

Covid Vaccination side effects: fact or fiction



Context:

- **AstraZeneca**, the company that makes the **Covishield vaccine** for Covid-19 pandemic, has admitted the inoculation has potential side effects.
- The company's admission, presented in a legal document before the **High Court of Justice in London**, conveys that the Covid vaccine can in extremely rare cases induce Thrombosis with **Thrombocytopenia Syndrome (TTS)**.

What is Covishield?

- The **Oxford-AstraZeneca Covid vaccine**, sold as **Covishield in India** and **Vaxzevria in Europe** is a **viral vector vaccine**.
- It is **adenovirus vector vaccine**, a **chimpanzee adenovirus - ChAdOx1** - has been modified to enable it to carry the Covid-19 (SARS-CoV-2) spike protein injected into the muscles of humans.

- It was manufactured and marketed in India in partnership with **Pune-based Serum Institute of India**, and was widely used during the country's fight against the deadly Covid-19 pandemic.
- Over **1.7 billion doses of Covishield** have been administered so far globally.
- More than **175 crore doses** of Covishield have been administered in **India**.

What is Thrombosis Thrombocytopenia Syndrome (TTS)?

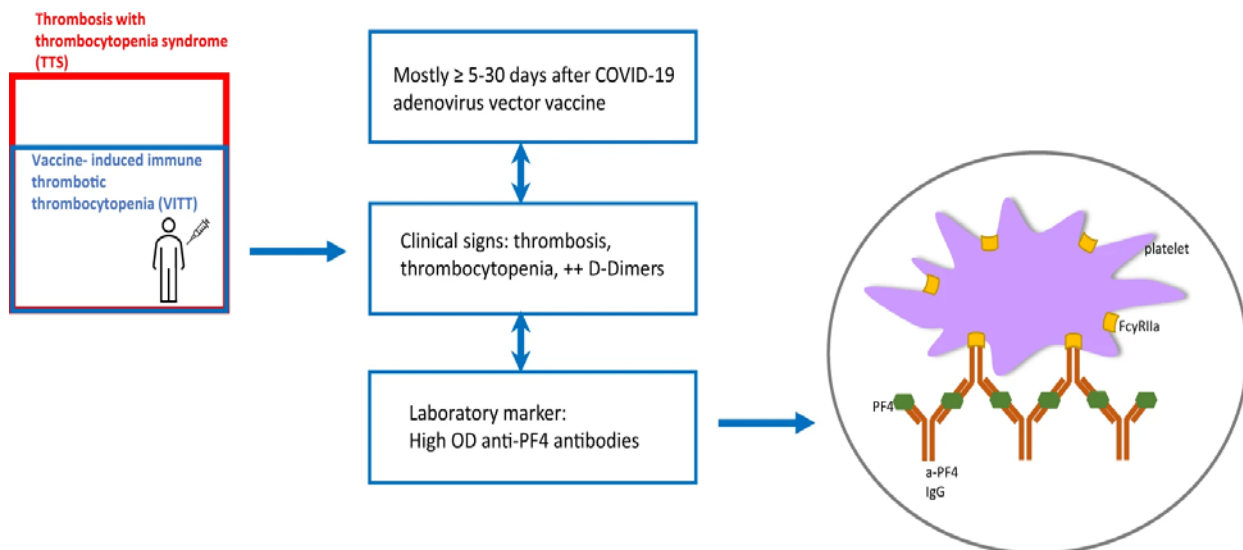
- **Thrombosis with thrombocytopenia syndrome (TTS) is a very rare syndrome.** It occurs when a person has blood clots (**thrombosis**) together with a low platelet count (**thrombocytopenia**). It's also referred to as '**vaccine-induced immune thrombotic thrombocytopenia**' (VITT).
- **Thrombosis** is the formation of a blood clot, which **can reduce normal blood flow** in an affected blood vessel.
- **Thrombocytopenia** is a condition where there **aren't enough platelets in the blood**. Platelets normally help the blood to clot (clump), which stops you from bleeding excessively (for example, if you cut yourself).

What are the Symptoms of TTS?

