

# Meningococcal Group B vaccine (Bexsero®) for the prevention of gonorrhoea

#### **Key Summary Points**

- Gonorrhoea rates are highest in people under 25 years of age and GBMSM populations.
- Bexsero® vaccine used for the prevention of gonorrhoea is an off-label use.
- Vaccination has an effectiveness of 32-42% against gonorrhoea infection. The main benefit is at a community level, with a significant reduction in overall cases.
- Vaccination should use a targeted, opportunistic approach focusing on those at highest risk (largely certain GBMSM groups, and some others with equivalent risk – see below).
- Vaccination course is 2 doses given intramuscularly, at least 4 weeks apart.

## **General information**

- Gonorrhoea is caused by *Neisseria gonorrhoeae*, a Gram-negative diplococcus bacterium, and is the second most common STI in Scotland and the UK.
- In Scotland, higher rates of gonorrhoea are seen in people under the age of 25, and in GBMSM.
- Natural infection does not induce protective immunity as the bacteria is very effective at evading the human immune response. Therefore, re-infections are common.
- A recent history of gonorrhoea infection is a reliable predictor of future reinfection with gonorrhoea, or other STIs including HIV.
- Gonorrhoea causes significant morbidity and can result in complications such as pelvic inflammatory disease, ectopic pregnancy, infertility, prostatitis, epididymo-orchitis, and disseminated systemic infection.
- Increased resistance to most antibiotics used to treat gonorrhoea has been reported worldwide. Extensively resistant strains have been reported, which are resistant to multiple antibiotic classes.
- Ceftriaxone resistance remains rare in Scotland, with only 3 cases being detected in 2024. All cases had links to the Asia-Pacific region, where ceftriaxone resistance is high.

#### **Vaccine information**

- There is no licensed vaccination for gonorrhoea. Efforts to develop one have proven difficult due to various reasons (absence of protection, high antigenic variability allowing the bacterium to evade the human immune response, and lack of suitable animal models).
- The 4CMenB vaccine is a quadrivalent meningococcal serogroup B vaccine used to protect against invasive meningococcal disease caused by *Neisseria* meningitidis serogroup B. It contains 3 main *Neisseria meningitidis* proteins (Neisseria heparin binding antigen - NHBA, Neisserial adhesion A – NadA,



factor H binding protein – fHbp) and meningococcal serogroup B outer membrane vesicles (OMVs).

- The 4CMenB vaccine has been recommended by the Joint Committee on Vaccination and Immunisation (JCVI) for prevention of gonorrhoea, targeting individuals at greatest risk of infection. This is because Neisseria meningitidis and Neisseria gonorrhoeae are closely genetically related (with 80-90% sequence homology) which gives the potential for cross-protection from OMV containing meningococcal B vaccines against Neisseria gonorrhoeae.
- Using the 4CMenB vaccine for gonorrhoea prevention remains an off-license use of the vaccine.
- The 4CMenB vaccine does not contain live organisms and so cannot cause the disease it offers protection against.
- The only licensed vaccine in the UK currently is Bexsero®, manufactured by GSK.
- Various real-world studies have shown that OMV containing vaccines in particular (mainly the 4CMenB vaccine) have an effectiveness of 32-42% against gonorrhoea, with a reduction in cases following administration of the vaccine.
- It should be noted that the duration of protection after vaccination against gonorrhoea remains unknown.
- Vaccination will not completely eliminate the possibility of infection with gonorrhoea. It should be highlighted to individuals that although it would reduce the risk of infection, the main benefit of the vaccination programme is expected to be at a community level, with a significant reduction in overall cases of gonorrhoea, and helping to tackle increasing levels of antibiotic-resistant strains.
- There is no evidence that 4CMenB vaccination clears acute gonococcal infection. Acute infections should still be managed as per BASHH guidelines and local protocols.

