UK Health Security Agency

Changes to the UK vaccine schedule

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UK Health Security Agency

Changes to the Childhood schedule

Current schedule to 30th June 2025

- Menitorix® vaccine provides protection against *Haemophilus influenzae type b* (Hib) and invasive capsular group C meningococcal (MenC) disease
  - currently given at 12 months of age
  - 4th Hib-containing vaccine
  - prior 3 doses of Hib antigen are given as a component of the hexavalent vaccine (DTaP/IPV/Hib/HepB) administered at 8, 12 and 16 weeks of age
  - currently the only remaining dose of MenC vaccine in the childhood schedule

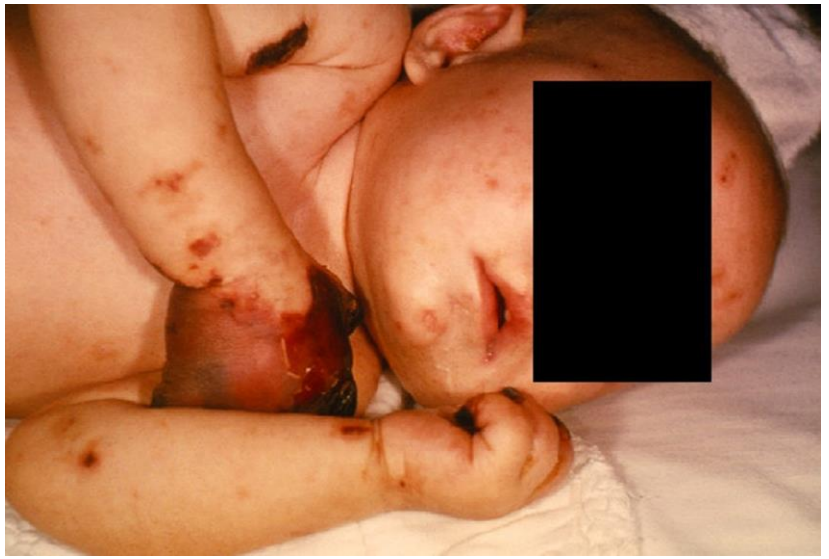
- manufacturing of Hib/MenC (Menitorix®) vaccine is to be discontinued
  - decision made by the manufacturer (GSK)
  - as this is the only Hib/MenC vaccine available, changes to the routine infant schedule are necessary
  - the UKHSA estimated that the central stock of this vaccine will be depleted by mid-2025

Group C meningococcal vaccine

- the **MenC vaccination programme, introduced in 1999,** led to a significant reduction in the number of cases of invasive meningococcal C disease
- the **adolescent MenACWY programme, commenced in 2015**, has further reduced the incidence of meningococcal C disease (as well as cases of meningococcal W disease)
- further significant decline in the spread and detection of invasive meningococcal disease (IMD) was seen because of the implementation of social distancing and lockdown measures as part of the emergency response to the COVID-19 pandemic
- modelling work found that indirect protection against MenC disease in infants is sustained by the adolescent MenACWY programme
- over time the adolescent vaccination programme is expected to reduce carriage prevalence of groups C, W and Y to near elimination levels (group A carriage has already been almost undetectable for many years in the UK)
- due to the reduction in carriage prevalence of these meningococcal serogroups, it is predicted that by the time Menitorix® is no longer available there will be very few IMD cases caused by meningococcus groups A, C, W and Y each year, and therefore very few cases which could be prevented by a MenC-containing vaccine in infancy
- it is therefore very unlikely that an infant or toddler MenACWY immunisation campaign would be cost effective

Hib disease and vaccination

- prior to the introduction of the *Haemophilus influenzae type B (Hib)* vaccine, about 1 in 600 children developed Hib disease prior to their 5th birthday
- the most common presentation of invasive Hib disease was meningitis (60% of all cases), but it also presented as epiglottitis (15%), bacteraemia (10%), septic arthritis, osteomyelitis, cellulitis, pneumonia and pericarditis
- before Hib vaccine was introduced, 4% of pre-school children carried the Hib organism - after the vaccine was introduced, carriage rates fell below the level of detection
- as a result, since the introduction of Hib immunisation in the UK in 1992, disease incidence has fallen in all age groups, not just in those who have been vaccinated
- the Hib vaccination programme has been highly successful at greatly reducing the incidence of Hib disease
- however, as immunity following a 3-dose primary course of Hib vaccination in infancy wanes, a 4th (booster) dose during the second year of life is needed to continue to prevent transmission in the community and maintain herd immunity