- **Symptoms of TTS affecting the brain included:**
 - Severe, persistent headache
 - Blurred vision
 - Difficulty speaking
 - Drowsiness
 - Seizures or confusion
- **Symptoms of TTS affecting the rest of the body included:**
 - Difficulty breathing

- Chest pain
- Leg swelling
- Persistent abdominal (stomach) pain
- Tiny blood spots under the skin, away from the site of injection
- Symptoms occurred **between 4 and 42 days after vaccination** with the AstraZeneca COVID-19 vaccine.

How are TTS and blood clots linked to the AstraZeneca vaccine?



- TTS is a very rare side effect that was seen in some people after getting the AstraZeneca COVID-19 vaccine. The AstraZeneca COVID-19 vaccine is no longer available in Australia.
- The risk of TTS appears to have been slightly higher in people younger than 60 years of age.
- The blood clots can occur in different parts of the body, including:
 - **The brain** (called cerebral venous sinus thrombosis, or CVST)
 - **The abdomen** (splanchnic vein thrombosis)
 - **The lungs** (pulmonary embolism)
 - **Limb veins** (deep vein thrombosis (DVT))
 - **Arteries** (arterial thrombosis)

- The process that causes TTS is not fully understood. It is thought to be similar to **heparin-induced thrombocytopenia (HIT)**. This is a rare reaction to a medicine called heparin that affects how platelets work.

How rare is rare?

- One of the keywords that was reported to have been used by **AstraZeneca**, in terms of adverse events occurring, was ‘**rare**’ – something that most of the commentary is now missing.
- As per data from the **UK and the European Union**, the **Global Advisory Committee on Vaccine Safety** assessed that the **risk was low**.
- The committee consists of independent vaccine and other domain experts. It **advises the World Health Organisation** on vaccine safety.
- The data from the **UK** suggest the **risk is approximately 4 cases per million adults** who receive the vaccine, while the rate is estimated to be approximately **1 per 100,000 in the European Union (EU)**.
- There are several other studies that looked into the rate of **TTS caused by the AstraZeneca vaccine**. One such study looked at the **AstraZeneca Global Safety Database in 2022**. They found the rate of this adverse event to be **7.5 per million vaccinated persons**.

Were incidents of blood clots reported in India as well?

- According to the data by the government’s committee on **Adverse Events Following Immunization (AEFI)** at least **36 cases of TTS** have been vetted and confirmed to have been **caused due to Covishield**.
- Almost **all of these TTS cases pertain to 2021**, which was the first year of Covid-19 vaccination in the country.
- The **Union Health Ministry** had termed this possibility as “**minuscule**”, and said that **Covishield “continues to have a definite**

positive benefit-risk profile” with “tremendous potential to prevent infections and reduce deaths” due to Covid-19.

- The Ministry had added that scientific literature suggests **“this risk (of blood clotting) is almost 70% less in persons of South and Southeast Asian descent in comparison to those from European descent”**.
- In the case of **Covaxin**, which was **India’s indigenous** vaccine manufactured by **Bharat Biotech**, **no potential thromboembolic events had** been reported.

Are there any risk factors for TTS?

- No medical conditions were found to increase your risk of developing TTS after vaccination.
- The risk of TTS was higher in young people, and young women often experienced a more severe form of TTS.
- The risk of TTS was lower after the second vaccine dose than the first.

How is TTS diagnosed and treated?

- Some people with TTS were very unwell and needed to go to hospital straight away for treatment. If a clot in the brain was suspected, patients were referred to an emergency department for urgent investigation.
- TTS was diagnosed using blood tests and scans including CT scans.

Treatment for TTS included:

- **Anticoagulant** (anti-clotting) medicines (other than heparin)
- **Intravenous immunoglobulin (IVIG)** — infusion of a blood product containing antibodies
- **High dose prednisone** — a type of steroid medicine

Do people who got Covishield vaccine need to worry?

- **Dr Pavitra Mohan**, pediatrician, public health expert, and co-founder of Basic Healthcare Services said, “Astra Zeneca’s admission does underscore the need for transparent communication by the pharmaceuticals and vaccine developers.
- **The side effects** are rare and were **seen only in young people and only within 4 to 6 weeks of the first dose of vaccination.**
- So, there is no need for panic.”

