95% CI: 7,441.8; 23,194.1]), S-antibody titres peaked 28 days after dose 1 (GMT=175,120.84 [N=28; 95% CI: 120,096.9; 255,354.8).

Spike-specific T cell responses as measured by IFN-γ enzyme-linked immunospot (ELISpot) assay are induced after a first dose of COVID-19 Vaccine AstraZeneca. These do not rise further after a second dose.

Immunogenicity data from the Indian study:

GMTs of IgG antibodies against spike (S) protein were comparable between the groups at baseline - Day 1. GMTs increased significantly after each dose of vaccine in both the groups and were comparable. There was 100% seroconversion in both the groups on Day 57. The immunogenicity data indicates that COVISHIELD is comparable in terms of anti-S IgG antibody titers and seroconversion rates to Oxford/AZ-ChAdOx1 nCoV-19 vaccine (see Tables 4 and 5).

Table 4 Summary of Anti-S IgG antibodies

Timepoint	Statistic	COVISHIELD™ (N=291) n (%)	Oxford/AZ-ChAdOx1 nCoV-19 (N=97) n (%)
Baseline	n GMT 95% CI	291 95.4 (77.8, 117.0)	97 80.7 (59.0, 110.4)
Visit 3 - Day 29 (+14)	n GMT 95% CI	289 9988.1 (8395.0, 11883.7)	97 6738.5 (4880.4, 9304.1)
Visit 4 - Day 57 (+14)	n GMT 95% CI	140 33331.6 (27756.0, 40027.2)	46 33263.6 (24383.1, 45378.3)

Table 5 Summary of Proportion of Participants with Seroconversion for Anti-S IgG Antibodies

Timepoint	COVISHIELD™ (N=291) n (%) 95(%) CI	Oxford/AZ-ChAdOx1 nCoV-19 (N=97) n (%) 95(%) CI
Visit 3 - Day 29 (+14)	279 (96.5) (93.7, 98.3)	89 (91.8) (84.4, 96.4)
Visit 4 - Day 57 (+14)	**140 (100.0)** (97.4, 100.00)	**46 (100.0)** (92.3, 100.0)

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Toxicity and local tolerance studies

Non-clinical data reveal no special hazard for humans based on a conventional study of repeat dose toxicity. Animal studies into potential toxicity to reproduction and development have not yet been completed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Histidine
L-Histidine hydrochloride monohydrate
Magnesium chloride hexahydrate
Polysorbate 80
Ethanol
Sucrose
Sodium chloride
Disodium edetate dihydrate (EDTA)
Water for injection

(The names of inactive ingredients may vary according to geographical region)

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf-life

The expiry date of vaccine is indicated on the label and packaging.

Once opened, multi-dose vials should be used as soon as practically possible and within 6 hours when kept between +2°C and +25°C. All opened multidose vials of **COVISHIELD™** should be discarded at the end of immunization session or within six hours whichever comes first.

6.4 Special precautions for storage

Store in a refrigerator (+2°C to +8°C).

Do not freeze. Protect from light.

Opened multidose vial

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

COVISHIELD™ is supplied as ready for use liquid in rubber-stoppered multidose vial and single dose vial in below listed presentations

1 dose - 0.5 ml per vial
2 dose - 1.0 ml per vial
5 dose - 2.5 ml per vial
10 dose - 5.0 ml per vial
20 dose - 10 ml per vial

6.6 Instructions for use, handling and disposal

Administration

COVISHIELD™ is a colourless to slightly brown, clear to slightly opaque solution. The vaccine should be inspected visually prior to administration and discarded if particulate matter or differences in the described appearance are observed.

Do not shake the vial.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. It is normal for liquid to remain in the vial after withdrawing the final dose.

The vaccine does not contain any preservative. Aseptic technique should be used for withdrawing the dose for administration.

Once opened, multi-dose vials should be used as soon as practically possible and within 6 hours when kept between +2°C and +25°C. Discard any unused vaccine.

To facilitate the traceability of the vaccine, the name and the batch number of the administered product must be recorded for each recipient.

Disposal

COVISHIELD™ contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant (e.g. Hydrogen peroxide based disinfectants).

Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411 028, INDIA

Marketed by:
SERUM INSTITUTE LIFE SCIENCES PVT. LTD.
401, Sarosh Bhavan, 16-B/1, Dr. Ambedkar Road, Pune - 411 001, INDIA

20017462/1

रजिस्टर्ड मेडिकल प्रैक्टिशनर या हॉस्पिटल या लेबोरेटरी के उपयोग हेतु

ChAdOx1 nCoV- 19 कोरोना वायरस टीका (पुनःसंयोजक)

कोविशील्ड™

1. ऑषधीय उत्पाद का नाम

कोविशील्ड™

ChAdOx1 nCoV- 19 कोरोना वायरस टीका (पुनःसंयोजक)

2. गुणात्मक और मात्रात्मक रचना

टीके की एक खुराक (0.5 ml) में है:

ChAdOx1 nCoV- 19 कोरोना वायरस टीका (पुनःसंयोजक) 5 × 10^{10} वायरस के कण (वीपी)

*पुनःसंयोजक, वेक्टर तकनीक पर आधारित चिंपांज़ी से लिए गए एडेनोवायरस जो मानव शरीर में प्रतिकृति बनाने में सक्षम नहीं है और जो सार्स-कोव-२ स्पाइक (एस) ग्लायकोप्रोटीन से प्रभावित हैं।

इसे आनुवांशिक रूप से परिवर्तित मानव भ्रूणीय गुर्दे (एचईके) 293 कोशिकाओं पर निर्मित किया गया है।

इस उत्पाद में आनुवांशिक रूप से परिवर्तित जीव हैं (जीएमओ)।

टीके में मिलाए गए निष्क्रिय पदार्थों की पूर्ण सूची के लिए खंड 6.1 देखें।

कोविशील्ड™ (निर्माता सीरम इंस्टिट्यूट ऑफ इंडिया प्राइवेट लिमिटेड) और कोविड-१९ वैक्सीन ऐस्ट्रा ज़ेनेका (निर्माता ऐस्ट्रा ज़ेनेका) दोनों ही ChAdOx1 nCoV- 19 कोरोना वायरस टीके (पुनःसंयोजक) हैं।

3 ऑषधीय रूप

इंजेक्शन के लिए घोल

यह बेरंग या हल्के भूरे रंग का साफ या फिर हल्का अपारदर्शी, कण-रहित घोल है जिसका पीएच 6.6 है।

4 रोग-विषयक विवरण

4.1 किन लोगों के लिए इसका प्रयोग किया जाना चाहिए

कोविशील्ड™ कोरोना वायरस रोग 2019 (कोविड-19) की रोकथाम के लिए 18 वर्ष या उससे अधिक उम्र के लोगों के सक्रिय टीकाकरण के लिए प्रयोग किया जा सकता है।

4.2 खुराक और टीका दिये जाने का तरीका

खुराक की मात्रा

कोविशील्ड™ टीके के कोर्स में 0.5 ml की दो अलग अलग खुराके हैं। प्रथम खुराक प्राप्त करने के 4 से 6 सप्ताह के बीच दूसरी खुराक दी जानी चाहिए। लेकिन विदेश में हुए अध्ययनों से उपलब्ध आकड़े और जानकारी दर्शाते है कि प्रथम खुराक प्राप्त करने के 12 सप्ताह तक दूसरी खुराक दी जा सकती है (खंड 5.1 देखें)।

अनुशंसा की जाती है कि जिन लोगों को कोविशील्ड की प्रथम खुराक दी जा चुकी है, वे टीकाकरण को **कोविशील्ड™** से ही पूरा करें (खंड 4.4 देखें)।

विशेष आबादी

बुजुर्ग

वर्तमान में 65 वर्ष या उससे अधिक उम्र के लोगों में प्रभावकारिता और सुरक्षा संबंधी जानकारी सीमित है (खंड 4.8 और 5.1 देखें)। 65 वर्ष या उससे अधिक उम्र के बुजुर्ग लोगों के लिए खुराक में किसी प्रकार के परिवर्तन की आवश्यकता नहीं है।

छोटे बच्चे

बच्चों और किशोरों (18 वर्ष से कम उम्र वाले) में **कोविशील्ड™** की प्रभावकारिता और सुरक्षा के बारे में जानकारी अभी तक स्थापित नहीं हुई है। कोई जानकारी उपलब्ध नहीं है।

टीका देने का तरीका

कोविशील्ड™ टीका केवल मांसपेशीय इंजेक्शन (आई.एम.) के रूप में दिया जाना चाहिए, आदर्श रूप से डेल्टॉइड मांसपेशी में। टीका लगाने के निर्देशों के लिए खंड 6.6 देखें।

4.3 किन लोगों के लिए इसका प्रयोग नहीं किया जाना चाहिए

खंड 6.1 में सूचीबद्ध सक्रिय सामग्री या टीके में मौजूद किसी भी अन्य निष्क्रिय पदार्थ के प्रति अतिसंवेदनशीलता।

4.4 प्रयोग संबंधी विशेष चेतावनी और विशेष एहतियात

अतिसंवेदनशीलता

जैसा कि प्रत्येक इंजेक्शन के रूप में लगने वाले टीके के साथ है, टीका लगाने के बाद गंभीर अलर्जिक प्रभाव होने पर तत्काल उपयुक्त चिकित्सीय उपचार और देखभाल उपलब्ध रहने चाहिए।

टीका लगाए जाने के समय रोग

अन्य टीकों की ही तरह, **कोविशील्ड™** टीके को लगाया जाना स्थगित करें अगर व्यक्ति गंभीर सज्वर व्याधि से पीड़ित है। हालांकि, सर्दी, और/या हल्का बुखार जैसे मामूली संक्रमण होने पर, टीकाकरण करने में विलंब नहीं करना चाहिए।

थ्रोम्बोसाइटोपेनिया (रक्त में प्लेटलेट की कमी) और स्कंदन विकार

अन्य मांसपेशिय इंजेक्शन की तरह, थ्रोम्बोसाइटोपेनिया, किसी प्रकार के स्कंदन विकार या ऐंटिकोऐग्युलेशन उपचार करा रहे लोगों को **कोविशील्ड™** टीका लगाते समय एहतियात बरता जाना चाहिए क्योंकि ऐसे लोगों में मांसपेशिय इंजेक्शन लगाने के कारण रक्तस्राव या क्षति हो सकती है।

ऐसे लोग जिनकी प्रतिरक्षा क्षमता कम है

इसका अभी तक पता नहीं चला है कि प्रतिरक्षा क्षमता कम करने वाली उपचार पद्धतियाँ कराने वाले लोगों सहित जिन लोगों की प्रतिरक्षा क्षमता कम है, उनमें भी क्या अच्छी प्रतिरक्षा क्षमता वाले लोगों के समान ही टीकाकरण किए जाने से टीके की प्रभावकारिता और रोग से सुरक्षा बनी रहेगी। कम प्रतिरक्षा क्षमता वाले लोगों में शायद टीकाकरण से रोग के प्रति प्रतिरक्षा औरों की तुलना में कम रहती है।

सुरक्षा बने रहने की अवधि और स्तर

सुरक्षा की अवधि अभी तक स्थापित नहीं हुई है।

अन्य टीकों के समान ही, हो सकता है कोविशील्ड से टीकाकरण कराने वाले हर टीका प्राप्तकर्ता को कोविड-19 से सुरक्षा न मिले (खंड 5.1 देखें)।

दो अलग अलग प्रकार के टीकों का लगाया जाना

उन व्यक्तियों में ChAdOx1 nCoV- 19 कोरोना वायरस टीके (पुनःसंयोजक) के उपयोग के बारे में कोई जानकारी उपलब्ध नहीं है जिन्हें पहले किसी अन्य कोविड -19 टीके से आंशिक रूप से टीकाकरण किया गया था।

4.5 अन्य चिकित्सीय उत्पादों के साथ परस्पर प्रभाव और अन्य रूपों में प्रभाव

दवाओं/टीकों के परस्पर प्रभाव पर कोई अध्ययन नहीं किया गया है।

कोविशील्ड™ का अन्य टीकों के साथ लगाए जाने पर कोई अध्ययन नहीं किया गया है (खंड 5.1 देखें)।

4.6 प्रजनन क्षमता, गर्भावस्था और स्तनपान

प्रजनन क्षमता

प्रजनन क्षमता के संबंध में प्रारंभिक पशु अध्ययन प्रत्यक्ष या अप्रत्यक्ष रूप से हानिकारक प्रभाव नहीं दर्शाते हैं।

गर्भावस्था

ChAdOx1 nCoV-19 कोरोना वायरस टीके (पुनःसंयोजक) का गर्भवती महिलाओं में उपयोग के संबंध में सीमित अनुभव है। गर्भावस्था, भ्रूण के विकास, प्रसव या प्रसवोत्तर विकास के संबंध में प्रारंभिक पशु अध्ययन प्रत्यक्ष या अप्रत्यक्ष रूप से हानिकारक प्रभाव नहीं दर्शाते हैं; निर्णायक पशु अध्ययन अभी तक पूरा नहीं किया गया है। पशु अध्ययन की मानव को कोविड-19 के टीके संबंधी जोखिमों के लिए प्रासंगिकता स्थापित होनी बाकी है।

गर्भावस्था के दौरान **कोविशील्ड™** को तभी लगाने पर विचार किया जाना चाहिए जब माँ और भ्रूण के लिए उसके संभावित फायदे टीके के संभावित खतरों से कहीं अधिक हों।

स्तनपान

अभी तक इसकी जानकारी नहीं है कि मानव दूध के साथ **कोविशील्ड™** का स्राव होता है या नहीं।

4.7 मशीने चलाने और प्रयोग करने पर इसका प्रभाव

ChAdOx1 nCoV- 19 कोरोना वायरस टीका (पुनःसंयोजक) का मशीने चलाने और प्रयोग करने की क्षमता पर कोई प्रभाव नहीं होता और अगर होता भी है तो ना के बराबर। लेकिन खंड 4.8 में उल्लिखित दुष्प्रभाव कुछ समय के लिए अस्थायी रूप से मशीने चलाने और प्रयोग करने की क्षमता को प्रभावित कर सकते हैं।

4.8 अवांछनीय प्रभाव

विदेश में हुए अध्ययनों के सुरक्षा पहलू का समग्र संक्षिप्त विवरण:

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका [ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक)] की समग्र सुरक्षा यूनाइटेड किंगडम, ब्राज़ील, और दक्षिण अफ्रीका में आयोजित किए गए चार नैदानिक परीक्षणों से प्राप्त आंकड़ों और जानकारी के अंतरिम विश्लेषण पर आधारित है। विश्लेषण के समय, 18 वर्ष या उससे अधिक उम्र के 23,745 सहभागियों को बिना किसी विशेष क्रम के कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका या फिर कंट्रोल टीका दिया गया। इनमें से 12,021 सहभागियों को कम से कम एक खुराक कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके की दी गई। कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका प्राप्त करने वाले समूह में अनुवर्ती जाँच के लिए औसत अवधि 1 खुराक के बाद 105 दिन, और 2 खुराक के बाद 62 दिन थी।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका और कंट्रोल टीका प्राप्त करने वाले सहभागियों की जनसांख्यिकीय विशेषताएँ आम तौर पर समान थीं। कुल मिलाकर जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका प्राप्त हुआ उनमें 90.3% लोगों की उम्र 18 से 64 वर्ष के बीच थी और 9.7% लोग 65 वर्ष या उससे अधिक उम्र के थे। टीका प्राप्त करने वाले लोगों में से अधिकांश व्हाइट्स (75.5%) थे, 10.1% ब्लैक्स थे और 3.5% एशियाई मूल के थे; 55.8% महिलाएं थीं और 44.2% पुरुष थे।

सबसे अक्सर रिपोर्ट किए गए प्रतिकूल प्रभाव थे - इंजेक्शन लगाए जाने के स्थान पर दबाने से दर्द (> 60%); इंजेक्शन लगाए जाने के स्थान पर दर्द, सिरदर्द, थकान (> 50%); मांसपेशियों का दर्द, बेचैनी(> 40%); बुखार, कंपकंपी (> 30%); और जोड़ों में दर्द, मतली (> 20%)।

प्रतिकूल प्रभावों में से ज्यादातर हल्के से मध्यम गंभीरता के थे और आमतौर पर टीकाकरण के कुछ दिनों के भीतर ठीक हो गए थे। दिन 7 तक कम से कम एक स्थानीय या दैहिक प्रभाव की घटनाएं क्रमशः 4% और 13% थी। प्रथम खुराक की तुलना में दूसरी खुराक के बाद रिपोर्ट किए गए प्रतिकूल प्रभाव की तीव्रता कम थी और प्रतिकूल प्रभाव रिपोर्ट करने वाले लोगों की संख्या भी कम थी।

बुजुर्ग लोगों (65 वर्ष और उससे अधिक की उम्र वाले लोग) में प्रतिकूल प्रभाव की तीव्रता कम देखी गई और प्रतिकूल प्रभाव रिपोर्ट करने वाले बुजुर्गों की संख्या भी कम थी।

अगर जरूरत पड़े तो, दर्द निवारक और/या बुखार के लिए चिकित्सीय उत्पाद (जैसे कि पैरासिटेमॉल युक्त उत्पाद) का प्रयोग इन टीकाकरण पश्चात प्रभावों से आराम देने के लिए किया जा सकता है।

दवाओं का प्रतिकूल प्रभाव

ऐड्वर्स ड्रग रीऐक्शन (एडीआर - दवाओं का दुष्प्रभाव) का आयोजन मेडडीआरए सिस्टम ऑर्गन क्लास (एसओसी) ने किया है। प्रत्येक एसओसी के तहत, पसंदीदा शब्दावली को कम होती आवृत्ति और कम होती गंभीरता के अनुसार व्यवस्थित किया गया है।

दुष्प्रभावों की आवृत्ति निम्नलिखित रूप से परिभाषित है: बहुत आम (1/10 या उससे अधिक); आम (1/100 या उससे अधिक लेकिन 1/10 से कम); आम नहीं है (1/1,000 या उससे अधिक लेकिन 1/100 से कम); गिनी-चुनी (1/10,000 या उससे अधिक लेकिन 1/1000 से कम); बहुत ही गिनी-चुनी (1/10,000 से कम) और पता नहीं चला है (उपलब्ध जानकारी से इनका अंदाज़ नहीं लगाया जा सकता है)।

सारणी 1 - टीके के प्रतिकूल प्रभाव

मेडडीआरए एसओसी	आवृत्ति	प्रतिकूल प्रभाव
रक्त और लिम्फैटिक (लसीका) तंत्र के विकार	आम नहीं है	लिम्फाडेनोपैथी (सूजी लिम्फैटिक नोड)[a]
चयापचय और पाचन विकार	आम नहीं है	भूख में कमी[a]
तंत्रिका के विकार	बहुत आम है	सरदर्द
	आम नहीं है	सिर में चक्कर आना[a]
पाचन तंत्र के विकार	बहुत आम है	मतली
	आम है	उलटी
	आम नहीं है	पेट में दर्द[a]
त्वचा और उपचर्म ऊतक संबंधी विकार	आम नहीं है	हाइपरहाइड्रोसिस (अत्यधिक पसीना आना)[a], खुजली[a], चकत्ते[a]
मस्क्युलोस्केलेटल विकार और कनेक्टिव ऊतक संबंधी विकार	बहुत आम है	मांसपेशियों में दर्द, जोड़ों में दर्द
आम विकार और इंजेक्शन लगने के स्थान पर समस्याएं	बहुत आम है	इंजेक्शन लगने के स्थान पर दबाने से दर्द, इंजेक्शन लगने के स्थान पर दर्द, इंजेक्शन लगने के स्थान पर गर्माहट, इंजेक्शन लगने के स्थान पर लालिमा, इंजेक्शन लगने के स्थान पर खुजली, इंजेक्शन लगने के स्थान पर सूजन, इंजेक्शन लगने के स्थान पर घाव[b], थकान, बेचैनी, बुखार[c], कंपकंपी
	आम है	इंजेक्शन लगने के स्थान पर कड़ापन, इन्फ्लूएंज़ा जैसी बीमारी[a]

[a] अव्यवस्थित रूपसे एकत्र प्रतिकूल प्रभाव

[b] इंजेक्शन लगने के स्थान पर रक्त के जमने के कारण लालिमा और घाव (आम नहीं है, अवांछित दुष्प्रभाव)

[c] बुखार सा लगने सहित उच्च तापमान (बहुत आम है) और बुखार 38°C या उससे अधिक (आम है)

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका से टीकाकरण कराने के बहुत ही गिने-चुने मामलो में तंत्रिका में सूजन संबंधी विकार रिपोर्ट किए गए हैं। दोनों के बीच कारणात्मक संबंध स्थापित नहीं हुआ है।

भारत में हुए अध्ययन के सुरक्षा पहलू का समग्र संक्षिप्त विवरण:

भारत में चरण II/III के नैदानिक परीक्षणों में **कोविशील्ड™** को सुरक्षित और सहनीय पाया गया था। अंतरिम विश्लेषण के लिए उन सभी 1600 सहभागियों के आकड़े और जानकारी शामिल थी जिन्हें प्रथम खुराक दी गई थी [1200 को **कोविशील्ड™** दिया गया था, 100 ऑक्सफोर्ड / AZ-ChAdOx1 nCoV-19 टीका प्राप्त करने वाले लोग थे और प्रयोगिक औषध प्राप्त करने वाले 300 लोग शामिल थे]। इस अंतरिम विश्लेषण में 14 दिसंबर 2020 तक उन सभी 1600 सहभागियों से एकत्र की गई जानकारी शामिल हैं, जिन्हें पहली खुराक दी गई थी और 1577 ऐसे सहभागी हैं जिन्हें दूसरी खुराक भी दी गई है।

तीनों समूहों के सहभागियों की जनसांख्यिकीय विशेषताएँ आम तौर पर समान थीं। समग्र रूप से जिन सहभागियों को **कोविशील्ड™** टीका प्राप्त हुआ उनमें 87.33% लोगों की उम्र 18 से 59 वर्ष के बीच थी और 12.67% लोग 60 वर्ष या उससे अधिक उम्र के थे।

समग्र रूप से व्यवस्थित तरीके से एकत्र किए गए प्रतिकूल प्रभाव (इंजेक्शन के स्थान पर दर्द, दबाने से दर्द, लालिमा, गर्माहट, खुजली, सूजन और कड़ापन; दैहिक प्रभावों में शामिल हैं बुखार, कंपकंपी, थकान, बेचैनी, सरदर्द, जोड़ों में दर्द और मांसपेशियों में दर्द), अव्यवस्थित तरीके से प्राप्त प्रतिकूल प्रभावों की जानकारी और गंभीर दुष्प्रभाव (एसएई) अध्ययन किए जाने वाले टीके और कंट्रोल टीके में लगभग एक समान थे। अध्ययन किए जाने वाले टीके के कारण कोई गंभीर प्रतिकूल प्रभाव (एसएई) नहीं हुआ।

4.9 टीका अधिक मात्रा में देना

टीके के अधिक मात्रा में देने के बारे में अनुभव सीमित है।

अधिक मात्रा में ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) के अधिक मात्रा में दिए जाने के लिए कोई विशिष्ट उपचार नहीं है।

अधिक मात्रा में टीका दिए जाने पर व्यक्ति का निरीक्षण किया जाना चाहिए और लक्षणों के आधार पर जैसा उपयुक्त हो, वैसा उपचार किया जाना चाहिए।

5 औषधीय गुण

5.1 टीके के शरीर को प्रभावित करने वाले गुण

क्रिया का तंत्र

कोविशील्ड™ एक मोनोवैलेंट टीका है जो एकल पुनःसंयोजक से बना है। यह वेक्टर तकनीक पर आधारित चिंपांज़ी से लिए गए एडेनोवायरस है जो मानव शरीर में प्रतिकृति बनाने में सक्षम नहीं है और जो सार्स-कोव-२ स्पाइक (एस) ग्लायकोप्रोटीन से प्रभावित हैं। इस टीके को लगाए जाने पर सार्स-कोव-२ का एस ग्लायकोप्रोटीन स्थानीय रूप से व्यक्त होता है जो प्रतिकारक ऐंटीबॉडी के बनने को बढ़ावा देता है और कोशिकीय स्तर पर प्रतिरक्षा प्रतिक्रिया प्रेरित करता है।

विदेश में हुए अध्ययन से प्राप्त आकड़े और जानकारी के आधार पर प्रभावकारिता और प्रतिरक्षाजनत्व

रोग-विषयक प्रभावकारिता

COV001, COV002, COV003, और COV005 से एकत्र किए गए आकड़े और जानकारी का अंतरिम विश्लेषण।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका [ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक)] का मूल्यांकन चार जारी, ब्लाइंडेड (जिसमें प्राप्तकर्ता नहीं जानता की उसे अध्ययन टीका दिया जा रहा है या कंट्रोल टीका), बिना किसी विशेष क्रम में अध्ययन टीके को देने वाले, नियंत्रित परीक्षणों से एकत्र किए गए आकड़े और जानकारी के अंतरिम विश्लेषण के आधार पर किया गया है: चरण I/II अध्ययन, COV001 (NCT04324606)), जो यूके में 18 से 55 वर्ष की उम्र के स्वस्थ वयस्कों पर किया गया; चरण II/III अध्ययन, COV002 (NCT04400838) जो यूके में 18 वर्ष या उससे अधिक उम्र के वयस्कों (बुजुर्गों सहित) पर किया गया; चरण III अध्ययन, COV003 (ISRCTN89951424) जो ब्राजील में 18 वर्ष या उससे अधिक उम्र के वयस्कों (बुजुर्गों सहित) पर किया गया; और चरण I/II का अध्ययन, COV005 (NCT04444674) जो दक्षिण अफ्रीका में 18 से 65 वर्ष की उम्र के वयस्कों पर किया गया।

इन अध्ययनों में वो सभी व्यक्ति शामिल नहीं किए गए जिनको पहले से तीव्रग्राहिता या वाहिकाशोफ की समस्या थी; गंभीर और / या अनियंत्रित हृदय तथा रक्तवाहिकाओं संबंधी विकार थे, जठरांत्र, यकृत, वृक्क, अंतःस्रावी / चयापचय रोग थे और प्रतिरक्षा क्षमता कम होने के साथ-साथ तंत्रिका संबंधी रोग थे। COV001 और COV002 अध्ययनों में अनुमोदित मौसमी इन्फ्लूएंज़ा और न्यूमोकोक्कल टीके लगाने की अनुमति दी गई थी (अध्ययन टीके के लगाए जाने से कम से कम 7 दिन पहले या उसके बाद)। सभी सहभागियों की कोविड-19 रोग से टीके के कारण सुरक्षा और टीके की प्रभावकारिता का मूल्यांकन करने के लिए 12 महीने तक अनुवर्ती जाँच करते रहने की योजना है।

अंतरिम प्रभावकारिता विश्लेषण के लिए पूर्व-निर्धारित मानदंडों के आधार पर, COV002 और COV003 ने प्रति अध्ययन 5 या उससे अधिक के वायरोलॉजी रूप से पुष्टि किए गए कोविड-19 के मामले की सीमा को पार कर लिया है, और इस प्रकार प्रभावकारिता विश्लेषण में योगदान दिया है; COV001 और COV005 को इससे बाहर रखा गया था। प्रभावकारिता के लिए एकत्रित विश्लेषण (COV002 और COV003) के लिए, 18 वर्ष या उससे अधिक उम्र के लोगों को कोविड -१९ वैक्सीन ऐस्ट्रा ज़ेनेका (N = 5,807) या कंट्रोल (मेनिंजोकोक्कल टीका या सलाइन) (N = 5,829) की दो खुराकें दी गई थी। व्यवस्था संबंधी बाधाओं के कारण, खुराक 1 और खुराक 2 के बीच अंतराल 4 से 26 सप्ताह तक था।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके और कंट्रोल टीके के लिए आधारभूत जनसांख्यिकी उपचार समूहों में प्रायः एक समान थी। कुल मिलाकर जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका प्राप्त हुआ उनमें 94.1% लोगों की उम्र 18 से 64 वर्ष के बीच थी और 5.9% लोग 65 वर्ष या उससे अधिक उम्र के थे; 60.7% सहभागी महिलाएं थी; 82.8% यूरोपीय मूल के थे, 4.6% एशियाई मूल के थे और 4.4% अफ्रीकी मूल के थे। कुल 2,070 (35.6%) सहभागियों को कम से कम एक पहले से मौजूद कोमोर्बिडिटी (बीएमआई 30 kg/m^2 या उससे अधिक, हृदय और रक्त वाहिका संबंधी विकार, श्वसन रोग या मधुमेह जैसी समस्याएं) थी। अंतरिम विश्लेषण के समय अनुवर्ती जाँच के लिए औसत अवधि 1 खुराक के बाद 132 दिन थी और 2 खुराक के बाद 63 दिन थी।

कोविड-19 मामलों का अंतिम निर्धारण एक अधिनिर्णायक समिति द्वारा किया गया था, जिन्होंने डब्लुएचओ के नैदानिक प्रगति पैमाने के अनुसार रोग की गंभीरता को भी निर्धारित किया था। कुल 131 सहभागियों को टीके की दूसरी खुराक प्राप्त करने के 15 दिन या उसके बाद वायरोलॉजिकल रूप से पुष्टि (न्यूक्लिक एसिड एम्प्लीफिकेशन टेस्ट द्वारा) किए गए सार्स-कोव-2 के कारण कोविड-19 हुआ और उनमें कम से कम कोविड-19 का एक लक्षण (बुखार (37.8°C या उससे अधिक का तापमान), खाँसी, सांस लेने में तकलीफ, एनोसिमिया (सूँघने की शक्ति का नाश) या एजुसिया(स्वाद न महसूस होना)) दिखाई दिया और इन सब लोगों में पहले सार्स-कोव-2 के संक्रमण का कोई सबूत नहीं मिला। कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके ने कंट्रोल की तुलना में कोविड-19 होने की घटनाओं में काफी कमी आई (सारणी 2a देखें)।

सारणी 2a- कोविड-19 के खिलाफ कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की प्रभावकारिता*

आबादी	कोविड-19 टीका ऐस्ट्रा ज़ेनेका		कंट्रोल		टीके की प्रभावकारिता % (95.84% CI)
	N	कोविड-19 मामलों की संख्या[b], n (%)	N	कोविड-19 मामलों की संख्या[b], n (%)	
प्राथमिक (ऊपर देखें)	5807		5829		
कोविड-19 के मामले		30 (0.52)		101 (1.73)	70.42 (58.84, 80.63)[a]
अस्पताल में भर्ती[b]		0		5 (0.09)	
गंभीर रोग[c]		0		1 (0.02)	
कोई भी खुराक	**10,014**		**10,000**		
खुराक 1 के बाद कोविड-19		108 (1.08)		227 (2.27)	52.69 (40.52, 62.37)[d]
खुराक 1 के बाद अस्पताल में भर्ती[b]		2 (0.02)[e]		16 (0.16)	
खुराक के बाद गंभीर रोग[c]		0		2 (0.02)	

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; n=उन सहभागियों की संख्या जिनके साथ पक्के तौर पर घटना हुई थी; CI = विश्वास्यता अंतराल;*यह LDSD + SDSD रेजिमेन के एकत्रित आकड़े हैं जिसमें दूसरी खुराक पहली खुराक के दिए जाने के 4 से 12 सप्ताह के बीच दी गई थी। LD – कम खुराक, SD – मानक खुराक।

[a] 95.84% CI; [b] डब्लुएचओ द्वारा गंभीरता का श्रेणी निर्धारण 4 या उससे अधिक है; [c] डब्लुएचओ द्वारा गंभीरता का श्रेणी निर्धारण 6 या उससे अधिक है; [d] 95% CI; [e] 2 मामलों में अस्पताल में भर्ती कराने की आवश्यकता टीकाकरण के बाद दिन 1 और दिन 10 को हुई।

सारणी 2b- कोविड-19 के खिलाफ कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की प्रभावकारिता

आबादी	कोविड-19 टीका ऐस्ट्रा ज़ेनेका		कंट्रोल		टीके की प्रभावकारिता % (95.84% CI)
	N	कोविड-19 मामलों की संख्या[b], n (%)	N	कोविड-19 मामलों की संख्या[b], n (%)	
आबादी का प्राथमिक विश्लेषण					
कुल (SDSD + LDSD)	5807	30 (0.52)	5829	101 (1.73)	70.42 (58.84, 80.63)
अनुमत टीके की मात्रा					
SDSD	4440	27 (0.61)	4455	71 (1.59)	62.10 (39.96, 76.08)
Exploratory analysis					
LDSD	1367	3 (0.22)	1374	30 (2.18)	90.05 (65.84, 97.10)

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; n = उन सहभागियों की संख्या जिनके साथ पक्के तौर पर घटना हुई थी; CI = विश्वास्यता अंतराल; LD = कम खुराक; SD = मानक खुराक

सारणी 2c- कोविड-19 के खिलाफ कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की प्रभावकारिता खुराकों के बीच अंतराल के अनुसार (SDSD)

खुराकों के बीच अंतराल	सहभागी जिनके साथ घटनाएं हुई, n (%)		टीके की प्रभावकारिता %	95% CI (%)	P- मान
	AZD1222 n / N (%)	कंट्रोल n / N (%)			
6 सप्ताह से कम	9 / 1702 (0.53)	19 / 1698 (1.12)	53.28	(-3.21, 8.86)	0.060
6-8 सप्ताह	5 / 562 (0.88)	9 / 521 (1.73)	51.08	(-45.57, 3.56)	0.199
9-11 सप्ताह	9 / 1056 (0.85)	24 / 1110 (2.16)	60.55	(15.23, 81.64)	0.017
12 सप्ताह या उससे अधिक	4 / 1120 (0.36)	19 / 1126 (1.69)	78.79	(37.63, 92.79)	0.005

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके की एक खुराक प्राप्त करने पर कोविड-19 से सुरक्षा के स्तर का आंकलन समन्वेशी विश्लेषण से किया गया जिसमें ऐसे सहभागी शामिल थे जिन्हें एक खुराक दी गई थी। विश्लेषण में से उन सभी सहभागियों को उस समय पर हटा दिया गया था जब उन्हें टीके की दूसरी खुराक दी गई या प्रथम खुराक प्राप्त करने के 12 सप्ताह बाद। इस तरह की आबादी में, टीके की प्रथम खुराक प्राप्त करने के 22 दिन बाद, टीके की प्रभावकारिता 73.00% थी (95% CI: 48,79; 85,76 [कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका 12/7,998 की तुलना में कंट्रोल 44/7,982]).

समन्वेशी विश्लेषण दर्शाते हैं कि बढ़ी प्रतिरक्षाजनत्व खुराकों के बीच लंबे अंतराल से जुड़ी है (सारणी ३ में प्रतिरक्षाजनत्व देखें)। वर्तमान में खुराक के बीच 8 से 12 सप्ताह तक के अंतराल के लिए प्रभावकारिता अधिक निश्चितता के साथ प्रदर्शित हुई है। दोनो खुराकों के बीच 12 सप्ताह से अधिक अंतराल के बारे में आकड़े सीमित है।

जिन सहभागियों में एक या उससे अधिक कोमॉर्बिडिटी थीं, उनमें टीके की प्रभावकारिता 73.43% [95% CI: 48.49; 86.29] देखी गई; कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके के लिए 11 (0.53%) थी और कंट्रोल के लिए 43 (2.02%) थी; जो कि समग्र आबादी में देखी गई टीके की प्रभावकारिता के समान थी। 660 सहभागियों में 65 वर्ष से अधिक उम्र के लोगों में कोविड -19 के मामले (2) इतने कम थे कि उनसे प्रभावकारिता के संबंध में किसी निष्कर्ष पर पहुँचना संभव नहीं था। हालांकि, इस उप-आबादी में प्रतिरक्षाजनत्व के संबंध में आकड़े उपलब्ध हैं, जिन्हें आप नीचे देख सकते हैं।

प्रतिरक्षाजनत्व

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका से टीकाकरण के बाद, जो सहभागी आधाररेखा पर सेरोनिगेटिव थे, उन में से 98% या उससे अधिक सहभागियों ने पहली खुराक प्राप्त करने के 28 दिन बाद और 99% सहभागियों ने दूसरी खुराक प्राप्त करने के बाद सेरोकन्वर्शन (जो एस-बाइंडिंग एंटिबॉडी में आधाररेखा से 4 गुना या उससे अधिक वृद्धि के द्वारा मापा गया) दर्शाया। खुराकों के बीच अंतराल के बढ़ने से अधिक एस-बाइंडिंग ऐंटिबॉडीज देखी गई थीं (सारणी 3)।

आमतौर पर ऐसी ही प्रवृत्तियाँ प्रतिकारक ऐंटिबॉडी और एस-बाइंडिंग ऐंटिबॉडी के विश्लेषण करने पर देखी गई। कोविड-19 से सुरक्षा का प्रतिरक्षा संबंधी सहसंबंध स्थापित नहीं हुआ है; इसलिए, कोविड-19 से सुरक्षा प्रदान करने वाली प्रतिरक्षा प्रतिक्रिया का स्तर अज्ञात है।

सारणी ३ - कोविड-१९ वैक्सीन ऐस्ट्रा ज़ेनेका के प्रति सार्स कोव-२-एस-बाइंडिंग ऐंटिबॉडी की प्रतिक्रिया[a,b]

आबादी	आधाररेखा	खुराक 1 के बाद 28 दिन	खुराक 2 के बाद 28 दिन
	GMT (95% CI)	GMT (95% CI)	GMT (95% CI)
कुल	(N=882) 57.18 (52.8, 62.0)	(N=817) 8386.46 (7758.6, 9065.1)	(N=819) 29034.74 (27118.2, 31086.7)
खुराकों के बीच अंतराल			
6 सप्ताह से कम	(N=481) 60.51 (54.1, 67.7)	(N=479) 8734.08 (7883.1, 9676.9)	(N=443) 22222.73 (20360.50, 24255.3)
6-8 सप्ताह	(N=137) 58.02 (46.3, 72.6)	(N=99) 7295.54 (5857.4, 9086.7)	(N=116) 24363.10 (20088.5, 29547.3)
9-11 सप्ताह	(N=110) 48.79 (39.6, 60.1)	(N=87) 7492.98 (5885.1, 9540.2)	(N=106) 34754.10 (30287.2, 39879.8)
12 सप्ताह या उससे अधिक	(N=154) 52.98 (44.4, 63.2)	(N=152) 8618.17 (7195.4, 10322.3)	(N=154) 63181.59 (55180.1, 72343.4)

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; GMT = जियोमेट्रिक मीन टाइटर; CI = विश्वास्यता अंतराल; S = स्पाइक

[a] मल्टिप्लेक्स इम्यूनऐसे प्रयोग करके प्रतिरक्षा प्रतिक्रिया मापी गई है। [b] उन लोगों में जिन्हें टीके की अनुशंसित खुराक दी गई है।

उन सहभागियों में जिन्हें एक या उससे अधिक कोबॉर्बिडिटी थीं, उनमें प्रतिरक्षा प्रतिक्रिया समस्य आबादी में पाई गई प्रतिरक्षा प्रतिक्रिया के अनुरूप थी। 65 वर्ष या उससे अधिक उम्र के वयस्कों में पहली (97.8% [N=136, 95% CI: 93.7; 99.5]) और दूसरी (100.0% [N=111, 95% CI: 96.7; NE]) अनुशंसित खुराक प्राप्त करने के बाद उच्च सेरोकन्वर्शन दर देखी गई। एस-बाइंडिंग ऐंटिबॉडी में वृद्धि 18-64 वर्ष की उम्र के सहभागियों (दूसरी खुराक के २८ दिन बाद: GMT=30,695.30 [N=703, 95% CI: 28,496.2; 33,064.1] की तुलना में 65 वर्ष या उससे अधिक उम्र के सहभागियों (दूसरी खुराक के 28 दिन बाद :GMT=20,727.02 [N=116, 95% CI: 17,646.6; 24,345.2]) में संख्यात्मक रूप से कम थी। 65 वर्ष या उससे अधिक उम्र के सहभागियों के लिए दोनों खुराकों के बीच अंतराल 6 सप्ताह से कम था जिसके कारण संख्यात्मक रूप से कम दिखे।

आधाररेखा (GMT=13,137.97 [N=29; 95% CI: 7,441.8; 23,194.1]) पर पूर्व सार्स-कोव-२ संक्रमण के सेरोलॉजिकल सबूत वाले सहभागियों में, एस-एंटीबॉडी टाइटर खुराक 1 के 28 दिन बाद (GMT=175,120.84 [N=28; 95% CI: 120,096.9; 255,354.8) शीर्ष पर पहुँचा।

IFN-ɣ एन्ज़ाइम लिंक्ड इम्यूनोस्पोट (ईएलआईस्पॉट) एसे से मापी गई स्पाइक-विशिष्ट टी सेल प्रतिक्रिया कोविड-१९ वैक्सीन ऐस्ट्रा ज़ेनेका की प्रथम खुराक दिए जाने के बाद प्रेरित हुई। दूसरी खुराक प्राप्त करने के बाद इनमें और बढ़त नहीं होती है।

भारत में हुए अध्ययन से प्रतिरक्षाजनत्व संबंधी आकड़े :

आईजीजी ऐंटिबॉडी का स्पाइक (एस) प्रोटीन के खिलाफ GMT आधाररेखा पर समूहों के बीच बराबर सी थी - दिन 1 दोनो समूहों में टीके की प्रत्येक खुराक के बाद GMT काफी ज्यादा बढ़ गई और बराबर सी थी। दिन ५७ को दोनो समूहों में 100% सेरोकन्वर्शन था। प्रतिरक्षाजनत्व आकड़े दर्शाते हैं कि ऐंटि -एस आईजीजी ऐंटिबॉडी टाइटर और सेरोकन्वर्शन दर के संबंध में **कोविशील्ड™** और ऑक्सफोर्ड/AZ-ChAdOx1 nCoV-19 टीके समान हैं (सारणी 4 और 5 देखें)।

सारणी 4 ऐंटि-एस आईजीजी ऐंटिबॉडी का संक्षिप्त विवरण

विशिष्ट समय	आकड़े	कोविशील्ड™ (N=291) n (%)	ऑक्सफोर्ड / AZ-ChAdOx१ nCoV-19 (N=97) n (%)
आधाररेखा	n GMT 95% CI	291 95.4 (77.8, 117.0)	97 80.7 (59.0, 110.4)
विज़िट 3 - दिन 29 (+14)	n GMT 95% CI	289 9988.1 (8395.0, 11883.7)	97 6738.5 (4880.4, 9304.1)
विज़िट 4 - दिन 57 (+14)	n GMT 95% CI	140 33331.6 (27756.0, 40027.2)	46 33263.6 (24383.1, 45378.3)

सारणी 5 ऐंटि-एस आईजीजी के लिए सेरोकन्वर्शन हुए सहभागियों के अनुपात का संक्षिप्त विवरण ऐंटिबॉडी

विशिष्ट समय	कोविशील्ड™ (N=291) n (%) 95 (%) CI	ऑक्सफोर्ड / AZ-ChAdOx१ nCoV-19 (N=97) n (%) 95(%) CI
विज़िट 3 - दिन 29 (+14)	279 (96.5) (93.7, 98.3)	89 (91.8) (84.4, 96.4)
विज़िट 4 - दिन 57 (+14)	**140 (100.0)** (97.4, 100.00)	**46 (100.0)** (92.3, 100.0)

5.2 फार्माकोकाइनेटिक (भेषज बलगतिकी) गुण

लागू नहीं है।

5.3 प्रीक्लीनिकल सुरक्षा आकड़े

विषाक्तता और स्थानीय सहिष्णुता संबंधी अध्ययन

खुराक के दोहराए जाने से विषाक्तता के पारंपरिक अध्ययन के आधार पर गैर-नैदानिक आकड़े और जानकारी मानवो के लिए कोई विशेष खतरा नहीं दर्शाते हैं। प्रजनन और विकास के लिए संभाव्य विषाक्तता के संबंध में पशु अध्ययन अभी तक पूरे नहीं हुए हैं।

6. ऑषधीय विवरण

6.1 टीके में मौजूद निष्क्रिय पदार्थों की सूची

एल-हिस्टिडीन, एल-हिस्टिडीन हाइड्रोक्लोराइड मोनोहाइड्रेट, मेग्नीशियम क्लोराइड हेक्साहाइड्रेट, पॉलिसॉर्बेट 80, इथेनॉल, सुकरोज़, सोडियम क्लोराइड, डायसोडियम इडेटेट डायहाइड्रेट (ईडीटीए), इंजेक्शन के लिए पानी

(निष्क्रिय सामग्री के नाम भौगोलिक क्षेत्र के हिसाब से अलग-अलग हो सकते हैं)

6.2 किनके टीकों या दवाओं के साथ इसे दिया जा सकता है

अन्य चिकित्सीय उत्पादों के साथ इसके दिए जाने के संबंध में अध्ययन परिणाम न होने के कारण, इस टीके को अन्य चिकित्सीय उत्पादों के साथ नहीं मिलाया जाना चाहिए।

6.3 शेल्फ़-लाइफ

लेबल और पैकेजिंग पर इन टीकों को इस्तेमाल करने की अंतिम तारीख लिखी हुई है।

एक बार खुलने पर, बहु-खुराक वायल जितनी जल्दि व्यावहारिक रूप से संभव हो, इसतेमाल हो जानी चाहिए और जब इन्हें +2ºC से +25ºC के बीच स्टोर किया जाए तो 6 घंटों के भीतर इन्हें इस्तेमाल किया जाना चाहिए। कोविशील्ड™ के खोले गए सभी बहु-खुराक वायलों को टीकाकरण सत्र के अंत में या फिर खोले जाने के छः घंटों के भीतर (जो भी पहले हो) फेंक देना चाहिए।

6.4 स्टोर करने संबंधी विशेष एहतियात

फ्रिज में इसे स्टोर करें (+2°C से +8°C के बीच)

इसे जमने न दें। प्रकाश से बचा कर रखें। खुली हुई बहु-खुराक वायल

ऑषधीय उत्पाद को पहली बार खोलने के बाद स्टोर करने के बारे में जानने के लिए खंड 6.3 देखें।

6.5 पात्र का प्रकार और उसकी सामग्री

कोविशील्ड™ प्रयोग के लिए तैयार रूप में रबड़ - ढक्कन वाले बहु-खुराक वायल और एकल खुराक वायल के रूप में नीचे सूचिबद्ध रूपों में सप्लाई किया जाता है।

1 खुराक - 0.5 ml प्रति वायल
2 खुराक - 1.0 ml प्रति वायल
5 खुराक - 2.5 ml प्रति वायल
10 खुराक - 5.0 ml प्रति वायल
20 खुराक - 10 ml प्रति वायल

6.6 प्रयोग, संभालने और निपटान संबंधी निर्देश

टीका देने का तरीका

कोविशील्ड™ बेरंग या हल्के भूरे रंग का साफ या फिर हल्का अपारदर्शी, कण-रहित घोल है। टीका देने से पहले दृष्टिगत रूप से उसका निरीक्षण करें और अगर उसमें कणिकीय पदार्थ दिखे या फिर जैसा वर्णन किया गया है, उससे कुछ अलग दिखे तो टीके को फेंक दें।

वायल को हिलाएं नहीं

टीके की 0.5 ml की खुराक सिरिंज में खींच कर मांसपेशिय इंजेक्शन लगाया जाता है। प्रत्येक व्यक्ति के लिए अलग अलग विसंक्रमित सुई और सिरिंज प्रयोग करें। यह आमतौर पर होता है कि अंतिम खुराक निकालने के बाद भी वायल में थोड़ा तरल पदार्थ बचा रहता है। इस टीके में कोई प्रेज़रवेटिव (परिरक्षक) नहीं है। टीका लगाने के लिए खुराक निकालते समय रोगाणुमुक्त तकनीक इस्तेमाल की जानी चाहिए।

एक बार खुलने पर, बहु-खुराक की बोतलें जितनी जल्दि व्यावहारिक रूप से संभव हो, इसतेमाल हो जानी चाहिए और जब इन्हें +2ºC से +25ºC के बीच स्टोर किया जाए तो 6 घंटों के भीतर इन्हें इस्तेमाल किया जाना चाहिए। इस्तेमाल के बाद बचा हुआ टीका फेंक दें।

टीके के विवरण पता करना सुविधाजनक हो, इसके लिए प्रत्येक प्राप्तकर्ता को दिए जा रहे टीके का नाम और बैच संख्या रिकॉर्ड किया जान चाहिए।

निपटान

कोविशील्ड™ में आनुवांशिक रूप से परिवर्तित जीव हैं (जीएमओ)। किसी भी अप्रयुक्त टीके या अपशिष्ट पदार्थ का स्थानीय आवश्यकताओं के अनुसार निपटान किया जाना चाहिए। छलकाव होने पर उपयुक्त ऐंटिवायरल डिस्इन्फेक्टेंट (जैसे कि हाइड्रोजेन परऑक्साइड आधारित डिस्इन्फेक्टेंट) से उसे रोगाणुमुक्त किया जाना चाहिए।

निर्माता:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411 028, INDIA

विपणन:
SERUM INSTITUTE LIFE SCIENCES PVT. LTD.
401, Sarosh Bhavan, 16-B/1, Dr. Ambedkar Road,
Pune - 411 001, INDIA

Annexure P-6

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant)

COVISHIELD™

1 NAME OF THE MEDICINAL PRODUCT

COVISHIELD™
ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5 ml) contains:

ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) 5×10^{10} virus particles (vp)

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.

This product contains genetically modified organisms (GMOs).

For the full list of excipients, see section 6.1.

Both **COVISHIELD™** (manufactured by Serum Institute of India Pvt Ltd) and COVID-19 Vaccine AstraZeneca (manufactured by AstraZeneca) are ChAdOx1 nCoV- 19 Corona Virus Vaccines (Recombinant).

3 PHARMACEUTICAL FORM

Solution for injection

The solution is colourless to slightly brown, clear to slightly opaque and particle free with a pH of 6.6.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

COVISHIELD™ is indicated for active immunisation of individuals ≥18 years old for the prevention of coronavirus disease 2019 (COVID-19).

4.2 Posology and method of administration

Posology

COVISHIELD™ vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 to 12 weeks after the first dose (see section 5.1).

It is recommended that individuals who receive a first dose of **COVISHIELD™** complete the vaccination course with **COVISHIELD™** (see section 4.4).

Special populations

Elderly population

No dosage adjustment is required in elderly individuals ≥ 65 years of age.

Paediatric population

The safety and efficacy of **COVISHIELD™** in children and adolescents (aged <18 years old) have not yet been established. No data are available.

Method of administration

COVISHIELD™ is for intramuscular (IM) injection only, preferably in the deltoid muscle.

For instructions on administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients who have experienced major venous and/or arterial thrombosis in combination with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant).

4.4 Special warnings and special precautions for use

Hypersensitivity including anaphylaxis

Hypersensitivity reactions including anaphylaxis and angioedema have occurred following administration of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant).

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

A second dose of the vaccine should not be given to those who have experienced a severe hypersensitivity reaction to the first dose of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant).

Concurrent illness

As with other vaccines, administration of **COVISHIELD™** should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, and/or low-grade fever should not delay vaccination.

Thromboembolism and Thrombocytopenia

A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed following vaccination with with ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) during post-authorisation use. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of the events occurred within the first 21 days following vaccination and some events had a fatal outcome.

Whilst specific risk factors for thromboembolism in combination with thrombocytopenia have not been identified, cases have occurred in patients with a previous history of thrombosis, as well as in patients with autoimmune disorders, including immune thrombocytopenia. The benefits and risks of vaccination should be considered in these patients.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and thrombocytopenia, as well as coagulopathies. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms such as a severe or persistent headaches, blurred vision, confusion, seizures, shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain or unusual skin bruising and or petechia a few days after vaccination.

Individuals diagnosed with thrombocytopenia within 21 days of vaccination with ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant), should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 21 days of vaccination should be evaluated for thrombocytopenia.

Healthcare professionals should consult applicable guidance and, if available, seek advice from specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.

Risk of bleeding with intramuscular administration

As with other intramuscular injections, **COVISHIELD™** should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Duration and level of protection and limitation of effectiveness

The duration of protection has not yet been established.

Protection starts from approximately 3 weeks after the first dose of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant). Individuals may not be fully protected until 15 days after the second dose is administered.

As with any vaccine, vaccination with **COVISHIELD™** may not protect all vaccine recipients (See section 5.1).

Interchangeability

There are no safety, immunogenicity or efficacy data to support interchangeability of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) with other COVID-19 vaccines.

4.5 Interaction with other medicinal products and other forms of interaction

The safety, immunogenicity and efficacy of co-administration of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) with other vaccines have not been evaluated.

4.6 Fertility, pregnancy and lactation

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to fertility.

Pregnancy

There is a limited experience with the use of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development;

Administration of **COVISHIELD™** in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Breastfeeding

It is unknown whether **COVISHIELD™** is excreted in human milk.

4.7 Effects on ability to drive and use machines

ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Overall summary of the safety profile from the Overseas studies:

COV001, COV002, COV003, and COV005:

The overall safety of COVID-19 Vaccine AstraZeneca [ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)] is based on an analysis of pooled data from four clinical trials (COV001, COV002, COV003, and COV005) conducted in the United Kingdom, Brazil, and South Africa. At the time of analysis, 24,244 participants ≥18 years old had been randomised and received either COVID-19 Vaccine AstraZeneca or control. Out of these, 12,282 received at least one dose of COVID-19 Vaccine AstraZeneca with a median duration of follow-up of 4.5 months.

Demographic characteristics were generally similar among participants who received COVID-19 Vaccine AstraZeneca and those who received control. Overall, among the participants who received COVID-19 Vaccine AstraZeneca, 89.8% were aged 18 to 64 years and 10.2% were 65 years of age or older. The majority of recipients were White (75.5%), 9.8% were Black and 3.7% were Asian; 55.8% were female and 44.2% male.

The most frequently reported adverse reactions were injection site tenderness (>60%); injection site pain, headache, fatigue (>50%); myalgia, malaise (>40%); pyrexia, chills (>30%); and arthralgia, nausea (>20%). The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination.

Following vaccination, recipients may experience multiple adverse reactions occurring at the same time (for example, myalgia/arthralgia, headache, chills, pyrexia and malaise). If a recipient reports persistent symptoms, alternative causes should be considered.

When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently. Adverse reactions were generally milder and reported less frequently in older adults (≥ 65 years old).

If required, analgesic and/or anti-pyretic medicinal products (e.g. paracetamol-containing products) may be used to provide symptomatic relief from post-vaccination adverse reactions.

Adverse drug reactions

Adverse drug reactions (ADRs) are organised by MedDRA System Organ Class (SOC). Within each SOC, preferred terms are arranged by decreasing frequency and then by decreasing seriousness. Frequencies of occurrence of adverse reactions are defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000) and not known (cannot be estimated from available data).

Table 1 - Adverse drug reactions

MedDRA SOC	Frequency	Adverse reactions
Blood and lymphatic system disorders	Uncommon	Lymphadenopathy[a]
Immune system disorders	Not known	Anaphylaxis[b]
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness[a], somnolence[a]
Gastrointestinal disorders	Very common	Nausea
	Common	Vomiting, diarrhea[a]
	Uncommon	Abdominal pain[a]
Skin and subcutaneous tissue disorders	Uncommon	Hyperhidrosis[a], pruritis[a], rash[a], uriticaria[a]
	Not known	Angioedema[b]
Musculoskeletal and connective tissue disorders	Very common	Myalgia, arthralgia
	Common	Pain in extremity[a]
General disorders and administration site conditions	Very common	Injection site tenderness, injection site pain, injection site warmth, injection site pruritus, fatigue, malaise, pyrexia[c], chills
	Common	Injection site swelling, injection site erythema, influenza like illness[a,*]

[a] Unsolicited adverse reaction
[b] Identified from post-authorisation experience
[c] Pyrexia includes feverishness (very common) and fever ≥38°C (common)
* See further description of adverse reaction below

Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID 19 Vaccine AstraZeneca. A causal relationship has not been established.

Summary of safety data from D8110C00001 (Phase 3 Study in US, Peru and Chile):

Additional safety of COVID-19 Vaccine AstraZeneca was established in a randomised phase III clinical trial conducted in the United States, Peru and Chile. At the time of the analysis, 32,379 participants ≥18 years old had received at least one dose, including 21,587 in the COVID-19 Vaccine AstraZeneca group and 10,792 in the placebo group.

Demographic characteristics were generally similar among participants who received COVID-19 Vaccine AstraZeneca and those who received placebo. Overall, among the participants who received COVID-19 Vaccine AstraZeneca 77.6% were 18 to 64 years and 22.4% were ≥ 65 years of age. Seventy-nine percent of the participants were White, 8.3% were Black, 4.4% were Asian, 4.0% were American Indian or Alaska Native, 0.3% were Native Hawaiian or Other Pacific Islander, 2.4% were of multiple races and 1.7% were not reported or unknown; 44.4% were female and 55.6% male.

The safety profile observed in this Phase III study was consistent with pooled analysis of data from the United Kingdom, Brazil and South Africa (COV001, COV002, COV003, and COV005). Adverse reactions seen in this Phase III trial were observed at similar frequencies as seen in the pooled analysis except the following: feverishness (pyrexia) (0.7%), arthralgia (1.1%), injection site warmth (<0.1%) and injection site pruritus (0.2%). These adverse reactions were solicited adverse events in the COV001, COV002, COV003, and COV005 studies whereas the D8110C00001 study did not include these as solicited symptoms to report.

Post-authorisation reports of influenza-like illness

Some recipients have reported chills, shivering (in some cases rigors), and increased body temperature possibly with sweating, headache (including migraine-like headaches), nausea, myalgia and malaise, starting within a day of vaccination. These effects usually last for a day or two.

If a patient reports unusually high or prolonged fever, or other symptoms, alternative causes should be considered and appropriate advice should be provided for diagnostic investigation and medical management as required.

Summary of global post-authorisation data of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of COVID-19 Vaccine AstraZeneca.

Immune system disorders: Anaphylactic reaction (frequency: not known)

Skin and subcutaneous tissue disorders: Angioedema (frequency: not known)

Vascular disorders: A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS) in some cases accompanied by bleeding, has been observed with a frequency less than 1/100,000. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see section 4.4).

Blood and lymphatic system disorders: Thrombocytopenia (frequency: very rare). The majority of reported events occurred in individuals aged 18-59 years old.

Overall summary of the safety profile from the Indian study:

COVISHIELD™ was also safe and well tolerated in the phase 2/3 clinical trial in India. An interim analysis included data of all 1600 participants who received first dose [1200 in COVISHIELD™ group, 100 in COVID-19 Vaccine AstraZeneca group and 300 in Placebo group]. This interim analysis includes data collected until Day 57 visit (28 days after second dose) of all 1600 participants who received first dose and 1577 participants who received second dose.

Demographic characteristics were generally similar among participants across the three groups. Overall, among the participants who received COVISHIELD™, 87.1% were aged 18 to 59 years and 12.9% were 60 years of age or older.

Overall, the incidence of solicited reactions (injection site reactions: pain, tenderness, redness, warmth, itch, swelling and induration; and systemic reactions : fever, chills, fatigue, malaise, headache, arthralgia and myalgia), unsolicited adverse events and serious adverse events (SAEs) was comparable in the study and control groups.

Among all 1600 participants who received a first dose, a total of 19 SAEs in 19 (1·2%) participants were reported, in 15 of 1200 (1·3%, 95% CI 0·7–2·1) participants who received **COVISHIELD™**, 2 (0·7%, 95% CI 0·1–2·4) who received placebo and 2 (2·0%, 95% CI 0·2–7·0) who received COVID-19 Vaccine AstraZeneca. These included COVID-19 (n=11), fracture/dislocation (n=3), malaria (n=1), megaloblastic anaemia (n=1), cataract (n=1), encephalopathy (n=1) and a vocal cord cyst (n=1). **All SAEs resolved without sequelae and none was assessed as related to study vaccine. There were no thromboembolic-associated or autoimmune-related SAEs** reported in the study.

Table 2 - Adverse drug reactions from COVISHIELD™ study in India (Data until Day 57 visit)

MedDRA SOC	Frequency	Adverse reactions
Gastrointestinal disorders	Common	Nausea
	Uncommon	Diarrhoea
General disorders and administration site conditions	Very common	Injection site pain
	Common	Pyrexia, malaise, fatigue, pain, chills, injection site erythema, injection site swelling, injection site induration, asthenia, injection site pruritus
Musculoskeletal and connective tissue disorders	Common	Myalgia, arthralgia
	Uncommon	Pain in extremity, back pain, neck pain
Nervous system disorders	Common	Headache
	Uncommon	Dizziness, somnolence
Skin and subcutaneous tissue disorders	Uncommon	Urticaria

Summary of post-authorisation data in India

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during post-authorisation use of COVISHIELD™ in India.

Immune system disorders: Anaphylactic reaction (frequency: very rare), Hypersensitivity reactions (frequency: very rare).

Vascular disorders: A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS) in some cases accompanied by bleeding, has been observed with a frequency less than 1/70,000,000. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see section 4.4).

Blood and lymphatic system disorders: Thrombocytopenia (frequency: very rare).

4.9 Overdose

Experience of overdose is limited.

There is no specific treatment for an overdose with ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant). In the event of an overdose, the individual should be monitored and provided with symptomatic treatment as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine, other viral vaccines, ATC code: J07BX03

Mechanism of action

COVISHIELD™ is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV-2. Following administration, the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralizing antibody and cellular immune responses.

Efficacy and immunogenicity data from the Overseas studies:

Clinical efficacy

Primary analysis of pooled data from COV001, COV002, COV003, and COV005

COVID-19 Vaccine AstraZeneca [ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)] has been evaluated based on pooled data from four on-going randomised, blinded, controlled trials: a Phase I/II Study, COV001 (NCT04324606), in healthy adults 18 to 55 years of age in the UK; a Phase II/III Study, COV002 (NCT04400838), in adults ≥18 years of age (including the elderly) in the UK; a Phase III Study, COV003 (ISRCTN89951424), in adults ≥18 years of age (including the elderly) in Brazil; and a Phase I/II study, COV005 (NCT04444674), in adults aged 18 to 65 years of age in South Africa. The studies excluded participants with history of anaphylaxis or angioedema; severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with immunosuppression. In studies COV001 and COV002, licensed seasonal influenza and pneumococcal vaccinations were permitted (at least 7 days before or after their study vaccine). All participants are planned to be followed for up to 12 months, for assessments of safety and efficacy against COVID-19 disease.

In the pooled analysis for efficacy, participants ≥18 years of age received two doses of COVID-19 Vaccine AstraZeneca (N=8,597) or control (meningococcal vaccine or saline) (N=8,581). Participants randomised to COVID-19 Vaccine AstraZeneca received either two standard doses [SD] (5×10^{10} vp per dose) or one low dose [LD] (2.2×10^{10} vp) followed by one SD (5×10^{10} vp), administered via IM injection. Overall, the majority of participants (83.8%) received two SD. Because of logistical constraints, the interval between dose 1 and dose 2 ranged from 3 to 28 weeks with 77.0% of participants receiving their two doses within the interval of 4 to 12 weeks.

Baseline demographics were well balanced across COVID-19 Vaccine AstraZeneca and control treatment groups. Overall, among the participants who received COVID-19 Vaccine AstraZeneca, 91.8% of participants were 18 to 64 years old (with 8.2% aged 65 or older); 56.0% of subjects were female; 74.9% were White, 10.1% were Black and 3.7% were Asian. A total of 3,056 (35.5%) participants had at least one pre-existing comorbidity (defined as a BMI ≥ 30 kg/m², cardiovascular disorder, respiratory disease or diabetes). At the time of primary analysis the median follow up time post-dose 1 and post-dose 2 was 143 days and 83 days, respectively.

Final determination of COVID-19 cases were made by an adjudication committee, who also assigned disease severity according to the WHO clinical progression scale. A total of 332 participants had SARS-CoV-2 virologically confirmed (by nucleic acid amplification tests) COVID-19 occurring ≥15 days post dose 2 with at least one COVID-19 symptom [objective fever (defined as ≥37.8°C)], cough, shortness of breath, anosmia, or ageusia) and were without evidence of previous SARS-CoV-2 infection. COVID-19 Vaccine AstraZeneca significantly decreased the incidence of COVID-19 compared to control (see Table 2a).

Table 2a - COVID-19 Vaccine AstraZeneca efficacy against COVID-19 in COV001, COV002, COV003 and COV005[a]

Population	COVID-19 Vaccine AstraZeneca		Control		Vaccine efficacy % (95% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
Primary analysis population					
Overall (SDSD + LDSD)	8597	84 (0.98)	8581	248 (2.89)	66.73 (57.41, 74.01)
Licensing regimen					
SDSD	7201	74 (1.03)	7179	197 (2.74)	63.09 (51.81, 71.73)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval; LD = Low Dose; SD = Standard Dose.

[a] Primary study endpoint was based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses (SDSD or LDSD) and were on-study ≥15 days post second dose.

[b] Virologically confirmed SARS-CoV-2 and at least one of the following symptoms: objective fever (defined as ≥37.8°C), cough, shortness of breath, anosmia, or ageusia. Confirmed by adjudication committee.

The level of protection gained from one SD of COVID-19 Vaccine AstraZeneca was assessed in an exploratory analysis that included participants who had received one dose of SD. Participants were censored from the analysis at the earliest time point of when they received a second dose or at 12 weeks post-dose 1. In this population, vaccine efficacy from 22 days post-dose 1 was 71.42% (95% CI: 51.11; 84.08 [COVID-19 Vaccine AstraZeneca 18/9,335 vs control 63/9,312]).

Exploratory analyses showed that increased vaccine efficacy was observed with increasing dose interval, see Table 2b.

Table 2b - COVID-19 Vaccine AstraZeneca efficacy by dosing interval in COV001, COV002, COV003 and COV005[a]

Dosing interval	COVID-19 Vaccine AstraZeneca		Control		Vaccine efficacy % (95% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
< 6 weeks	3,905	35 (0.90)	3,871	76 (1.96)	55.09 (33.0, 69.90)
6-8 weeks	1,124	20 (1.78)	1,023	44 (4.30)	59.72 (31.68, 76.25)
9-11 weeks	1,530	14 (0.92)	1,594	52 (3.26)	72.25 (49.95, 84.61)
≥ 12 weeks	2,038	15 (0.74)	2,093	76 (3.63)	79.99 (65.20, 88.50)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval.

[a] Primary study endpoint was based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses (SDSD or LDSD) and were on-study ≥15 days post second dose.

[b] Virologically confirmed SARS-CoV-2 and at least one of the following symptoms: objective fever (defined as ≥37.8°C), cough, shortness of breath, anosmia, or ageusia. Confirmed by adjudication committee.

Efficacy against COVID-19 hospital admission and severe COVID-19 disease

COVID-19 Vaccine AstraZeneca reduced COVID-19 hospitalisation (WHO severity grading ≥4).

In participants who had received two doses of COVID-19 Vaccine AstraZeneca (SDSD + LDSD, ≥15 days post-dose 2) as compared to control, there were 0 (N=8,597) vs 9 (0.10%; N=8,581) cases of hospitalised COVID-19, respectively. Corresponding to a vaccine efficacy of 100% (97.5% CI: 50.19; Not Evaluable).

Efficacy against COVID-19 in subgroups

Participants who had one or more comorbidities had a vaccine efficacy of 62.71% [95% CI: 44.79; 74.82]; 34 (1.11%) vs 93 (3.00%) cases of COVID-19 for COVID-19 Vaccine AstraZeneca (SDSD + LDSD, ≥15 days post-dose 2, N=3,056) and control (N=3,102), respectively; which was similar to the vaccine efficacy observed in the overall population.

In participants ≥65 years old who had received 2 doses of COVID-19 Vaccine AstraZeneca (SDSD + LDSD, ≥15 days post-dose 2, N=703), there were 4 cases of COVID-19 compared to 8 cases for control (N=680), corresponding to a vaccine efficacy of 51.91% [95% CI: -59.98, 85.54]). A large proportion (89.6%) of older adults received their second dose <6 weeks after their first. In older adults (≥65 years old) who had received SD as a first dose (≥22 days post-dose 1), there were 6 cases of COVID-19 for COVID-19 Vaccine AstraZeneca (N=945) compared to 13 for control (N=896), with 0 vs 2 cases in the COVID-19 Vaccine AstraZeneca and control groups, respectively, leading to hospitalisation (WHO severity grading ≥4).

Analysis of efficacy data from D8110C00001

COVID-19 Vaccine AstraZeneca has been evaluated based on an analysis from a randomised, double-blinded, placebo-controlled Phase III trial conducted in the United States, Peru and Chile. The trial randomised 32,451 healthy adults or those with medically-stable chronic diseases ≥18 years of age. The study excluded participants with severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with severe immunosuppression. All participants are planned to be followed for up to 1 year for assessments of efficacy against COVID-19 disease.

In the updated primary efficacy analysis 26,212 participants received two doses of COVID-19 Vaccine AstraZeneca (N=17,662) or placebo (N=8,550). Participants randomised to COVID-19 Vaccine AstraZeneca received (5×10^{10} vp per dose) administered via IM injection on Day 1 and Day 29 (-3 to +7 days). The median dose interval was 29 days and the majority of participants received the second dose ≥26 to ≤36 days (95.7% and 95.3%, respectively) after dose 1.

Baseline demographics were balanced across the COVID-19 Vaccine AstraZeneca and the placebo groups. Of the participants who received COVID-19 Vaccine AstraZeneca, 79.1% were aged 18 to 64 years and 20.9% were ≥65 years of age; 43.8% of subjects were female. Of those randomized, 79.3% were White, 7.9% were Black, 4.2% were Asian, 4.2% were American Indian or Alaska Native, 0.3% were Native Hawaiian or Other Pacific Islander, and 2.4% were of multiple races (1.7% were unknown or not reported). A total of 10,376 (58.8%) participants who received COVID-19 Vaccine AstraZeneca versus 5,105 (59.7%) who received placebo had at least one pre-existing comorbidity. At the time of analysis, the median follow up time post-dose 2 was 61 days.

Comorbidity was defined as a chronic kidney disease, chronic obstructive pulmonary disease (COPD), lower immune health because of a solid organ transplant, history of obesity (BMI>30), serious heart conditions, sickle cell disease, type 1 and 2 diabetes, asthma, dementia, cerebrovascular diseases, cystic fibrosis, high blood pressure, liver disease, scarring in the lungs (pulmonary fibrosis), thalassemia, history of smoking.

Final determination of COVID-19 cases was made by an adjudication committee. A total of 203 participants had SARS-CoV-2 virologically confirmed COVID-19 occurring ≥15 days post second dose and met either the Category A or Category B criteria, and had no prior evidence of a previous SARS-CoV-2 infection

Category A: One or more of the following:

- Pneumonia diagnosed by chest x-ray, or computed tomography scan
- Oxygen saturation of ≤94% on room air or requiring either new initiation or escalation in supplemental oxygen
- New or worsening dyspnoea/shortness of breath

Category B: Two or more of the following:

- Fever >100°F (>37.8°C) or feverishness
- New or worsening cough
- Myalgia/muscle pain
- Fatigue that interferes with activities of daily living
- Vomiting and/or diarrhoea (only one finding to be counted toward endpoint definition)
- Anosmia and/or ageusia (only one finding to be counted toward endpoint definition)

COVID-19 Vaccine AstraZeneca significantly decreased the incidence of COVID-19 compared to placebo (see Table 3).