JCVI advice

The JCVI has advised that the following changes should come into effect nationally once the current supply of Menitorix® vaccine has been exhausted:

- an additional dose of a Hib-containing multivalent vaccine (such as the hexavalent DTaP/IPV/Hib/HepB vaccine which is given in infancy) should be administered at age 18 months.
- this replaces the Hib component of the Hib/MenC (Menitorix) given at 12 months
- this requires the introduction of a new appointment slot at 18 months of age
- the age 18 months appointment provides an opportunity for the second dose of MMR vaccine (MMR2) to be brought forward from 3 years 4 months to 18 months of age

Infants eligible for the selective Hepatitis B vaccination programme

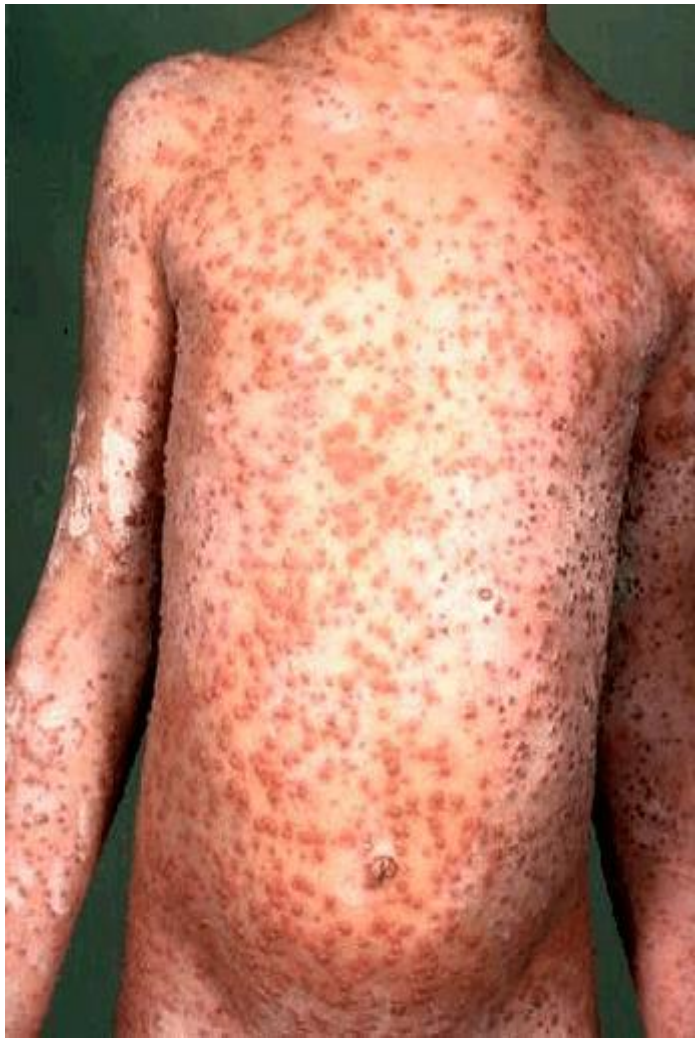
- as a result of the introduction of a 4th hexavalent vaccine at 18 months from 1 January 2026, JCVI have also recommended a change to the selective hepatitis B vaccination programme for children born to mothers who are hepatitis B positive
- since hepatitis B is a component of the 18-month hexavalent vaccine dose, for children on this pathway born from 1 July 2024, the monovalent hepatitis B vaccine at 1 year will no longer be necessary

Children born on/after 01/07/24 who are on the selective hepatitis B vaccination programme will no longer be offered a monovalent vaccine at 12 months of age as they will now receive a further dose of hepatitis B vaccine as part of the hexavalent vaccine being offered at 18 months.

However, it is important that these children are tested for infection using the Dried Blood Spot (DBS) test. DBS testing can be performed at their 12- or 18-month vaccine appointments or any time in between.

