

# Update on **Safety monitoring of COVID-19 vaccines**

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THE LATEST ON THE COVID-19 GLOBAL SITUATION  
& MONITORING VACCINE SAFETY



World Health  
Organization

**EPI**•WiN

infodemic  
MANAGEMENT

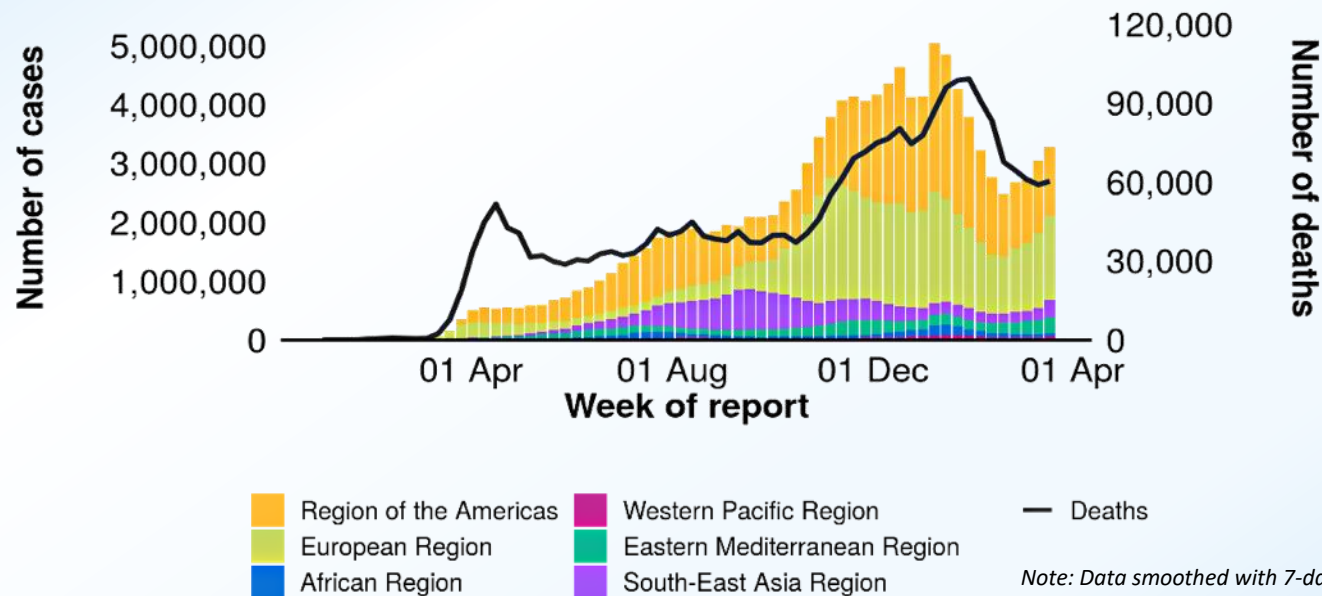
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# Current global situation

CASES REPORTED TO WHO AS OF 18 APRIL 2021, 10:00 CEST

- Cases: > 140 million
- Deaths: > 3 million



CHECK OUT THE LATEST  
GLOBAL SITUATION

[WHO](#)  
[Coronavirus](#)  
[Disease \(COVID-19\)](#)  
[Dashboard](#)

