United Nations
INTEROFFICE MEMORANDUM

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Immediate

DATE: 12 April 2021

REFERENCE: DOS-2021-01681

TO: Heads of Departments, Offices, Regional Commissions,
A: Offices Away from Headquarters and Field Missions
(see Distribution List)
Resident Coordinators (through the Development Coordination Office)

THROUGH:
S/C DE:

FROM: Atul Khare, Under-Secretary-General
DE: for Operational Support

SUBJECT: **Update on the United Nations System-wide COVID-19 Vaccination Programme**
OBJET:

1. I am writing to update you regarding recent reports in the media of issues related to the AstraZeneca vaccine which is being used in the UN vaccination programme. As you will be aware, there have been recent reports of very rare cases of vaccine-induced prothrombotic immune thrombocytopenia (VIPIT), following vaccination with the AstraZeneca COVID-19 vaccine (including Covishield). VIPIT is a condition of blood clots associated with low platelet counts, that occurs following vaccination. Available evidence so far continues to suggest that this syndrome is extremely rare. Specifically, 169 reported cases of cerebral venous sinus thrombosis (CVST) and 53 cases of abdominal blood clots were reported in 34 million vaccine recipients in the United Kingdom and European Economic Area. Most cases occurred within 15 days of receiving the first dose, and in women under 60 years of age.

2. The WHO has stated that the very rare incidence should be weighed against the risk of morbidity from COVID-19 and that a causal relationship, while plausible, has yet to be confirmed. The statement from WHO is attached for your reference as Annex 1. Due to the rarity of these events and the potential severity of COVID-19, the European Medicines Agency (EMA) concluded that the overall benefits of the vaccine continue to outweigh the risk.

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3. Based on these assurances, we have decided that the best course of action would be to continue the United Nations-led effort, while mitigating the risks of this rare condition occurring among those we vaccinate, through the following steps:

- **Staff Communications**: The current Staff FAQ on the United Nations-led vaccination effort has been updated to include comprehensive information related to VIPIT (Annex 2).

- **United Nations Vaccination Administration Processes:** The informed consent form/patient information leaflet for the United Nations-led vaccination effort is being updated to include VIPIT information.

- **Physician Guidance:** Guidance for all United Nations healthcare workers on the diagnosis, management and reporting of VIPIT has been shared on 9 April 2021 (Annex 3); a training webinar for the United Nations medical community on this topic was delivered today.

- **United Nations Clinic/Hospital preparations:** In general, VIPIT is diagnosed through clinical evaluation and identification of low platelets (which is a basic laboratory service available in our clinics/medical services). When a suspect case is diagnosed, the patient will need specialist care to be managed. This may involve referral to local hospitals with such specialist care or medical evacuation, which will likely be needed for most of our locations. Intravenous Immunoglobulin (IVIG) is also an important treatment, along with anticoagulant treatment, for such patients – and we are reviewing the procurement of these therapeutics in case the need arises for their use in our clinics. The MEDEVAC Task Force is currently reviewing to where such patients would be evacuated if the need were to arise.

4. I wish to thank all of you for your unwavering cooperation since the commencement of this important venture. I remain convinced that, together, we will be able to provide, whether through national immunization plans of host countries or through our own delivery of vaccines, the needed assurance to those of our personnel who wish to be vaccinated.

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Annex 1

Interim statement of the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety on AstraZeneca COVID-19 vaccine, 7 April 2021

The COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) has reviewed reports of rare cases of blood clots with low platelets following vaccination with the AstraZeneca COVID-19 vaccine (including Covishield) since their onset a few weeks ago.

At its most recent meeting on 7 April, 2021, the subcommittee reviewed latest information from the European Medicines Agency along with information from the United Kingdom's Medicines and other Health products Regulatory Agency (MHRA), and other Member States and noted the following:

