Update on J&J COVID 19 vaccine and risk of thrombosis with thrombocytopenia syndrome (TTS)
GACVS sub-committee conclusions

• As of 7 May 2021, the FDA/CDC had reviewed **28 reports of TTS (out of more than 8 million vaccinations)**; to date, FDA/CDC have not identified any cases of TTS after use of over 240 million doses of mRNA vaccines.

• **Clinical picture of TTS with Janssen vaccine is similar to those reported following vaccination with the AstraZeneca vaccine**

• Most cases of TTS have involved thrombosis in unusual locations (including cerebral venous sinuses, portal vein…other rare venous/arterial thrombosis), cases including thrombosis in more common locations, such as DVT* and PE*, have been identified in the US (in combination with thrombocytopenia).

*DVT Deep Vein Thrombosis – PE Pulmonary Embolism*
GACVS sub-committee recommendations

- Adequate education should be provided to health-care professionals and persons being vaccinated to recognize the signs and symptoms of TTS
  - Clinicians should be alert to any new, severe, persistent headaches 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 investigation of thrombosis.
  - Clinicians should also be aware that heparin in TTS may be dangerous and alternative treatments such as immunoglobulins and non-heparin anticoagulants should be considered.
The benefits of the J&J vaccine continue to outweigh the risks of TTS

The risk of TTS from use of the J&J vaccine should be assessed against the benefits. Countries should perform such a benefit-risk analysis taking into account local epidemiology (including incidence/mortality from COVID-19), age groups targeted for vaccination, and the availability of alternative vaccines.

The GACVS subcommittee acknowledges that TTS has occurred with two adenoviral-vectored vaccines. Ongoing assessment for and review of TTS cases, as well as related research, should include all vaccines using adenoviral vector platforms.

The GACVS COVID-19 subcommittee will continue to review the safety data from all COVID-19 vaccines and update any advice as necessary.
Thank you
Interim Brighton Collaboration case definition for thrombosis with thrombocytopenia syndrome (TTS)

- New onset thrombocytopenia: platelet count <150,000 per microliter
- No known recent exposure to heparin
- Presence of venous or arterial thrombosis
  - In addition to rare thromboses (e.g., cerebral venous thrombosis), currently includes more common thromboses (e.g., as deep vein thrombosis, pulmonary thromboembolism, ischemic stroke, and myocardial infarction)

* A blood smear should be evaluated to rule out platelet clumping that could falsely indicate a low platelet count

https://brightoncollaboration.us/wp-content/uploads/2021/04/TTS-Interim-Case-Definition-v9.2-April22-202116538.docx