Table 3 - COVID-19 Vaccine AstraZeneca efficacy against COVID-19[a]

	COVID-19 Vaccine AstraZeneca		Placebo		Vaccine efficacy % (95% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
Updated Primary Efficacy Analysis[c]					
Symptomatic Illness	17,662	73 (0.4)	8,550	130 (1.5)	73.98 (65.34, 80.47)
Key Secondary Efficacy Analyses					
Symptomatic Illness Regardless of Evidence of Prior COVID-19 Infection	18,563	76 (0.4)	9,031	135 (1.5)	73.68 (65.13, 80.13)
Severe or Critical Symptomatic COVID-19[d]	17,662	0 (0.0)	8,550	8 (< 0.1)	100.0 (71.62, NE)[e]
COVID-19 Emergency Department Visits	17,662	1 (< 0.1)	8,550	9 (0.1)	94.80 (58.98, 99.34)
Post-treatment response for SARS- CoV-2 Nucleocapsid	17,662	156 (0.9)	8,550	202 (2.4)	64.32 (56.05, 71.03)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval;

[a] Based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses and were on-study ≥15 days post second dose.

[b] Virologically confirmed SARS-CoV-2 using the Category A and B criteria.

[c] Updated primary analysis included all outstanding adjudicated events.

[d] Based on laboratory-confirmed COVID-19, plus any of the following: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥ 125 beats per minute, oxygen saturation ≤ 93% on room air at sea level, or partial pressure of oxygen to fraction of inspired oxygen ratio < 300 mmHg); or respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation), evidence of shock (systolic blood pressure < 90 mmHg, diastolic blood pressure < 60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurological dysfunction; or admission to an intensive care unit, or death.

[e] 97.5%CI

[f] Negative at baseline to positive post treatment with study intervention.

In the pre-specified primary efficacy analysis, based on 190 adjudicated cases, there were 65 (0.4%) COVID-19 cases in participants receiving COVID-19 Vaccine AstraZeneca (N=17,817) and 125 (1.5%) COVID-19 cases in participants receiving placebo (N=8,589), with a vaccine efficacy of 76.0%, [95% CI 67.6, 82.2].

When cumulative incidence of viral shedding was examined with cases occurring ≥15 days post-dose-2, time to clearance of SARS-CoV-2 in saliva samples in COVID-19 Vaccine AstraZeneca participants was notably shorter (11 vs 16 days).

Efficacy in subgroups

Participants with one or more comorbidities who received the COVID-19 Vaccine AstraZeneca ≥15 days post-dose-2 had an efficacy of 75.24% (64.18, 82.88) and participants without comorbidities had a vaccine efficacy of 71.81% (95% CI: 55.5, 82.14).

In participants ≥ 65 years old who had received COVID-19 Vaccine AstraZeneca (≥15 days post-dose N=3,696), there were 5 (0.1%) cases of COVID-19 compared to 14 (0.8%) cases for placebo (N=1,812), corresponding to a vaccine efficacy of 83.5% [95% CI: 54.17, 94.06].

Immunogenicity

Primary analysis of pooled data from COV001, COV002, COV003, and COV005

Following vaccination with COVID-19 Vaccine AstraZeneca, in participants who were seronegative at baseline, seroconversion (as measured by a ≥ 4 fold increase from baseline in S-binding antibodies) was demonstrated in ≥ 98% of participants at 28 days after the first dose and >99% at 28 days after the second. Higher S-binding antibodies were observed with increasing dose interval (Table 4).

Generally similar trends were observed between analyses of neutralising antibodies and S-binding antibodies. An immunological correlate of protection has not been established; therefore, the level of immune response that provides protection against COVID-19 is unknown.

Table 4 - SARS CoV-2 S-binding antibody response to COVID-19 Vaccine AstraZeneca[a,b]

Population	Baseline	28 days after dose 1	28 days after dose 2
	GMT (95% CI)	GMT (95% CI)	GMT (95% CI)
Overall	(N=1538) 57.1 (53.8, 60.6)	(N=1466) 8358.0 (7879.2, 8866.0)	(N=1511) 30,599.8 (29,137.1, 32,135.9)
Dose Interval			
< 6 weeks	(N=578) 61.4 (55.3, 68.0)	(N=578) 8,184.5 (7,423.9, 9,023.1)	(N=564) 21,384.2 (19,750.7, 23,152.8)
6-8 weeks	(N=339) 56.1 (49.6, 63.3)	(N=290) 9,103.9 (8,063.1, 10,279.1)	(N=331) 28,764.8 (25,990.8, 31,834.9)
9-11 weeks	(N=331) 53.6 (47.5, 60.4)	(N=309) 8,120.9 (7,100.2, 9,288.4)	(N=327) 37,596.1 (34,494.2, 40,976.8)
≥ 12 weeks	(N=290) 54.3 (47.6, 61.9)	(N=289) 8,249.7 (7,254.5, 9,381.4)	(N=289) 52,360.9 (47,135.2, 58,165.9)

N = Number of subjects included in each group; GMT = Geometric mean titre; CI = Confidence interval; S = Spike
[a] Immune response evaluated using a multiplex immunoassay. [b] Individuals were seronegative at baseline.

The immune response observed in participants with one or more comorbidities was consistent with the overall population.

High seroconversion rates were observed in older adults (≥65 years) after the first SD (97.3% [N=149, 95% CI: 93.3; 99.3]) and the second SD (100.0% [N=156, 95% CI: 97.7; Not Evaluable]). The majority of older adults had a dose interval of < 6 weeks. The increase in S-binding antibodies for older adults with a dose interval of < 6 weeks (28 days after second SD: GMT=18759.6 [N=126, 95% CI: 15,764.8; 22,323.3]) was comparable to all participants who received their second dose after an interval of < 6 weeks (Table 3). The majority of participants ≥ 65 years old had a dose interval of < 6 weeks, which may have contributed to the numerically lower titres observed.

In participants with serological evidence of prior SARS-CoV-2 infection at baseline (GMT=10,979.1 [N=36; 95% CI: 6,452.7; 18,680.5]), S-antibody titres peaked 28 days after dose 1 (GMT=139,010.4 [N=35; 95% CI: 95,429.0; 202,495.1), but did not increase further after the second dose.

Spike-specific T cell responses as measured by IFN-γ enzyme-linked immunospot (ELISpot) assay are induced after a first dose of COVID-19 Vaccine AstraZeneca. Geometric mean responses are generally similar across age strata and regardless of presence of comorbidity. These do not rise further after a second dose. Th1 cytokines are induced by COVID-19 AstraZeneca with cells expressing IFN-γ, IL-2, and/or TNFα which are generally similar between age categories.

Immunogenicity data from the Indian study:

GMTs of IgG antibodies against spike (S) protein were comparable between the groups at baseline - Day 1. GMTs increased significantly after each dose of vaccine in both the groups and were comparable. There was > 98% seroconversion in both the groups on Day 57. The immunogenicity data indicates that **COVISHIELD™** is comparable in terms of anti-S IgG antibody titers and seroconversion rates to COVID-19 Vaccine AstraZeneca vaccine (see Tables 5 and 6).

Table 5 Summary of Anti-S IgG antibodies

Timepoint	Statistic	COVISHIELD™ (N=297) n (%)	COVID-19 Vaccine AstraZeneca (N=98) n (%)
Baseline	N GMT 95% CI	297 95.4 (78.1, 116.6)	98 79.4 (58.2, 108.4)
28 days after Dose 1	N GMT 95% CI	296 10045.4 (8473.2, 11909.2)	98 6660.8 (4836.3, 9173.7)
28 days after Dose 2	n GMT 95% CI	293 30245.6 (26794.0, 34141.8)	95 28558.3 (23479.3, 34735.8)

Table 6 Summary of Proportion of Participants with Seroconversion for Anti-S IgG Antibodies

Timepoint	Statistic	COVISHIELD™ (N=297)	COVID-19 Vaccine AstraZeneca (N=98)
28 days after Dose 1	N Evaluated Seroconversion, n (%) 95% CI	296 286 (96.6) (93.9, 98.4)	98 90 (91.8) (84.5, 96.4)
28 days after Dose 2	N Evaluated Seroconversion, n (%) 95% CI	293 287 (98.0) (95.6, 99.2)	95 94 (98.9) (94.3, 100.0)

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Toxicity and local tolerance studies

In a repeat-dose toxicity study in mice, IM administration of COVID-19 Vaccine AstraZeneca was well tolerated. Non adverse, mixed and/or mononuclear cell inflammation was observed in the subcutaneous tissues and skeletal muscle of the administration sites and adjacent sciatic nerve consistent with the anticipated findings after IM injection of vaccines. There were no findings in the administration sites or sciatic nerves at the end of the recovery period, indicating complete recovery of the COVID-19 Vaccine AstraZeneca related inflammation.

Reproductive toxicity

Biodistribution studies conducted in mice did not show measurable distribution of COVID-19 Vaccine AstraZeneca to the gonads (testes, ovaries) following IM injection.

In a reproductive and development toxicity study, COVID-19 Vaccine AstraZeneca did not induce maternal or developmental toxicity following maternal exposure during the pre-mating, gestation or lactating periods. In this study, vaccine elicited detectable anti-SARS-CoV-2 S-glycoprotein maternal antibodies were transferred to the fetuses and pups, indicating placental and lactational transfer, respectively.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Histidine
L-Histidine hydrochloride monohydrate
Magnesium chloride hexahydrate
Polysorbate 80
Ethanol
Sucrose
Sodium chloride
Disodium edetate dihydrate (EDTA)
Water for injection
(The names of inactive ingredients may vary according to geographical region)

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf-life

The expiry date of vaccine is indicated on the label and packaging.

Once opened, multi-dose vials should be used as soon as practically possible and within 6 hours when kept between +2°C and +25°C. All opened multidose vials of **COVISHIELD™** should be discarded at the end of immunization session or within six hours whichever comes first.

6.4 Special precautions for storage

Store in a refrigerator (+2°C to +8°C). Do not freeze. Keep vials in outer carton to protect from light. Discard if vaccine has been frozen.

Opened multidose vial (After first use)

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

COVISHIELD™ is supplied as ready to use liquid in rubber-stoppered multidose vial and single dose vial in below listed presentations

1 dose - 0.5 ml per vial
2 dose - 1.0 ml per vial
5 dose - 2.5 ml per vial
10 dose - 5.0 ml per vial
20 dose - 10 ml per vial

6.6 Instructions for use, handling and disposal

Administration

COVISHIELD™ is a colourless to slightly brown, clear to slightly opaque solution. The vaccine should be inspected visually prior to administration and discarded if particulate matter or differences in the described appearance are observed.

Do not shake the vial.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 ml dose is administered. Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials.

The vaccine does not contain any preservative. Aseptic technique should be used for withdrawing the dose for administration.

After first opening, multi-dose vials should be used as soon as practically possible and within 6 hours when kept between +2°C and +25°C. Discard any unused vaccine.

To facilitate the traceability of the vaccine, the name and the batch number of the administered product must be recorded for each recipient.

Disposal

COVISHIELD™ contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant (e.g. Hydrogen peroxide based disinfectants).

Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411 028, INDIA

Marketed by:
SERUM INSTITUTE LIFE SCIENCES PVT. LTD.
401, Sarosh Bhavan, 16-B/1, Dr. Ambedkar Road,
Pune - 411 001, INDIA

केवल रेजिस्टर्ड चिकित्सक अथवा अस्पताल या लैबोरेटरी में प्रयोग के लिए

ChAdOx1 nCoV- 19 कोरोना वायरस टीका (पुनःसंयोजक)

कोविशील्ड™

1. ऑषधीय उत्पाद का नाम

कोविशील्ड™

ChAdOx1 nCoV- 19 कोरोना वायरस टीका (पुनःसंयोजक)

2. गुणात्मक और मात्रात्मक रचना

टीके की एक खुराक (0.5 ml) में है:

ChAdOx1nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) 5 × 10^{10} वायरस के कण (वीपी)

*पुनःसंयोजक, वेक्टर तकनीक पर आधारित चिंपांज़ी से लिए गए एडेनोवायरस जो मानव शरीर में प्रतिकृति बनाने में सक्षम नहीं है और जो सार्स-कोव-2 स्पाइक (एस) ग्लायकोप्रोटीन से प्रभावित हैं।

इसे आनुवांशिक रूप से परिवर्तित मानव भ्रूणीय गुर्दे (एचईके) 293 कोशिकाओं पर निर्मित किया गया है।

इस उत्पाद में आनुवांशिक रूप से परिवर्तित जीव हैं (जीएमओ)।

टीके में मिलाए गए निष्क्रिय पदार्थों की पूर्ण सूची के लिए खंड 6.1 देखें।

कोविशील्ड™ (निर्माता सीरम इंस्टिट्यूट ऑफ इंडिया प्राइवेट लिमिटेड) और कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका (निर्माता ऐस्ट्रा ज़ेनेका) दोनों ही ChAdOx1 nCoV-19 कोरोना वायरस टीके (पुनःसंयोजक) हैं।

3 ऑषधीय रूप

इंजेक्शन के लिए घोल

यह बेरंग या हल्के भूरे रंग का साफ या फिर हल्का अपारदर्शी, कण-रहित घोल है जिसका पीएच 6.6 है।

4 रोग-विषयक विवरण

4.1 किन लोगों के लिए इसका प्रयोग किया जाना चाहिए

कोविशील्ड™ कोरोना वायरस रोग 2019 (कोविड-19) की रोकथाम के लिए 18 वर्ष या उससे अधिक उम्र के लोगों के सक्रिय टीकाकरण के लिए प्रयोग किया जा सकता है।

4.2 खुराक और टीका दिये जाने का तरीका

खुराक की मात्रा

कोविशील्ड™ टीके के कोर्स में 0.5 ml की दो अलग अलग खुराके हैं। प्रथम खुराक प्राप्त करने के 4 से 12 सप्ताह के बीच दूसरी खुराक दी जानी चाहिए (खंड 5.1 देखें)।

अनुशंसा की जाती है कि जिन लोगों को **कोविशील्ड™** की प्रथम खुराक दी जा चुकी है, वे टीकाकरण को **कोविशील्ड™** से ही पूरा करें (खंड 4.4 देखें)।

विशेष आबादी

बुजुर्ग

65 वर्ष या उससे अधिक उम्र के बुजुर्ग लोगों के लिए खुराक में किसी प्रकार के परिवर्तन की आवश्यकता नहीं है।

छोटे बच्चे

बच्चों और किशोरों (18 वर्ष से कम उम्र वाले) में **कोविशील्ड™** की प्रभावकारिता और सुरक्षा के बारे में जानकारी अभी तक स्थापित नहीं हुई है।कोई जानकारी उपलब्ध नहीं है।

टीका देने का तरीका

कोविशील्ड™ टीका केवल मांसपेशीय इंजेक्शन (आई.एम.) के रूप में दिया जाना चाहिए, आदर्श रूप से डेल्टॉइड मांसपेशी में। टीका लगाने के निर्देशों के लिए खंड 6.6 देखें।

4.3 किन स्थितियों में यह टीका नहीं लिया जाना चाहिए

खंड 6.1 में सूचीबद्ध सक्रिय सामग्री या टीके में मौजूद किसी भी अन्य निष्क्रिय पदार्थ के प्रति अतिसंवेदनशीलता।

जिन रोगियों को किसी भी कोविड-19 टीके से टीकाकरण कराने पर थ्रोम्बोसाइटोपेनिया के साथ-साथ गंभीर शिरापरक और / या धमनी घनास्त्रता हुआ है, उन्हें ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) की दूसरी खुराक नहीं दी जानी चाहिए।

4.4 प्रयोग संबंधी विशेष चेतावनी और विशेष एहतियात

तीव्रग्राहिता सहित अतिसंवेदनशीलता

ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) दिए जाने के बाद तीव्रग्राहिता और वाहिकाशोफ सहित अतिसंवेदनशीलता के प्रभाव देखे गए हैं।

जैसा कि प्रत्येक इंजेक्शन के रूप में लगने वाले टीके के साथ है, टीका लगाने के बाद गंभीर अलर्जिक प्रभाव होने पर तत्काल उपयुक्त चिकित्सीय उपचार और देखभाल उपलब्ध रहने चाहिए।

ChAdOx1 nCoV-19 कोरोना वायरस टीके (पुनःसंयोजक) की पहली खुराक दिए जाने पर गंभीर तीव्रग्राहिता अनुभव करने वाले व्यक्तियों को टीके की दूसरी खुराक नहीं दी जानी चाहिए।

टीका लगाए जाने के समय रोग

अन्य टीकों की ही तरह, **कोविशील्ड™** टीके को लगाया जाना स्थगित करें अगर व्यक्ति गंभीर सज्वर व्याधि से पीड़ित है। हालांकि, सर्दी, और/या हल्का बुखार जैसे मामूली संक्रमण होने पर, टीकाकरण करने में विलंब नहीं करना चाहिए।

थ्रोम्बोम्बोलिज़्म और थ्रोम्बोसाइटोपेनिया (रक्त में प्लेटलेट की कमी)

ChAdOx1 nCoV-19 कोरोना वायरस टीके (पुनःसंयोजक) से अधिकृत टीकाकरण के बाद कुछ मामलों में थ्रोम्बोसिस और थ्रोम्बोसाइटोपेनियासिंड्रोम (टीटीएस) सहित थ्रोम्बोसिस और थ्रोम्बोसाइटोपेनिया की गिनी-चुनी और गंभीर घटनाएं हुई हैं। इसमें शामिल है सेरेब्रल वेनस साइनस और स्प्लेनचेनिक वेन जैसे गैरमामूली स्थानो में थ्रोम्बोसिस तथा थ्रोम्बोसाइटोपेनिया के साथ आर्टीरियल थ्रोम्बोसिस से संबंधित मामले। टीकाकरण के बाद 21 दिनों के भीतर अधिकांश घटनाएं हुईं और कुछ घटनाओं में घातक परिणाम हुए।

जबकि थ्रोम्बोसाइटोपेनिया के साथ होने वाले थ्रोम्बोम्बोलिज़्म के लिए विशिष्ट जोखिम के कारणों का पता नहीं लगा है, जिन लोगों को पहले कभी थ्रोम्बोसिस हुआ या प्रतिरक्षा थ्रोम्बोसाइटोपेनिया सहित ऑटोइम्यून विकारों से पीड़ित रोगियों में इसके मामले नज़र आए। इन रोगियों में टीकाकरण के लाभों और जोखिमों पर विचार किया जाना चाहिए।

स्वास्थ्य देखभालकर्ताओं को कोगुलोपेथी सहित थ्रोम्बोएम्बोलिज़्म और थ्रोम्बोसाइटोपेनिया के संकेतों और लक्षणों पर ध्यान देना चाहिए। यदि टीकाकरण के कुछ दिनों बाद लोगों में गंभीर या लगातार सिरदर्द, धुंधला दिखाई देना, विभ्रांति, दौरा पड़ना (फिट),सांस फूलना, सीने में दर्द, पैर में सूजन, पैर में दर्द, लगातार पेट में दर्द या असामान्य रूप से त्वचा में नील पड़ना और/ या पेटीसिया जैसे लक्षण दिखाई देते हैं, तो उन्हें तत्काल चिकित्सीय सलाह लेने के लिए कहा जाना चाहिए।

ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) से टीकाकरण कराने के 21 दिनों के भीतर जिन लोगों में थ्रोम्बोसाइटोपीनिया का रोगनिदान होता है, उनकी थ्रोम्बोसिस के लक्षणों के लिए सक्रिय रूप से जांच की जानी चाहिए। उसी प्रकार जिन लोगों में टीकाकरण कराने के 21 दिनों के भीतर थ्रोम्बोसिस के लक्षण दिखते हैं, उनकी थ्रोम्बोसाइटोपीनिया के लिए जाँच की जानी चाहिए।

स्वास्थ्य देखभाल पेशेवरों को आवश्यकतानुसार पेशेवरों से परामर्श लेना चाहिए और, यदि उपलब्ध हो, तो इस स्थिति का निदान और उपचार करने के लिए विशेषज्ञों (जैसे, हेमेटोलॉजिस्ट, कोगुलेशन में विशेषज्ञ) से सलाह लेनी चाहिए।

मांसपेशिय इंजेक्शन से रक्त बहने का जोखिम

अन्य मांसपेशिय इंजेक्शन की तरह, थ्रोम्बोसाइटोपेनिया, किसी प्रकार के स्कंदन विकार या ऐंटिकोऐगुलेशन उपचार करा रहे लोगों को **कोविशील्ड™** टीका लगाते समय एहतियात बरता जाना चाहिए क्योंकि ऐसे लोगों में मांसपेशिय इंजेक्शन लगाने के कारण रक्तस्राव या क्षति हो सकती है।

ऐसे लोग जिनकी प्रतिरक्षा क्षमता कम है

प्रतिरक्षा क्षमता कम करने वाली उपचार पद्धतियाँ कराने वाले लोगों सहित जिन लोगों की प्रतिरक्षा क्षमता कम है, उनमें भी क्या टीकाकरण किए जाने पर मजबूत प्रतिरक्षा वाले लोगों के समान प्रभावकारिता और रोग से सुरक्षा बनी रहेगी, इसका अभी तक पता नहीं चला है।

व्यग्रता संबंधी प्रभाव

टीके को इंजेक्शन के रूप में देने के कारण वैसोवेगल प्रभाव (बेहोशी), हाइपरवेंटिलेशन या तनाव-संबंधी प्रभाव सहित व्यग्रता संबंधी प्रभाव के रूप में साइकोजेनिक प्रतिक्रिया हो सकती हैं। बेहोशी के कारण चोट से बचाव करने के लिए एहतियात बरतना जरूरी है।

सुरक्षा बने रहने की अवधि और स्तर और प्रभावकारिता का परिसीमन

सुरक्षा की अवधि अभी तक स्थापित नहीं हुई है। ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) की पहली खुराक दिए जाने से लगभग 3 सप्ताह बाद से कोविड-19 के खिलाफ सुरक्षा मिलनी शुरू होती है। दूसरी खुराक दिए जाने के पश्चात 15 दिन तक व्यक्ति पूर्ण रूप से सुरक्षित नहीं होता है। अन्य टीकों के समान ही, हो सकता है **कोविशील्ड™** से टीकाकरण कराने वाले हर टीका प्राप्तकर्ता को कोविड-19 से सुरक्षा न मिले (खंड 5.1 देखें)।

दो अलग अलग प्रकार के टीकों का लगाया जाना

ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) को अन्य कोविड-19 टीके के साथ लगाए जाने के समर्थन में कोई सुरक्षा, प्रतिरक्षाजनत्व या प्रभावकारिता संबंधी डेटा नहीं है।

4.5 अन्य चिकित्सीय उत्पादों के साथ परस्पर प्रभाव और अन्य रूपों में प्रभाव

ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) को अन्य टीकों के साथ लगाए जाने से संबंधित सुरक्षा, प्रतिरक्षाजनत्व या प्रभावकारिता का मूल्यांकन नहीं किया गया है।

4.6 प्रजनन क्षमता, गर्भावस्था और स्तनपान

प्रजनन क्षमता

प्रजनन क्षमता के संबंध में पशु अध्ययन प्रत्यक्ष या अप्रत्यक्ष रूप से हानिकारक प्रभाव नहीं दर्शाते हैं।

गर्भावस्था

ChAdOx1 nCoV-19 कोरोना वायरस टीके (पुनःसंयोजक) का गर्भवती महिलाओं में उपयोग के संबंध में सीमित अनुभव है।

गर्भावस्था, भ्रूण का विकास, प्रसव या प्रसवोत्तर विकास के संबंध में पशु अध्ययन प्रत्यक्ष या अप्रत्यक्ष रूप से हानिकारक प्रभाव नहीं दर्शाते हैं।

गर्भावस्था के दौरान **कोविशील्ड™** को तभी लगाने पर विचार किया जाना चाहिए जब माँ और भ्रूण के लिए उसके संभावित फायदे टीके के संभावित खतरों से कहीं अधिक हों।

स्तनपान

अभी तक इसकी जानकारी नहीं है कि मानव दूध के साथ **कोविशील्ड™** का स्राव होता है या नहीं।

4.7 मशीने चलाने और प्रयोग करने पर इसका प्रभाव

ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) का मशीने चलाने और प्रयोग करने की क्षमता पर कोई प्रभाव नहीं होता और अगर होता भी है तो ना के बराबर। लेकिन खंड 4.8 में उल्लिखित दुष्प्रभाव कुछ समय के लिए अस्थायी रूप से मशीने चलाने और प्रयोग करने की क्षमता को प्रभावित कर सकते हैं।

4.8 अवांछनीय प्रभाव

विदेश में हुए अध्ययनों के सुरक्षा पहलू का समग्र संक्षिप्त विवरण:

COV001, COV002, COV003, और COV005:

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका [ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक)] की समग्र सुरक्षा यूनाइटेड किंगडम, ब्राज़ील, और दक्षिण अफ्रीका में आयोजित किए गए चार नैदानिक परीक्षणों (COV001, COV002, COV003, और COV005) से प्राप्त आंकड़ों और जानकारी के विश्लेषण पर आधारित है। विश्लेषण के समय, 18 वर्ष या उससे अधिक उम्र के 24,244 सहभागियों को बिना किसी विशेष क्रम के कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका या फिर कंट्रोल टीका दिया गया। इनमें से 12,282 सहभागियों को कम से कम एक खुराक कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके की दी गई जिनकी अनुवर्ती जाँच की औसत अवधि 4.5 महीने की थी।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका और कंट्रोल टीका प्राप्त करने वाले सहभागियों की जनसांख्यिकीय विशेषताएँ आम तौर पर समान थीं। कुल मिलाकर जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका प्राप्त हुआ उनमें 89.8% लोगों की उम्र 18 से 64 वर्ष के बीच थी और 10.2% लोग 65 वर्ष या उससे अधिक उम्र के थे। टीका प्राप्त करने वाले लोगों में से अधिकांश व्हाइट्स (75.5%) थे, 9.8% ब्लैक्स थे और 3.7% एशियाई मूल के थे; 55.8% महिलाएं थीं और 44.2% पुरुष थे।

सबसे अक्सर रिपोर्ट किए गए प्रतिकूल प्रभाव थे - इंजेक्शन लगाए जाने के स्थान पर दबाने से दर्द (> 60%); इंजेक्शन लगाए जाने के स्थान पर दर्द, सिरदर्द, थकान (> 50%); मांसपेशियों का दर्द, बेचैनी(> 40%); बुखार, कंपकंपी (> 30%); और जोड़ों में दर्द, मतली (> 20%)। प्रतिकूल प्रभावों में से ज्यादातर हल्के से मध्यम गंभीरता के थे और आमतौर पर टीकाकरण के कुछ दिनों के भीतर ठीक हो गए थे।

टीकाकरण कराने के बाद, टीका प्राप्तकर्ताओं को एक साथ कई प्रतिकूल प्रभावों का अनुभव हो सकता है (जैसे कि, मांसपेशियों में दर्द/जोड़ों में दर्द, सिरदर्द, कंपकंपी, पाइरेक्सिया और तबियत ठीक न लगना)। यदि टीका प्राप्तकर्ता लक्षण बने रहने की रिपोर्ट करता है तो इन लक्षणों के अन्य कारणों की जांच की जानी चाहिए।

प्रथम खुराक की तुलना में दूसरी खुराक के बाद रिपोर्ट किए गए प्रतिकूल प्रभाव की तीव्रता कम थी और प्रतिकूल प्रभाव रिपोर्ट करने वाले लोगों की संख्या भी कम थी। बुजुर्ग लोगों (65 वर्ष और उससे अधिक की उम्र वाले लोग) में प्रतिकूल प्रभाव की तीव्रता कम देखी गई और प्रतिकूल प्रभाव रिपोर्ट करने वाले बुजुर्गों की संख्या भी कम थी।

अगर जरूरत पड़े तो, दर्द निवारक और/या बुखार के लिए चिकित्सीय उत्पाद (जैसे कि पैरासिटेमॉल युक्त उत्पाद)का प्रयोग इन टीकाकरण पश्चात प्रभावों से आराम देने के लिए किया जा सकता है।

दवाओं का प्रतिकूल प्रभाव

ऐड्वर्स ड्रग रीऐक्शन (एडीआर - दवाओं का दुष्प्रभाव) का आयोजन मेडडीआरए सिस्टम ऑर्गन क्लास (एसओसी) ने किया है। प्रत्येक एसओसी के तहत, पसंदीदा शब्दावली को कम होती आवृत्ति और कम होती गंभीरता के अनुसार व्यवस्थित किया गया है। दुष्प्रभावों की आवृत्ति निम्नलिखित रूप से परिभाषित है: बहुत आम (1/10 या उससे अधिक); आम (1/100 या उससे अधिक लेकिन 1/10 से कम); आम नहीं है (1/1,000 या उससे अधिक लेकिन1/100 से कम); गिनी-चुनी (1/10,000 या उससे अधिक लेकिन 1/1000 से कम); बहुत ही गिनी-चुनी (1/10,000 से कम) और पता नहीं चला है (उपलब्ध जानकारी से इनका अंदाज़ नहीं लगाया जा सकता है)।

सारणी 1 - टीके के प्रतिकूल प्रभाव

मेडडीआरए एसओसी	आवृत्ति	प्रतिकूल प्रभाव
रक्त और लिम्फैटिक (लसीका) तंत्र के विकार	आम नहीं है	लिम्फाडेनोपैथी (सूजी लिम्फैटिक नोड)[a]
प्रतिरक्षा तंत्र के विकार	जानकारी नहीं है	तीव्रग्राहिता[b]
तंत्रिका के विकार	बहुत आम है	सरदर्द
	आम नहीं है	सिर में चक्कर आना[a], उनींदापन[a]
पाचन तंत्र के विकार	बहुत आम है	मतली
	आम है	उलटी, दस्त[a]
	आम नहीं है	पेट में दर्द[a]
त्वचा और उपचर्म ऊतक संबंधी विकार	आम नहीं है	हाइपरहाइड्रोसिस[a], प्रचंड खुजली[a], चकत्ते[a], पित्ती[a]
	जानकारी नहीं है	वाहिकाशोफ[b]
मस्क्युलोस्केलेटल विकार और कनेक्टिव ऊतक संबंधी विकार	बहुत आम है	मांसपेशियों में दर्द, जोड़ों में दर्द
	आम है	एक्सट्रीमिटीज़ में दर्द[a]
आम विकार और इंजेक्शन लगने के स्थान पर समस्याएं	बहुत आम है	इंजेक्शन लगने के स्थान पर दबाने से दर्द, इंजेक्शन लगने के स्थान पर दर्द, इंजेक्शन लगने के स्थान पर गर्माहट, इंजेक्शन लगने के स्थान पर लालिमा, थकान, बेचैनी, पाइरेक्सिया[c], कंपकंपी
	आम है	इंजेक्शन लगने के स्थान पर सूजन, इंजेक्शन लगने के स्थान पर लालिमा, इन्फ्लूएंज़ा जैसा रोग[a,*]

a अव्यवस्थित रूप से एकत्र प्रतिकूल प्रभाव

b अधिकृत टीकाकरण के बाद के अनुभवों से जिनका पता लगा

c पाइरेक्सिया में शामिल है बुखार सा लगना (बहुत आम है) और 38°C या उससे अधिक बुखार (आम है)

* प्रतिकूल प्रभावों का और वर्णन देखें

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका से टीकाकरण कराने के बहुत ही गिने-चुने मामलो में तंत्रिका में सूजन संबंधी विकार रिपोर्ट किए गए हैं। दोनों के बीच कारणात्मक संबंध स्थापित नहीं हुआ है।

D8110C00001 (यूएस, पेरु और चिलि में आयोजित चरण 3 का अध्ययन) से प्राप्त सुरक्षा संबंधी डेटा का संक्षिप्त वर्णन:

संयुक्त राज्य अमरीका, पेरू और चिली में आयोजित चरण III के बिना किसी विशेष क्रम के दिए कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके के नैदानिक परीक्षण में इस टीके की अतिरिक्त सुरक्षा स्थापित की गई। विश्लेषण के समय, 18 वर्ष या उससे अधिक उम्र के 32,379 सहभागियों को कम से कम एक खुराक दी गई जिनमें से 21,587 लोगों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका दिया गया और 10,792 को कूटभेषज टीका दिया गया।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका और कूटभेषज टीका प्राप्त करने वाले सहभागियों की जनसांख्यिकीय विशेषताएँ आम तौर पर समान थीं। कुल मिलाकर जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका प्राप्त हुआ उनमें 77.6% लोगों की उम्र 18 से 64 वर्ष के बीच थी और 22.4% लोग 65 वर्ष या उससे अधिक उम्र के थे। टीका प्राप्त करने वाले सहभागियों में उनासी-प्रतिशत लोग व्हाइट्स थे, 8.3% ब्लैक्स थे और 4.4% एशियाई मूल के थे; 4.0% अमरीकी इंडियन या अलास्का के मूल निवासी हैं,0.3% हवाई या अन्य प्रशांत द्वीप वासी, 2.44% कई भिन्न जातियों के लोग थे और 1.7% की जातियता का पता नहीं था; उनमें से 44.4% महिलाएं थीं और 55.6% पुरुष थे।

इस चरण III के अध्ययन में देखे गए सुरक्षा वर्णन यूनाइटेड किंगडम, ब्राजील और दक्षिण अफ्रीका (COV001, COV002, COV003, और COV005) के एकत्रित डेटा के विश्लेषण के अनुरूप थे। बुखार (पाइरेक्सिया) (0.7%), जोड़ों में दर्द (1.1%), इंजेक्शन के स्थान पर गर्माहट (<0.1%) और इंजेक्शन के स्थान पर लालिमा (0.2%) के अलावा चरण III परीक्षण में देखे गए प्रतिकूल प्रभावों की आवृत्तियाँ वैसी ही थीं, जैसा कि एकत्रित डेटा के विश्लेषण में पाई गई थीं । इन प्रतिकूल प्रभावों को COV001, COV002, COV003, और COV005 अध्ययनों के दौरान पूछने पर बताई गई प्रतिकूल घटनाएं थी जबकि D8110C00001 अध्ययन में इन्हें रिपोर्ट किए गए लक्षणों के रूप में शामिल नहीं किया गया था।

अधिकृत टीकाकण के बाद रिपोर्ट की गई इन्फ्लूएंज़ा जैसी बीमारी

कुछ प्राप्तकर्ताओं ने टीकाकरण के एक दिन के भीतर ठंड लगना, कंपकंपी (कुछ मामलों में कठोरता), और पसीना आना, सिरदर्द (माइग्रेन जैसे सिरदर्द सहित), मतली, मायलगिया और अस्वस्थता के साथ शरीर के तापमान में वृद्धि की सूचना दी है। ये प्रभाव आमतौर पर एक या दो दिन तक रहते हैं।

यदि कोई रोगी असामान्य रूप से तेज बुखार या लंबे समय तक बुखार, या अन्य लक्षणों की रिपोर्ट करता है, तो अन्य कारणों पर विचार किया जाना चाहिए और आवश्यकतानुसार नैदानिक जांच और चिकित्सा प्रबंधन के लिए उचित सलाह दी जानी चाहिए।

ChAdOx1 nCoV-19 कोरोना वायरस टीके (पुनःसंयोजक) से वैश्विक स्तर पर अधिकृत टीकाकरण के बाद एकत्र किए गए आकड़ों का संक्षिप्त वर्णन

नैदानिक परीक्षणों के दौरान निम्नलिखित प्रतिकूल प्रभाव नहीं देखे गए और कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका के दुनिया भर में अधिकृत टीका लगाए जाने के बाद उपयोग के दौरान अनायास इन लक्षणों की रिपोर्ट की गई हैं।

प्रतिरक्षा तंत्र के विकार: तीव्रग्राहिता के प्रभाव (आवृत्ति: जानकारी नहीं है)

त्वचा और उपचर्म ऊतक संबंधी विकार: वाहिकाशोफ (आवृत्ति: जानकारी नहीं है)

वाहिका विकार कुछ मामलों में थ्रोम्बोसिस और थ्रोम्बोसाइटोपेनिया सिंड्रोम (टीटीएस) सहित थ्रोमबोसिस और थ्रोम्बोसाइटोपेनिया की गिनी-चुनी और गंभीर घटनाएं हुई हैं जिनमें से कुछ मामलों में रक्तस्राव होता पाया गया जिसकी आवृत्ति 1/100,000 से कम देखी गई है। इसमें शामिल है सेरेब्रल वेनस साइनस और स्प्लेनचेनिक वेन जैसे गैरमामूली स्थानो में वेनस थ्रोम्बोसिस तथा थ्रोम्बोसाइटोपेनिया के साथ आर्टीरियल थ्रोम्बोसिस से संबंधित मामले।(खंड 4.4 देखें)

रक्त और लिम्फैटिक (लसीका) तंत्र के विकार थ्रोम्बोसाइटोपीनिया (आवृत्ति: बहुत गैरमामूली) की अधिकांश घटनाएं 18 -59 की उम्र के लोगों में रिपोर्ट की गई।

भारत में हुए अध्ययन के सुरक्षा पहलू का समग्र संक्षिप्त विवरण:

भारत में चरण 2/3 के नैदानिक परीक्षणों में **कोविशील्ड™** को सुरक्षित और सहनीय पाया गया था। अंतरिम विश्लेषण के लिए उन सभी 1600 सहभागियों के आकड़े और जानकारी शामिल थी जिन्हें प्रथम खुराक दी गई थी [1200 को **कोविशील्ड™** दिया गया था, 100 कोविड -19 टीका ऐस्ट्रा ज़ेनेका टीका प्राप्त करने वाले लोग थे और कूटभेषज प्राप्त करने वाले 300 लोग शामिल थे]। इस अंतरिम विश्लेषण में दिन 57 (दूसरी खुराक प्राप्त करने के 28 दिन बाद) तक उन सभी 1600 सहभागियों से एकत्र की गई जानकारी शामिल हैं, जिन्हें पहली खुराक दी गई थी और 1577 ऐसे सहभागी हैं जिन्हें दूसरी खुराक भी दी गई है।

तीनों समूहों के सहभागियों की जनसांख्यिकीय विशेषताएँ आम तौर पर समान थीं। समग्र रूप से जिन सहभागियों को **कोविशील्ड™** टीका प्राप्त हुआ उनमें 87.1% लोगों की उम्र 18 से 59 वर्ष के बीच थी और 12.9% लोग 60 वर्ष या उससे अधिक उम्र के थे।

समग्र रूप से व्यवस्थित तरीके से एकत्र किए गए प्रतिकूल प्रभाव (इंजेक्शन के स्थान पर दर्द, दबाने से दर्द, लालिमा, गर्माहट, खुजली, सूजन और कड़ापन; दैहिक प्रभावों में हैं: बुखार, कंपकंपी, थकान, बेचैनी, सरदर्द, जोड़ों में दर्द और मांसपेशियों में दर्द), अव्यवस्थित तरीके से प्राप्त प्रतिकूल प्रभावों की जानकारी और गंभीर प्रतिकूल प्रभाव (एसएई) अध्ययन किए जाने वाले टीके और कंट्रोल टीके के लिए लगभग एक समान थे।

सभी 1600 सहभागी जिन्हें पहली खुराक दी गई, उनमें से कुल 19 (1.2%) सहभागियों में 19 गंभीर प्रतिकूल प्रभाव (एसएई) रिपोर्ट किए गए, 1200 (1·3%, 95% CI 0·7–2·1) सहभागी जिन्हें **कोविशील्ड™** टीका दिया गया उनमें से 15 ने एसएई की रिपोर्ट की, कूटभेषज टीका पाने वाले सहभागियों में 2 (0·7%, 95% CI 0·1–2·4) और कोविड -19 टीका ऐस्ट्रा ज़ेनेका प्राप्त करने वालों में 2(2·0%, 95% CI 0·2–7·0) नें एसएई की रिपोर्ट की। इनमें शामिल हैं कोविड-19 (n=11), फ्रैक्चर/डिस्लोकेशन (n=3), मलेरिया (n=1), मेगालोब्लास्टिक ऐनिमिया (n=1), मोतियाबिंद (n=1), एन्सेफैलोपेथी (n=1) और वोकल कॉर्ड सिस्ट (n=1) । **सभी एसएई बिना रोगोत्तर लक्षण के ठीक हो गए और इनके विश्लेषण के दौरान किसी भी एसएई को अध्ययन किए जाने वाले टीके से संबंधित नहीं पाया गया। अध्ययन में कोई भी थ्रोम्बोएम्बोलिक या ऑटोइम्यून संबंधी एसएई** की रिपोर्ट नहीं की गई।

सारणी 2 - भारत में कोविशील्ड™ टीके के अध्ययन से प्राप्त प्रतिकूल प्रभाव(डेटा दिन 57 विज़िट तक का है)

मेडडीआरए एसओसी	आवृत्ति	प्रतिकूल प्रभाव
पाचन तंत्र के विकार	आम है	मतली
	आम नहीं है	दस्त
आम विकार और इंजेक्शन लगने के स्थान पर समस्याएं	बहुत आम है	इंजेक्शन लगने के स्थान में दर्द
	आम है	पाएरेक्सिया, अस्वस्थता, थकान, दर्द, कंपकंपी, इंजेक्शन के स्थान पर लालिमा, इंजेक्शन के स्थान पर सूजन, इंजेक्शन के स्थान पर कड़ापन, दुर्बलता, इंजेक्शन स्थल पर प्रुरिटस
मस्क्युलोस्केलेटल विकार और कनेक्टिव ऊतक संबंधी विकार	आम है	मांसपेशियों में दर्द, जोड़ों में दर्द
	आम नहीं है	एक्सट्रीमिटीज़ में दर्द, पीठ में दर्द, गर्दन में दर्द
तंत्रिका के विकार	आम है	सरदर्द
	आम नहीं है	सिर में चक्कर आना, उनींदापन
त्वचा और उपचर्म ऊतक संबंधी विकार	आम नहीं है	उर्टिकैरिया

भारत में अधिकृत टीकाकरण के बाद एकत्र की गई जानकारी का सक्षिप्त विवरण

भारत में **कोविशील्ड™** के नैदानिक परीक्षणों के दौरान निम्नलिखित प्रतिकूल प्रभाव नहीं देखे गए लेकिन भारत में **कोविशील्ड™** से अधिकृत टीका लगाए जाने के बाद उपयोग के दौरान अनायास इन लक्षणों की रिपोर्ट की गई हैं।

प्रतिरक्षा तंत्र के विकार: तीव्रग्राहिता के प्रभाव (आवृत्ति: बहुत ही गैरमामूली), अतिसंवेदनशीलता के प्रभाव (आवृत्ति: बहुत ही गैरमामूली)।

वाहिका विकार: कुछ मामलों में थ्रोम्बोसिस और थ्रोम्बोसाइटोपेनिया सिंड्रोम (टीटीएस) सहित थ्रोमबोसिस और थ्रोम्बोसाइटोपेनिया की गिनी-चुनी और गंभीर घटनाएं हुई हैं जिनमें से कुछ मामलों में रक्तस्राव होता पाया गया जिसकी आवृत्ति 1/70,000,000 से कम देखी गई है। इसमें शामिल है सेरेब्रल वेनस साइनस जैसे गैरमामूली स्थानो में वेनस थ्रोम्बोसिस तथा थ्रोम्बोसाइटोपेनिया के साथ आर्टीरियल थ्रोम्बोसिस से संबंधित मामले।(खंड 4.4 देखें)

रक्त और लिम्फैटिक (लसीका) तंत्र के विकार : थ्रोम्बोसाइटोपीनिया (आवृत्ति: बहुत गैरमामूली)

4.9 टीका अधिक मात्रा में देना

टीके के अधिक मात्रा में देने के बारे में अनुभव सीमित है।

अधिक मात्रा में ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक) के अधिक मात्रा में दिए जाने के लिए कोई विशिष्ट उपचार नहीं है। अधिक मात्रा में टीका दिए जाने पर व्यक्ति का निरीक्षण किया जाना चाहिए और लक्षणों के आधार पर जैसा उपयुक्त हो, वैसा उपचार किया जाना चाहिए।

5 औषधीय गुण

फार्माकोडायनामिक गुण

भेषज समूह: टीका, अन्य वाइरल टीके, एटीसी कोड: J07BX03

क्रिया का तंत्र

कोविशील्ड™ एक मोनोवेलेंट टीका है जो एकल पुनःसंयोजक से बना है। यह वेक्टर तकनीक पर आधारित चिंपांज़ी से लिए गए एडेनोवायरस है जो मानव शरीर में प्रतिकृति बनाने में सक्षम नहीं है और जो सार्स-कोव-2 स्पाइक (एस) ग्लायकोप्रोटीन से प्रभावित हैं। इस टीके को लगाए जाने पर सार्स-कोव-2 का एस ग्लायकोप्रोटीन स्थानीय रूप से व्यक्त होता है जो प्रतिकारक ऐंटीबॉडी के बनने को बढ़ावा देता है और कोशिकीय स्तर पर प्रतिरक्षा प्रतिक्रिया प्रेरित करता है।

विदेश में हुए अध्ययन से प्राप्त आकड़े और जानकारी के आधार पर प्रभावकारिता और प्रतिरक्षाजनत्व

रोग-विषयक प्रभावकारिता

COV001, COV002, COV003, और COV005 से एकत्र किए गए आकड़े और जानकारी का प्राथमिक विश्लेषण।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका [ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक)] का मूल्यांकन चार जारी, बिना किसी विशेष क्रम में अध्ययन टीके को देने वाले, ब्लाइंडेड (जिसमें प्राप्तकर्ता नहीं जानता की उसे अध्ययन टीका दिया जा रहा है या कंट्रोल टीका),नियंत्रित परीक्षणों से एकत्र किए गए आकड़े और जानकारी के आधार पर किया गया है: चरण I / II अध्ययन, COV001 (NCT04324606)), जो यूके में 18 से 55 वर्ष की उम्र के स्वस्थ वयस्कों पर किया गया; चरण II / III अध्ययन, COV002 (NCT04400838) जो यूके में 18 वर्ष या उससे अधिक उम्र के वयस्कों (बुजुर्गों सहित) पर किया गया; चरण III अध्ययन, COV003 (ISRCTN89951424) जो ब्राजील में 18 वर्ष या उससे अधिक उम्र के वयस्कों (बुजुर्गों सहित) पर किया गया; और चरण I / II का अध्ययन, COV005 (NCT04444674) जो दक्षिण अफ्रीका में 18 से 65 वर्ष की उम्र के वयस्कों पर किया गया। इन अध्ययनों में वो सभी व्यक्ति शामिल नहीं किए गए जिनको पहले से तीव्रग्राहिता या वाहिकाशोफ की समस्या थी; गंभीर और / या अनियंत्रित हृदय तथा रक्तवाहिकाओं संबंधी विकार थे, जठरांत्र, यकृत, वृक्क, अंतःस्रावी / चयापचय रोग थे और प्रतिरक्षा क्षमता कम होने के साथ-साथ तंत्रिका संबंधी रोग थे। COV001 और COV002 अध्ययनों में अनुमोदित मौसमी इन्फ्लूएंज़ा और न्यूमोकोक्कल टीके लगाने की अनुमति दी गई थी (अध्ययन टीके के लगाए जाने से कम से कम 7 दिन पहले या उसके बाद)। सभी सहभागियों की कोविड-19 रोग से टीके के कारण सुरक्षा और टीके की प्रभावकारिता का मूल्यांकन करने के लिए 12 महीने तक अनुवर्ती जाँच करते रहने की योजना है।

प्रभावकारिता के लिए एकत्रित विश्लेषण के लिए, 18 वर्ष या उससे अधिक उम्र के लोगों को कोविड -19 वैक्सीन ऐस्ट्रा ज़ेनेका (N = 8,597) या कंट्रोल (मेनिंगोकोकल टीका या सलाइन) (N = 8,581) की दो खुराकें दी गई थी। जिन प्रतिभागियों को बिना किसी विशेष क्रम के कोविड -19 टीका ऐस्ट्रा ज़ेनेका दिया गया उन्हें या तो दो मानक खुराक [एसडी] (5 × 10^{10} वीपी प्रति खुराक) या एक कम खुराक [एलडी] (2.2 × 10^{10} वीपी) मिली, उसके बाद एक एसडी (5 × 10^{10} वीपी) खुराक मांसपेशियों में दिए जाने वाले इंजेक्शन के रूप में दी गई। कुल अधिकांश सहभागियों (83.8%) को दो मानक टीके दिए गए। व्यवस्था संबंधी बाधाओं के कारण, खुराक 1 और खुराक 2 के बीच अंतराल 3 से 28 सप्ताह तक था जिसमें से 77.0% सहभागियों के लिए दोनों खुराकों के बीच अंतराल 4 से 12 सप्ताह तक का था।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके और कंट्रोल टीके के लिए आधारभूत जनसांख्यिकी उपचार समूहों में प्रायः एक समान थी। कुल मिलाकर जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका प्राप्त हुआ उनमें 91.8% लोगों की उम्र 18 से 64 वर्ष के बीच थी और 8.2% लोग 65 वर्ष या उससे अधिक उम्र के थे; 56.0% सहभागी महिलाएं थीं; 74.9% व्हाइट्स थे, 10.1% ब्लैक्स के थे और 3.7% एशियाई मूल के थे। कुल 3,056 (35.5%) सहभागियों को कम से कम एक पहले से मौजूद कोमोर्बिडिटी (बीएमआई 30 kg/m² या उससे अधिक, हृदय और रक्त वाहिका संबंधी विकार, श्वसन रोग या मधुमेह जैसी समस्याएं) थी। प्राथमिक विश्लेषण के समय अनुवर्ती जाँच के लिए औसत अवधि 1 खुराक के बाद 143 दिन थी और 2 खुराक के बाद 83 दिन थी।

कोविड-19 मामलों का अंतिम निर्धारण एक अधिनिर्णायक समिति द्वारा किया गया था, जिन्होंने डब्लुएचओ के नैदानिक प्रगति पैमाने के अनुसार रोग की गंभीरता को भी निर्धारित किया था। कुल 332 सहभागियों को टीके की खुराक 2 प्राप्त करने के 15 दिन या उसके बाद वायरोलॉजिकल रूप से पुष्टि (न्यूक्लिक एसिड एम्प्लीफिकेशन टेस्ट द्वारा) किए गए सार्स-कोव-2 के कारण कोविड-19 हुआ और उनमें कम से कम कोविड-19 का एक लक्षण (बुखार (37.8°C या उससे अधिक का तापमान), खाँसी, सांस लेने में तकलीफ, एनोसिमिया (सूँघने की शक्ति का नाश) या एजुसिया(स्वाद न महसूस होना)) दिखाई दिया और इन सब लोगों में पहले सार्स-कोव-2 के संक्रमण का कोई सबूत नहीं मिला। कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके ने कंट्रोल की तुलना में कोविड -19 होने की घटनाओं में काफी कमी आई (सारणी 2a देखें)।

सारणी 2a- COV001, COV002, COV003 और COV005[a] में कोविड-19 के खिलाफ कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की प्रभावकारिता

आबादी	कोविड-19 टीका ऐस्ट्रा ज़ेनेका		कंट्रोल		टीके की प्रभावकारिता % (95% सीआई)
	N	कोविड-19 मामलों की संख्या[b], n (%)	N	कोविड-19 मामलों की संख्या[b], n (%)	
आबादी का प्राथमिक विश्लेषण					
कुल (SDSD + LDSD)	8597	84 (0.98)	8581	248 (2.89)	66.73 (57.41, 74.01)
अनुमत टीके की मात्रा					
SDSD	7201	74 (1.03)	7179	197 (2.74)	63.09 (51.81, 71.73)

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; n =उन सहभागियों की संख्या जिनके साथ पक्के तौर पर घटना हुई थी; CI = विश्वास्यता अंतराल; LD = कम खुराक; SD = मानक खुराक

[a] प्राथमिक अध्ययन एंडपॉइंट18 वर्ष और उससे अधिक आयु के सहभागियों में पुष्टि किए गए कोविड -19 के मामलों पर आधारित था, जो आधाररेखा पर सेरोनिगेटिव थे, और जिन्हें दो खुराक (एसडीएसडी या एलडीएसडी) दी गई थीं और दूसरी खुराक प्राप्त करने के 15 दिन या उसके बाद अध्ययन में सहभागी थे।

[b] वायरोलॉजिकल रूप से पुष्टि किए गए सार्स-कोव-2 और कम से कम निम्न में से एक लक्षण: बुखार (37.8°C या उससे अधिक का तापमान), खाँसी, सांस लेने में तकलीफ, एनोसिमिया (सूँघने की शक्ति का नाश) या एजुसिया(स्वाद न महसूस होना)। अधिनिर्णायक समिति द्वारा पुष्टि की गई।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके की एक एसडी खुराक प्राप्त करने पर कोविड-19 से सुरक्षा के स्तर का आंकलन समन्वेशी विश्लेषण से किया गया जिसमें ऐसे सहभागी शामिल थे जिन्हें एक एसडी की खुराक दी गई थी। विश्लेषण में से उन सभी सहभागियों को उस समय पर हटा दिया गया था जब उन्हें टीके की दूसरी खुराक दी गई या प्रथम खुराक प्राप्त करने के 12 सप्ताह बाद। इस तरह की आबादी में, टीके की प्रथम खुराक प्राप्त करने के 22 दिन बाद, टीके की प्रभावकारिता 71.42% थी (95% CI: 51,11; 84,08 [कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका 18/9,335 की तुलना में कंट्रोल 63/9,312])।

समन्वेशी विश्लेषण ने दर्शाया है कि टीके की प्रभावकारिता बढ़ गई जब खुराकों के बीच अंतराल बढ़ाया गया, तालिका 2b देखें।

सारणी 2b- COV001, COV002, COV003 और COV005[a] में खुराक के बीच अंतराल के आधार पर कोविड-19 के खिलाफ कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की प्रभावकारिता

खुराकों के बीच अंतराल	कोविड -19 टीका ऐस्ट्रा ज़ेनेका		कंट्रोल		टीके की प्रभावकारिता % (95 % सीआई)
	N	कोविड-19 मामलों की संख्या[b], n (%)	N	कोविड-19 मामलों की संख्या[b], n (%)	
6 सप्ताह से कम	3,905	35 (0.90)	3,871	76 (1.96)	55.09 (33.0, 69.90)
6-8 सप्ताह	1,124	20 (1.78)	1,023	44 (4.30)	59.72 (31.68, 76.25)
9-11 सप्ताह	1,530	14 (0.92)	1,594	52 (3.26)	72.25 (49.95, 84.61)
12 सप्ताह या उससे अधिक	2,038	15 (0.74)	2,093	76 (3.63)	79.99 (65.20, 88.50)

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; n =उन सहभागियों की संख्या जिनके साथ पक्के तौर पर घटना हुई थी; CI = विश्वास्यता अंतराल;

[a] प्राथमिक अध्ययन एंडपॉइंट18 वर्ष और उससे अधिक आयु के सहभागियों में पुष्टि किए गए कोविड -19 के मामलों पर आधारित था, जो आधाररेखा पर सेरोनिगेटिव थे, और जिन्हें दो खुराक (एसडीएसडी या एलडीएसडी) दी गई थीं और दूसरी खुराक प्राप्त करने के 15 दिन या उसके बाद अध्ययन में सहभागी थे।

[b] वायरोलॉजिकल रूप से पुष्टि किए गए सार्स-कोव-2 और कम से कम निम्न में से एक लक्षण: बुखार (37.8°C या उससे अधिक का तापमान), खाँसी, सांस लेने में तकलीफ, एनोसिमिया (सूँघने की शक्ति का नाश) या एजुसिया(स्वाद न महसूस होना)। अधिनिर्णायक समिति द्वारा पुष्टि की गई।

कोविड-19 से पीड़ित होने के कारण अस्पताल में भर्ती और गंभीर कोविड-19 के खिलाफ प्रभावकारिता

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका कोविड-19 से पीड़ित होने के कारण अस्पताल में भर्ती (डब्लुएचओ सेवरिटि ग्रेडिंग ≥ 4) होने के मामलों में कमी लाता है।

कंट्रोल की तुलना में जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की दो खुराक प्राप्त हुई (SDSD + LDSD, ≥15 दिन दूसरी खुराक के बाद) उनमें 0 (N=8,597) जबकि कंट्रोल प्राप्त करने वाले लोगों में अस्पताल में भर्ती होने के 9 (0.10%; N=8,581) मामले रहे।

यह दर्शाता है कि टीके की प्रभावकारिता 100 % (97.5% CI: 50.19; मूल्यांकन नहीं किया जा सकता) है।

उपसमूहों में कोविड-19 के खिलाफ प्रभावकारिता

जिन सहभागियों में एक या उससे अधिक कोमॉर्बिडिटीज़ थीं, उनके लिए टीके की प्रभावकारिता 62.71% [95% CI: 44.79; 74.82]; कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका प्राप्त करने वालों (SDSD + LDSD, खुराक 2 प्राप्त करने के 15 दिन या उससे ज्यादा दिन के बाद, N=3,056) में कोविड-19 मामले 34 (1.11%) थे जबकि कंट्रोल प्राप्त करने वालों में (N=3,102) कोविड-19 के मामले 93 (3.00%) थे।यह समग्र आबादी में टीके के खिलाफ देखी गई प्रभावकारिता के समान ही थी।

65 वर्ष या उससे अधिक उम्र के सहभागी जिन्हें कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका (SDSD + LDSD, ≥15 दिन खुराक2 के बाद, N=703) दिया गया उनमें कोविड-19 से संक्रमित होने के 4 मामले हुए जबकि कंट्रोल टीका (N=680) प्राप्त करने वालों में 8 मामले पाए गए, जो दर्शाता है कि टीके की प्रभावकारिता 51.91% [95% CI: -59.98, 85.54] थी। वृद्ध वयस्कों के एक बड़े अनुपात (89.6%) ने अपनी पहली खुराक के <6 सप्ताह बाद अपनी दूसरी खुराक प्राप्त की। वृद्ध वयस्कों (≥65 वर्ष की उम्र) में, जिन्होंने पहली खुराक एसडी की प्राप्त की (≥22 दिन बाद खुराक 1 के), कोविड -19 टीका ऐस्ट्रा ज़ेनेका (N = 945) के लिए कोविड-19 के 6 मामले थे जबकी इसकी तुलना में कंट्रोल (N = 896) पाने वालों में कोविड-19 के 13 मामले थे, जहां पर कोविड -19 टीका ऐस्ट्रा ज़ेनेका प्राप्त करने वालों में अस्पताल में भर्ती होने वाले 0 मामले थे और कंट्रोल समूह में 2 मामलों में अस्पताल में भर्ती कराने की जरूरत पड़ी (डब्ल्यूएचओ की गंभीरता ग्रेडिंग के अनुसार ≥4)।

D8110C00001 से प्राप्त डेटा का प्रभावकारिता विश्लेषण

संयुक्त राज्य अमरीका, पेरू और चिली में आयोजित चरण III के बिना किसी विशेष क्रम के दिए कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके के नैदानिक परीक्षण में इस टीके का मूल्यांकन किया गया है। इस परीक्षण में 32,451 स्वस्थ वयस्कों या ऐसे 18 वर्ष या उससे ज्यादा उम्र के लोग जो मेडिकल रूप से स्टेबल दीर्घकालिक बीमारियों से पीड़ित हैं, उन्हें बिना किसी विशेष क्रम के खुराक दी गई। इस अध्यय में वो सभी व्यक्ति शामिल नहीं किए गए जिनको पहले से गंभीर और / या अनियंत्रित हृदय तथा रक्तवाहिकाओं संबंधी विकार थे, जठरांत्र, यकृत, वृक्क, अंतःस्रावी / चयापचय रोग थे और गंभीर रूप से प्रतिरक्षा क्षमता कम होने के साथ-साथ तंत्रिका संबंधी रोग थे। सभी सहभागियों की कोविड-19 रोग से टीके के कारण टीके की प्रभावकारिता का मूल्यांकन करने के लिए 1 साल तक अनुवर्ती जाँच करते रहने की योजना है।

अद्यतन की गई प्राथमिक प्रभावकारिता विश्लेषण में 26,212 प्रतिभागियों को कोविड -19 टीका ऐस्ट्रा ज़ेनेका (N=17,662) मिला या फिर कूटभेषज (N=8,550) मिला। जिन प्रतिभागियों को बिना किसी विशेष क्रम के कोविड -19 टीका ऐस्ट्रा ज़ेनेका दिया गया उन्हें दिन 1 और दिन 29 (-3 से लेकर +7 दिनों तक) पर मांसपेशिय इंजेक्शन के रूप में (5 × 10^{10} वीपी प्रति खुराक) दी गई। दोनों खुराकों के बीच अंतराल औसत रूप से 29 दिनों का था और अधिकांश प्रतिभागियों को खुराक 1 दिए जाने के बाद दूसरी खुराक ≥26 से लेकर ≤36 दिनं (95.7% और 95.3% क्रमशः) के बीच दी गई।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके और कूटभेषज टीके के लिए आधारभूत जनसांख्यिकी उपचार समूहों में प्रायः एक समान थी। कुल मिलाकर जिन सहभागियों को कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीका प्राप्त हुआ उनमें 79.1% लोगों की उम्र 18 से 64 वर्ष के बीच थी और 20.9% लोग 65 वर्ष या उससे अधिक उम्र के थे, 43.8% प्रतिभागी महिलाएं थीं। जिन लोगों को बिना किसी विशेष क्रम के टीका दिया गया उनमें 79.3% व्हाइट्स थे, 7.9% ब्लैक्स थे और 4.2% एशियाई मूल के थे; 4.2% अमरीकी इंडियन या अलास्का के मूल निवासी थे,0.3% हवाई या अन्य प्रशांत द्वीप वासी, 2.4% कई भिन्न जातियों के लोग थे (1.7% की जातियता का पता नहीं था या उनकी जाती की जानकारी नहीं दी गई थी)। कुल 10,376 (58.8%) सहभागी जिन्हें कोविड -19 टीका ऐस्ट्रा ज़ेनेका दिया उनमे और कूटभेषज टीका पाने वालों में 5,105 (59.7%) को कम से कम एक पहले से मौजूद कोमोर्बिडिटी थी। विश्लेषण के समय अनुवर्ती जाँच के लिए औसत अवधि खुराक 2 के बाद 61 दिन थी।

कोमोरबिडिटी को क्रोनिक किडनी रोग, क्रॉनिक ऑब्सट्रक्टिव पल्मोनरी रोग (सीओपीडी), एक ठोस अंग प्रत्यारोपण के कारण कम प्रतिरक्षा स्वास्थ्य, मोटापा होना (बीएमआई> 30), हृदय की गंभीर बीमारी, सिकल सेल रोग, टाइप 1 और 2 मधुमेह, अस्थमा, मनोभ्रंश, मस्तिष्कवाहिकीय रोग, सिस्टिक फाइब्रोसिस, उच्च रक्तचाप, यकृत रोग, फेफड़ों में घाव (ल्मनरी फाइब्रोसिस), थैलेसीमिया, धूम्रपान का इतिहास के रूप में परिभाषित किया गया था।

कोविड-19 मामलों का अंतिम निर्धारण एक अधिनिर्णायक समिति द्वारा किया गया था। कुल मिलाकर 203 सहभागियों में दूसरी खुराक दिए जाने के 15 दिन या उसके बाद सार्स-CoV-2 की विरोलॉजिकल रूप से पुष्टि की गई और वे मानदंड A या मानदंड B को पूरा करते पाए गए तथा इनमें सार्स-CoV-2 से पहले कभी संक्रमित होने का कोई सबूत नहीं मिला

श्रेणी A: निम्नलिखित में से एक या उससे ज्यादा:

- छाति के एक्स-रे, या कम्प्यूटेड टोमोग्राफी स्कैन से पता किया गया निमोनिया
- 94% या उससे कम का ऑक्सीजन सैचुरेशन सामान्य हवा में या सप्लिमेंटरी ऑक्सीजन की जिसे जरूरत हो या फिर सप्लिमेंटरी ऑक्सीजन पर जो हो और उसकी सप्लाई को बढ़ाना पड़े।
- नई या बढ़ती सांस की तकलीफ /सांस फूलना

श्रेणी B: निम्नलिखित में से दो या उससे ज्यादा:

- 100°F (>37.8°C) से ज्यादा बुखार या बुखार सा महसूस होना
- नई या बढ़ती खांसी
- माइयागलिया/मांसपेशियों में दर्द
- थकान जो रोज़मर्रा की जिंदगी को बाधित करती है
- उल्टी और/या दस्त (एंडपॉइंट परिभाषित करने के लिए दोनों में से केवल एक को गिना जाए)
- एनोसिमिया (सूँघने की शक्ति का नाश) और/या एजुसिया(स्वाद न महसूस होना) (एंडपॉइंट परिभाषित करने के लिए दोनों में से केवल एक को गिना जाए)

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका टीके से कूटभेषज की तुलना में कोविड -19 होने की घटनाओं में काफी कमी आई (सारणी 3 देखें)।

सारणी 3- कोविड-19 के खिलाफ कोविड-19[a] वैक्सीन ऐस्ट्रा ज़ेनेका की प्रभावकारिता

	कोविड -19 टीका ऐस्ट्रा ज़ेनेका		कूटभेषज		टीके की प्रभावकारिता % (95 % सीआई)
	N	कोविड-19 मामलों की संख्या[b], n (%)	N	कोविड-19 मामलों की संख्या[b], n (%)	
अध्यतन की हुई प्राथमिक प्रभावकारिता विश्लेषण[c]					
लक्षणात्मक बीमारी	17,662	73 (0.4)	8,550	130 (1.5)	73.98 (65.34, 80.47)
प्रमुख सेकेन्डरी प्रभावकारिता विश्लेषण					
पहले हुए कोविड-19 संक्रमण के सबूत के बावजूद लक्षणात्मक बीमारी	18,563	76 (0.4)	9,031	135 (1.5)	73.68 (65.13, 80.13)
गंभीर या क्रिटिकल लक्षणात्मक कोविड-19[d]	17,662	0 (0.0)	8,550	8 (< 0.1)	100.0 (71.62, NE)[e]
कोविड-19 आपातसेवा विभाग में विज़िट	17,662	1 (< 0.1)	8,550	9 (0.1)	94.80 (58.98, 99.34)
SARS-CoV-2 के उपचार के बाद की प्रतिक्रिया	17,662	156 (0.9)	8,550	202 (2.4)	64.32 (56.05, 71.03)

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; n =उन सहभागियों की संख्या जिनके साथ पक्के तौर पर घटना हुई थी; CI = विश्वास्यता अंतराल;

[a] 18 वर्ष और उससे अधिक आयु के सहभागियों में पुष्टि किए गए कोविड -19 के मामलों के आधार पर, जो लोग आधाररेखा पर सेरोनिगेटिव थे, और जिन्हें दो खुराक दी गई थीं और दूसरी खुराक प्राप्त करने के 15 दिन या उसके बाद अध्ययन में सहभागी थे।

[b] श्रेणी A और श्रेणी B के मानदंडों को इस्तेमाल करते हुए वायरोलॉजिकल रूप से पुष्टि किया गया सार्स-कोव-2 ।

[c] अद्यतन किए गए प्राथमिक डेटा में सभी प्रकांड निर्णायन घटनाएं शामिल थीं।

[d] प्रयोगशाला द्वारा पुष्टि किए गए कोविड-19 और निम्न में से कोई भी समस्या के आधार पर: आराम करने की स्थिति में नैदानिक संकेत गंभीर प्रणालीगत बीमारी का संकेत देते हैं (श्वसन दर 30 सांस प्रति मिनट, हृदय गति ≥ 125 बीट प्रति मिनट, ऑक्सीजन सैचुरेशन ≤ 93% कमरे की हवा में समुद्र स्तर पर, या सांस से अंदर ली गई ऑक्सीजन के अनुपात में ऑक्सीजन का आंशिक दबाव <300 mmHg); या सांस न ली जा सके (उच्च प्रवाह ऑक्सीजन, गैर-हस्तक्षेपीय वेंटिलेशन, मैकेनिकल वेंटिलेशन, या एक्स्ट्राकोर्पोरियल मेम्ब्रेन ऑक्सीजनेशन की आवश्यकता के रूप में परिभाषित), शॉक का सबूत (सिस्टोलिक रक्तचाप <90 मिमीएचजी, डायस्टोलिक रक्तचाप <60 मिमीएचजी या वैसोप्रेसर्स की आवश्यकता); या गंभीर गुर्दे, यकृत, या तंत्रिका का डिस्फंक्शन; या इन्टेन्सिव केयर यूनिट में भर्ती, या मृत्यु।

[e] 97.5%CI

[f] आधाररेखा पर निगेटिव जो अध्ययन हस्तक्षेप के साथ उपचार के बाद पॉजिटिव हुआ

पूर्व-निर्दिष्ट प्राथमिक प्रभावकारिता विश्लेषण में, 190 निर्णायन मामलों के आधार पर, कोविड -19 टीका ऐस्ट्रा ज़ेनेका (N = 17,817) प्राप्त करने वाले प्रतिभागियों में 65 (0.4%) और कूटभेषज टीका (N=8,589) प्राप्त करने वालों में 125 (1.5%) कोविड-19 के मामले थे जो दर्शाता है कि टीके की प्रभावकारिता 76.0%, [95% CI 67.6, 82.2] है।

जब वायरल शेडिंग की संचयी घटनाओं की जांच खुराक -2 दिए जाने के 15 दिनों या उसके बाद की गई तो लार के नमूनों में सार्स-कोव-2 के मौजूद न होने के मामलों में देखा गया कि कोविड -19 टीका ऐस्ट्रा ज़ेनेका प्राप्त करने वाले प्रतिभागियों की लार में सार्स-कोव-2 के मौजूद रहने की अवधि काफी कम थी (11 बनाम 16 दिन)।

उपसमूहों में कोविड-19 के खिलाफ प्रभावकारिता

जिन सहभागियों में एक या उससे अधिक कोमॉर्बिडिटीज़ थीं, जिनको कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका दिया गया उनमें खुराक 2 प्राप्त करने के 15 दिन या उससे ज्यादा दिन के बाद, टीके की प्रभावकारिता 75.24% (64.18, 82.88) थी जिन लोगों में किसी प्रकार की कोमॉर्बिडिटीज़ नहीं थी उनमें टीके की प्रभावकारिता 71.81% (95% CI: 55.5, 82.14) थी।

65 वर्ष या उससे अधिक उम्र के सहभागी जिन्हें कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका (≥15 दिन खुराक के बाद, N=3,696) दिया गया उनमें कोविड-19 से संक्रमित होने के 5 मामले हुए जबकि कूटभेषज टीका (N=1,812) प्राप्त करने वालों में 14 मामले पाए गए, जो दर्शाता है कि टीके की प्रभावकारिता 83.51% [95% CI: -54.17, 94.06] थी।

प्रतिरक्षाजनत्व

COV001, COV002, COV003, और COV005 से एकत्र किए गए आकड़े और जानकारी का प्राथमिक विश्लेषण।

कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका से टीकाकरण के बाद, जो सहभागी आधाररेखा पर सेरोनिगेटिव थे, उन में से 98% या उससे अधिक सहभागियों ने पहली खुराक प्राप्त करने के 28 दिन बाद और 99% से अधिक सहभागियों ने दूसरी खुराक प्राप्त करने के बाद सेरोकन्वर्शन (जो एस-बाइंडिंग एंटिबॉडी में आधाररेखा से 4 गुना या उससे अधिक वृद्धि के द्वारा मापा गया) दर्शाया। खुराकों के बीच अंतराल के बढ़ने से अधिक एस-बाइंडिंग ऐंटिबॉडीज देखी गई थीं (सारणी 4)।