Varicella (Chickenpox) vaccination (policy decision awaited)

- currently no universal varicella vaccination programme in the UK
- Vaccine recommended for certain groups e.g. healthcare workers with patient contact and household contacts of immunocompromised individuals
- most cases of varicella infection are mild, although children are unwell and usually have 5 or more days off school or nursery (parents may also need to take time off work)
- complications include bacterial infection of skin lesions (including group A streptococcus) and in rare cases, encephalitis, pneumonitis and stroke
- often more serious in very young infants (under 4 weeks of age) and adults, in particular in pregnancy, and in adults who are immunosuppressed



Varicella (Chickenpox) vaccination (final policy decision awaited)

- JCVI advised a two-dose varicella schedule, with vaccination being offered at 12 and 18 months of age using the combined MMRV (measles, mumps, rubella and varicella) vaccine
- a catch-up programme should also be initiated following the implementation of the programme to prevent a gap in immunity
- varicella vaccination is included in the routine vaccine schedules of several countries either as a 2-dose or single-dose strategy including the USA, Canada, Australia and Germany
- more information at JCVI statement on a childhood varicella (chickenpox) vaccination programme

Maximising the benefit of MenB (Bexsero) vaccination

8 weeks
- DTaP/IPV/Hib/HepB
- MenB
- Rotavirus (oral)

12 weeks
- DTaP/IPV/Hib/HepB
- PCV
- Rotavirus (oral)

16 weeks
- DTaP/IPV/Hib/HepB
- MenB

1st birthday
- MenB
- PCV
- MMR

- MenB vaccine programme → large & significant declines in MenB cases in vaccine-eligible children

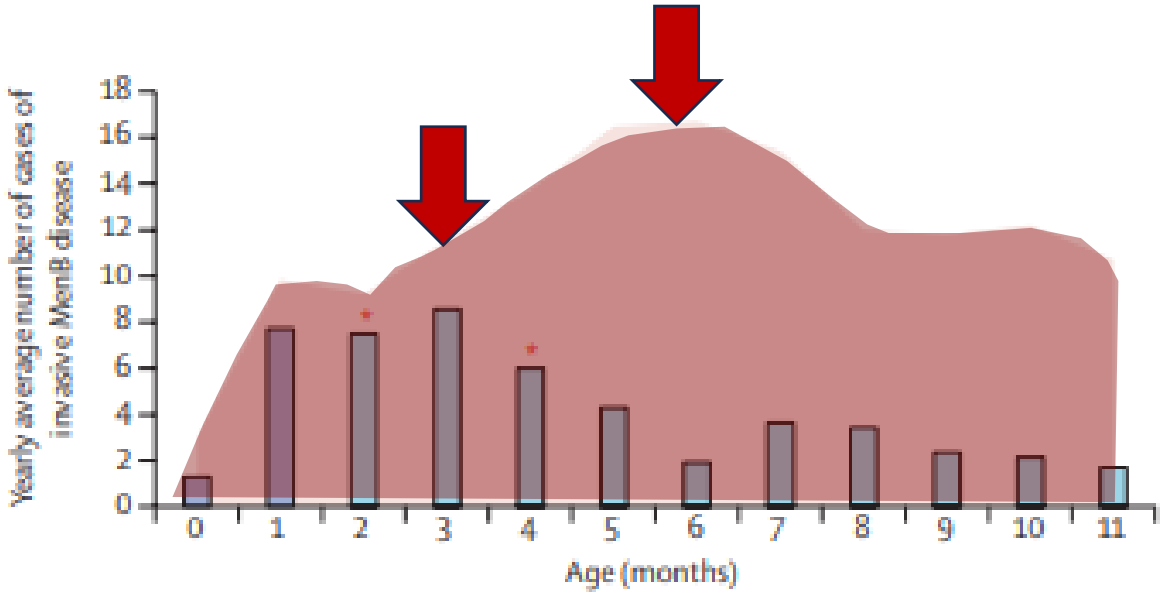
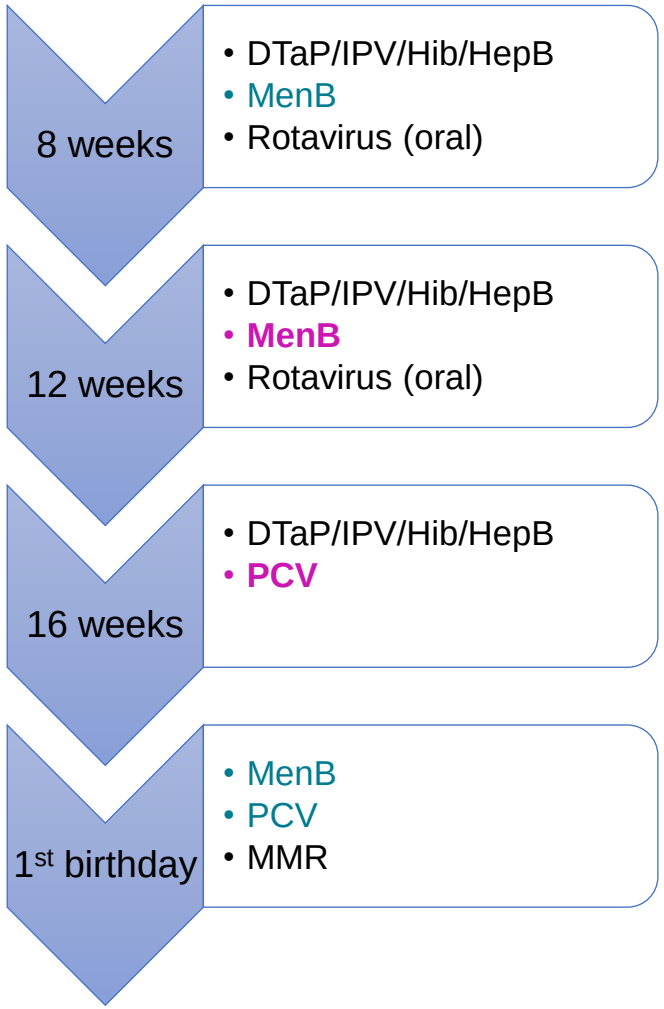