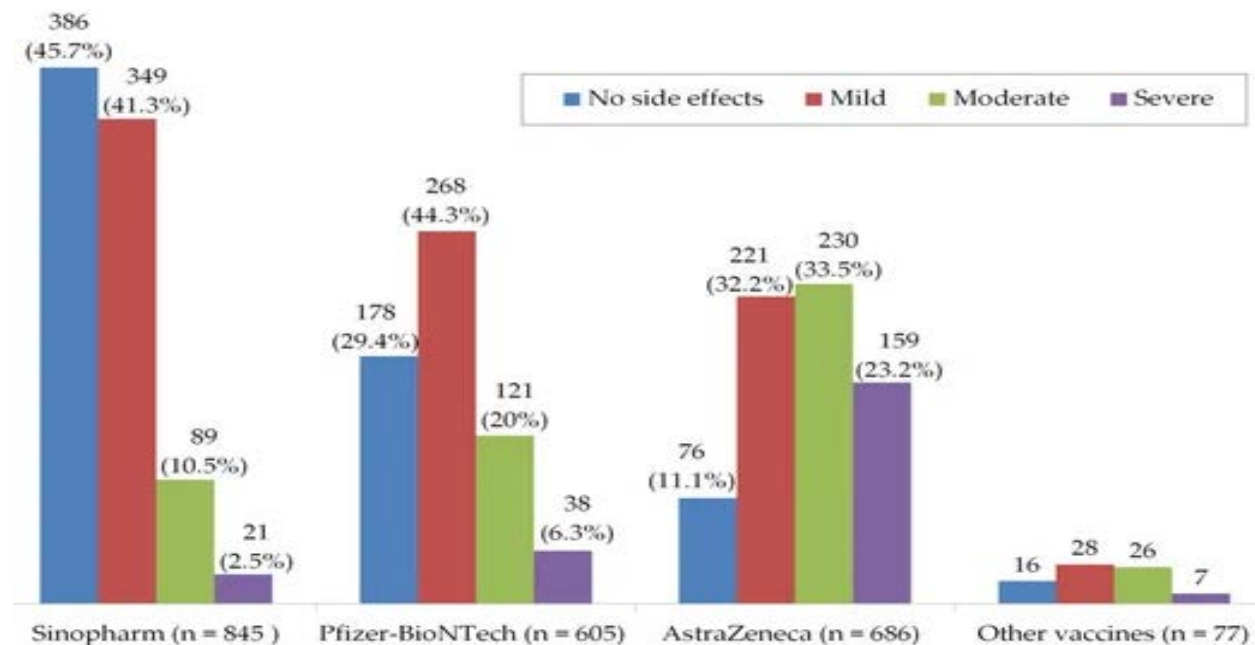
Why have these concerns surfaced now, four years after the outbreak?

- These concerns have in fact been reported earlier. But this is the **first time that AstraZeneca has confirmed the link between TTS and its vaccines.**
- Before the Covid-19 vaccines were rolled out in India, the **Indian government** had issued a fact sheet in **January 2021**, in which it specifically said that Covishield (the Indian variant of AstraZeneca’s vaccine) should be given with “**caution**” to **individuals with thrombocytopenia**, that is, a condition of low platelet counts.
- Then, in **March 2021, the European countries** France, Germany, Italy, Netherlands, Denmark, Norway, Iceland, Austria, Estonia, Bulgaria, Romania, Estonia, Lithuania, Luxembourg, and Latvia **temporarily paused the use of the AstraZeneca vaccine** after a few cases of blood clotting were reported.
- The following month, the **World Health Organisation (WHO)** said **TTS was being reported in some cases after vaccinations with Covishield and Vaxzevria** (which was the other trade name for AstraZeneca’s vaccine).
- However, the **WHO had added**, “**Based on latest available data, the risk of TTS with Vaxzevria and Covishield vaccines appears to be very low**”.

