

# Update on J&J COVID 19 vaccine and risk of thrombosis with thrombocytopenia syndrome (TTS)

**SAGE Meeting**

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## 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.

## GACVS sub-committee recommendations

- **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

