ČESKÁ VAKCINOLOGICKÁ SPOLEČNOST ČLS JEP

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 Recommendations of the Czech Vaccinology Society of the J. E. Purkyně Czech Medical Association for Vaccination against Invasive Meningococcal Disease of 1 June 2020.

Invasive meningococcal disease (IMD) is a serious, human-to-human transmissible disease caused by the gramnegative 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 IMD have a peracute course and may lead to death within 24-48 hours after the onset of symptoms despite early treatment. Delay in diagnosis may occur due to initial nonspecific symptoms. Fatal outcomes have been reported in 10-20 % of patients. In the Czech Republic, the average case fatality rate has been 10% since 1993 and has not decreased over the years under review. 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 rates and risk of 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 proportion of causative serogroups has been changing over the years. After about 20 years of dominance of serogroup B, the proportion of serogroups B and C has been levelling off in recent years. The occurrence of IMD caused by N. *meningitidis* W and Y, which cause the highest case fatality rates of all meningococci in the Czech Republic (and worldwide), is also recorded every year. The population groups at highest risk for IMD in the Czech Republic are the individuals from the most affected age groups, those with some health conditions in selected risk groups, those living in large collectives, selected categories of health professionals, and travellers to high incidence countries.

Options of vaccination against invasive meningococcal disease

The European Medicines Agency (EMA) has authorised three 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 (MenB4C and MenB-FHbp vaccines). MenACWY vaccine has proved protective not only against IMD caused by *N.meningitidis* ofserogroups A, C, W and Y, but also against their carriage. In the case of MenB vaccines, there is no evidence of a reduction in carriage, therefore individual prevention of IMD by vaccination plays an effective role. All these vaccines are licensed for use in both children and adults. MenACWY-TT (Nimenrix) is indicated for use in children from the age of six weeks,

MenACWY-CRM (Menveo) vaccine from the age of two years, and MenACWY-TT (MenQuadfi) from the age of 12 months. MenB-4C (Bexsero) vaccine can be administered from 2 months of age and MenB-FHbp (Trumenba) from 10 years of age. 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 MenACWY and Men B vaccines. To maintain long-term immunity, revaccination is recommended in some cases.

Antibody testing before nor after vaccination with MenACWY and MenB vaccines is not recommended.

Vaccination of infants and young children

1. Vaccination with MenB-4C vaccine is recommended for:

Infants and young children aged 2-59 months,

- Basic vaccination schedule: 2+1 starting at 2 months of age, with an interval between doses of 2 months (at least 8 weeks apart) and administration of a booster dose at 12-15 months of age, at least 6 months after the second dose.

When the schedule is initiated (at least one dose administered) before the age of 1 year, the vaccination is fully covered by public health insurance. For serious medical reasons, it may be paid for by the public health insurance even later. The Czech Vaccinology Society of the J. E. Purkyně Czech Medical Association recommends starting vaccination at the earliest possible age, i.e. at 2 months, in order to ensure the earliest possible protection. The recommendation for early initiation of vaccination is also valid for preterm infants, including the use of the 2+1 dose schedule, similar to that for full-term infants. The peak incidence of IMD caused by *N. menigitidis* serogroup B in the Czech Republic is around 5 months of age.

Capture vaccination schedules:

- 6-11 months of age: 2 doses 2 months apart (minimum 8 weeks) with a booster dose given at 2 years of age, at least 8 weeks after the previous (second) dose;
- 12-23 months of age: 2 doses 2 months apart (minimum 8 weeks) with a booster dose administered 12 months after the second dose;
- 24-59 months of age: 2 doses 2 months apart (minimum 4 weeks) without a booster dose.

The vaccine can be administered simultaneously with any other vaccine. Prophylactic administration of antipyretics at the time of vaccination and shortly after vaccination may reduce the incidence and intensity of post-vaccination febrile reactions and is particularly useful when co-administering multiple vaccines.

2. Vaccination with MenACWY vaccines is recommended for:

Toddlers aged 12-23 months,

- Basic vaccination schedule: 1 dose of MenACWY-TT vaccine. Administration of 1 dose of the vaccine at this age is fully covered by public health insurance.

With the agreement of the parent and the health care provider, vaccination with MenACWY-TT vaccine, which is not covered by public health insurance, may be considered for:

Infants aged 6 weeks to 5 months,

- Basic vaccination schedule: 2 doses of MenACWY-TT vaccine 2 months apart (minimum 8 weeks) with a booster dose given at 12 months of age, no earlier than 8 weeks after the previous (second) dose.