आमतौर पर ऐसी ही प्रवृत्तियाँ प्रतिकारक ऐंटिबॉडी और एस-बाइंडिंग ऐंटिबॉडी के विश्लेषण करने पर देखी गई।

कोविड-19 से सुरक्षा का प्रतिरक्षा संबंधी सहसंबंध स्थापित नहीं हुआ है; इसलिए, कोविड-19 से सुरक्षा प्रदान करने वाली प्रतिरक्षा प्रतिक्रिया का स्तर अज्ञात है।

सारणी 4 - कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका के प्रति सार्स कोव-2-एस-बाइंडिंग ऐंटिबॉडी की प्रतिक्रिया[a,b]

आबादी	आधाररेखा	खुराक 1 के 28 दिन बाद	खुराक 2 के 28 दिन बाद
	जीएमटी (95% CI)	जीएमटी (95% CI)	जीएमटी (95% CI)
कुल	(N=1538) 57.1 (53.8, 60.6)	(N=1466) 8358.0 (7879.2, 8866.0)	(N=1511) 30,599.8 (29,137.1, 32,135.9)
खुराकों के बीच अंतराल			
6 सप्ताह से कम	(N=578) 61.4 (55.3, 68.0)	(N=578) 8,184.5 (7,423.9, 9,023.1)	(N=564) 21,384.2 (19,750.7, 23,152.8)
6-8 सप्ताह	(N=339) 56.1 (49.6, 63.3)	(N=290) 9,103.9 (8,063.1, 10,279.1)	(N=331) 28,764.8 (25,990.8, 31,834.9)
9-11 सप्ताह	(N=331) 53.6 (47.5, 60.4)	(N=309) 8,120.9 (7,100.2, 9,288.4)	(N=327) 37,596.1 (34,494.2, 40,976.8)
12 सप्ताह या उससे अधिक	(N=290) 54.3 (47.6, 61.9)	(N=289) 8,249.7 (7,254.5, 9,381.4)	(N=289) 52,360.9 (47,135.2, 58,165.9)

N = प्रत्येक समूह में मौजूद सहभागियों की संख्या; GMT = जियोमेट्रिक मीन टाइटर; CI = विश्वास्यता अंतराल; S = स्पाइक

[a] मल्टिप्लेक्स इम्यूनऐसे प्रयोग करके प्रतिरक्षा प्रतिक्रिया मापी गई है।

[b] सहभागी आधाररेखा पर सेरोनिगेटिव थे।

उन सहभागियों में जिन्हें एक या उससे अधिक कोबॉर्बिडिटी थीं, उनमें प्रतिरक्षा प्रतिक्रिया समग्र आबादी में पाई गई प्रतिरक्षा प्रतिक्रिया के अनुरूप थी।

उच्च सेरोकन्वर्शन दर देखी गई जब 65 वर्ष या उससे अधिक उम्र के वयस्कों में पहली मानक खुराक (SD) (97.3% [N=149, 95% CI: 93.3; 99.3]) और दूसरी मानक खुराक (SD)(100.0% [N=156, 95% CI: 97.7; मूल्यांकन संभव नहीं]) प्राप्त कर चुके थे। अधिकांश अधिक उम्र के वयस्क सहभागियों के लिए दोनों खुराकों के बीच अंतराल 6 सप्ताह से कम था। अधिक उम्र के वयस्क सहभागियों के लिए दोनों खुराकों के बीच अंतराल 6 सप्ताह से कम (दूसरी एसडीके 28 दिन बाद : GMT=18759.6 [N=126, 95% CI: 15,764.8; 22,323.3]) उन सभी सहभागियों के समान थी जिन्हें दूसरी खुराक पहली खुराक दिए जाने के 6 सप्ताह के भीतर दी गई (सारणी 3)। 65 वर्ष या उससे अधिक उम्र के सहभागियों के लिए दोनों खुराकों के बीच अंतराल 6 सप्ताह से कम था जिसके कारण संख्यात्मक रूप से कम दिखे।

आधाररेखा (GMT=10,979.1 [N=36; 95% CI: 6,452.7; 18,680.5]) पर पूर्व सार्स-कोव-2 संक्रमण के सेरोलॉजिकल सबूत वाले सहभागियों में, एस-एंटीबॉडी टाइटर खुराक 1 के 28 दिन बाद(GMT=139,010.4 [N=35; 95% CI: 95,429.0; 202,495.1) शीर्ष पर पहुँचे, लेकिन खुराक 2 के बाद यह और नहीं बढ़े।

IFN-ϒ एन्ज़ाइम लिंक्ड इम्यूनोस्पोट (ईएलआईस्पॉट) एसे से मापी गई स्पाइक-विशिष्ट टी सेल प्रतिक्रिया कोविड-19 वैक्सीन ऐस्ट्रा ज़ेनेका की प्रथम खुराक दिए जाने के बाद प्रेरित हुई। विभिन्न उम्र के वर्गों में और कोमॉर्बिडिटी हो या न हो, जियॉमेट्रिक औसत प्रतिक्रिया सामान्य तौर पर एक समान ही रही। दूसरी खुराक प्राप्त करने के बाद इनमें और बढ़त नहीं होती है। Th1 साइटोकिन्स कोविड-19 ऐस्ट्रा ज़ेनेका द्वारा प्रेरित होते हैं जिसके कारण IFN-ϒ, IL-2, और / या TNFα व्यक्त करते हैं जो आमतौर पर आयु श्रेणियों के बीच समान होते हैं।

भारत में हुए अध्ययन से प्रतिरक्षाजनत्व संबंधी आकड़े:

आईजीजी ऐंटिबॉडी का स्पाइक (एस) प्रोटीन के खिलाफ GMT आधाररेखा पर समूहों के बीच बराबर सी थी - दिन 1। दोनो समूहों में टीके की प्रत्येक खुराक के बाद GMT काफी ज्यादा बढ़ गई और बराबर सी थी। दिन 57 को दोनो समूहों में > 98% सेरोकन्वर्शन था। प्रतिरक्षाजनत्व आकड़े दर्शाते हैं कि ऐंटि -एस आईजीजी ऐंटिबॉडी टाइटर और सेरोकन्वर्शन दर के संबंध में **कोविशील्ड™** और कोविड -19 टीका ऐस्ट्रा ज़ेनेका टीके समान हैं (सारणी 5 और 6 देखें)।

सारणी 5 ऐंटि-एस आईजीजी ऐंटिबॉडी का संक्षिप्त विवरण

विशिष्ट समय	आकड़े	कोविशील्ड™ (N=297) n (%)	कोविड-19 टीका ऐस्ट्रा ज़ेनेका (N=98) n (%)
आधाररेखा	N GMT 95% CI	297 95.4 (78.1, 116.6)	98 79.4 (58.2, 108.4)
खुराक 1 के बाद 28 दिन	N GMT 95% CI	296 10045.4 (8473.2, 11909.2)	98 6660.8 (4836.3, 9173.7)
खुराक 2 के 28 दिन बाद	n GMT 95% CI	293 30245.6 (26794.0, 34141.8)	95 28558.3 (23479.3, 34735.8)

सारणी 6 ऐंटि-एस आईजीजी ऐंटिबॉडी के लिए सेरोकन्वर्शन हुए सहभागियों के अनुपात का संक्षिप्त विवरण

विशिष्ट समय	आकड़े	कोविशील्ड™ (N=297)	कोविड-19 टीका ऐस्ट्रा ज़ेनेका (N=98)
खुराक 1 के 28 दिन बाद	N मूल्यांकन किए हुए सेरोकन्वर्शन, n (%) 95% CI	296 286 (96.6) (93.9, 98.4)	98 90 (91.8) (84.5, 96.4)
खुराक 2 के 28 दिन बाद	N मूल्यांकन किए हुए सेरोकन्वर्शन, n (%) 95% CI	293 287 (98.0) (95.6, 99.2)	95 94 (98.9) (94.3, 100.0)

5.2 फार्माकोकाइनेटिक (भेषज बलगतिकी) गुण

लागू नहीं है।

5.3 प्रीक्लीनिकल सुरक्षा आकड़े

विषाक्तता और स्थानीय सहिष्णुता संबंधी अध्ययन

चूहों को जब खुराक को दोहराने के लिए कोविड -19 टीका ऐस्ट्रा ज़ेनेका टीका मांसपेशिय इंजेक्शन के रूप में दिया गया तो उसे सहनीय पाया गया। टीके को मांसपेशीय इंजेक्शन के रूप में लगाए जाने पर इंजेक्शन लगाए जाने के स्थान पर सबक्यूटेनियस टिशु और स्केलिटल मांसपेशियों तथा पास की सायटिका तंत्रिका में गैर-प्रतिकूल, मिश्रित और/या मोनोन्यूक्लियर सेल सूजन और जलन देखी गई जो कि प्रत्याशित निष्कर्षों के अनुरूप थी। स्वास्थ्य लाभ प्राप्त करने के बाद इंजेक्शन लगाए जाने के स्थान पर या सायटिका तंत्रिका में कुछ असामान्य नहीं दिखा, जो दर्शाता है कि कोविड -19 टीका ऐस्ट्रा ज़ेनेका टीका लगाए जाने के बाद पूर्ण रूप से ठीक हो जाता है और सूजन तथा जलन खत्म हो जाती है।

प्रजनन के लिए विषाक्तता

चूहों में किए गए बायोडिस्ट्रिब्यूशन अध्ययनों ने कोविड-19 टीका ऐस्ट्रा ज़ेनेका टीके के मांसपेशीय इंजेक्शन के बाद गोनाड्स (वृषण, अंडाशय) पर टीके के कोई महत्वपूर्ण प्रभाव नहीं देखे गए ।

एक प्रजनन और विकास विषाक्तता अध्ययन में पाया गया कि कोविड-19 टीका ऐस्ट्रा ज़ेनेका ने पूर्व-संभोग, गर्भधारण या स्तनपान अवधि के दौरान मातृ जोखिम के बाद मातृ या विकासात्मक विषाक्तता को प्रेरित नहीं किया। इस अध्ययन में, टीके ने एंटी-सार्स-कोव-2 एस-ग्लाइकोप्रोटीन मेटर्नल एंटीबॉडी को भ्रूण और पिल्लों में पाया गया, जो क्रमशः प्लेसेंटल और लैक्टेशनल ट्रांसफर का संकेत देता है।

6. ऑषधीय विवरण

6.1 टीके में मौजूद निष्क्रिय पदार्थों की सूची

एल-हिस्टिडीन

एल-हिस्टिडीन हाइड्रोक्लोराइड मोनोहाइड्रेट

मेग्नीशियम क्लोराइड हेक्साहाइड्रेट

पॉलिसॉर्बेट 80

इथेनॉल

सुकरोज़

सोडियम क्लोराइड

डायसोडियम इडेटेट डायहाइड्रेट (ईडीटीए)

इंजेक्शन के लिए पानी

(निष्क्रिय सामग्री के नाम भौगोलिक क्षेत्र के हिसाब से अलग-अलग हो सकते हैं)

6.2 किन टीकों या दवाओं के साथ इसे दिया जा सकता है

अन्य चिकित्सीय उत्पादों के साथ इसके दिए जाने के संबंध में अध्ययन परिणाम न होने के कारण, इस टीके को अन्य चिकित्सीय उत्पादों के साथ नहीं मिलाया जाना चाहिए।

6.3 शेल्फ़-लाइफ

लेबल औऱ पैकेजिंग पर इन टीकों को इस्तेमाल करने की अंतिम तारीख लिखी हुई है।

एक बार खुलने पर, बहु-खुराक वायल जितनी जल्दि व्यावहारिक रूप से संभव हो, इसतेमाल हो जानी चाहिए और जब इन्हें +2°C से +25°C के बीच स्टोर किया जाए तो 6 घंटों के भीतर इन्हें इस्तेमाल किया जाना चाहिए। कोविशील्ड™ के खोले गए सभी बहु-खुराक वायलों को टीकाकरण सत्र के अंत में या फिर खोले जाने के छः घंटों के भीतर (जो भी पहले हो) फेंक देना चाहिए।

6.4 स्टोर करने संबंधी विशेष एहतियात

फ्रिज में इसे स्टोर करें ((+2°C से +8°C के बीच) इसे जमने न दें। प्रकाश से बचा कर रखने के लिए इन वायलों को बाह्य कार्टन में रखें। अगर टीका जम जाए, तो उसे फेंक दें।

खुली हुई बहु-खुराक वायल (पहले इस्तेमाल के बाद)

ऑषधीय उत्पाद को पहली बार खोलने के बाद स्टोर करने के बारे में जानने के लिए खंड 6.3 देखें।

6.5 पात्र का प्रकार और उसकी सामग्री

कोविशील्ड™ प्रयोग के लिए तैयार रूप में रबड़ - ढक्कन वाले बहु-खुराक वायल और एकल खुराक वायल के रूप में नीचे सूचिबद्ध रूपों में सप्लाई किया जाता है।

1 खुराक - 0.5 ml प्रति वायल

2 खुराक - 1.0 ml प्रति वायल

5 खुराक - 2.5 ml प्रति वायल

10 खुराक - 5.0 ml प्रति वायल

20 खुराक - 10 ml प्रति वायल

6.6 प्रयोग, संभालने और निपटान संबंधी निर्देश

टीका देने का तरीका

कोविशील्ड™ बेरंग या हल्के भूरे रंग का साफ या फिर हल्का अपारदर्शी, कण-रहित घोल है। टीका देने से पहले दृष्टिगत रूप से उसका निरीक्षण करें और अगर उसमें कणिकीय पदार्थ दिखे या फिर जैसा वर्णन किया गया है, उससे कुछ अलग दिखे तो टीके को फेंक दें।

वायल को हिलाएं नहीं

टीके की 0.5 ml की खुराक सिरिंज में खींच कर मांसपेशिय इंजेक्शन लगाया जाता है। प्रत्येक व्यक्ति के लिए अलग अलग विसंक्रमित सुई और सिरिंज प्रयोग करें। यह आमतौर पर होता है कि अंतिम खुराक निकालने के बाद भी वायल में थोड़ा तरल पदार्थ बचा रहता है। जब लो डेड वॉल्यूम सिरिंज और / या सूई प्रयोग की जाती हैं तो वायल में बचे हुए टीके की मात्रा एक और टीका के लिए पर्याप्त हो सकती है। ध्यान दिया जाना चाहिए कि 0.5 ml की पूरी खुराक दी जाए। अगर वायल में बचे टीके से 0.5 ml की पूरी खुराक नहीं दी जा सकती तो इंजेक्शन को फेंक देना चाहिए। अलग अलग वायलों में अंत में बचे टीके को एकत्र न करें।

इस टीके में कोई प्रेज़रवेटिव (परिरक्षक) नहीं है। टीका लगाने के लिए खुराक निकालते समय रोगाणुमुक्त तकनीक इस्तेमाल की जानी चाहिए।

पहली बार खोले जाने पर, बहु-खुराक वायल जितनी जल्दि व्यावहारिक रूप से संभव हो, इसतेमाल हो जानी चाहिए और जब इन्हें +2°C से +25°C के बीच स्टोर किया जाए तो 6 घंटों के भीतर इन्हें इस्तेमाल किया जाना चाहिए। इस्तेमाल के बाद बचा हुआ टीका फेंक दें।टीके के विवरण पता करना सुविधाजनक हो, इसके लिए प्रत्येक प्राप्तकर्ता को दिए जा रहे टीके का नाम और बैच संख्या रिकॉर्ड किया जाना चाहिए।

निपटान

कोविशील्ड™ में आनुवांशिक रूप से परिवर्तित जीव हैं (जीएमओ)। किसी भी अप्रयुक्त टीके या अपशिष्ट पदार्थ का स्थानीय आवश्यकताओं के अनुसार निपटान किया जाना चाहिए। छलकाव होने पर उपयुक्त ऐंटिवायरल डिस्इन्फेक्टेंट (जैसे कि हाइड्रोजेन परऑक्साइड आधारित डिस्इन्फेक्टेंट) से उसे रोगाणुमुक्त किया जाना चाहिए।

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FAQs on COVID-19 Vaccines and Vaccination Program

A. GENERAL

1. Which COVID-19 vaccines are licenced and used in the country at present for COVID Vaccination?

Three vaccines that have been granted authorization for restricted use in emergency situation by the Central Drugs Standard Control Organization (CDSCO) in India are Covishield® (AstraZeneca's vaccine manufactured by Serum Institute of India), Covaxin® (manufactured by Bharat Biotech Limited) and Sputnik V (developed by Gamaleya Research Institute, Russia), which is the third vaccine to get approval from the Drugs Controller General of India (DCGI).

2. 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.

3. 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. As of January 2021, nine COVID-19 vaccines were in emergency use in numerous countries around the globe.

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

Both the Indian COVID-19 vaccines and the Russian vaccine Sputnik V have conducted their phase I, II & III trials. Covishield® has completed its Phase III trials in UK and the bridging trial in India.

5. 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)

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

COVID-19 affects all age groups, however, the morbidity & mortality is several times higher in adults particularly in those above the age of 50 years. Children have either asymptomatic or mild infection.

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. The currently available vaccines in the country have not been evaluated in children so far. There are some clinical trials now underway to test the effectiveness and safety of the COVID 19 vaccines in children.

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 developed by Gamaleya Institute in Russia and is working closely with Dr Reddy's Laboratories for Gam-COVID-Vac Combined vector 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.

3. All three vaccines require cold chain temperature. How is the cold chain been maintained during storage and transportation of vaccine?

The two vaccines (Covishield & Covaxin) need to be stored and transported at $+2^0$ to $+8^o$ 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 (minus eighteen degrees centigrade) or below. The deep freezers are available under Universal Immunization Programme across the country for storage of this vaccine.

4. Is COVISHIELD® same as the vaccine been given 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.

5. What is the dose schedule of the vaccines under the national vaccination program?

As per the permission granted by the Drugs Controller General (India), the dose schedule is as follows:

- Covishield®: two doses, an interval of 12-16 weeks
- Covaxin®: two doses at an interval of 4-6 weeks

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. The beneficiary can choose to get vaccinated with a particular vaccine at a particular CVC of his/her choice.

7. General Indications of COVID-19 vaccine:

a. **Authorized Age Group:** COVID-19 vaccination is indicated only for people aged 18 years and above.

b. **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 injection may be provided.

c. **Interchangeability of COVID-19 vaccines is not permitted**: As per the available global evidence till now, second dose should also be of the same COVID-19 vaccine which was administered as the first dose.

C. EFFICACY & PROTECTION

1. Developing a vaccine takes years. But 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 which used to take several months have been fast-tracked. 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 step.

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. So, 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 which 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.

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 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?

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.

6. Which vaccine is better between Covishield® / Covaxin®/Sputnik V

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 preventing the infection as well as prevent a person from going into severe state of the disease. As a long-term effect, it would be preventing death for elderly people or those who have co-morbidities.

7. 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®, COVAXIN®, SPUTNIK V.

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 have been reported following vaccination with this vaccine but without the causal relationship establishment.

   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. No other vaccine-related serious adverse effects have been reported.

   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

2. **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.
      iv. Persons with any serious general illness requiring hospitalization or ICU case should also wait for 4-8 weeks before getting COVID-19 vaccine.

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

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

In case of minor adverse effects such as injection site pain, tenderness, malaise, pyrexia, etc., paracetamol tablet may be used to alleviate the symptoms.

4. Should you avoid alcohol after receiving the COVID-19 vaccine?

As per experts, there is no evidence of alcohol impairing the effectiveness of the vaccine.

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 too for e.g. polio and measles. None of the available 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 use only after their safety and efficacy is assured.

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

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

7. Do I need to get myself tested before taking the vaccine?

No there is no requirement for screening of the vaccine recipient by Rapid Antigen Test (RAT) prior to COVID-19 vaccination.

E. PRECAUTIONS

1. What precautions do I need to take after receiving the vaccine?

COVID-19 vaccines are safe but in case of any discomfort or complaint, the beneficiary should 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. The maximum benefit of getting the COVID vaccine is for those who have such co-morbidities. However, if you are concerned for any specific reason, please consult your doctor.

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.

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. For them, vaccines are absolutely safe.

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 vaccinator should have a record of one's 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.

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.

- <u>Individuals who are yet to receive COVID vaccine</u>
    - Persons having laboratory test proven SARS-CoV-2 illness should defer the COVID 19 vaccination till 12 weeks after recovery
- <u>Individuals who have received at least the first dose and develop SARS-CoV-2 infection before completion of the dosing schedule</u>
    - Such individuals should wait for 12 weeks after clinical recovery from the COVID illness

7. Is the vaccine contraindicated in person with chronic diseases?

Chronic diseases and morbidities like the Cardiac, neurological, pulmonary, 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. Any other serious illness requiring hospitalization/ICU care should also wait for 4-8 weeks before getting the next COVID-19 vaccine.

F. FOLLOW-UP & BOOSTER

1. Is it important for me to receive the same vaccine during second dose?

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

2. How long I will remain protected?

The duration of protection is yet to be established.

3. Will this require any repeated vaccination or booster dose after the 2nd dose in future?

The requirement of booster dose is yet to be determined.

4. Will I get any certificate that I am vaccinated?

Yes, a provisional certificate would be provided after the first dose of the vaccine. On completion of the second dose, the vaccine recipient will receive a message on completion of schedule which would include a link to download digital certificate of vaccination for your perusal. This certificate can then be saved in the digi-locker.

5. 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).

Symptoms occurring within 20 days after receiving any COVID 19 vaccines
(Recipient should report to the health facility where vaccine was administered)

- 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
- Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache)
- 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.

G. 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.

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 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. Nearly 88% of all COVID deaths in the country have been reported in the age group of 45 years and above. Starting 1st May, 2021 the eligible age for vaccination was expanded to cover all adults above 18 years.

From 21st June 2021, Revised Guidelines for Implementation of National COVID Vaccination Program came into effect under which Government of India is procuring COVID-19 vaccines and providing it free of cost to States/UTs Government. The domestic vaccine manufacturers can provide upto 25% of their monthly vaccine production directly to private hospitals. All citizens irrespective of their income status are entitled to free vaccination. Those who have the ability to pay are encouraged to use private hospital's vaccination centres.

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. Presently, they have started vaccination of younger population.

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 now COVID-19 vaccination is available to all adults. 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 CoWIN platform, the backbone of vaccine delivery which is a very citizen friendly platform, is being 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. Will COVID vaccination be available for eligible citizens at Public as well as Private facilities?

Yes, vaccination can be availed at government or private COVID Vaccination Centre (CVC) as per convenience. The nearest CVC can be located on Co-WIN portal and appointment can be booked as per the choice of CVC.

8. Is there a difference in registration process at private and at public facilities?

There is no difference between registration process for vaccination at Public & Private CVCs. In both cases, beneficiaries need to register on Co-WIN. The various modes of registration include:

- Online registration and appointment
- On-site or walk-in registration and vaccination of either single individual or groups of individual (such as those who do not have access to internet or smart phones) at COVID-19 Vaccination Centre (CVC)
- Registration at Common Service Centres (CSCs)
- Assisted registration through National COVID-19 Helpline (1075)/State Integrated Helplines

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

COVID-19 vaccination is available free of cost to all citizens aged 18 years and above at government CVCs. Those who have the capacity to pay may approach COVID Vaccination Centres at private hospitals. The price of different vaccine products at private CVC may differ and will be dynamic as per vaccine pricing offered by the manufacturers, which will be declared by each vaccine manufacturer. The private hospitals may charge upto a maximum of Rs 150 per dose as service charge. The price of vaccination would also be displayed on CoWIN portal and would be visible to citizens at the time of seeking online appointment.

H. COVID-19 VACCINATION IN PREGNANT AND LACTATING WOMEN

1. Is it safe to get COVID vaccine during pregnancy?

The vaccines being used under the national vaccination program are found to be safe and effective. Based on how these vaccines work in the body, experts believe they are unlikely to pose a risk for people who are pregnant. The National Technical Advisory Group on Immunization (NTAGI) has recommended that "pregnant women may take any one of the two Covid-19 vaccines and lactating women are also eligible for jabs at 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's important that pregnant women make an informed choice.

2. Are risks of Covid vaccination more than benefits for a pregnant /lactating woman?

No, the very real benefits of vaccinating pregnant and lactating women seem to far outweigh any theoretical and remote risks of vaccination. Lactating women are also considered for Covid vaccine as there are no known adverse effects on the neonate who is breastfeeding. In fact, there is a possibility of passage of protective antibodies to the child, which may have a beneficial effect.

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. What effect will COVID -19 have on my baby if I am diagnosed with the infection?

It has been seen that most (over 95%) of the newborns of COVID-19 mothers have been in good condition at birth. Current evidence suggests that if you have the virus it is unlikely to cause problems with your baby's development.

6. 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 in the market in India or globally. Historically, vaccines are being provided to pregnant women such as tetanus and diphtheria which are safe. Therefore, there is no 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. The COVID19 vaccination reduces the risk of serious disease in those with co-morbid conditions

7. 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.

8. I am a pregnant / lactating mother. Is it mandatory to take COVID-19 vaccine?

COVID-19 vaccination is not mandatory, however, you can make an informed choice regarding receiving the vaccine. The Health Care Worker or doctor would brief you about COVID-19 vaccines and its benefits.

9. If I take COVID-19 vaccine during pregnancy, would it have any abnormal effect on the baby?

Currently, there is no evidence that shows COVID-19 vaccine administration affects the feotus/baby. The manufacturers of mRNA vaccines have done DART studies, which didn't show any safety issues, and the post marketing surveillance data did not show any safety signals in pregnancy.

10. Are there any additional risks with COVID-19 vaccination if taken during pregnancy or lactation?

No, based on reported risks from the general population, any additional risk during pregnancy or lactation is likely to be rare. As such, no such reports have emerged.

11. I have recently got COVID-19 vaccination. Can I plan for pregnancy?

Yes, you can plan for pregnancy as per your choice.

12. Does COVID-19 vaccine have any detrimental effect on pregnancy outcome?

Currently, there is no evidence that shows COVID-19 vaccine administration increases miscarriage rates or affects pregnancy outcome. It protects against serious COVID19 disease in pregnancy.

13. My pregnancy was confirmed recently and I want to take COVID-19 vaccine. What is the best time to get the Covid vaccine?

COVID-19 vaccine can be taken any time during pregnancy as per recommendation of the National Technical Advisory Group on Immunization (NTAGI).

14. 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.

15. I am convinced to take COVID-19 vaccine during my pregnancy, but how should I proceed?

You can register on the Co-WIN portal and schedule your vaccination appointment as per your convenience, through website-https://www.cowin.gov.in/home . There is also option of onsite registration in the Government and private covid vaccination centers. You could call at 1075 to assist you on the process.

16. Are the body immune responses following COVID-19 vaccination in a pregnant or lactating woman same as in non-pregnant person?

Yes, pregnant and lactating women elicit comparable vaccine induced humoral immune responses as in non-pregnant persons. Vaccine-generated antibodies are also present in umbilical cord blood and breast milk after maternal vaccination.

17. Will I experience any side effects after vaccination?

Yes and No**.** Side effects are variable after vaccination but there is no reason to think that the vaccine will have worse side-effects in pregnant women. These effects are usually similar to side effects in non-pregnant women, and usually are not serious and do not require any specific medical attention except symptomatic relief.

18. What are the common side effects after vaccination?

Commonly seen minor side-effects may be immediate in the form of pain at injection site, sweating and nausea. In the first seven days, the vaccine may even cause fever, fatigue, myalgia, arthralgia, local pain, swelling, redness, rash and diarrhea. Please consult your doctor immediately if fever or other symptoms persist.

19. Which vaccines should I take if I am pregnant?

National Technical Advisory Group on Immunization (NTAGI) recommends that pregnant women may take any one of the two Covid-19 vaccines (Covishield or Covaxin). You must consult your doctor about the choice of vaccine in particular case. Both COVISHIELD and COVAXIN can be used during pregnancy or lactation.

20. 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 district immunization officer for guidance.

21. Can women who are on contraception courses and women planning for pregnancy get vaccinated?

Yes, women on contraceptives can certainly get vaccinated. Pregnant women fall in the vulnerable group in terms of risk of serious disease in case of exposure. It might be safer for them to be fully immunized before she conceives.

22. 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.

23. What should pregnant woman consider before getting the vaccine?

Expectant woman may consider to discuss the following with their doctor/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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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.

*****

ANNEXURE P-9

KEM Hospital 1

KEM Hospital 2

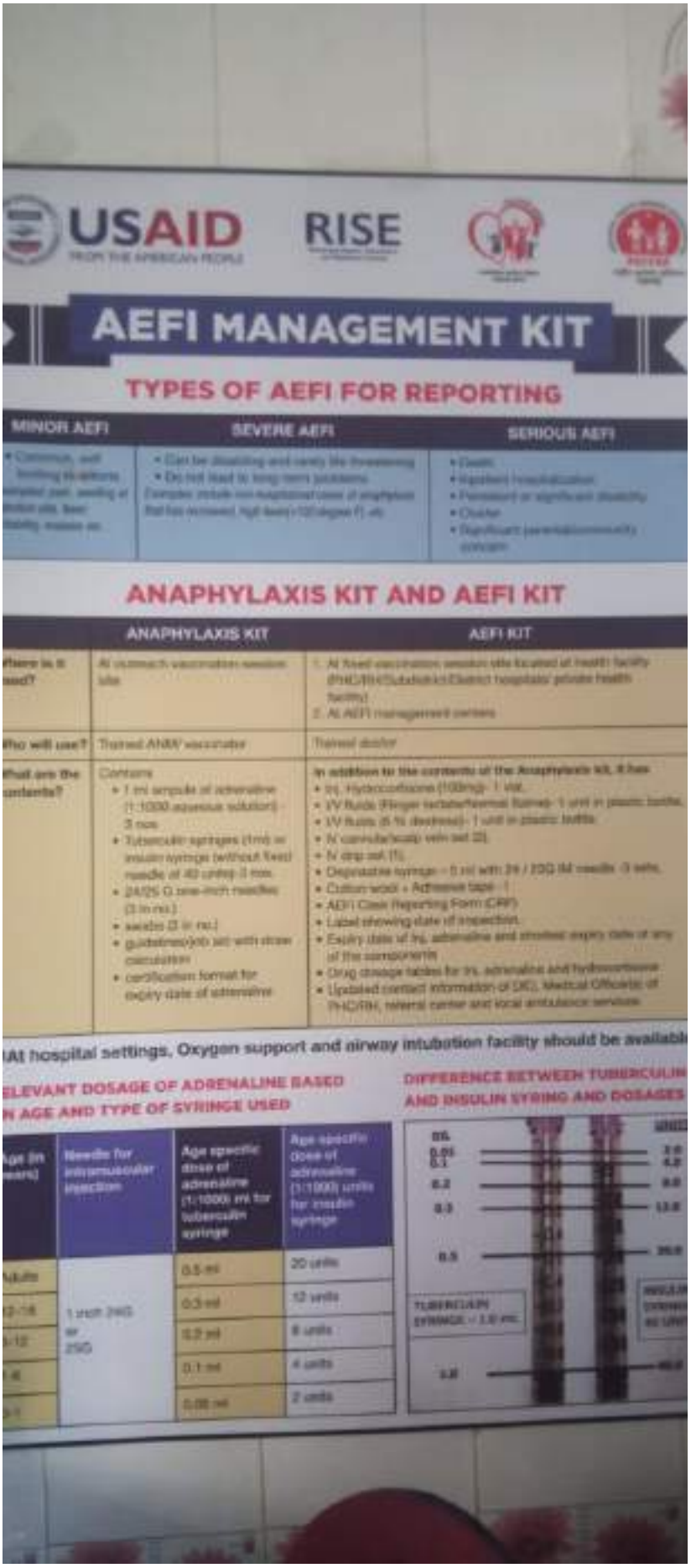
KEM Hospital 3

KEM Hospital 4

KEM Hospital 5


COVID-19 Vaccine is safe!
Be ready for COVID Vaccination! Follow the prescribed process for vaccination.
Helpline No.: 1075 (Tollfree)
When we are safe
Nation is safe!

KEM Hospital 6



Civil Hospital 1

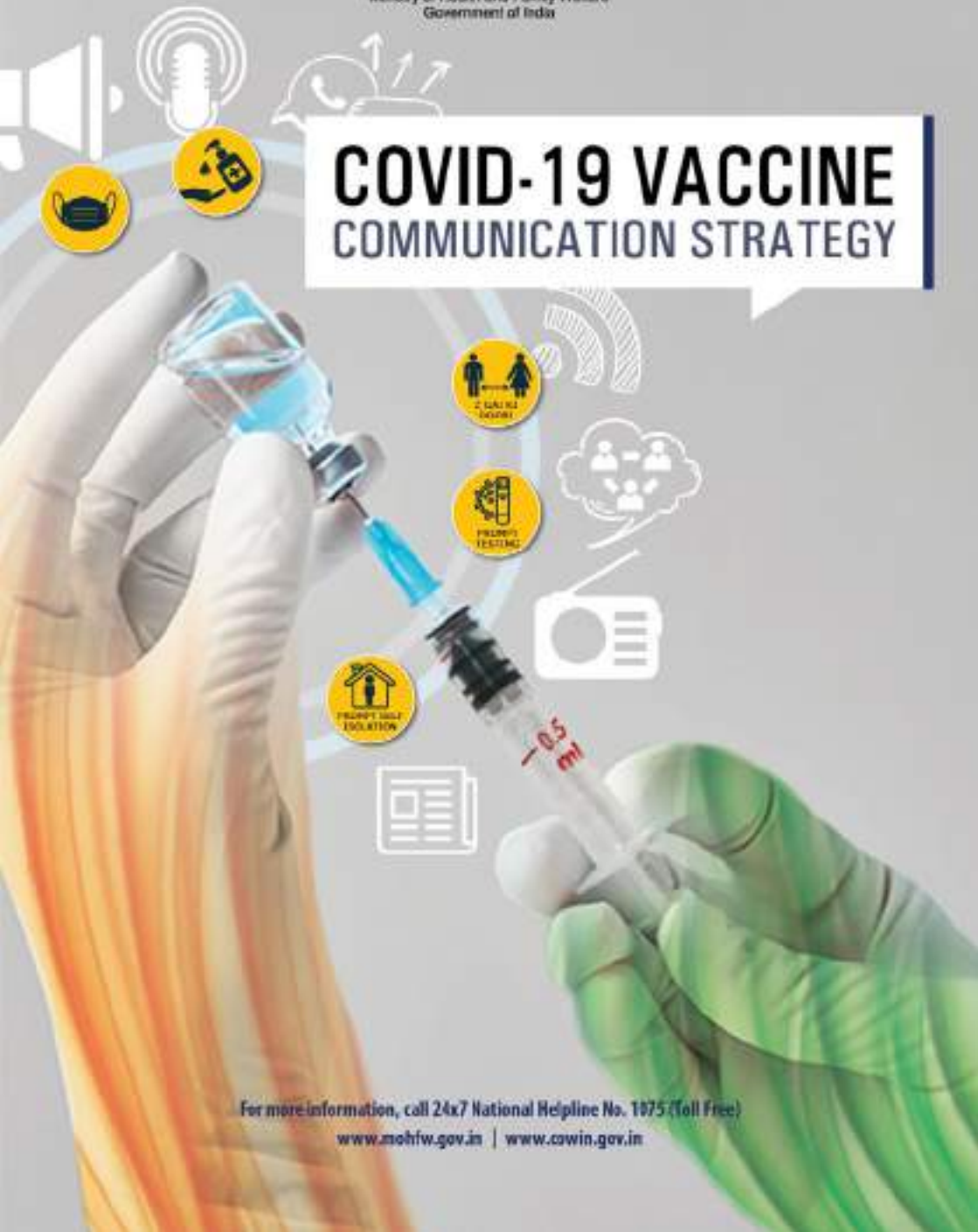
Civil Hospital 2

ANNEXURE P-10

Help us to help you

Ministry of Health and Family Welfare
Government of India

COVID-19 VACCINE
COMMUNICATION STRATEGY



For more information, call 24x7 National Helpline No. 1075 (Toll Free)

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

COVID-19 VACCINE
COMMUNICATION STRATEGY

Contents

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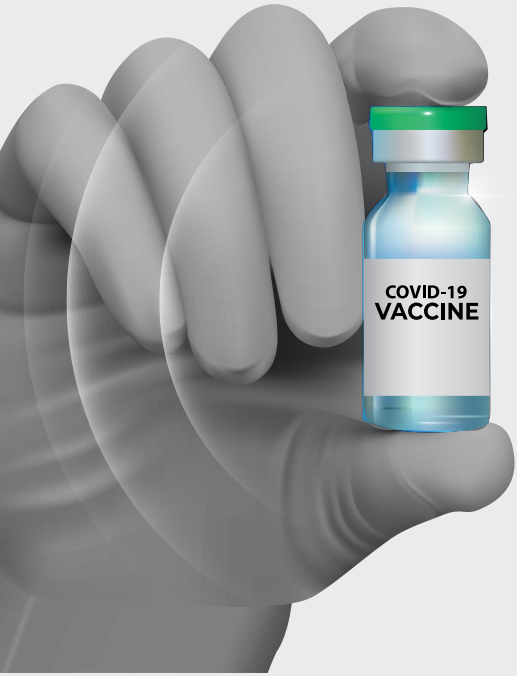
Introduction

The communication strategy that supports the COVID-19 vaccines rollout in India seeks to disseminate **timely, accurate and transparent information about the vaccine(s) to alleviate apprehensions about the vaccine, ensure its acceptance and encourage uptake**.

The strategy will also serve to guide national, state and district level communication activities, so that the information on the COVID-19 vaccines and vaccination process reaches all people, across all states in the country.



To support and encourage appropriate uptake of the vaccines by:

- Managing and mitigating any potential disappointment expressed by unmet demand for the vaccine or **'eagerness'** amongst people.
- Addressing vaccine **'hesitancy'** that could arise because of apprehensions around vaccine safety, efficacy; and any other myths and misconceptions.
- Provide information on potential risks and mitigate unintended **crisis** (e.g. AEFI clusters, delay in vaccine rollout for certain population categories) during the introduction and rollout.

The strategy also seeks to build trust and enable greater confidence in the COVID-19 vaccine amongst all people by employing transparency in communication, while also managing any mis/disinformation and rumours around it.

This will be achieved by:

1 Using the social influence or endorsements from experts and official voices to:

- a Spell out the process of immunization (where, how, who, when - date and time)
- b Emphasize on the safety and efficacy of vaccines
- c Explain the decision to conduct the drive in a phased manner

2 Establishment of a National Media Rapid Response Cell (NMRRC) at MoHFW to:

- a Ensure preparedness through media monitoring and social listening and respond in real time
- b Unfold media and public discourse, through extensive monitoring of print, electronic and digital media

3 Involving community mobilizers and frontline workers to engage with the community at various levels:

- a Through community consultations, faith leaders and religious meetings
- b Engaging youth, civil-society organizations, self-help groups
- c Panchayats and other community-based platforms

There are **Four Key Areas** that will be addressed as part of interventions under the strategy:

By using an integrated advocacy, communication and social mobilization strategy nationwide, four key areas will be addressed as shown below:

Information on the new COVID-19 vaccine: Provide prompt, simple and focused communication on the COVID-19 vaccine(s) and vaccination processes

Vaccine Hesitancy: Build public confidence on the safety and efficacy of the new vaccine

Vaccine Eagerness: Ensure understanding and acceptance of the phased and prioritized approach to overcome concerns of the population waiting for vaccination

COVID Appropriate Behaviours: Maintain and sustain key preventive behaviours: wearing masks, maintaining physical distance and hand washing with soap

The communications approach will further steer the spirit of the Prime Minister of India through Jan Andolan or people's movement such that citizens feel confident to engage and participate in the vaccination process. COVID Appropriate Behaviours (CAB) must be followed not just during and after vaccination but even otherwise, and also by the people not getting the vaccination in the initial phases.

1. Objectives of the COVID-19 Vaccine Communication Strategy

- Ensure that all eligible groups receive the vaccine with confidence
- All people get correct information and are not influenced by mis/disinformation, myths or misconceptions
- Hesitancy of public is addressed on the COVID-19 vaccination process
- Provide correct, consistent and timely information on the new COVID-19 vaccine(s) (availability, safety, and timelines) and vaccination processes
- Generate awareness and understanding of the phased approach of prioritizing target groups
- Address low-risk perception of the infection amongst people and build an enabling environment to adopt and maintain COVID appropriate behaviours to reduce any risks of infection

2. Target Audiences

All citizens; vaccine eager and vaccine hesitant groups; with a focus on priority for people to be vaccinated in the first phase – health care workers, frontline functionaries, people over 50 years of age and people under 50 years with co-morbidities.

National media including traditional and digital media, which will disseminate correct/factual information by proactively addressing any mis/disinformation or incorrect messaging.

Civil society organizations, professional bodies including hesitant groups, medical fraternity, social influencers and youth platforms & networks.

Elected representatives like MPs, MLAs including panchayat representatives.

Academia, alternative medicine practitioners, traditional healers, naturopaths, homeopaths etc.

3. Information on COVID – 19 Vaccines

Information on vaccines will clarify:

- **The vaccine has gone through various trials and is safe**
- **Eligibility criteria and vaccination process**
- **Where to access the vaccine**
- **Process of registration and pre-conditions for vaccination**
- **Post vaccination care and support**

3.1 Vaccine Eagerness (VE)

There is significant keenness amongst the public as people have been waiting for the COVID-19 vaccine so that they are able to get back to their normal life. It is therefore important to:

1. Acknowledge that there might be a degree of vaccine eagerness but people will have to wait to get vaccine access, based on the defined prioritization criteria
2. Refer to key messages (shared as annexures with this document) and communication package addressing the potential for vaccine eagerness and engaging people to support the vaccination rollout
3. Share accurate information, consistently with general public and those waiting for the vaccine to address any knowledge gaps
4. Advocate for and refer to reliable sources of information (MoHFW website and official social media handles), and proactively manage any mis/ disinformation or fake news

3.2 Vaccine Hesitancy (VH)

Suggested actions to tackle and address any concerns of vaccine hesitant and resistant groups:

- Community engagement with credible communication approaches for each target group to build trust in vaccines
- Identify traditionally known vaccine-hesitant and resistant areas/groups/communities, based on prior experience. Orient credible influencers from local communities to build their trust and acceptance
- Develop articles with support from influencers about the safety and efficacy of the COVID-19 vaccine in national, state and regional media
- Use articles and research in support of the vaccine, scientific explanations and clips of credible influencers during interaction with the hesitant groups
- Create a pool of editors who will write and share opinion editorials in national, state and regional media
- Ensure real-time, round-the-clock monitoring of digital media to facilitate appropriate and timely action to address hesitancy

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INDIVIDUALS/ INFLUENCERS *

CELEBRITY

Entertainment Industry, Sport, Politics

INFLUENCERS

Local Leaders, Faith Leaders, Social-cultural Leaders, Panchayat Leaders, Teacher

FRONTLINE WORKERS

Supervisor, AWW, ANM, ASHA

COMMUNITY GROUPS *

COMMUNITY GROUPS

DAY-NRLM, Gram Sabha, School Management Committee, Children's School Cabinet, NSS, NYKS, Scouts & Guides, Cooperatives

MEDIA **

SOCIAL MEDIA

Twitter, Facebook, WhatsApp, Youtube

COMMUNITY MEDIA

Nukkad Nataks+Local Folk Songs, Drama, Dance, Story-telling, Leaflet

MASS MEDIA

DTH, Cable TV Networks, Television, Radio, Mobile, Print

OUTDOOR MEDIA

Wall Paintings, Hoardings, Bus Panels, LED Scroll, Poster, Banner

TOOLS/MATERIALS FOR EACH TYPE OF PLATFORM

* Games, Songs, Prayers, Pledge, Posters, Flipbooks, Dialogue Cards/Interpersonal Communication Videos, Interactive Radio Programmes

** Tweets, Videos, Messages, Scripts, Folk Song Lyrics, Stories, Community Radio Programmes, TV Programmes, Radio Programmes, TV commercials, Radio spots, Ringtone, Mobile Games, Prototype Designs of Wall Painting, Hoarding, Bus Panels, LED Scrolls

To achieve a wide reach for the messages and in order to get a greater degree of engagement from all target audiences, a wide variety of trusted sources and communication channels and platforms will be leveraged in both urban and rural areas. Each platform will have specific communication tools and materials for activation, mobilization and broadcast.

4.1 Key Components of the Advocacy Strategy

Advocacy efforts will aim to engage the maximum number of people by promoting the benefits of COVID-19 vaccine and support in building an enabling environment. Various stakeholders and experts will lead the advocacy campaigns at national, state and district level. These include (but are not limited to):

- **Hon'ble PM, Parliamentarians**
- **Ministry of Health and Family Welfare and Line Ministries in the Central Government and their field-level networks**
- **Professional bodies IMA, doctors and health workers, alternate medicine practitioners, Rotary and Lions Club**
- **National and local media representatives**
- **Public and private sector companies**
- **Development partners, Civil Society, Community Based Organizations**
- **Religious/faith-based leaders**

4.1.1 Key Actions at **National Level**

At the national level, the following advocacy actions will be implemented:

- Development of advocacy package- FAQs, leaflets, factsheet, multimedia material, along with their language versions
- Adequate preparation for the launch of the vaccine, by holding pre-launch sensitization events with journalists; develop media kits
- Organizing inter-ministerial meeting/ briefing on the COVID-19 Vaccine Communication Strategy and vaccination process to ensure that all political and bureaucratic leadership is reinforcing the same messaging
- Sharing communication materials and messages for efficient use of platforms owned by the above-mentioned influential voices
- Leveraging national and state-owned media agencies for organizing advocacy activities
- Publishing opinion pieces, organizing interviews and discussions with scientists, experts and other credible voices
- Implement Standard Operating Procedures (SOPs) for AEFI management, spokespersons' training, preparedness, rumour management, planning for press releases and conferences

4.2 Capacity Building of Key Stakeholders

Since the vaccine for COVID-19 is new, it will be important to orient and train all those stakeholders who will be responsible for the implementation of communications actions, in both urban and rural areas. Communications training will be carried out in line with the training modules that have been developed to plan and implement communications actions at all levels. States will be required to identify training mechanisms to reach the extensive network of frontline workers, health care providers, community based volunteers, influencers and other stakeholders in remote areas to ensure outreach to the last mile, while also ensuring an equal focus on the urban areas.

The following cadres will be trained to support the implementation of the communications plan:

- **IEC Officers of government departments at National, State and District levels**
- **Development partners**
- **Key Officials from ministries of Panchayati Raj, Human Resource Development, Urban Development, Youth, Women & Child Development, Railways, Labour among others**
- **CSOs, CBOs, FLWs, Influencers, Youth Networks, Volunteers, PRIs and, SHGs**
- **Staff of COVID-19 National and State Helpline Call Centres (1075 & 104)**

4.3 Strengthening Mass Media, Social Media, Engaging International Media, Social Mobilization and Community Engagement

For the COVID-19 Vaccination rollout, media and social media will play a critical role in creating and influencing perceptions across the wider public.

Media engagement will involve activities at the national, state and district levels; customized for different audience segments in the three phases – pre-vaccine introduction, during vaccine rollout and post vaccine introduction.

Key Stakeholders

- Media houses at the national level
- News channels at national, state and regional levels
- Senior editors and health, education and business journalists
- Media from regional dailies and local dailies

4.3.1.1 Key Actions at **National Level**

- Establishing a National Media Rapid Response Cell at MoHFW
  - Development of Co-WIN dashboard to monitor communication actions

National Media Rapid Response Cell (NMRRC)

A National Media Rapid Response Cell has been set up at MoHFW, to enable both proactive engagement as well as rapid response to news in traditional media and social media, especially during crisis. The National Media Rapid Response Cell will enable real-time monitoring and tracking of the large volume of conversations on the theme of COVID-19 vaccination. It will capture the pulse of the discussion across the country by extensive and constant monitoring of topics related to vaccine eagerness, vaccine hesitancy and any misreporting or false information regarding COVID-19 vaccine.

Print, electronic and digital media platforms will be monitored, including national media as well as nationally representative state and language media to enable coordination in rapid response across messages, media and channels for appropriate response management.

A similar Rapid Response Cell (RRC) is recommended to be set up at the State level, supported by the Ministry of Health and Family Welfare and Information& Broadcasting.

The cell will do fact-checking, draft rejoinders, collate, advise and share key messages which will be disseminated by PIB/designated media unit of MoHFW.

A real-time digital media dashboard, and overall social media monitoring will also be managed by the NMRRC. The cell will have live data feeds and digital media visualizations that will provide a clear view of the real-time conversations and themes that are emerging from the public discourse. It will also have linkages with the designated State Nodal Officers, as well as field staff to get updated information from the states and any on-ground information that might not otherwise be captured through its monitoring tools. Further, the NMRRC will also be integrated very closely with the AEFI (Adverse Event Following Immunization) and crisis management unit being managed by the Immunization Technical Support Unit (ITSU).

- The NMRRC will be managed by senior professionals from traditional and new media agencies. These cells will alert MoHFW on news/social media reports with designated MoHFW officials, Ministry of Information and Broadcasting, other Line Ministries and state focal points for all external and internal communication in the pre, during and post phase rollout of the vaccine. The cell will also proactively develop simulations for possible scenarios and activate set-up for probable emergent responses on crisis and negative media.

Proactive messaging

Building a positive media narrative

- Media sensitization, including radio, community radio at national and regional levels
- Positive op-eds, articles by experts, scientists, influencers, in national and state media
- Clear and simple content, debunking myths correcting and factually incorrect information to be shared with media as fact sheets / updates
- Hold regular media briefings or share press notes to help drive the discussion and proactively address gaps

Approved key messages and FAQs to guide the messages, talk points, collateral and creative content

Work closely with positive voices and influencers, national and regional, to enhance messages and address any negatives

Connect with platforms such as Facebook/Google/ Twitter to leverage them positively

Incorporate any fake news/ mis/disinformation or AEFI crisis into the messaging to strengthen the discourse and evolve the narrative

Building a positive public discourse

- Create attractive messaging for use across various social media platforms
- Develop short videos (under 60 secs.), GIFs, simple explainers to enable easy understanding among urban and rural audiences
- Develop social media toolkits regularly and share with partners for wider reach and dissemination. Also identify and address handles that spread anti-vaccine narratives
- Leverage influencer networks to amplify the core messages and clarify any doubts or negatives.

- The cell will also maintain a repository of all key briefings and statements made by the Prime Minister, Parliamentarians, Ministers, and Secretaries to maintain consistent messaging across the campaign. A central mailbox will also be created so that the cell has a standard, centralized and easy access for anyone who needs to share or request any information.
- Tracking information on print and eletronic media across all regions

- Creating a pool of editors for Op-Eds / articles at the national / international level. Development of articles with support from influencers about safety and efficacy of COVID-19 vaccine.
- Conducting regular media engagement to amplify key messages and leverage existing PIB platforms for media.
- Engaging influencers, celebrities for interviews, short videos and gifs on key messages, to counter negative media
- Engaging Google, Facebook, WhatsApp and Telegram to amplify positive messages and information and nip rumors through chatbots and tracking of social media
- Development of positive stories and testimonials from beneficiaries on the vaccine

4.3.1.2 Key Actions at **State Level**

- Establishing a Communication Response Room at State level, on the lines of NMRRC
- Engaging media to establish vaccine confidence, share positive examples of vaccine acceptance
- Engaging State Information and Public Relations Department and their field staff through Ministry of I&B
- Working with scriptwriters to incorporate messaging on prioritized and hesitant groups
- Engaging state level influencers for interviews, short videos and opinion articles
- Development of positive stories and testimonials from beneficiaries on the vaccine
- Leveraging regional, local media and online news, community radio stations, to reach the underserved and marginalized groups

4.5 Managing Crisis Emerging from AEFI, or Otherwise

Any crisis resulting from vaccine eagerness issues, vaccine hesitancy barriers and AEFI, will be managed by rapid response and adequate preparation for managing a crisis, should it emerge. The following are some of the possible crisis scenarios:

- **Vaccine Eagerness:**
  Given the context of the pandemic, people have been eagerly waiting for a vaccine. It is expected that once the vaccine is available there will be a huge demand to access it, which may lead to unrest.
- **Vaccine Hesitancy:**
  On the other hand, there could be vaccine hesitancy – a possible result of rumours, plain indifference or misinformation from anti-vaccination groups. Further, certain geographies or communities might continue to resist accepting the vaccine owing to their long-standing aversion to vaccination.
- Protests/unrest as a result of rumours and misinformation about the vaccine.
- Sudden AEFI deaths or reactions.
- Logistics issues, delay in delivery and other local triggers.
- Pressure from lobby groups – educational institutes, corporates asking for prioritization.
- AEFI situation and associated reactions, logistics issues plus other local triggers to be pre-empted and be prepared to respond Pressure from lobby groups – Educational institutes, Corporates asking for prioritization.

The key actions required at the national, state and district level are outlined below:

Annexure D: Detailed Media Engagement Plan

Annexure D/1:

Media Engagement Plan for COVID-19

For the success of the COVIID-19 vaccine rollout, media needs to be brought on-board as an ally and be engaged as a strong stakeholder to provide much-needed information, allay fears, establish public confidence and encourage right behaviours. Not engaging with media could fan emotions, rumours and undermine vaccine confidence.

Media needs to be engaged at four levels:

- Media advocacy for it to be a strong ally.
- Capacity-building of media
- Media engagement workshops before the launch of the vaccine and at critical stages of the vaccine campaign
- Routine media outreach

Media Advocacy:

Advocacy with heads of media organizations (CSOs, editors, heads of media institutes, whatsapp group administrators etc) along with educational and business heads to inform and build their understanding for greater media support for the smooth COVID-19 vaccine rollout. It can also strengthen trust between media and public health officials; help gain media buy-in into the programme and create sustained space for a positive discourse on the vaccine. It can take shape of small roundtable discussions/one- on ones.

Capacity Building of Media:

Enhancing the capacity of media on evidence-based reporting is needed. Backed by data and facts to address potentially widespread misinformation is critical and can pre-empt any misinformation and negative reporting leading to a crisis. Media also depend on public health officials for timely and accurate information and regular sharing of specific facets of the campaign during different phases of the vaccine rollout is essential. This capacity building may be done through online/ hybrid workshops (refer to annexure on Training Plan).

Media Engagement Workshops:

The pre-launch workshop should ideally be held at least two weeks before the rollout of the campaign at the National and State level. Engage with the regional media to reach the underserved and marginalized groups. The workshops should focus on information about the need for the vaccine, its safety and efficacy, emphasis on evidence-based reporting and the need to address both vaccine eagerness, hesitancy and Covid Appropriate Behaviours CAB. Share positive examples of COVID Warriors, bust myths and rumours. Health officials from the Government, UNICEF, WHO, medical professionals and other programme partners could address the media and establish early communication between media and spokespersons.

Routine media outreach:

Ensure regular media outreach through virtual/ facilitated media field visits of the media on safety measures implemented as well as on the efficacy of the vaccines. Share positive field stories and photographs and short videos of the beneficiaries. Continue stories of CAB and positive experiences in the post-vaccination phase.

Media Monitoring and Analysis

Media monitoring and analysis of vaccine related public sentiment over time can help the COVID-19 vaccination programme to tailor more effective and timely strategies to address specific public concerns. Hence, it is important to make media monitoring central to the media engagement plan through:

- Media monitoring, including television, mainstream print, and social media
- Ongoing exchange of information with the key partners, thinktanks and State health departments, business houses, educational institutes and partners

Documentation:

Document all press mentions/releases, achievements, lessons learnt from the media engagement/advocacy and media engagement activities at the National, State and district levels. High-resolution pictures with consents and testimonials must be shared with media for positive stories, stories of COVID warriors/ champions and overall media coverage.

Action Plan for Media Engagement

Responsible Persons @ National level: Secretary (Health), AS (Health), ADG (PIB), MoI&B, JS-IEC, MoHFW

Responsible Persons @ State level: Secretary (Health) Mission Director, SEPIO, State IEC Officer

Responsible Persons @ District level: District Magistrate / Collector / DIO / IEC Officer

Preparation

- Maintain an updated list of print and electronic media journalists covering health (local, National, International) with contact information.
- Maintain a list of technical experts and influencers who can be roped in to write positive articles/Op-eds
- Leverage existing strategic relationships with media houses, digital media as well as citizen journalists
- Ensure that all information packages are constantly updated.
- An information package may contain the following documents in both hard copy and e-copies:
  - Frequently asked questions (FAQs); fact sheet or a technical brief on COVID-19, including the burden of the disease, background information on expected side-effects, given that this is a dynamic field with ongoing research.Recent updates/statistics
  - Contact addresses of spokespersons (domain experts).

Remember: Share information specific to media characteristics:

- Local media are read and believed by more people in the community than the national media
- National media has a wide reach and and more influence over national agendas
- International media can influence national agendas
- Social media is all-pervasive and influences media and vice-versa

Six Steps to an Effective Media Communication	
STEP 1: Assess media needs, media constraints, and internal media-relations capabilities	Assess the needs of the media Assess the constraints of the media Assess internal media-relations capabilities, assign dedicated staff for the same
STEP 2: Train the communicators	Train the media communication team for timely handling media queries, outreach and need for agility in response. Identify and train the designated lead spokesperson
STEP 3: Prepare messages	Prepare clear, concise and targeted messages (refer to key messages developed by the MoHFW, as given in annexure) Gather and share positive stories including photos/short videos of the people being vaccinated, including influencers
STEP 4: Identify media outlets and media activities	Identify existing media houses, including the most influential ones
STEP 5: Deliver messages	Deliver clear, timely and targeted messages through appropriate channels such as roundtable discussion/ press releases/ photos/ videos/ press conference/interviews etc
STEP 6: Evaluate messages and performance	Monitor media for coverage, potential crisis Analyze public responses to messages Evaluate and improve performance based on feedback Monitor social media for any pickups and feedback

Annexure D/2

Crisis and Adverse Events Following Immunization (AEFI)

Communicating with the media during a crisis including AEFI requires particular skills and preparation. Reporters are highly trained professionals and their broad perspective must be properly understood. The media are interested in stories that will attract attention. While the success of a vaccination programme can attract attention, so can a programme that has not gone as planned.

An important fact to be understood is that the media wants early responses to their questions and therefore waiting for the conclusion of an investigation to speak to them is rarely possible. Information may need to be disseminated early and often, and it is vital to make it available to media and speaking about what is known and what is not known than being unresponsive. The role of the spokespersons is critical here.

Annexure H: Key Messages

Key messages from Indian leadership

Hon'ble Prime Minister

- Continue to practice the preventive behaviours with and even after the availability of the vaccine.
- Vaccines will be made available only after they pass all tests for validation of data and regulatory frameworks.
- Every vaccine distributed in our country would have passed all scientific parameters to defeat this pandemic.
- We have to prepare ourselves as a nation to carry forward a Jan Andolan for COVID -19 vaccination and ensure that all people in are protected.
- What we develop and use will be scientifically validated; for we believe safety is as important as speed to develop the vaccine'

Hon'ble Minister Health & Family Welfare, Government of India

- The government is working round-the-clock to ensure that there is a fair and equitable distribution of vaccines, once they are ready.
- India has the advantage of running the world's largest and immunization programme; vaccinating nearly 2.7 crore newborns annually.
- Our rich immunization experience, our best practices and the robustness of our health care delivery system will be leveraged and augmented using a strong IT platform to ensure that this humongous national mission of vaccinating identified priority groups with COVID-19 vaccine is achieved in a timely manner.
- Vaccine efficacy and safety are the two most important priorities for the government.
- Due emphasis has been laid on equitable distribution of the vaccine(s). Therefore populations groups have been prioiritised.Those most at risk such as our health care workers, frontline workers, people over the age of 50 and people less than 50 but living with co-morbidities have been identified for vaccination in the first phase.
- We urge everyone to continue following the COVID-19 Appropriate Behaviours (CAB) such as wearing masks, frequent handwashing with soap or sanitization and maintaining a physical distancing of at least 6 feet (Do Gaj Ki Doori) . These are important for your safety and the safety of your friends and family

VACCINE INTRODUCTION

- This is the first time that a vaccine for COVID- 19 has been developed and launched in the country.
- The vaccine will help to protect you, your family and communities from the Coronavirus
- The vaccine provides immunity against the Coronavirus disease and reduces the risk of contracting the COVID-19 infection
- This is an injectable vaccine
- This is a safe vaccine, has gone through various trials and has been developed after scientific research.
- All safety protocols including CAB behaviours will be strictly followed in the vaccination centers and sites while providing the vaccine.All vaccinators are trained in vaccine safety protocols and familiar with COVID Appropriate Behaviour
- All vaccinators are trained in vaccine safety protocols and are familiar with COVID Appropriate BehavioursIf you are a health worker, or work as a health care provider get yourself registered for the vaccine using the online registration system
- Once you have registered yourself, you will receivethe vaccine in the selected location near your home. The vaccination date, time and site will be intimated to you on your registered mobie number through SMS.
- If you are a health worker, or work as a health care provider get yourself registered for the vaccine using the online registration system known as the CO- WIN platform
- If you work as a frontline worker (police, home-guard, municipal workers, armed force) you will probably receive the vaccine in first phase be a part of the priority group
- The vaccine will be provided free of cost in the government health facility or at the designated vaccination centers

VACCINE EAGERNESS

- The government is planning to provide the vaccine for COVID-19 to whoever needs it. However, because of limited vaccine availability in the initial phase, it might take some time before it can be made available widely. Some people may have to wait for their turn to get the vaccine.
- With limited supply of vaccines in the initial phase, it will be provided to those people first who are at maximum risk of getting infected or spreading the infection.
- If you work as a Healthcare worker, municipal worker or Frontline worker such as State and Central Police Department, Armed Forces, home guards or civil -defense; you will be in first list along with the people from the high risk population like people over 50 years old and those less than 50 years but with comorbid conditions
- Only registered beneficiaries will be vaccinated. All beneficiaries have to be registered online. There will be no on -spot registrations at the vaccination site.Only registered beneficiaries will be vaccinated . There will be no on -spot registrations at the vaccination site.

- The Government of India has decided to adhere to phased vaccination process and identified the priority groups for the first phase keeping in view the high risk population groups and vaccine availability in the initial phase.
- The priority groups are: 1. Health Care Workers 2. Frontline Workers 3. People over 50 years of age 4. People under 50 years of age with co-morbidities.
- As you know health care workers and frontline workers are at the greatest risk of getting infected and are the most vulnerable.

VACCINE HESITANCY

- Vaccination saves lives at every stage of life
- Immunization has been a great public health success story
- Vaccines provide immunity and protect us, and our communities from contracting diseases.
- It is critical for us to get the COVID -19 vaccine, when our turn comes, so that we can protect ourselves, our families, friends and communities from the infection.
- The vaccination process will be a phased one; we need to ensure adherence to CAB behaviours at all times by all members
- The COVID-19 vaccines have been developed after thorough scientific research and are introduced to the public after undergoing various trials and after they were declared safe for the public.
- It is true that the COVID-19 vaccine has been developed in a short time frame, but it has undergone the protocols of various levels of trials, following due scientific processes and after due diligence. All safety protocols have been followed and there have been no compromises in bringing the vaccine to the general public.
- Adequate safety and efficacy tests have been done on this vaccine, and the regulatory approval has been given after all required checks have been confirmed.
- While administering the vaccine, all safety protocols including CAB behaviours will be followed at the vaccination centers and vaccination sites
- All vaccinators have been adequately trained in vaccine safety protocols and the need to follow COVID Appropriate Behaviours.

COVID Appropriate Behaviour during and after vaccination

- While vaccines are now available for some people in the initial phase, it is critical that all of us continue to follow all the COVID Appropriate Behaviours, to ensure that we stay protected.
- While the vaccine will protect you and your families, it needs to be supported by following of the key preventive behaviours: use of masks, frequent handwashing with soaps and sanitisers, and maintaining physical distance of at least 6 feet (Do Gaj ki Doori).
- We must continue to watch for any COVID-19 symptoms and be prompt to isolate ourselves and get tested if we experience any symptoms.
- COVID Appropriate Behaviours need to be followed and continued diligently during and after the vaccination session as well.
- COVID Appropriate Behaviours are a must for all of us to follow, till the world can adequately address and fight the virus and put in place all the right tools to deal with it.

RELIGIOUS LEADERS' ROLE BEFORE VACCINATION DAY

- Attend orientation meeting on COVID-19 vaccine to get accurate information.
- Educate community members on importance of following CAB and benefits of COVID-19 vaccine.
- Disseminate positive information about COVID-19 vaccine through WhatsApp or other social network groups and announce at events you organise.
- Answer questions from the community members, address negative information, rumours, myths about COVID-19 vaccine. Highlight positive messages related to COVID-19 vaccine from Religious Heads/Institutions.
- Manage vaccine eagerness by helping community to understand why only certain population groups (occupation and age specific) need to get vaccinated in Phase 1.
- Manage vaccine hesitancy by helping community understand that the vaccine is introduced after adequate testing and trials.
- Inform community that they should not attend a vaccination appointment if self-isolating or waiting for a COVID-19 test or unsure if they are well or not.
- Promote MoHFW as a trusted source of information. Call out against fake news and discourage community from circulating messages from unverified sources.

RELIGIOUS LEADERS' ROLE ON DAY OF VACCINATION

- Support in inauguration of vaccination sessions at the local level.
- Support in mobilizing registered beneficiaries to vaccination site as per the given time slot.
- Support health workers in organizing and conducting vaccination sessions.
- Support in managing vaccine eagerness by explaining the need to cover certain groups on priority.
- Support in resolving disputes arising out of beneficiaries being refused vaccination without proper identification or registration.
- Insure CAB are followed at the session site.
- Inform the health workers of any untoward incident and provide active help.

Leaflet on Role of Religious Leaders

YOUR ROLE POST VACCINATION

Support in identifying any drop outs from the list of registered beneficiaries and inform ANM/ASHA.

Conduct home-visits to ensure well being of the beneficiaries and to remind about the second dose of the vaccine.

In case of any adverse effects following immunization (AEFI), support the mobilisers and Health Care Workers in managing crisis situation by appealing to the community to stay calm while waiting for a proper diagnosis and prevent aggressive behavior against health workers.

Regularly update the community regarding the vaccination progress and address any questions related to vaccine eagerness and hesitancy.

Inform beneficiaries that they will receive the date and venue of the second dose through SMS.

Inform people that if they are unwell at the time of the second vaccination dose, it is better to wait for a full recovery and after recovery they should get the second dose as soon as possible.

FOR MORE INFORMATION

Call 24x7 National Helpline No. 1075 (Toll Free) www.mohfw.gov.in, www.cowin.gov.in

www.facebook.com/MoHFWIndia/

www. twitter.com/MoHFW_INDIA

www.youtube.com/user/mohfwindia

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RTI MATTER
BY E-MAIL/ SPEED POST

अखिल भारतीय आयुर्विज्ञान संस्थान, भुवनेश्वर
All India Institute of Medical Sciences, Bhubaneswar
(A Statutory Body under aegis of Ministry of H & F.W., Govt. of India)
सिजुआ, डाकडूमुडुमा :-, भुवनेश्वर-751019
Sijua, Post: Dumuduma, Bhubaneswar-751019
E-Mail: rticell@aiimsbhubaneswar.edu.in

पत्रांक/F. No: AIIMS/BBSR/Admin/RTI/142/3328/2391 **दिनांक/Date:** 05.08.2021

प्रति /To,

Shri Sitaram Kumar
Jaipur Rajasthan, Mukunpura Bharkota,
State: Rajasthan, Pin:302026
Email: golumagg@gmail.com

सूचना का अधिकार

विषय/Subject: Providing of information under RTI Act,2005 – regarding.

महोदय / Sir,

With reference to your RTI application Registration No. **AMSBN/R/E/21/00101** dated **19/07/2021**, received at AIIMS, Bhubaneswar on **19/07/2021** from the online Portal and the information sought by you is/are furnished below:

Sl. No	Information Sought	Reply
01.	what is informed consent of Vaccines form formats provide me	A **Consent Form** is a document, in which a beneficiary needs to read, understand and sign before taking the vaccine. This Consent Form has information such as: 1) Name and Type of Vaccine, Manufacturer 2) Route and Site of Administration, Doser 3) Risks and Benefits of Vaccination 4) Side effects if any and whom to contact and what to do in case of any side effect 5) Any additional source of information related to the vaccine, etc. Thus, after reading it (**Consent Form**) and understanding, a beneficiary needs to sign the document and thereafter should get the vaccine. The beneficiary may or may not sign the informed consent form. Further, for the second part of the query as requested, an **Informed Consent Form for Yellow Fever** is enclosed herewith at Annexure- 'A' (01 Sheet) for your reference.

2. In case, you are not satisfied with the information furnished to you as applicable under RTI Act-2005, you may prefer an appeal within the stipulated period in terms of applicable provision of the said Act. The detail of the First Appellate Authority is as under:

Shri P.K. Ray, Deputy Director (Admin.)
First Appellate Authority, AIIMS, Bhubaneswar,
Sijua, Post-Dumuduma, Bhubaneswar, Odisha-751019

भवदीय/Yours faithfully,

Enclosure: As Above (01 Sheet of A4 size paper provided free of cost)

(D. C. Pattnaik)
CPIO & Administrative Officer
AIIMS, Bhubaneswar
Email: adminofficer@aiimsbhubaneswar.edu.in

ANNEXURE P-12

scroll.in

How India failed those who were harmed by the Covid-19 vaccine

Tabassum Barnagarwala

28-35 minutes

In May 2021, 18-year-old Rithaika Sri Omtri received the first dose of a Covid-19 vaccination at a centre in the locality of Bagh Amberpet in Hyderabad. She was administered the Covishield vaccine, developed by the University of Oxford and the British-Swedish firm AstraZeneca, and licensed to the Indian firm Serum Institute of India.

The 18-year-old had just passed her twelfth grade and was planning to study architecture. “We heard that vaccination may become mandatory for office-goers and college students. Hence she went,” her mother, Rachana Gangu, told *Scroll.in* in October.

The nurse gave Omtri a jab, asked her to wait for 30 minutes, then let her leave. Gangu found this odd. Just a week earlier, a cousin of Omtri’s had received the same vaccine in London – there, the nurse had explained possible adverse effects that could result after the shot, and asked the cousin to sign a consent form.

In fact in May 2021, as a precaution, the United Kingdom government had advised against the use of Covishield, or AstraZeneca, for those below the age of 39 if an alternative vaccine was available.

But Gangu didn’t think much more of the matter at that point.

The rest of the day after Omtri’s vaccination went well. But within five days, she developed a prickling sensation in her fingers; then, a high fever. The family consulted a physician from the city’s Apollo Hospital, who suspected that Omtri was just having an allergic reaction, and prescribed her an anti-allergic medication. When her fever did not subside for a few days, he advised a blood examination. It revealed that Omtri’s platelets had dropped to a dangerous 40,000 per cubic millimetre, against a normal range of between 1.5 lakh and 4 lakh.

Eleven days later, she began to vomit, and could not walk. That night, an MRI scan showed that her brain had several blood clots and a haemorrhage in the right frontal region. Doctors in Apollo Hospital immediately performed a craniotomy surgery on her, but her condition steadily worsened from that point on.

On June 14, two weeks after her vaccination, doctors declared Omtri brain dead. Her desperate parents first explored all medical options to save her. Eventually, on June 19, they decided to donate her heart, lungs, liver, and kidneys for transplants. “In the hope of seeing her live through others,” Gangu said.