Figure: **Yearly average of invasive MenB disease cases in England, pre-vaccine implementation (Sept 1, 2010, to March 31, 2015) and post-vaccine implementation (Sept 1, 2015, to March 31, 2020)**

MenB=meningococcal serogroup B. *Ineligible because of age younger than 8 weeks or because they were born before May 1, 2015.

Mensah AA, Campbell H, Clark SA, Ribeiro S, Lucidarme J, Bai X, Borrow R, Ladhani SN. Outcomes of meningococcal serogroup B disease in children after implementation of routine infant 4CMenB vaccination in England: an active, prospective, national surveillance study. Lancet Child Adolesc Health. 2023 Mar;7(3):190-198. doi: 10.1016/S2352-4642(22)00379-0. Epub 2023 Jan 31. PMID: 36736341.

Maximising the benefit of MenB (Bexsero) vaccination



- UKHSA study found 8- and 12-week schedule had potential to offer an additional dose ➔ 35/58 (58.6%) infants with MenB disease aged 10 to 18 weeks
- Lion MenB study (St Georges1) ➔ accelerated MenB at 8,12 weeks + 1 year and at 8,16 weeks + 1 year with PCV vaccine at 12 weeks + 1 year or 16 weeks + 1 year
- provides earlier direct protection against MenB and does not compromise protection against invasive pneumococcal disease
- No reactogenicity concerns

[1] With thanks to Paul Heath and Natasha Thorn St Georges Vaccine Institute

Summary of the changes to the routine childhood schedule from 1 July 2025

From	Proposed changes
01 July 2025	First PCV13 dose moved from 12 weeks of age to 16 weeks of age. Second MenB dose brought forward from 16 weeks of age to 12 weeks of age Cessation of routine Hib/MenC (Menitorix) offer to those turning 12 months Removal of monovalent HepB dose at 1 year for infants on the selective HepB pathway schedule born on or after 01/07/24
01 January 2026	Introduction of an additional (4th dose) of DTaP/IPV/Hib/HepB (hexavalent) vaccine at a new routine appointment at 18 months for children born on or after 01/07/24
01 January 2026	Second MMR dose moved from 3 years 4 months to the new routine 18-month appointment Possible introduction of varicella

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Mpox vaccination programme

Background information

- Mpox is a disease caused by infection with the monkeypox virus. Monkeypox virus (MPXV) is related to but distinct from the viruses that cause smallpox (variola virus) and cowpox (vaccinia virus)
- there are two genetic groups of MPXV: Clade I (previously known as Central African or Congo Basin Clade) and Clade II (previously known as West African Clade)
- between 2018 and 2022 the UK experienced a small number of Clade II cases, all associated with travel to or from countries in west Africa where mpox is endemic and in 2022, a Clade II outbreak in England mainly affecting gay, bisexual and other men who have sex with men (GBMSM), resulted in over 3,500 lab confirmed cases in the UK, predominantly in London
- in Nov 2023 JCVI recommended that a routine vaccination programme for protection of GBMSM at highest risk of exposure to mpox, offered through sexual health services, should be developed to prevent future outbreaks
- as vaccine supply becomes available, the routine mpox vaccination programme in sexual health services across the UK is being stood up