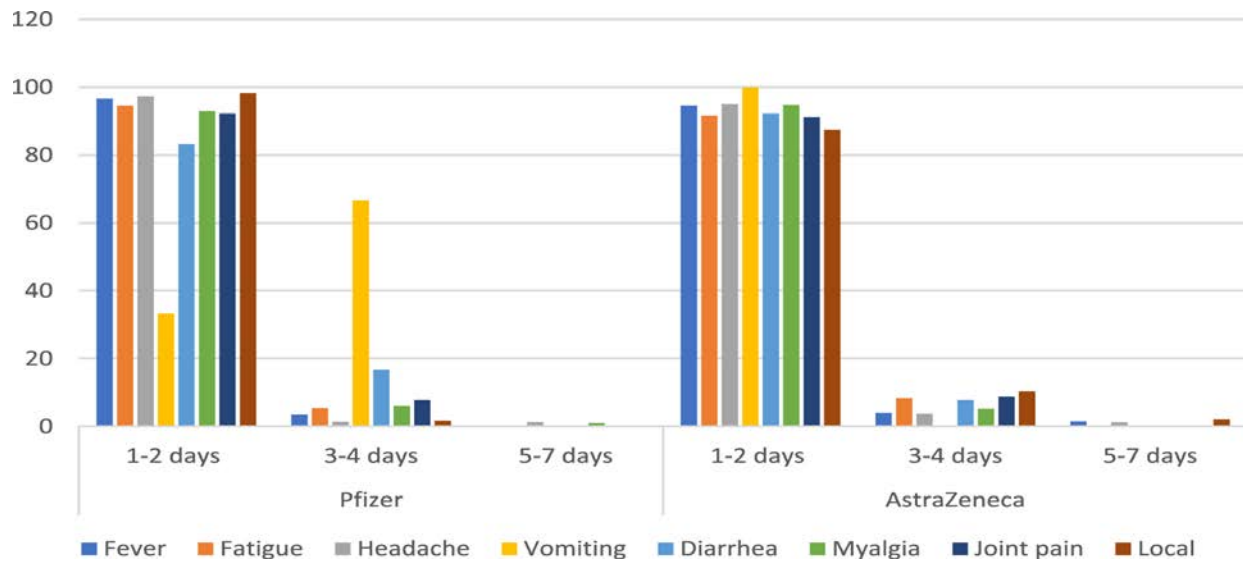
Where was the AstraZeneca Covid-19 vaccine banned?

- Following close scrutiny of the AstraZeneca vaccine, the product was **banned in several countries.**
- **Denmark was the first country to suspend Covid-19 vaccine AstraZeneca,** and Ireland, Thailand, the Netherlands, Norway, Iceland, Congo, and Bulgaria soon followed suit.
- European countries, including **Germany, France, Italy, and Spain, also stopped using AstraZeneca's Covid-19 vaccine in 2021** after multiple cases of blood clots were reported in patients who were administered the vaccine.
- **Canada, Sweden, Latvia, and Slovenia joined the league in banning the use of the vaccine in the same year.**
- The vaccine was **further banned in Australia, Indonesia, and Malaysia due to public concerns about its safety.**

What are the severity of side effects based on the types of COVID-19 vaccine?



Other vaccines are **Sputnik V, Moderna, Covaxin, and Johnson & Johnson.**



What is the relevance of the topic for UPSC CSE?

For Prelims: Vaccines and types, Virus Strain and Mutation. Corbevax and Covovax, Molnupiravir, Spike Protein.

Mains GS-III: Science & Technology-Mechanism of Vaccine in treating viral infection. Types of Vaccines.

Some previous years prelims questions

Q1. In the context of vaccines manufactured to prevent COVID-19 pandemic, consider the following statements: (2022)

1. The Serum Institute of India produced COVID-19 vaccine named Covishield using mRNA platform.
2. Sputnik V vaccine is manufactured using a vector-based platform.
3. COVAXIN is an inactivated pathogen-based vaccine.

Which of the statements given above are correct?

- (a) 1 and 2 only
- (b) 2 and 3 only

- (c) 1 and 3 only
- (d) 1, 2 and 3

Ans: (b)

Some previous years mains questions

Q1. What is the basic principle behind vaccine development? How do vaccines work? What approaches were adopted by the Indian vaccine manufacturers to produce COVID-19 vaccines? (2022)

Some questions from this year and previous years interview transcripts.

Board BB Swain sir:(2024)

- Did we tackle Corona well ?
- (Black swan event, Atma Nirbhar package , Vaccine program)

Board BB Swain sir:(2024)

- During covid, there have been numerous strides in vaccine development.
- In this context, explain the working of mRNA vaccine
- What are the advantages and disadvantages?

Board Preeti Sudan mam:(2023)

- Can you tell me how crispr-cas9 can help in the development of vaccines?

Board Manoj Soni sir:(2023)

- What is the difference between traditional vaccines and newer genetically engineered vaccines ?
- Why do we need to take booster doses of vaccines ?

Some questions for QUIZ.