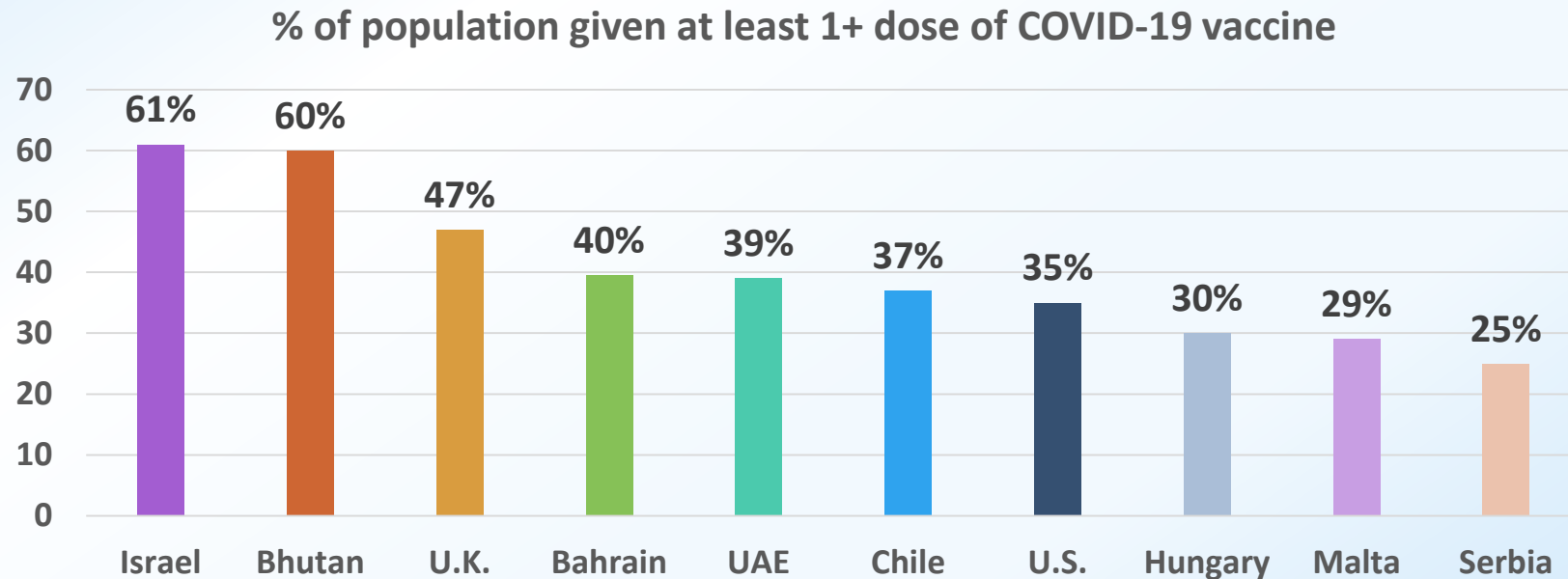
\* Data are incomplete for the current week. Cases depicted by bars; deaths depicted by line

# COVID-19 vaccine administration worldwide

AS OF 19 April 2021

- **> 792 million COVID-19 vaccine doses administered**

Figure. WHO COVID-19 vaccines tracker on global distribution: % of population given at least 1 dose of COVID-19 vaccine as of 19 April 2021



Source: Data retrieved from WHO dashboard on 19 April 2021, <https://covid19.who.int/>