What Gangu didn’t know at that point, she said, was that her daughter had suffered a vaccine-induced thrombotic thrombocytopenia, a rare adverse event in which blood clots restrict the flow of blood into vital organs, and also result in a low platelet count. The parents only heard later of the possible link between the vaccine and thrombotic thrombocytopenia from an uncle of Gangu’s, who was also a doctor.

It was also only later that the family learnt, they told *Scroll.in*, that the hospital had informed the district immunisation committee that Omtri's death was likely a result of an AEFI, or an adverse event following immunisation. This, in medical terms, is any health complication that results from a vaccine or drug, or the process of delivering either.

In fact, much before Omtri's death, there was wider evidence of the link between the AstraZeneca vaccine and cases of thrombotic thrombocytopenia across the world. Beginning March 2021, several European countries, starting with Denmark, suspended its use over these concerns. By April, early estimates suggested that one in every 1,00,000 people who were administered the vaccine suffered these complications.

In India, however, there was limited awareness of the problem. The government, as well as the Serum Institute of India, had published information about AEFIs at that point, but thrombotic thrombocytopenia had found no mention as a possible outcome.

Rithaika Sri Omtri died in June 2021, a month after passing twelfth grade and a fortnight after she received the Covishield vaccination. It was only after her family filed an RTI application that they confirmed the link between the vaccination and her death. Photo: Special arrangement

Further, data suggests that in India, the system of reporting cases and collating data on AEFI, which is crucial to devising strategies to deal with them, is faring poorly.

India launched its Covid-19 vaccination programme on January 16, 2021. It has so far administered 2.1 billion doses to more than a billion people, making it the second-largest Covid-19 vaccination drive globally, after China's. According to information on CoWIN, the government portal that records daily vaccinations, adverse reactions have so far been noted in 0.006% of all vaccine doses administered in India. Across the world, countries have reported far higher AEFI rates. Argentina has reported AEFIs in 0.06% of vaccinations, ten times

more than India. Canada, Brazil and Colombia's AEFI rate is 0.05%, eight times higher, while Chile and Paraguay reported AEFI in 0.03% of vaccinations, five times higher than India. Dr Jacob Puliyel, a former member of National Technical Advisory Group on Immunisation, or NTAGI, which advises the Indian government on vaccines, noted that this discrepancy was unusual, since it is unlikely that "the Indian population is immune to adverse effects of vaccines". Puliyel concluded, "There is underreporting."

In fact, according to data that the health ministry shared with *Scroll.in,* the country has so far recorded 89,231 instances of AEFI in response to the Covid-19 vaccination, of which 1,148 resulted in deaths. The total number accounts for only 0.004% of the 2.1 billion doses administered up to October 29 – an even lower rate than that stated on CoWIN.

There are also significant discrepancies within India. According to health ministry data that *Scroll.in* procured through a Right to Information application, across India, Kerala has reported the most AEFI cases – a total of 490, including 242 deaths. The most populous state Uttar Pradesh, which has administered six time more doses of vaccine than Kerala, has reported less than half this number, with 159 AEFIs, including 85 deaths.

Dr NK Arora, who heads the national expert group on vaccination administration, agreed that the apparent lower rate of AEFI in India could be a result of underreporting. "In India, data shows most adverse events are reported within the first seven days," he said, adding that those that occur later than are often not reported. "In Western countries, adverse events that occur up to 28 days are usually reported," he noted.

"There is no doubt that a vaccine's benefit outweighs its risks," said Malini Aisola, a public health activist. "But when vaccination began, districts avoided reporting adverse events with the excuse to ostensibly avoid vaccine hesitancy in people."

Research suggests that there is not enough public awareness in India on the kinds of adverse events that may occur, and the ways that they can be reported. A Bengaluru study found that 76.5% of 217 Covid vaccine recipients who suffered an AEFI did not report it. "It is, therefore, important to take up more awareness campaigns about reporting of AEFIs through the CoWIN," the study said.

Given this lack of awareness and poor dissemination of information, it is unsurprising that Omtri's parents struggled to obtain information about their daughter's death. Ahead of donating her organs, a government doctor conducted an autopsy on her, as is mandatory, in Apollo Hospital. Her parents told *Scroll.in* that the autopsy report was not shared with them. When they asked for information about the possibility of an AEFI, they recounted, the hospital told them to approach district authorities, who had been given the relevant information.

Omtri's father, Pavan Omtri, decided to get to the bottom of the matter. In October, he filed two Right to Information applications with the state and Central government to access information on the autopsy and the inquiry into the possibility of an AEFI. His request was rejected by both. Unwilling to give up, he filed an appeal and a third RTI application with the state in November.

A few months after Omtri's death, her family received a new shock.

"In November we came across a medical journal which spoke about a successful organ donation of an AEFI case in Hyderabad," Gangu said. "The similarities were right there. We were shocked that as parents we were not informed about what caused our daughter's death, while the hospital published a report publicly."

Finally, in December 2021, following an appeal under the Right to Information Act, the Union health ministry provided the family with an answer. They confirmed that Omtri had suffered "thrombosis with thrombocytopenia syndrome" and succumbed to "vaccine product related reaction" – that is, that the vaccine had led to her death. However, Apollo Hospital told *Scroll.in* that the district AEFI committee in Hyderabad had informed them that it was not a case of an adverse event. They also maintained that the hospital had informed the family about their suspicions of an AEFI when Omtri died.

As the family struggled through RTI applications, in October 2021, Gangu also filed a writ petition in the Supreme Court demanding that the government establish a protocol for early detection and treatment of AEFIs, that it set up an expert medical board to investigate her daughter's death, and provide the family with a significant monetary compensation. This August, the Supreme Court issued notice to the Centre to respond to Gangu's writ petition.

Gangu noted that there were some who sought to downplay the importance of AEFI deaths, because, they argue, these deaths are rare. But, she said, even if the problen only affected one individual in several thousands, "that one life also has a right to live".

Health activists point out that a more efficient reporting system for adverse events in response to the Covid-19 vaccine would also have allowed the country to lead the world in establishing an early treatment protocol for dealing with such cases. "India was busy suppressing its data," Aisola said. "In the initial six months, the World Health Organisation did not have access to our data on adverse events because India was evaluating at a snail's pace."

Aisola said that although the government had laid down a clear and systematic protocol on paper, the adverse event mechanism remains "weakest at the district level" because "district officials were either brushing aside cases of adverse events or not collecting adequate evidence to substantiate it".

A detailed email to the Ministry of Health and Family welfare about the lack of data, poor reporting and investigation into AEFIs, had yielded no response as of the time of publishing.

This story is part of** Common Ground**, our in-depth and investigative reporting project. Sign up here to get a fresh story in your inbox every Wednesday.

A minor AEFI, according to health ministry guidelines, can include symptoms such as fever, vomiting, body pain and swelling. A severe AEFI can include high grade fever, and more swelling – but can typically be managed without hospitalisation. A serious AEFI usually involve conditions for which a person needs hospitalisation, and which may lead to disability or death. So far, major adverse events documented following Covid-19 vaccinations include an allergic reaction called anaphylaxis, thrombosis and paralysis.

The eminent virologist Dr Shahid Jameel, who was head of the Indian Sars-CoV-2 Genomics Consortium, a government panel to study mutations in the coronavirus, said that most Western countries had a well-established system to inquire into AEFI cases. "They capture the data, record it and also make this information public," Jameel said. "In India this system does not work well."

Jameel cited his own example. He was vaccinated in March 2021. For three days after, he had high fever. "I called a government helpline number," he said. "The guy at the other end

did not know anything. Then I called the hospital where I was vaccinated. He said he will call back, but he never did."

Jameel suspects his case, although a minor adverse event, was never officially recorded in the government system. "Underreporting is a big problem in India," he said.

Jameel added, however, "But the country is doing vaccination on such a large scale. Vaccination is not just in health centres but elsewhere too" – in community centres, schools, colleges. "It may not be possible to capture adverse events everywhere," he noted.

The virologist Shahid Jameel was among those who suffered an adverse event following immunisation. He was unable to report the problem to the government helpline or the hospital. Photo: Wikimedia Commons

An individual experiencing an adverse event can report it through one of a few different channels. They may, for instance, report it to the local district immunisation officer, or to the vaccination site where they received the jab. Alternatively, they can approach the Indian Pharmacopoeia Commission, or the vaccine manufacturer. Government workers and officials, meanwhile, can report cases on a portal known as Safe-Vac.

In May, the Central government also enabled reporting by the public on CoWIN, after the Supreme Court directed it to make the process easier for patients and doctors. The court also directed the Centre to publish data on AEFI cases publicly, while ensuring confidentiality – the government is yet to act on this.

Coimbatore-based Venugopalan Govindan, aged 51, who suffered hyperthyroidism and Graves' ophthalmopathy after his vaccination last year, and registered his AEFI through CoWIN, described the portal as "a black hole". He noted, "Nobody called me to ask for symptoms or medical reports. There is no acknowledgment if my report has been inquired. There is silence from the government."

Aisola explained that whatever channel a person chose to report through, it was essential that the information quickly reached the district immunisation officer, who bears the responsibility of inquiring into AEFI cases. The officer has to fill a preliminary case investigation form and submit it to a state and a national committee within 10 days. These committees were created in 1988, when the AEFI surveillance system was set-up – their responsibilities include ensuring that safe immunisation procedures are followed, encouraging vaccine uptake and investigating adverse events.

The district AEFI committee has to visit the immunisation site, vaccine storage points, the patient's residence and neighbourhood, and the treatment centre, to collect information about the patient's health before vaccination, hospitalisation or postmortem reports, and the vaccine storage facility. The committee has to submit a final case investigation form, along with all relevant medical documents, to the state and national committee within 70 days.

The cases are classified into one of eight categories, ranging from A1, which are caused by a "vaccine product related reaction", and A3, which are caused by "immunisation error related reaction", to C, which refers to cases deemed "coincidental", to D, or unclassifiable cases. Broadly, the district committee classifies minor cases, and forwards severe and serious cases to the state and national committee for final classification.

But the state and national committees rely on documents and evidence collected by the district committee, and in many instances the reports submitted by the latter are incomplete, a senior World Health Organisation representative in Maharashtra said.

In fact, in Govindan's case, the government's lack of response to his attempt to report his AEFI was particularly distressing because he suffered a tragedy last year, and could not find closure because of a paucity of information. In July 2021, his daughter Karunya Venugopal, a data science student, died, a month after she was vaccinated. The 20-year-old suffered multisystem inflammatory syndrome and died after four weeks of hospitalisation. In October, the national committee classified her death under the B1 category: cases where the AEFI has a "temporal relationship" with the vaccination, but where there is insufficient evidence to determine whether the vaccination was the cause.

Venugopal Govindan's daughter Karunya died in July 2021, a month after her vaccination. The national committee concluded there was insufficient evidence to conclude that her death was caused by the vaccine.

In some cases, families continue to wait for the final report more than a year after losing a member to suspected AEFIs. Among them is Dr Satish Chandra, who was director at the National Institute for Mental Health and Neurosciences, or NIMHANS, in Bengaluru in 2015.

Chandra told *Scroll.in* that after vaccination, his brother-in-law, K Sarvottam, suffered thrombosis, and then a brain haemorrhage, and died in Bengaluru in March 2021. "I reached out to top decision makers in the health ministry when he was on a ventilator," he said. "Till date there is no response."

Chandra reported the case to the district AEFI committee. Sarvottam's treating doctor, Gurucharan Adoor, even made a presentation to the committee, showing members evidence of vaccine-induced haemorrhage. "We showed them records and recommended this be categorised as AEFI," Adoor told *Scroll.in*. But, Chandra said, after that they heard nothing from the government.

The health ministry's website lists 1,527 reports of AEFIs from across India. *Scroll.in* analysed these and found that it typically took between three and eight months for the final reports to be published. Sarvottam's case was not among them – suggesting that in the 18 months since his death, either his case had not been discussed in the national committee, or that it had been discussed, but that there was a delay by the AEFI secretariat in publishing its report.

Chandra said that he later learnt that vaccine-induced thrombosis can be treated with intravenous immunoglobulin. "Our intention to report this was to bring it in records," he said. "But the local AEFI committee

did not bother to visit the hospital or family to gather evidence."

On the ground, district officers explain they are ill equipped to handle adverse event investigations when they are overseeing such massive vaccination numbers: while currently, between 3 lakh and 4 lakh people are vaccinated against Covid-19 in India each day, until last year the number was between 60 lakh and 80 lakh. "That is a huge number to follow up with," said a health official in Nandurbar, a tribal-dominated district north of Maharashtra.

That strikingly low numbers of AEFI events are reported is apparent in the district: Nandurbar has not reported even a single serious adverse event related to Covid-19 vaccinations, despite having administered 20 lakh doses of vaccine. It reported 34 minor AEFIs up to mid-October – this accounts for a reporting rate of less than 0.002% of total vaccinations, lower even than the national average.

Last year, India vaccinated between 60 lakh and 80 lakh people a day. District officers say given this work load, they are ill equipped to handle adverse event investigations. Photo: Money Sharma/AFP

Puliyel said district officials fear reporting high AEFI numbers because they consider it "a big black mark on themselves". He explained, "It could mean their vaccine storage, handling or immunisation process is at fault. No one likes to be held accountable when such a big campaign is at work."

Until 2020, national vaccination programmes in India, such as for polio, measles and rubella, had only focused on children. The committees at the district level had paediatricians, forensic experts, and government authorities. When the Covid-19 vaccination programme was rolled out, these were expanded to include other experts, such as a gynaecologist, neurologist and cardiac specialist. But several district officials said the committee members were not given adequate training on the process.

According to Aisola, "Districts frequently discard adverse events without investigation, claiming that they were linked to comorbidities."

The failure to adequately report these adverse events can have serious repercussions. It can, for instance, deprive patients of the right treatment at the right time and drive families deep into debt. Such was the case with 13-year-old Mahi Manek and her family in Solapur district's Ropale village.

Manek's family says the sixth-grade student was healthy and fit until July 1. That day, her primary school organised a Covid-19 immunisation camp in collaboration with Ropale's primary health centre. Her parents were not informed about it. She received a second shot of Biological E's Corbevax, which, in December 2021, was approved for emergency use in India.

Manek developed high fever the same day. Two days later, she collapsed while walking to school. Ever since, she has been unable to lift her right hand or move her right foot. Her family took her to several hospitals, in Pandharpur, Solapur, Belgaum and Mumbai. Her uncle, Chaitanya Rokade, told *Scroll.in* that she suffered a brain haemorrhage and was operated on twice, once in Solapur and then in Mumbai.The cost of her treatment had totaled to Rs 7.5 lakh.

Manek requires a third surgery now, but the family has run out of savings. In early September, when this reporter met her, a fragile Manek lay on a bed in Mumbai's KEM hospital's ward number 33. Her right hand and leg were still paralysed. In October, she returned home, but her parents had to travel frequently to Mumbai to seek donations for her third surgery.

Thirteen-year-old Mahi Manek, from Solapur district, with her mother Jyotsana. Manek lost her ability to lift her right hand or move her right foot after her vaccination in July. Photo: Tabassum Barnagarwala

Manek's case is not listed in government AEFI records. This is unsurprising, given that though Rokade informed the school principal, the latter did not report the case. "We did not know we were supposed to inform the health

centre," principal Bibhishan Patil said. "She collapsed two days after vaccine, not the same day."

When *Scroll.in* contacted the health centre's medical officer, Dr Vijay Sarade, he said that Manek had suffered a cerebral bleed. "It looks like AEFI," he said, but added he had "not reported this as AEFI yet". The Ropale PHC administered 77,000 doses up to early October, and had not reported any AEFIs up till then.

Manek's mother Jyotsana believes the family will never know if the child had suffered an adverse event following immunisation. "We could either go after authorities or get her treated," she said. "We chose the latter."

Even when cases of AEFI are reported in India, they are often poorly investigated. "Chances of developing something severe is minimised if we have a vigilant system and provide care fast," said virologist Dr Gagandeep Kang, from Vellore's Christian Medical College.

Rushil Tamboli, from Awaken India Movement, which is providing people with legal assistance to seek compensation in cases of AEFI, said in many cases of suspected AEFI deaths, post-mortems are not conducted to gather strong evidence, as required by health ministry guidelines. "How will a committee with its members sitting in another city understand the case if autopsy is not carried?" he said. A government health official from Madhya Pradesh explained that in cases where the port-mortem is carried out, the detailed analysis of organs or tissues, known as histopathology, which is to be conducted by a government forensic laboratory, can be delayed by months, leading to a delay in evidence collection for the AEFI report.

The 1,527 reports uploaded on the health ministry's website include minor, severe and serious cases. The last of these was uploaded five months ago – indicating either that the committee hasn't generated any further reports, or that there is a delay in publishing them.

Arora, who heads the national expert group, said the committee meets two or three times a month. "Sometimes we discuss one case for an hour," he said. "You may feel the progress is slow, but we do detailed evaluation." He added that in the last one-and-a-half years, 24 "sentinel sites" have been set-up across India to improve reporting and investigations – these refer to health institutes or medical departments that have been specifically tasked with monitoring the reporting of AEFIs.

Scroll.in's analysis of the 1,527 reports on the health ministry website revealed that in 51% cases, the adverse reaction was found to be "coincidental", while 18% cases were found to have occurred due to an immunisation error, or vaccine product related reaction. Strikingly, the national AEFI committee found 17% of the cases to be "inconclusive" or "unclassifiable".

Kang explained that another hurdle when it came to determining AEFIs was that India did not have baseline assessments of several specific health problems, particularly with regard to their occurrence at different ages. For instance, she said, if a 30-year-old suffers a seizure after vaccination, and the AEFI committee finds overall that the number of such seizures among that age group after vaccination is higher than in the general population of the group, it can determine that the vaccine caused the seizure. "But in absence of baseline data, we cannot say that the vaccine is 100% responsible," she said. "Seizures could be caused by a number of factors. That is where the problem begins."

The problems with India's handling of Covid-19 AEFI cases are compounded by the fact that the country does not have a system to compensate those who are affected.

Scroll.in filed a Right to Information application seeking details of the government's compensation policy for AEFIs resulting from Covid-19 vaccinations. The health ministry responded that "there is no policy for compensation for recipient of Covid-19 vaccines after its approval against any kind of side effects or medical complications that may arise due to inoculation." An email to Serum Institute of India and Bharat Biotech, the manufacturer of Covaxin, the other of the two most common vaccines used in India, yielded no response.

In March 2021, the World Health Organisation introduced a "no-fault compensation programme" as part of its Covax initiative, which seeks to ensure equitable access to vaccines across the world. Under this programme, for vaccines procured through the initiative, Covax provides a lump-sum compensation to those suffering serious adverse events in 92 low and middle income countries. The programme protects manufacturers from liability – in recognition of the fact that they had to deliver a vaccine quickly, and could not spend years to assess clinical safety data.

Though India is listed among the 92 countries, a health ministry official told *Scroll.in* that it had only received a small quantity of vaccine under the initiative, and had not accessed any compensation under it.

In some countries, manufacturers sought indemnity from different governments before entering their market. Many countries, including the United States, United Kingdom, Canada, and most countries in the European Union, provided this indemnity to manufacturers, essentially taking on the responsibility of dealing with AEFI cases themselves.

India did not sign such an indemnity clause with manufacturers. But so far, a senior government official confirmed, the government has not directed any manufacturer to pay compensation to any patient who had suffered an AEFI following a Covid-19 vaccination.

Government officials told *Scroll.in* that the Central government had assured free treatment to those who suffered adverse events – but on the ground, patients have received little support from government hospitals.

Sudhir Waghmare, who is 40, and who lives in Pune, is a case in point. In October 2021, Waghmare received his first shot of Covishield at a Pune government school. Ten days later, he felt like there was "current passing through his hand", then he felt weak, and found himself unable to swallow food or to balance properly while walking. Within three weeks of vaccination, he experienced paralysis in his limbs, and could no longer hold a kettle at his stall. He was hospitalised for 13 days, then required home-rest for six months to recuperate.

Sudhir Waghmare received his first shot of Covishield in October 2021. Ten days, later, he began to feel like there was "a current passing through his hand", and struggled with swallowing food and balancing properly. Photo: Special arrangement

Waghmare owns a tea stall in a busy timber market in the city, and earlier managed to earn between Rs 2,000 and Rs 3,000 per day. But his visits to numerous doctors, and his various treatments, ate up Rs 6 lakh. He exhausted his savings, and borrowed money from friends and family.

He blames the vaccine for the sudden paralysis attack. “Nothing else explains it,” he said. “I had no other health complications before that.”

Waghmare suffered Guillain-Barré syndrome, an adverse event well documented in some recipients of the AstraZeneca vaccine. A United Kingdom study noted that among those who received a first dose of the vaccine were at greater risk of contracting this syndrome than those who received other vaccines.

Waghmare said that after he began experiencing these symptoms, he returned to the vaccination site and informed the nurse. The nurse asked him to visit a municipal hospital but did not report it on CoWIN. Even as he struggles to get make ends meet again, Waghmare believes that he should be provided “compensation for the medical bills I incurred and the months I could not work due to treatment”.

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- Health
- Covid-19
- Vaccination
- CoWIN
- Covishield

ANNEXURE P-13

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How covid-19 vaccines exposed India's adverse events reporting system

Adverse events are among the most heavily scrutinised parts of the covid-19 vaccine process. But India's system was woefully unprepared for this, leaving families confused, sowing vaccine hesitancy in communities, while robbing the system of valuable data, reports Priyanka Pulla

Priyanka Pulla *freelance journalist*

Around a week after she received her first dose of Covishield, the Indian version of AstraZeneca's covid-19 vaccine, 20 year old Rijuta developed a blinding headache. On 2 June 2021, she was admitted to a large corporate hospital in Bhopal city, Madhya Pradesh. Imaging and blood tests revealed a clot in her brain, says her friend Ajay, while her platelet counts dropped precipitously.

Concerned, the family approached a reputable neurosurgeon for a second opinion. The neurosurgeon told the family that Rijuta's symptoms were consistent with thrombosis with thrombocytopenia syndrome (TTS), the very rare adverse event that occurs between 0.5 and 6.8 times for every 100 000 jabs.[1] "But she said that no one could confirm it," Ajay told *TheBMJ*. When the family raised the possibility of Rijuta's illness being linked to the vaccine with the doctors treating her, they dismissed the idea. Rijuta, who was studying for her bachelor's degree in arts, died on 20 June.

Despite the strong evidence that existed by then that TTS could be caused by the AstraZeneca vaccine,[2] the Bhopal hospital didn't report Rijuta's case to India's covid-19 vaccine safety surveillance system. Ajay says Rijuta's family couldn't do so either because they didn't know how to report it.

Rijuta's case highlights just two of the many gaps that plague India's covid-19 vaccine safety system: hospitals are failing to report adverse events following immunisation (AEFI), while patients and their families don't know how to do it. But the system is also constrained by other problems, including the slow pace at which officials are investigating whether reported adverse events are due to vaccines and the non-communication of their findings with patients.

This has left not only an incomplete picture of vaccine safety in India but also confusion among the families of the victims of serious AEFIs that result in death or prolonged hospitalisation.

Such a situation is likely to trigger vaccine hesitancy, says Gagandeep Kang, a public health microbiologist at the Christian Medical College, Vellore, who helped develop India's first rotavirus vaccine. "For families to not even have acknowledgment of the reason they lost a child is callous," she said.

Multitude of challenges

Among the hurdles facing the covid vaccine safety system is the difficulty in adapting India's existing paediatric immunisation programme to adults. Before January 2021, the Indian government's immunisation programme was aimed at children. So, when the country began vaccinating healthcare workers that month, the post-licensure safety surveillance system for children's vaccines had to be modified for adult vaccines.

This system is three tiered. Once a hospital or healthcare provider voluntarily reports a serious AEFI, a district committee gathers all related data and sends them to a state committee. The state committee then investigates whether the AEFI is causally related to the vaccine, and sends the data to a national committee for verification. After verification, these data are supposed to go back to immunisers and vaccine recipients. This feedback loop is critical because it helps immunisers avoid errors and handle AEFIs better, while also bringing closure to victims of serious adverse events.

However, before the pandemic most of the experts sitting on state and national committees were paediatricians. When covid-19 vaccines were developed, the committees had to hurriedly recruit adult physicians, such as cardiologists and neurologists, and train them in causality assessments.

Furthermore, adult physicians have not been used to reporting vaccine adverse events. "Many of them may never have heard of AEFIs, they may not know where to report them," said Jyoti Joshi Jain, who previously worked with New Delhi's Immunisation Technical Support Unit, which advises the Indian health ministry on its immunisation programmes.

Even though the central government sent letters asking district officials to sensitise hospitals about reporting, "relatively fewer reports" are coming from India's large private healthcare sector, said Satinder Aneja, who leads the national committee which investigates vaccine AEFIs. This data gap is significant, because over half of all Indians approach the private sector for treatment when they become ill.[3]

On top of this, the pandemic and the immunisation programme itself have stretched the safety system. The members of the national committee, for instance, not only continue to evaluate AEFIs arising from childhood immunisation but are also involved in covid policy making. Meanwhile, district immunisation officers have to meet high vaccination targets, while also pushing hospitals to report adverse events and collecting the necessary medical records to investigate them.

The net result is very low levels of reporting, delay in the collection of medical records, and slow causality assessments. As of 30 November 2021, the national committee had received 49 819 adverse events reports, according to a response filed by India's health ministry in the country's parliamentary upper house.[4] By then, India had administered 1.23 billion vaccine doses, which means that Indian healthcare providers had reported only about four adverse events for every 100 000 doses. In contrast, the Canadian safety surveillance system received 48 reports for 100 000 doses until 3 December 2021,[5] while the UK had received 300-700 per 100 000 doses up to 16 December 2021.[6]

Reporting rates for TTS are similarly low, with only 26 reports having reached the national committee so far. And the reports that do reach the national committee are investigated slowly. Of the 946 deaths reported up to November 2021, the committee had completed investigations for only 89. And of the 26 TTS cases by mid-December 2021, only six have been investigated at the time of writing, with five attributed to Covishield.

Aneja said the speed of investigation was hampered by how long it was taking states to send medical records and postmortem reports. Distinguishing between causally related and coincidental adverse events often requires sophisticated medical investigations, which aren't always done by hospitals, especially in the chaos of the pandemic. "The safety system relies on the healthcare system, and the healthcare system itself has been overburdened and overwhelmed in the last two years," she said.

Fixing the system

Many of the problems with India's covid vaccine safety system were presaged by its paediatric vaccine safety system. In a 2017 paper, Jain and her colleagues described how the system had grown rapidly,[7] but still suffered from considerable under-reporting. Against a global benchmark of at least 10 AEFI reports for every 100 000 live births, the country was then reporting only 4.2 AEFIs.

Asked how the system could be strengthened, a senior official, who requested not to be named, said there was an urgent need to facilitate self-reporting by patients and their families. A government body known as the Indian Pharmacopoeia Commission does allow patients to report drug and vaccine adverse reactions, but poor awareness of this service means that it hasn't contributed much to AEFI reports. As of mid-December 2021, the commission had received only around 225 of the 49 819 reports, the official told *The BMJ*.

Another key intervention would be an active surveillance programme to identify rare events such as TTS and multisystem inflammatory syndrome. Compared with the current passive system, in which doctors can choose whether to report an adverse event, an active one would solicit such information from healthcare providers. Aneja says the Indian government has had plans to roll out an active surveillance system since 2020, but the exercise was taking time, given how resource intensive it was. She added that a self-reporting system was also expected to be up and running next year.

Aneja says that it is also necessary to supplement the national and state committees. Since India began its covid immunisation programme, the government has appointed a 30 member sub-committee dedicated to covid vaccine causality analysis, which supports the 27 member national committee. Even so, Aneja says, these committees cannot handle the large load of verifying causality assessments from across India in a short time. "We may need to decentralise and put in place 3-4 regional committees."

The need for these interventions couldn't be more urgent. With only half of India's adults fully immunised, and the threat of omicron looming large, improving vaccination rates is crucial. And a few surveys[8] show that hesitancy could be a significant barrier to this goal.

A strong safety system will also allow finer calculations of a vaccine's benefit-risk ratio in specific age groups. For instance, on the basis of data showing that younger people had a higher risk of TTS and a lower risk of severe covid-19, the UK is now offering alternatives to AstraZeneca's vaccine among healthy adults under 40.[9] In December 2021 India opened up vaccinations to 15-17 year olds, among whom severe covid-19 is even rarer, making a sensitive safety surveillance system critical.[10]

Such a system will also prevent needless deaths due to vaccines, as in the case of TTS, where the right treatment can cut mortality. "We need to know that TTS is being recognised, because we know that recognising it allows for appropriate early treatment," Kang says. With India's slow rate of investigation into TTS, this information currently doesn't exist.

Families left in the dark

In July 2021, Tamil Nadu based entrepreneur Venugopalan Govindan lost his 20 year old daughter, Karunya, after she became ill following her first Covishield jab. Karunya, who was studying for a masters degree in data science, was diagnosed with multisystem inflammatory syndrome, a condition that appears on the World Health Organization's list of adverse events of special interest for covid vaccines.[11] These events are so called because there is a theoretical possibility that they may occur after covid vaccination, although no evidence exists yet. For this reason, WHO advises that such events be monitored carefully.

When Karunya was admitted to hospital, Govindan suspected a link with the vaccine, but did not know where to report it. In desperation, he contacted the Serum Institute of India, the manufacturer of Covishield. The institute says it reported this information to a pharmacovigilance programme for manufacturers, which is supposed to forward the information to the covid vaccine safety system.

Aneja said that government policy was to communicate the results of causality analysis for all serious adverse events to recipients. Yet several state officials told *The BMJ* they were not aware of any such policy. "We only communicate the results to the district committee. There is no policy to tell patients," Vinay Kumar, state immunisation officer for Tamil Nadu said. In any case, Govindan says he didn't receive any updates on the information he submitted to the Serum Institute of India.

Frustrated, he has taken to social media to publicise his daughter's story. His appeals were then heard by a senior official associated with the safety system, who collected Karunya's medical records again. Eventually, on 29 October 2021, the official informed Govindan that the committee had classified the link between his daughter's death and the vaccine as "indeterminate"—a term used when an adverse event occurs soon after vaccination, but there isn't enough evidence to arrive at a causal link.

For other families, who didn't go public with their stories, getting the results of causality analyses has proved harder, if not impossible. Govindan says several families have found it difficult to persuade doctors to report deaths in the first place. "No one knows that a reporting system exists. Even when someone knows, they have to be extremely persistent to get deaths registered." Once reported, the system is "a black hole," he adds, with no assurance that a case

will be dealt with in a time bound manner. Also, India doesn't currently have any countrywide compensation programme for vaccine related injury.

For Govindan, the entire situation is especially grating because Indian government officials have frequently miscommunicated the risk from covid vaccines in the last year. In their eagerness to promote vaccination, government officials often claimed that covid vaccines were completely safe,[12] even though this statement isn't true of any vaccine. Further, recipients were rarely counselled during their appointments about the small possibility of serious adverse events.

The entire experience has left Govindan and many of his family unwilling to take their second doses of vaccine. "Myself and my wife, who are single jabbed, are totally staying away from that poison. And so also my brother and his wife," he says.

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Commissioning and peer review: Commissioned; not externally peer reviewed.

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INDIAN DOCTORS FOR TRUTH
First Do No Harm
An Initiative By:
Awaken India Movement- AIM
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PMOPG/E/2021/0588364

8.12.21

To,
The Hon'ble Prime Minister of India

Sub: Petition to improve and make functional, AEFI Reporting and it's active Monitoring in India

Dear Sir,

We, Indian Doctors for Truth are alarmed that there is practically no proper protocol to report Adverse Event Following Immunization (AEFI) in India, as mass vaccination drive for Covid vaccines is implemented.

Following the 11 deaths of health care and frontline workers that were reported from across the country after administration of Serum Institute's Covishield vaccine, the issue of AEFI reporting was raised by two-dozen scientists including Virologist, Dr Jacob T John in a letter to Health Minister Dr. Harsh Vardhan and Drugs Controller General of India (DCGI) V.G. Somani, dated 31st January 2021. Despite the warning, no action was taken, although Dr. N. K. Arora is the Working Group chairman of National Technical Advisory Group on Immunization (NTAGI) and as a member of National AEFI Committee, he himself had raised the issue about the absence of a proper mechanism in May 2021.

Briefing the press, Dr NK Arora had said, "As of now, monitoring the vaccine recipient up to 72 hours post-vaccination is the norm. It should be done in at least 28 days. There must be a proper mechanism to report AEFI on the CoWin app and all the data should be available in

the public domain," adding that severe AEFIs were reported in less than 0.5 percent of recipients out of seven crore vaccinated people assessed so far. This translates to 5 severe cases out of 1,000 vaccinations.

Dr. Shailesh Mohite, superintendent of Mumbai's civic-run BYL Nair Hospital, said, "If someone dies within a day or two of the anti-COVID vaccination, it is usually being reported. But there is no protocol available to document or report the deaths days later." No AEFI assessment is complete without knowledge of background rates of adverse effects, according to Dr. Anupam Singh from Santosh University, Ghaziabad

Most cases of serious AEFIs are not being documented or reported to authorities. "The government's silence over such incidents and non-transparency with regards to AEFI data are adding to vaccine hesitancy. Proper investigation of serious AEFIs and gene sequencing of samples of such vaccine recipients can help find whether the new variants are evading existing vaccines," experts say.

Though some advisory might exist on paper, "there is so much chaos that nobody knows who to approach in the system and how," says Shobhit, son of a victim.
https://thedialogue.co.in/article/kxmSPNKRrW2UjCjY6Lqk/post-vaccination-deaths-raise-concerns-in-india-government-and-vaccine-makers-silent-?s=08

However, *in the absence of proper reporting mechanism and proactive approach of authorities to trace vaccinated people after they leave the vaccination site, such a claim may not be reflecting the true picture and full magnitude of AEFI and it is possible several cases of AEFI may be going unreported or undetected,* says Vineeta Pandey, while writing about her first hand struggle to get her 21 yr old son's AEFI.
Reporting of vaccination adverse effects made hugely difficult, going unreported (asianage.com)

Dr Arora keeps reassuring but does not implement what the experts in our country recommend. For example, in February in response to the concerns raised by experts he had

said, *"The causality assessment by the National AEFI Committee will be on a rolling basis. This is because we want everyone to know if the vaccine caused the deaths."*

The importance of a robust AEFI reporting system was summed up by Dr. Jacob John, Virologist, when he said, "The sequence (death following vaccination) is not an evidence of consequence. Causality association is through exclusion. The time relationship of the deaths with vaccination should be explained, for which alternative cause of death should be established through investigation in each case. Only then can the vaccine be exonerated. *If you can't find any cause of death in a young person, then you have to attribute the cause of death to the vaccine."*
Vaccine death reports will be published, says adverse events panel expert - The Hindu

On 16 March 2021, a group of doctors, lawyers and journalists wrote to the central government asking for an *"urgent investigation of deaths and serious adverse events following administration of COVID-19 vaccine."*
Covid-19 vaccines: Investigate adverse events and make reports public, say health experts - The Hindu Business Line

Karnataka has scored poorly in investigating deaths following Covid-19 immunisation. The Centre's data shows that more than 30 percent of severe adverse events following immunisation (AEFI) cases in the state resulted in deaths. However, post-mortems were done only in seven of the 40 deaths reported till 20 July 2021.

The absence of proper protocols, strict guidelines and awareness about AEFI, has resulted in loss of AEFI data critical to current third phase efficacy trials. Sources confirmed that the health ministry attributed the trend to *delays in verification by district officers, incomplete investigations and causality assessment reports including a low percentage of post-mortems or delay in sending reports. Infrequent meetings of AEFI committees, inadequate capacity at the district level and lack of awareness about Thrombosis Thrombocytopenia Syndrome (TTS) are also affecting reportage.*
https://www.deccanherald.com/state/top-karnataka-stories/karnataka-lax-in-probing-deaths-following-covid-19-vaccinations-1052248.html

And whereas after the analysis by EMA, many countries have either completely stopped using Astrazeneca vaccine or restricted its use below a certain age, no such analysis could be done for AstraZeneca (Covishield) in India.

According to The Hindu, *the EMA included only six deaths from India after vaccination with Covishield because of a massive backlog in processing assessments in India, according to Malini Aisola, co-convenor of All India Drug Network (AIDN). In addition, Dr Gagandeep Kang also said in an interview with Karan Thapar for The Wire, that while the risk is low, the issue has been compounded by the Indian government's secretive deliberations on the matter.*
617 Serious Adverse Events After Vaccination Reported In India Until March 29 - The Wire Science

There have been multiple reports of people dying of blood clots following the vaccine or other injuries in the media.

"Patient Dies of Covid Vaccine-induced Blood Clot, 7 Other Cases Reported: Delhi's Sir Ganga Ram Hospital" https://www.news18.com/news/india/delhi-7-cases-one-death-of-covid-vaccine-induced-thrombotic-thrombocytopenia-reported-in-sir-ganga-ram-4336937.html

"Rare neurological disorder documented following COVID-19 vaccination,"
"Seven cases were reported from a regional medical center in Kerala,"
"The frequency of Guillain-Barré syndrome in these areas was estimated to be up to 10 times greater than expected."
https://medicalxpress.com/news/2021-06-rare-neurological-disorder-documented-covid-.html

April, 2021: "India reviewing 700 serious post-vaccine adverse events."
http://timesofindia.indiatimes.com/articleshow/81979541.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

The National AEFI Committee has assessed only 363 of severe or serious AEFIs till 18th October 2021, of which only 4 cases of death were found to be directly linked to Covid Vaccine Product Related. Though 3 out of 4 were cases of anaphylaxis, there was one case where the diagnosis given was "Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia". We beg to ask the question, is it really possible that we have only one confirmed case Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), when 16 countries have banned or age-restricted Astrazeneca (Covishield) Covid vaccine for the same reason?!

Thus in the absence of proper protocol such reports do not generate confidence in people and doctors alike. Other moderate AEFIs like severe rashes, severe headache, are not even reported. As doctors we have seen many cases going unreported.

In the EU, anyone can report post-vaccine illness directly to the national authority or vaccine makers. The patient volunteers are followed up for at least six weeks post-vaccination and tracking of even long-term effects, says European Medicines Agency (EMA) rules for COVID vaccines. In the US there is an online system of reporting VAERS. Given the scale of vaccination in India, why isn't there a proper AEFI reporting mechanism in India?
In the US, we can see 18,853 deaths as per the official US VAERS database (a total of 894,143 Adverse Event reports till 12/11/21). In Europe, in just 27 countries, 31,014 death reports are available in the official European Union database Eudra Vigilance (a total of 2,890,600 Adverse Event reports till 20/11/21). What are the equivalent numbers in a huge country such as India? It is unbelievable that a country of our size with the largest Covid Vaccination drive on this planet has only 2116 AEFIs which also includes death. The following link itself provides media reports of over 10,600 deaths that have occurred post vaccination in India.
https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

Regretfully, almost 12 months after the frenzied rollout of the third phase of the Covid-19 vaccine, there have been no guidelines issued or protocol designed for the proper surveillance of AEFIs. Absence of information pertaining to safety makes it impossible for both doctors and patients to make informed decisions based on the risk/benefit profile of the vaccine. It

also compounds the difficulty in diagnosing and treating AEFIs. The need for an Active Surveillance System cannot be more emphasized.

Looking at the current system of AEFI reporting, we demand immediate implementation of the following steps.

1. Immediate development of AEFI Online reporting system on the lines of VAERS system in US, with retrospective effect from the beginning of the vaccination drive.
2. Wide publicity of this system for the general public, including doctors to know the existence of the system.
3. Easy and Open public access to AEFI reports with rolling weekly updates.
4. Compulsory post-mortem of all sudden deaths post covid-19 vaccination, where obvious cause of death is not found or where cause of death is blood clotting in one part of the body (to rule out clotting in other parts of the body).
5. Immediate setting up of Vaccine Courts at State level to adjudicate on compensation payable to victims of vaccine injury/death.

We urge you to kindly look into the matter and expedite the setting up of an AEFI reporting system by MoHFW, including an advisory for diagnosis, treatment and reporting of adverse events occurring post Covid-19 vaccination.

Thanking You For Your Concern,

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Dr. Ajay Gupta, MBBS, MS-Ortho (AIIMS), New Delhi
Dr Lenny Da Costa, MBBS DGM FINEM FCMT, Goa
Dr. Tarun Kothari, MBBS, MD, New Delhi
Dr. Banu Prakash A.S., Neurosurgeon, MBBS, MS, MCh.NS, PGIMER, Bangalore
Dr. Priya Mohod Shirsat, MBBS, CIDESCO (Zurich), DGA, DBC, DBT, Mumbai
Dr. Veena Raghava, MBBS, DA, Bangalore
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Dr. Rashmi R. Raut, MBBS, Fellowship in Family Medicine from CMC Vellore

Dr. Kuldeep Kumar, MBBS MS (GENERAL SURGERY), Haridwar, Uttarakhand

Dr. Lalitkumar Anande, MBBS, PG Diploma in Clinical Research, Mumbai

Dr Ramkrishna Babu, MBBS, MS, Hyderabad

Dr. Piyush Kumar, MBBS, EMOC, Public Health, Bihar

Dr. Swati Thakur, MBBS, Himachal Pradesh

Dr Aashal parikh, MBBS, Ahmedabad

Dr. Gautam Das, MBBS, Kolkata

Dr. Sanjay Jain, MS Ortho, Meerut

ANNEXURE P-15

Prescription with Dr.Anish Anand on June 8th

Apollo 24|7

Dr. Anish Anand
MD (Int. Med.)
General Physician/ Internal Medicine | Reg.No. 41404
Apollo Hospitals Jubilee Hills
Jubilee Hills
Hyderabad - 500033 | Telangana, India
WhatsApp: +91 80471 04009
E-mail: Helpdesk@apollo247.com

APPOINTMENT DETAILS

Patient	RITHAIKA OMTRI | FEMALE | 18 yrs	Consult Date	08/06/2021 at 11:53 AM
Contact	+919573151818	Consult Type	Online
UHID	RJUB.0000020835		
Appt ID	1291454		

CHIEF COMPLAINTS

Fever joint pains rash

Since: few days | Details: had taken covishield vaccine on may 30 ASSOCIATED TOE PAIN AND SKIN PATCH

VITALS (as declared by patient)

Weight : 47 | Height : 152.4 cm | BP: Not Recorded | Temperature: 99-100

MEDICATION PRESCRIBED

1. Crocin 650 mg, 15 tablets

Contains PARACETAMOL (650 MG)

one if necessary for fever or body pains maximum 3 per day

2. Matilda plus capsule 10's

Contains ALPHA LIPOIC ACID (100 MG) + FOLIC ACID (1.5 MG) + METHOBALAMIN (750 MCG) + PYRIDOXINE (3 MG)

Take 1 tablet(s) once a day for 10 days after food in the morning.

To be taken: Orally

3. Haem up syrup 200ml

Contains CUPRIC SULFATE (30 MCG) + CYANOCOBALAMIN (7.5 MCG) + FERRIC AMMONIUM CITRATE (160 MG) + FOLIC ACID (0.5 MG) + MANGANESE SULFATE (30 MCG)

5ML MORNING DAILY ONCE FOR 3 MONTHS

Apollo 24|7

Dr. Anish Anand
MD (Int. Med.)
General Physician/ Internal Medicine | Reg.No. 41404
Apollo Hospitals Jubilee Hills
Jubilee Hills
Hyderabad - 500033 | Telangana, India
WhatsApp: +91 80471 04009
Email: Helpdesk@apollo247.com

DIAGNOSTIC TESTS

1. CBP AND ESR
2. NS1 AND IGM DENGUE

ADVICE/ INSTRUCTIONS

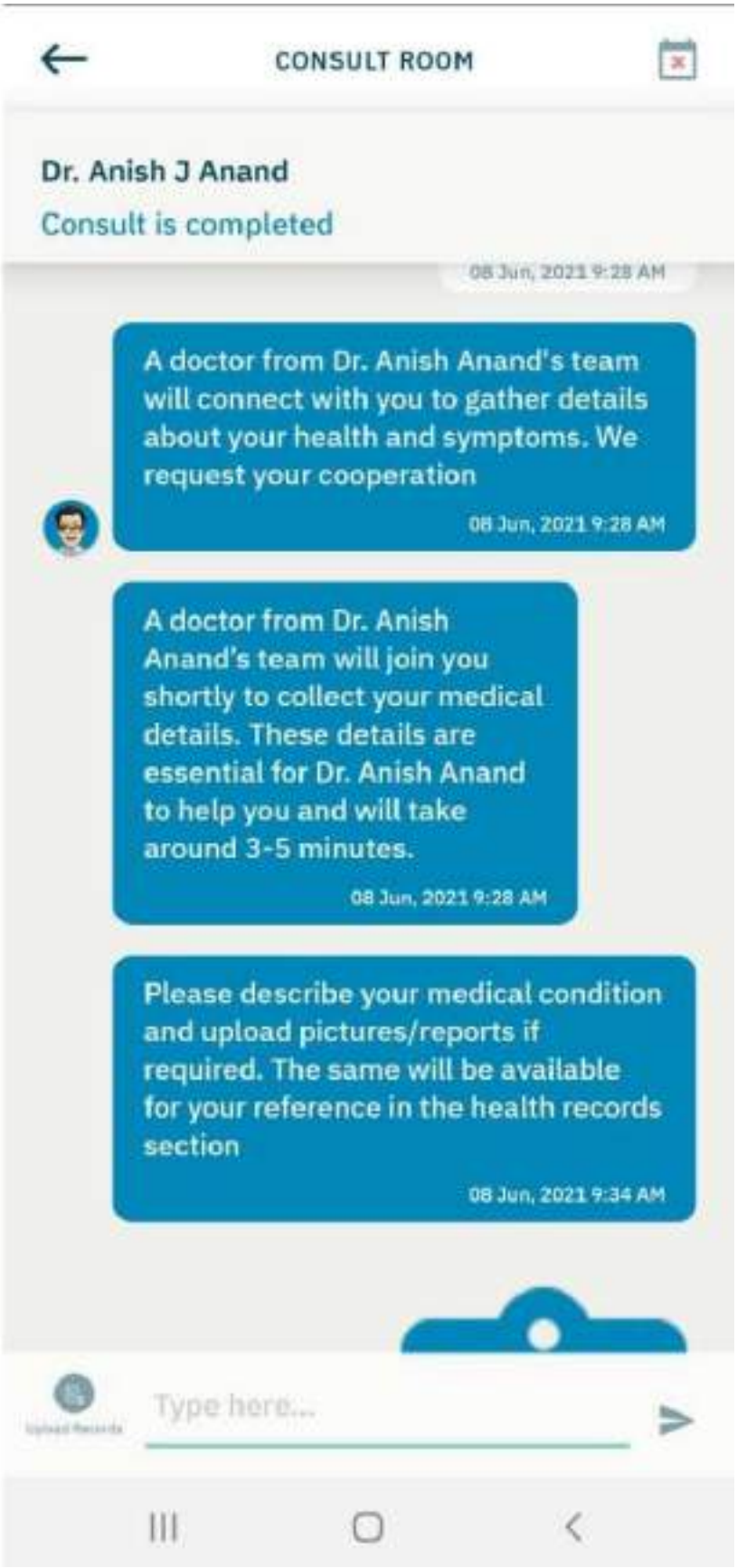
Doctor's Advice: TAKE COMPLETE REST AND LOT OF WATER

MONITOR PULSE RATE(SHOULD BE BETWEEN 60 TO 90/MINUTE), BLOOD PRESSURE(SHOULD BE 120/80MM HG), OXYGEN SATURATION (SHOULD BE ABOVE 95 PERCENT), AND BODY TEMPERATURE(SHOULD BE 98.4 DEGREES FARENHEIT)

Prescribed on 08/06/2021 by

Dr. Anish Anand
MD (Int. Med.)
General Physician/ Internal Medicine | Reg.No. 41404

Consultation with Dr.Anish Anand on June 8th



CONSULT ROOM

Dr. Anish J Anand

Consult is completed

Rithaika has been having severe pain, itching and burning sensation on both her hands for past 3 days. Also noticing red spots under the skin on both her palms and fingers. She also feels as if blood is rushing through her hands. At first we thought it probably was some kind of an allergic reaction and gave her Avil 25mg for 2 days, but that did not help. She also has severe pain in one of the left toes, and is having difficulty walking due to the pain. That particular toe is red and slightly inflammed. She has been bandaging her painful toe with another toe with gauze to prevent it from moving.
She also has been getting mild fever around 99.4 in the evenings/nights. Has headache. I have been giving her Calpol 500mg twice a day for last 3 days, for pain. She is not able to sleep due to pain and discomfort.

08 Jun, 2021 9:49 AM

She got Covishield vaccine on May 30th, and had fever of upto 102.5, with body aches and headache for 2 days. But was

Type here...

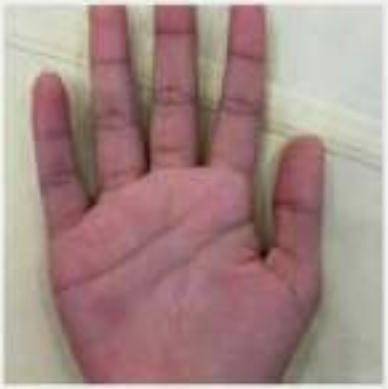
CONSULT ROOM

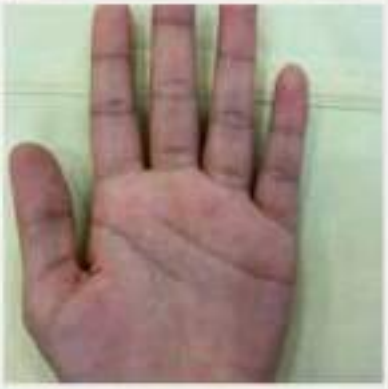
Dr. Anish J Anand

Consult is completed

She got Covishield vaccine on May 30th, and had fever of upto 102.5, with body aches and headache for 2 days. But was fine afterwards.

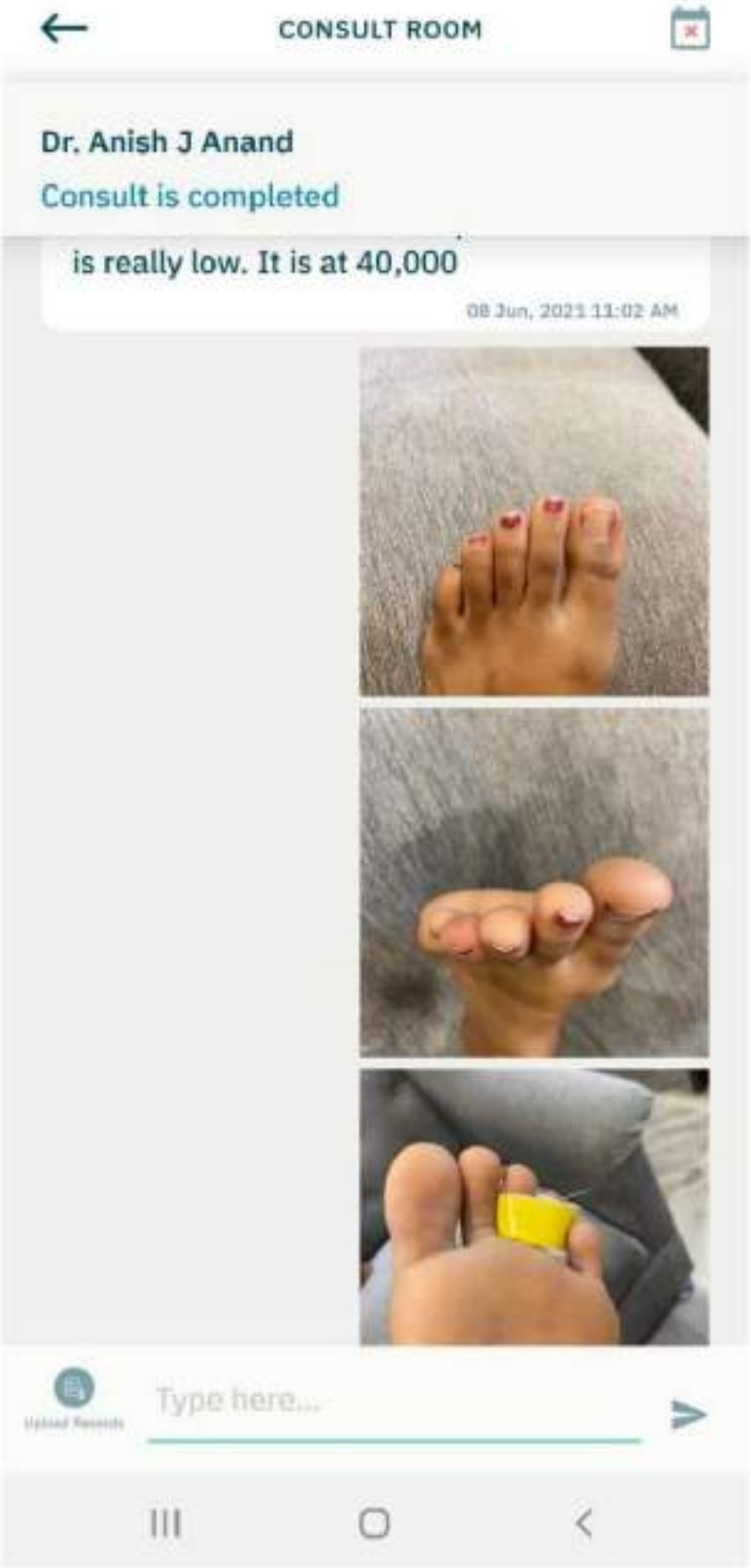
08 Jun, 2021 9:56 AM

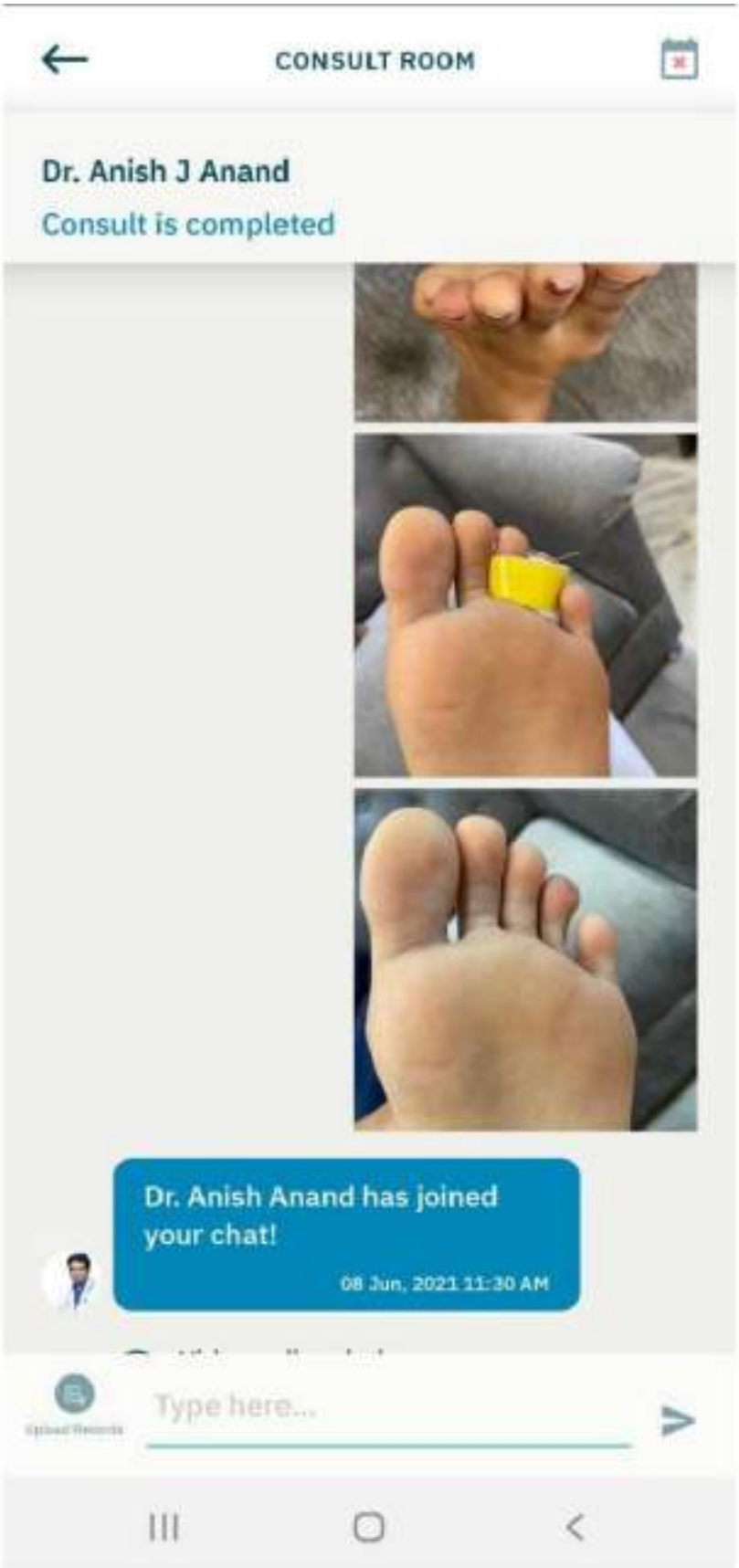




Got a call from Vijaya Diagnostics about her CBP test and said her platelet count is really low. It is at 40,000

Type here...


CONSULT ROOM
Dr. Anish J Anand
Consult is completed
is really low. It is at 40,000
08 Jun, 2021 11:02 AM
Type here...


CONSULT ROOM
Dr. Anish J Anand
Consult is completed
Dr. Anish Anand has joined your chat!
08 Jun, 2021 11:30 AM
Type here...

CONSULT ROOM

Dr. Anish J Anand

Consult is completed

Can you please call me

08 Jun, 2021 11:18 PM

We have notified the query you raised to Dr. Anish Anand. You will get a response from the doctor at the earliest.

Rithu has vomited 5 times ans ia very weak

08 Jun, 2021 11:18 PM

Copy of the Blood Test indicating Rithaika's platelet count at 40000

Vijaya Diagnostic Centre

3-6-16 & 17, Street No. 19, Himayatnagar, Hyderabad - 500 029
Email : info@vijayadiagnostic.com

LABORATORY TEST REPORT

Regn Date	: 07/06/2021 11:57:17	Sample Collection	: 07/06/2021 11:58
Name	: **MS. RITHAIKA**	Released Date	: 08/06/2021 10:47
		Print Date	: 22/12/2022 09:29
Regn No	: **382141745**	Age / Sex	: **18 Years / Female**
Ref By	: SELF	Regn Centre	: Film Nagar - 38
Sample Type	: Whole Blood - EDTA	Ref no.	:

MC-2657

COMPLETE BLOOD PICTURE (CBP)

TEST NAME		RESULT	BIOLOGICAL REFERENCE INTERVAL
Haemoglobin *Photometric measurement*	:	**8.8**	12.0 - 15.0 g/dL
Total RBC Count *Coulter Principle*	:	4.49	3.8 - 4.8 millions/cumm
Packed Cell Volume / Hematocrit *Calculated*	:	**29.2**	36.0 - 46.0 Vol%
MCV *Derived from RBC Histogram*	:	**65**	83.0 - 101.0 fl
MCH *Calculated*	:	**19.5**	27 - 32 pg
MCHC *Calculated*	:	**30**	31.5 - 34.5 gm/dL
RDW *Derived from RBC Histogram*	:	**19.9**	11.6 - 14.0 %
Total WBC Count *Coulter Principle*	:	6300	4000 - 10000 Cells/cumm
Differential count			
Neutrophils *VCSn Technology / Microscopy*	:	63	40 - 80 %
Lymphocytes *VCSn Technology / Microscopy*	:	27	20 - 40 %
Eosinophils *VCSn Technology / Microscopy*	:	5	1 - 6 %
Monocytes *VCSn Technology / Microscopy*	:	5	2 - 10 %
Basophils *VCSn Technology / Microscopy*	:	0	0 - 2 %
Absolute Leucocyte Count			
Absolute Neutrophil Count *Method : Calculation*	:	3969	2000 - 7000 Cells/cumm
Absolute Lymphocyte Count *Method : Calculation*	:	1701	1000 - 3000 Cells/cumm
Absolute Eosinophil Count *Method : Calculation*	:	315	20 - 500 Cells/cumm
Absolute Monocyte Count *Method : Calculation*	:	315	200 - 1000 Cells/cumm
Platelet Count *Coulter Principle*	:	**40000**	150000 - 410000 /cumm
Peripheral Smear			

Consult and prescription from Dr.Dhanraj K. K. on June 5th

Apollo 247

Dr. Dhanraj K K
MSBBS, MD (Gen. Med.)
General Physician/ Internal Medicine | Reg.No. 36981
Apollo Hospitals Jubilee Hills
Jubilee Hills
Hyderabad - 500033 | Telangana, India
WhatsApp +91 80471 04009
E-mail Helpdesk@apollo247.com

APPOINTMENT DETAILS

Patient	RITHAIKA OMTRI | FEMALE | 18 yrs	Consult Date	05/06/2021 at 09:04 PM
Contact	+919573151818	Consult Type	Online
UHID	RJUB.0000020835		
Appt ID	1280636		

CHIEF COMPLAINTS

Mild pain in left toes/pain and swelling of left thumb

DIAGNOSIS

?Allergic reaction

MEDICATION PRESCRIBED

1. Avil 25mg tablet 15's

   Contains PHENIRAMINE (25 MG)

   Take 1 tablet(s) once a day for 2 days in the night.

   To be taken: Orally

2. Calpol 650mg tablet 15's

   Take 1 tablet(s) as needed for 2 days after food in the morning and night.

   To be taken: Orally

   Instructions: For Mild to moderate pain

Apollo 247

Dr. Dhanraj K K
MSBBS, MD (Gen. Med.)
General Physician/ Internal Medicine | Reg.No. 36981
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WhatsApp +91 80471 04009
E-mail Helpdesk@apollo247.com

DIAGNOSTIC TESTS

1. CBP/ESR
2. RBS
3. absolute eosinophil count

ADVICE/ INSTRUCTIONS

Doctor's Advice
Plenty of oral fluids
Breathing exercise

Prescribed on 05/06/2021 by

Dr. Dhanraj K K
MSBBS, MD (Gen. Med.)
General Physician/ Internal Medicine | Reg.No. 36981

Annex 1

Updated (October 2022) COVID-19 AESI including status of associated Brighton case definitions

TABLE 1. Updated (October 2022) COVID-19 AESI including status of associated Brighton case definitions

AESI	Brighton Case Definition Status
Acute respiratory distress syndrome	Published
Multisystem inflammatory syndrome (children & adults)[3,4]	Published
• Myocarditis / pericarditis • Other forms of acute cardiac injury including arrhythmias, heart failure, coronary artery disease, myocardial infarction, stress cardiomyopathy	• Published • No Brighton case definition to be developed but companion guide to myocarditis/pericarditis includes background rates and ICD/MedDRA codes
Thrombosis and Thromboembolism[3,4]	Published
Hemorrhagic disorders including DIC	Not yet started
• Anosmia[3,4] • Ageusia[3,4]	• To be submitted to Vaccine by Oct 31, 2022 • No case definition to be developed
Chilblain – like lesions	Not yet started
Erythema multiforme[3,4]	Not yet started
Single Organ Cutaneous Vasculitis	Published
Acute kidney injury[3,4]	Published lab-based criteria (see *)
Acute liver injury	Published lab-based criteria (see #)
Acute pancreatitis[3,4]	Not yet started
Rhabdomyolysis	Not yet started
Subacute thyroiditis[3,4]	Not yet started
Anaphylaxis [1,2]	Published
Thrombocytopenia[1,2,3,4]	Published
Generalized convulsion[1,2]	Published
Acute disseminated encephalomyelitis[4]	Published
Guillain Barré Syndrome[3,4]	Published
Acute aseptic arthritis [r-VSV]	Published
Aseptic meningitis [Live vaccines]	Published
Encephalitis / Encephalomyelitis [Live vaccines]	Published
Bell's Palsy [Intranasal EColi Heat Labile Toxin Adjuvanted Vaccine]	Published
Vaccine associated enhanced disease [1(Formalin inactivated measles/RSV; HIV), 2(Chimeric YF Dengue), 5 (SARS / MERS-CoVs)]	Published
Thrombocytopenia and Thrombosis Syndrome[6]	Proposed case definition posted online; Working group to be formed by end of 2022
Immune Thrombocytyopenia (ITP)[6]	Thrombocytopenia published; revision needed
Capillary Leak Syndrome[6] (Flare up in individuals with prior history of capillary leak syndrome)	Not yet started
Delayed hypersensitivity reaction[6]	Not yet started
Extensive limb swelling[6]	Not yet started

Facial swelling in individuals with dermal fillers[6]	Not yet started
Dizziness and tinnitus[6]	Not yet started

[1] Proven association with immunization encompassing several different vaccines
[2] Proven association with vaccine that could theoretically be true for novel COVID-19 vaccines
[3] Theoretical concern based on wild type disease immunopathogenesis
[4] Theoretical concern related to viral replication during wild type disease
[5] Theoretical concern because it has been demonstrated in an animal model with ≥ 1 vaccine platform
[6] Signal recognized and validated during COVID-19 mass campaigns or regaultor(s) required update to product information
* Acute kidney injury–consensus definition of Kidney Disease Improving Global Outcomes expert consensus group www.kdigo.org

- Increase in serum creatinine by ≥ 0.3 mg/dl (≥26 µmol/l) within 48 hours; OR
- Increase in serum creatinine to ≥ 1.5 times baseline, known or presumed to have occurred within prior 7 days OR
- Urine volume ≤0.5 ml/ kg/ hour for 6 hours

Acute liver injury – definition as used in majority of COVID-19 publications (but no international consensus):

- > 3-fold elevation above the upper normal limit for ALT or AST OR
- > 2-fold elevation above the upper normal limit for total serum bilirubin or GGT or ALP

- Case Definition and resources available at: https://docs.google.com/spreadsheets/d/1QgF35nYcsaFN3DZTOtV_lP0TYqQzsDMUQBAd5M9brrM/edit#gid=1666959512

AROGHYA NURSING HOME

11/B, SELVAM NAGAR, VADAVALLI, COIMBATORE-641 041
Phone:2423399, 2422939 Cell: 98946 03424

TRANSFER SUMMARY

PtName: ***MISS. V. KARUNYA*** 20 Female IP No: **224/21-22**

D/O. MR. VENUGOPALAN,
"KARUNYAM",
5, E.B.COLONY,
VADAVALLI,
COIMBATORE - 641041.

DOA: **21-Jun-21** DOS: DOD: **25-Jun-21**

Diagnosis: ***? VIRAL FEVER / SEPSIS / ? SIRS / ANEMIA / COVID VACCINE I DOSE GIVEN 10-DAYS BEFORE.***

CONSULTANTS
Dr. T.C.RAMAKRISHNAN, MD DM (Neuro).,
Dr. M.S.SRINIVASAN MB BS.,

ADMISSION NOTES

This girl presented with c/o high grade fever with chills, throat pain, headache and tiredness of 4-days duraiton. She was apparently normal until 4-days ago, when she developed the above symptoms with giddiness, bitter taste. She had no c/o anosmia / taste loss. She had Lt. ear pain and severe back, hip and shoulder pain. She was unable to lift her hands and legs. She had no h/o vomiting / loose stools. Her bladder and bowel habits were normal. She had taken Inj. Covishield vaccination 1st dose on 08.06.2021. She is not a known DM / HTN / CAHD / asthmatic / epileptic / hypothyroid patient and is not on any long term medications.

ON ADMISSION:

Patient toxic, profoundly tired, dehydrated; Temp 100.8 deg F; conscious, oriented; clear sensorium; mild neck stiffness+; extreme tachycardia; anemia+; no pallor / icterus / cyanosis / clubbing / pedal edema / lymphadenopathy; no nodes in the neck; no rashes; no skin ulcer or eschar reported; no joint warmth, tenderness or swelling; BP 112/76; HR 141/mt; SaO2 99% (in room air); CVS-S1S2 heard, no murmur; RS-NVBS+; ENT-clear; Abd-soft, no organomegaly; CNS-DTR preserved; all jerks preserved; ankle jerks brisk; no sensory / neurological deficits.

PROVISIONAL DIAGNOSIS

? Viral fever / ? Vaccination reaction

INVESTIGATION:

21.06.2021
Random blood glucose - 172 mg/dl;
Hb 10.4; PCV 30; TC 23,100; DC-G90, L07, M03; ESR 92mm fall in 1hr; RBC 3.88millions; Platelets 2,04,000;
Absolute eosinophil count - 30;
Widal - Negative;
Dengue NS1, IgM, IgG - Negative; Malaria Pan-Pf card test - Negative;
SGPT 19.2; Bilirubin T 0.9, D 0.3, I 0.6;
ASO titre - 70.9 (N upto 116); CRP 323.2; Serum LDH 296;
Covid-19 IgM 0.37; IgG 485;
Covid-19 RT PCR - Negative;
Urine RE - Blood+; RBC 1-2/hpf; EC 2-3/hpf; PC 5-10/hpf;
ECG in all leads - sinus tachycardia; otherwise normal ECG;

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Regn No 49854
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2423399 98946-03424

AROGHYA NURSING HOME
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TRANSFER SUMMARY

PtName: ***MISS. V. KARUNYA*** 20 Female IP No: **224/21-22**

D/O. MR. VENUGOPALAN,
"KARUNYAM",
5, E.B.COLONY,
VADAVALLI,
COIMBATORE - 641041.

22.06.2021
PS by pathologist - mild microcytic anemia with neutrophilic leucocytosis;
Blood c/s (Bact Alert) preliminary report - no growth so far; final report on 28.06.2021;
HbA1C 5.6%; MBG 122.1 mg/dl;

23.06.2021
Hb 9.7; PCV 30; TC 22,000; DC-G90, L06, M04; RBC 3.78millions; Platelets 2,44,000;
CRP 246.1; IL-6 52.2; CPK total 37.5 (N 20-180); RA factor <10;
Urine c/s - no growth in culture;

24.06.2021
Hb 9.1; PCV 25; TC 18,900; DC-G88, L08, M04; ESR 92mm fall in 1hr; RBC 3.29millions;
Platelets 2,28,000;
Urea 17.4; Creatinine 0.49;
SGOT 21.1; SGPT 28.5; AlkPO4 74.2; Bilirubin T 0.52, D 0.29, I 0.23;
CPK MB 10.01; Troponin I - Negative;
CRP 219.9; Anti CCP 0.8;
ANA (IF method) - Negative; ANA (Elisa method) - 5.34;
Throat swab c/s - no growth in culture;
ECG in all leads - probable atrial tachycardia; Leftward axis; anterolateral ST-T abnormality;
Echocardiography - no RWMA; moderate PAH; no vegetations seen; mild MR;

25.06.2021
CRP 217.1; D-Dimer 3700;
FT3 1.58, FT4 0.98, TSH 0.9;
Mantoux test - Negative.

TREATMENT: IV fluids, Inj. MVI, Inj. Neurobion, Inj. Polybion, T. Azithral - T. Doxt, T. Ivermectin, Betadine gargle, T. Pantosec, Inj. Nosocef, T. HCQS, Riflus forte liquid, Nasivion paed nasal drops, Otogesic ear drops, Candid mouth paint, T. Lonazep, Inj. Zocon, T. Cipmol.

SURGERY: None.