Q1. Consider the following statements regarding Thrombocytopenia Syndrome (TTS)

1. It is a rare condition in which there is simultaneous occurrence of blood clots and a low platelet count
2. High-dose prednisone which is a form of steroid medication can induce TTS.
3. Intravenous immunoglobulin (IVIG) which involves infusing a blood product containing antibodies is used to treat TTS.

How many of the above statements are incorrect?

Select the correct answer using the code given below:

- (a) Only one
- (b) Only two
- (c) All three
- (d) None

Ans: (a)

Q2. Consider the following statements regarding the Central Drugs Standard Control Organisation (CDSCO).

1. CDSCO is a statutory body established under the Drugs and Cosmetics Act, 1940.
2. It works under the administrative control of the Department of Pharmaceuticals.
3. It is responsible for approval of Drugs and conducting Clinical Trials.

How many of the above statements are correct?

Select the correct answer using the code given below:

- (a) Only one
- (b) Only two
- (c) All three
- (d) None

Ans: (b)

Some questions for POLL.

Q1. Which vaccine have you taken?

- (a) Covishield
- (b) Covaxin
- (c) Sputnik

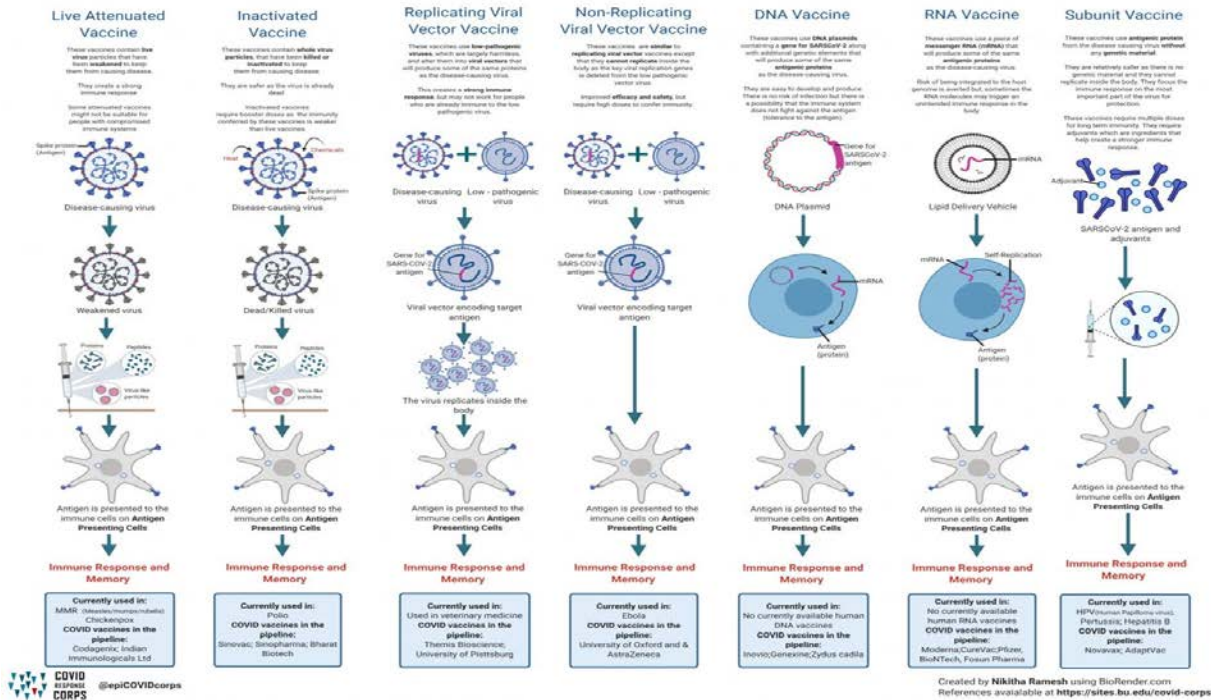
Q2. Has the government hid side effects of vaccines ?

- (a) YES
- (b) NO
- (c) Can't say.

Q3. Is there need for worry ?

- (a) YES
- (b) NO
- (c) Can't say.