- Based on current information, a causal relationship between the vaccine and the occurrence of blood clots with low platelets is considered plausible but is not confirmed. Specialized studies are needed to fully understand the potential relationship between vaccination and possible risk factors.
- The GACVS subcommittee will continue to gather and review further data, as it has done since the beginning of the COVID vaccine programme.
- It is important to note that whilst concerning, the events under assessment are very rare, with low numbers reported among the almost 200 million individuals who have received the AstraZeneca COVID-19 vaccine around the world.
- Rare adverse events following immunizations should be assessed against the risk of deaths from COVID-19 disease and the potential of the vaccines to prevent infections and reduce deaths due to diseases. In this context, it should be noted that as of today, at least 2.86 million people have died of COVID-19 disease worldwide.
- Side effects within two- or three-days following vaccination, the majority of which are mild and local in nature, are expected and common. However, individuals who experience any severe symptoms – such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms, such as severe and persistent headaches or blurred vision, tiny blood spots under the skin beyond the site of the injection - from around four to 20 days following vaccination, should seek urgent medical attention. Clinicians should be aware of relevant case definitions and clinical guidance for patients presenting thrombosis and thrombocytopaenia following COVID-19 vaccination. To this end, the GACVS subcommittee also suggested that a committee of clinical experts including haematologists and other specialists is convened, for advice on clinical diagnosis and case management.
- Active surveillance, including sentinel site / hospital case-based investigations should be considered, to further characterize these rare events. WHO has developed template protocols that countries could adapt for such studies. The GACVS will meet again next week to review additional data and will be issuing further recommendations as relevant

WHO is carefully monitoring the rollout of all COVID-19 vaccines and will continue to work closely with countries to manage potential risks, and to use science and data to drive response and recommendations.

In extensive vaccination campaigns, it is normal for countries to identify potential adverse events following immunization. This does not necessarily mean that the events are linked to vaccination itself, but they must be investigated to ensure that any safety concerns are addressed quickly. Vaccines, like all medicines, can have side effects. The administration of vaccines is based on a risk versus benefit analysis.

Annex 2

Staff Frequently Asked Questions (FAQs) Concerning Vaccine Safety on AstraZeneca COVID-19 Vaccine

1. **Which vaccine is the UN administering as part of the UN System-Wide COVID-19 Programme?**

The UN has acquired doses of Covishield, the version of AstraZeneca/Oxford COVID-19 vaccine manufactured by the Serum Institute of India, the world's largest vaccine manufacturer, approved under emergency use listing procedures (EUL) by WHO. The UN expects to acquire or receive donations of other EUL WHO-approved vaccine doses as they become available.

See COVISHIELD fact Sheet here: https://www.seruminstitute.com/pdf/covishield_fact_sheet.pdf

2. **Is the Oxford-AstraZeneca/CoviShield vaccine safe?**

The available science indicates that the Oxford-AstraZeneca (AZ) vaccine is highly effective and safe to take. It prevents severe disease, hospitalization, and is saving lives.

As of 9 April, almost 200 million individuals had received the AZ vaccine. Among those, a small number of individuals (reportedly, 1 in 100,000) has experienced rare types of thromboembolic events (unusual blood clots with low blood platelets). Reported incidence is variable, ranging from 1 /100,000,000 to 1/100,000 vaccination. This is an area of ongoing study to understand true risk. These rare events have prompted a thorough assessment of all available data by WHO's Global Advisory Committee on Vaccine Safety (GAVCS) and the European Medicines Agency (EMA) with a view to ascertain whether a causal link with the AZ vaccine can be established.

On 7 April 2021, the GACVS and the EMA as well as other national health authorities in Europe all issued statements indicating that:

> 1. A causal relationship between the vaccine and the occurrence of these thromboembolic events is considered plausible but is not confirmed.
>
> 2. The events are very rare and therefore, if there is a causal link, the risk is extremely low. In comparison, as of 7 April 2021, at least 2.86 million people worldwide have died of COVID-19, and infections continue to rise.
>
> 3. The benefits of taking the AZ vaccine far outweigh the very rare potential risks. Specialized studies are needed to fully understand the potential relationship between vaccination and possible risk factors, such as gender or age as well as comorbidities or other factors which so far have not been identified. However, out of an abundance of caution, some countries decided to restrict the vaccine to certain categories of population.

See full GAVCVS statement here: https://www.who.int/news/item/07-04-2021-interim-statement-of-the-covid-19-subcommittee-of-the-who-global-advisory-committee-on-vaccine-safety

In sum, while the vaccine may cause severe blood clotting events, such events were deemed by all health experts as very rare, and not altering the risk/benefit balance, which remains overwhelmingly in favour of getting the AZ vaccine, if and when available. In case of doubt, you are advised to consult with your health care provider.

The above information is dynamic and subject to change. As more information becomes available, this FAQ will be updated.