COURSE IN THE HOSPITAL: On presentation, she was very sick and had to be wheel chaired. She was started on judicious IV fluids, parenteral antibiotics (after drawing specimen for c/s) and other supportives. Pertinent labs showed anemia, elevated TC, negative blood widal, Dengue, Malaria tests, negative Covid-19 RT PCR. ASO titre normal and CRP elevated. ECG normal and Covid-19 IgG high, as expected post Covid vaccination. No steroids were administered.

Initially she was improving symptomatically though her tiredness persisted. Her movements were very painful. No respiratory distress. Suspecting early post vaccination Guillain Barre syndrome, she was advised further workup, echo, LP and NCS.

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AROGHYA NURSING HOME

11/8, SELVAM NAGAR, VADAVALLI, COIMBATORE-641 041

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TRANSFER SUMMARY

PtName: ***MISS. V. KARUNYA*** 20 Female IP No: **224/21-22**

D/O. MR. VENUGOPALAN,
"KARUNYAM",
5, E.B.COLONY,
VADAVALLI,
COIMBATORE - 641041.

Understanding her parents anxiety, she was referred to a higher centre for further management. Parents opted to get neurologist's opinion as an OP at the higher centre. Hence referred to Dr. T.C.Ramakrishnan sir, KG Hospital. There NCS done was normal. He ruled out any neurological issues and suggested autoimmune workup. She came back here for further treatment.

She was slowly improving. Auto immune markers were within limits. She developed tachypnea with central chest discomfort. Tachycardia settled down. HR 104/mt; ECG, cardiac enzymes were non informative. Echo showed mild MR with PAH. She developed mild aphthous ulceration of the tongue. No anosmia or taste loss. Her throat and ear pain reduced. HRCT of lungs, venous doppler of legs, D-Dimer, repeat counts, procalcitonin, PCR profile for viral and bacterial sepsis, repeat CRP were planned. T. Doxycycline introduced to cover Ricketssial illness.

Parents were understandably anxious. They implied to continue further treatment at a higher centre now. Her fever reduced much, but persisted. She was tired; myalgia reduced. Able to take food; ambulant. She was tachypneic, talking, maintaining SpO2 in room air at the time of referral.

CONDITION AT DISCHARGE: She had mild fever, less tired, tachypneic, ambulant and talking while referral with stable vitals.

CASE DISCUSSION:

Miss. Karunya, a 20-year-old female was admitted with ?viral illness and sepsis. She had taken 1st dose of Covid vaccination 10-days before. She was administered judicious IV fluids, parenteral antibiotics and other supportives. Labs showed elevated TC, negative Covid-19 RT PCR, elevated Covid-19 IgG as expected post vaccination, and elevated CRP level. She was improving symptomatically but as early GB syndrome post Covid vaccination suspected, she was advised treatment at a higher centre. They preferred to obtain neurologist, Dr. T.C.Ramakrishnan sir's opinion as OP who ruled out neurological issues and suggested auto immune workup. She came back and autoimmune workup was normal. She developed tachypnea and central chest discomfort. ECG non informative and echo showed mild MR with PAH. She also developed mild aphthous ulcer. Further workup planned. Parents were anxious and transferred to higher centre for further management with stable vitals.

DISCHARGE ADVICE: *Collect blood c/s final report on 28.06.2021;*
To follow instructions given at higher centre.

REVIEW: –

Dr M S. SRINIVASAN, MBBS
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PSG HOSPITALS

POST BOX 1674, COIMBATORE 641 004 INDIA
PHONE : 2570170 (7 Lines) Fax : 0422 - 2594401

DEATH REPORT

Name of deceased : KARUNYA . V Age : 20 Sex : Male / Female

Name of Father or Husband : VENUGOPALAN. G. Nationality or Caste : HINDU

Date of Death : 10/7/2021. 6.34 AM Department : GENERAL MEDICINE Ward : MICU

Address : No-5, KARUNYAM, EB COLONY
VADAVALLI, COIMBATORE, NORTH, COIMBATORE

Cause of Death		Approximate Interval between onset and death
I Disease or condition directly leading to death ※	a) MULTI SYSTEM INFLAMMATORY SYNDROME due to (or as a consequence of)	
Antecedent Causes Morbid conditions, if any giving rise to the above cause stating the underlying condition last	b) ..... due to (or as a consequence of) c)	
II Other Significant conditions contributing to the death, but not related to the disease or condition causing it.	....	
※ This does not mean the mode of death, e.g. heart failure, asthenia etc. It means the disease, injury, or complication which caused death.		

Manner of Death

1. Natural
2. Accident
3. Suicide
4. Homicide
5. Pending Investigation

PSG HOSPITALS COIMBATORE-4

If deceased was a female, was pregnancy associated with the death ? YES / NO

If yes, was there a delivery? YES / NO

DR. KRISHNA S NAIR
TNMC 136601

Signature of the Medical Attendant

PSG IMSR & HOSPITALS
PEELAMEDU
COIMBATORE-641004

332

DEATH SUMMARY

Name	: KARUNYA.V	Age : 20 Yrs	Sex: Female
Patient Id	: I21020770 / O21031951		
Dept	: MEDICINE	Unit : 2	
Ward	: MICU	Room No : 318	
Admin Date: 25-JUN-2021 13:56 PM		Death Date : 10-JUL-2021 06:34 AM	

Cause Of Death, Summary :

MULTISYSTEM INFLAMMATORY SYNDROME

Summary:

MISS KARUNYA .V 20 YEAR OLD FEMALE PATIENT PRESENTED WITH COMPLAINTS OF FEVER SINCE 17.06.2021. HISTORY OF THROAT PAIN , ARTHRALGIA, HEAD ACHE AND MYALGIA WAS ALSO PRESENT. ALSO GAVE HISTORY OF EXERTIONAL DYSPNOEA . GAVE HISTORY OF VACCINATION (COVI SHILED) OUTSIDE ON 8.6.2021. ON EXAMINATION PATIENT WAS FEBRILE , TACHYCARDIC , BP : 117/65MM OF HG, MILD PALLOR , OTHER SYSTEMIC EXAMINATION WAS FAIRLY NORMAL. OUTSIDE INVESTIGATIONS REVIEWED - ANEMIA (LOW MCV) , LEUCOCYTOSIS, ELEVATED D-DIMER , CRP . LFT AND CREATNINE WAS NORMAL. CPK- MB WAS 10 , TROP T NEGATIVE , RF AND ANTI CCP WERE ALSO NEGATIVE. URINE AND THROAT SWAB WAS ALSO STERILE. ECHO SHOWED NORMAL LV FUNCTION AND MODERATE PULMONARY ARTERIAL HYPERTENSION . PATIENT WAS ADMITTED TO THE WARD WITH A PROVISIONAL DIAGNOSIS OF FEVER UNDER EVALUATION , POSSIBILTIES : 1. AUTO IMMUNE INFLAMMATION .2. MIS-C ., TO RULE OUT PULMONARY THROMBO EMBOLISM.
ON INVESTIGATION CBC SHOWED ANEMIA , NEUTROHILIC LEUCOCYTOSIS, ESR WAS 16, CREATININE WAS NORMAL , LIVER FUNCTIONS WERE MILDLY DE RANGED. ALL INFLAMMATORY MARKERS DONE WERE ELEVATED. CTPA DONE SHOWED BILATERAL MINIMAL PLEURAL EFFUSION WITH SUBPLEURAL PARENCHYMAL STRANDING IN BILATERAL BASAL LOWER LOBES, MILD SUBPLEURAL PARENCHYMAL STRANDING IN RIGHT MIDDLE LOBE, NO PULMONARY THROMBOEMBOLISM- CO - RADS : 1, MILD CARDIOMEGALY WITH MINIMAL PERICARDIAL FLUID. PATIENT WAS STARTED WITH NSAIDS, PPI S AND OTHER SUPPORTIVE MEASURES. IN VIEW OF

DEATH SUMMARY

RECENT VACCINATION AND FEVER COVID ANTI BODY TITRE WAS DONE - IgG WAS REACTIVE . AUTO IMMUNE WORK UP SHOWED PmScL- POSITIVE AND ANCA PROFILE GBM POSITIVE. RHEUMATOLOGIST OPINION WAS ALSO TAKEN - OPINED TO BE POSSIBLE REACTIVE ARTHRTITIS, ADVISED TO CONTINUE NSAID .

IN VIEW OF PERSISTING FEVER AFTER SENDING CULTURES PATIENT WAS EMPIRICALLY STARTED ON IV ANTI BIOTICS , IV FLUIDS , ANTI PYRETICS , PPI AND SUPPORTIVE CARE. PATIENT CONTINUED TO HAVE PERSISITNG FEVER , CULTURES WERE STERILE . HENCE PET CT WAS TAKEN SHOWED HETERO GENOUS FDG AVIDITY IN THE BONE MARROW AND SPLEEN- LIKELY HAEMATOPOIETIC STIMULATION , FDG AVID -PROMINENT LEFT AXILLARY NODES -LIKLEY REACTIVE , MILD BILATERAL PLEURAL EFFUSION - DID NO SHOW ANY OTHER FOCUS OF INFECTION.

REPEAT LABS DONE SHOWED FURTHER ELEVATION OF INFLAMMATORY MARKERS , HENCE WAS STARTED ON ORAL ANTI COAGULANTS (ELEVATED D DIMER) IV STEROIDS(METHYL PREDNISOLONE), ATYPICAL COVERAGE OF ANTI BIOTICS WERE ALSO GIVEN. SINCE THERE WAS A STRONG SUSPICION OF MULTI SYSTEM INFLAMMATORY SYNDROME, PAEDIATRIC CARDIOLGIST OPINION WAS ALSO TAKEN - ECHO WAS DONE SHOWED NORMAL EF, MILD RIGHT CORONARY ARTERY DIALATATION, NO FEATURES OF EFFUSION OR VEGETATION. SINCE PATIENT WAS NOT RESPONDING TO IV STEROIDS , NSAIDS (PERSISITNG FEVER , MYALGIA , TACHYCARDIA) OPTION OF IV IMMUNOGLOBULIN WAS DISCUSSED WITH THE FAMILY . AFTER OBTANING CONSENT - IV IG WAS STARTED AS PER PROTOCOL. PATIENT DEVELOPED TACHYCARDIA, FEVER - REQUIRING O2 SUPPORT. IV IG WAS STOPPED AND PATIENT WAS SHIFTED TO MICU FOR FURTHER STABILISATION. PATIENT WAS STABILISED. IV IG WAS RE CONSIDERED AFTER DISCUSSION. PATIENT DEVELOPED TACHYCARDIA . HENCE WAS DEFERRED AND STEROIDS WAS ESCALATED AS A SECOND OPTION. REPEAT ECHO WAS DONE BY CARDIOLOGIST -SHOWED GOOD LV FUNCTION, NO PERICARDIAL EFFUSION. ONCE STABILISED PATIENT WAS SHIFTED TO WARD WITH 2 LITRES O2 VIA NASAL PRONGS. IN THE WARD PATIENT DEVELOPED SYNCOPE AFTER EXERTION WITH WORSENING TACHYCARDIA, DESATURATION, TACHYPNOEA, HYPOTENSION. AFTER INITIATING IV FLUIDS AND IONOTROPIC SUPPORT (LOW DOSE) PATIENT WAS SHIFTED BACK TO MICU . ON RECEIVING TO MICU - PATIENT HAD TACHYCARDIA- 152/MIN , WORSENING HYPOTENSION AND TACHYPNOEA. PATIENT WAS INITIATED ON NIV SUPPORT, IONOTROPS WERE ESCALATED. REPEAT LABS DONE SHOWED WORSENING METABOLIC ACIDOSIS (INCREASING LACTATES) . IN VIEW OF HIGH IONOTROPIC SUPPORTS, WORSENING ACIDOSIS PATIENT WAS INTUBATED AND VENTILATED AT 1.30AM . PATIENT WENT IN FOR ASYSTOLE AT 5AM, CPR WAS INITIATED AS PER ACLS PROTOCOL, ROSC ACHIEVED AT 5.20AM. AGAIN AT 6.20AM PATIENT WENT INTO ASYSTOLE , CPR WAS RE INITIATED AS PER ACLS PROTOCOL , PATIENT COULD NOT BE REVIVED INSPITE OF MAXIMUM RE SUSCITATIVE MEASURES.PATIENT DECLARED DEAD AT 6.34AM ON 10.7.2021

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FROM,

DR. MURALI,
INFECTIOUS DISEASE CONSULTANT,
PSG HOSPITALS

To:

DEPARTMENT OF NUCLEAR MEDICINE,
ROYAL CARE HOSPITALS

Sir/Mam,

HEREWITH REFERRING THIS PATIENT, MS. KARUNYA, 20 yr OLD FEMALE WITH FEVER, MYALGIA, ARTHRALGIA SINCE 11/6/21. STERNAL TENDERNESS +. PROVISIONAL DIAGNOSIS: ADULT ONSET STILL'S DISEASE VS. MIS(C) VS STERNAL OSTEOMYELITIS. RELEVANT INVESTIGATIONS ATTACHED. KINDLY DO PET-CT FOR THIS PATIENT.

THANKING YOU

Yours.

(FOR DR. MURALI)
(Dr. RAJ GOKUL,
MEDICINE JR.,
PSG HOSPITALS)

ANNEXURE P-18

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Case Report
Immunology, Allergic Disorders & Rheumatology

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Multisystem Inflammatory Syndrome in an Adult after COVID-19 Vaccination: a Case Report and Literature Review

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ABSTRACT

As the number of people vaccinated increases, people who complain of adverse reactions continue to occur. We experienced a case characterized by low blood pressure, persistent fever, edema due to increased systemic vascular permeability, and systemic inflammation confirmed by image and laboratory examinations after ChAdOx1 coronavirus disease 2019 (COVID-19) vaccination. The diagnostic criteria for multisystem inflammatory syndrome (MIS) in adults are known as fever of 3 days or more in adults, 2 or more mucocutaneous/gastrointestinal/neurologic symptoms, elevation of inflammatory markers, and clinical/imaging diagnosis of heart failure. A 67-year-old man who was medicated for hypertension and diabetes was admitted complaining of fever, maculopapular rash, diarrhea, headache, chills, and dizziness 6 days after the first vaccination of ChAdOx1 nCoV-19 in Korea. The COVID-19 test was negative but with low blood pressure, leukocytosis, skin rash, pulmonary edema, and increased inflammation markers. His lab findings and clinical course were consistent with those of MIS after COVID-19 vaccination. He was medicated with methylprednisolone 1 mg/kg and diuretics and recovered rapidly. He was discharged after 2 weeks and confirmed cure at outpatient clinic. We report an MIS case after COVID-19 vaccination in Korea.

Keywords: Coronavirus Disease 2019 (COVID-19); COVID-19 Vaccination; Multisystem Inflammatory Syndrome; Methylprednisolone

INTRODUCTION

We are living in the coronavirus disease 2019 (COVID-19) pandemic era and are actively introducing vaccination as a way to overcome it. As of July 12, 2021, the Republic of Korea was counted as having completed 30.4% of the primary vaccination. As the number of people vaccinated increases, people who complain of adverse reactions continue to occur.[1] The case

Author Contributions
Conceptualization: Jeon MH. Data curation: Park JW, Ahn YH. Formal analysis: Park JW. Investigation: Park JW, Chang SH. Visualization: Park JW. Writing - original draft: Park JW, Jeon MH. Writing - review & editing: Jeon MH, Yu SN, Chang SH, Ahn YH.

definition of multisystem inflammatory syndrome in adults 21 years of age or older includes the following: 1) severe dysfunction of one or more extra-pulmonary organs in association with severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2), 2) evidence of severe inflammation.[2] Cases of multisystem inflammatory syndrome have been reported after COVID-19 vaccination,[3,4] and we have experienced similar cases. Therefore, we would like to describe this case.

CASE DESCRIPTION

A 67-year-old male patient was taking medication for hypertension and diabetes. He received his first dose of ChAdOx1 nCoV-19 vaccine on June 1, 2021, and since June 7, symptoms of fever, maculopapular rash, diarrhea, headache, chills, and dizziness continued, and he was hospitalized at a local hospital. The COVID-19 polymerase chain reaction (PCR) performed at the local hospital on June 13 was negative. However, the fever could not be controlled continuously, so on June 14, he was transferred through the emergency room of the hospital. He had no prior diagnosis of COVID-19 and had no close contact with known COVID-19 patients. At the time of admission, his vital signs were blood pressure 90/60 mmHg, pulse rate 106/min, respiratory rate 20/min, body temperature 38.9 °C, and O_2 saturation was 95%. At the time the patient was admitted, the result of the COVID-19 PCR test was negative. His lab findings were as follows: white blood cell (WBC) 18,790 (neutrophil 88.9%), hemoglobin 13.6 g/dL, platelet count 158,000/μL, BUN/Cr 17.0/1.07 mg/dL (eGFR 71.45), aspartate transaminase (AST)/alanine aminotransferase (ALT) 15/87 IU/L, lactate dehydrogenase (LDH) 228 U/L, ferritin 1,948.0 ng/mL, lactic acid 32.0 mg/dL, C-reactive protein (CRP) 247.28 mg/L, procalcitonin 4.420 ng/mL, adenosis deaminase (ADA) 33.7 IU/L, and B-type natriuretic peptide (BNP) 4,687.0 pg/mg. The anti-nuclear antibody was 1:40 (weak positive), the anti-double-stranded DNA antibody was negative, and the rheumatoid factor was 12.1 IU/mL (normal range, 0–15). The level of triglycerides was 183 mg/dL (normal range, 0–200). Blood culture, urine and sputum results were all confirmed as negative. Arterial blood gas analysis (aBGA) result was 7.404-34.0-70.8-20.8-94.8%. Proteinuria was confirmed in a 24-hour urine chemistry test (total protein 344.586 mg/day). Natural killer (NK) cell activity was also checked, and it was confirmed that the activity was very low at 1 pg/mL. Chest computed tomography (CT) performed at an external hospital showed no specific lesions other than a 1 cm sized anterior mediastinal nodule. No specific lesions other than fatty liver were observed in abdomen pelvic CT (APCT). Echocardiography was performed to differentiate heart failure due to BNP elevation. The echocardiography findings were confirmed by normal left ventricle contractility without definite regional wall motion abnormality, trivial tricuspid valve regurgitation with normal pulmonary arterial pressure, and moderate left atrial enlargement. However, as his hospitalization length increased, pulmonary edema gradually increased and he gained weight (at the time of admission he weighed 86.6 kg and after 12 days he reached his maximum weight of 96.8 kg).

Because the fever persisted, inflammatory markers were elevated, and relative bradycardia was present, it was difficult to rule out the possibility of salmonellosis, so we started ciprofloxacin. We performed Positron Emission Tomography-CT (PET-CT) to determine the cause of inflammation. PET-CT showed reactive lymph nodes (Lt. cervical chain, Lt. supraclavicular regions, both axillae, mediastinum, portocaval, pericaval, Lt. paraaortic, bilateral external iliac chains, inguinal regions), and splenic hyperplasia. No other focal inflammatory lesions were observed (**Fig. 1**).

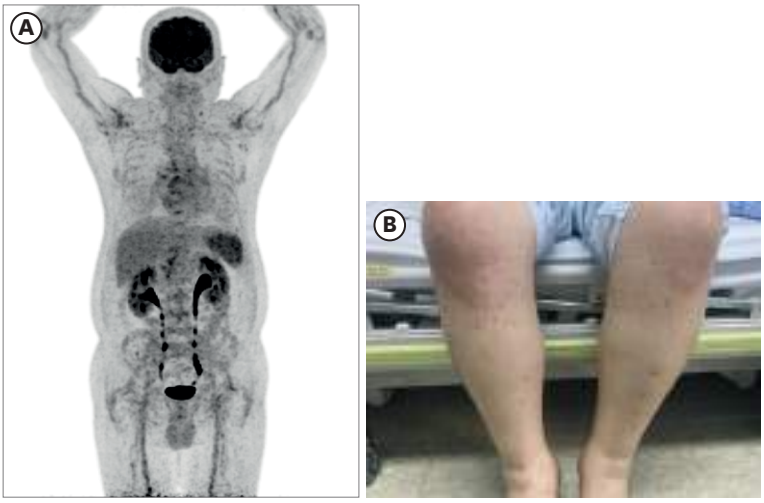

Fig. 1. Clinical features of the patient. (**A**) Patient's Positron Emission Tomography findings: Lt. cervical chain, Lt. There are nodular FDG uptakes in the supraclavicular region, both axillae and mediastinum. Moreover, there is nodular uptake in the portocaval (SUVmax: 4.06) and pericaval (3.54) regions. Lt. Mild nodular uptakes in the paraaortic region, bilateral external iliac chains, and inguinal regions. Spleen's FDG uptake increased overall. (**B**) Maculopapular rash finding developed in the patient.
FDG = fluorodeoxyglucose.

The diagnostic criteria for MIS-A are known as fever of 3 days or more in adults, 2 or more mucocutaneous/gastrointestinal/neurological symptoms, elevation of inflammatory markers, and clinical/imaging diagnosis of heart failure. The patient had a fever, diarrhea, rash and neurological symptoms such as dizziness that had persisted for more than 3 days. The patient's examination results showed a decrease in blood pressure, an increase in the markers of inflammation (C-reactive protein/ferritin/procalcitonin), neutrophilia, and pulmonary edema. Since the patient met all five of these criteria, we were able to diagnose this patient's symptoms using the MIS-A result (2). So, we started using methylprednisolone 1 mg/kg and a diuretic (Furosemide). One day after steroid use, fever was normalized from 38.7°C to 36.5°C (**Fig. 2**), O_2 saturation was maintained well over 97% in room air, and blood pressure was also maintained stably. The procalcitonin level was also improved to 0.460 ng/mL. After 2 weeks of steroid application, the patient was discharged, and just before discharge, the body weight improved to a normal level (81.6 kg), and the labs also recovered (CBC WBC count 12,730 (neutrophil 51.3%) BUN/Cr 20.0/0.75 mg/dL (eGFR 94.92), CRP 3.34 mg/L, lactic acid 14.0 mg/dL). Ferritin was still confirmed at 1,051 ng/mL when followed up at the outpatient clinic 2 weeks after discharge (**Fig. 2**).

DISCUSSION

We experienced a case characterized by low blood pressure, persistent fever, edema due to increased systemic vascular permeability, and systemic inflammation confirmed by image and lab examinations after COVID-19 vaccination.

Cases of systemic vasculitis have been reported not only with the COVID-19 vaccine, but also with several other vaccinations. In particular, since vaccination is mainly conducted on children, a systematic review has reported that Kawasaki's disease can occur after vaccination.[5] Kawasaki's disease is a disease characterized by systemic inflammation,

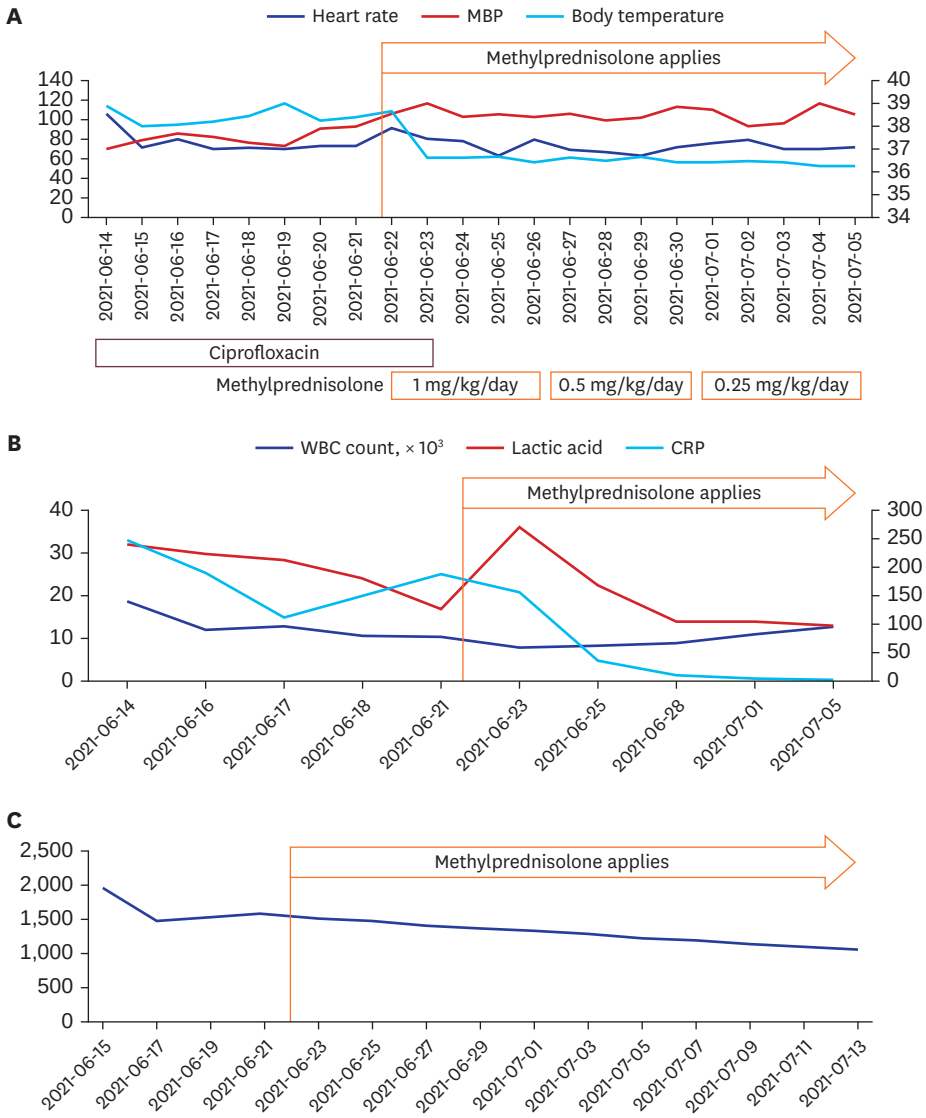

Fig. 2. Patient's clinical course: changes in vital sign indicators and laboratory results. (**A**) Vital sings; (**B**) Laboratory tests: WBC count, lactic acid, CRP (**C**) Ferritin levels (ng/mL).
MBP = mean blood pressure, WBC = white blood cell, CRP = C-reactive protein.

particularly vasculitis, and can be thought of as a disease similar to the multisystem inflammatory syndrome presumed in our case.

Multisystem inflammatory syndrome (MIS) was a concept initially introduced in children (MIS-C). MIS-C is a febrile hyper-inflammatory syndrome developed in children with recent SARS-CoV-2 infection and is known to cause symptoms similar to Kawasaki's disease.[6] Although rare, similar symptoms occurred in adults, so the concept of MIS in adult (MIS-A) was introduced.[7,8] The case definition of MIS-A is as follows: 1) In adults 21 years of age or older; 2) If fever persists for more than 3 days; 3) Two or more mucocutaneous symptoms, gastrointestinal symptoms, hypotension, and neurologic symptoms; 4) Elevation of inflammatory markers (ESR, CRP, ferritin, or procalcitonin); 5) Two or more of BNP elevation, neutrophilia/thrombocytopenia, clinical or echocardiography evidence of heart failure, or myo-pericarditis in EKG.[2]

MIS-A cases after COVID-19 vaccination are rare. When searching Pubmed with "COVID-19 vaccine" AND "multisystem inflammatory syndrome," 5 cases have been reported. These 5 cases and our case are summarized and described in **Table 1**.[3,4,9] Most cases were vaccinated with the COVID-19 vaccine within 2 to 6 weeks of onset of symptoms. There were different types of COVID-19 vaccines. They complained of various systemic illness symptoms (fever, rash, sore throat, dyspnea on exertion, headache, abdominal pain with diarrhea, etc.). Their lab data also showed variation. There were cases in which leukocytosis was severe (32,300/μL), and there was a case in which WBC count was normal (7,000/μL) but thrombocytopenia (63,000/μL) occurred. The ferritin level also varied from 533 to 3,002 ng/mL, and the degree of elevation of BNP also varied from 106 to 1,498 pg/mL. In common, CRP level and procalcitonin level showed a tendency to rise, and LDH was almost normal level. Their symptoms improved after using methylprednisolone and IVIG.[4] One special case occurred in Abu Dhabi, United Arab Emirates, this patient was previously confirmed to have COVID-19 and was vaccinated 2 times, 4 weeks apart, and the symptoms developed a few hours later.[3]

In our case, persistent fever and hypotension occurred, and clinical symptoms of diarrhea and heart failure were accompanied by elevation of CRP, ferritin, and procalcitonin levels, so it met the MIS-A case definition. In addition to the symptoms of case definition, symptoms such as systemic edema and pleural effusion presumably caused by an increase in vascular permeability due to systemic inflammation were also accompanied. A characteristic feature of the lab results was a decrease in NK cell activity. Although it is difficult to know the exact relationship with the pathophysiology of MIS, it is presumed that it is probably related to the abnormal activation of innate immunity.

Several reports describe the possibility of exacerbation of an autoimmune disease after the application of the COVID-19 vaccine.[10-12] This turned out to be due to the cascade of immune reaction after vaccination. In other words, the COVID-19 vaccine is recognized by MHC I and II molecules in antigen presenting cells and activates T cells and B cells. In antigen presenting cells, mRNA detects TLR7 and 8, resulting in the activation of the descending cascade and the secretion of pro-inflammatory cytokines and type I interferons is stimulated.[13] We speculate that this cascade of immune responses may have had a significant impact on the induction of MIS-A in our patients.

We checked the possibility of MIS-A caused by the COVID-19 vaccine using various tools such as PET-CT. Since there are not many reports of it, we think it will be helpful to physicians treating adverse reactions. So far, no cases of death have been reported as a result of MIS following vaccination. However, as the number of COVID-19 vaccinations increases, the incidence of related cases will also increase, and it is thought that more severe cases will occur among them. Therefore, in the future, it will be necessary to collect and accurately analyze the adverse reactions of vaccination, especially cases related to MIS.

Looking at cases of MIS-A, cases occurring after infection with SARS-CoV-2 are slightly more common and appear to progress to slightly more severe severity than cases occurring after vaccination.[8] Therefore, we do not believe that it is necessary not to vaccinate because of the adverse reactions. In addition, it is necessary for doctors to closely monitor and treat patients with systemic inflammation after vaccination.

COVID-19 vaccines are the most powerful weapon to end the pandemic, but concerns about rare and threatening adverse reactions are deterring some people from getting the vaccine.

Table 1. Cases of multisystemic inflammatory syndrome in adults after COVID-19 vaccination: review of literature

Variables	Case 1	Case 2	Case 3	Case 4	Case 5	Our patient
Age/sex	20/female	40/male	18/male	22/male	44/female	67/male
Underlying disease	Asthma	Depression, hyperlipidemia	Asthma	None	Asthma	Hypertension, diabetes mellitus
Types of COVID-19 vaccine	Inactivated SARS-CoV-2 vaccine	No description	No description	No description	BNT162b2	ChAdOx1 nCoV-19 vaccine
Previous COVID-19 infection history	None	None	None	COVID-19 (12 days before vaccination)	None	None
Time to onset of symptoms after vaccination	15 days	48 days	18 days	Few hours later	2 days	7 days
Symptom	Fever, rash, diarrhea, vomiting, cardiogenic shock, acute renal failure	Fever, malaise, diarrhea, neck pain, headache, lethargy	Fever, abdominal pain, diarrhea, vomiting, headache	Fever, sore throat, abdominal pain, headache, fatigue, conjunctival hemorrhage, generalized erythematous maculopapular rash	Fever, hypotension, Left arm pain with worse on limb movement	Fever, rash, diarrhea, headache, chills, and dizziness
Initial vital signs	BP 73/56 mmHg HR 130/min RR 20/min BT 37.4°C O_2 saturation 99%	BP 136/88 mmHg HR 102/min RR 20/min BT 37.3°C O_2 saturation 97%	BP 98/58 mmHg HR 96/min RR 20/min BT 36.6°C O_2 saturation 97%	BP 110/- mmHg HR 140/min RR -/min BT 39°C O_2 saturation -%	BP 81/38 mmHg HR 100/min RR -/min BT > 38°C O_2 saturation -%	BP 90/60 mmHg HR 106/min RR 20/min BT 38.9°C O_2 saturation 95%
White blood cell count, /μL	32,300	11,300	7,000	15,000	17,100	18,790
Platelet count, /μL	155,000	312,000	63,000	122,000	-	158,000
Creatinine, mg/dL	2.64	1.12	1.12	1.15	1.93	1.07
C-reactive protein, mg/L	378	199.4	185.5	249	539	247.28
D-dimer, μg FEU/mL	3.01	1.15	3.44	14	2.564	-
Ferritin, ng/mL	533	1,079.7	3,002	4,357	Normal	1,948
Fibrinogen, mg/dL	801	875	639	-	-	-
BNP, pg/mL	1,498	672	106	> 8,000	-	4,687
LDH, U/L	251	156	291	-	-	228
AST/ALT, IU/L	43/28	55/83	59/58	53/81	-	15/87
Procalcitonin, ng/mL	160.92	0.01	4.41	9	-	4.42
Imaging	TTE: normal LV, EF 45% → 30–35%, the next day chest radiograph: subtle bibasilar ground glass opacities	TTE: normal LV; EF: 50–55%; CT angiogram: no pulmonary embolism, minimal ground glass opacities	TTE: normal LV size EF 40–45%, right ventricle mildly dilated with normal systolic function; chest radiograph: right pleural effusion; CT abdomen and pelvis: hepatomegaly, splenomegaly, small ascites; pericholecystic fluid; retroperitoneal adenopathy	Chest CT: Negative for pulmonary embolism, bilateral moderate pleural effusion, basal atelectasis TTE: severe tricuspid regurgitation, pulmonary hypertension, RAE, RVH, EF 45%, thin pericardial effusion	Chest CT: Left chest wall muscle oedema with subcutaneous fat stranding	PET-CT: reactive lymph node (Lt. cervical chain, Lt. Supraclavicular regions, both axillae, mediastinum, portocaval, pericaval, Lt. paraaortic, bilateral external iliac chains, inguinal regions), splenic hyperplasia No other focal inflammatory lesions were observed
Treatment	Vasopressors × 3 d, IVIG 100 g, methylprednisolone 1 g/d for 3 days, heparin, broad spectrum antibiotics, remdesivir	Dexamethasone 6 mg/d for 10 days, ceftriaxone, azithromycin, enoxaparin	IVIG 100 g, methylprednisolone 1 g/d for 3 days, anakinra 100 mg/d for 3 days, broad-spectrum antibiotics, aspirin	Dexamethasone 6 mg daily	Methylprednisolone 1 g/day for 3 days Enoxaparin → Aapixaban 5 mg two times per day for 6 months	Methyprednisolone 1 mg/kg/day for 5 days, and tapering as a half dose
Outcome	Survived	Survived	Survived	Survived	Survived	Survived

COVID-19 = coronavirus disease 2019, SARS-CoV-2 = severe acute respiratory syndrome-coronavirus-2, BP = blood pressure, HR = heart rate, RR = respiratory rate, BT = body temperature, BNP = B-type natriuretic peptide, LDH = lactate dehydrogenase, AST = aspartate transaminase, ALT = alanine aminotransferase, TTE = transthoracic echocardiography, LV = left ventricular, EF = ejection fraction, CT = computed tomography, PET-CT = Positron Emission Tomography-CT, Lt. = left, RAE = right atrial enlargement, RVH = right ventricular hypertrophy, IVIG = intravenous immunoglobulin.

MIS is known to be a rare consequence of COVID-19 infection and there are few reports indicating that a similar clinical syndrome can occur with vaccination alone. Our case is significant insofar as it is the first to be reported in Korea, especially in Asia. Doctors should check for any rare and serious adverse reactions after vaccination to ensure safe vaccination.

Ethics statement

This report was approved by our Institutional Review Board, and the requirement for informed consent was waived (subject number: SCHCA 2021-10-009).

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ANNEXURE P-19

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A case of multisystem inflammatory syndrome (MIS-A) in an adult woman 18 days after COVID-19 vaccination

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CASE REPORT

A case of multisystem inflammatory syndrome (MIS-A) in an adult woman 18 days after COVID-19 vaccination

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ABSTRACT
We discuss a case of a young woman, presenting a constellation of clinical and biochemical features meeting the current case definition of multisystem inflammatory syndrome in adults (MIS-A), 18 days after receiving her first dose of the Oxford/AstraZeneca vaccine. Therapy by means of intravenous immunoglobulins was initiated, leading to clinical and biochemical recovery. Although a relationship between MIS-A and the preceding vaccination cannot be confirmed, it can also not be excluded, given the temporal association and the fact that there were no indicators of a preceding SARS-CoV-2 infection.

KEYWORDS
Multisystem inflammatory syndrome; COVID-19; SARS-CoV-2; vaccine

Background

Since the emergence of SARS-CoV-2 in Wuhan, China, the spectrum of COVID-19 manifestations and sequelae continues to evolve. During the first peak of the pandemic in April 2020, a report came out regarding a cluster of children who suffered from hyperinflammatory shock [1]. Most – but not all – of these children, who presented with Kawasaki disease-like features, had serological evidence of a SARS-CoV-2 infection. This association between SARS-CoV-2 and the dysregulated immune sequela in children and adolescents has in the meantime been defined as 'multisystemic inflammatory syndrome in children (MIS-C)', formerly known as 'pediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2' (PIMS-TS) [2].

Starting from June 2020, several case reports described a similar hyperinflammatory syndrome in adults (MIS-A), which led to the formulation of a case working definition by the Centers for Disease Control and Prevention (CDC) [3–5]. The CDC case definition of MIS-A considers patients aged ≥21 years old hospitalized for ≥24 hours or with an illness resulting in death, presenting with fever and at least three of the clinical criteria for which at least one must be a primary clinical criterion. These criteria should be present for ≥24 hours prior to hospitalization or must be met by the end of day 3 of hospitalization. Primary clinical criteria include severe cardiac illness or rash and non-purulent conjunctivitis. Secondary clinical criteria include new onset of neurological signs and symptoms, shock and hypotension, abdominal symptoms (pain, diarrhea, and vomiting), or thrombocytopenia. There should also be laboratory evidence of inflammation and a positive SARS-CoV-2 test during the current illness, and the patient should not have a more likely alternative diagnosis for the illness [4,5].

In contrast to the acute cytokine storm, MIS-A has been observed to occur later in SARS-CoV-2 disease progression. It is considered to be a postinfectious process, which can lead to patients having negative nucleic acid testing but positive antibody testing at presentation [3,5].

The underlying pathophysiology of MIS, both in children and adults, is not yet fully clear. The median time between the presentation with COVID-19 symptoms and MIS-A onset was 2–5 weeks in the majority of patients [5]. Nevertheless, 8 of 27 adults (29.6%) in the previously mentioned CDC case series did not experience any respiratory symptoms preceding MIS-A 5. Here, we describe the case of a 32-year-old woman who was diagnosed with MIS-A 3 weeks after receiving her first dose of the Oxford/AstraZeneca vaccination for SARS-CoV-2.

Case presentation

A 32-year-old female healthcare worker without significant medical history was referred to our emergency department with 5 days of fever and a purpuric, vasculitis-like rash localized on both arms and legs. She had

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taken paracetamol for the past 7 days because of headache and arthralgias in both hands, wrists and shoulders. She did not report any nausea or vomiting and did not complain of photo- or phonophobia. She stated not having had significant respiratory symptoms suggestive of COVID-19 in the year prior to presentation. To her knowledge, she had not yet been exposed to SARS-CoV-2. Four weeks before presentation, she underwent routine SARS-CoV-2 PCR screening at her workplace, which turned out to be negative. Concerning the topic, she mentioned that she received her first dose of the Oxford/AstraZeneca vaccine 18 days prior to the hospital presentation.

The lady had an oxygen saturation of 98% without oxygen, heart rate of 154 beats per minute, a blood pressure of 144/83mm Hg and a temperature of 39.1°C. Cardiac monitoring at the emergency department showed sinus tachycardia. Our initial physical examination revealed a conscious and orientated patient with a non-blanching, non-palpable petechial to purpuric rash on the extremities (Figures 1–4). We did not report any other mucocutaneous manifestations and no swelling of the painful joints. There was no hepatosplenomegaly, and palpation of the lymph nodes was unremarkable. There were no signs indicating meningeal irritation.

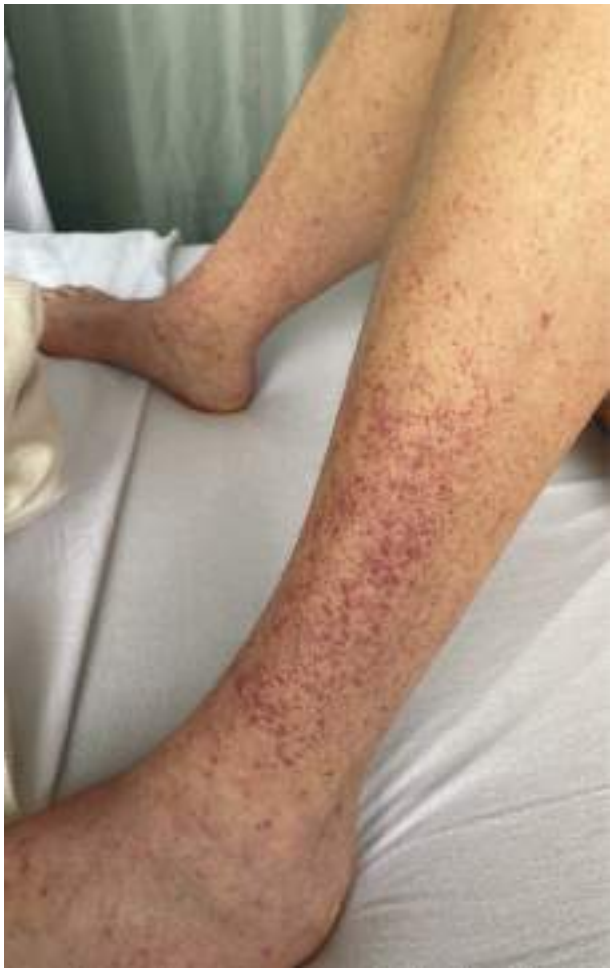

Figure 1. Petechial to purpuric rash on the legs.

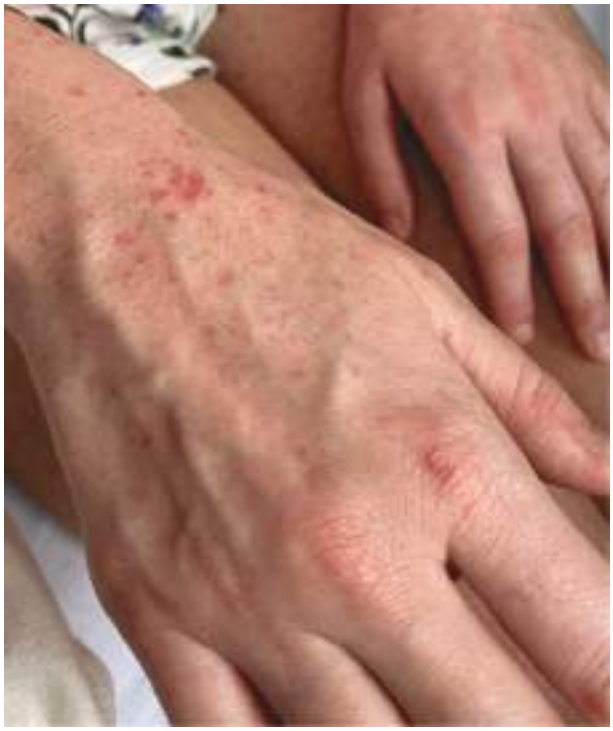

Figure 2. Petechial to purpuric rash on the hands and wrists.

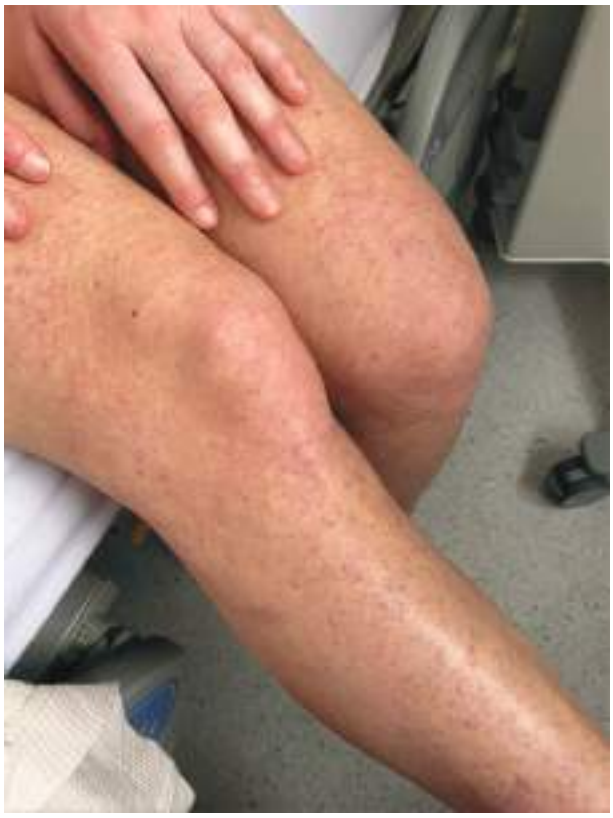

Figure 3. Petechial rash on the legs.

The initial work-up included a negative lumbar puncture and negative PCR for influenza A/B and SARS-CoV-2 on a nasopharyngeal swab. The complete blood count (Table 1) revealed thrombocytopenia with leukopenia, lymphopenia and neutropenia. There were no schistocytes on the peripheral blood smear. Markers of

345

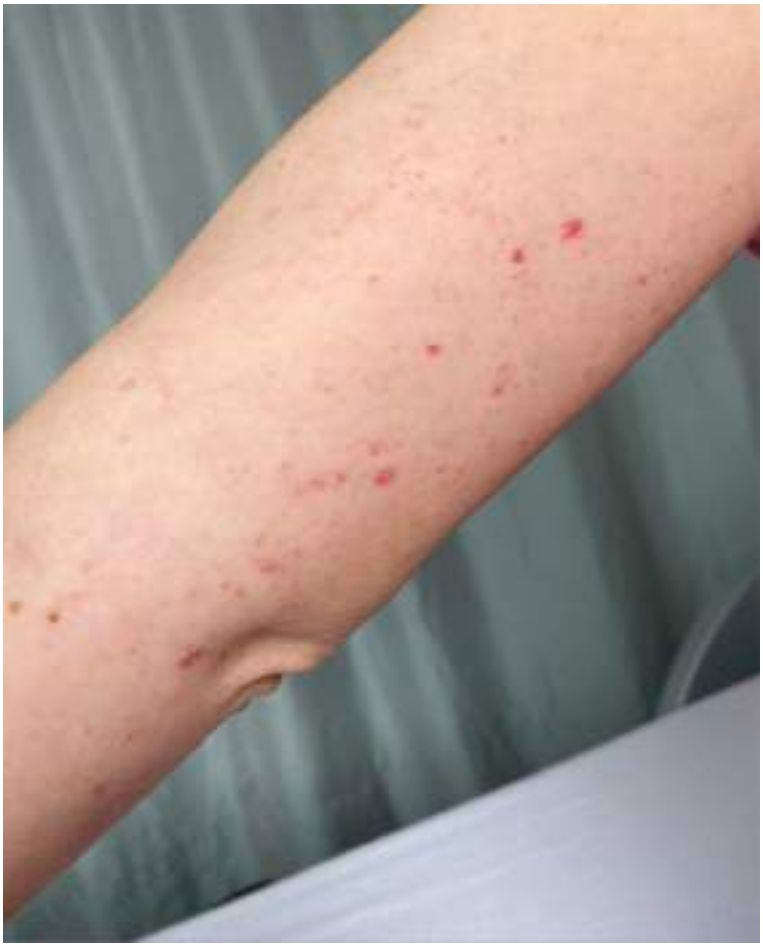

Figure 4. Petechial to purpuric rash on the right arm.

inflammation and coagulopathy were elevated. A comprehensive biochemical panel showed low albumin, hypovitaminosis B12 and a low iron status. Additional infectious serological testing (Table 1) showed IgG anti-spike-binding domain (anti-S) antibody positivity for SARS-CoV-2 (246.3 AU/mL), hepatitis B and Epstein–Barr virus with isolated positive IgM serology for Borrelia Burgdorferi. Re-evaluation of Borrelia Burgdorferi serology 4 weeks later has now shown positive IgG antibodies. HIV testing was negative.

Urinalysis and computed tomography (CT) of the chest and blood cultures did not suggest any possible etiological infectious agent. Abdominal imaging was not performed. Empirical antibiotic treatment for sepsis of unknown origin by means of intravenous Amoxicillin/Clavulanic acid was started at the moment of hospitalization. The aforementioned icytopenia with hypovitaminosis B12 led to the supplementation of vitamin B12 parenterally.

On day 2 of her admission, our patient developed diarrhea, but fecal culture was negative. She remained febrile despite antibiotic and antipyretic treatment. Biochemical re-evaluation (Table 1) showed pancytopenia with normal reticulocyte count and without peripheral blood blasts. A more extensive laboratory work-up showed elevated inflammatory markers, now including erythrocyte sedimentation rate, triglycerides, procalcitonin and interleukin-6. Complement activation was suspected, given the low C3 and C4 levels. Antinuclear antibodies were positive at low titers, but the anti-double-stranded DNA antibodies were negative. Concerning cardiac biomarkers, troponin was found to be normal, but N-terminal prohormone of brain natriuretic peptide (pro-BNP) was high. Transthoracic echocardiography showed no peculiarities and objectified normal cardiac function (LVEF 66%).

The clinical case definition of MIS-A was met, so therapy by means of intravenous immunoglobulins (2 g per kilogram for 2 days) was started after performing some other serological tests (Table 1). On this treatment, we saw decreasing inflammatory markers with recuperation of all three blood cell lines. A bone marrow biopsy was performed on day 3 of admission to exclude hemophagocytic lymphohistiocytosis (HLH), given the pancytopenia associated with hyperinflammation. It showed a normocellular bone marrow with a lesser degree of maturation in the white blood cells. The examination revealed insufficient arguments for hemophagocytic lymphohistiocytosis and the changes observed were compatible with a reactive bone marrow.

Table 1. Laboratory results.

	Day 7 (23/02/2021)	Day 4 (20/03/2021)	Day 3 (19/03/2021)	Day 2 (18/03/2021)	Day 0 (16/03/2021)	Unit	Normal value
Haematology							
Hemoglobin	11.6	↓ **9.1**	↓ **9.7**	↓ **10.3**	12	g/dL	11.6–14.4
MCV	92.9	89.1	89.7	89.6	90.3	fL	79.8–93.6
MCH	30.4	30	30.2	30.5	30.6	pg	26.4–32.7
MCHC	32.8	33.7	33.7	34	33.9	g/dL	32.4–35.9
Leucocyte count	4.6	↓ **2.45**	↓ **1.38**	↓ **1.12**	↓ **2.85**	$\times 10^9$/L	4.2–10.3
Neutrophil count	↓ **1.48**	↓ **0.96**	↓ **0.43**	↓ **0.29**	2.36	$\times 10^9$/L	2.0–6.7
Lymphocyte count	2.21	1.00	↓ **0.6**	↓ **0.57**	↓ **0;30**	$\times 10^9$/L	0.9–3.4
Monocyte count	0.65	↓ **0.26**	↓ **0.17**	↓ **0.15**	↓ **0.10**	$\times 10^9$/L	0.3–0.8
Eosinophil count	0.08	0.21	0.17	0.11	0.07	$\times 10^9$/L	0.02–0.25
Thrombocytes	335	↓ **77**	↓ **55**	↓ **49**	↓ **99**	$\times 10^9$/L	166–396
Reticulocyte count			↓ **23**	↓ **22**		$\times 10^9$/L	24–102
Hemostasis							
APTT	23.4			28.3	28.8	s	23–31
PT	97			111	89	%	78–123
Fibrinogen	289			↑ **624**	↑ **521**	mg/dL	170–420
D-dimers	↑ **2.1**			↑ **0.9**	↑ **2.37**	µg/mL	<0.48
Biochemistry							
Creatinine	0.71	0.64	0.57	0.55	0.55	mg/dL	0,55–1,02
AST	↑ **111**	↑ **60**		18	18	U/L	<34
ALT	49	13		<5	<5	U/L	<55
GGT	33	20		8	8	U/L	8–33
ALP	68	51		52	64	U/L	43–160
LDH	↑ **247**	148		160	153	U/L	125–220
Sedimentation			↑ **94**			mm/u	0–19
CRP	↑ **23.2**	↑ **68.6**	↑ **126**	↑ **197.3**	↑ **217**	mg/L	< 10
Albumin	↓ **34**	↓ **29**	↓ **30**		37	g/L	35–52
NT-proBNP				↑ **652**		pg/mL	<126
Triglycerides				↑ **255**		mg/dL	
Iron				↓ **13**	↓ **11**	µg/dL	50–170
Iron saturation				↓ **5**	↓ **3**	%	15–50
Ferritin				192	247	µg/L	10–291
Vitamin B12				↑ **1975**	↓ **< 148**	ng/L	211–911
Hormonology							
Interleukin-6	3.3	↑ **12.2**		↑ **26.1**		pg/mL	<7
Procalcitonin				↑ **0.51**		ng/mL	<0.5
Complement cascade							
C3				↓ **0.63**		g/L	0.80–1.60
C4				↓ **<0.010**		g/L	0.12–0.36
Specific serum proteins							
Haptoglobin				↑ **2.86**		g/L	0.40–2.80
Autoimmunity							
Anti-IF Ab				<0.5		U/mL	<10
Anti-parietal cell Ab				Negative			Negative
ANA				**1:160**			Negative
dsDNA				Negative			Negative
ENA				Negative			Negative

Ab: antibodies; Ag: antigen; ANA: antinuclear antibodies; ANCA: antineutrophil cytoplasmic antibodies; CLIA: chemiluminescence immunoassay; CMV: cytomegalovirus; CRP: C-reactive protein; dsDNA: anti-double stranded DNA; EBV: Epstein–Barr virus; EBNA: EBV nuclear antigen; ELISA: enzyme-linked immunosorbent assay; ENA: extractable nuclear antigen antibodies; HBV: hepatitis B-virus; HCV: hepatitis C-virus; HIV: human immunodeficiency virus; HSV: herpes simplex virus; IF: intrinsic factor; MCH: mean corpuscular hemoglobin; MCHC: mean corpuscular hemoglobin concentration; MCV: mean corpuscular volume; NT-proBNP: N-terminal pro-brain natriuretic peptide; sAb: surface antibody; sAg: surface antigen; VCA: viral-capsid antigen; VZV: varicella zoster virus.

Discussion

We discuss a case of a 32-year-old woman presenting with a 5-day history of fever, headache, arthralgia and a purpuric, vasculitis-like rash. Laboratory tests showed a new-onset pancytopenia, hyperinflammation, hypoalbuminemia, low C3 and C4 counts and a high pro-BNP. Although partially explained by the vitamin B12 and iron deficiency, the pancytopenia is thought to be a consequence of the associated hyperinflammatory state. Other causes of new-onset pancytopenia were regarded as very unlikely, given the results of our serological examination and bone marrow puncture. In the context of the constitutional symptoms our patient presented with, we found isolated IgM positivity in two-tiered serological testing for Lyme's disease (LD). Serological reevaluation 3 weeks later showed seroconversion with positive IgG antibodies, which

raised the suspicion of a possible underlying acute Borrelia infection. This seroconversion could be the representation of the first stage of the disease, compromising erythema migrans and constitutional symptoms [6,7]. However, our extensive laboratory findings cannot fully be explained by LD. The fact that most Borrelia infections are reported in the months May to September and our patient presented herself in March is an argument against Borrelia. Furthermore, as stated by the CDC, cross-reactivity in serological testing for LD is seen in many viral and autoimmune disorders with overlapping humoral responses, yielding false-positive results [8–11]. The administration of IVIG could have also led to a false-positive result of our serological reevaluation. Thus, the individual clinical picture should guide serological testing, and when symptoms are not suggestive for LD, clinicians should avoid further testing [7]. The relatively low pre-test probability in our case leads to a low positive predictive value and thus higher probability of false-positive test results. However, given the possibility that this clinical image could indeed be a manifestation of Borreliosis, treatment by means of Doxycycline 100 mg two times daily for 14 days was started after the second-tier tests came back positive (approximately 3 weeks after admission). Unfortunately, additional serology for tick-borne co-infections was not requested. Alternatively, our patients' clinical and biochemical features do meet the current CDC case definition of MIS-A [5].

Being a multisystemic disease, the presentation of MIS-A can be notoriously heterogeneous [5,12]. In our case, organ involvement was seen in the neurological, gastrointestinal, dermatological and, most prominently, the hematological system. The pronounced extrapulmonary involvement coupled with minimal respiratory symptoms or radiographic abnormalities consistent with respiratory inflammation is another key finding in MIS-A and distinguishes it from acute and severe COVID-19 disease [5]. Aside from these extrapulmonary manifestations, we observed laboratory parameters leading to a diagnosis of MIS-A. Not only did we find evidence of a hyperinflammation, we also found other laboratory findings described in MIS-A such as elevated cardiac markers, lymphopenia and hypoalbuminemia [9,10].

Thorough history revealed no previous symptoms of COVID-19 and no epidemiological links to COVID-19 cases. However, our patient did have high (>200 AU/mL) anti-spike receptor-binding domain (anti-S) SARS-CoV-2 IgG antibody titers, what could be expected on day 18 after first Oxford/AstraZeneca vaccination in an adult without previous SARS-CoV-2 infection [11]. Although in our case a relationship between MIS-A and the preceding vaccination cannot be confirmed, it can also not be excluded, given the temporal association and the fact that a previous SARS-CoV-2 infection had not been documented. The combination of positive anti-S IgG antibodies and negative anti-nucleoside IgG antibodies would strongly support the linkage to the Astra-Zeneca vaccine rather than to (PCR negative or negativized) COVID-19 [13]. Unfortunately, our lab was not capable of testing for these aforementioned anti-nucleoside antibodies.

The Brighton Collaboration listed MIS-C and MIS-A as postvaccination adverse events of special interest with respect to SARS-CoV-2 vaccine. As per these criteria, patients should have onset of MIS symptoms within 12 weeks after SARS-CoV-2 vaccination [14]. In the current literature, only one case of MIS-A after vaccination (Pfizer-BioNTech mRNA vaccine) was reported [15]. In the other four cases that report MIS-A after vaccination, all patients also had a recent SARS-CoV-2 infection [16,17]. The pathogenesis of MIS-A related to vaccines is not yet understood. Therefore, we highlight the need of reporting all plausible, unforeseen sequalae. With this in mind, this case of MIS-A was reported to the Federal Agency for Medicines and Health Products (FAMHP), given the possibility that this hyperinflammatory syndrome and the pancytopenia are indeed vaccine-related.

Currently, there are no data available concerning the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A). The Centers for Disease Control and Prevention (CDC) allows vaccination after recovery from MIS-A but suggests a time interval of at least 90 days between the diagnosis of MIS-A and vaccination [18]. In our patient, anti-spike IgG antibodies were still positive (1.21 U/ml) 3.5 months after the diagnosis of MIS-A. Until this day, the second dose of the SARS-CoV-2 vaccination was not yet administered to our patient. However, this could be considered in the future, depending on the advice of the Superior Health Council.

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Patient consent

Written consent was obtained.

Authors' contributions

- *Sofie Stappers*: writing – original draft, investigation, data curation, visualisation
- *Britt Ceuleers*: writing – original draft, investigation, data curation
- *Daan Van Brusselen*: writing – review and editing, investigation
- *Philippe Willems*: writing – review and editing, investigation
- *Brecht De Tavernier*: writing – review and editing, supervision, investigation
- *Anke Verlinden*: supervision, investigation

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Postvaccination Multisystem Inflammatory Syndrome in Adult with No Evidence of Prior SARS-CoV-2 Infection

Young Kyun Choi, Jae Young Moon, Jungok Kim, In Seol Yoo, Geun-Yong Kwon, Heuisoon Bae, Min Seob Song, Sungmin Kym

Ten days after receiving the first dose of coronavirus disease vaccine, a 22-year-old woman in South Korea experienced myocarditis, myopathy, pericarditis, and gastroenteritis; rash subsequently developed. There was no evidence of prior infection with severe acute respiratory syndrome coronavirus 2. The diagnosis was multisystem inflammatory syndrome resulting from coronavirus disease vaccination.

Multisystem inflammatory syndrome (MIS) is a serious complication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection that affects multiple body systems (cardiovascular, gastrointestinal, skin). It occurs predominantly in children (MIS-C) (*1*) and only rarely in adults (MIS-A) (*2*). The Brighton Collaboration Network (https://brightoncollaboration.us) includes MIS-C and MIS-A as possible coronavirus disease (COVID-19) vaccination–related adverse events (*3*). Most MIS cases occur in persons previously or concurrently infected with SARS-CoV-2 (*4*–*6*). We report a case of MIS-A that occurred after vaccination of a patient with no evidence of prior SARS-CoV-2 infection.

The Case

In April 2021, a previously healthy 22-year-old female healthcare worker visited the emergency department of Chungnam National University Sejong Hospital (Sejong, South Korea) with a 2-day history of fever, myalgia, sore throat, diarrhea, and vomiting and a 1-day history of continuous chest pain. She had received her first dose of the ChAdOx1 COVID-19 vaccine (AstraZeneca, https://www.astrazeneca.com) 10 days earlier and had undergone wisdom tooth extraction 8 days earlier. She had no other notable medical history and had not experienced COVID-19 symptoms in the previous 12 weeks. She tested negative for SARS-CoV-2 by real-time reverse transcription PCR. Antipyretics were ineffective.

At initial examination, the patient appeared acutely ill and had an elevated temperature (37.8°C), tachycardia (122 beats/min), mild pharyngeal injection, muscle tenderness, and limb weakness; she exhibited no signs of dental infection. Laboratory tests revealed increased levels of inflammatory markers (Table, https://wwwnc.cdc.gov/EID/article/28/2/21-1938-T1.htm). Chest radiographs and computed tomography (CT) images showed no signs of lung infiltration; abdominal CT images showed enterocolitis of the small and large intestines. Chest angiography and CT of the lower legs showed no evidence of pulmonary embolism or deep vein thrombosis.

Approximately 6 hours after arrival, the patient's blood pressure dropped to 70/45 mm Hg. After she received norepinephrine, her blood pressure normalized, and she was transferred to the intensive care unit, where we diagnosed myocarditis and pericarditis. Additional findings were elevated cardiac enzymes, ST segment elevation on electrocardiogram, and a small pericardial effusion on echocardiogram. Cardiac magnetic resonance imaging and biopsy sampling were not performed because of the patient's hemodynamic instability. PCR results were negative for adenovirus, metapneumovirus, rhinovirus, bocavirus, parainfluenza virus, respiratory syncytial

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virus, influenza virus, enterovirus, norovirus, rotavirus, astrovirus, and sapovirus, as were results for other tests for viruses causing viral myocarditis. Test results for C-rheumatoid factors and antineutrophil cytoplasmic, P-antineutrophil cytoplasmic, and antinuclear antibodies were also negative.

On hospital day 4, atrial fibrillation with a rapid ventricular response accompanied by hypotension (80/50 mm Hg) developed. After 2 treatments with cardioversion, the patient's cardiac rhythm reverted to sinus tachycardia, and her blood pressure normalized.

On day 7, a generalized macular rash developed and was treated with dexamethasone (5 mg/d for 3 d, followed by 2.5 mg/d for 4 d), after which methylprednisolone was administered for a possible antimicrobial drug–induced eruption. The patient's fever, rash, and inflammatory marker levels fluctuated according to steroid dose (Figure 1, panel B). Echocardiography images (day 12) showed an increased 1-cm deep pericardial effusion during diastole through the heart circumference without evidence of endocarditis.

On day 15, SARS-CoV-2 serologic testing with a chemiluminescence immunoassay (Liaison SARS-CoV-2 TrimericS IgG assay; DiaSorin, https://ww.diasorin.com) was performed. Antibody level was 21.88, which is high compared with the average value of 5.56 after first vaccination among healthcare workers without prior SARS-CoV-2 infection but low compared with the average value of 46.34 among those with prior infection (7). Antibody analysis using an in-house colloidal gold qualitative immunoassay was positive for anti–spike protein receptor-binding antibodies and negative for antinucleocapsid antibodies (Figure 2).

We empirically administered multiple regimens of antimicrobial drugs during the first 21 days of hospitalization. Bacterial cultures were negative, and no focal signs of infection were found. MIS-A was diagnosed on day 21 after the possibility of infection was excluded, and empiric administration of antimicrobial drugs was discontinued.

On days 28 and 29, human immunoglobulin therapy (1 g/kg) was administered because after 2 weeks of steroid therapy, the patient's rash had subsided but her body temperature and C-reactive protein (CRP) level remained high. Muscle weakness, especially hip flexion, had worsened, and the patient was unable to stand without assistance. At that time, the steroid dose was increased, but the disease was not controlled. The immunoglobulin therapy also produced no therapeutic response. The patient's fever spiked to 40°C, and her CRP level increased. On day 34, steroid pulse therapy (methylprednisolone 1 g/d for 3 d) was initiated, resulting in defervescence and decreased CRP levels. When the steroid dose was tapered, her body temperature and CRP level increased, and steroid pulse therapy was extended for another week.

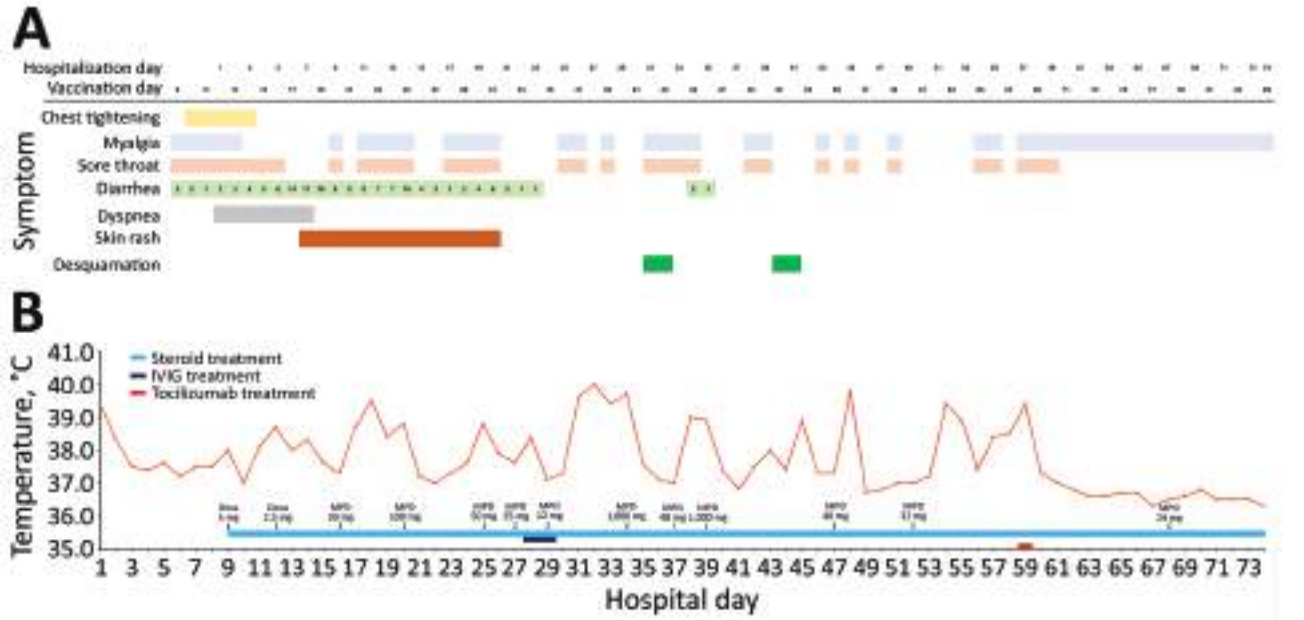

Figure 1. Clinical course of illness in adult with postvaccination multisystem inflammatory syndrome and no evidence of prior SARS-CoV-2 infection, South Korea. A) Signs/symptoms according to the day of hospitalization and the days since vaccination. B) Patient's maximum body temperature and anti-inflammatory therapy according to the day of hospitalization. Dexa, dexamethasone; IVIG, intravenous immunoglobulin; MPD, methylprednisolone.

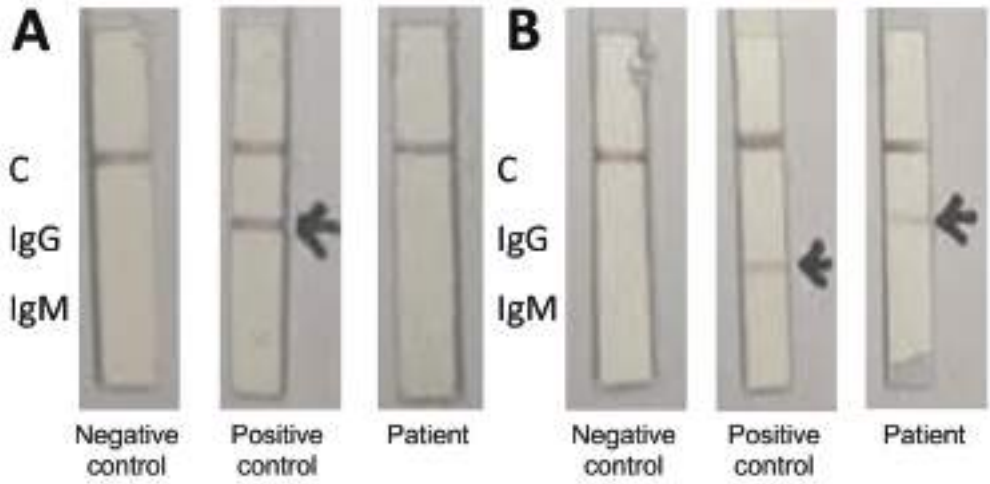

Figure 2. Colloidal gold qualitative immunoassay for antibodies against severe acute respiratory syndrome coronavirus 2, South Korea. A) Nucleocapsid protein conjugate; B) spike receptor-binding domain conjugate. The positive control serum contains antinucleocapsid IgG and anti–spike protein receptor-binding IgM. C, control.

After steroid therapy was discontinued, the patient's body temperature and CRP levels again increased. She experienced desquamation of the skin on her fingers on day 30 and of her toes on day 40.

On day 30, a nerve conduction velocity test and electromyogram showed signs of myopathy. Interventional angiography (day 43) showed no abnormality of her coronary arteries. Positron emission tomography (day 59) showed increased contrast medium uptake by soft tissues resulting from inflammation but no focal signs of infection.

On day 60, tocilizumab (8 mg/kg) was administered, after which the patient remained afebrile and the muscle pain in her extremities decreased (Figure 1). She was discharged on day 74 despite residual muscle weakness requiring rehabilitation therapy.

Conclusions

Most vaccine-related MIS cases have been associated with past or concurrent SARS-CoV-2 infection; recently, MIS cases occurring after mRNA vaccine administration in children and adults in the absence of SARS-CoV-2 infection have also been reported (*8*,*9*). To our knowledge, this case of MIS in an adult was induced by a viral-vector vaccine. This case meets the Brighton Collaboration Criteria for definite MIS-A on the basis of patient age, fever (>3 days), multiorgan involvement, elevated inflammatory markers, elevated N-terminal–pro B-type natriuretic peptide, neutrophilia, lymphopenia, pericardial effusion, and electrocardiographic changes consistent with myopericarditis (*3*).