# Monitoring the safety of COVID-19 vaccines

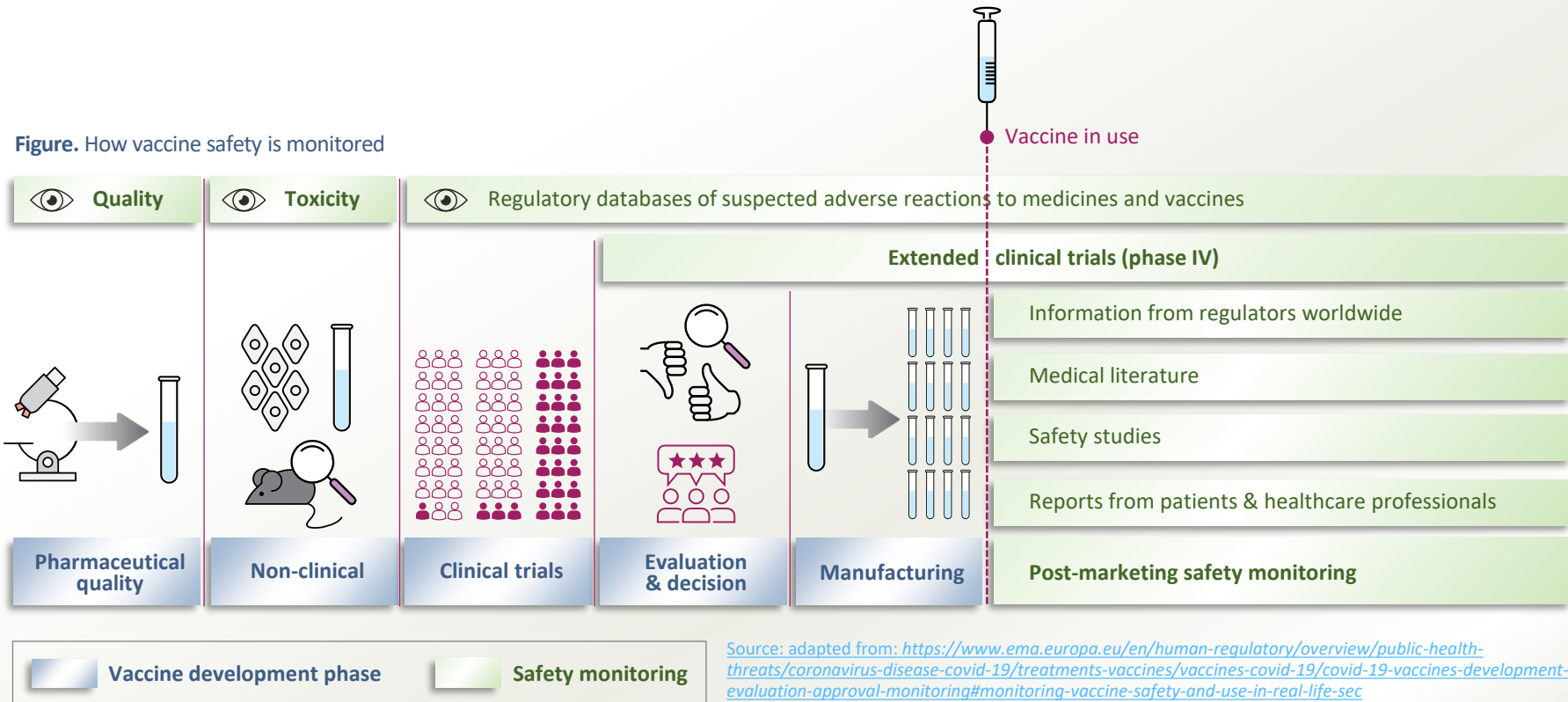
- A vaccine is approved after efficacy and safety data is reviewed from controlled, randomized clinical trials
- These clinical trials are evaluating COVID-19 vaccines in tens of thousands of study participants
- After approval, vaccines are used in the real world by a much larger population than in clinical trials
- To safeguard public health, a strong pharmacovigilance system is in place to continue to monitor for any adverse events after deployment of vaccines



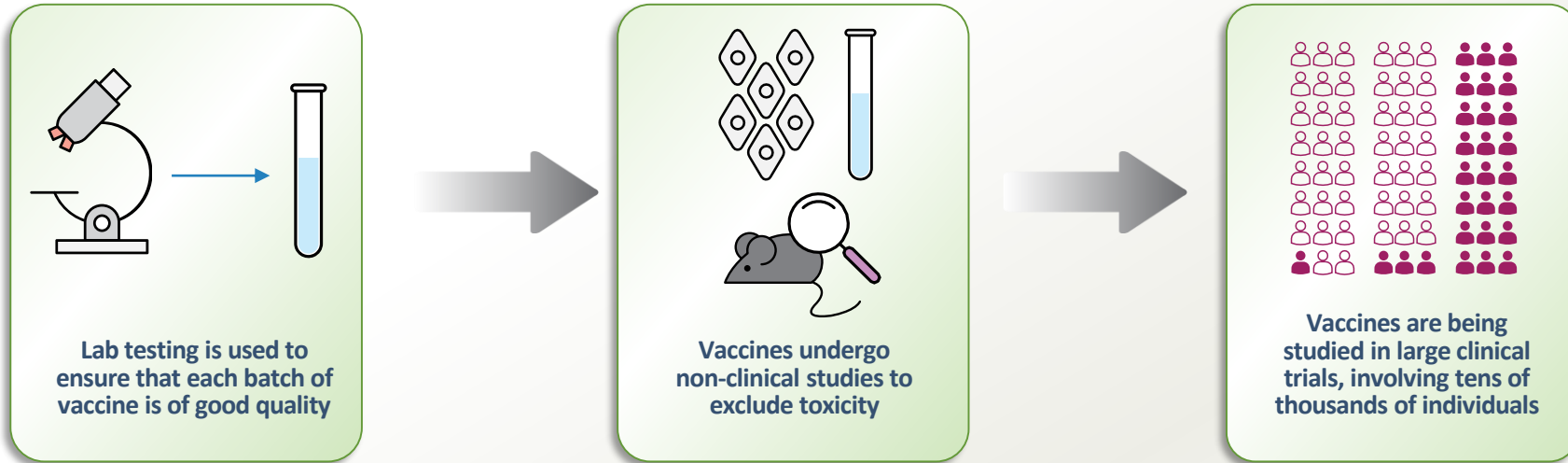
Source: CDC

# How vaccine safety is monitored during and after the vaccine development process

- Safety of vaccines is studied from the first development stage through to use in real life