3. **Shall I expect side effects following the AZ vaccine, and are any of these side effects associated with gender or age?**

Serious side effects may occur from any vaccine but are extremely rare. It is important to remember that we are witnessing the largest mass vaccination campaign in history, and some rare reactions are to be expected.

Whilst mild and local side effects within two/ three days following vaccination are expected and common, individuals who experience any severe symptoms potentially related to blood clotting – such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms, such as severe and persistent headaches or blurred vision, tiny blood spots under the skin beyond the site of the injection – typically around 4 to 20 days following vaccination - should seek urgent medical attention.

Unusual blood clots with low blood platelets (as reported after vaccination with the AZ vaccine) should be considered as extremely rare side effects presenting a low risk. While the rare event seems to occur more frequently among women of younger age, more studies are needed to know whether females are really at greater risk since in general there have been more women who have received the vaccine.

Those who develop severe symptoms after receiving the vaccine should seek medical attention immediately. By recognizing the signs of bloods clots and treating them early, healthcare professionals can help those affected in their recovery and avoid complications.

Annex 3

Interim Guidelines: Diagnosis and Management of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following AstraZeneca COVID-19 Vaccinations

12 April 2021

Introduction

Rare cases of blood clots with low platelets after receipt of AstraZeneca (AZ) COVID-19 vaccine have been reported. At present there is no clear signal of risk factors for this condition. This document provides guidance to UN medical staff globally on the diagnosis, management and reporting of vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) cases. **UN medical staff need to be alert for this syndrome and arrange for early referral to local hospitals or haematologists and/or consider early medical evacuation for further lab confirmation and treatment of this condition.**

For any questions, contact DHMOSH Public Health at dos-dhmosh-public-health@un.org **Note that this is a living document which will be updated as more information emerges.**

Current Situation Update

At the time of writing, the AstraZeneca vaccine is currently being authorized for use in the EU and several other countries, including the UK, Canada and India. Based on a multinational Phase 3 trial, the vaccine had 70.4% efficacy in preventing symptomatic COVID-19 at/after 14 days post second dose. Although there is some concern about vaccine efficacy against certain "variants", the WHO continues to recommend use of this vaccine even if those variants are circulating in a country[1,2].

"Vaccine induced prothrombotic immune thrombocytopenia", or VIPIT, is a condition of blood clots associated with low platelet counts, that occurs following receipt of the vaccine. The likely mechanism is antibodies that induce massive platelet activation, reducing platelet count and causing thrombosis although the full mechanism remains to be elucidated. This syndrome is thought to mimic "heparin-induced thrombocytopenia" (HIT) but does not require heparin itself as a trigger. Most cases occurred 5 to 28 days[3] after receipt of the AZ vaccine, and in women[4] under 60 years old[5].

Available evidence so far, at the time of writing, continues to suggest that **this syndrome is extremely rare**[6] though information continues to evolve.

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[1] https://www.who.int/news-room/feature-stories/detail/the-effects-of-virus-variants-on-covid-19-vaccines

[2] AstraZeneca ChAdOx1-S/nCoV-19 [recombinant], COVID-19 vaccine (who.int)

[3] https://b-s-h.org.uk/media/19530/guidance-version-13-on-mngmt-of-thrombosis-with-thrombocytopenia-occurring-after-c-19-vaccine_20210407.pdf

[4] Note that additional studies needed on this since many vaccine recipients are women as they fall under the high priority first responders groups such as teachers and healthcare workers being prioritized early for vaccination.

[5] https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood

[6] At the time of writing, Norway has reported a rate of 1 in every 25,000 doses, Germany reported 1 in 100,000 doses, while Europe's overall figures are 1 in 210,000. The UK has reported about 1 in 500,000 doses. Specifically, 169 reported cases of cerebral venous sinus thrombosis (CVST) and 53 cases of splanchnic vein thrombosis were reported in 34 million vaccine recipients in the UK and European Economic Area as of time of writing this document.

Because of the rarity of events and potential severity of COVID-19, the European Medicines Agency (EMA) concluded that the overall benefits of the vaccine continue to outweigh the risk. The WHO has also stated that the very rare incidence should be weighed against the risk of morbidity from COVID-19. See WHO statement here. The WHO has stated that a causal relationship, while plausible, has still yet to be confirmed.