Antinucleocapsid antibodies typically appear ≥2 weeks after onset of SARS-CoV-2 infection (*10*), although in some patients they do not appear (*11*). For the patient reported here, at the time she visited the hospital, the cumulative incidence of COVID-19 in her community was 333 cases/100,000 population and the average daily number of cases in the 12 weeks before her visit remained low (n = 1.95). The medical institution where she worked did not treat COVID-19 patients. Given that she had not had COVID-19 signs/symptoms within the previous 12 weeks, the likelihood of prior infection is low.

The clinical features of Kawasaki disease, including desquamation, are similar to those reported for this patient. Desquamation has reportedly occurred in COVID-19 patients, MIS patients, and COVID-19 vaccine recipients (*11*–*13*). Kawasaki disease primarily affects children; gastrointestinal involvement is uncommon, and coronary artery dilatation is the main cardiac problem observed. MIS almost universally involves the gastrointestinal and cardiac systems; incidence of shock and myocarditis/pericarditis is high (*3*). We ruled out adult-onset Still's disease on the basis of absence of arthritis, liver enzyme levels within reference range, and an inconsistent skin rash (*14*). Features of toxic shock syndrome are also similar to those reported for this patient, including fever, rash, desquamation, hypotension, gastrointestinal symptoms, myalgia, and mucosal inflammation. However, we found no evidence of staphylococcal or streptococcal infection, and the patient had not used tampons. Although we cannot rule out other infections, autoimmune causes, or malignancies, the most reasonable diagnosis for this patient is MIS-A.

MIS mainly occurs after SARS-CoV-2 infection in children. The reason for this age predilection is unknown, but if it is associated with the SARS-CoV-2 spike protein or antibodies induced by the spike protein (the target of SARS-CoV-2 vaccines), vaccine-associated MIS-C may become more common as more children receive SARS-CoV-2 vaccination.

About the Author

Prof. Choi is an infectious disease physician at the Division of Infectious Diseases and the Department of Intensive Care at the Chungnam National University Sejong Hospital. He is actively engaged in COVID-19 treatment. His primary research interests include intensive care unit infection control and sepsis.

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ANNEXURE P-21

www.ndtv.com

India's Wait Over, Drug Regulator Says Covid Vaccines Cleared "110% Safe"

Sukirti Dwivedi

5-6 minutes

Drug Controller General of India gave approval for emergency use to two Covid vaccines.

New Delhi: Two vaccines for coronavirus, Oxford University's Covishield, which is being developed by the Pune-based Serum Institute, and Bharat Biotech's Covaxin, received emergency approval from the country's drug regulator on Sunday. "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe," Drug Controller General of India VG Somani said, adding Covishield was found to be 70.42 per cent effective and Bharat Biotech's Covaxin was "safe and provides a robust immune response". Hailing the scientific community and frontline Corona warriors, Prime Minister Narendra Modi tweeted, "It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India". There is no word yet on when the vaccination process will begin.

Here are the top 10 points in this big story:

1. "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe. Some side effects like mild fever, pain and allergy are common for every vaccine," Drug Controller General of India VG Somani said. The approval from the Drug Controller comes days after a government-appointed experts' panel gave clearance to the vaccines.

2. Both vaccines have to be administered in two doses and stored at temperatures between 2 and 8 degrees Celsius. The government will give priority to 1 crore healthcare workers and 2 crore frontline workers when the vaccinations begin, Union Health Minister Dr Harshvardhan said as a countrywide dry run for the vaccination process was conducted on Saturday.

3. "It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India! This shows the eagerness of our scientific community to fulfil the dream of an Aatmanirbhar Bharat, at the root of which is care and compassion," PM Modi tweeted.

4. Pune-based Serum Institute, the Drug Controller General said, conducted Phase 2 and Phase 3 trials on 1,600 participants in India. Recommendation was made for restricted use and the trials will continue, he added. The vaccine, developed by the Oxford University and pharma giant AstraZenca is already in use abroad.

5. Bharat Biotech's Covaxin is conducting trials in collaboration with the Indian Council of Medical Research. The Drug Controller said that its Phase I and Phase II trials were conducted in around 800 people and the results showed that it is "safe and provides a robust immune response". The Phase III trial in on and 22,500 of the 25,800 participants have been vaccinated.

6. The health ministry said the government's expert committee has reviewed Bharat Biotech's data on "safety and immunogenicity" and gave permission for "restricted use in emergency situation in public interest". The idea was to have "more options for vaccinations, especially in case of infection by mutant strains," the ministry said, adding that the clinical trials will continue.

7. "Happy new year, everyone! All the risks @SerumInstIndia took with stockpiling the vaccine, have finally paid off. COVISHIELD, India's first COVID-19 vaccine is approved, safe, effective and ready to roll-out in the coming weeks," Serum Institute chief Adar Poonawalla tweeted.

8. "It has been learnt that the vaccines of Bharat Biotech and the Serum Institute have received emergency approval. All preparations are underway for the Delhi government. First health workers and frontline workers will be given the vaccine, Then those above age 50 will be given the vaccine. Health workers and frontline workers will be vaccinated under First phase," Delhi health minister Satyendar Jain said. The vaccines will be given free of cost in Delhi, the minister earlier said.

9. Flagging concerns over Bharat Biotech's Covaxin, senior Congress leader Shashi Tharoor tweeted, "The Covaxin has not yet had Phase 3 trials. Approval was premature and could be dangerous. @drharshvardhan should please clarify. Its use should be avoided till full trials are over. India can start with the AstraZeneca vaccine in the meantime".

10. India has reported 18,177 new infections in the last 24 hours - 4.7 per cent lower than yesterday - taking the total Coronavirus cases to 1,03,23,965. Data from the health ministry showed the country has also logged 217 deaths, taking the total number of fatalities to 1,49435.

154Comments

ANNEXURE P-22

medicaldialogues.in

There is no side effect that would result in death: AIIMS Director allays covid-19 vaccine fears

Medical Dialogues Bureau

4-5 minutes

Published On 19 Jan 2021 9:30 AM | Updated On 19 Jan 2021 9:30 AM

"Even if a person takes Crocin or Paracetamol, they may develop allergic reactions. There is nothing to worry about. There is no side effect that would result in death," AIIMS Director, Dr Guleria said.

New Delhi: AIIMS Director Randeep Guleria on Monday allayed apprehensions about the coronavirus vaccines and assured that the side-effects will not result in the death of the beneficiary. The nationwide Covid vaccination drive had commenced on January 16 and a total of 447 adverse events following immunization (AEFI) were reported during the first two days, with most of them being minor...

New Delhi: AIIMS Director Randeep Guleria on Monday allayed apprehensions about the coronavirus vaccines and assured that the side-effects will not result in the death of the beneficiary.

The nationwide Covid vaccination drive had commenced on January 16 and a total of 447 adverse events following immunization (AEFI) were reported during the first two days, with most of them being minor along with three cases of hospitalization.

Also Read: AIIMS Director clarifies nod to Covaxin is for emergency situation, not emergency use authorization

"Even if a person takes Crocin or Paracetamol, they may develop allergic reactions. There is nothing to worry about. There is no side-effect that would result in death," Dr Guleria said.

He added, "Main side-effects are body ache, fever, pain at injection site which subside in 1-2 days and take place in less than 10 per cent of people. If the side-effects are severe, there could be skin rashes, nausea, difficulty in breathing."

The AIIMS Director said that people must come forth to get vaccinated if they want India to come out of the Covid-19 pandemic, decrease the mortality rate, bring the economy back on track and reopen schools.

On January 16, moments after Prime Minister Narendra Modi launched the vaccination drive across the country, the jab was administered to the AIIMS chief on live telecast. Dr Guleria was the third person to take the shot in the institute.

"I have no side-effects. I am feeling perfectly alright," he told the media, two days after taking the jab, in a bid to allay fears and apprehensions about the safety of the coronavirus vaccines.

The rollout of Oxford's 'Covishield' vaccine, manufactured by Serum Institute of India, and Bharat Biotech's 'Covaxin' began in the country amid apprehensions about the safety of the latter. Covaxin is currently undergoing late-stage clinical trials which are crucial to determining the efficacy of the shot.

'Covaxin' has been in the spotlight ever since it received the green signal from the drug regulator for restricted emergency use. The approval without adequate efficacy data drew flak from public health advocacy groups, researchers, scientists and activists.

Meanwhile, as many as 2,24,311 beneficiaries have received doses of Covid-19 vaccines in the last two days. Only 17,072 beneficiaries were vaccinated in six states on Day 2.

Also Read: Former AIIMS director, experts come in defense of Covid-19 vaccines- Covaxin, Covishield, slam skeptics

Source : IANS

Medical Dialogues Bureau consists of a team of passionate medical/scientific writers, led by doctors and healthcare researchers. Our team efforts to bring you updated and timely news about the important happenings of the medical and healthcare sector. Our editorial team can be reached at editorial@medicaldialogues.in.

Next Story

358

ANNEXURE P-23

pib.gov.in

Frequently Asked Questions on COVID-19 Vaccination

10-12 minutes

Ministry of Health and Family Welfare

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.

ANNEXURE P-24

zeenews.india.com

Covishield is 'safe and immunogenic', has no side effects, asserts Serum Institute of India

Zee Media Bureau

3-3 minutes

PUNE: Pune-based Serum Institute of India (SII) on Tuesday (December 01, 2020) claimed that Covishield - the anti-Covid-19 vaccine - being developed jointly by it is completely ''safe and immunogenic''. The company also categorically refuted claims that the Covishield anti-Covid-19 vaccine has side-effects.

"Covishield is safe & immunogenic," the Pune-based company said.

The clarification from the company came after a Chennai-based man claimed that he suffered neurological and psychological side effects taking a shot of Covid-19 vaccine Covishield during the human trial being conducted by Serum Institute of India's (SII).

Refuting the charge, the company said there was no correlation between the two. In a social media post, the institute asserted, "Covishield is safe & immunogenic, the incident with the Chennai volunteer no way induced by the vaccine."

“Incident with the Chennai volunteer no way induced by the vaccine. All regulatory and ethical processes and guidelines were followed. Principal Investigator, DSMB and Ethics Committee stated it was not related to the vaccine trial,” the Serum Institute of India said.

"While the Serum Institute of India is sympathetic to the volunteer`s medical condition, there is absolutely no correlation between the vaccine trial and the medical condition of the volunteer. The volunteer is falsely laying the blame for his medical problems on the COVID vaccine trial,'' the company said.

"The SII had stated that the volunteer was specifically informed by the medical team that the complications he suffered were independent of the vaccine trial he underwent. It is evident that the intention behind the spreading of such malicious information is an oblique pecuniary motive. The Serum Institute of India will seek damages in excess of Rs 100 crore for the same and will defend such malicious claims," the vaccine manufacturer said.

It added, “The legal notice was sent to safeguard the reputation of the company which is being unfairly maligned.”

SII is conducting clinical trials of AstraZeneca-Oxford's Covid-19 vaccine candidate in India. Currently, the phase-3 clinical trial of Covaxin is being conducted across India involving 26,000 participants. The vaccine will be produced in the Biosafety Level 3 production facility of the company.

The vaccine candidate, Covishield, is being developed by the UK's Oxford University and US pharma giant AstraZeneca. The SII is a manufacturing partner for the vaccine.

Live TV

अजय भल्ला, भा.प्र.से.
AJAY BHALLA, IAS

सत्यमेव जयते

गृह सचिव
Home Secretary
भारत सरकार
Government of India
नॉर्थ ब्लॉक/North Block
नई दिल्ली/New Delhi

No. 40-3/2020-DM-I(A)

26th April, 2021

Dear Chief Secretary,

Please refer to the guidelines for effective control of COVID-19, issued vide Ministry of Home Affairs' (MHA) Order of even No. dated 23.03.2021, wherein it is prescribed that States and UTs, based on their assessment of the situation, may impose local restrictions at district/sub-district and city/ward level, with a view to contain the spread of COVID-19.

2. In the recent past, a sharp increase in COVID-19 cases has been observed along with high positivity rate. Considering this unprecedented surge, there is an urgent need for States/UTs to consider strict COVID management and control measures, in the surge areas to bring the situation under control. Accordingly, Ministry of Health & Family Welfare (MoHFW), vide their DO no. Z.28015/85/2021-DM Cell dated 25th April 2021, has advised all States and UT Governments to implement an intensive, local and focused containment framework, focused on specific districts/ cities/ areas, and identified based on a prescribed criterion. The containment framework has been outlined in detail in the Annexure to the said MoHFW letter (copy enclosed). All States/UTs have also been advised to consider a further graded response in accordance with local situation, requirements and resources.

3. I would, therefore, urge you to issue directions to district authorities in your State/UT, to take all necessary measures, as advised by MoHFW in their letter, for the implementation of the containment framework, so as to flatten the curve. I would also advise that Orders issued by the respective State Governments/UT Administrations/district authorities, for imposing restrictions, should be widely disseminated to the public and to the field functionaries for their effective implementation.

With regards,

Yours sincerely,

26/04/21

(Ajay Bhalla)

Encl. as above

Chief Secretaries of all States

Annexure to Ministry of Health & Family Welfare (MoHFW) DO no. Z.28015/85/2021-DM Cell dated 25th April 2021

Annexure – A

Implementation Framework for community containment/large containment areas

Understanding the virus transmission dynamics:

The virus transmits through the human host. It is imperative to understand that in order to contain the transmission of the virus, the strategies involve not just containing the virus but also the human host.

Broadly, the **strategies** are:

1. **Individual actions** such as wearing of masks, maintaining a distance of 6 feet from others, sanitizing one's hands frequently and not attending any mass gathering; and

2. **Public Health measures** to contain the virus by:

   - **quarantining** and testing individuals suspected to be positive including contacts of SARS-CoV-2 positive persons, SARI cases, persons with flu like symptoms etc. and ensuring that they are not mobile and thus able to spread the infection
   - **isolating** all those who are positive, tracing their contacts, quarantining and testing them.
   - where there are clusters of cases, simply quarantining individuals or families will not help. In that case, **containment zones** with clear boundaries and stringent controls will be required to ensure that the infection does not spread outside. This is in line with the containment strategy followed worldwide and also already enumerated in SOPs of the Ministry of Health. This would mean a large geographical area like a city or district or well defined parts thereof, where cases are high and spiraling up, gets contained physically, However, regulated movement of public transport would be permitted.

3. **Evidence Based Decision:** The decision on where and when to go for large Containment Zone (CZ) has to be evidence based and done at the State/UT level after proper analysis of the situation, such as; the population affected, the geographical spread, the hospital infrastructure, manpower, the ease of enforcing boundaries etc.

4. However, in order to facilitate objective, transparent, and epidemiologically sound decision making, the following broad-based framework is provided to aid States UTs in selection of districts/areas:

S. No.	Parameter	Thresholds
1	**Test positivity**	Test positivity of **10%** or more in the last one week
OR		
2	**Bed occupancy**	Bed occupancy of **more than 60%** on either **oxygen supported or ICU beds**

.....contd/-

5. The areas requiring **Intensive action and local containment connotes** specific and well defined geographical units such as cities/town/part of the towns/district headquarters/semi-urban localities/municipal wards/*panchayat areas* etc.

6. The areas so identified for intensive action and local containment will primarily focus on **the following strategic areas of intervention**:

A. Containment

i. Focus will be on **containment** as a **major approach to** flatten the current curve of the epidemic.
ii. **Night curfew:** Movement of individuals shall be strictly prohibited during night hours, except for essential activities. Local administration shall decide the duration of the night curfew hours and issue orders, in the entire area of their jurisdiction, under appropriate provisions of law, such as under Section 144 of CrPC, and ensure strict compliance.
iii. The spread of the infection has to be controlled through **restricting the intermingling amongst people,** the only known host for the COVID-19 virus.
iv. Social/ political / sports / entertainment / academic / cultural / religious / festival-related and other **gathering and congregations shall be prohibited.**
v. **Marriages (attended by up to 50 persons) and funerals/ last rites (attended by up to 20 persons) may be allowed.**
vi. All shopping complexes, cinema halls, restaurants & bars, sports complexes, gym, spas, swimming pool and religious places should remain closed.
vii. **Essential services and activities** such as **healthcare services, police, fire, banks, electricity, water and sanitation, regulated movement of public transport** including all **incidental services and activities** needed for a smooth functioning of these activities **shall continue**. Such services shall continue in both **public and private sector.**
viii. **Public transport** (railways, metros, buses, cabs) **to operate at a maximum capacity of 50%.**
ix. There shall be **no restrictions on inter-state and intra-state movement including transportation of essential goods.**
x. All **offices,** both government and private, to function with **a maximum staff strength of 50%.**
xi. **All industrial and scientific establishments,** both government and private may be **allowed** subject to **the workforce following physical distancing norms.** They shall also be tested through RAT (in case of individuals identified with flu like symptoms) from time to time.
xii. The SOPs already issued by MoHFW, including training manuals for surveillance teams and supervisors are available on the website & must be followed.
xiii. **However, these are indicative activities, and States/ UTs should make a careful analysis of the local situation, areas to be covered, and probability of transmission and then take a decision.**

.....contd/-

xiv. The restrictions as above shall continue for a **period of 14 days.**

xv. **Before declaring a containment area, make a public announcement, outlining the rationale for the same and the kind of restrictions that will be in place (a leaflet in local language may be distributed highlighting the gravity of the situation and restrictions to be followed)**

xvi. **Community volunteers, civil society organizations, ex- servicemen, and members of the local NYK/NSS centers etc.** should be involved for sustainable management of containment activities, translating the aforementioned leaflets and for encouraging people in the community for sustained behavior change as well as vaccination.

B. Testing and Surveillance

Districts will continue with the strategy of **'Test-Track-Treat-Vaccinate' and Implementation of Covid Appropriate Behavior across the district** as the ongoing strategy for the management of COVID-19.

i. Ensure **adequate testing and door to door case search** in the area through adequate number of teams formed for such purpose.

ii. Plan for **testing of all clinically resembling** cases of Influenza like illness (ILI) & SARI through **RAT**. All symptomatic individuals turning out to be negative for SARS-CoV-2 infection with RAT need to be **retested through RT PCR.**

iii. Ensuring **compliance of COVID Appropriate Behaviour** aggressively both through creation of awareness through involvement of the community based organizations and through stringent regulatory framework.

C. Clinical Management

i. Analysis to be undertaken with respect to **requirement of health infrastructure** so as to **manage the present and projected cases (next one month)** and necessary action initiated to ensure sufficient oxygen-supported beds, ICU beds, ventilators, ambulances including creation of makeshift hospitals, as needed. Sufficient quarantine facilities shall also be re-activated.

ii. Leverage **government, private health facilities** including hospital facilities available with **central ministries, railway coaches, temporary field hospitals etc.**

iii. Ensure that people satisfying protocol for home isolation only are allowed under **home isolation**. Create a **mechanism for their regular monitoring** through Call Centres along with **regular visit of surveillance teams** to such houses.

iv. Provision of a **customized kit** for all patients under home isolation, **including detailed dos and don'ts** to be followed by them.

v. Specific **monitoring** shall be done for **high risk cases** and their timely shifting to the health facility. Similarly, **elderly and co-morbid contacts** of positive cases shall be **shifted to quarantine centres** and monitored.

.....contd/-

vi. Appoint **senior district officials as In-charge** for all Covid dedicated hospitals and create a **mechanism for seamless shifting** of patients (**including home isolation** cases) as per their symptom to the relevant facilities.

vii. Ensure availability of **sufficient ambulances** for such purpose.

viii. Coordinate **availability of oxygen, other related logistics, drugs** etc. in collaboration with state officials and ensure their rational use.

ix. **Oxygen therapy** for the admitted cases shall follow the **guidelines issued by Ministry of Health** on the **rational use** of oxygen

x. Use of **investigative drugs** (Remdesivir / Tocilizumab etc.) shall also **strictly follow the clinical management protocol/advisories issued by Ministry of Health**.

xi. **Facility wise cases and deaths** shall be analyzed on **daily basis** by the **Incident Commander/District Collector/Municipal Commissioner**. **Death-audit** shall be undertaken for **all deaths** in the hospitals and in the community to provide supportive supervision to field staff/hospitals.

D. Vaccination

100% vaccination for the **eligible age-groups** shall be undertaken duly **creating additional vaccination centres and optimal capacity utilization of existing Centres.**

E. Community Engagement

i. Ensure **adequate advance information to community**, also highlighting the need for stringent containment actions so as to win their involvement and support.

ii. Provide enough time for people movement for essential requirements etc. before announcing the large scale containment

iii. Take necessary actions to **avoid misinformation & panic** in the community.

iv. **Involve local level NGOs/CBOs/CSOs, Opinion Makers and subject experts** to create a positive environment and for sustained dialogue with the community.

v. **Create wide publicity** on **early warning signals** and self-reporting so as to identify cases early and to prevent avoidable deaths among home isolation patients.

vi. Give **wide publicity on the mechanism** whereby people can get themselves tested, details of available health facilities, requisitioning an ambulance etc (community based organizations should be encouraged to create WhatsApp groups for quick dissemination of information so that the individuals in need of prevention and/or care services do not suffer delay).

vii. Ensure that **details of hospital beds and their vacancy status is made available on-line and also released to media on a daily basis**.

viii. Details on **availability of oxygen, drugs, vaccine and vaccination centres**; including the guidelines related with use of Remdesivir/Tocilizumab etc. be also widely publicized so as to create confidence in the community.

.....contd/-

ix. Community should be oriented about the feasibility of managing mild COVID-19 cases at home with appropriate monitoring of vital parameters such as temperature and oxygen saturation with the help of pulse oxymeter.

x. **Need for COVID Appropriate Behaviour** including **regulatory framework for enforcement** should be **widely publicized.**

xi. **Build confidence** in community duly highlighting the nature of disease, the fact **that early identification** helps in early recovery and more than 98% people recover to **remove fear as well as stigma** related with Covid-19. Involvement of civil society organizations to hold such orientations go a long way in this regard.

अजय भल्ला, भा.प्र.से.
AJAY BHALLA, IAS

सत्यमेव जयते

गृह सचिव
Home Secretary
भारत सरकार
Government of India
नॉर्थ ब्लॉक/North Block
नई दिल्ली/New Delhi

No. 40-3/2020-DM-I(A)

27th May, 2021

Dear Administrator,

Kindly refer to Ministry of Home Affairs (MHA) Order of even number issued today, vide which MHA Order dated 29.04.2021, issued to ensure compliance to the containment measures for COVID-19, as conveyed by Ministry of Health & Family Welfare (MoHFW) D.O. letter dated 25.04.2021, has been extended upto 30th June, 2021.

2. The strict implementation of containment and other measures has led to a declining trend in the number of new and active cases, across States & UTs, barring some areas in the Southern and North-Eastern regions.

3. I would like to highlight that in spite of the declining trend, the number of active cases presently is still very high. It is, therefore, important that containment measures may continue to be implemented strictly. Any relaxation by States/UTs, may be considered at an appropriate time, in a graded manner, after assessing the local situation, requirements and resources.

4. I would, therefore, urge you to continue compliance to the containment measures, as has been advised by MoHFW in their letter dated 25.04.2021, so as to fully overcome the pandemic. In this regard, necessary directions may be issued to district authorities in your State/UT, for taking all necessary measures. I would also advise that Orders/guidelines, issued by the respective State Governments/UT Administrations/district authorities, for implementing containment measures, should be widely disseminated to the public and to the field functionaries, for their effective implementation.

With regards,

Yours sincerely,

27/05/2021

(Ajay Bhalla)

Administrators of all UTs

Annexure to Ministry of Health & Family Welfare (MoHFW) DO no. Z.28015/85/2021-DM Cell dated 25th April 2021

Annexure – A

Implementation Framework for community containment/large containment areas

Understanding the virus transmission dynamics:

The virus transmits through the human host. It is imperative to understand that in order to contain the transmission of the virus, the strategies involve not just containing the virus but also the human host.

Broadly, the **strategies** are:

1. **Individual actions** such as wearing of masks, maintaining a distance of 6 feet from others, sanitizing one's hands frequently and not attending any mass gathering; and

2. **Public Health measures** to contain the virus by:

   - **quarantining** and testing individuals suspected to be positive including contacts of SARS-CoV-2 positive persons, SARI cases, persons with flu like symptoms etc. and ensuring that they are not mobile and thus able to spread the infection
   - **isolating** all those who are positive, tracing their contacts, quarantining and testing them.
   - where there are clusters of cases, simply quarantining individuals or families will not help. In that case, **containment zones** with clear boundaries and stringent controls will be required to ensure that the infection does not spread outside. This is in line with the containment strategy followed worldwide and also already enumerated in SOPs of the Ministry of Health. This would mean a large geographical area like a city or district or well defined parts thereof, where cases are high and spiraling up, gets contained physically, However, regulated movement of public transport would be permitted.

3. **Evidence Based Decision:** The decision on where and when to go for large Containment Zone (CZ) has to be evidence based and done at the State/UT level after proper analysis of the situation, such as; the population affected, the geographical spread, the hospital infrastructure, manpower, the ease of enforcing boundaries etc.

4. However, in order to facilitate objective, transparent, and epidemiologically sound decision making, the following broad-based framework is provided to aid States UTs in selection of districts/areas:

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vii. **Essential services and activities** such as **healthcare services, police, fire, banks, electricity, water and sanitation, regulated movement of public transport** including all **incidental services and activities** needed for a smooth functioning of these activities **shall continue**. Such services shall continue in both **public and private sector.**
viii. **Public transport** (railways, metros, buses, cabs) **to operate at a maximum capacity of 50%.**
ix. There shall be **no restrictions on inter-state and intra-state movement including transportation of essential goods.**
x. All **offices,** both government and private, to function with **a maximum staff strength of 50%.**
xi. **All industrial and scientific establishments,** both government and private may be **allowed** subject to **the workforce following physical distancing norms.** They shall also be tested through RAT (in case of individuals identified with flu like symptoms) from time to time.
xii. The SOPs already issued by MoHFW, including training manuals for surveillance teams and supervisors are available on the website & must be followed.
xiii. **However, these are indicative activities, and States/ UTs should make a careful analysis of the local situation, areas to be covered, and probability of transmission and then take a decision.**

.....contd/-

xiv. The restrictions as above shall continue for a **period of 14 days.**

xv. **Before declaring a containment area, make a public announcement, outlining the rationale for the same and the kind of restrictions that will be in place (a leaflet in local language may be distributed highlighting the gravity of the situation and restrictions to be followed)**

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iii. Ensure that people satisfying protocol for home isolation only are allowed under **home isolation**. Create a **mechanism for their regular monitoring** through Call Centres along with **regular visit of surveillance teams** to such houses.

iv. Provision of a **customized kit** for all patients under home isolation, **including detailed dos and don'ts** to be followed by them.

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.....contd/-

vi. Appoint **senior district officials as In-charge** for all Covid dedicated hospitals and create a **mechanism for seamless shifting** of patients (**including home isolation** cases) as per their symptom to the relevant facilities.

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xi. **Facility wise cases and deaths** shall be analyzed on **daily basis** by the **Incident Commander/District Collector/Municipal Commissioner**. **Death-audit** shall be undertaken for **all deaths** in the hospitals and in the community to provide supportive supervision to field staff/hospitals.

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100% vaccination for the **eligible age-groups** shall be undertaken duly **creating additional vaccination centres and optimal capacity utilization of existing Centres.**

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.....contd/-

ix. Community should be oriented about the feasibility of managing mild COVID-19 cases at home with appropriate monitoring of vital parameters such as temperature and oxygen saturation with the help of pulse oxymeter.

x. **Need for COVID Appropriate Behaviour** including **regulatory framework for enforcement** should be **widely publicized.**

xi. **Build confidence** in community duly highlighting the nature of disease, the fact **that early identification** helps in early recovery and more than 98% people recover to **remove fear as well as stigma** related with Covid-19. Involvement of civil society organizations to hold such orientations go a long way in this regard.

No. 40-3/2020-DM-I(A)
Government of India
Ministry of Home Affairs

North Block, New Delhi-110001
Dated 27th December, 2021

ORDER

Whereas, an Order of even number dated 28th September 2021, was issued to ensure compliance with the containment measures for COVID-19, as conveyed *vide* Ministry of Health & Family Welfare (MoHFW) DO letter No. Z.28015/85/2021-DM Cell, dated 21st September, 2021, which was further extended for a period upto 31.12.2021 *vide* Order of even number, dated 30.11.2021;

And whereas, in view of the initial signs of surge in cases of COVID-19 as well as increased detection of the Variant of Concern (VoC), 'Omicron', in different parts of the country, MoHFW vide D.O. letter No. Z.28015/318/21-EMR, dated 21st December, 2021, has issued an advisory to all the States and Union Territories (UTs), prescribing a normative framework for taking evidence based containment measures at district/ local level;

Whereas, in exercise of the powers conferred under section 6(2)(i) of the Disaster Management Act, 2005 (DM Act), the National Disaster Management Authority (NDMA) has directed the undersigned to issue an Order, for containment of COVID-19 in the country;

Now, therefore, in exercise of the powers, conferred under Section 10(2)(I) of the DM Act, the undersigned, hereby directs the State/ UT Governments and State/ UT Authorities to consider implementation of the normative framework, as conveyed *vide* aforesaid MoHFW advisory, dated 21st December, 2021, as per **Annexure-I**, until 31.01.2022. States/ UTs will take necessary measures, under the relevant provisions of the DM Act. It is further directed that:

(i) The National Directives for COVID-19 Management, as specified in **Annexure II**, shall continue to be strictly followed throughout the country.

(ii) All the District Magistrates shall strictly enforce the above measures. For the enforcement of social distancing, State/ UT Governments may, as far as possible, use the provisions of Section 144 of the Criminal Procedure Code (CrPC) of 1973.

(iii) Any person violating these measures will be liable to be proceeded against as per the provisions of Sections 51 to 60 of the DM Act, besides legal action under Section 188 of the IPC, and other legal provisions, as applicable.

27/12/2021

Union Home Secretary
and, Chairperson, National Executive Committee (NEC)

To:

1. The Secretaries of Ministries/ Departments of Government of India
2. The Chief Secretaries/Administrators of States/Union Territories

(As per list attached)

Copy to:

i. All Members of the National Executive Committee

ii. Member Secretary, National Disaster Management Authority

Annexure-I

राजेश भूषण, आईएएस
सचिव

RAJESH BHUSHAN, IAS
SECRETARY

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

D.O.No.Z.28015/318/21-EMR
21 December, 2021

Dear Colleague,

This is regarding the measures that need to be taken in view of initial signs of surge in cases of Covid-19 as well as increased detection of the Variant of Concern (VoC), 'Omicron' in different parts of the country.

2. In this context kindly recall this Ministry's earlier guidance shared with States/UTs on multiple occasions regarding the recommended strategies for containment and restrictions, keeping the District as a unit.

3. At the **district level** there should be constant review of emerging data regarding the population affected by COVID-19, geographical spread, hospital infrastructure and its utilization, manpower, notifying Containment Zones, enforcement of perimeter of containment zones etc. This evidence should be the basis for effective decision making at the district level itself. Such a strategy ensures that infection is contained at the local level itself before it spreads to other parts of the state.

4. The main elements of the framework to be used by States and UTs to facilitate decision making at the District Level are as follows:

i) Test positivity of 10% or more in the last one week
OR
ii) Bed occupancy of 40% or more on oxygen supported or ICU beds

In case any one of these parameters are met in any District, district level containment measures and restrictions may be put in place forthwith. Equally important, the restrictions must be strictly enforced.

5. Based on current scientific evidence, the VOC Omicron is at least 3 times more transmissible than the Delta VOC. Besides, the Delta VOC is still present in different parts of the country. Hence, even greater foresight, data analysis, dynamic decision making and strict & prompt containment action is required at the local and district level. The decision making at the State/UT and district level must be very prompt and focussed.

6. The template above provides a normative framework. However, based on the **local situation** and population characteristics such as density etc., and keeping in mind the higher transmissibility of Omicron, States/UTs can take containment measures and restrictions **even before these thresholds** are reached.

7. Some of the **strategic areas of intervention** focusing on containment, test, track, surveillance, clinical management, vaccination and Covid Appropriate Behaviour to be taken up are as follows:

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
Tele : (O) 011-23061863, 23063221, Fax : 011-23061252, E-mail : secyhfw@nic.in

A -**Containment**: imposition of night curfew, strict regulation of large gatherings, curtailing numbers in marriages and funerals, restricting numbers in offices, industries, public transport etc. In case of all new clusters of Covid positive cases, prompt notification of "Containment Zones", "Buffer Zones" should be done, strict perimeter control of Containment Zone as per extant guidelines must be ensured. All cluster samples must be sent to INSACOG Labs for Genome Sequencing without delay.

B- **Testing and surveillance**: testing as per ICMR and MoHFW guidelines, door to door case search, testing of all SARI/ILI and vulnerable/co-morbid people, ensuring right proportion of RT-PCR tests in total tests being conducted daily, contact tracing of all Covid positive persons & their timely testing, utilizing the access to "AIR SUVIDHA" Portal by State Surveillance Officers (SSOs) & District Surveillance Officers (DSOs) to monitor the international passengers who have arrived in their States & Districts etc.

C- **Clinical Management**: increase bed capacity, other logistics like ambulances, mechanism for seamless shifting of patients, availability and operational readiness of oxygen equipments, buffer stock of drugs to be ensured by prompt utilization of Emergency Covid Response Package (ECRP-II) funds released by Central Government & other available resources etc. The existing National Clinical Management Protocol remains unchanged for Omicron.

Ensure stringent enforcement of home isolation as per extant guidelines. This would include among others: customized kit for persons undergoing home isolation, their regular monitoring through call centers as well as home visits etc. This will be a very critical activity in the days to come specially to ensure that persons under home isolation do not spread the virus to others in view of its higher transmissibility.

D- **Vaccination:** ensure 100% coverage of left out first and second dose eligible beneficiaries in an accelerated manner. Special focus to be given to those districts where the first & second dose coverage is less than the national average. The door-to-door vaccination campaign need to be strengthened.

E- **Community engagement and Covid Appropriate Behaviour**: Ensure advance engagement and information so that there is no misinformation or panic, transparent communication on hospital and testing infrastructure availability, regular press briefings etc. Participation of community backed by strict enforcement is necessary for ensuring Covid Appropriate Behaviour.

8. Kindly activate the War rooms/EOCs and keep analyzing all trends and surges, no matter how small and keep taking proactive action at the district/local level.

Regular reviews with field officers and proactive action in this regard will definitely control the spread of infection and flatten the curve.

Warm Regards.

Yours sincerely

(Rajesh Bhushan)

Chief Secretary/Administrator of all States / UTs

Annexure II

NATIONAL DIRECTIVES FOR COVID-19 MANAGEMENT

1. **Face covering:** Wearing of face cover is compulsory in public places; in workplaces; and during transport.

2. **Social distancing:** Individuals must maintain a minimum distance of 6 feet (*2 gaz ki doori*) in public places.

   Shops will ensure physical distancing among customers.

3. **Spitting in public places** will be punishable with fine, as may be prescribed by the State/ UT local authority in accordance with its laws, rules or regulations.

   Additional directives for Work Places

4. **Work from home (WfH):** As far as possible the practice of WfH should be followed.

5. **Staggering of work/ business hours** will be followed in offices, work places, shops, markets and industrial & commercial establishments.

6. **Screening & hygiene:** Provision for thermal scanning, hand wash or sanitizer will be made at all entry points and of hand wash or sanitizer at exit points and common areas.

7. **Frequent sanitization** of entire workplace, common facilities and all points which come into human contact e.g. door handles etc., will be ensured, including between shifts.

8. **Social distancing:** All persons in charge of work places will ensure adequate distance between workers and other staff.

ANNEXURE P-28

No. 40-3/2020-DM-I(A)
Government of India
Ministry of Home Affairs

North Block, New Delhi-110001
Dated 25th February, 2022

ORDER

Whereas, an Order of even number dated 27th December 2021, was issued to ensure compliance with the containment measures for COVID-19, as conveyed *vide* Ministry of Health & Family Welfare (MoHFW) DO letter No. Z.28015/318/21-EMR, dated 21st December, 2021, which was further extended for a period upto 28.02.2022 *vide* Order of even number, dated 27.01.2022;

And whereas, in view of the significant decline in the COVID-19 cases across the country, MoHFW vide D.O. letter No. Z.26015/1/2022-DM Cell, dated 18th February, 2022, has issued an advisory to all the States and Union Territories (UTs), stressing the need to follow a risk assessment based approach on the opening of economic activities;

Whereas, in exercise of the powers conferred under section 6(2)(i) of the Disaster Management Act, 2005 (DM Act), the National Disaster Management Authority (NDMA) has directed the undersigned to issue an Order, for containment of COVID-19 in the country;

Now, therefore, in exercise of the powers, conferred under Section 10(2)(l) of the DM Act, the undersigned, hereby directs the State/ UT Governments and State/ UT Authorities to implement a risk assessment based approach on the opening of economic activities, as conveyed *vide* aforesaid MoHFW advisory, dated 18th February, 2022, as per **Annexure-I**, until 31.03.2022. It is further directed that the National Directives for COVID-19 Management, as specified in **Annexure II**, shall continue to be followed throughout the country.

25/02/22

Union Home Secretary
and, Chairperson, National Executive Committee (NEC)

To:

1. The Secretaries of Ministries/ Departments of Government of India
2. The Chief Secretaries/Administrators of States/Union Territories

   (As per list attached)

Copy to:

i. All Members of the National Executive Committee

ii. Member Secretary, National Disaster Management Authority

Annexure-I

राजेश भूषण, आईएएस
सचिव
RAJESH BHUSHAN, IAS
SECRETARY

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

D.O No. Z.26015/1/2022-DMCell
18th February 2022

Dear Chief Secretary,

This is regarding measures that need to be taken in view of the sustained decline in the number of new Covid-19 cases across the country. From time to time, this Ministry has been advising and guiding the States/UTs regarding recommended strategies for testing, surveillance, containment and restrictions keeping in view the District as a unit.

2. Taking into account the significant decline in the Covid-19 cases across the country, the States have been undertaking various measures to reopen economic and social activities. There is a need to follow a risk assessment-based approach on the opening of economic activities without losing the gains made so far in the fight against the virus.

3. In this context, this Ministry's earlier guidance shared with States/UTs on multiple occasions regarding the recommended strategies for testing, surveillance and containment based restrictions, keeping the District as a unit for decision making, are still valid.

4. **Evidence-Based Decision making**: At the **district level** there should be constant review of emerging data based on a sustained and critical level of testing to facilitate decision for restrictions/relaxation based on evidence. Such decisions should be taken at State/UT level after proper analysis of the local situation, such as the emergence of new cases/clusters, case positivity, population affected, the geographical spread of cases & hospital infrastructure preparedness.

5. **Broad-based framework for relaxation/restrictions:** In order to identify areas where restrictions need to be imposed/continued in districts/areas, the following broad-based framework is provided to aid States UTs:

S. No.	Parameter	Thresholds
1	**Test positivity**	Test positivity of 10% or more in the last week
OR		
2	**Bed occupancy**	Bed occupancy of **more than 40%** on either **oxygen supported or ICU beds**

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a) States need to watch the trajectory of cases in particular geographies to ensure that the areas reporting positivity rate above 10% and/or bed occupancy more than 40% on either oxygen supported or ICU beds should undertake required enforcement, containment, and restriction measures.

b) As the case trajectory may vary from State to State and there would be variation in the spread of infection within States also, there is a need to take decisions with respect to containment and restriction measures primarily at the local/sub-national level by concerned State and District Administration.

c) Continued focus on community participation for adherence to Covid Appropriate behavior including proper wearing of mask and physical distancing (2 gaz ki doori), as directed under the national directives for Covid-19 management under Disaster Management Act, will however be important measures to be undertaken across the country.

6. Some of the **strategic· areas of intervention** focusing on containment, test, track, surveillance, clinical management, vaccination and Covid Appropriate Behaviour to be taken up are as follows:

I. Relaxation in various activities duly following the National Directives for Covid-19 management under Disaster Management Act

i. Focus will be on graded relaxation to support the resumption of economic activities.

ii. Social/sports/entertainment/academic/cultural/religious/festival-related and other gatherings and congregations may be resumed. The decision for allowing these activities shall be taken up by the concerned States duly guided by the principles as enunciated above.

iii. Offline classes can be resumed in academic institutes without any restrictions. However, the school administration may also leverage a hybrid model of imparting education through online and offline modes.

iv. Marriages and funerals/last rites may be allowed.

v. All shopping complexes, cinema halls, restaurants & bars, sports complexes, gyms, spas, swimming pools, and religious places may be allowed to operate at full capacity.

vi. Public transport (railways, metros, buses, cabs) to operate without any capacity restrictions.

vii. There shall be no restrictions on inter-state and intra-state movement including transportation of essential goods.

viii. All offices, both government and private, may function without any capacity restrictions.

ix. All industrial and scientific establishments, both government and private may be allowed.

x. While allowing all such activities, it is imperative that the national directive including use of mask & physical distancing shall be strictly followed in all public places.

xi. The activities as mentioned above are primarily indicative and States/UTs should make a careful analysis of the local situation, areas to be covered, and extent of case positivity and transmission to decide on the relaxations/restrictions. Such decisions by States/UTs must be linked to the local epidemiological situation of Covid-19, based on a sustained critical level of testing and monitoring of case positivity.

II. Testing and surveillance:

States will continue with the strategy of 'Test-Track-Treat-Vaccinate' and implementation of Covid Appropriate Behavior across the district as the ongoing strategy in managing COVID-19.

a) Ensure sustained critical level of testing as per the testing guidelines.

b) Monitoring of Influenza-like illness (ILI) & SARI cases to be taken up in all Health facilities for early warning signals of the spread of infection.

c) The surge in cases including clustering of cases should be monitored.

d) States to ensure continued focus on genomic sequencing of international passengers, collection of samples from sentinel sites (identified health facilities) and local clusters of cases, duly following the guidelines laid by MoHFW to capture early warning signals on variants.

III. Clinical Management

i. States to ensure **sufficient availability of dedicated Covid health infrastructure** as per the ongoing case trajectory.

ii. Ensure that **Home isolation protocol** is followed wherever required for asymptomatic and mild cases and specific monitoring shall be continued for **high-risk cases**.

iii. **Non-Covid health services** shall also be fully operationalized in all health facilities.

IV. Vaccination: Ensure 100% coverage of left out first and second dose eligible beneficiaries in an accelerated manner. Special focus to be given to those districts where the first & second dose coverage is less than the national average. The door-to-door vaccination campaign need to be strengthened. Similarly, precaution dose & adolescent vaccination shall also be taken up for all eligible people.

As far as schools are concerned, the district administration, in collaboration with school management, may ensure vaccination of **all teaching and non-teaching staff.**

All activities, like restaurants, gym, spas, sports, swimming pools, etc. considered for resumption of services shall **promote 100% vaccination of the eligible staff.**

V. Community engagement and Covid Appropriate Behaviour:

Ensure advance engagement and information so that there is no misinformation or panic, transparent communication on hospital and testing infrastructure availability, regular press briefings etc. Participation of community backed by strict enforcement is necessary for ensuring Covid Appropriate Behaviour. **Evidence-based information** shall be regularly made available to the community accordingly.

Warm Regards.

Yours sincerely,

(Rajesh Bhushan)

To : Chief Secretary/ Administrators of all States/UTs

Annexure II

NATIONAL DIRECTIVES FOR COVID-19 MANAGEMENT

1. **Face covering:** Wearing of face cover is compulsory in public places; in workplaces; and during transport.
2. **Social distancing:** Individuals must maintain an adequate distance in public place and at work places.
3. **Spitting in public places** will be punishable with fine, as may be prescribed by the State/ UT local authority in accordance with its laws, rules or regulations.
4. **Screening & hygiene:** Provisions for hand wash or sanitizer will be made at work places.
5. **Ventilation:** In closed places, proper ventilation should be ensured.

ANNEXURE P-29

राजेश भूषण, आईएएस
सचिव
RAJESH BHUSHAN, IAS
SECRETARY

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

D.O No.Z.26015/1/202-DMCell
23rd March 2022

Dear Colleagues,

A sustained and significant decline in the number of Covid-19 cases across the country is being observed since last 2 months. From time to time, this Ministry has been advising and guiding the States/UTs regarding recommended strategies for tackling the Covid-19 pandemic through Testing, Surveillance, Containment and Restrictions keeping in view the District as a unit.

2. Taking into account the sustained & steep decline in the Covid-19 cases across the country, the States/UTs have been undertaking various measures to reopen economic and social activities. There is a need to follow a risk assessment-based approach on the opening of economic and social activities without losing the gains made so far in the fight against the pandemic.

3. The States/UTs are advised to continue implementation and monitoring of necessary measures for prompt and effective management of Covid-19 and to ensure effective compliance of various advisories issued by this Ministry. In this context, this Ministry's guidance dated 18th February 2022 regarding recommended strategies for Testing, Surveillance and Containment based restrictions, keeping the District as a unit for decision making, are still valid.

4. There should be continued focus on the five-fold strategy, i.e., Test-Track-Treat-Vaccination and adherence to COVID Appropriate Behaviour. The State enforcement machinery should effectively enforce the norms of COVID Appropriate Behaviour, i.e., wearing of face masks and maintaining safe physical distancing in all public areas/gatherings.

5. **Evidence-Based Decision making:** At the district level there should be constant review of emerging data of new cases based on a **sustained and critical level of testing** to facilitate evidence based decision for restrictions/relaxation. Such decisions should be taken at State/UT level after proper analysis of the local situation, such as the emergence of new cases/clusters, case positivity, population affected, the geographical spread of cases & hospital infrastructure preparedness, keeping the District as a unit.

6. **Broad-based framework for relaxation/restrictions:** In order to identify areas where restrictions need to be imposed/continued in districts/areas, the following broad-based framework is provided to aid States UTs:

S. No.	Parameter	Thresholds
1	**Test positivity**	Test positivity of 10% or more, in the last week
OR		
2	**Bed occupancy**	Bed occupancy of **more than 40%** on either **oxygen supported or ICU beds**

a) States need to watch the trajectory of cases in particular geographies to ensure that the areas reporting positivity rate above 10% and bed occupancy more than 40% on either oxygen supported or ICU beds should undertake required enforcement, containment, and restriction measures.

b) As the case trajectory may vary from State to State and there would be variation in the spread of infection within States also, hence there is a need to take decisions with respect to containment and restriction measures primarily at the local/sub-national level by concerned State and District Administration.

c) Continued focus on community participation for adherence to Covid Appropriate behavior including mask-wearing and physical distancing (2 gaz ki doori), will however be important measures to be undertaken across the country.

7. Some of the **strategic areas of intervention** focusing on Containment, Test, Track, Surveillance, Clinical Management, Vaccination and Covid Appropriate Behaviour to be taken up are as follows:

I. Relaxation in various activities duly following the Covid Appropriate Behaviour

i. Focus will be on graded relaxation of activities to support the resumption of economic activities.

ii. Social/sports/entertainment/academic/cultural/religious/festival-related and other gatherings and congregations may be resumed. The decision for allowing these activities shall be taken up by the concerned States duly guided by the principles as enunciated above.

iii. Offline classes can be resumed in academic institutions without any restrictions. However, the academic institutions may also leverage a hybrid model of imparting education through online and offline modes.

iv. Marriages and funerals/last rites may be allowed.

v. All shopping complexes, cinema halls, restaurants & bars, sports complexes, gyms, spas, swimming pools, and religious places may be allowed to operate at full capacity.

vi. Public transport (railways, metros, buses, cabs) to operate without any capacity restrictions.

vii. There shall be no restrictions on inter-state and intra-state movement including transportation of essential goods.

viii. All offices, both government and private, may function without any capacity restrictions.

ix. All industrial and scientific establishments, both government and private may be allowed.

x. While allowing all such activities it is imperative that the adherence to COVID appropriate behavior including use of mask & physical distancing shall be followed in all public places.

xi. The activities as mentioned above are primarily indicative and States/UTs should make a careful analysis of the local situation, areas to be covered, and probability of transmission to decide on the relaxations/restrictions.

xii. Such decisions by the States/UTs must be linked to the local epidemiological situation of COVID-19, based on a sustained critical level of testing and monitoring of case positivity.

II. Testing and surveillance:

States will continue with the strategy of 'Test-Track-Treat-Vaccinate' and implementation of Covid Appropriate Behavior in managing COVID-19. States to ensure:

i. Adequate testing as per the testing guidelines.

ii. Monitoring of Influenza-like illness (ILI) & SARI cases must be taken up in all Health facilities on a regular basis for early warning signals of the spread of infection.

iii. The surge in cases including clusters of new cases should be monitored.

iv. Continued focus on genomic sequencing for prescribed samples of international passengers, collection of samples from sentinel sites (identified health facilities) and local clusters of cases, duly following the guidelines laid by MoHFW to capture early warning signals on variants.

III. Clinical Management:

i. States to ensure **sufficient availability of dedicated Covid health infrastructure** as per the ongoing case trajectory.

ii. Ensure that **Home Isolation Protocol** is followed for asymptomatic and mild cases and specific monitoring shall be continued for **high-risk cases**.

iii. **Non-Covid Health Services** shall also be fully operationalized in all health facilities.

IV. Vaccination is an important strategy to prevent disease, reduce hospitalization and case severity. States shall strive towards ensuring **100% vaccination for all the eligible age-groups**. Particular focus shall be given to cover left-out first and eligible second dose beneficiaries. Similarly, administration of Precaution doses and vaccination amongst young adolescents (12 years and above) shall also be taken up for all eligible people. The resumption of services shall be undertaken while promoting 100% vaccination of the eligible staff/employees.

V. Community engagement and Covid Appropriate Behaviour:

Ensure advance engagement and information among the community so that there is no misinformation or panic, transparent communication on hospital and testing infrastructure availability, regular press briefings etc. Participation of community backed by strict enforcement is necessary for ensuring Covid Appropriate Behaviour. **Evidence-based information** shall be regularly made available to the community accordingly.

Yours sincerely

(Rajesh Bhushan)

To: Chief Secretary/ Administrators of all States/UTs

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF:

Jacob Puliyel …Petitioner

Versus

Union of India & Ors. … Respondents

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PAPER BOOK

ADVOCATE FOR THE RESPONDENT: DR. JOSEPH ARISTOTLE S.

IN THE SUPREME COURT OF INDIA
(CIVIL ORIGINAL JURISDICTION)
Writ Petition (Civil) No. 607 / 2021

IN THE MATTER OF:

JACOB PULIYEL .... **Petitioner**

Versus

UNION OF INDIA AND OTHERS ... **Respondents(s)**

COUNTER AFFIDAVIT FILED ON BEHALF OF THE STATE OF TAMIL NADU

I, Dr.J.Radhakrishnan, I.A.S., S/o. Thiru V.Jegannathan, Hindu aged about 55 years, residing at No.65, 6th Main Road, Thiruvalluvar Nagar, Tiruvanmaiyur, Chennai – 600 041, do hereby solemnly affirm and sincerely state as follows:

I am the Principal Secretary to the Government, Health and Family Welfare Department, Fort St.George, Secretariat, Chennai – 600 009, State of Tamil Nadu and as such I am well acquainted with the facts of the case from the available records. On behalf of the Chief Secretary to Government of Tamil Nadu, Secretariat, Chennai – 600 009, I have been authorised to file this Counter Affidavit and I am filing this Counter Affidavit in the Writ Petition (C) No. 607 of 2021.

2. It is submitted that the Petitioner has filed the Writ Petition (C) No. 607 of 2021 in the Hon'ble Supreme Court of India with a prayer to Strike down as unconstitutional the vaccine mandates of the State of Tamil Nadu vide circular no. R.No.91298/Immn/S1/2019 dated 18.11.2021 issued by the Directorate of Public Health, Tamil Nadu and to pass any further orders.

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CITY OF MADRAS
GOVT. OF TAMIL NADU, INDIA

3. I have read the affidavit filed by the petitioner herein and I deny all the averments made therein except those that are specifically admitted herein. It is submitted that the disease COVID-19 has been declared as a notified disease, under Sec.76(1) of Tamil Nadu Public Health Act, 1939 vide Notification No 11(2)/HF/197(i)/2020, which has been published in the Tamil Nadu Government Gazette No. 119 (Part II – Section 2), dated 15.03.2020. It is further respectively submitted that, as per the provisions of the Tamil Nadu Public Health Act, 1939, [Tamil Nadu Act III of 1939] the Director of Public Health and Preventive Medicine was appointed by the Government of Tamil Nadu. As per section 76a, of the Tamil Nadu Public Health Act, 1939, the Director of Public Health and Preventive Medicine has issued a circular no. R.No. 91298/Immn/S1/2019, dated 18.11.2021 in which he has indicated to all citizen to follow the Covid Appropriate Behaviour, such as maintaining social distance, wearing masks, hand washing and avoiding crowd etc. In this regard, he has instructed the Subordinates to that effect as per the Tamil Nadu Public Health Act, 1939.

- *".....Under Chapter – II, Section-7, the Director of Public Health and Preventive Medicine may, from time to time as occasion requires, recommend for adoption, by any local authority, such measures as may be necessary for improving the Public Health administration in the local area, or for safeguarding the public health therein.*
- *Under Sub-section (1) of Section 71 of the Tamil Nadu Public Health Act, 1939, No person who knows that he is suffering from a notified disease shall expose other persons to the risk of infection by his presence or conduct in-*

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(a) any street or Public place, or

(b) any market, Theater or other place of entertainment or assembly, or

(c) any School, College, Playground or such other place, of

(d) any hotel, hostel, Boarding House, Choultry, rest-House, or Club or

(e) any factory or Shop.

- *Chapter – VII, Part-1 of Clause (b) of sub-section (2) of section 76 of the Tamil Nadu Public Health Act 1939, the Director of Public Health and Preventive Medicine has the power to make vaccination and preventive inoculations compulsory, subject to the provision of sub-section (3).*

Hence, all the Deputy Director of Health Services are hereby instructed to implement the above said provisions of the Tamil Nadu Public Health Act, 1939, by suitably informing the owner / occupier of the above places and ensure that all the places notified under sub-section (1) of section 71, are occupied by the persons ***"Who are vaccinated against COVID-19"*** *so as to prevent the spread of infection from the infected persons to other persons."*

4. It is respectively submitted that the above instruction given by the Director of Public Health and Preventive Medicine to the subordinates to control the new stream of variants. Large Unvaccinated population results in emergence of virus variants. Therefore, to protect the people of Tamil Nadu, he has exercised his powers under the Tamil Nadu Public Health Act 1939, in the larger interest of the society. Sub-section (3) of section 76 of the Tamil Nadu Public Health Act, 1939 also provides immunity to the person, if the vaccination or inoculation is injurious to the health of the person subject to the conditions specified thereon. There is no illegality

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in the order issued by the Director of Public Health and Preventive Medicine of the State of Tamil Nadu.

5. It is respectively submitted that section 76 of the Tamil Nadu Public Health Act 1939, states as follows:-

".. 76. (1) (a) In the event of the prevalence or threatened outbreak of a notified disease in any place or area, Government may declare that such place or area is visited by, or threatened with, an outbreak of such disease.

(b) The power conferred on the Government by clause (a) may also be exercised, in the case of a place or area situated in a district, by the Collector of the district subject to the control of the Government.

(c) Any declaration made by the Government under clause (a) or withdrawal thereof in whole or in part shall be published in the Fort St. George Gazette and shall come into operation on the date of such publication.

(a) Any declaration made by the Collector under clause (a) or withdrawal thereof in whole or in part shall be published in the District Gazette, and shall come into operation on the date of such publication.]

(2) '[When a declaration under clause (a) or clause (b) of sub-section (1) comes into operation and until it is withdrawn, the Collector of the district or any person duly authorized by him by general or special order, or if empowered in this behalf by rules made under this Act, the Health Officer or any other officer of the local authority concerned or any officer of the Government other than the Collector may, subject to such exceptions, restrictions, limitations and conditions and to such

control as may be prescribed, either generally or in the case of the notified disease to which the declaration relates, exercise the following powers, namely : -]

(a) Power to order the evacuation of infected houses and housed adjoining them or in their neighbourhood, or generally of all houses in an infected locality.

(b) power to make vaccination and preventive inoculations compulsory subject to the provisions of subsection (3).

(c) power to direct – (i) that persons arriving from places outside the local area, or residing in any building adjacent to, or in the neighbourhood of, an infected building, shall be examined by any specified medical officer or by any one of a specified class of medical officers.

(ii) that the clothing, bedding or other articles belonging to such persons shall be disinfected, if there is reason to suspect that they have been exposed to infection and

(iii) that any such person shall give his address and present himself daily for medical examination at a specified time and place, for a period not exceeding ten days ;

(d) Power to take such measures as may be necessary –

(i) In respect of, or in relation to, persons exposed to infection from any notified disease, or likely to infect other persons with any such disease, and

(ii) in respect of, or in relation to, articles exposed to infection from any notified disease, or likely to infect persons with any such disease,

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Including, in case (i) the placing of restrictions on the movements of such persons, and in case (ii), the destruction of such articles and the placing of restrictions on their export from, import into, or transport within, the local area

(e) Power to direct that at any place within or outside the local area, any consignment of grain exported form or imported into, such area by rail, road or otherwise, shall be examined and, if necessary unloaded and disinfected in any specified manner and

(f) power to close all or any existing markets and to appoint special places where markets may be held.

(3) (a) If any person who, or a child in whose care, is sought to be vaccinated or inoculated in pursuance of the power referred to in clause (b) of sub-section (2), declares before a Magistrate specially empowered by the Government in this behalf that as a result of a careful inquiry into the subject, he believes that such vaccination or inoculation will be injurious to his health or the health of the child, as the case may be, the Magistrate may, after giving notice to the Health Officer and hearing any representations made by him or on his behalf, exempt such person or child form vaccination or inoculation, on condition of the person aforesaid undertaking to subject himself and the members of his family to isolation of such description and for such period and to such further restrictions, if any, as maybe directed by the Magistrate.

Provided that any exemption granted under this clause shall cease to have effect after a conviction under clause (b) and no exemption shall be granted to any person who has been so convicted.

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(b) Any person who commits a breach of any undertaking given by him under clause (a) shall be punished with imprisonment which may extend to three months, or with fine, or with both. 1[.....]

[(4)] The local authority may, in its discretion, give compensation to any person who in its opinions, has sustained substantial loss by the destruction of any property under the powers conferred by this section ; but save as provided in this sub-section, no claim for compensation shall lie for any loss or damage caused by any exercise of the powers aforesaid."

6. It is respectfully submitted that the overarching goal of COVID-19 vaccines is to contribute significantly to the equitable protection and promotion of human well-being among people globally. Vaccines are very important, particularly for protecting health care workers and those most-at-risk is the only way to mitigate the public health and economic impact of the pandemic. In the longer term, the vaccine is intended to be used for active immunization of people at risk to prevent COVID-19. As part of the global efforts for rapid development of a safe and effective COVID-19 vaccine, various scientific techniques have been used to develop safe vaccine.

7. It is respectfully submitted that 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). The National Expert Group on Vaccine Administration for COVID-19 has representation of Secretaries from Ministry of External Affairs, Department of Biotechnology, Department 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 National Expert Group on Vaccine Administration for COVID-19 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 and media response etc.

8. It is respectfully submitted that based on the recommendations of NEGVAC and approval of Government of India, 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 co-morbidities 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. Nearly 88% of all COVID deaths in the country have been reported in the age group of 45 years and above. Starting 1st May, 2021, the eligible age for vaccination was expanded to cover all adults above 18 years. From 21st June 2021, Revised Guidelines for Implementation of National COVID Vaccination Program came into effect. All citizens irrespective of their income status are entitled to free vaccination.

9. It is respectfully submitted that 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.

10. It is respectfully submitted that 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.

11. It is respectfully submitted that in the order-dated 30.06.2021, in W.P.No. 11850/2021, on Covid-19 Management, the Division Bench of the Hon'ble High Court of Madras, among other things, has ordered as follows:-

xxx xxx xxx

"2. ... The State should try and persuade persons with awareness campaigns and scientific data to indicate the efficacy of the vaccines and the indispensable nature thereof in dealing with the present pandemic. ***Indeed, vaccinating oneself may not only be to protect oneself but also in the larger interest of public health. When such larger interest of public health comes into play and it is possible that a person who has not taken the vaccine may not reveal any***

symptoms but still be a silent carrier, it is doubtful whether the right to refuse to take the vaccine can be exercised in such circumstances...." xxx

Further, in the order-dated 31.05.2021, in W.P.No. 10486/2021 etc., the Division Bench of the Hon'ble High Court of Madras, among other things, has ordered as follows:-

xxx xxx xxx

"7. ... It is hoped that the vaccination drive and the awareness drive to administer vaccine are kept up and the superstitions and the unsubstantiated myths built around the vaccine are dispelled."

Further, in the order dated 24.05.2021, in W.P.No. 10486/2021, the Hon'ble High Court of Madras, among other things, has ordered as follows:-

xxx xxx xxx

"6. ...Awareness campaigns and like measures need to be undertaken to educate the citizens, particularly in the rural areas, to step forward and take the vaccine. Superstitions and archaic beliefs practiced in some communities stand in the way of scientific measures being implemented and there continues to be a resistance to accepting vaccination in certain sections of the society. Both the Centre and the State should take appropriate measures to allay the misgivings that may be harboured in such regard."

12. It is respectfully submitted that in the Letter dated 23.03.2021, the Department of Health and Family Welfare Department, Government of India, among others has instructed that:-

"...National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has been guiding all aspects of COVID-19 vaccination drive on the basis of available scientific evidence. Based on the recommendation of NEGVAC, Government of India has now decided to expand the prioritized age group to include all persons aged 45 years and above for COVID-19 vaccination from 1st April 2021."

Further, in the letter, dated 03.12.2021, the Department of Health and Family Welfare Department, Government of India, among others, has instructed that:-

"...Evidence indicates that fully vaccinated individuals are protected from severity of the disease. Please ensure that the remaining 1st and 2nd dose gaps in Covid Vaccination in respect of your State are addressed and filled up though proactive measures. "

Further, in the letter dated 21.12.2021, the Department of Health and Family Welfare Department, Government of India, among others has instructed that:-

"... Ensure cent per cent coverage of left out first and second dose eligible beneficiaries in an accelerated manner. Special focus to be given to those districts where the first and second dose coverage is less that the national average. The door to door vaccination campaign need to be strengthened."

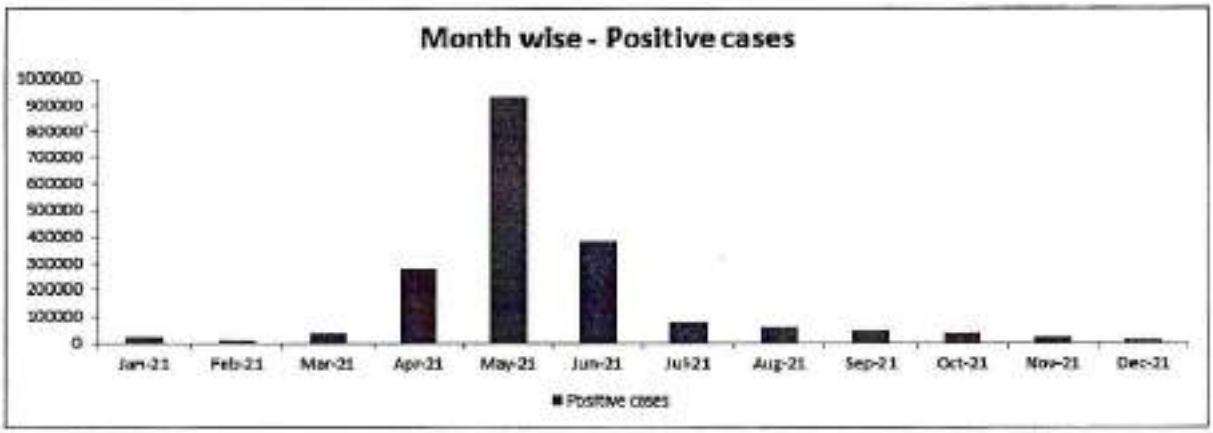
13. It is respectfully submitted that an Academic Resources Advancement Movement Trust and NGO had filed a Public Interest Litigation petition in W.P.No. 24530/2021 before the Hon'ble High Court of Madras with a prayer of all public authorities, establishments and institutions including public and private

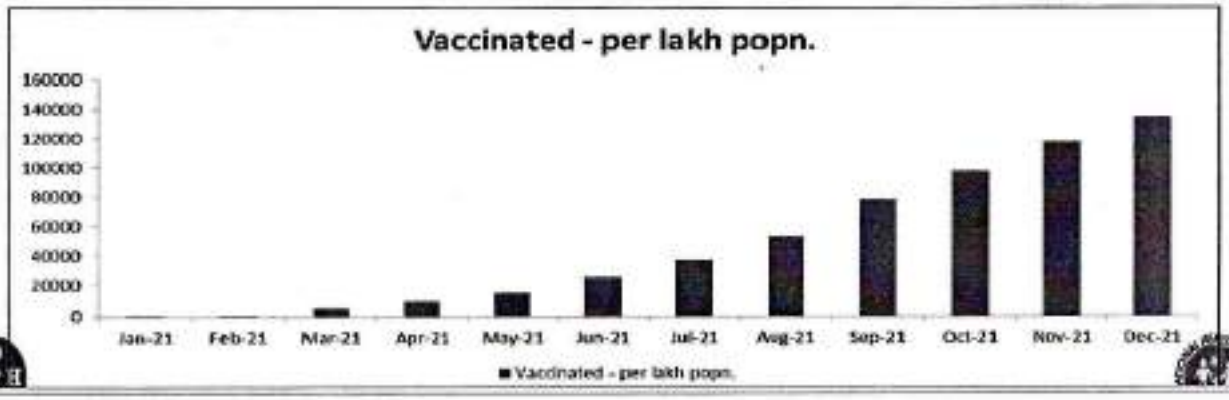
educational institutions to not insist on COVID-19 vaccination as a precondition for permitting the staff and students to physically attend duties and/or classes in such establishments and institutions.

The Division Bench of the Hon'ble High Court of Madras in its order dated 22.11.2021 has observed as follows:-

"..The Vaccine Mandate is there for the safety of all. You are going against Public Interest in this Petition. Since it is a PIL, we must consider the application of equity and look at the entire situation." *Further the High Court highlighted that the Supreme Court has laid down in two Judgments that Public Interest Litigations are not maintainable in service matters and that this Petition has been exposed as a service matter.* ***Furthermore, the Court allowed the Petitioner to withdraw the Petition.*** *The Public Interest Litigation (PIL) was hence dismissed as withdrawn and the Petitioner was permitted liberty to approach the Court in case the teachers' service gets affected due to Double Vaccination Mandate.* ***The Court sternly adjudicated*** **"It is not a question of your individual liberty alone, it's a question of individual liberty of the students as well."** ***The Court highlighted that the Vaccines protect the population to a large extent, including students and that the Court cannot strike down a Government Mandate."***

14. It is respectively submitted that with increase in Covid-19 vaccine coverage in the State of Tamil Nadu, the daily Covid cases of the State of Tamil Nadu have seen a declining trend. The following Bar Graph shows this clearly:-





15. It is respectively submitted that the fundamental freedom guaranteed by Article 14 and Article 19 of the Indian Constitution are not absolute. They are subject to reasonable restrictions owing to the simple rationale that for the society to function in an orderly manner, people cannot exercise their rights in such a manner which is injurious to the society as a whole because if it is done, it will lead to spread the disease which cannot be controlled. Therefore, the reasonable restrictions are imposed on the enjoyment of fundamental rights due to the fact that in certain circumstances, individual liberty has to be subordinated to certain other larger interests of the society.

NOTARY
G. GHEENADHAYALAN
G.O.Ms.No. 162/2020
CITY OF MADRAS
GOVT. OF TAMILNADU

16. The State of Tamil Nadu act upon the provision confined by the Tamil Nadu Public Health Act, 1939, to protect the society from the spread of Covid-19 and variants. While some variants of Covid-19 do not manifest symptom in one individual, it can spread easily to others, who have some comorbidities resulting in severe complications. Pandemic cannot be controlled unless significant population is vaccinated. Hence, in the larger public interest and in the interest of Public Health State need to have reasonable restrictions. It is prayed that there is no illegality in the order issued by the Director of Public Health and Preventive Medicine, Government of Tamil Nadu and the Tamil Nadu Public Health Act, 1939, Director of Public Health has been empowered to issue reasonable restrictions.

17. Therefore, the prayer of the Writ Petition is not valid and the instruction issued by the Director of Public Health and Preventive Medicine vide circular no. R.No. 91298/Immn/S1/2019, dated 18.11.2021 is to be in action to the larger interest of the society .

In view of the above submission, it is humbly prayed that this Hon'ble Court may be pleased to accept this Counter Affidavit and dismiss the writ petition and pass appropriate orders as this Hon'ble Court may deem fit and proper and thus render justice.

NOTARY ★ D. DHEENADHAYALAN G.O.Ms.No. 162/2020 CITY OF MADRAS ★ GOVT. OF TAMILNADU, INDIA

DEPONENT

03/01/22

D. DHEENADHAYALAN, M.A., B.L.,
ADVOCATE & NOTARY PUBLIC
400, LAW CHAMBER,
MADRAS HIGH COURT, CHENNAI-104
EXPIRE ON 22/10/25
CELL No : 9381016780

VERIFICATION

I, Dr. J. Radhakrishnan, I.A.S, S/o. Thiru V. Jegannathan, Hindu aged about 55 years, residing at No.65, 6th Main Road, Thiruvalluvar Nagar, Thiruvanmiyur, Chennai – 600 041 do hereby solemnly affirm and sincerely state as follows, do hereby declare that this is my name, signature and official designation and what are all stated in the above said paragraphs are true and correct to the best of my knowledge, belief and information on record. No material facts have been concealed and verified the same on this the 3rd day of January, 2022.

3/1/22

DEPONENT

IDENTIFIED BY ME

Notary

NOTARY
D. DHEENADHAYALAN
G.O.Ms.No. 162/2020
CITY OF MADRAS
GOVT. OF TAMILNADU, INDIA

03/01/22

D. DHEENADHAYALAN, M.A., B.L.,
ADVOCATE & NOTARY PUBLIC
400, LAW CHAMBER,
MADRAS HIGH COURT, CHENNAI-104
EXPIRE ON 22/10/25
CELL No : 9381016780

404

ANNEXURE P-31

www.outlookindia.com

Puducherry LG Mandates Covid-19 Vaccination, Punishment For Those Who Refuse

View All

2-3 minutes

According to Puducherry's Lieutenant Governor, Tamilisai Soundararajan, compulsory vaccination against Covid-19 became mandatory from Sunday. She asked the people to carry with them the certificates of vaccination as there would be checked by the health authorities.

Talking to reporters after visiting a Primary Health Centre (PHC) in neighbouring Villianoor to see for herself the implementation of the vaccination drive, she said, "The government is keen to ensure that Puducherry emerges as a fully vaccinated Union Territory."

She said no stone was left unturned to reach the goal and vaccination was aimed at protecting the people against pandemic and also to prevent the occurrence of the new variant of the virus - Omicron.

She was all-praise for the health staff in implementing the vaccination programme even on Sundays. "People should extend their cooperation," she said.

The territorial administration announced last week that vaccination would be mandatory in the Union Territory and those skipping the inoculation would face penal action under the Public Health Act.

Secretary to Health Udhayakumar, Director of Health G.Sriramulu and a host of officials of the Department of Health were present.

The Union Territory has so far administered the vaccine to 13,06,706 people, according to a press release.

Former Health Minister Dr. Harsh Vardhan said, "The government will reach out to people to get their vaccines but if someone does not want to take the vaccine, they cannot be forced."