# The safety of COVID-19 vaccines is studied before approval in pre-clinical and clinical trials

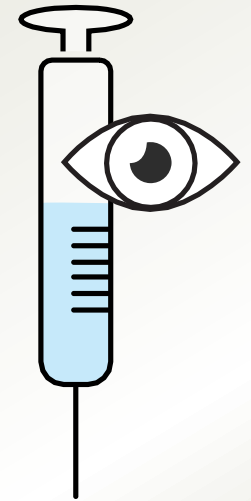


- **Rigorous safety monitoring during clinical trials** allows to estimate the frequency of common side effects
- **Follow up of trial participants** and extended clinical trials will identify longer-term effects

[https://www.ema.europa.eu/en/documents/presentation/presentation-how-safety-new-covid-19-vaccines-will-be-monitored-sstrauss-prac\\_en.pdf](https://www.ema.europa.eu/en/documents/presentation/presentation-how-safety-new-covid-19-vaccines-will-be-monitored-sstrauss-prac_en.pdf)

# The safety of COVID-19 vaccines continues to be monitored after approval

- **Safety monitoring after approval is important** to detect previously unrecognized **adverse events**
- **Vaccine safety monitoring after approval involves:**
  - Intensive analysis of reports of suspected adverse events from patients and healthcare professionals through passive reporting
  - Active surveillance systems in the countries
  - Safety studies conducted by vaccine manufacturers
  - Research studies to examine the safety of COVID-19 vaccines when they are used in real life
  - Sharing of information on COVID-19 vaccine safety between regulators around the world



<https://www.who.int/publications/i/item/10665338400>



# Vaccine safety monitoring can detect adverse events

- An **adverse event following immunization (AEFI)** may be any unintended sign, abnormal laboratory finding, symptom or disease
- The presence of an adverse event does not necessarily mean the vaccine has caused the reported adverse event
- The assessment of adverse events establishes **whether or not there is a causal relationship** between the vaccine and the reported adverse event\*
- An **adverse event of special interest (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

Figure. AEFI surveillance circle



\* [https://www.who.int/vaccine\\_safety/publications/qvs\\_aefi/en/](https://www.who.int/vaccine_safety/publications/qvs_aefi/en/)

# Causality assessment of adverse events

- **Established analysis techniques** are in place to assess whether an adverse event is likely caused by the vaccine
- A systematic approach is undertaken to determine the causality of an adverse event to the vaccine
  - Findings are supported by
    - Post-marketing safety monitoring
    - Safety studies
    - Information from regulators worldwide
    - Medical literature
- If analysis concludes that a new adverse event is caused by a vaccine, action is taken. This may include listing the adverse event on the vaccine packaging or a medical alert



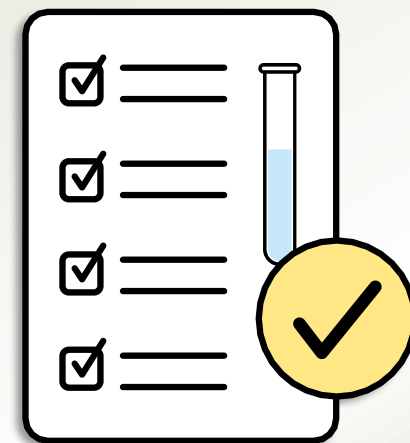
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[https://www.who.int/vaccine\\_safety/publications/qvs\\_aefi/en/](https://www.who.int/vaccine_safety/publications/qvs_aefi/en/)

<https://www.who.int/initiatives/the-global-vaccine-safety-initiative/investigation-of-safety-signals>

# The role of the Global Advisory Committee on Vaccine Safety

- The **Global Advisory Committee on Vaccine Safety** is a group of experts that provide independent guidance on vaccine safety issues of potential global importance to WHO
- A WHO COVID-19 subcommittee of the Global Advisory Committee on Vaccine Safety is established to assess the latest safety data for COVID-19 vaccines during weekly meetings