Clinical Presentation of VIPIT

Patients with VIPIT may present with cerebral sinus vein thrombosis (CSVT), or with other arterial or venous clots.

Symptoms that make you suspect VIPIT include:

- **persistent and severe headache**
- **focal neurological symptoms**
- **seizures, or blurred or double vision (suggesting CSVT or arterial stroke)**
- **shortness of breath or chest pain (suggesting pulmonary embolism or acute coronary syndrome)**
- **abdominal pain (suggesting portal vein thrombosis) or limb swelling, redness, pallor, or coldness (suggesting deep vein thrombosis or acute limb ischemia).**

VIPIT cases usually present 5 to 28 days[7] after vaccination, so the above symptoms occurring within this time frame should raise clinical suspicion of VIPIT.

What To Do When An Individual Presents with the Above Symptoms

1. Ask patient about their COVID-19 vaccine history and note the date that they received the doses, if any
2. Draw a complete blood count (CBC) from the patient
3. If platelet count is equal or less than 150 x 10^9 /L, **AND** their symptoms occur within 28 days after COVID-19 vaccination, such patients are considered a **suspect case of VIPIT**.
4. **Suspect VIPIT patients need to be further evaluated for VIPIT through D-dimer and fibrinogen levels, blood films drawn to confirm thrombocytopenia, PF4 antibody assay (ELISA HIT assay), and imaging (e.g. CT or MRI) to rule out in particular CSVT.**
    a. *Cases are often characterized also with very raised D Dimer levels (>4000 mcg/L) above the level expected for VTE and many develop low fibrinogen levels.*
    b. *Antibodies to platelet factor 4 (PF4), as detected by ELISA Heparin-Induced Thrombocytopenia (HIT) assay, have also been identified in this syndrome.*
5. **If such lab tests and services in #4 are not available in your clinic, you need to organize a referral to a local hospital with these services, or medically evacuate to rule out and/or treat VIPIT.**

A summary of these steps is found at the end of this Annex.

Treatment of VIPIT

[7] https://b-s-h.org.uk/media/19530/guidance-version-13-on-mngmt-of-thrombosis-with-thrombocytopenia-occurring-after-c-19-vaccine_20210407.pdf

Treatment of suspect or confirmed VIPIT requires consultation with a specialist hematologist. However, please bear in mind the following principles for treating such patients:

1. DO NOT give heparin
2. Avoid platelet transfusions
3. Consult a hematologist (in person, virtually, by phone)
4. Give intravenous immunoglobulin 1 g/kg daily for 2 days for severe or life-threatening clots, if available. Further IVIG may require balancing bleeding and thrombotic ris
5. Use first line anticoagulants: direct oral anti-Xa inhibitors (e.g. rivaroxaban, apixaban, edoxaban)

Until VIPIT has been ruled out, anticoagulation with heparin (both unfractionated heparin and low molecular weight heparins) should **not** be given. Platelet transfusions should **not** be given.

Further information concerning specialized guidance on how to confirm VIPIT diagnosis and its clinical management is available at UK: Guidance Produced from the Expert Haematology Panel (EHP) focused on Covid-19 Vaccine induced Thrombosis and Thrombocytopenia (VITT)

Treatment of VIPIT With Life Threatening Blood Clots

In patients with confirmed VIPIT and severe or life-threatening blood clots (e.g., CSVT, splanchnic vein thrombosis), it is important to administer **high dose intravenous immunoglobulin (IVIG) at 1g/kg of body weight daily for two days** urgently, if available. This treatment should be guided by a consulting hematologist and can be given whilst awaiting confirmatory diagnosis.

Reporting VIPIT

Prompt reporting of such cases amongst UN personnel is essential to learn more about this rare but serious thrombotic phenomenon.

All cases of thrombosis, thrombocytopenia occurring within 28 days of COVID-19 vaccine must be reported immediately to DHMOSH Public Health at dos-dhmosh-public-health@un.org

References

- UK: Guidance Produced from the Expert Haematology Panel (EHP) focused on Covid-19 Vaccine induced Thrombosis and Thrombocytopenia (VITT)
- Ontario: Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) Following AstraZeneca COVID-19 Vaccination
- Interim statement of the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety on AstraZeneca COVID-19 vaccine
- https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood
- NEJM: Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination (9 April 2021)

Summary of Algorithm for VIPIT