A Meghalaya High Court bench held in June, "Vaccination by force or being made mandatory by adopting coercive methods, vitiates the very fundamental purpose of the welfare attached to it. It impinges on the fundamental right(s) as such, especially when it affects the right to means of livelihood which makes it possible for a person to live.”

ANNEXURE P-32

Government of India
Ministry Women and Child Development
(Child Welfare-II Section)

Room No.640, A-Wing.
Shastri Bhawan, New Delhi
Dated: 04th January, 2022

To,

The Principal Secretaries / Secretaries
WCD/SJE (All States/UTs)

Subject: Preventive measures to contain spread of COVID 19 & new variant Omicron - Vaccination of Children in CCIs – Reg

Madam/Sir,

Please refer to the Order of Ministry of Home Affairs No. 40-3/2020-DM-1 (A) dated 27th December 2021, whereby States/UTs have been directed in view of the initial surge in cases of COVID-19 as well as detection of the Variant of Concern (Voc), Omicron in different parts of the country, to consider implementation of the normative framework to contain spread of COVID-19. MOHFW vide D.O letter No. Z.28015/318/21-EMR, dated 21st December, 2021 has issued an advisory to all States/UTs, prescribing a framework for taking evidence based containment measures at district/local level.

2. In continuation of the advisories/guidelines issued by Ministry of Women and Child Development requesting the States/UTs to ensure care and protection of Children adversely impacted by COVID especially Children living in Child Care Institutions (CCI), while following the protocol as mandated under Juvenile Justice (Care and Protection of Children) Act, 2015; it is stated that while number of actions have been taken by the States/UTs, it is necessary to continue the efforts relentlessly, to bring all children under the safety net provided under the Government Schemes and programmes.

3. Further it is brought to the notice that in light of the compulsory vaccination of children against COVID-19 falling in the 15-18 age group, it is requested that all District Magistrates may be directed to make appropriate arrangements on for vaccination of the Children living in CCIs as well, on priority basis.

4. An update on Children vaccinated in CCIs may be shared on a fortnightly basis with MWCD. The Person In-charge of CCI/Superintendent shall keep record of the vaccination administered to these Children along with vaccination teams in the following format:

Date	No. of eligible Children	No. of Children Vaccinated	Percentage of Vaccination

5. It is further requested to ensure that report for first fortnight from 1st January 2022 – 15th January 2022 is sent to the Ministry in the above format at email **cw2section-mwcd@gov.in** on the next working day. The regular progress of vaccination may be mailed for every fortnight thereafter, till completion of vaccination process.

Encl.: As above.

Yours faithfully,
(Navendra Singh)
Director to the Govt. of India
e-mail: navendra.singh@nic.in

Copy for information to:
1. Principal Secretary (H&FW), Health and Family Welfare Department (All States/UTs).
2. MD, NHM, All States/UTs.
3. Member Secretary, National Disaster Management Authority

ANNEXURE P-33

CLW/Chittaranjan

No. GMA/Ruling/COVID-19 Vaccination

Dated: 28.02.2022

All PHODs / CHODs / HODs
All Dy HODs, All Controlling Officers

Sub: Instructions regarding vaccination for Covid-19.
Ref: (i)This office letter of even no. dt. 02.08.2021.
(ii)This office letter of even no. dt. 29.12.2021.

All controlling officers were instructed vide this office letter of even no. dated **02.08.2021** for advising the Staff to get themselves vaccinated. Again, vide letter dated **29.12.2021**, it was advise that the staff who have not yet taken first dose of vaccine, should be get themselves vaccinated by **08.1.2022**, considering the raising threat of Omicron/Covid-19 variant, which was in the interest of health & safety of the employees of CLW, who were working in the Workshops/Offices were required to be vaccinated.

Further, it was also advised that, employees who were not vaccinated, should not be allowed to join duty w.e.f. **10.1.2022**, till such time they get themselves vaccinated by first dose. **The period on and from 10.1.2022 to till such time, the employees, get themselves vaccinated is to be treated as "Leave Due".**

The above instructions were issued in order to ensure **100%** vaccination of the staff working in Workshops/Offices, keeping in mind the threat of Omicron/Covid-19, prevalent at that particular time. Now, most of the employees are vaccinated and Covid-19 pandemic is also slowing down.

In view of changed circumstances, the instructions circulated vide letter dated **29.12.2021** as referred above, are hereby **withdrawn w.e.f. 28.02.2022**. The detailed report of employees, who have not been vaccinated even the first dose, till date, due to some reasons may be sent to this office for record. Further, all such staff who were being treated as "**Leave Due**" may be allowed to join duty w.e.f. **01.03.2022** positively.

All controlling officers and supervisors are advised to adhere to the Covid-19 protocols. This is for information and needful action.

28/02/22
PCPO/CLW

Copy to:

Secy to GM – for kind information please.
PCMO - for information and necessary action please.
Dy GM – for information please.
PCE, IG-cum-PCSC - for information please.
All POs & CS&WI / S&WI - for necessary action please.
Jt Secy. /Staff Council - for information please.
Zonal Secy. /AISCTREA & AIOBCREA - for information please

28/02/22
PCPO/CLW

EASTERN RAILWAY

No.W/Genl. 2020 Contagious Disease

Date: 30.06.2021.

ALL CONCERNED

Sub: Preventive Measures to contain the spread of COVID-19.

Ref:
(i) Chief Secretary/Govt. of West Bengal's Order No.753/II-ISS/2M-22/2020 dated 28.06.2021.
(ii) Chief Secretary/Govt. of West Bengal's Order No.753-ISS/2M-22/2020 dated 14.06.2021.
(iii) Chief Secretary/Govt. of West Bengal's Order No.707-ISS/2M-22/2020 dated 29.05.2021.
(iv) Chief Secretary/Govt. of West Bengal's Order No.647-ISS/2M-22/2020 dated 15-05-2021.
(v) This office letter of even No. dt. 16.05.2021,30.05.2021 & 15.06.2021.

Chief Secretary, Govt. of West Bengal vide Order Dated 28.06.2021 under reference (i) has issued an order regarding restrictive measures stand extended up to 15th July 2021as notified in aforesaid orders (ii).

In supersession of all previous orders regarding the functioning of KPAW and in pursuance to the above directives (Contained in Para-18) , restrictive measures stand extended up to 15th July 2021 and during this period KPAW will function as under subject to vaccination of employees, wearing of masks and maintenance of physical distancing, health & hygiene protocol etc.

1)a) POH/ROH of BLC & Match Truck which are used for interstate Transportation of Cryogenic Oxygen Containers.
b) Overhauling and Supply of CTRB, Air Brake Equipments, Wheels & IOHed Bogies of Coaches and Wagons.
c) POH & IOH of Power Cars which are to be used as Stand by Power Supply in case of Emergency.
d) POH & ROH of Wagons which is most essential for ensuring Safety of movement of Freight Trains in Pan India basis.
e) POH & IOH of Coaches which are most essential for ensuring Safety in movement of Inter-State Mail/Express Trains.
f) POH of EMU coaches for maintaining skeletal services for movement of emergency duty staff.
g) POH of 140 tonne breakdown crane, tower wagons and camp coaches of accident relief trains, required for disaster management and relief of railway accidents.
h) Providing oxygen and other activities concerned with Workshop Hospitals for treatment of COVID-19.

2) The daily duties of staff working in Shop floors are to be staggered in two shifts of 06.00 hrs to 14.00 hrs & 12.00 hrs to 20.00 hrs.
3) The intervening period between 2 shifts, i.e. 12.00 hrs to 14.00 hrs is to be utilized as handing over and taking over time and release of workspace for next shift staff.
4) To strengthen the essential services as mentioned at Sl.1, above and to meet the requirements of the Divisions/Workshop for smooth train operation, all supporting Shops shall operate with 50%or optimum staff in each shift. The controlling officers and SSEs/In-charges shall prepare rosters with 50% staff in each shift to ensure that targeted outturn is achieved.

5) The attendance of staff working in administrative buildings shall continue to be restricted to 50% in a day. These staff shall attend office on alternate days and are to work from home on other days. Their duty hrs from 10.00 hrs to 17.30 hrs.

6) There shall however be no restrictions in attendance for staff engaged in essential services of power, water supply, Mill Wright, security, sanitation etc.

Continued.... P/2

7) Staff residing in containment zones (if declared as such by State/local Govt.) may work from home till their area is de notified. They shall necessarily be available on telephone/ mail.
8) Staff who has co morbidities or undergoing treatment for serious ailments or are pregnant may be exempted from attending duty subject to their producing supportive documents and approval of their controlling officer. They shall be available on their mobile / mail and are liable to attend office in exigencies.
9) All staff should invariably get themselves vaccinated on priority and mandatory basis. Respective BOs shall monitor and impress upon staff under their control for their immediate vaccination.

However, this is not a Holiday and officials should be available for contact through electronic means of communication at all time i.e. through Phone calls, text messages, e-mails etc for meeting any exigencies of services. No staff is allowed to leave HQ Station/Place of residence under any circumstances without the prior specific approval of their Controlling Officer.

This order shall come into effect from 01.07.2021.

This issues with the approval of Competent Authority.

(A.K.Roy) 30/06/2021
Dy Chief Personnel Officer(W),
For Chief Works Manager,
E.Rly/Kanchrapara

Copy to: PCME/ER for kind information.
Copy to: CWE/ER for kind information.
Copy to: CWM/ER/KPA for kind information.
Copy to: ASC/ER/KPA for information and necessary action please.
Copy to: Secretary- ERMU, ERMC, AISCSTREA, AIOBCREA for information please.

(A.K.Roy) 30/06/2021
Dy Chief Personnel Officer(W),
For Chief Works Manager,
E.Rly/Kanchrapara

ANNEXURE P-35

RECRUITMENT RALLY NOTIFICATION

ONLINE REGISTRATION IS MANDATORY. ALL CANDIDATES TO LOG INTO JOIN INDIAN ARMY WEBSITE (JOININDIANARMY.NIC.IN). REGISTRATION WILL BE OPENED FROM JUL 2022 ONWARDS BY RESPECTIVE AROs FOR AGNIVEER GENERAL DUTY, AGNIVEER TECHNICAL, AGNIVEER CLERK/ STORE KEEPER TECHNICAL, AGNIVEER TRADESMAN 10TH PASS AND AGNIVEER TRADESMAN 8TH PASS AS PER THE ARO RALLY SCHEDULE

Special Instructions

1. The salient aspects of terms and conditions of service for persons enrolled through the Agnipath Scheme for service in the IA are mentioned in the succeeding paragraphs.

2. **Terms and Conditions**.

(a) **Enrolment**

(i) Candidates will be enrolled under Army Act 1950 for a service duration of four (04) years including the training period.

(ii) Agniveers so enrolled will be subject to Army Act, 1950 and will be liable to go wherever ordered, by land, sea or air

(iii) Agniveers enrolled under the scheme, will not be eligible for any kind of Pension or Gratuity.

(b) **Service**.

(i) Service of Agniveers will commence from the date of enrolment

(ii) Agniveers would form a distinct rank in the IA, different from any other existing ranks.

(iii) Leave, Uniform, Pay & Allowances during the service period of four years will be governed by orders and instructions in respect of such individuals issued by the Government of India (GoI) from time to time.

(iv) Agniveeers will be liable to be assigned any duty in organisational interest, as decided from time to time.

(v) Personnel enrolled through Agniveers Scheme, will be required to undergo periodical medical check-ups and physical/ written/ field tests as governed by orders issued. The performance so demonstrated would be considered for subsequent offer for enrolment in the Regular Cadre

(vi) Agniveers can be posted to any regiment/unit and can be further transferred in organisational interest.

(c) **Discharge**.

(i) All Agniveers will be discharged on completion of four years of service

(ii) On discharge after completion of four years, Agniveers will be paid a 'Seva Nidhi' package to enable them to return to the society for pursuing employment in other sectors.

(iii) Agniveers will not be eligible for any kind of pension or gratuity, neither will they be eligible for Ex Servicemen Contributory Health Scheme (ECHS), Canteen Stores Department (CSD) facilities. Ex Serviceman status and other related benefits.

(iv) Agniveers will be barred from disclosing classified information gained during service to any unauthorised person or source under Official Secrets Act, 1923

(d) **Enrolment for Regular Cadre**.

(i) Based on organizational requirements and policies promulgated Agniveers who are completing their engagement period in each batch will be offered an opportunity to apply for enrolment in the regular cadre of IA. These applications will be considered in a centralised manner by the army based on an objective criteria including performance during their engagement period and not more than 25% of each specific batch of Agniveers will be enrolled in regular cadre of the IA, post completion of their four years engagement period.

(ii) Agniveers so enrolled as regular cadre would be required to serve for a further engagement period of 15 years and will be governed by terms and conditions of service (of Junior Commissioned Officers/Other Ranks in IA) currently in vogue (as amended from time to time). Agniveers will not have any right to be selected. Selection will be exclusive jurisdiction of the IA.

(iii) With introduction of this Scheme, the enrolment of Soldiers in the regular cadre of IA, except technical cadres of Medical Branch, will be available only to those personnel who have completed their engagement period as Agniveer.

3 **Employability**

(a) Agniveers will be liable to be assigned any duty in organisational interest, as decided from time to time.

(b) Agniveers can be posted to any regiment/ unit and can be further transferred to other regiments/ units in organisational interest.

4. **Leave**. Grant of leave will be subject to exigencies of service. The following leave may be applicable for Agniveers during their engagement period :-

(a) **Annual Leave**. Upto 30 days per year.

(c) **Sick Leave**. Based on medical advice.

5. **Pay, Allowances & Allied Benefits**.

(a) **Agniveer Package**.

(i) The pay & emoluments of Agniveers will be as given below :-

(aa) **Year 1**. Customised Package - ₹ 30,000/- (plus applicable allowances.)

(ab) **Year 2**. Customised Package - ₹33,000/- (plus applicable allowances.)

33 Negative marking will be applicable in CEE

34. At the rally site, all candidate should report duly shaved (beard, chest hair, axillary hair, pubic hair and with crew hair cut (except Sikh Candidates), for identification at various stages of rally process failing which candidate can be barred from participation in recruitment rally.

35 Candidates may have to present themselves at rally site for two to three times. Candidates should make arrangements for stay under their own arrangements.

36. Candidates are advised in their own interest to undergo medical exam before coming for selection especially with respect to flat foot, poor vision, deformities and physical measurements. All are advised to ensure that their ears are free of wax by getting it cleaned by a doctor prior to the rally.

37. If 180 days or more lapse between screening medical at the rally and despatch, medical will be done again and unfit candidates in this review will not be recruited.

38. **Vaccination Certificate**. All candidates appearing for rally should be fully vaccinated for Covid-19. The certificate to be produced to auth upon asking

39. No use of contact lenses.

40. **Result of written examination will be declared on the official website joinindianarmy.nic.in.** No separate letter will be sent to the candidate. It is responsibility of candidate to check his result and report to ARO for documentation.

41. **For more details, contact your nearest ARO.**

Disclaimer. The terms and conditions, given in the notification and on the website are subject to change and should, therefore, be treated as guidelines only. In case of any ambiguity, the existing policies, rules and regulations of Indian Army/Government of India will be final. **Details are also available on website www.joinindianarmy.nic.in.**

"Rally can be cancelled/ postponed at any time without giving any reason"

Place :

Dated : 2022

Appendix 'E-II'

CERTIFICATE (ONE CERTIFICATE FOR EACH TATTOO) FOR PERMANENT BODY TATTOO IN RESPECT OF CANDIDATES FROM TRIBAL COMMUNITIES

1. This is to certify that _____ (Name of the Candidate), whose date of birth is _____ is the Son/Daughter of _____ (Name of Father/Mother/Guardian as applicable) and belongs to _____ (Name of the Tribe Community) of _____ (Name of the District) in the State of _____ (Name of the State).

2. It is certified that the permanent body tattoo (s) inked at the following parts of the body of _____ (Name of the candidate) is as per existing customs and traditions of _____Tribe and is in practice as on date :-

(a)

(b)

(c)

(d)

(Total No of Tattoos _____ (in figure) _____ (in words)

3. Post card size photographs of each of the tattoo as given in Paragraph 2 of Appendix 'H' above is correct and placed as under for any future reference/record hereafter :-

Photographs of Tattoo	Details o Tattoo
(Post card size to be pasted here duly signed by the candidate and official issuing this certificate with their respective names. Please do not use staple pins/clips)	Size of Tattoo – (In Cms) Language – (If Applicable) Significance of Tattoo – (If Applicable)

Note - Each Tattoo will have a separate photograph with details and will be described separately. Additional pages will be used for the purpose and each page will be attested separately.

Place :

Dated :

Affix Round Stamp

(Signature with Name Designation and Stamp of DC/DM/SDM of the District/Tehsil)

OR

(Signature with Name, Designation if any and Address of Chairman/Secretary or enior member of the Tribe to which the candidate belongs to with their Stamp).

ANNEXURE P-36

उप महानिरीक्षक उक्षेत्र–II का कार्यालय
OFFICE OF THE DY. INSPECTOR GENERAL NZ-II
केन्द्रीय औद्योगिकसुरक्षा बल
CENTRAL INDUSTRIAL SECURITY FORCE
(गृह मंत्रालय)
(MINISTRY OF HOME AFFAIRS)
CISF NZ-II HQrs, PLOT NO.07 SECTOR -04, CHANNI HIMMAT, JAMMU

सं0ई–42099 / केऔसुब / उक्षे0– II / प्रशा / Vaccination/2023–2725 दिनांक:18 / 02 / 2023

सेवामें,

समूहकमांडेण्टकेऔसुबसमूहमुख्यालय चंडीगढ़
वरिष्ठकमांडेण्टकेऔसुब 7वीं आ.वा. किश्तवाड़
वरिष्ठ कमांडेण्टकेऔसुबइकाईपंहसिसचंडीगढ़
कमांडेण्ट केऔसुब इकाई केजीपीएस बांदीपोरा
कमांडेण्टकेऔसुबइकाई एचईपीउड़ी–।
कमांडेण्टकेऔसुबइकाईडीएचईपीदुलहस्ती
कमांडेण्टकेऔसुबइकाई एसएचईपीसलाल

विषयः–**PRECAUTIONARY DOSE FOR ALL CITIZENS ABOVE 18 YEARS OF AGE: REG.**

Please find enclosed herewith a copy of CISFHQ letter No. (14) dated 17.02.2023received through IG/NS, NS HQ, Mahipalpur NewDelhi office letter No (25679-E) dated 17.02.2023 (copy enclosed) on the above cited subject.

02. CISF HQvide letter under reference has intimated that as per CISF Covid-19 portal available in monthly strength report (MSR) the following is the status of vaccination in respect of CISF personnel as on 14.02.2023

Total Strength	Personnel who have received both the doses of vaccine	Personnel who have received only one dose of vaccine	Personnel who have not received both the doses of vaccine	Personnel who have received precautionary / Booster dose of vaccine.	Due personnel for precautionary dose of vaccine
12954	11980	401	573	8597	3383

03. Further, IG/NS CISF HQ New Delhi has intimated that on perusal of MSR report pertaining to NS are still due for precautionary dose of Covid-19. However, **only 288 personnel** are due for precautionary dose of vaccine under NZ-II. The variation indicates that MSR data is not being updated on daily basis. It is pertinent to mention that the MHA is pressing hard to get administered the precautionary dose at the earliest to all vaccine due personnel.

04. In view of the above, I have been directed by the Competent authority to convey and request to all Unit/Bn. Commanders under this NZ-II HQ to pay personnel attention by organizing a special drive for administering the Covid-19 vaccination to all CISF Personnel are due for vaccine. Status of vaccination may be uploaded in CISF Covid-19 portal available in Monthly strength report (MSR) on daily basis so that real time data may be

obtained from MSR for onward submission to MHA on weekly basis. The matter may be given **top priority** and submit a compliance report of 100% vaccination (except personnel with medical issues) duly updated in MSR data may be sent to this **HQ by 22.02.2023 positively** for the perusal of DIG/NZ-II and onward submission to NS HQ, New Delhi in time please.

Encl: As above.
Sdxxx/-18.02.2023

सहायक कमाण्डेन्ट / प्रशा0
कृते उप महानिरीक्षक
केऔसुब उ0क्षे0–।। मुख्यालय जम्मू

प्रतिलिपि:

1. महानिरीक्षक / उ0ख0, केऔसुब उ0ख0 मुख्यालय, नईदिल्ली : कृप्या आपके कार्यलय के पत्र सं (25679–ई) दिनांक 17.02.2023के संबंध में सूचनार्थ।

2. सभी उप कमांडेण्ट / सहायक कमांडेण्ट: सूचनार्थ एवंआवश्यक कार्यवाही हेतू।
इकाईयाँ अधीनस्थकेऔसुब उक्षे–।।
मुख्यालय जम्मू

आंतरिक:–

आरक्षित निरीक्षक : सूचनार्थ एवं आवश्यक कार्यवाही हेतू।
केऔसुब उक्षे–2 मुख्यालय जम्मू

ANNEXURE P-37

Government to pay out NT$2 million in COVID-19 vaccine case - Focus Taiwan

2-2 minutes

Taipei, Dec. 3 (CNA) The Ministry of Health and Welfare has agreed to pay NT$2 million (US$65,460) under the Vaccine Injury Compensation Program (VICP) to a Nantou County man who had a stroke after receiving the AstraZeneca (AZ) COVID-19 vaccine.

Meetings are regularly held under the program to determine if individuals should receive compensation for serious side effects from vaccines, including COVID-19 vaccines, even if no direct link between the vaccine and side effects can be definitively established.

Central Epidemic Command Center spokesman Chuang Jen-hsiang (莊人祥) said Saturday that the Nantou man in his 60s, surnamed Lee (李), showed symptoms such as exhaustion and dysarthria (a motor speech disorder) 26 days after getting a dose of the AZ vaccine.

Doctors then diagnosed Lee as having had a stroke and eosinophilia, which occurs when the body produces an unusually high number of a type of white blood cell called eosinophils.

The panel said it could not establish a correlation between the vaccine and eosinophilia and did not announce whether the stroke was triggered by the vaccine or not, but it decided on paying the man NT$2 million in compensation.

That case was one of 90 compensation claims covered at a VICP meeting on Nov. 10. A panel convened under the VICP approved a total of six of the 90 claims, five of which were related to the AZ vaccine for COVID-19 and one to the Bacillus Calmette-Guérin vaccine for tuberculosis.

The AZ vaccine recipients who won their claims received between NT$20,000 and NT$2 million in compensation.

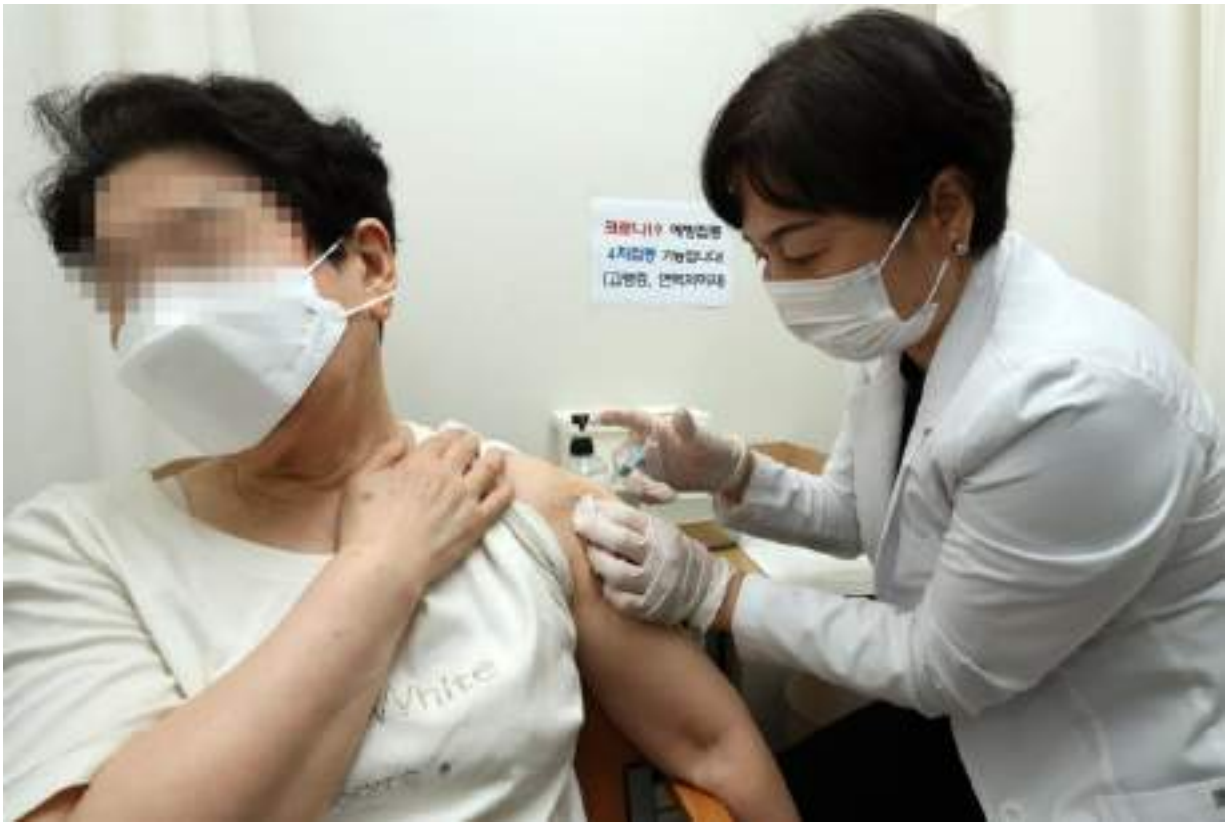
The highest payout allowed under the VICP is NT$6 million.

ANNEXURE P-38

www.koreatimes.co.kr

Court orders gov't to compensate man for coronavirus vaccine side effects

2-3 minutes



This photo shows a man receiving a COVID-19 vaccine shot at a health facility in Seoul, July 13. Yonhap

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.

The KDCA appealed the ruling.

Currently, eight other lawsuits are proceeding over compensation for COVID-19 vaccine adverse events, according to the agency. (Yonhap)

MINISTRY OF HEALTH AND FAMILY WELFARE GOVERNMENT OF INDIA

AEFI - ADVERSE EVENT FOLLOWING IMMUNIZATION

SURVEILLANCE AND RESPONSE OPERATIONAL GUIDELINES 2015

CHAPTER 4 - RECORDING AND REPORTING AEFI

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4.2.2 Immediate serious AEFI notification (by the first person Who identifies the event)

In India, depending on the type of AEFI, the place Where the event occurs, its severity and the confidence of the beneficiary in the care provider, serious AEFI are first brought to the notice of the health system by the

- patient directly

- health-care worker who administered the vaccine
- care provider treating the case
- supervising immunization staff
- pharmacy dispensing the vaccine (usually in the private sector)
- local media
- ADR monitoring centres.

It is therefore important that each potential reporter be aware of the process and procedure adopted for reporting serious and severe AEFI.

Immediately after the identification/notification of a serious/severe AEFI, a two-step process is initiated:

— Step 1: reporting serious/severe AEFI to the appropriate authority

— Step 2: district-level investigation of selected reported AEFI.

All serious/severe AEFI are to be immediately notified by the first person who identifies the event. This person should notify the case to the nearest government PHC/CHC and/or the D10 by the quickest

means of communication (telephone, messenger, etc.) All persons involved in reporting AEFI should be aware of the timeline and channels of reporting. A11 notified AEFI should be documented on a case reporting form (CRF) (see Annex l) and submitted to the next level as soon as possible.

Which events should be reported?

It is essential to remember that the health staff should identify and report all severe, serious and minor AEFI. Reporting on serious of all minor AEFI brought to the notice of the health staff by parents and/or guardians as a concern, such as high fever and minor local reactions, should be done on a monthly basis. Monitoring crude numbers is helpful to record and compare with background rates that could identify product quality defects, immunization errors, or even increased susceptibility to vaccine reactions among the given population.

AEFI that require prompt reporting and investigation include:

- serious AEFI (death, hospitalization, cluster, disability)

- signals and events associated with a newly-introduced vaccine

- AEFI that may have been caused by an immunization error-related reaction
- significant events of unexplained cause occurring Within 30 days after vaccination, and
- events causing significant parental or community concern.

Serious AEFI should be treated as a medical emergency and need to be immediately investigated, managed and reported on standardized AEFI formats.

4.3. Serious/Severe AEFI- Forms, routing and timelines

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Steps in completing CRF

AT DISTRICT LEVEL-

2. The MO should examine the patient, complete section A of the CRF and submit his reporting form to the D10 within 24 hours of notification of the event to the health system. In case of a reported unexplained death, the MO should make all efforts to ensure a postmortem is conducted at the earliest.

4.4 Steps to encourage reporting

Staff should be encouraged to report AEFI Without fear of penalty. Reporting can be enhanced by:

- training
- positive feedback
- ensuring there is enough support available at all levels
- sharing results of the investigation and any corrective action taken.

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5.3 Steps in investigating AEFI

The following are the steps in an AEFI investigation:

1. Immediate AEFI case notification by the reporter (health worker/ clinician/ ASHA/ AWW/ ADR monitoring centre/ community/ media) in person, Via phone, fax or e-mail
2. Case Visit for confirmation and reporting in the CRF by the M0 to the district
3. Evaluation of completed CRF and decision regarding further investigation by D10 and district AEFI committee

4. Completion of preliminary CIF form, sending laboratory investigations and submission of form with action at the local level by D10 and district AEFI committee

5. Review of lab reports, completion of final CIF and submission by D10 and district AEFI committee to the state AEFI committee.

6. Causality assessment by the state AEFI committee and conclusion of the investigation.

7. Review and finalisation of submitted causality assessment by National AEFI Committee

8. Coordination with state and DCGI for action at state and national level.

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5.3.2 Confirming and reporting the AEFI

On receiving information of an AEFI from the area from the health worker or through print or electronic media, the MO should begin an enquiry immediately. He should Visit the case, interview the family and collect detailed data about the patient, vaccine/s administered, immunization session in question, vaccine batch and lot numbers used (in the session and in the stored stock of the facility), etc. Based

on first—hand information obtained, he should frame a suspected diagnosis, complete section A of the CRF and submit the CRF t0 the D10 within 24 hours of case notification.

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6.2 Guidance on conducting autopsy

The investigation of deaths due to AEFI would not be complete without an autopsy and related laboratory investigations. An autopsy must ideally be performed in every case of an AEFI death. It may be especially mandatory in those instances when there have been previous reports of similar deaths that went uninvestigated and When public at large are worried about such deaths and are likely to lose or have lost faith in the vaccination program.

9.3.3 Analysis of AEFI reports

It is essential that all minor, severe and serious AEFI get reported. In addition to basic time, place and person analysis that should be done by the district and state programme managers from the data received, key analysis outcomes that will help the district document effectiveness of the AEFI surveillance system include:

10.1 Goals and objectives of AEFI surveillance

The specific objectives of AEFI surveillance are to:

- Promptly detect, report and respond to AEFI
- Identify unusually high rates of AEFI related to a specific vaccine lot/brand
- Promptly address programmatic errors through implementation of corrective measures
- Estimate serious AEFI rates in the population and compare these with local and global data
- Identify signals of unexpected adverse events and generate new hypotheses about these events that must be confirmed by planned studies and laboratory investigations.

10.3.1 Community level

Anganwadi and ASHA/volunteers/frontline workers

- Follow up with beneficiaries to identify AEFI after vaccination session using the beneficiaries list provided by the ANM (Auxillary Nurse Midwife)

- Pass information of any adverse event immediately by telephone to the concerned ANM, MO and other concerned persons.
- Assist in referral of any suspected cases
- Support in building community confidence

10.3.2 Sub Centre level

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- For all other cases (serious/severe), provide immediate first aid and refer the AEFI t0 the MO (PHC) or to the appropriate health facility for prompt treatment and reporting. Inform the MO (PHC) at the health centre immediately by the fastest means possible.

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Health supervisors (HS)

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- Encourage health workers to report AEFI. The serious/severe AEFI should be notified immediately by the fastest means possible.

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10.3.5 District level

DIO/CMO

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- Ensure that a line list of all serious/severe and minor AEFI cases which were notified and reported but not investigated is maintained, as well as a folder with the CRFs citing reasons why the cases were not investigated. Discuss each case not investigated in the next district AEFI committee meeting to ensure that no AEFI case deserving to be reported and investigated is ignored.

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10.4 National/state regulatory authorities, central drug laboratories

AEFI is a Vital functional component of the National Regulatory Authority (NRA). The NRA is essential not only for assurance of vaccine quality in the country but also for pre qualification of vaccines. The core functions of the NRA are:

- Marketing authorization and licensing activities of vaccines

- Post-marketing surveillance including surveillance for adverse events through collection, collation, regulatory action of vaccines based on post marketing surveillance (PMS), periodic safety update report (PSUR) and AEFI reports/data.

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11.1.3 Interacting with families and communities

Respond in a prompt manner.

An immediate response to the bereaved family the moment an AEFI occurs is a good response.

Table 11.1 Key action points for serious/severe AEFI

Serious/severe AEFI such as death/hospitalization/cluster		
Level of Intervention		Communication Action points
Community Level	Health Worker	Meet the family — parents/ caregivers and empathise with level them.

		….
Block level	MO	… -Get to the source of information and check factual accuracy of the information
District level	DIO	-Investigate the report completely and in time -
State level	State EPI officer	… -Review media coverage reports — look into the style and accuracy of reporting

National level	Government official/National AEFI Committee	-Review media coverage reports — look into the style and accuracy of reporting.

11.4. **Samples for media communication**

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2- **Press Release**

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Give names and contact details of district/state immunization officers, experts among the AEFI committee members. IAP/IMA, name and contact details of the spokesperson.

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12.1 National Drug Regulatory Authority of India (NRA)

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Post licensure, the marketing authorization holders (licensed vaccine manufacturers or importers) are required to submit the PSURs to

CDSCO for all vaccines for a period of 4 years. In addition, CDSCO functions in close coordination With the PvPI and Immunization Division of the MoHFW for the continued monitoring of vaccine safety.

12.2. Roles and responsibilities of stakeholders

12.2.1 CDSCO

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The roles and responsibilities of the CDSCO are as per the Drugs and Cosmetics Act and Rules.

- CDSCO is also responsible for taking regulatory decisions on the basis of analysis of the PMS, PSUR and AEFI data collected by expert committees. As part of the conditions of the marketing authorization (MA), the MA holder is also required to submit PMS/PSUR data after licensure of the product. The PSURs are to be submitted every six months for the first two years of the approval and annually for the subsequent two years. The licensing authority may extend the total duration of submission of PSURs if it is considered necessary in the interest of public health. However, all cases involved in serious unexpected

adverse reactions (SUARs) must be reported to the licensing authority (DCGI) within 15 days of initial receipt of information by the marketing authorization holder (MAH) in the format of Appendix XI of Schedule Y, Drugs and Cosmetics Rules, 1945.

- The licensing authority may also advise the MAH to conduct Phase IV trials which go beyond the prior demonstration of product safety, efficacy and dose definitions.

Revised AEFI Guidelines:

Executive Summary

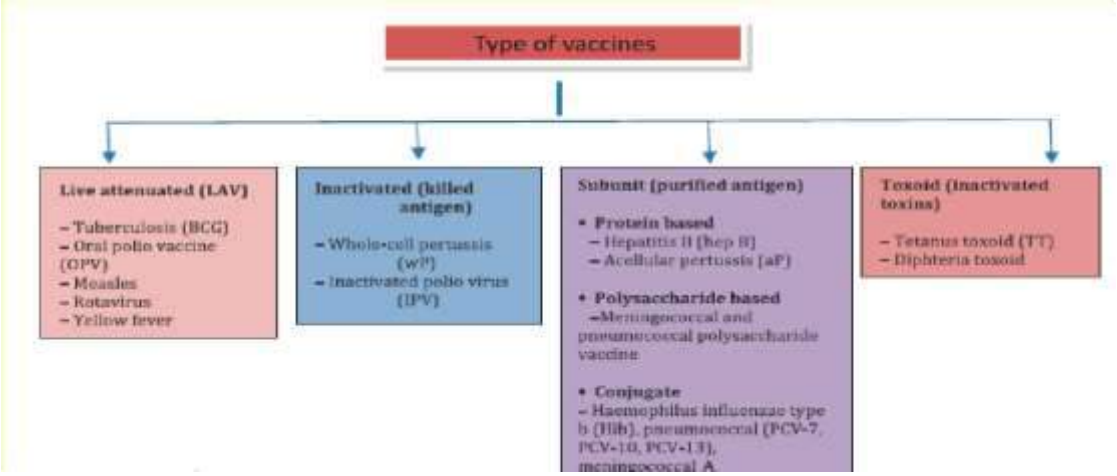
Introduction:

India"s Universal Immunization Programme (UIP), targets around 27 million newborns and about 30 million pregnant women each year. The goal of immunization is to protect the individuals and the public from vaccine preventable diseases. India is the largest developing country manufacturer of vaccines and vaccines manufactured in India are used in all continents. Vaccines used in the country are safe and effective. However, like drugs and other pharmaceutical products, vaccines are not entirely without risk and adverse reactions may occur. Being a large consumer, leading manufacturer and exporter of vaccines, India is expected to have a well-developed AEFI Surveillance system. AEFI surveillance program demonstrates the country"s intent of delivering quality immunization services with safe vaccines and ensure vaccine confidence. The AEFI surveillance system has been in place since

1988. The national AEFI guidelines were revised in 2005, 2010 and 2015. The guidelines provide information to health care providers and programme managers at national, state, district, block and primary health care levels for establishing a sensitive AEFI surveillance system. The national AEFI guidelines provide complete guidance and other details for reporting, investigating and conducting the causality assessment of cases reported as AEFIs.

Principles of immunization and vaccines process

Immunity is body"s ability to protect against diseases. There are two basic mechanisms for acquiring immunity: active and passive. Active immunity can be natural, following an infection, can last a lifetime or through vaccination, which also lasts for a long period. Passive immunity also can be either natural or artificial both last for relatively shorter period. Vaccine is a biological product that improves immunity to a given disease. The vaccines could be a live attenuated, inactivated whole cell (killed), subunit and toxoid. The vaccines consist of excipients in the form of preservatives, adjuvants and other additives.



Basics of AEFI; recording and reporting of AEFIs in India

The new guidelines define Adverse Events Following Immunization (AEFI) as any **untoward medical occurrence** which **follows immunization** and which **does not necessarily have a causal relationship** with the usage of vaccines. These events may include one or more unfavorable or unintended sign, symptoms or laboratory findings which raises concern among immunization program managers, policy makers, family of beneficiary and the community. AEFIs can be common and minor (like fever, local pain and swelling), severe (like pain and swelling which spreads beyond the nearest joint or high grade fever) and

serious AEFIs (conditions requiring hospitalization or leading to

death or disability).

The AEFI Surveillance guidelines are an update to the AEFI Operational Guidelines, 2010 and are in line with the revised WHO/Council for International Organisations of Medical Sciences (CIOMS) guidelines. The key issues covered are:

- Strategies and systems for ensuring quality and safety of vaccines in the country
- Objectives of immunization safety and AEFI surveillance
- New classification of AEFI
- AEFI surveillance system - reporting, investigation, causality assessment and response processes

- Optimum use of vaccine surveillance safety data
- Communication strategy on immunization safety for public and media.

New classification:

In 2012, revised classification relevant to cause-specific categorization of AEFIs has been introduced (Table 1)

Table 1: Cause-specific categorization of AEFIs

Cause-specific type of AEFI	Definition
Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product
Vaccine quality defect-	An AEFI that is caused or

related reaction	precipitated by a vaccine due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer
Immunization error-related reaction (formerly "programme error")	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable
Immunization anxiety-related reaction	An AEFI arising from anxiety about the immunization
Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety

Types of AEFIs by severity and frequency

1. Common minor AEFIs
2. Severe AEFIs
3. Serious AEFIs

Common minor AEFIs:

A vaccine induces immunity by causing the recipient"s immune system to react to the vaccine. Therefore, local reaction, fever and systemic symptoms can result as part of the immune response. In addition, some of the vaccine"s components (e.g. adjuvant, stabilizers or preservatives) can lead to reactions.

Severe AEFIs and serious AEFIs:

An AEFI will be considered serious if it results in death, requires hospitalization, results in persistent or significant disability/ incapacity or a cluster (two or more cases) of AEFIs occur in a geographical area.

AEFIs that are not minor but do not result in death, hospitalization or disability are categorized as severe. „Severe" is used to

describe the intensity of a specific event (as in mild, moderate or severe). The event itself, however, may be of relatively minor medical significance.

Reporting

The reporting of serious/severe AEFI is done using Case Reporting Format (CRF) (formerly First Information Report), which is prepared by the Medical Officer of the PHC or the reporter and then sent to the District Immunization Officer within 24 hours of getting the information of the case. In the next 24 hours, the DIO verifies the case details and sends it simultaneously to the state and national level. The CRF gives only the most basic details of the affected person, vaccines and session details and status at the time of filling the format.

The other channel of reporting serious and minor AEFI from the level of occurrence of the AEFI up to the national level is through monthly progress reports. This is done using existing monthly immunization reporting formats such as the ones for National Rural Health Mission (NRHM), Health Management Information system (HMIS) etc. It is necessary for the peripheral health staff

to submit a NIL monthly report in case no AEFI is detected from their area during the month. Minor AEFI that are brought to the notice of the health staff as a concern should be reported and documented in a linelist.

The guidelines provide directions to the State and District authorities that the key private health facilities, focal persons are identified and sensitized about the AEFI Surveillance and reporting system and encouraged to report AEFI. Involvement of ADR Monitoring centers in assisting the MO/DIO in reporting and investigation is also mentioned.

AEFI Investigation including lab sample collection

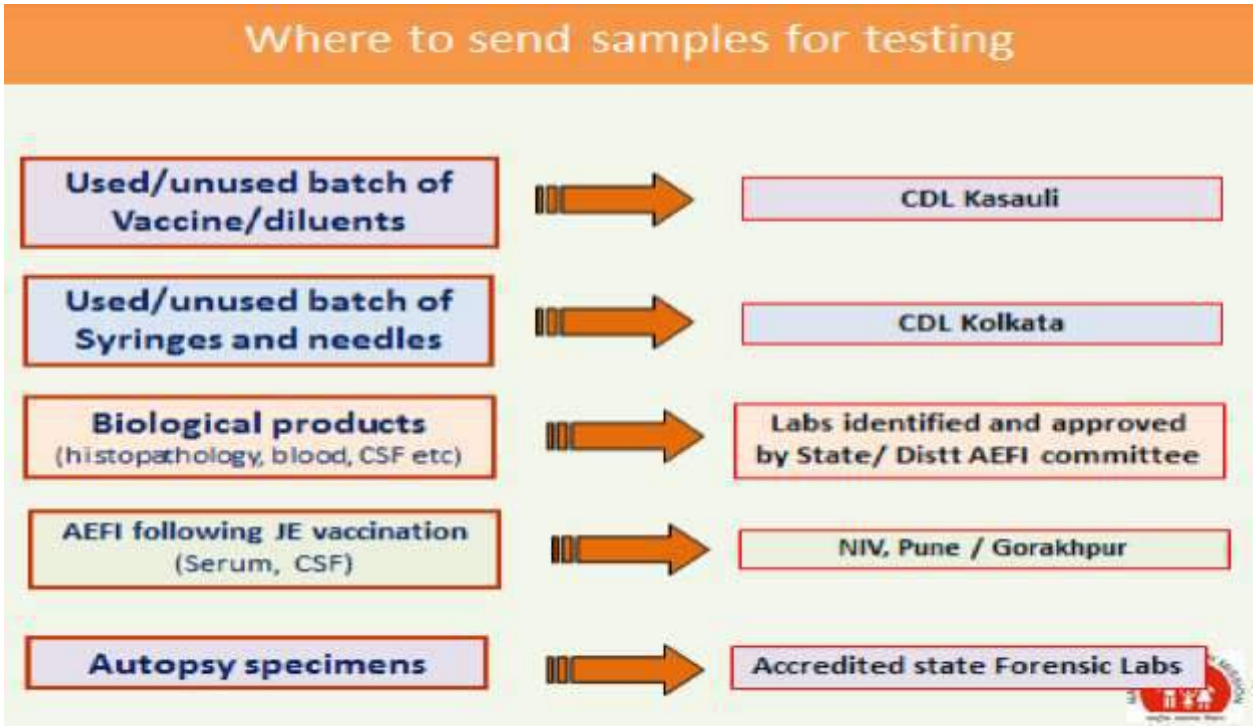
The ultimate goal of a case investigation is to make a clinical diagnosis based on the chronology of medical events, detailed medical history and other available evidence. The guidelines provide the directions to the State and district officials with regard to the steps to be followed while investigating the case. The DIO along with the members of the District AEFI Committee visits the immunization site, vaccine storage points, residence and locality of the patient and the treatment center to collect information

regarding the pre-vaccination health status, treatment taken, hospitalization or postmortem reports, details of vaccination and cold chain. The epidemiological investigation is also an important aspect while investigating an AEFI. DIO ensures that the filled Preliminary Case Investigation Format (PCIF) is submitted to the state and the national level simultaneously within 10 days of notification.

The District AEFI Committee meets and discusses the case and summarizes the findings of the investigation in the Final CIF (FCIF) and gives its opinion on the probable diagnosis. The FCIF is sent within 70 days of notification to the State AEFI Committee and the Immunization Division along with all the relevant documents of the case. The guidelines mention that the investigation of reported AEFI death and cluster (two or more cases of the same adverse event related in time, place or vaccine administration) should be conducted without any delay. It is recommended that an autopsy in a death suspected to be due to an AEFI be performed as soon as possible (within 72 hours) to avoid tissue damage, development of postmortem artifacts and lysisof the adrenal glands, which can alter diagnosis. Use of Verbal

Autopsy form in case of unexplained death/home death/inadequate information/insufficient medical records is a new addition in the guidelines. The format collects information regarding history, circumstances of death, medical examination, feeding history, etc. to rule out causes of death. Emphasis on timely, comprehensive and methodical investigation is given.

Guideline gives direction regarding the specimen collection and handling of implicated vaccine. The appropriate specimen in the correct quantity required for investigation should be collected and sent to the respective laboratory. ***Specimen collection is NOT needed for all cases. Only if appropriate****, the implicated vaccine, logistic samples, CSF, Serum (or other biological products) should be collected and dispatched to appropriate laboratories with LRF.*



Investigation of reported sudden unexplained deaths following vaccination:

Investigation of unexplained deaths following immunization is an issue of great importance with regard to the immunization programme. Proper causality assessment would enable differentiation of vaccine related deaths from deaths due to other causes. A special document has been developed to improve investigation of unexplained AEFI deaths. The verbal autopsy form has been designed based on the WHO and Centers for Disease

Control and Prevention (CDC) sudden infant death investigation (SUIDI) form, whereas the guidance on conducting autopsy has been developed by a committee of leading experts in the field of immunology. The format should be filled by the investigating team while investigating the reports of AEFI deaths where information regarding the event is inadequate, such as

- brought dead to health facility,
- home death,
- insufficient medical records regarding the event,
- death in case that was not hospitalized or
- if clinical diagnosis is not possible based on available evidence.

The guidelines gives the guidance for conducting autopsy in cases of reported deaths. An autopsy must ideally be performed in every case of an AEFI death within 72 hours of death by forensic specialist or medical officer.

Causality Assessment:

Causality Assessment is the systematic evaluation of the information obtained about an AEFI to determine the likelihood of the event having been caused by the vaccine/s received. It is a critical part of AEFI monitoring and enhances confidence in the national immunization programme. The revised guidelines use the new revised WHO/CIOMS Causality (2014). The Guidelines encourages the state to conduct Causality Assessment for reported AEFI cases. The AEFI report must have investigation formats, relevant documents and a diagnosis for being eligible for Causality Assessment. The Causality Assessment process has four steps:

1. ***Eligibility***: To determine if the reported AEFI case satisfies the minimum criteria for Causality Assessment as mentioned above.
2. ***Checklist***: To systematically review the relevant and available information to address possible causal aspects of the AEFI
3. ***Algorithm***: To obtain a direction as to the Causality with the information gathered in the checklist.
4. ***Classification***: To categorize the AEFI"s association to

the vaccine/vaccination based on direction determined in the algorithm.

All the cases being investigated by the district should be assessed by the causality assessment experts of the state AEFI committee after discussing all the investigation formats and reports available. It is recommended to disseminate the results so that others can learn from the experience. Immunization errors will need to be corrected and for coincidental incidents, communication to maintain confidence is necessary.

AEFI Committees

The revised guidelines also give the detailed information on the AEFI Committees (district/state/ national) along with the terms of reference of the committee members. AEFI Committees provide technical inputs to review the factors leading to the adverse event and provide inputs to improve the system to provide safe and effective immunization. The committee should include members from various departments like pediatrician, microbiologist, pathologist, epidemiologist, neurologist, forensic expert, cold

chain officer, representatives from IDSP, drug authority, and municipal corporation and partner agencies.

Monitoring of AEFI surveillance

The guideline emphasizes on monitoring performance of the AEFI Surveillance system. The key indicators defined are as follows:

For routine AEFI:

1. Percent of routine reports (zero reports) received on time
2. Percent of AEFI cases line listed
3. Percent of

Serious AEFI cases

For serious AEFI:

1. Percent of Serious AEFI cases reported on time
2. Percent serious AEFI cases with Case Reporting Form (CRF) shared with the state and centre on time
3. Percent of Serious AEFI cases investigated on time
4. Percent of Serious AEFI cases with completed investigation
5. Percent of Serious AEFI cases classified for causality by

the state AEFI Committee on time

Operational aspects of AEFI surveillance:

The overall goal of AEFI Surveillance is to reduce morbidity and mortality due to AEFI and minimize the negative impact of AEFI on public health. The revised guidelines describes the roles and responsibility of the key personnel involved in the AEFI Surveillance system. The importance of involvement of ASHA, anganwadi worker, Health supervisor at all the levels (community, sub-center) in the surveillance system is emphasized. The medical officer apart from detecting and reporting the event is responsible for management of the case as well. AEFI surveillance can be improved by involvement of professional organizations such as IAP and IMA. Use of online software (IDSurv) for reporting infectious disease is a provision for reporting AEFI. Role and responsibilities of the District Officials in the form of reporting, investigating, maintaining linelist of reported AEFI, coordinating with ADR monitoring center and private/government medical colleges is mentioned. At the State level, the State Immunization officer should maintain AEFI documentation, help in investigation of cases if required and involve State Drug controller and other

partner agencies. The State should perform the Causality Assessment of reported cases. SEPIO should also review and analyze the AEFI reported through HMIS and other reporting channels.

AEFI is a vital functional component of the National Regulatory Authority (NRA). The NRA is essential not only for assurance of vaccine quality in the country but also for prequalification of vaccines.

AEFI Secretariat is established in 2012 within the Ministry of Health & Family Welfare to strengthen AEFI surveillance in the country. It is hosted at the Immunization Technical Support Unit (ITSU) set up by the MOHFW, Government of India. Four Zonal AEFI Consultants have been appointed to liaise with the immunization program managers and the other vaccine safety stakeholders at the state and district levels. The AEFI Secretariat receives constant guidance and support from the National AEFI Committee and has established collaboration with Lady

Hardinge Medical College, New Delhi which is designated as National AEFI Technical Collaborating Center (NATCC) to provide oversight and support to the AEFI Secretariat.

The guidelines also describes the need for liaison of the District Committee with the police in investigation of the reported AEFI.

Vaccine risk communication and handling of media:

Effective communication around vaccine safety including management of public reactions requires serious investment of resources and efforts towards strategic communication for Immunization.

The guidelines introduced the strategic communication plan to address the short term crisis (in cases of AEFI) and long term support that the immunization programme require at the national and local level. The plan focuses on regular communication with the community and local media on RI activities to encourage use of vaccines and thus help in improving the vaccine coverage levels.

An AEFI response protocol has standardized procedures for

communication to help handle a crisis promptly and in the correct manner. It identifies the spokesperson who will respond in crisis situations at all the levels. The protocol recommends that in case of media interest in an AEFI crisis, a press release should be issued as early as possible (preferably within first 6 hours).

National Regulatory Authority and its affiliated institutions and convergence with AEFI Surveillance Program:

The guideline describes the role of National Drug Regulatory Authority and Pharmacovigilance Program of India PVPI and the importance of coordination between the CDSCO and the Immunization Division, MOHFW. The results of the causality assessment approved by the National AEFI Committee is shared with the CDSCO which analyses the results to take further necessary regulatory actions (such as inspections, amendments to product inserts, reporting by manufacturers, etc.). The IPC (Indian Pharmacopoeia Commission) has established a data sharing arrangement with the AEFI Secretariat for ensuring convergence in vaccine safety reports and their adequate

investigations.

Reference:

1. Adverse Events Following Immunization - Surveillance and Response Operational Guidelines, MOHFW, 2015. http://itsu.org.in/repository-resources/AEFI-Surveillance-and-Response-Operational-Guidelines-2015.pdf

2020 WHO Guidelines

COVID-19 VACCINES: SAFETY SURVEILLANCE MANUAL

Establishing Surveillance Systems in Countries Using Covid-19 Vaccines.

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Key points

• The role of vaccine safety surveillance during COVID-19 vaccine introduction is to facilitate the early detection, investigation and analysis of adverse events following immunization (AEFIs) and adverse events of special interest (AESIs) to ensure an appropriate and rapid response

• The type and scope of vaccine safety monitoring activities that countries can undertake will depend on the resources available and the maturity of their pharmacovigilance surveillance systems but they should aim to strengthen their activities before and during COVID-19 vaccine introduction

• Countries will need to adapt their established AEFI surveillance systems to address the specific challenges associated with COVID-19 pandemic

• Following up of specific vaccinated cohorts for at least one year will enable potential vaccine-type specific AESIs to be detected, including potential vaccine-associated enhanced disease (VAED) in vaccinated individuals who develop COVID-19 disease

• Surveillance systems will need to accommodate large numbers of AEFI/AESI reports expected because of the numbers of people who will be vaccinated • Coordination between all stakeholders handling deaths should be established for reporting deaths in persons with a history of COVID-19 vaccination and specific protocols for investigating these deaths should be defined.

• Communication about any adverse events and response to public concerns should be rapid in order to maintain public confidence, in the setting of high media and public attention on COVID-19 vaccines

1. Introduction

The role of vaccine safety surveillance during COVID-19 vaccine introduction is to facilitate the early detection, investigation and analysis of adverse events following immunization (AEFIs) and adverse events of special interest (AESIs) to ensure an appropriate and rapid response. This will decrease the negative impact of these events on the health of individuals and the immunization programmes and maintain the confidence of health care workers (HCWs) and the

general population.

To achieve this, the global goals of COVID-19 vaccine safety surveillance are to:

• detect serious AEFIs/AESIs rapidly in order to provide timely data that can be shared with relevant stakeholders for action;
• generate data to characterize the safety profile of the COVID-19 vaccines in use;

• help to monitor the acceptable benefit-risk ratio throughout the COVID-19 vaccine life-cycle;

• identify, investigate, assess and validate safety signals and recommend appropriate public health or other interventions; and

• maintain public and stakeholder confidence in vaccines and immunization by ensuring high quality safety surveillance.

The type and scope of vaccine safety monitoring activities that countries choose to adopt to achieve these goals will depend on the resources available and the maturity of their pharmacovigilance

surveillance systems. However, all countries should aim to strengthen their ability to detect, investigate, assess, report and respond to serious AEFIs before and during COVID-19 vaccine introduction. The key objectives are to:

• strengthen routine passive surveillance reporting systems to enable them to cope with the expected increase in frequency or severity of AEFI (mild, moderate, and severe);
• detect and investigate safety signals or clustering of serious events, immunization errors, community concerns etc.;
• perform systematic causality assessments for AESIs;
• prepare comprehensive plans to respond rapidly to any COVID-19 vaccine-related events; and
• be able to respond to any concerns expressed by HCWs and maintain community confidence.

Countries that have mature pharmacovigilance systems or have to face particular situations, such as, the introduction of a novel vaccine platform requiring enhanced safety monitoring may consider the following additional safety monitoring objectives:

• implement active surveillance systems for AESIs;
• conduct research on identified or newly observed vaccine safety concerns in large populations or target groups, for example, comparison between vaccinated and unvaccinated cohorts to identify immunological markers of risk for severe COVID-19 disease and types of adverse events among vaccinated;

…

2. Key considerations for adaptation of vaccine safety surveillance systems

…

Following up specific vaccinated cohorts for at least one year will enable potential vaccine-type specific AESIs to be included, including potential vaccine associated enhanced disease (VAED) in vaccinated individuals, who develop COVID-19 disease.

It is likely that Covid-19 immunization programmes will focus on adult population initially. Hence, it will be important to ensure that the surveillance systems are capable of capturing AEFIs in adults, as is

necessary for seasonal influenza and pneumococcal polysaccharide vaccination used in adults and for other novel vaccines that have been introduced, e.g., Ebola, meningococcal A and pandemic influenza vaccines.2,3 Clinics, hospitals and other settings that care for adults may not be familiar with AEFI reporting processes. There may be higher rates of coincidental AEFIs since adults have higher rates of comorbidities than children.

…

Surveillance systems will need to be able to accommodate the large numbers of AEFI/AESI reports expected because a large proportion of the population will be vaccinated. ***AEFI reporting from health facilities or districts may need to be more frequent than routine reporting, to ensure that any safety signals can be detected rapidly and responded to in an appropriate and timely manner.***

Finally, as for any new vaccine, the safety data from clinical trials that will be available at the time of the COVID-19 vaccine introduction will be limited and insufficient to detect rare adverse events. There will

also be limited safety data for certain populations and for adverse events with a latency longer than the trial follow-up period.

…

It is highly likely that phase III clinical trials will still be ongoing when some vaccination programmes are implemented with COVID-19 vaccines that have been granted emergency use listing status. ***It will be important that rapid access to periodic safety update reports (PSURs) and other safety reports is coordinated between regulatory agencies and vaccine sponsors and vaccine manufacturers in each country. This shared information will be valuable for interpreting passive system safety data and for conducting causality assessments by AEFI committees.***

Increases in immunization-error related reactions may occur due to lack of experience in the management of the new COVID-19 vaccines with special handling conditions, e.g., vaccine storage at -80oC or new administration devices or methods and the participation of HCWs who are not traditionally involved in vaccination in many countries.

…

Table 1: Recommended AEFI surveillance activities for all countries introducing COVID-19 vaccination, regardless of their AEFI surveillance capacities

Objective	Recommended AEFI Surveillance Activities
Strengthen routine passive AEFI surveillance reporting systems for the management of increased frequency or severity of AEFI reports (mild, moderate and severe)	1. Conduct training on identification and reporting of AEFI for health care workers. 2. Update, print and distribute AEFI surveillance tools. 3. Use both vaccine tracking information and passive AEFI reporting information to perform vaccine-specific safety analyses. …

Investigate potential AEFIs causing concern, such as clusters, serious events, programmatic errors, community concerns	1. Prepare investigation teams and train them for AEFI investigation activities that are relevant to the population being vaccinated. 2. Update, print and distribute AEFI investigation tools to obtain information on specific outcomes. 3. Ensure the collection and storage of all relevant data to help make a causality assessment (AEFI reporting and investigation forms, clinical case record, laboratory reports, autopsy reports, etc.). …

Perform systematic causality assessment of AEFIs causing concern	… 2.Provide training on causality assessment processes using WHO causality assessment guidelines for members of the National AEFI committee. … 5. Anticipate an increased number of AEFI reports that will need to be reviewed and consider including AEFI committees at subnational as well as national level, particularly in large countries.
…	
Prepare comprehensive plans to respond rapidly to all COVID-19 vaccine related events	1. Outline roles and responsibilities of key stakeholders (both public and

	private, including vaccine manufacturers) for the implementation of safety surveillance activities and response to vaccine-related events. …

3. Surveillance strategies to be adapted to COVID-19 vaccination strategies.

The adaptations of AEFI surveillance systems needed will depend on the capacity and functionality of existing systems. All countries should strive to strengthen or enhance their routine passive surveillance capacities by, for example, streamlining processes such as data entry into national databases. ***Increasing functionality by introducing cohort event monitoring, sentinel site based active reporting, and use of electronic data systems at sentinel sites or at population levels, if possible should be considered. In addition, some countries may consider active surveillance or***

specific studies to assess the causal relationship between specific events and COVID-19 vaccination.

3.1 Application of surveillance concepts to COVID-19 vaccine-related AEFI and AESI

The primary purpose of passive AEFI surveillance is to identify and respond to events that are temporally associated with immunization. In contrast, AESI surveillance focuses on the specific events irrespective of vaccination, and then assessments are performed to determine if the event occurs more frequently in vaccinated individuals than in non-vaccinated individuals or following up vaccinated cohorts and assessing the health status.

As there are similarities between the terminology used for the surveillance of AEFIs and AESIs, it is important that HCWs are trained to understand the differences and the implications of the differences. Some key basic concepts are outlined below.

• Routine passive surveillance (spontaneous reporting): Cases are not

actively sought; surveillance sites passively notify a network when they encounter AEFIs and reports are generated and sent by local staff.

In some countries, passive surveillance also includes spontaneous reporting by patients themselves.

• Active surveillance: Active surveillance is a data collection system that seeks to ascertain as completely as possible the number of AEFIs in a given population through a continuous, organised process. This may involve designated staff visiting health care facilities, talking to HCWs and reviewing medical records to identify suspected cases of AESI. It can also be done remotely using electronic health databases. When cases are identified, their vaccination status is determined. Active surveillance can also be done through cohort event monitoring or sentinel surveillance.

• Cohort event monitoring (CEM): AEFIs are reported by HCWs who are trained to encourage reporting and follow-up of a cohort of those vaccinated through defined channels, e.g., phone call, email, home visit. The system is closely

monitored by a central coordinating unit through identified reporting points. Cohort event monitoring could be useful for close monitoring of serious AEFIs and signals following the introduction of COVID-19 vaccines or after mass COVID-19 vaccination campaigns.

• Sentinel surveillance: This system is used when high-quality data are needed for a particular disease that cannot be obtained through a passive system. Selected reporting units, with a high probability of seeing patients with the disease, good laboratory facilities and experienced well-qualified staff, identify and report AEFIs. Unlike most passive surveillance systems that receive data from as many HCWs and health care facilities as possible, a sentinel system deliberately collects data from only a limited network of carefully selected reporting sites.

3.2 Routine Passive Surveillance for AEFIs following Covid-19 vaccine introduction

However, routine passive reporting systems will not be sufficient to allow the rapid assessment and appropriate public health response that will be needed during COVID-19

vaccine introduction. Routine systems will need to be enhanced with active surveillance to improve detection of AEFIs (Table 2). Another approach to enhancing passive systems could involve raising stakeholders' awareness, including the National AEFI committee, about certain events reported as AEFIs that should trigger additional investigation and potential categorization of specific events.

Active surveillance for AESIs following COVID-19 vaccine introduction

The staff of active surveillance systems initiate and maintain regular contact with HCWs to identify individuals with the health condition(s) of interest. This information can also be obtained by regularly extracting data from health care databases. Some approaches used for active surveillance of AESIs are cohort event monitoring (CEM) and sentinel surveillance. Pregnancy registries are an important tool for determining pregnancy outcomes when vaccines are likely to be administered inadvertently or intentionally to women who are pregnant or to women of reproductive age who become pregnant post-immunization.

Table 2: Recommended activities for enhancing safety surveillance systems in countries, based on their current surveillance systems

Level of existing surveillance capacity	Relevant additional objectives	Recommended additional activities
Established passive surveillance – partially functioning	— improve the use of local and national safety data to generate information to communicate with the public, the community, media, NRAs, vaccine manufacturers, WHO and other stakeholders about the safety of COVID-19 vaccines being	1. Assess the functionality of the existing AEFI surveillance system to identify key gaps and ability to expand capacity needed to take on additional safety activities. 2. Strengthen national AEFI committee capacity to review and respond to AEFI

	used; and — contribute to continuous updating of the safety profile of COVID-19 vaccines being used;	safety signals, public concerns or collaborate with WHO to provide this capacity. 3. Consider sentinel site surveillance for AESIs if the above can be achieved and activities can be supported. 4. Consider implementing active surveillance for AESIs, if relevant objectives are addressed.

Established passive surveillance – fully functioning	— consider active surveillance for AESIs.	1. Establish active AESI surveillance at selected sentinel sites. 2. Inform the National AEFI committee about potential concerns for COVID-19 vaccines.
Established passive, active (e.g. database or other) surveillance systems Ability to detect and evaluate signals consistently	— implement active surveillance for AESIs; — conduct research on predefined or newly identified important vaccine safety concerns in large populations or	1. Inform the national AEFI committee about potential concerns for COVID-19 vaccines. 6. Consider specific studies, e.g., plan to identify and evaluate

	particular target groups, e.g., VAED;	VAED in the context of vaccine failure.

Specific provisions for additional national safety monitoring activities by COVID-19 vaccine manufacturers

COVID-19 vaccine manufacturers are also responsible for monitoring the safety of their COVID-19 vaccines introduced and for addressing any safety issues that occur. Additional safety surveillance activities should be carried out by vaccine manufacturers to continue collecting information on safety beyond that collected during pre-licensure COVID-19 vaccine trials.

The processes of engaging with the pharmaceutical industry, reviewing risk management plans and outlining the legal provisions and guidelines for COVID-19 vaccine safety are described in the engaging with the pharmaceutical industry module. Additional pharmacovigilance activities such as post-authorization safety studies (PASS) that should be performed to assess any identified risks or

potential risks and provide important missing information are also described.

Table 3: A comparison of post-licensure pharmacovigilance with passive and active surveillance systems for AEFIs and AESIs and for post-licensure safety studies

	Passive surveillance for AEFIs	Active surveillance for AESIs	Post-authorization safety studies (PASS)
Purpose of information collection	To identify AEFIs, assess their severity and perform causality assessment	To identify predefined specific events and assess association with COVID-19 vaccination or actively follow	To provide safety information missing at the time of licensure

		up a vaccinated cohort	
Relevant for	HCWs, NIP/EPI managers, NRAs, surveillance and information managers, epidemiologists, vaccine manufacturers, surveillance and information managers, media, vaccine safety partners, including the community	Sentinel site staff, NIP/ EPI managers, NRAs, epidemiologists, vaccine manufacturers, national AEFI committees, study teams	NRAs, NIPs/EPIs

Method for data collection	**Through spontaneous reporting** or detection by HCWs	As per specific protocols for AESIs by sentinel site surveillance of cases or electronic health records, using appropriate methods	As per study protocol designed by vaccine manufacturers and approved by relevant authorities
Initiated by	Pre-existing system	Countries or regions wanting to investigate significant knowledge gaps	Vaccine manufacturer

Responsibility	NIPs/EPIs, NRAs and MoHs	Principal investigator appointed by the country	Vaccine manufacturers with oversight from relevant authorities
Preparedness assessment	Preparedness checklist	Protocol reviewed by NITAG/ National AEFI committee	Based on criteria for site selection by NRA, NIP/EPI and vaccine manufacturers
Stakeholder training	All frontline immunization staff in health care facilities	Sentinel site staff, immunization staff and	Principle investigator at study site

	(public and private); and other relevant staff in reporting, investigation, data analysis, and causality assessment	clinicians in sentinel sites and predefined active surveillance systems, NIP/EPI mangers, NRA, research staff, national AEFI committee	

Serious AEFIs and AESIs

In the event of serious AEFIs or AESIs all documentation generated during the management of the event, including hospitalization, should be appended to the investigation form and submitted as a dossier to the national AEFI committee for causality assessment. The communication team should be made aware of the occurrence of a

serious event as soon as possible in order to coordinate communication responses at the appropriate levels.

The communication team should be made aware of the occurrence of a serious event as soon as possible in order to coordinate communication responses at the appropriate levels

Deaths following COVID-19 immunization

Individuals who die following COVID-19 vaccination, including those with any related diagnosis that is an AESI, should be included in the protocol for investigating deaths following COVID-19 vaccination.

Specific protocols for autopsies of people with a suspected cause of death given as COVID-19 have been developed, and these could be used for the autopsy of COVID-19 vaccinated individuals who die. If indicated, tissue samples should be collected for in-depth pathologic, virologic and genetic testing. If an autopsy is not done, a complete verbal autopsy using standard protocol should be conducted and the

findings documented and sent to the national AEFI committee.

Key considerations and managerial principles when using the pandemic preparedness checklist

- ***Ensure that high-quality training is available at all levels, and that vaccination staff (and staff monitoring safety) are knowledgeable, empowered and confident about making important decisions.***

ANNEXURE P-42

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More Flaws in the Vaccine Model Claiming 20 Million Lives Saved ⋆ Brownstone Institute

Bhaskaran Raman

6-7 minutes

A study titled "Global impact of the first year of COVID-19 vaccination: a mathematical modelling study" has appeared in the *Lancet Infectious Diseases* journal, on 23 June 2022. It has concluded that nearly 14-20 million lives have been saved by the rollout of the Covid-19 jabs. This study immediately gained widespread news coverage worldwide: e.g. The *Hindu* (India), M*int* (India), The *Guardian* (UK), CBS Detroit (USA), etc. It is thus worth looking at the technical validity of the study.

Flawed assumptions in the jab impact modeling study: The modeling study necessarily incorporates various important parameters. A close look reveals that much of the critical parameters are based on assumptions which are *known* in the literature to be wrong. The table below summarizes this.

Aspect	Assumption in modeling study	Critique, Reality check of the assumption
Immunity after natural infection	"loss of infection-derived immunity.. follows an Erlang distribution with a **mean duration of one year**" (see study supplement).	Immunity after natural infection is **robust and long-lasting**; protection against infection lasts much longer than for the jabbed; protection from severe disease is likely lifelong.
Immune evasion to new variants after exposure to earlier variants	"**Immune evasion** for infection-derived immunity occurs for 27% of the previously infected population."	The study cited for this 27% number is interpreted incorrectly. In the cohort study, 27% of the participants showed a decline in antibodies followed by an increase. Rather than meaning that these individuals became susceptible again, it means that these individuals were re-exposed and their **immune system worked** exactly as it was supposed to.
Vaccine efficacy against infection with Delta variant	Adenovirus: **67%**, mRNA: **88%** (see Table 1 of supplement)	Efficacy wanes in 6 months:Adenovirus: **44%**, mRNA: **63%**Such waning efficacy is not modeled.
Vaccine efficacy against mortality	Adenovirus: **92%**, mRNA: **93%** (see Table 1 of supplement)	Efficacy against mortality must be calculated considering *all-cause* mortality; a preprint study shows a more modest **73%** for the adenovirus jabs, and a *negative* efficacy of **–3%** for the mRNA jabs; so the modeled numbers are way too optimistic and incorrect; protection against

		hospitalization and mortality is also known to be waning and this is not modeled.
Vaccine efficacy against transmission	"We assume that all vaccinatedindividuals have a **50% reduction** in infectiousness for breakthrough infections."	The study cited for this 50% reduction clearly says that efficacy against transmission **nears zero after 12 weeks** of the jab; other studies have also shown that efficacy against onward transmission is near nil; hence the modeled number is wrong.

All of the above erroneous assumptions are in the direction of amplifying the possible impact of the jabs, while at the same time diminishing the role of immunity after natural infection. Hence it is likely that the modeling study overestimates the lives saved by the Covid-19 jab rollout. Aside from the above parameters, there is yet another technical flaw, as explained below.