<https://www.who.int/initiatives/the-global-vaccine-safety-initiative>

<https://www.who.int/news/item/17-03-2021-who-statement-on-astrazeneca-covid-19-vaccine-safety-signals>

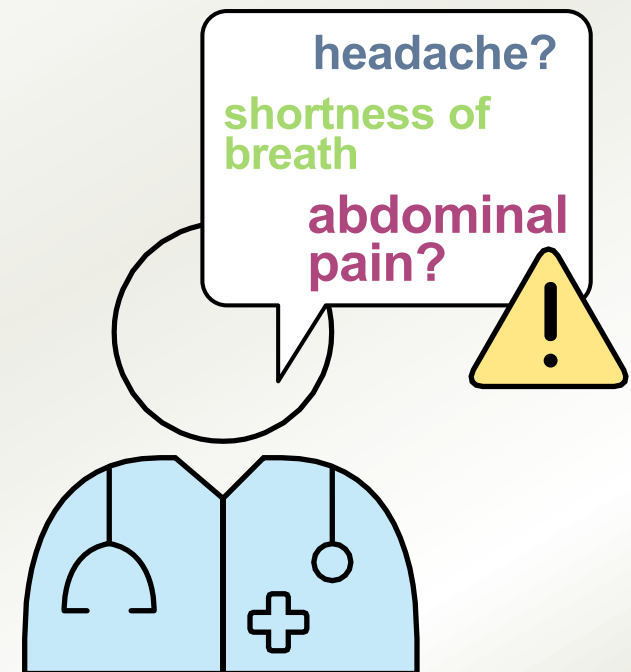
# Blood clotting events associated with low platelet counts have been reported after COVID-19 vaccination

- A very rare new type of adverse event called **Thrombosis with Thrombocytopenia Syndrome (TTS)**, involving unusual and severe blood clotting events associated with low platelet counts, has been reported after vaccination with AstraZeneca COVID-19 vaccines
- Thrombosis in specific sites such as the brain and abdomen appears to be a key feature of TTS
- Data from the UK suggest that the risk is approximately four cases per million adults (1 case per 250 000) who receive the vaccine, while the rate is estimated to be approximately 1 per 100 000 in the European Union
- The TTS syndrome has not been linked to mRNA-based vaccines, such as the Pfizer and Moderna COVID-19 vaccines
- Whilst we have some information on the Pfizer, Moderna and AstraZeneca vaccines, there is limited post-market surveillance data on other COVID-19 vaccines and from low- and middle-income countries

[https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-\(gacvs\)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-\(vaxzevria-and-covishield\)](https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-(gacvs)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-(vaxzevria-and-covishield))

# Considerations for health workers in the context of TTS

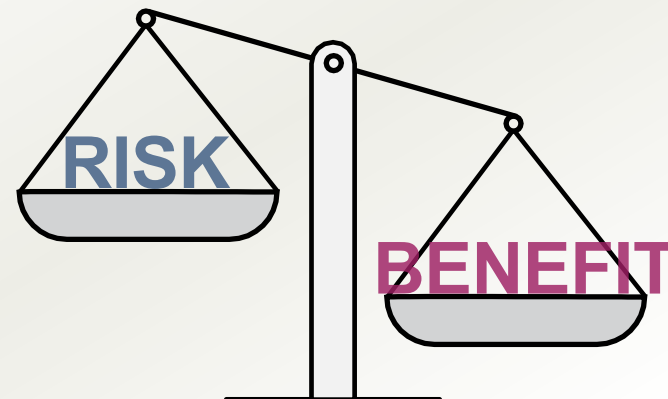
- Clinicians should be alert to any new, severe, persistent headache or other significant symptoms, such as severe abdominal pain and shortness of breath, with an onset between 4 to 20 days after adenovirus vectored COVID-19 vaccination
- At a minimum, countries should encourage clinicians to measure platelet levels and conduct appropriate radiological imaging studies as part of the investigation of thrombosis
- Clinicians should also be aware that although heparin is used to treat blood clots in general, **administration of heparin in TTS may be dangerous**, and alternative treatments such as immunoglobulins and non-heparin anticoagulants should be considered



