RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES ON THE TBE VACCINE LICENSED IN THE UNITED STATES

Background

On August 13, 2021, the Food and Drug Administration (FDA) of the United States approved the TBE vaccine manufactured by Pfizer for persons aged at least 1 year old. The vaccine is licensed in the US under the trade name Ticovac. In Europe, it is also marketed as FSME-IMMUN.

The current adult and pediatric formulations became available in Europe in 2001 and 2003, respectively. Before 2021, no TBE vaccine, had been licensed in the US, and the Advisory Committee on Immunization Practices (ACIP) had no recommendations for use of TBE vaccine among US travelers and laboratory workers. Ticovac is the only licensed TBE vaccine in the US. Other TBE vaccines are manufactured in Europe, Russia and China, but these vaccines are not available in the US.

Results and discussion

In the ACIP publication, various issues of TBE and TBE virus are discussed: modes of TBE virus transmission, epidemiology of TBE, clinical manifestations and diagnostics, TBE among travelers, TBE among laboratory workers, and findings on TBE vaccine including effectiveness and safety.

For most US travelers to TBE endemic areas, the risk of TBE is low. Eleven TBE cases have been reported among US adults and pediatric civilians from 2001 to 2021. However, TBE cases might not have been identified if the illness was diagnosed overseas or if the clinician did not consider TBE in the differential diagnosis for a returning traveler. The reported TBE virus infections were acquired in Europe, Russia or China.

A total of 12 TBE cases were diagnosed among US military personnel (n=8) or their dependent children (n=4) during 2012 to 2021. 11/12 cases occurred during 2017–2021. All TBE virus infections were acquired in Germany (Baden-Wuerttemberg and Bavaria). At least four TBE virus infections occurred among US laboratory workers; all occurred before 1980.

The risk-benefit assessment for TBE vaccination should consider multiple factors, including the likelihood of exposure to TBE virus-infected ticks based on activities and itinerary, and one should consider that higher risk for severe disease exists among older persons. Extensive exposure can be considered based on the duration of travel and frequency of exposure and might include short-term (e.g., <1 month) travelers' exposure to environments that might harbor infected ticks. It is also said in the document that travelers to areas where TBE is endemic should be advised to avoid the consumption of unpasteurized dairy products.

Dosage, schedule and administration of the TBE vaccine concur with the recommendations in Europe. A booster dose can be administered at least three years after completion of the primary 3-dose series if ongoing exposure of TBE virus is expected. No ACIP recommendations are made on the need for subsequent booster doses (the US FDA only approved one booster dose, and therefore the ACIP did not review any data for additional booster doses).

As one of the future research aspects, it is said that evaluation of potential immunological interactions between TBE vaccine and other flavivirus vaccines (e.g., yellow fever of Japanese encephalitis vaccines) is needed. Previous exposure to other flaviviruses endemic in the US (e.g., Powassan virus or West Nile virus) might affect the immune response to the TBE vaccine.

The TBE vaccine recommendations will be reviewed and updated as needed if new data become available or if additional TBE vaccines are licensed in the US.

Literature

Hills et al.

Tick-borne encephalitis vaccine:
Recommendations of the Advisory Committee on Immunization Practices, United States, 2023

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Author: Dr. Michael Bröker

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