#### Eligibility criteria

The JCVI recommend a targeted, opportunistic vaccination programme aimed at those at higher risk of gonorrhoea infection. This includes:

- GBMSM at increased risk:
  - o Those diagnosed with gonorrhoea in sexual health clinics
  - Those with a bacterial STI in the previous 12 months
  - o Those reporting at least 5 sexual partners in the previous 3 months
- Individuals deemed at similar increased risk as GBMSM listed above after individual risk assessment performed by sexual health clinical professionals (may include, but not limited to, transgender women, gender diverse people assigned male at birth, and transactional sex workers engaging in condomless sex). The number of these individuals is expected to be small.



#### **Exclusion criteria**

- Anyone with a confirmed anaphylactic reaction to a previous dose of meningococcal group B vaccine.
- Anyone with a confirmed anaphylactic reaction to any constituent or excipient of meningococcal group B vaccine.
- Individuals who have previously received 2 doses of 4CMenB either as part of primary immunisation or due to higher risk of meningococcal disease.
- Those with a history of severe reaction to latex where the vaccine is not latex free (including syringe, tip, and plunger).
- Those with acute severe febrile illness postpone immunisation until fully recovered.

#### **Dosage & Schedule**

Bexsero® 0.5mL IM (or SC in specific circumstances – see below)
A total course of 2 doses should be administered at least 4 weeks apart.

- There is no maximum time interval limit between vaccination doses so the course does <u>not</u> need to be restarted <u>at any point</u>. The second dose can be given opportunistically at the individual's next attendance.
- The vaccination can be administered at the same time as treatment is given for gonococcal infection.
- There are no recommendations for booster doses.

#### <u>Administration</u>

- 4CMenB vaccination can be co-administered alongside, or at any interval before or after, all other vaccines routinely offered in sexual health clinics.
- Vaccine should be administered intramuscularly into the upper arm or anterolateral thigh.
- Deep subcutaneous injection should be given to individuals with known bleeding disorders, to reduce the risk of bleeding.
- It is recommended to give 4CMenB in a separate site from other vaccines, to enable monitoring of local reactions. However, if separate vaccines are given in the same limb, they should be administered at least 2.5cm apart.
- There is no data on immunogenicity or protection offered when 4CMenB is administered during active or recent gonorrhoea infection. Acute infection may affect immune response to vaccination as natural infection does not confer protection against reinfection. However, the Green Book advises that 4CMenB vaccination can be given to individuals at the time of gonorrhoea testing and/or treatment, in order to avoid delaying potential protection to those at highest risk who may be re-infected before their next attendance.
- The most common adverse reactions are pain at injection site, malaise and headache. Anaphylaxis is possible but rare.



## Record keeping and documentation

- All individuals should be offered a Patient Information Leaflet. NHS Informinformation and PIL.
- If individual declines vaccination, record reason on NaSH.
- If individual accepts vaccination:
  - Prescribe (or under PGD) on NaSH, including dose number and site of administration
  - Advise the patient they will be eligible to receive their second dose of the vaccine at their next routine sexual health appointment (such as a PrEP review), provided it is more than 4 weeks since the first dose. Reassure the patient this can be given anytime after the 4 weeks so they do not need to be seen sooner than their next routine appointment.

#### References

<u>UKHSA Guidance - Introduction of new routine mpox and 4CMenB for gonorrhoea vaccination programmes letter</u> (accessed online June 2025)

<u>UKHSA Guidance - Annexe A: information and resources for healthcare professionals and commissioners to support implementation (accessed online June 2025)</u>

<u>UKHSA Independent report - JCVI advice on the use of meningococcal B vaccination</u> for the prevention of gonorrhoea (accessed online June 2025)

Green Book - Gonorrhoea Chapter (accessed online June 2025)

<u>CMO Scotland Letter - Gonorrhoea Vaccination Programme 2025</u> (accessed online July 2025)

Public Health Scotland - Sexually transmitted infections in Scotland 2015-2024 (accessed online July 2025)



# Appendix 1: Information for switchboard/admin staff

- If individuals call up requesting vaccination, please advise the following:
  - the vaccination programme is a targeted approach, focusing on those at highest risk of infection
  - those who have been identified in this highest risk group will be receiving SMS correspondence from ourselves, with details of how to book an appointment for vaccination, or will be offered the vaccine at their next routine sexual health appointment
  - they can be directed to the Sandyford website for further information if required.