[https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-\(gacvs\)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-\(vaxzevria-and-covishield\)](https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-(gacvs)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-(vaxzevria-and-covishield))

# Considerations for countries in the context of TTS

- Countries assessing the risk of TTS following COVID-19 vaccination should perform a benefit-risk analysis that takes into account **local epidemiology** (including incidence and mortality from COVID-19 disease), **age groups** targeted for vaccination and the **availability of alternative vaccines**\*
- **To support evidence-based recommendations**, countries should:
  - review, report and investigate all cases of TTS following COVID-19 vaccinations
  - assess cases according to the presence of thrombosis with thrombocytopenia and the time to onset following vaccination using the Brighton Case Definition of TTS\*\*
  - provide data to their local authorities and to the WHO global database of individual case safety reports.
- There may be a geographic variation in the risk of these rare adverse events. Therefore, it is important that all countries evaluate potential cases of TTS



\* [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/976877/CovidStats\\_07-04-21-final.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/976877/CovidStats_07-04-21-final.pdf)

\*\* <https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-case-finding-definition/>

# TTS after COVID-19 vaccination continues to be investigated

- A specific case definition for TTS is being developed by the Brighton Collaboration\*
- The biological mechanism for this syndrome of TTS is still being investigated. At this stage, a 'platform specific' mechanism related to the adenovirus-vectored vaccines is not certain but cannot be excluded
- Ongoing review of TTS cases and related research should include all vaccines using adenoviral vector platforms
- Global Advisory Committee on Vaccine Safety (GACVS) recommends further epidemiological, clinical and mechanistic studies to fully understand TTS including:
  - an increased risk in younger adults
  - gender-related risk (although more cases have been reported in women; it is important to underscore that more women have been vaccinated and some TTS cases have also been reported in men)



\* <https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-case-finding-definition/>



# Informing the public about suspected adverse events

- **Listen** to the media and communities – to understand the main questions and concerns and any associated rumours
- **Communicate** clearly, proactively, early and frequently, through trusted spokespeople. Demonstrate competence in science, the systems and programme, with empathy, honesty, transparency. Do not over-reassure. Put the data in context. Visuals can help explain risk/benefit ratios
- **Connect** with your networks and identify and engage all the various influencers, advocates, champions, who can be trusted intermediaries and amplifiers to answer questions and provide context



Source: WHO



# Communicate vaccine safety numbers visually and recognizably for the public

- **Avoid** the use of numbers such as 1 in 2 million. These comparisons tend to be too abstract for people to grasp the true meaning
- Instead, **be visual** by using familiar settings and items to show numbers. For example:
  - one person in a large football stadium
  - one grain of sand in a teaspoon
- **Test** the comparison of risk with the audiences that receive the information. Ensure that the message intended is conveyed clearly
- **Use empathy** in referring to deaths and harm. Even one death may feel like too much for something that people choose to do (e.g. vaccination)
- **Emphasize** the benefits over the risks of getting vaccinated

# Online mentions on blood clots & thrombosis in relation to the AstraZeneca vaccine

17 MARCH to 06 APRIL 2021

Conversation on

Blood clots



up by **+78%**

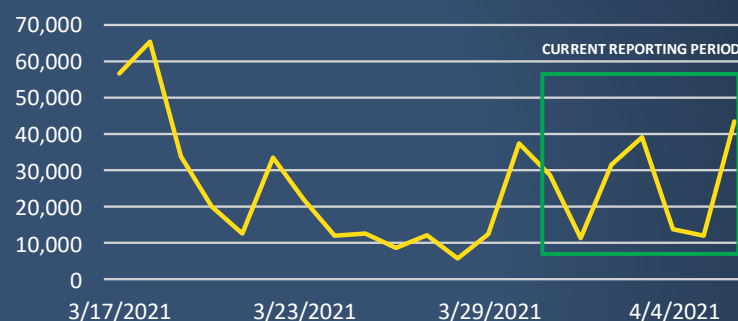
## RISK OF THROMBOSIS: THE ASTRAZENECA VACCINE vs. THE CONTRACEPTIVE PILL

- The top liked tweet from the period (21.8k engagements) noted that 'the contraceptive pill has a higher potential blood clot rate than the AstraZeneca vaccine'
- The comparison has been resonating strongly on social media platforms. Users expressed confusion and frustration over why the risk of thrombosis was enough for authorities to allegedly take the AstraZeneca jab off the market in some countries, whilst comparable levels of risk are seemingly deemed acceptable for contraceptive products