Infants aged 6-11 months,

- Basic vaccination schedule: 1 dose of MenACWY-TT vaccine with a booster dose administered at 12 months of age, no earlier than 8 weeks after the previous (first) dose. Infants and young children aged 6-11 months,

Capture vaccination schedule:

- 24-59 months of age: 1 dose of MenACWY-TT or MenACWY-CRM vaccine.

Adolescent and young adults vaccination

Vaccination is recommended for:

All adolescents aged 14-19 years with any available MenB and MenACWY vaccine,

- Basic schedule of MenB vaccine: two doses at least 1 month apart for the MenB-4C vaccine and 6 months apart for MenB-FHbp vaccine,
- Basic schedule of the MenACWY: one dose.

When starting MenB vaccine schedule at the age interval from 14 to 16 years, vaccination is fully covered by public health insurance. Reimbursement also applies to vaccination with MenACWY vaccine at this age. The same vaccine must be used for both doses of MenB; the vaccines are not interchangeable.

MenB and MenACWY vaccines can be administered simultaneously and with any other vaccine indicated in adolescence.

Revaccination

In case of vaccination with MenACWY or MenC vaccines at any time before the 14th birthday, to ensure protection throughout the whole risk period 14-19 years, we recommend a single dose of the vaccine no earlier than 5 years after the previous dose and no earlier than at 14 years of age. MenACWY-TT vaccine (Nimenrix) has been shown to persist immune response for up to 10 years.

There are currently insufficient data for revaccination with MenB vaccines at adolescent age in the group of previously vaccinated children. For the MenB-4C vaccine (Bexsero), data are available demonstrating persistence of antibody response of 7.5 years after the baseline vaccination, but after 4 years there is a significant decline and sufficient protection is restored by administration of 1 booster dose. In case of immunization with MenB vaccine at any time before the 14th birthday, we recommend a booster dose of the vaccine no earlier than 5 years after the previous dose and no earlier than at the age of 14. If adolescents who have been previously vaccinated with MenB-4C vaccine are to be immunized with MenB-FHbp (Trumenba) vaccine, the full schedule (2 doses) should be administered. The two available vaccines are not mutually interchangeable.

Vaccination of groups with high risk of IMD

1. Medical indications

Vaccination with both MenB and MenACWY vaccines is recommended for people of all ages for the following medical indications:

a) impaired or lost splenic function (hyposplenism/asplenism); in the case of planned splenectomy, vaccination should be performed at least 14 days prior to the procedure,

b) autologous and allogeneic haemopoietic stem cell transplantation,

c) primary or secondary immunodeficiency or anticipated immunodeficiency,

d) terminal complement deficiency,

e) history of bacterial meningitis or sepsis,

f) prior to initiation of eculizumab therapy.

Vaccination schedule for groups with high risk of IMD with the medical indication
MenACWY vaccine:

- Basic vaccination schedule: 2 doses of MenACWY vaccine 2 months apart, and in case of persistent risk, one dose every 5 years is recommended.

MenB vaccines:

- Basic vaccination schedule: 2 doses of the MenB-4C vaccine 1-month apart or 3 doses of MenB-FHbp vaccine at 1- and 5-month intervals between doses. If the risk is persistent, re-vaccination 1 year after the last dose and then every 2-3 years with one dose is recommended.

For these medical indications, vaccination with both MenB and MenACWY vaccines is fully covered by public health insurance regardless of age at the time of vaccination.

2. Other indications

Vaccination with both MenB and MenACWY vaccines is recommended, regardless of age, for the following individuals who are at increased risk of IMD:

a) Travellers or persons planning permanent residence in countries with hyperendemic or epidemic IMD,

b) persons at occupational risk of IMD (medical personnel caring for patients with IMD, laboratory workers working with IMD agents),

c) persons in an IMD outbreak (choice of vaccine depending on the serogroup active in the outbreak),

d) persons in a new team, taking into account the individual risk assessment.

Approved by the Committee of the Czech Vaccinology Society of the J. E. Purkyně Czech Medical Association on March 6, 2023
Approved by the Committee of the Society for Epidemiology and Microbiology of the J. E. Purkyně Czech Medical Association on March 6, 2023

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