## **Appendix 2: Information for vaccinator staff**

- Please follow GC vaccine PH clinic SOP.
- Please ensure you are familiar with the content of the latest version of the 'Meningococcal Group B vaccine (Bexsero®) to prevent gonorrhoea' PGD for use in sexual health services, and have signed this.
- Confirm correct individual by clarifying name and date of birth.
- Offer patient information leaflet (PIL), which is available from staff base in Sandyford Central.
- Ensure correct Meningococcal Group B vaccine (Bexsero®) and BLUE intramuscular needle are available, and in date.
- Make use of Bexsero® information for vaccine consent form during consultation, ensuring patient understands information and gives consent for vaccination.
- Document consultation into clinical notes section of individual's record on NaSH
- Document correct Bexsero® preparation and dose number using prescribing special form on NaSH. Select yes for given under PGD, unless you are a prescriber.
- Document administration of correct Bexsero® preparation using the administration special form in NaSH, specifying the batch number, site of administration, and expiry date of the vaccine.
- Provide individual with relevant aftercare information.
- Mark individual as complete on NaSH.
- Advise the patient they will be eligible to receive their second dose of the
  vaccine at their next routine sexual health appointment (such as a PrEP
  review), provided it is more than 4 weeks since the first dose. Reassure
  the patient this can be given anytime after the 4 weeks so they do not
  need to be seen sooner than their next routine appointment.
- If patient asks about other vaccinations please direct them to reception to discuss this.



## Appendix 3: Information for clinical staff offering opportunistic vaccination

- Ensure individual meets eligibility criteria for vaccination listed above. Please note, individuals receiving testing or treatment for gonorrhoea can be offered their first vaccination at the same appointment, if they meet the eligibility criteria.
- Please ensure you are familiar with the content of the latest version of the 'Meningococcal Group B vaccine (Bexsero®) to prevent gonorrhoea' PGD for use in sexual health services, and have signed this, if not a prescriber.
- Offer patient information leaflet (PIL).
- Make use of Bexsero® information for vaccine consent form during consultation, ensuring patient understands information and gives consent for vaccination.
- Document consultation into clinical notes section of individual's record on NaSH
- Document correct Bexsero® preparation and dose number using prescribing special form on NaSH. Select yes for given under PGD, unless you are a prescriber.
- Document administration of correct Bexsero® preparation using the administration special form in NaSH, specifying the batch number, site of administration, and expiry date of the vaccine.
- Provide individual with relevant aftercare information.
- Mark individual as complete on NaSH.
- Advise the patient they will be eligible to receive their second dose of the
  vaccine at their next routine sexual health appointment (such as a PrEP
  review), provided it is more than 4 weeks since the first dose. Reassure
  the patient this can be given anytime after the 4 weeks so they do not
  need to be seen sooner than their next routine appointment.



#### Appendix 4: Information for Brownlee staff offering opportunistic vaccination

- Ensure individual meets eligibility criteria for vaccination listed above.
- Please ensure you are familiar with the content of the latest version of the 'Meningococcal Group B vaccine (Bexsero®) to prevent gonorrhoea' PGD for use in sexual health services, and have signed this, if not a prescriber.
- Offer patient information leaflet (PIL).
- Make use of Bexsero® information for vaccine consent form during consultation, ensuring patient understands information and gives consent for vaccination.
- Document consultation into clinical notes section of individual's record on NaSH.
- Document correct Bexsero® preparation and dose number using prescribing special form on NaSH. Select yes for given under PGD, unless you are a prescriber.
- Document administration of correct Bexsero® preparation using the administration special form in NaSH, specifying the batch number, site of administration, and expiry date of the vaccine.
- Provide individual with relevant aftercare information.
- Advise the patient they will be eligible to receive their second dose of the
  vaccine at their next routine appointment, provided it is more than 4
  weeks since the first dose. Reassure the patient this can be given anytime
  after the 4 weeks so they do not need to be seen sooner than their next
  routine appointment.