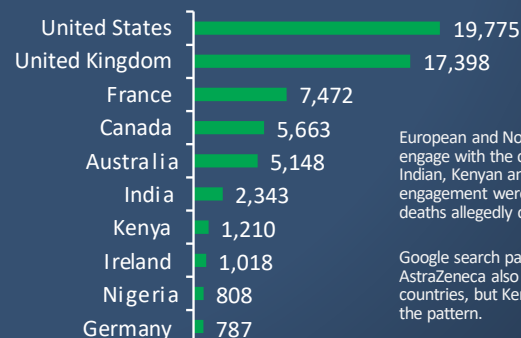
## VACCINE COMPARISONS (GLOBAL)

- Users have expressed confusion over why cases of blood clots have been linked to the AstraZeneca vaccine in particular and not to other vaccines

**Figure.** Online mentions of blood clots or thrombosis *after* the global peak\* (17 Mar - 6 Apr 2021)



**Figure.** Conversation on blood clots by country (top 10)



European and North American countries were likely to engage with the conversation the most. On the other hand, Indian, Kenyan and Nigerian profiles that attracted most engagement were most likely to share news reports of deaths allegedly caused by vaccine-elicited blood clots.

Google search patterns around thrombosis, blood clots, and AstraZeneca also saw an overrepresentation of European countries, but Kenya, Uruguay, Australia and Namibia broke the pattern.

# Additional resources



- **COVID-19 vaccine introduction toolkit**

The COVID-19 vaccine introduction toolbox equips all countries to prepare for and implement COVID-19 vaccination by providing guidance, tools, and training.

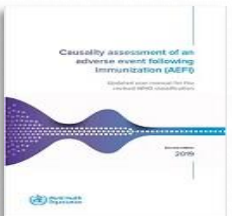
<https://www.who.int/tools/covid-19-vaccine-introduction-toolkit>



- **WHO Coronavirus (COVID-19) Dashboard**

A global overview of confirmed COVID-19 cases, deaths and vaccine doses administered.

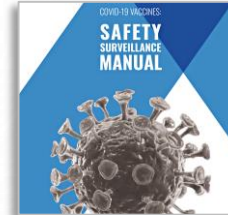
<https://covid19.who.int/>



- **Causality assessment of an adverse event following immunization (AEFI)**

User manual on causality assessment

[https://www.who.int/vaccine\\_safety/publications/gvs\\_aefi/en/](https://www.who.int/vaccine_safety/publications/gvs_aefi/en/)



- **Vaccine safety surveillance manual**

vaccine safety surveillance manual for COVID-19 vaccines

<https://www.who.int/publications/i/item/10665338400>



- **Investigation of safety signals**

vaccine safety signal is information that indicates a potential link between a vaccine and an event previously unknown or incompletely documented, that could affect health.

<https://www.who.int/initiatives/the-global-vaccine-safety-initiative/investigation-of-safety-signals>

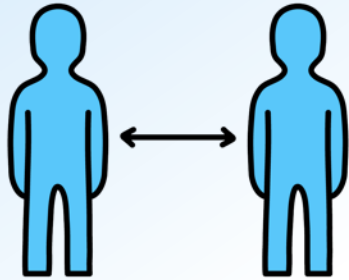


- **WHO statement on AstraZeneca COVID-19 vaccine safety signals**

<https://www.who.int/news/item/17-03-2021-who-statement-on-astrazeneca-covid-19-vaccine-safety-signals>

# COVID-19 protective measures

Protect yourself & others



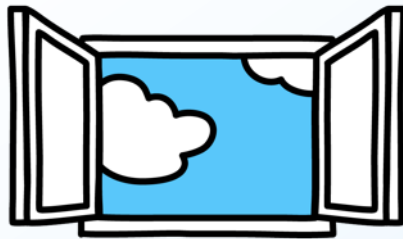
Keep your distance



Wash your hands frequently



Cough & sneeze into your elbow



Ventilate or open windows



Wear a mask



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[www.who.int/epi-win](http://www.who.int/epi-win)