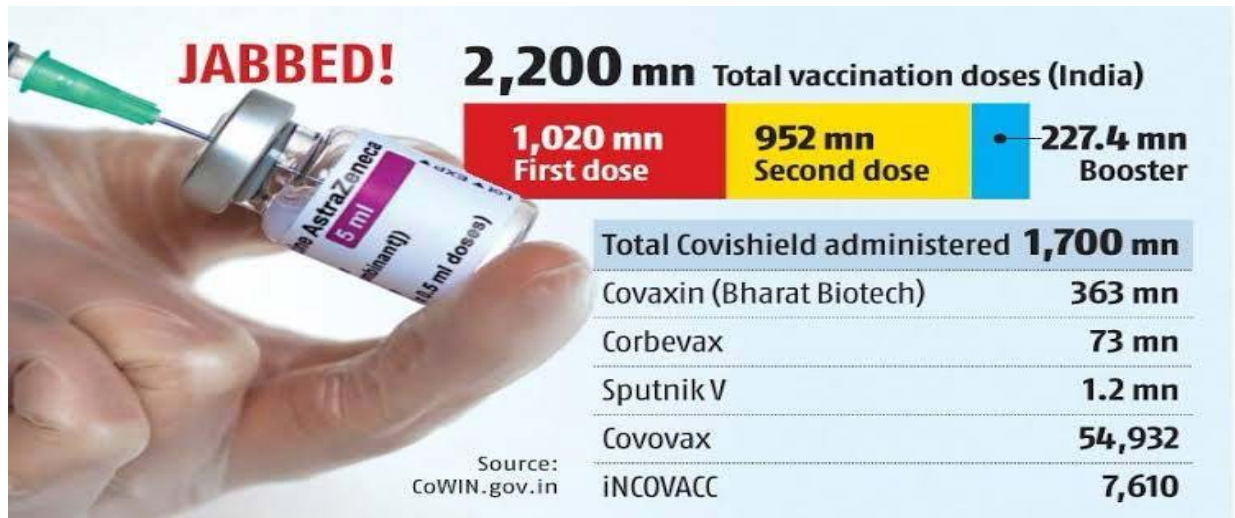
TYPES OF VACCINES



How some of the Covid-19 vaccines compare

Company	Type	Doses	How effective*	Storage	Cost per dose
Oxford Uni-AstraZeneca	Viral vector (genetically modified virus)	x2	62-90%	Regular fridge temperature	£3 (\$4)
Moderna	RNA (part of virus genetic code)	x2	95%	-20C up to 6 months	£25 (\$33)
Pfizer-BioNTech	RNA	x2	95%	-70C	£15 (\$20)
Gamaleya (Sputnik V)	Viral vector	x2	92%	Regular fridge temperature (in dry form)	£7.50 (\$10)

*preliminary phase three results, not yet peer-reviewed



HOW TO MONITOR & REPORT COVID-19 VACCINE SIDE EFFECTS

Health workers play a key role in ensuring the continued safety of COVID-19 vaccines

BEFORE VACCINATING



STEP ONE ASK
if the person getting vaccinated has ever had a severe allergic reaction to a vaccine

IF YES, refer the person to an allergy specialist or health provider, who will recommend next steps



STEP TWO ASSESS

any health or medical conditions listed as precautions by the vaccine manufacturer or by your local immunization programme

These conditions may include:

- Pregnancy
- Compromised immune system
- Severe frailty among older persons

People with these conditions are eligible for vaccination, but should be offered information & counselling



STEP THREE COMMUNICATE

common side effects after vaccination, which indicate that a person's body is building protection to COVID-19

Common side effects include:

- Arm soreness
- Mild fever
- Tiredness
- Headaches
- Muscle or joint aches

STEP FOUR VACCINATE



AFTER VACCINATING



STEP FIVE OBSERVE

the vaccinated person for 15 minutes - tell them how & where to report severe reactions

- Observe people with a past vaccine allergy for 30 minutes, after they have been approved by a specialist (step 1).

STEP SIX INFORM

your supervisor immediately of any unexpected or severe reactions during the observation period or reported later

- Complete an electronic or paper Adverse Events Following Immunization (AEFI) form, available online at investigation.gvsi-aefi-tools.org
- Health officials will then investigate the event

It's extremely rare for severe health reactions to be directly caused by vaccines. But reporting & investigating adverse events will ensure that COVID-19 vaccines continue to meet high safety standards.



World Health Organization



POST-VACCINATION INFECTION: THE TRUTH

The numbers are out, and it's obvious now that the proportion of Covid infections in the vaccinated is insignificant

