

# **Recommendations of the Czech Vaccinology Society of the J. E. Purkyně Czech Medical Association for Vaccination against Invasive Meningococcal Disease**

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These recommendations update the Recommendations of the Czech Vaccinology Society of the J. E. Purkyně Czech Medical Association for Vaccination against Invasive Meningococcal Disease of 15 January 2018.

Invasive meningococcal disease (IMD) is a serious, human-to-human transmissible disease caused by the Gram-negative diplococcus *Neisseria meningitidis*, most often by its serogroups A, B, C, W, and Y. The source of infection can be an asymptomatic carrier or a diseased person. The most serious clinical forms are meningococcal meningitis and septicaemia. These invasive meningococcal diseases have a peracute course and despite early treatment, may lead to death within 24-48 hours after the onset of symptoms. Delay in diagnosis may occur due to nonspecific initial symptoms. Fatal outcomes have been reported in 10-20% of patients. In the Czech Republic, the average case fatality rate was 9% over the last decade (range 4.7 % to 14.7%). About 20% of survivors have lifelong sequelae, such as limb amputation, deafness, or mental retardation.

## **Epidemiology of invasive meningococcal disease**

The incidence of IMD is declining worldwide, possibly as a result of more vaccine options becoming available. However, the case fatality rate and risk for lifelong sequelae still remain rather high. In the Czech Republic, the incidence of IMD has been low over the last decade, ranging from 0.4 to 0.8 cases per 100 000 population. The most affected age groups are children 0-11 months and 1–4 years and adolescents 15-19 years. The proportions of the causative serogroups are changing over years. After about 20 years of the predominance of serogroup B, serogroup C is on the rise. In 2019, serogroup C accounted for 42.9% of cases while serogroup B for 36.7% of cases. Cases caused by meningococcal serogroups W and Y (6.1% and 4.1%, respectively) are also reported every year. Although much less commonly involved in IMD, meningococcal serogroups W and Y have the highest case fatality rates both in the Czech Republic and worldwide. The highest incidence of IMD is regularly reported in children aged 0-11 months. The analysis of long-term morbidity in selected age groups shows that serogroup B accounts for the highest number of cases in the youngest age group 0-11 months. The population groups at highest risk for IMD in the Czech Republic are the most affected age categories, patients with selected chronic diseases, persons living in large collectives, selected categories of health professionals, and travellers to high incidence countries.

## **Meningococcal vaccine options**

The European Medicines Agency (EMA) has authorised two meningococcal conjugate tetravalent vaccines containing antigens of four meningococcal serogroups, A, C, W, and Y (MenACWY-TT and MenACWY-CRM vaccines) and two recombinant meningococcal vaccines containing serogroup B antigens (MenB-4C and MenB-FHbp vaccines). The MenACWY vaccine has proved protective not only against IMD caused by the respective serogroups but also against their carriage. All these vaccines are licensed for use in both children and adults. The MenACWY-TT vaccine (Nimenrix) is indicated for use in children from the age of six weeks, and the MenACWY-CRM vaccine (Menveo) is given from the age of two years. The MenB-4C vaccine (Bexsero) can be used from the age of two months, and the MenB-FHbp vaccine (Trumenba) from the age of 10 years. The goal of vaccination against IMD is to provide protective immunity for the vaccinated individual as early as possible, and it should be as complex and as long-lasting as possible.

## Recommended vaccination against invasive meningococcal disease

To achieve as high serogroup coverage as possible, it is recommended to use both the MenACWY and Men B vaccines. In some cases, a booster dose is required to maintain long-term immunity.

### Vaccination for infants and small children

The MenB-4C vaccine is recommended for:

- Infants and small children aged from 2 to 59 months, with the first dose given preferably as early as possible;
  - Basic dosing schedule: as a 2+1 dose series from the age of 2 months, with two doses given two months (at least 8 weeks) apart, followed by a booster dose at the age of 12-15 months given not earlier than 6 months after the second dose. When the dosing schedule is started before the age of 6 months, the vaccine is fully covered by the public health insurance system.
  - Capture schemes:
    - at the age of 6-11 months: 2 doses given 2 months (at least 8 weeks) apart, followed by a booster dose in the second year of life not earlier than 8 weeks after the second dose;
    - at the age of 12-23 months: 2 doses given 2 months (at least 8 weeks) apart, followed by a booster dose 12 months after the second dose;
    - at the age of 24-59 months: 2 doses given 2 months (at least 4 weeks) apart, without a booster dose.
  - The vaccine can be given at the same time with any other vaccine. Prophylactic antipyretics at the time of vaccination or shortly afterwards can reduce postvaccination febrile reactions and their intensity and are recommended when multiple vaccines are co-administered.
  - The Czech Vaccinology Society recommends that vaccination should be started as early as possible, i.e. at the age of two months, to provide protection as quickly as possible. In the Czech Republic, the incidence of MenB IMD peaks around the age of 5 months.
  - Early vaccination is recommended even in preterm children.

Men ACWY vaccines are recommended for:

- toddlers aged 12-23 months are given a single dose of MenACWY-TT without a booster dose. At this age, the dose is covered by the public health insurance system.
- based on agreement between the parents and the provider, MenACWY-TT is to be considered in infants:
  - between the ages of 6 weeks and 5 months: 2 doses given two months (at least 8 weeks) apart, followed by a booster dose at the age of 12 months and not earlier than 8 weeks after the second dose;
  - between the ages of 6 and 11 months: 1 dose followed by a booster dose at the age of 12 months and not earlier than 8 weeks after the first dose;
- between the ages of 24 and 59 months: 1 dose of MenACWY-TT or MenACWY-CRM

## **Vaccination for adolescents and young adults**

Any available MenB and MenACWY vaccine is recommended for all adolescents and young adults aged between 15 and 25, preferably at the age of 15. Two doses of MenB-4C should be given at least 1 month apart while MenB-FHbp is applied in a two-dose series 6 months apart. The same vaccine should be used for both doses as the MenB vaccines are not interchangeable.

MenB and MenACWY can be given at the same time and along with any other vaccine indicated for adolescents and young adults.

## **Vaccination for high-risk groups**

The MenB and MenACWY vaccines are recommended for patients, regardless of age, with the following health conditions:

- Defective or absent splenic function (hyposplenism/asplenism). When the patient is scheduled for splenectomy, the vaccine is given at least 14 days prior to the procedure.
- Autologous or allogeneic transplantation of hematopoietic stem cells;
- Primary or secondary immunodeficiency or expected immunodeficiency;
- Terminal complement deficiency;
- A history of meningococcal meningitis and septicaemia;
- Before starting eculizumab therapy.

The MenB and MenACWY vaccines are also recommended for persons, regardless of age, at high risk for IMD:

- Travellers to hyperendemic or epidemic areas or those planning to reside in such areas;
- Persons at occupational risk for IMD (health professionals providing care to patients with IMD and laboratory staff at risk of exposure to the causative agent);
- Persons present in a focus of IMD infection (with the vaccine selected depending on the serogroup active in the focus).

Dosing schedules for high-risk groups:

- MenACWY:
  - Persons at occupational risk for IMD are immunised with 2 doses of the MenACWY vaccine two months apart, followed by a booster dose every five years in case of persistent risk.
- MenB:
  - Persons at occupational risk for IMD are immunised with 2 doses of the MenB-4C vaccine one month apart or with three doses of the MenB-FHbp vaccine one and five months apart, respectively, followed by a booster dose one year after the last dose and then every 2-3 years in case of persistent risk.