Background information continued

- in August 2024, a public health emergency of internal concern (PHEIC) was declared by WHO following identification of a new Clade Ib variant, initially in the Democratic Republic of Congo, which has spread across the African region with cases seen in areas and demographics (primarily children) not previously seen. Cases have also been reported outside of Africa. To date (Dec 24), all Clade I cases reported outside of Africa have been associated with travel to affected areas in Africa

- separate to a routine vaccination programme offered through sexual health services for GBMSM at highest risk of exposure to mpox, identification of an imported case of MPXV Clade I or a cluster/outbreak of mpox may mean Incident Management Teams and/or Health Protection Teams identify individuals or groups who should also be offered vaccination

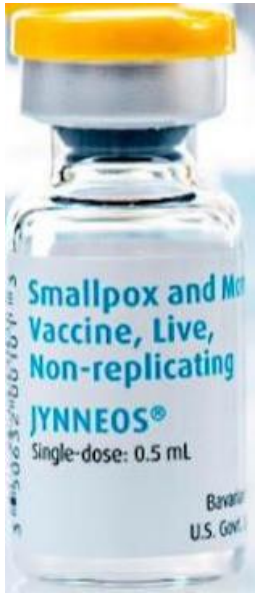
- the third-generation smallpox vaccine, Modified vaccinia Ankara (MVA-BN), is licensed for use against mpox (both Clade I and Clade II)

- MVA-BN vaccine does not contain smallpox virus and cannot cause/spread smallpox disease or mpox

- MVA-BN is administered subcutaneously or off-label intramuscularly; smaller doses (fractional dosing) can also be effectively administered via the intradermal route to minimise wastage and during periods of supply constraints

MVA-BN vaccine

- product name: Imvanex® (European brand name) or Jynneos® (US brand name)
- vaccine type: live modified vaccinia Ankara (MVA) vaccine
- manufacturer: Bavarian Nordic (BN)
- pharmaceutical form: suspension for injection (light yellow to pale white, milky suspension)
- route and volume: 0.5ml intramuscular (IM) or subcutaneous (SC). Fractional doses of 0.1ml intradermally (ID) as per the Green Book chapter 29
- presentation: 0.5ml vial
- storage: after thawing, store for up to 8 weeks at 2°C to 8°C in the original package to protect from light



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4CMenB: meningococcal vaccine and protection against gonorrhoea

Background

- there is currently no licensed vaccine against *Neisseria gonorrhoeae,* the bacterium which causes gonorrhoea
- although clinically different, the bacterium which causes gonorrhoea (Neisseria gonorrhoeae) is very closely genetically related to the bacterium which causes meningococcal disease (*Neisseria meningitidis*)
- following a group B meningococcal disease outbreak in New Zealand in 2004, a MenB vaccine (MeNZB) was offered universally to children and young people. Post-implementation surveillance identified that as well as a decline in MenB infection, there was also a decline in gonorrhoea rates in adolescents and young adults who were eligible for the vaccine, suggesting that it may have had a protective effect against *Neisseria gonorrhoeae*

JCVI advice

in November 2023, JCVI considered the evidence and advised that:

- a targeted programme should be initiated using the 4CMenB vaccine for the prevention of gonorrhoea in those who are at greatest risk of infection
- the programme should be offered opportunistically through sexual health services
- as protection against gonorrhoea isn’t currently a licensed indication for 4CMenB vaccine, this advice is based on off-label use of the vaccine

4CMenB vaccine: Bexsero®

Bexsero®:

- is the only 4CMenB vaccine available for use in the UK
- is licensed for use against meningococcal B meaning use in the gonorrhoea vaccination programme is off label
- is centrally supplied through ImmForm in packs of one or ten

It is important that immunisers familiarise themselves with the vaccine and its product information to avoid administration errors

Image courtesy of GSK

Gonorrhoea vaccination eligibility

GBMSM who are increased risk of gonorrhoea infection attending a sexual health clinic. This group includes those:

- with bacterial sexually transmitted infection (such as gonorrhoea, chlamydia or syphilis) in the previous 12 months
- reporting sex with 5+ sexual partners in the previous 3 months

whilst gonorrhoea incidence remains highest in the eligible GBMSM group as defined above, sexual health clinical professionals may perform an individual risk assessment and offer 4CMenB to selected individuals with equivalent risk, such as sex workers, irrespective of their gender or sexual orientation

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Horizon scanning