The colossal failure of Covid-19 transmission model used: In general, among scientific studies, mathematical modeling carries far lower weight than real-world studies, since modeling necessarily has to make simplifying assumptions.

In particular, Covid-19 modeling has failed spectacularly. More specifically, the transmission model for Covid-19 proposed in late March 2020, from Imperial College (UK) has been off by a factor of 10-40, as depicted in the table below (data source: website, spreadsheet).

Country	Prediction	Real world data	Factor of miscalculation by model
Sweden	80,000 deaths with no mitigation	~6,000 deaths in first wave with no lockdown	**13 times**
India	4.0 million deaths with "social distancing whole population"5.9 million deaths with no mitigation	150,000 deaths in 2020 with 3 months of strict lockdown, 6 months of different levels of relaxation	**26-39 times**

It is important to note that the current jab impact modeling study has used the same above Covid-19 transmission modeling, which is known to have failed by a huge factor. Since the earlier transmission model hugely overestimated Covid-19 spread and deaths, it stands to reason that the current jab impact model using the transmission model has grossly overestimated the number of lives saved by the jab rollout.

Financial conflicts of interest: Independent of the above technical flaws, there is another important aspect here. The *Lancet* publication clearly mentions that the funding sources for this work include the WHO, Gavi, Bill & Melinda Gates Foundation, all of whom have a financial conflict of interest in mass jabs. However, most of the news outlets have left out this critical information. This is inappropriate and unacceptable in honest journalism.

Summary: In conclusion, it is possible that the jabs may have saved some lives, but the modeling study is likely grossly overestimating the same. Further, that (a) scientists have to resort to a modeling study with so many flaws, and that (b) news outlets have to resort to imbalanced coverage of the same without mention of financial conflicts of interest, does not speak too well of the possibility of a huge impact on lives saved. The scientific evidence to substantiate a jab as life-saving should always be a rigorous randomized control trial.

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Commentary on "Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. The Lancet Infectious Diseases. 2022, Jun 23"

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Introduction

In a recent study published in The Lancet Infectious Diseases, Watson et al. applied mathematical modeling to estimate that mass COVID-19 vaccinations saved between 14-20 million lives worldwide during the first year of the COVID-19 vaccination program [1]. The study uses a generative model of COVID-19 transmission dynamics that includes 20-25 assumed parameters (i.e. vaccine effectiveness against transmission, infection, and death, age-mixtures of each country, age-stratified infection fatality rates etc.) that is fitted to reported excess deaths in order to infer (but not validate) virus transmissibility across time in 185 countries. The study compares actual 2021 excess deaths to simulations (counterfactuals) that are supposed to predict the trajectory of excess deaths in each country if no vaccines had been introduced (i.e. by running multiple simulations of the above fitted models after removing the effects of vaccines). The difference between these counterfactual curves and actual excess deaths result in the estimated deaths averted due to vaccination.

The authors' models do not appear to account for evolution of the infectivity or lethality of the virus, other than explicitly modeling an increase in infection hospitalization rates due to the Delta variant (see 1.2.3 Variants of Concern section in the Supplement). The primary assumption in the counterfactual stimulations is that excess deaths are explained by the "natural" evolution of the virus as reflected in its time-varying transmissibility, which can only be inferred (fitted) and not validated. *It is thus important to note that, if the models assume parameters that misestimate vaccine effectiveness against transmission, infection and death as well as the duration of vaccine protection, while ignoring other sources of pandemic-related excess deaths, this will lead to a misestimation of time-varying virus transmissibility in order to achieve a good fit with the excess death curves in each country.* This in turn, would artificially inflate the estimated excess deaths when the effects of vaccination are subsequently removed from the counterfactual simulations. We elaborate on these points below.

The models in Watson et al. rely on unrealistic assumptions about vaccine-derived immunity

It is not clear whether the authors consider waning vaccine effectiveness in their models, and it appears that all their models assumed constant vaccine protection across the entire 1 yr study period, even though studies have suggested it is somewhere between 3 to 6 months[1]. The model they cite, Hogan et al. 2021 by default assumes "long term" (i.e. >1 year) vaccine protection (see Table 1. in Hogan et al. 2021[2]).

In addition, virtually every study of vaccine efficacy or effectiveness either exclude or include symptomatic cases within 21 days of 1st dose or within 14 days of second dose with their "unvaccinated" comparator groups [3]. This is problematic in light of evidence that COVID infectivity may increase almost 3-fold during the first week post-injection[2] (see Figure 1).This suggests that reported vaccine effectiveness estimates that are based on lower case rates observed >6 weeks may (at least partially) be accounted for by *infection*-, not vaccine-, induced immunity due to short term increases in COVID-19 infectivity immediately following vaccination.

[1] See https://brownstone.org/articles/16-studies-on-vaccine-efficacy
[2] See https://www.hartgroup.org/it-gets-worse-before-it-gets-better

While the models in Watson et al. include a latency period between vaccination and when protection kicks in, they do not account for a potential increase in vaccine-induced infectivity and transmissibility during this period. Not accounting for this effect in the models would overestimate naturally evolving and time-varying virus transmissibility and thus inflate excess deaths in the counterfactual simulations that exclude vaccination effects.

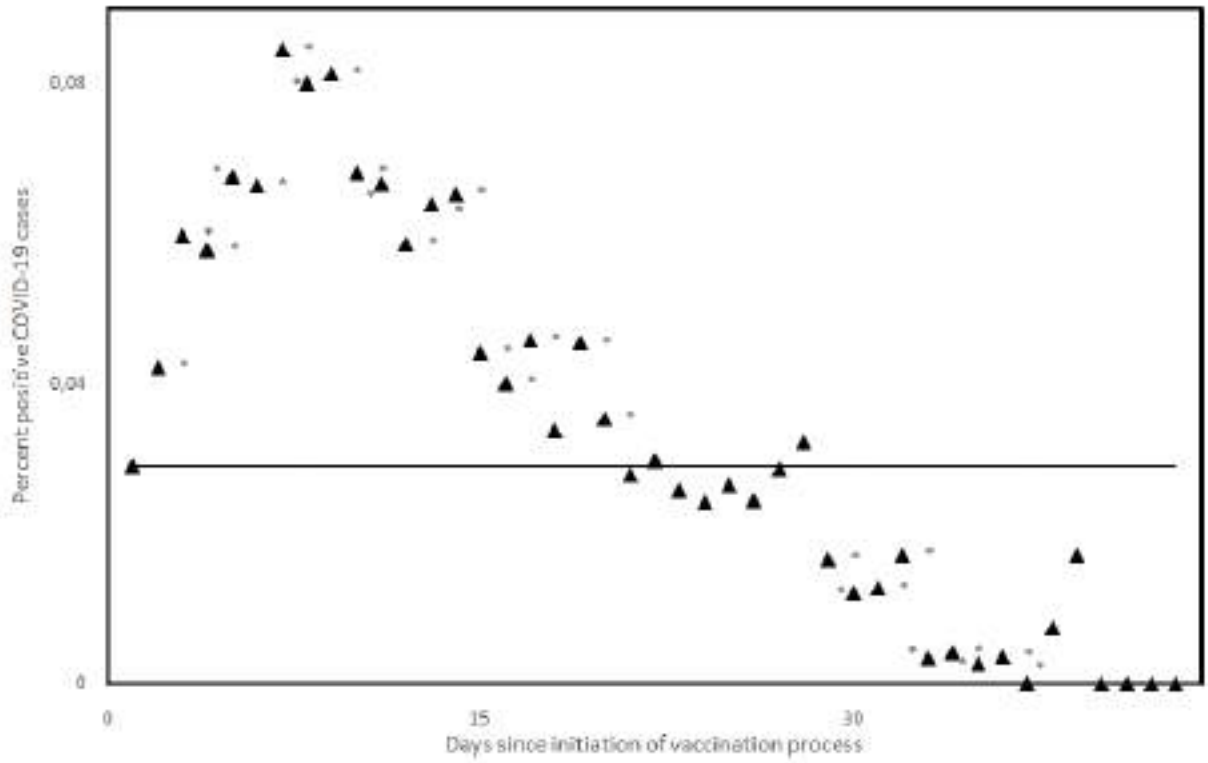

Figure 1. Adapted from [4] based on reanalysis of [5]. Daily COVID-19 incidence rates among vaccinated, as a function of days since initiation of the vaccination process. Values taken from Table S7 Discrete Time Hazard per 100,000 in Vaccinated column in Dagan et al. 2021 [5]. The baseline is defined by COVID-19 incidence on day 1. * indicates $p<0.05$ as compared to that baseline.

Finally, the authors explored the impact of immune evasion from infection-derived immunity by conducting a sensitivity analysis to estimate the deaths averted by vaccinations with different immune escape percentages ranging from 0% to 80% (see Supplementary Figure 4). In these models, the authors make clear that they assume a constant (non-waning) vaccine protection which is an unrealistic assumption (see above paragraph). However, the authors do not appear to do a similar sensitivity analysis of immune evasion from vaccine-derived immunity, which is important given the point raised in the above paragraph.

Models ignore excess death due to factors other than COVID-19

The fitted models and their counterfactuals assume that excess deaths in each country are explained *solely* by a naturally evolving COVID-19 virus and its (fitted model-inferred) time-varying transmissibility. The models do not attempt to account for excess deaths caused by other pandemic-related factors, for example the vaccines themselves as well as other non-pharmaceutical compulsory interventions. The CDC reports a vaccine-induced death risk of 0.0026% on average *per dose* based on the Vaccine Adverse Events Reporting System, or VAERS[3]. VAERS is a passive reporting system and it is well known it suffers from under ascertainment in that it only captures ~1% of all vaccine-related side effects [6].

[3] See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

Recent independent lines of evidence suggest that VAERS may only capture 3-5% of all vaccine-induced deaths [7,8]. In addition, the models do not account for excess deaths resulting from other factors such as lockdown-induced "deaths of despair".[4] By ignoring other potential sources of pandemic-related excess deaths in their models, the fitted models will over- and/or misestimate the effects of natural, time-varying virus transmissibility in order to achieve a good model fit with reported excess deaths, which in turn would lead to inflated excess death counts in their counterfactual simulations.

Lack of face validity

According to the authors' country level estimates 1.9 Million deaths were averted in the US assuming a 61% vaccine coverage (see Supplementary Table 3 in original study). In the first year of the pandemic when no vaccines were available (2020), there were 351,039 confirmed COVID deaths in the US[5]. The authors' models thus suggest that 1.9M / 350k = ~5.5x as many COVID deaths in the US would have occurred in 2021 (vs. 2020) had no vaccines been introduced. This is highly implausible as there is very little reason to believe the virus would have naturally evolved to be that much more transmissible, infective and lethal.

The authors allude to higher transmissibility in 2021 due to the relaxing and/or lifting of public health measures and restrictions (lockdowns, travel restrictions, mask mandates etc.). However, the assumption that this could account for a >5-fold increase in COVID deaths in 2021 contradicts >400 studies that have concluded there were very little to no public health benefits of these measures in reducing COVID outcomes[6].

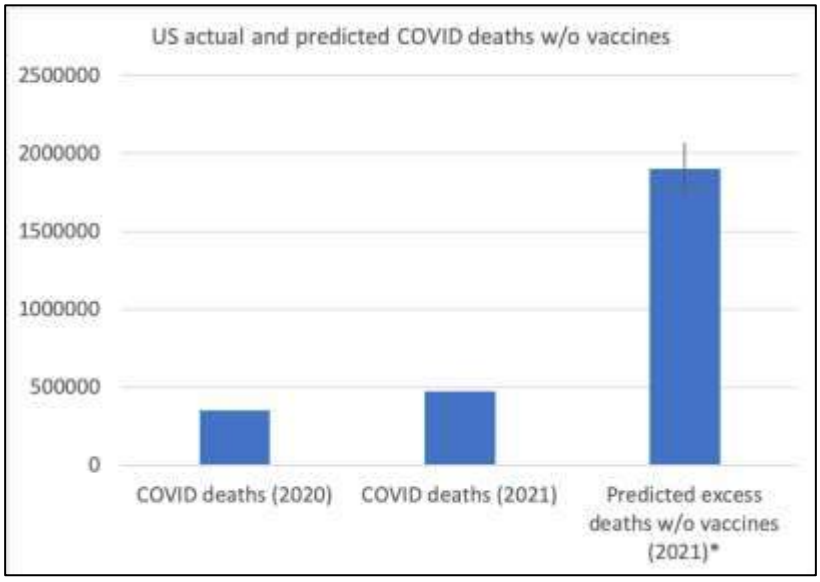

Figure 2. Two left bars show total confirmed COVID-19 deaths in the US in 2020 and 2021 from Our World in Data. Rightmost bar (*) indicates predicted number of averted US deaths due to vaccines in the Watson et al. article (Supplementary Table 3).

Moreover, in 2021 (after vaccination was introduced), there were 474,890 confirmed COVID deaths in the US according[5]. This suggests crude evidence that mass vaccination may have *worsened* COVID outcomes overall, consistent with observations of increased infectivity before vaccine protection kicks in (see 1st point above) as well as previous predictions and observations of enhanced respiratory disease via antibody dependent enhancement based on preclinical studies [9,10].

Summary

While generative models are a useful tool to simulate scenarios that have not occurred, not accounting properly for relevant variables in the model may lead to model misspecification. In such cases, counterfactuals may grossly inflate estimates of deaths averted due to mass vaccinations. Rather than rely on simulations which may be sensitive to input parameters, prone to overfitting, and that are difficult, if not impossible to validate, more accurate and reliable approaches to inform public health vaccination policies are quantitative risk-benefit ratio analyses for specific outcomes using clinical trial or real-world data [7,11,12].

[4] See https://www.aier.org/article/study-indicates-lockdowns-have-increased-deaths-of-despair
[5] See https://ourworldindata.org/coronavirus/country/united-states
[6] See https://brownstone.org/articles/more-than-400-studies-on-the-failure-of-compulsory-covid-interventions

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ANNEXURE P-44

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Indian strategy on Covid-19 is like 'treating' a wart in a patient with disease of the heart

Share

11-14 minutes

Indian strategy on Covid-19 is like 'treating' a wart in a patient with disease of the heart

By Dr Amitav Banerjee*

Community diagnosis in public health is similar to the role of clinical diagnosis when treating an individual patient. In practice of clinical medicine, one does not get down first to treating a wart on the leg of a patient who has come to the hospital with severe chest pain suggestive of a heart attack.

One surely does not resort to such stupidity while practicing clinical medicine. However, in the present pandemic such blunders are being committed with impunity. The table below shows our major disease burden based on incidence and deaths, the proper community diagnosis.[Table 1].

Compared to the community diagnosis of the Indian population as seen in Table 1 the impact of Covid-19 particularly in young Indians and children is negligible as shown in Table 2.

Basic public health principle demands that resources should be used to control diseases with high death rates and morbidity. For this proper monitoring and surveillance to generate good data is essential, which is lacking for our major killer diseases of childhood.

On the contrary, we are blindly spending resources for RT-PCR and contact tracing for Covid-19, an exercise in an extravagant waste of scarce resources and on a disease, which rarely kills young people. Moreover, once community transmission is established, test, trace and isolate is futile.

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Table 1: Overview of our disease burden. [Community Diagnosis – the [illegible] young people & children]

Road Traffic Accidents	Indian roads witness 415 deaths per day & three times crippled 70% in young people.	Source: According to Union Minister Nitin Gadkari much serious than Covid-19 Pandemic, https://economictimes.indiatimes.com/news/politics-and-nation/road-accident-scenario-more-serious-in-india-than-covid-19-with-415-deaths-daily-nitin-gadkari/articleshow/80771875.cms
Typhoid	Fatality is 1-4% even after treatment. Untreated fatality 10-30%. No proper data updated estimated more than one lakhs deaths in young children annually. Vaccine available but coverage poor.	Sources: https://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_Surveillance/VaccinePreventable_21_Typhoid_R2.pdf?ua=1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4013325/
Dengue	70% of global burden from Asian countries in India. With treatment mortality 1% but can be as high as 20% in absence of proper diagnosis. Presently large areas of the country facing surge with deaths of children. Very few samples are tested, miniscule compared to number of Rt-PCR for Covid where even without treatment survival is 99.99% in the young.	Sources: https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3617850/ https://www.nationalheraldindia.com/health/mysterious-fever-a-bigger-challenge-than-covid
Japanese Encephalitis	Case fatality ranges from 10% - 60%. 50% of those who recover may be left with paralysis. Vaccine available in spite of which children are dying in Uttar Pradesh and monitoring and surveillance is inadequate.	Sources https://pubmed.ncbi.nlm.nih.gov/10771844/#:~:text=Case%20fatality%20rate%20has%20ranged,ccs.med%20equally%20in%20both%20sexes. https://www.nationalheraldindia.com/health/mysterious-fever-a-bigger-challenge-than-covid
Scrub Typhus	Fatality ranges from 1.3% to 33.5% depending on early diagnosis and treatment. Presently suspected cause of deaths of children in UP	Sources: https://www.nationalheraldindia.com/health/mysterious-fever-a-bigger-challenge-than-covid (Recently 11 districts in UP reported deaths in children due to "mysterious fever" suspected to be either dengue, scrub typhus, leptospirosis. Only 185 samples tested in peak of this outbreak of mysterious fever compared to lakhs of tests done for Covid-19 which has almost zero fatality for children). Just in one district, Firozabad in UP, around September, thousands of people were bedridden. Over the month there were 208 deaths, out of which 178 were children. The investigation to cause of deaths was sloppy.
Tuberculosis	TB in India Kills about 480,000 every year or 1400 mostly young every day. The case fatality rate even with treatment can be over 5% and for MDR TB 20%	Source: https://pubmed.ncbi.nlm.nih.gov/31813430/
Child Deaths	Daily more than 2000 children die in India from from diarrhea, other respiratory infections against a background of malnutrition(among highest in world).	Sources: https://data.unicef.org/country/ind/ NFHS-5 (http://rchiips.org/nfhs/factsheet_NFHS-5.shtml)

The 4th round of serosurvey conducted in June 2021 by the Indian Council for Medical Reseach ICMR found 67% of seropositivity. From this we can estimate that over 90 crores of Indians have encountered the corona virus. At that time only 3 crores cumulative cases were reported, indicating that hardly 3-4% of cases of Covid-19 could be detected by this cost & resource intensive test, test, isolate policy.

The biggest public health blunder is spending Rs 35,000 crores for mass vaccination for a disease which has more than 99% survival across all age groups, the lowest among all our endemic diseases, while only 20,000 crores have been earmarked for hygiene and sanitation/water supply lack of which kills over 2000 children every day in India due to diarrhoeal and other diseases.

The latest serosurvey from Delhi has revealed that over 80% of people below 18 years already have antibodies against Covid-19 Do we need to develop and roll out vaccines for children? Studies from various parts of the world have established that immunity after natural infection, which the bulk of young people in our country seem to have acquired, is 13 to 27 times more robust than vaccine-induced immunity.

It would be unethical to risk adverse effects of vaccines particularly in children with Natural Immunity, when both the efficacy and long term side-effects are still unknown.Against this background, it is very imprudent to have allocated Rs 35,000 crores for covid-19 vaccination almost equal to half the amount of Rs 71,269 crore allocated to department of Health and Family Welfare (click here).

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Table 2: Age wise survival rates of Covid-19 (Negligible Threat to young people & Children)

(Source: https://apanthaword.org/2021/06/30/survival-rates-after-contracting-covid/-
https://www.medrxiv.org/content/10.1101/2021.07.08.21260210v1)

Age in Years	Survival Rate (%)
0 - 19	99.9973
20 - 29	99.986
30 - 39	99.969
40 - 49	99.918
50 - 59	99.71
60 - 69	99.41
70+	97.6
70+ (in care homes)	94.5%

The developed countries enjoy the luxury of overcoming most of these infections and may afford to invest heavily to control the novel coronavirus in children. In developing countries like India, on the other hand other prevalent diseases including malnutrition takes a far heavier toll of children and young people, many times more than Covid-19.
Public Health practice keeps encountering difficult choices. It challenges us to be fair and also accountable when making rational decisions. We need reliable data about our own endemic diseases to make such choices. The current model of real-time monitoring of cases and deaths of the novel coronavirus can be more efficiently used for our own major killer diseases. These data would enable rational allocation of health resources to improve the health of our population.

Currently, our strategy of focusing all on Covid-19 is like treating a wart in a patient with disease of the heart.

Professor & Head, Community Medicine, Clinical Epidemiologist, Editor in Chief, Medical Journal Dr DY Patil Vidyapeeth, Pune. Website: https://amitavb.wixsite.com/amitav-banerjee

TRENDING

By Bhaskar Sur* Swami Vivekananda now belongs more to the modern Hindu mythology than reality. It makes a daunting job to discover the real human being who knew unemployment, humiliation of losing a teaching job for 'incompetence', longed in vain for the bliss of a happy conjugal life only to suffer the consequent frustration.

Counterview Desk ActionAid, an international advocacy group which claims to work for a world without poverty, patriarchy and injustice, has wondered if the Union budget 2023-24, which is being acclaimed for providing succour to the middle classes, has anything to offer to the India's poor. In a statement, it said, while the budget may have "prioritised inclusive development", the financial outlay for ensuring it "does not show the zeal as hoped." Stating that the Finance Minister said Rs 35,000 crore revenue would have to be "forgone" due to a reduction in personal income taxes, "fiscal prudence is not enough to expand public employment, social security, welfare, education and health expenditures considerably." "The need of the hour is to raise revenues through the reduction of revenues forgone and innovative mechanisms such as wealth tax on super accumulation of wealth", it added. Text: The Union Budget 2023 has given significant

By Shamsul Islam* RSS-BJP rulers of India have been trying to show off as great fans of Netaji. But Indians must know what role ideological parents of today's RSS/BJP played against Netaji and Indian National Army (INA). The Hindu Mahasabha and RSS which always had prominent lawyers on their rolls made no attempt to defend the INA accused at Red Fort trials.

Nalanda mahavihara By Our Representative Prominent historian DN Jha, an expert in India's ancient and medieval past, in his new book , "Against the Grain: Notes on Identity, Intolerance and History", in a sharp critique of "Hindutva ideologues", who look at the ancient period of Indian history as "a golden age marked by

social harmony, devoid of any religious violence", has said, "Demolition and desecration of rival religious establishments, and the appropriation of their idols, was not uncommon in India before the advent of Islam".

By Nava Thakuria According to official claims, incidents of poaching related to rhinoceros in various forest reserves of Assam in northeast India have decreased drastically. Brutal laws against the poachers, strengthening of ground staff inside the protected forest areas and increasing public awareness in the fringe localities of national parks and wildlife sanctuaries across the State are the reasons cited for positively impacting the mission to save the one-horned rhinos. Officials records suggest, only two rhinos were poached in Kaziranga National Park and Tiger Reserve since 1 January 2021 till date. The last incident took place probably in the last week of December 2021, as a decomposed carcass of a fully-grown (around 30 years old) female rhino was recovered inside the world-famous forest reserve next month. As the precious horn was missing, for which the gigantic animal was apparently hunted down, it could not be a natural death. Ironically, however, it was not confirmed when

By Our Representative Civil rights activists have alleged, quoting top intelligence officers as also multiple international forensic reports, that recent developments with regard to the Bhima Koregaon and the Citizenship Amendment Act-National Register of Citizens (CAA-NRC) cases suggest, there was "no connection between the Elgaar Parishad event and the Bhima Koregaon violence." Activists of the Campaign Against State Repression (CASR) told a media event at the HKS Surjeet Bhawan, New Delhi, that, despite this, several political prisoners continue to be behind bars on being accused under the anti-terror the draconian Unlawful Activities (Prevention) Act. Addressed by family members of the political prisoners, academics, as well as social activists, it was highlighted how cases were sought to be fabricated against progressive individuals, democratic activists and intellectuals, who spoke out against "corporate loot of Indian resources, suppression of basic democratic

Counterview Desk The top civil rights network, National Alliance of People's Movements (NAPM), has said that the new Forest (Conservation) Rules 2022, pending in Parliament and may be passed any day in the current Budget session, needs to be "strongly opposed" in Parliament. These Rules will allow easy diversion of forest land for projects and companies without the consent of gram sabhas and will allow the eviction of forest communities without the recognition of forest rights", it alleged.

By Rosamma Thomas Babu Joseph, general secretary of the National Federation of Rubber Producers Societies (NFRPS) at a recent discussion at Mahatma Gandhi University, Kottayam, explained that it is high time the Union government paid greater heed to the troubles plaguing the rubber production sector in India – rubber is a strategic product, important for the military establishment and for industry, since natural rubber is still used in the manufacture of tyres for large vehicles and aeroplanes. Synthetic rubber is now quite widespread, but styrene, which is used in making synthetic rubber and plastics, and also butadiene, another major constituent of synthetic rubber, are both hazardous. Prolonged exposure to these even in recycled rubber can cause neurological damage. Kerala produces the bulk of India's natural rubber. In 2019-20, Kerala's share in the national production of rubber was over 74%. Over 20% of the gross cropped area in the state is under rubber cultivation, with total

Counterview Desk The advocacy group Coalition for a GM-Free India in response to Food Safety and Standards Authority of India's FSSAI's) "weak forms" for licensing of GM foods, has insisted on the need to have "strong regulations to ensure safe food for citizens". Stating that this form is different from the FSSAI GM draft regulation which had come out recently for which it had shared its response, the NGO network said in letter to Pushp Vanam, joint director, Science and Standards, FSSAI, it is problematic that these forms were not shared at the same time as the GM regulation draft as it would have enabled more people who read and respond to it.

Text: This is in regards to the notification from FSSAI asking for inputs on the forms. We find it problematic that these forms were not shared at the same time as the GM Regulation draft as it would have enabled more people who read and responded on the regulation draft to have been able to comment on the forms too. Our response to the

By Tilottama Rani Charulata* In December 2021, in addition to the Rapid Action Battalion (RAB), the United States imposed sanctions on seven former and current officers of the force, alleging serious human rights violations. Benazir Ahmed and former RAB-7 commander Miftah Uddin Ahmed were banned from entering the US. RAB as an institution was also canceled the support it was getting from the US and its allies. At the same time, those under the ban have been notified of confiscation of assets held abroad. The anti-crime and anti-terrorism unit of the Bangladesh Police, RAB is the elite force consisting of members of the Bangladesh Army, Bangladesh Police, Bangladesh Navy, Bangladesh Air Force, Border Guard Bangladesh, Bangladesh Civil Service and Bangladesh Ansar, and has been criticized by rights groups for its use of extrajudicial killings and is accused of forced disappearances. The government of Bangladesh has been insisting about lifting the ban on RAB, but the US had till recen

ANNEXURE P-45

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Exclusive: Centre Approved Corbevax for 12-14 Year Olds Without NTAGI Clearance

15/03/2022

9-11 minutes

Healthcare workers administer COVID-19 vaccines to recipients aged 15-18 years, Mumbai, January 31, 2022. Photo: PTI

- *The Centre has announced that children aged 12-14 years will become eligible for COVID-19 vaccination from March 16.*
- *A health ministry press release on March 14 said the government had taken the call after "due deliberations with scientific bodies" – but didn't specify which bodies.*
- The Wire Science *has learnt that the National Technical Advisory Group on Immunisation wasn't one of these bodies.*
- *The NTAGI has a three-level approval process that includes the inputs of topical experts, and its approval is required before the NEGVAC's clearance.*
- *The Centre's decision to skip the NTAGI's approval for Corbevax deprives the vetting process of three levels of checks, including by subject experts.*

New Delhi: The Centre announced on March 14 that children aged 12-14 years will become eligible for COVID-19 vaccination from March 16. A press release issued by the Union health ministry on March 14 said the government had taken the call after "due deliberations with scientific bodies".

However, the government did not specify which were those "bodies", and the reason for the ambiguity in the health ministry release wasn't clear.

But *The Wire Science* has since learnt that the National Technical Advisory Group on Immunisation (NTAGI) wasn't one of these bodies. The NTAGI is one of the bodies whose clearance is required before a vaccine, approved by the drug regulator, can become part of the national COVID-19 vaccination drive.

The Centre's approval for Corbevax is the first to defy this step of the vaccine clearance process, at least according to the public record.

The NTAGI is one of the most important groups in the chain of granting approval to vaccines. After a recommendation from the Drugs Controller General of India (DCGI), the NTAGI, constituted by the Centre itself, deliberates on the vaccine's ability to participate in the national vaccination drive.

The body comprises government officials as well as independent subject experts. After the NTAGI's approval, the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has to make a decision. The Union health ministry finally approves a COVID-19 vaccine only after the NEGVAC's decision.

"NTAGI has not recommended it. I don't know which other body has done it," Jayaprakash Muliyil, a member of NTAGI, told *The Wire Science* on March 14 evening. Muliyil is also a former professor of community medicine at

the Christian Medical College, Vellore.

Since the NTAGI hasn't given its go-ahead for Corbevax, it is not clear if NEGVAC has done so either, or if it has, on what basis.

Another NTAGI member confirmed Muliyil's statement. "It was only the working group of the NTAGI that had discussed Corbevax," the member said. (They requested anonymity as they weren't authorised to talk to the press.)

The NTAGI has a three-tier decision-making system. The working group of the body is the first level. According to NTAGI's 'Code of Practice', this group deliberates on the evidence submitted by the vaccine's manufacturer from the shot's clinical trials. It also reviews the existing scientific literature on the subject. Then it builds its case, to be presented to the NTAGI's Standing Technical Sub-Committee (STSC).

The STSC is the second level. "The STSC will meet to analyse the evidence that is synthesised and presented by the working group and any external subject matter experts, whose contribution the working group considers essential," according to the code.

STSC members once again review the evidence, discuss the recommendations of the working group and come to a conclusion. They then pass this on to the main group of NTAGI, which makes NTAGI's final decision on the vaccine.

Both members of the NTAGI said neither STSC nor the main group had approved Corbevax for those aged 12-14 years. "Yes, we have seen the data. But we didn't give any final submission," Muliyil said. He added, "There was no post-omicron data" for Corbevax.

They also confirmed that STSC and the main NTAGI group have only seen the safety and immunogenicity data for Corbevax – and not the efficacy data.

Immunogenicity measures a vaccine's ability to induce the production of antibodies. Efficacy is a measure of how robust the immune response (which includes the antibodies) is. Immunogenicity trials are almost always smaller than efficacy trials, and as such their data can't be extrapolated to estimate the efficacy.

"The safety data was fine but the total number of subjects was small," Muliyil said.

According to the Corbevax trial for children registered on the Clinical Trial Registry of India (CTRI), 624 children volunteered for the trial.

Currently, adolescents aged 15-18 years are eligible to receive Covaxin, the COVID-19 vaccine made by Bharat Biotech. According to the CTRI, 525 children enrolled in the clinical trial for Covaxin. Like Corbevax, Covaxin had not been tested against the omicron variant when the government approved its use among children in December 2021.

"But if you are approving a vaccine *now*, that too for children, why shouldn't you consider a scenario which is post-omicron specific?" Muliyil asked.

India experienced its third COVID-19 wave, driven by the omicron variant, from December 2021 to January 2022.

All other variants of SARS-CoV-2 have by and large faded away; the omicron variant remains the dominant strain in populations worldwide, including in India. Thus, Muliyil added, the need for a vaccine that has been tested against the omicron variant is important.

"We don't have any evidence that [Corbevax] will really suppress" a new variant, he told *The Wire Science*.

The Wire Science had reported on March 2, 2022, that the Centre didn't wait for NTAGI's nod before it placed an order for 5 crore Corbevax doses from its manufacturer in India, Biological E. The state governments of West Bengal and Tamil Nadu have also received at least 4 lakh doses each, to vaccinate children aged 12-18 years. Rajasthan has also received 30 lakh doses for those aged 12-14 years.

The Wire Science also found that there is no data vis-à-vis Corbevax in the public domain even for use among adults.

In response to our report, the National COVID-19 Taskforce chairman Vinod K. Paul said in a press conference on March 3 only that the country should "trust" the DCGI's decisions.

Paul had also said that the NTAGI would take an appropriate decision at the 'right' time regarding the use of Corbevax. He added that a scientific paper regarding the Corbevax trial should be published soon and that it would be in the public domain. He refused to share any data himself, however.

The Wire Science asked Biological E, on March 14, about such a paper containing clinical trial data. Company spokesperson Vijay K. Amruth Raj only said, however, that "The work is still under progress".

Questions on Corbevax for children

Some experts have also raised doubts about the very need for vaccines for children – Muliyil among them. He said a large chunk of the population, including children, have natural immunity thanks to the rapid spread of the delta and omicron variants. "Omicron, especially, was a very, very strong immune-potentiator1. This context can't be ignored while making decisions now," he told *The Wire Science*.

The Indian Academy of Paediatrics (IAP) has, however, been demanding that the country's children be vaccinated. While children make up a very small fraction of COVID-19 cases in the country, the number of paediatric infections did increase when more transmissible variants, like the delta, surfaced, the IAP had said in December.

Nonetheless, experts at large remain divided on the issue. One group has said that even if children are infected, they get only mild disease, so they should only be vaccinated after a risk-benefit analysis. Another group, including the IAP, has maintained that all children should be vaccinated, even if it admits that only a few get serious COVID-19.

In addition, there have been news reports of some parents around the country who have insisted on vaccinating their wards to protect them against future surges.

Muliyil said he had no objection if a certain section of parents wanted to have their children vaccinated, if vaccines are available. "But the problem arises when, for example, students are not allowed to sit in examinations without showing their vaccination status."

He warned that expanding the vaccination drive to include younger and younger children in haste, especially without creating adequate safeguards for those who don't want it, could be unethical and dangerous.

At this point, irrespective of which group prevails, the Centre's decision to skip over the NTAGI's approval for Corbevax for 12-14 year-olds has effectively deprived the vetting process of three levels of checks, including the opinions of subject experts.

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 130th meeting held on 09.12.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/20/000182 mRNA vaccine (Phase I/II)	M/s Gennova Biopharmaceuticals Limited, Pune	The firm presented their proposal for grant of permission to conduct Phase I/II clinical trial along with animal toxicity study data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/II clinical trial subject to the condition that the interim results of Phase I study shall be submitted to the committee before proceeding to the next phase.
2.	BIO/MA/20/000102 ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (EUA)	M/s Serum Institute of India Pvt. Ltd., Pune	The firm presented their proposal for grant of Emergency Use Authorization (EUA) of ChAdOx1 nCoV-19 vaccine (COVISHIELD) along with the interim safety data from Phase II/III clinical trial carried out in the country and the interim safety and efficacy results of Phase II/III and Phase III clinical trials carried out in UK, other countries & India before the committee. The committee noted that as per the condition of the permission to conduct phase II/III clinical trial in the country, the clinical data generated in the trial shall be considered along with the data from the OXFORD clinical trial outcome. Further, the firm stated that the proposal for grant of emergency use authorization is currently under evaluation with MHRA. It is also noted that the Phase II/III clinical trial is still ongoing in the country. Further, the firm has submitted the safety data till 14.11.2020 only. After detailed deliberation, the committee recommended that the firm should submit the following data/information for further review: 1. Updated safety data of the Phase II/III clinical trial in the country. 2. Immunogenicity data from the clinical trial in UK and India. 3. The outcome of the assessment of UK-MHRA for grant of EUA. Dr. Sushant Meshram did not participate in the discussion.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (EUA)	M/s Bharat Biotech International Limited, Hyderabad	The firm presented their proposal for grant of Emergency Use Authorization (EUA) of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) along with the interim safety and immunogenicity data of Phase I and II clinical trial carried out in the country before the committee. After detailed deliberation, the committee recommended that the firm should present the safety and efficacy data from the ongoing Phase III clinical trial in the country for further consideration.
4.	BIO/IMP/20/000110 COVID-19 mRNA Vaccine BNT162b2	M/s Pfizer Ltd., Mumbai	The firm has requested more time for making presentation before the committee.

Press Information Bureau
Government of India
Ministry of Health and Family Welfare

19 MAY 2021 4:17PM by PIB Delhi

New Recommendations of NEGVAC accepted by Union Ministry of Health

The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has shared fresh recommendations regarding COVID-19 vaccination with the Union Ministry of Health and Family Welfare. These recommendations have been based on the evolving situation of the COVID-19 pandemic and emerging global scientific evidence & experience.

Union Ministry of Health and Family Welfare has accepted these recommendations, which are as follows, and has communicated these to the States and UTs also:

Deferring the COVID-19 vaccination in the following scenario**:**

i. Individuals having lab test proven SARS-2 COVID-19 illness: COVID-19 vaccination to be deferred by 3 months after recovery.
ii. SARS-2 COVID-19 patients who have been given anti-SARS-2 monoclonal antibodies or convalescent plasma: COVID-19 vaccination to be deferred by 3 months from the date of discharge from the hospital.
iii. Individuals who have received at least the 1st dose and got COVID-19 infection before completion of the dosing schedule: the 2nd dose should be deferred by 3 months after clinical recovery from COVID-19 illness.
iv. Persons with any other serious general illness requiring hospitalization or ICU care should also wait for 4-8 weeks before getting the COVID-19 vaccine.

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

COVID-19 vaccination is recommended for all lactating women.

There is no requirement for screening of the vaccine recipients by rapid antigen test (RAT) prior to COVID-19 vaccination.

Regarding COVID-19 Vaccination of pregnant women, the matter is under discussion and further deliberation by the National Technical Advisory Group on Immunization (NTAGI).

The Union Health Ministry has written to States and UTs to direct the concerned officials to take note of these recommendations and undertake necessary action for their effective implementation. States have been advised to ensure effective dissemination of the information to service provides as well as the general public, through use of all channels of information and communication in the local languages. States have also been advised to undertake training of the vaccination staff at all levels.

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MV

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ANNEXURE P-48

Online RTI Request Form Details

RTI Request Details :-

RTI Request Registration number	CDSCO/R/E/22/00241
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION

Personal Details of RTI Applicant:-

Name	[redacted]
Gender	Male
Address	[redacted]
Country	India
State	Gujarat
Status	Details not provided
Educational Status	Details not provided
Phone Number	[redacted]
Mobile Number	Details not provided
Email-ID	[redacted]

Request Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No

(Description of Information sought (upto 500 characters)

Description of Information Sought	
Please provide details of any safety trials conducted on pregnant women and breast feeding women for the following Covid 19 Vaccines: 1. Covishield 2. Covaxin 3. ZyCoV-D	
Concerned CPIO	Sushanta Sarkar
Supporting document *(only pdf upto 1 MB)*	Supporting document not provided

Print Close

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A+ A A-

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Home Submit Request Submit First Appeal View Status View History new Login User Manual Contact Us FAQ

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	CDSCO/R/E/22/00241
Name	[redacted]
Received Date	30/07/2022
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	25/08/2022
Reply :- As per reply received from the concerned division: The details of safety results from the clinical trials of Covishield, Covaxin and ZyCOV-D vaccines are available in Summary of Product Characteristics (SmPC) which are publicly available on CDSCO website i.e. www.cdsco.gov.in and also on the manufacturers official website, Further details of clinical trials are also mentioned on the ICMR CTRI website i.e. www.ctri.nic.in.	
CPIO Details :-	Sushanta Sarkar Phone: 011-23216367 rti[dot]cell[at]cdsco[dot]nic[dot]in
First Appellate Authority Details :-	A[dot] K[dot] Pradhan Phone: 011-23216367 rti[dot]cell[at]cdsco[dot]nic[dot]in
Nodal Officer Details :-	
Telephone Number	011-23236973
Email Id	jayantwz[at]gmail[dot]com

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Online RTI Appeal Form Details

RTI Appeal Details :-

RTI Appeal Registration number	CDSCO/A/E/22/00091
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION

Personal Details of Appellant:-

Request Registration Number	CDSCO/R/E/22/00241
Request Registration Date	30/07/2022
Name	[redacted]
Gender	Male
Address	[redacted]
Country	India
State	Gujarat
Status	Details not provided
Educational Status	Literate
Phone Number	[redacted]
Mobile Number	Details not provided
Email-ID	[redacted]

Appeal Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No
Ground For Appeal	Provided Incomplete,Misleading or False Information
CPIO of Public Authority approached	Sushanta Sarkar
CPIO's Order/Decision Number	Details not provided
CPIO's Order/Decision Date	

(Description of Information sought (upto 500 characters)

Prayer or Relief Sought

Respected Shri A. K. Pradhan sir,

I had made a straightforward request for information on safety trials conducted on pregnant women and breast feeding women for 3 Covid 19 Vaccines in India.

The response provided was long winding and dismissive.

The CPIO has asked me to refer to information provided in SMPC uploaded on CDSCO website, however no link to the same has been provided. Upon looking at CDSCO website, it is not possible to locate the suggested files. I have located SMPC for one vaccine on the manufacturers website, https://www.bharatbiotech.com/images/covaxin/covaxin-smpc.pdf

However, this done not mention whether safety trials have been conducted or even authorised by the regulatory body.

Also the CPIO requested to refer to a website, ctri.nic.in, however, they do not mention how or where I can locate the requisite information. I was unable to get the information I had requested, whether safety trials have been conducted for pregnant women and lactating mothers for 3 Covid vaccines available in India.

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A simple yes or no response would have sufficed for the RTI query. Instead the CPIO seems to be trying to mislead, distract and withhold information available with the office.

I humbly request you to provide the requested information in a simple manner without trying to mislead or dismiss the request. I am repeating my query below for your ready reference:

Please provide details of any safety trials conducted on pregnant women and breast feeding women for the following Covid 19 Vaccines:

1. Covishield
2. Covaxin
3. ZyCoV-D

Looking forward to your prompt and appreciable response.

Thank you.

Supporting document ***(only pdf upto 1 MB)***	Supporting document not provided

Print Close

Z-28020 [illegible] 2022-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization,
(RTI CELL)

FDA Bhawan,
Kotla Road, New Delhi
Date: 13th Sep. 2022

To,

[redacted]

Subject: Information under RTI Act, 2005 – Regarding

Refer: Registration Number: CDSCO/A/E/22/00091 (Dated 25th August 2022) and CDSCO/R/E/22/00241 (Dated 30th July 2022)

Dear Sir/Madam,

With reference to your RTI appeal application number: CDSCO/A/E/22/00091 Dated 25th August 2022 with regards to your application no.: CDSCO/R/E/22/00241 Dated 30th July 2022 on the subject cited above.

The matter has been examined and it was found that the reply of above cited RTI application was already provided by the CPIO vide letter even number dated 25th August 2022.

However, on your appeal reply is mentioned as below:

As per reply received from concerned division, this office has not received application from M/s Serum and M/s Cadila for the grant of permission to conduct such clinical trial. Further, M/s Bharat Biotech had submitted application for grant of permission to conduct clinical trial of Covaxin in pregnant women. Subsequently, however, the said firm has withdrawn the application.

Accordingly, the RTI appeal is disposed off

In case the applicant is not satisfy with the same. He/she may prefer appeal to the Central Information Commission within the prescribed time line.

Yours faithfully

(A. K. Pradhan)
First Appellate Authority &
Joint Drugs Controller (India)

Address of Second Appellate Authority:
The chairman,
Central Information Commission,
CIC Bhawan, Baba Gang Nath Marg, Munirka,
New Delhi – 110067

T.13013/01/2018-Imm
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Dated: 2nd June, 2021

To,

All NTAGI members/Participants
(As per list enclosed)

Subject: Minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI), held on 28th May, 2021 under the Chairpersonship of Secretary (Health & Family Welfare) at Nirman Bhawan, New Delhi.

Sir/Madam,

Please find enclosed herewith the minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI), held on 28th May, 2021 at Nirman Bhawan, New Delhi, under the Chairpersonship of Secretary (Health & Family Welfare), for kind perusal.

Yours faithfully,

Enclosure: as above

(Dr Pradeep Haldar)
Advisor, RCH

Copy to:

1. PPS to Secretary (H&FW), MoHFW
2. PPS to DGHS, MoHFW
3. PPS to Secretary (Department of Health Research), MoHFW
4. PPS to Secretary (Department of Bio-technology), MoS&T
5. PPS to AS&MD (NHM), MoHFW
6. PPS to JS (RCH), MoHFW
7. Office copy

ANNEXURE P-49

16th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
May 28, 2021, Friday, 11:00 AM to 12:45 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Minutes of the Meeting

Welcome & Introduction

The 16th NTAGI meeting was held virtually on Friday, May 28, 2021 at MoHFW, New Delhi, under the Chairpersonship of Shri Rajesh Bhushan, Secretary Health & Family Welfare (H&FW), Dr Renu Swarup, Secretary, Department of Biotechnology (DBT) and Dr Balram Bhargava, Secretary, Department of Health Research & Director General, Indian Council of Medical Research (ICMR).

All participating NTAGI members and invited attendees had duly filled and signed the confidentiality agreement, and declared conflict of interests (if any), and shared them with the NTAGI Secretariat. No conflict of interest was noted. The list of attendees is Annexed as Annexure-1 and agenda as Annexure-2.

It was informed that the minutes of the NTAGI meeting held on December 10, 2020 were shared with the members and no comments were received. The minutes were formally confirmed by the NTAGI.

Opening Remarks

All participants were welcomed by the Chairperson and Co-Chairpersons. Shri Rajesh Bhushan, Chairperson informed the purpose of the meeting. Further it was shared that all members and invited participants must respect the confidentiality agreement. Recently, it has been noticed that information on NTAGI-STSC meeting deliberations were circulating in the print and electronic media. As per the NTAGI code of practice confidentiality on meeting proceeding must be ensured by all participants. Proceedings of the NTAGI and its STSC meetings are confidential and no member/invited attendees who is not authorized by the NTAGI should speak on its behalf, shall communicate externally about the discussions, decisions and opinions expressed by the NTAGI or STSC, or by individual members during the course of this meeting, on a public or private forum.

Dr Renu Swarup, Co-chairperson, shared that since the last NTAGI meeting, five NTAGI-STSC meetings were held. It was informed that in these 5 meetings following agenda items were discussed: Priority Research Studies on COVID-19 Vaccines recommended by the Standing Working Group on Immunization and Vaccine Research & Capacity Builiding (SWG-IVRCB), and approved by the NTAGI-STSC, JE vaccines working group proceeding and recommendations which were endorsed by the NTAGI-STSC, Immunization and Vaccine Research Capacity Building (IVRCB) initiatives taken up in past few months and strategies for further capacity building, Dosing interval between two doses of COVID-19 vaccines, Contraindications and Precautions for COVID-19 vaccines, Blood donation deferral in view of COVID-19 disease and vaccination, COVID-19 vaccines for lactating and pregnant women, Rapid Antigen Testing prior to COVID-19 vaccination, and issue of quarantining or testing fully vaccinated individuals during domestic or international travel. Regarding pregnant women, it was agreed that COVID-19 vaccine should be offered, and simultaneously studies should be initiated to monitor the safety and effectiveness of COVID-19 vaccines in pregnant women.

Dr Balram Bhargava, Co-chairperson, congratulated the COVID-19 working group for conducting a total of 24 meetings during the course of the pandemic which were fruitful for the country's COVID-19 immunization program. It was shared that the meeting will be primarily focused on two key aspects. First one, role of COVID-

19 vaccines in pregnancy, for lactation vaccines are already approved. The second issue was the efficacy of the scientific criteria for procurement of international vaccines, if the efficacy of those vaccines against the B 1.617.2 strain in the lab and in the real world is optimal and if they can be tweaked very rapidly for new strains, and international manufacturers will be able to match the timelines of supply, given the present situation of shortage. Further, it was informed that looking at the breakthrough infections, ICMR has formed a group and the first meeting is scheduled next week. Data from the first week of April to May 27, 2021 is showing a 0.1% mortality in those who are fully vaccinated.

The Chairperson introduced new Joint Secretary, Reproductive and Child Health (JS-RCH), Dr P Ashok Babu. Following the introduction, the meeting was called to order. Following items were discussed:

Agenda Item 1: Action Taken Report on previous NTAGI meeting held on December 10, 2020: JS-RCH

The Joint Secretary-RCH informed that the last meeting of NTAGI was held on December 10, 2020. The action taken report (ATR) based on the recommendations made in the previous NTAGI meeting, held on December 10, 2020 were presented.

Japanese Encephalitis (JE) Vaccines: The members and invited attendees of the meeting were apprised that in the previous meeting it was recommended that there is a need for immediate recommendations from STSC for taking urgent programmatic decision on account of a study showing low efficacy of single dose JE vaccine from M/s Biological Evans Limited. It was notified that the JE Working Group deliberated with all stakeholders including Immunization Division, National Vector Borne Disease Control Program (NVBDCP) and subject matter experts on Januray 15, 2021. Findings of the JE WG were presented in the 30th NTAGI-STSC meeting held on April 06, 2021. A report on the same will be presented by the Chairperson, JE working group in the meeting.

Human Vaccines Interchangeability Standard Operating Procedures (SOP): During the last NTAGI meeting, the NTAGI accepted the SOP on vaccines interchangeability, with an advice to carefully examine feasibility of interchangeability of vaccines developed on different platforms. Further, it was advised to include possible types of study designs in the SOP of vaccine interchangeability. It was informed that as per procedures laid down in SOP (BIV-P-23) for review of clinical trial applications including issue of Human vaccines interchangeability, Central Drugs Standard Control Organization (CDSCO) in consultation with the Subject Expert Committee (SEC) will examine the feasibility of interchangeability of vaccines developed on different platforms. Further it was mentioned that one design may not be a suitable fit for all the vaccine types, interchangeability study design will be considered based on the proposal of the vaccine manufacturer in consultation with the SEC. Recommendations of the NTAGI are being followed by the CDSCO.

NTAGI Secretariat's Strengthening: The members were apprised that in last meeting it was observed that in view of surge in the work of NTAGI secretariat and requirements of NTAGI-STSC, a proposal for strengthening of the NTAGI Secretariat in terms of additional human resources and advanced trainings will be processed. Additionally, efforts will be made to establish national capacity to model disease burden and the impact of

vaccination. In this regard a communication has been sent to the NIHFW to direct NTAGI Secretariat for developing and submitting a proposal on required number of human resources.

PhD and Internship in Vaccinology: It was informed that Tata Institute of Social Sciences, Mumbai (TISS) is willing to start the program from 2021, funding for first two PhD candidates identified and AIIMS-Patna has agreed to start a PhD program in vaccinology. Further a list of multidisciplinary experts for guidance of the PhD candidates is being prepared by NTAGI Secretariat. PGDPHM and MD CHA students at NIHFW will be posted at NTAGI Secretariat on rotation basis. Further, communication on the same is being sent to Medical and Public health Institutions.

COVID-19 Vaccines: Members were apprised that a preliminary guidance document on use of COVID-19 vaccines was prepared and shared with the MoHFW and NEGVAC. Further, it was informed that a preliminary modeling exercise on seroprevalence based COVID-19 vaccination strategies was conducted with the help of Dr. Sarang's group. It has been suggested to refine the model using ICMR, NCDC and Delhi Government's data. In addition, as recommended, a document on contraindications and precautions associated with COVID-19 vaccines was shared with MoHFW in January, 2021. An updated version of the document will be presented in the meeting.

Agenda Item 2.1: Japanese Encephalitis Vaccines: Chairperson, JE Working Group

Dr Rakesh Aggarwal, chairperson, JE working group shared that because there are lots of complex issues involved around JE and JE vaccination, it was decided that the Japanese encephalitis vaccine working group, to have a one full day meeting with all stakeholders and all members of the working group. The messages at the end of this meeting were that encephalitis epidemiology varies across the country, it is very variable. Secondly, of the acute encephalitis syndrome (AES) cases seen around the country, Japanese encephalitis accounts for only 15 to 18% of cases in different regions. Most of the cases in India are in the age group of three to seven years with a median of five years with very few cases below 2 years of age. In some areas, cases are seen among adults. As the vaccines are available in limited quantities, vaccination is done only in districts where the disease burden is moderate to high. However, neighboring districts remain vulnerable to outbreaks in absence of vaccination as the amplifying vector that is the mosquito that can transmit Japanese encephalitis remain there. Finally, vaccination coverage rate needs to be improved to above 75% to effectively prevent outbreaks. Based on these observations, following recommendations were made by the JE working group and endorsed by the STSC:

- Reasons for variation in immunization coverage across the country needs to be evaluated
- NVBDCP: should share data of JE cases among JE vaccinees in past 10 years in different geographical locations.
- A close review of epidemiological data is needed: are boosters needed after 5-7 years, in different ages and regions
- Routine immunization: Since cases below 2 years age are few, all 3 vaccines (for Jeev: 3-µg dose) can be used

- Campaigns in endemic areas: Single dose of any of the 3 vaccines (JenVaC, LAJEV or 6-µg Jeev) may be used in both children (2-15 years) and adults (above 15 years)
- M/s Biological E: Need to generate evidence in the Indian population regarding:
  - Equivalence of Indian (Jeev) and international (XIARO) products across age range of 2 months to 80 years.
  - Effect of dose interval variation
- M/s Bharat Biotech: Need to generate evidence on Jenvac vaccine for 9-12 months and 1-65 years age groups (single dose) for long term efficacy.
- NIE is requested to include Jeev (3 µg) in the proposed interchangeability study, because JE burden below 2 years of age is low and data on interchangeability are important

Discussion

It was informed that the immunization program has been doing the JE campaign from 1 to 15 years, and a clarification was requested if children between 1-2 years may be excluded from JE campaigns. Further, it was informed that as per the routine immunization schedule a child can be given the missed dose of JE vaccine up to 15 years. A clarification was requested if a child misses JE vaccine dose of M/s BE limited and comes in contact with the program after 3 years of age then s/he would be given 3 µg or 6 µg formulation.

It was informed that as the disease burden in less than 2 years is very low and this group could be spared from JE vaccine campaigns, however feasibility of the program may also be looked**.** Further, it was shared that issue of missed dose will be discussed within next 2 weeks and a report will be shared.

Recommendation

Based on the presentation the NTAGI endorsed the recommendations of the STSC with following:

- JE working group may deliberate on the formulation of the Jeev vaccine (3 µg or 6 µg) which could be administered under routine immunization if a child misses its scheduled dose and comes in contact with program after the age of 3 years.

<u>Agenda 2.2: Covid-19 Vaccines: Chairperson, COVID-19 Working Group</u>

Dr NK Arora, Chairperson, COVID-19 Working Group shared that there was exponential increase of SARS-CoV-2 cases from first 1st march onwards, around March 15, 2021, the case incidence was one per 100,000 population per day, and increased highest to 28.5 on the May 7, 2021 and on May 26, 2021 it was around 17 cases per 100,000 population. Trend of deaths followed similar pattern and increased during this period of April and May.

Not many countries are using AZD1222/Covishield vaccine. The two largest and the highest consumer of this vaccine are UK and India. UK is using a dose interval of three months, which has been reduced to 2 months recently for people above the age of 50 years. Canada has recommended 4 months interval, Sri Lanka has recommended around 2.5 months, Bangladesh has 2-3 months, Spain has 4 months interval, EMA has recommended 1-3 months interval, and WHO has recommended 2-3 months interval between two doses of AZD1222/Covishield vaccine. India has started with a four-week interval. Later it was extended to 4-8 weeks

based on the available evidence at that time. Recently, real world data from UK showed 65% to 88% protection rate after the first dose, if the interval is up to 12 weeks. Therefore, based on the real-world evidence, dose intervals between two doses of Covishield was increased from 4-8 weeks to 12-16 weeks. No change in dose interval of Covaxin was recommended. An interval of 3-6 weeks between two doses of Sputnik V vaccine is recommended.

It has been strongly recommended to establish a National Vaccine tracking platform to determine the impact of COVID-19 vaccines and track breakthrough infections. Breakthrough infections are those infections, which occurred two weeks after getting the second dose or full schedule of the vaccine.

ICMR is currently doing the harmonization works for different administrative data, including RT PCR data, the disease data and genomic surveillance data. If these are all harmonized, that would give a very close look at what is happening on the ground in real time basis.

It is recommended that a randomized trial of varying dose interval of Covishield and other vaccine as they come in should also be planned and immediately embedded in the proposed study, and the manufacture should be asked to do the study.

There is this evidence that if somebody has a proven infection, probably for next six months, there is reasonable protection from reinfection. It has been recommended that the vaccination for individuals may be deferred for three months after recovery. Similarly, who have received the first dose and before completion of the dosing schedule get infected with COVID-19, they may take next dose 3 months after complete recovery. Same deferral duration has been recommended for patients who are given plasma or convalescent or monoclonal antibodies. In addition, people who may be hospitalized for other serious illnesses, may take covid-19 vaccine 4-8 weeks after discharge from hospital.

The issue of rapid antigen testing prior to COVID vaccination was rejected for following reasons: (i) It will lead to huge physical burden and accumulation and breakage of all COVID-19 appropriate behavior at immunization centers, (ii) rapid antigen test has a very low sensitivity, (iii)even if a vaccine is given, there is no data to suggest that it alters the course of the disease or makes it more serious or changing the course of disease.

Information on benefit and risk associated with AZD-1222/Covishield vaccine were presented based on level of exposure risk (low, medium or high) and stratified by age groups. The risk of blood clots in the younger population, especially in less than 40 years is stable and risk of ICU admission is low. As one moves to medium exposure (1.9 versus 2.2), and high exposure (1.9 versus 6.9) the benefit outweighs the risk.

Regrading young women who are at stage of pregnancy, overall COVID-19 exposure risk is three to eight times higher as compared to the risks of clotting and bleeding which can occur after receiving Covishield vaccine.

As far as pregnant women are concerned, it was presented that, initial experiences from mRNA vaccines are encouraging and these have been approved by WHO for pregnant women. These vaccine manufacturers have done DART studies, which didn't show any safety issues, further post marketing surveillance data did not

show any safety signals in pregnancy. Considering the current situation of pandemic, the NTAGI-STSC recommended pregnant women should not be excluded from vaccination because exposure probability is very high and therefore the benefit far outweighs the risk. However, before vaccination, pregnant women should be fully informed that the long-term adverse reactions, and the safety of the vaccine for fetus and child is not yet established. Mandatory 30 minutes of in hospital observation after vaccination is recommended. An educational tool comprising information on the risk of COVID-19 infection during pregnancy, benefits associated with the COVID-19 vaccination and rare complications associated with vaccines e.g., thrombosis and thrombocytopenia (with COVISHIELD) may be developed to be communicated to every pregnant woman before administering the vaccine. Vaccine may be provided at any time during pregnancy.

Blood donation may be deferred up to 14 days after recovery from active COVID infection, or vaccination. Further, fully vaccinated people can*:

- Avoid quarantine and testing following a known exposure if asymptomatic
- For domestic travel (interstate or within state) there is no need for testing before or after travel or self-quarantine after travel
- Avoid testing before leaving India for international travel (unless required by the destination) and refrain from self-quarantine after arriving back in India.
- COVID-19 appropriate behavior must be followed by all during domestic or international travel

Fully vaccinated*: If a person meets following two criteria: (i) It's been two or more weeks since the person had received the final dose of recommended schedule and (ii) Remains asymptomatic since current COVID-19 exposure. If both criteria are not met an individual should not be considered as fully vaccinated.

Scientific criteria for importing COVID-19 Vaccines: There are 15 vaccines which have received emergency use authorization in different parts of the world. Two of them are RNA vaccine and mRNA platform, six are inactivated, two are protein subunit and remaining five are on non-replicating vector-based platform vaccines. Five of these have qualified for WHO emergency use listing: Pfizer mRNA, Moderna mRNA, Johnson & Johnson, AZD-1222/Covishield, and BBIP Coronavirus vaccine. Based on the deliberations of the COVID-19 working group following has been recommended:

- Consider only vaccines those which received EUA from regulatory authority of any of the following: USA, UK, Japan, EMA and WHO.
- Trial & other data indicate significant serological response with appropriate neutralizing antibody response and at least more than 50% efficacy in clinical trial or effectiveness in real world.
- If large number of doses (e.g., more than 100 million) have been administered elsewhere,
    - Real world data do not show any safety signals and benefit outweighs risks

- In the context of prevailing Pandemic context, symbolic bridging study might be waived off as many individuals of Indian origin may already have received vaccine elsewhere

- Vaccines fulfill the programmatic feasibility considerations e.g., cold chain, storage, transport, and administration.

- Rapid and continous assessment of these vaccines for effectiveness against Variants of Concern (VOC) & Variants of Interest (VOI) by the manufacturers

Interchanged and Additional doses of COVID-19 Vaccines: There are reports of individuals particularly health personnel taking additional doses or taking another COVID-19 vaccine after completing the schedule. These people have got serological testing after having the vaccine, some of the people have got breakthrough COVID-19 infection due to which they have got worried and some doctors have been prescribing it. Studies have, shown that in some individuals, it takes around three months for the development of antibodies, although adequate protection due to cellular immune system may still be present post 14 days of vaccination. Therefore, people going for additional dose are wasting scarce commodity. People need to be informed about this aspect clearly. Further, due to program error, individuals have received vaccines produced by different manufacturers as first and second dose respectively. Some reports have come from different states. There are studies ongoing in different parts of the world including UK, where Covishield followed by mRNA vaccine had been given. There is a need to undertake well planned vaccine interchangeability studies.

Discussion

Few members expressed concern over the recently increased dose interval of the Covishield vaccine, as a preprint paper suggested only 33% protection from B.1.617.2 after single dose of AZD-1222/Covishield. It was informed that the confidence interval of protection after single dose and two doses' overlaps [single dose: 32.9 (19.3 to 44.3); two doses:59.8 (28.9 to 77.3)]. The paper is about all symptomatic infections. Further it was shared that dosing interval between two doses may be reconsidered for individuals of age more than 45 years. It was mentioned that national vaccine tracking platform will monitor all breakthrough infections.

All members agreed that the pregnant women should be offered COVID-19 vaccines with information about risks associated with COVID-19 in pregnancy and benefits of vaccination. A member suggested to compare the risk of complication with exposure with the risk of clotting after Covishield vaccine. Further it was suggested that the risk benefit ratio of administration of vaccine during surge of pandemic in pregnant women has been thought off while recommending the COVID-19 vaccination for pregnant women and when the surge is coming down the risk may be monitored to see risk versus the benefits. In addition, safest type

of COVID-19 vaccines must be considered for pregnancy as it's a matter of two lives. It was mentioned that outcome of the pregnancy may also be taken in account while considering the risks.

Regarding the import of international manufactured COVID-19 vaccines it was suggested to look into the logistics requirement, cold chain etc. Vaccines requiring stringent cold chain may not be transported to peripheral level. Further it was suggested that vaccines which are protective against new variant must be preferred, having an efficacy of more than 50% against new variant or vaccines which could be tweaked with time to protect from emerging variants.

One of the members requested duration for which the stroke from the clotting can occur. It was informed that the Thrombosis and Thrombocytopenia Syndrome (TTS) can occur 4-28 days after Covishield vaccine. Another member suggested special programmatic considerations for mentally or physically challenged people. Further, issue of equity was raised. It was suggested that the pregnant women of rural areas must be clearly informed about the benefits of vaccines and extremely rare risk of clotting in local language so that they can have a choice of vaccination. It was informed that MoHFW has initiated a near to home COVID-19 vaccination drive for people with special needs.

A member requested if the rate of 0.61 thromboembolic phenomenon per million doses is thromboembolism or thromboembolism with thrombocytopenia. It was informed that primarily a very broad definition has been used to look up even the remote possibilities of the phenomenon. Thrombocytopenia was not so frequently seen; most of the events were thromboembolism and venous thromboembolism. It was clarified that the data quality is not optimum, but the phenomenon does not appear to be widely prevalent.

Concluding Remarks

The chairperson and co-chairperson expressed satisfaction that decisions have been taken on very important matters, which are of direct and immediate relevance. It was mentioned that a network for the genome sequencing has been formed with coordination of DBT, ICMR, CSIR and MoHFW and NCDC is doing this coordination. Lot of that data including data of breakthrough infection and reinfections, are being studied. This data will be shared in public domain. Correct data will help in building public confidence for current as well as future vaccines. Variants will keep coming; therefore, it is important to have some system in place to see how vaccines work against variants.

Recommendations

Based on the presentation and deliberations NTAGI endorsed the STSC recommendations including following:

COVID 19 Vaccination for pregnant and lactating women:

- All pregnant women visiting for Antenatal care may be informed about the risks and benefits associated with the COVID-19 vaccines (COVISHIELD and COVAXIN) available in the country
- Based on the information provided a pregnant woman may be offered the available COVID-19 vaccine at the nearest center. The COVID-19 vaccine can be given anytime during the pregnancy.
- All lactating women are eligible to receive the COVID-19 vaccines any time after delivery
- Studies to be put in place immediately to monitor the safety of COVISHIELD and COVAXIN among pregnant women
- An educational tool comprising information on the risk of COVID 19 infection during pregnancy, benefits associated with the COVID-19 vaccination and rare complications associated with vaccines e.g., thrombosis and thrombocytopenia (with COVISHIELD) may be developed and communicated to pregnant women before administering the vaccine
- It was highlighted that there is a recent report of death of a pregnant woman vaccinated with Astra Zeneca vaccine in Brazil, due to which the immunization program of pregnant women in Brazil has been put to hold. The AEFI is being investigated. Since killed vaccines have an established safety profile in pregnant women, Covaxin/killed vaccines may be the first choice in pregnant women, as per availability.

Interchanged and Additional doses of COVID-19 Vaccines:

- From both, protective effectiveness and programmatic perspective mix and match dosing studies are required
- Well planned study embedded in to program structures are required for assessment of effectiveness and safety

The NTAGI will continuously review the new evidence on COVID-19 vaccines and SARS-CoV-2 variants epidemiology, and will revisit its recommendations every 3 months or earlier when deemed appropriate.

The Chairperson thanked all the participants for their invaluable contribution to all the agenda items considered in the meeting and concluded the meeting.

16th National Technical Advisory Group on Immunization (NTAGI)
Meeting (Through Video Conferencing)
May 28, 2021, Friday, 11:00 AM to 12:45 PM
1st Floor Nirman Bhawan, MoHFW, New Delhi

Annexure -1

List of Participants

S.No.	Name	Designation
Chairperson		
1	Shri Rajesh Bhushan	Secretary, Department of Health & Family Welfare
Co-Chairpersons		
2	Dr Renu Swarup	Secretary, Department of Biotechnology
3	Dr Balram Bhargava	Secretary, Department of Health Research & DG-ICMR
Core Members, Ex-officio		
4	Dr Sunil Kumar	Director General of Health Services
5	Ms Vandana Gurnani	Additional Secretary & Mission Director, NHM
6	Dr Sujeet Singh	Director, National Centre of Disease Control
7	Dr Priya Abraham	Director, National Institute of Virology
8	Dr Pramod Garg	Executive Director, THSTI, Faridabad
9	Dr Amulya Panda	Director, National Institute of Immunology
Core Members, Independent Experts		
10	Dr Y K Gupta	Principle Adviser THSTI-DBT
11	Dr Gagandeep Kang	Professor, CMC, Vellore
12	Dr Indrani Gupta	Professor, Institute for Economic Growth, Delhi
13	Dr Rakesh Aggarwal	Director, JIPMER, Puducherry
14	Dr Mathew Varghese	Head of the Dept, Orthopedics, St. Stephan's Hospital, New Delhi
15	Dr Satinder Aneja	Professor and Head, Dept. of Pediatrics, Sharda University
16	Dr Neerja Bhatla	Professor, AIIMS, New Delhi
17	Dr M D Gupte	Former Director, NIE, Chennai
18	Dr Arun Kumar Agarwal	Professor, PGI, Chandigarh
19	Dr Lalit Dar	Professor, AIIMS, New Delhi
20	Dr Dilip Kumar Das	Professor, Burdwan Medical College, Burdwan
21	Dr Parvaiz Koul	Professor, Sher-i-Kashmir Institute of Medical Sciences, Srinagar
22	Dr Surinder Jaswal	Professor, Tata Institute of Social Sciences
23	Dr F U Ahmed	Pro-Vice Chancellor, Khaja Bandanawaz University, Gulbarga
Liaison Members		
24	Dr P Ashok Babu	Joint Secretary-RCH, MoHFW
25	Dr Pradeep Haldar	Advisor-RCH, MoHFW
26	Dr M K Aggarwal	Additional Commissioner-UIP, MoHFW
27	Dr Veena Dhawan	Joint Commissioner-Immunization, MoHFW
28	Dr V G Somani	Drugs Controller General of India, CDSCO, MoHFW

Professional Organization Representatives		
29	Dr Piyush Gupta	President, Indian Association of Paediatrics
30	Dr J A Jayalal	President, Indian Medical Association
31	Dr K Srinath Reddy	President, Public Health Foundation of India
International Partners Representatives		
32	Dr Roderico Ofrin	Country Representative, WHO, India
33	Dr Rija Andriamihantanirina	Immunization specialist, UNICEF
34	Dr Bhrigu Kapuria	Health Specialist (Immunization), UNICEF
State Representatives		
35	Shri Amit Mohan Prasad	Additional Chief Secretary (Health & FW), Uttar Pradesh
36	Dr Jayanti S Ravi	Principal Secretary (Health & FW), Gujarat
37	Shri Ajit Ranjan Kumar	Joint Secretary (Health & FW), Nagaland
38	Dr Ritu Thurr	State Immunization Officer, Nagaland
39	Dr Vinay Kumar	Joint Director Immunization and Public Health Director, Tamil Nadu
Special Invitees		
40	Dr N K Arora	Chair COVID-19 Working Group, Executive Director, INCLEN International
41	Dr Navin Khanna	Group Leader, ICGEB
42	Dr Harshad Thakur	Director, NIHFW
43	Dr Alka Sharma	Scientist H
44	Dr Nivedita Gupta	Scientist F
45	Dr Disha Aggarwal	Immunization Division, MoHFW
NTAGI Secretariat		
46	Dr Dinesh Paul	Advisor-cum-Manager
47	Dr Awnish Kumar Singh	Research Analyst
Member Apologized		
48	Dr J P Muliyil	Professor, CMC Vellore

16th National Technical Advisory Group on Immunization (NTAGI)
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Agenda

Chairperson: Shri. Rajesh Bhushan, Secretary (H&FW), MoHFW	***Co-Chairperson: Dr Renu Swarup, Secretary DBT***	***Co-Chairperson: Prof Balram Bhargava, Secretary DHR & DG-ICMR***

11:00 AM-11:05 AM	General Business	NTAGI Secretariat
11:05 AM-11:10 AM	Welcome and Introduction Submission of minutes of the NTAGI meeting held on December 10, 2020	Chairperson and Co-Chairpersons NTAGI
Agenda no. 1: Action Taken Report		
11:10 AM-11:15 AM	Agenda no. 1.1: Action taken report on the recommendations made in previous meeting of NTAGI held on December 10, 2020	JS-RCH
Agenda no. 2: STSC Meeting Discussion and Recommendations (closed session)		
11:15 AM-11:45 AM	**For Information Only:** Agenda 2.1: • JE Vaccines	Dr Rakesh Aggarwal, Chairperson, JE Working Group
	Agenda 2.2: **For Information Only:** • Dosing Interval of COVID-19 vaccines • COVID-19 Vaccination for lactating mothers and • COVID-19 Vaccines-Precautions and Contraindications **For Discussion:** • COVID-19 Vaccination in Pregnancy • Scientific criteria for importing COVID-19 vaccines • Additional doses of currently available COVID-19 vaccines being taken by some health professionals	Dr N K Arora Chairperson, COVID-19 Working Group
11:45 AM-12:30 PM	Discussion and Decision	
Concluding Remarks & Recommendations		
12:30 PM-12:40 PM	Concluding Remarks	Chairperson and Co-Chairpersons NTAGI
12:40 PM-12:45 PM	Recommendations	Chairperson and Co-Chairpersons NTAGI