

Dear Colleague,

Gonorrhoea Vaccination Programme 2025

We are writing to advise you of a new targeted vaccination programme for the prevention of gonorrhoea in those at greatest risk of infection.

The programme uses a 2 dose schedule of the 4CMenB vaccine (Bexsero®). This vaccine is currently used to provide protection against meningococcal group B infection in the childhood immunisation programme.

As protection against gonorrhoea isn't currently a licensed indication for 4CMenB vaccine, the JCVI advice for this programme is based on off-label use of vaccine.

The programme will offer vaccination, through sexual health services, to those eligible, , from 1 August 2025.

Key Objectives

The aims of the gonorrhoea vaccination programme are:

- Reduce gonorrhoea transmission and (re)infection rates in those at the highest risk.
- Help address rising antimicrobial resistance in Neisseria meningitis isolates (by virtue of reduced number of infections requiring antibiotic treatment).
- Improve health equity among the disproportionately affected populations.

Eligibility

The programme should primarily target high risk Gay, Bisexual and other Men who have Sex with Men (GBMSM) attending sexual health clinics, who are at greatest risk of gonorrhoea.

High risk includes, but is not limited to:

- GBMSM with a bacterial sexually transmitted infection (STI) in the previous 12 months and/or;
- GBMSM reporting high risk sexual behaviours with multiple sexual partners.

From Chief Medical Officer Chief Pharmaceutical Officer

Professor Sir Gregor Smith Professor Alison Strath

DATE: 24/06/2025

SGHD/CMO (2025) 10

Addresses

For action Chief Executives, NHS Boards Medical Directors, NHS Boards Nurse Directors, NHS Boards GUM and Sexual health services Chief Officers of Integration Authorities Directors of Pharmacy Directors of Public Health Immunisation Co-ordinators **CPHMs**

For information Chairs, NHS Boards Infectious Disease Consultants Consultant Physicians General practitioners Public Health Scotland Chief Executive, Public Health Scotland, **NHS 24**

Community Pharmacy Scotland

Further Enquiries

Vaccine Issues **Scottish Government** ImmunisationPolicy@gov.scot

Medical Issues Senior Medical Officer St Andrew's House ImmunisationPolicy@gov.scot

PGD/Pharmaceutical Barry Melia Public Health Scotland Barry.Melia@phs.scot

Vaccine Supply Issues nss.vaccineenquiries@nhs.scot





Whilst gonorrhoea incidence remains the highest in the eligible GBMSM group as defined above, sexual health clinical professionals may perform individual risk assessment and consider the offer of 4CMenB to the small numbers of individuals with an incidence of gonorrhoea approaching that in the eligible GBMSM group. The number of eligible non-GBMSM is anticipated to be very small.

JCVI Advice and Vaccine Effectiveness

In November 2023, the JCVI advised the introduction of a targeted gonorrhoea vaccination programme using the 4CMenB (Bexsero®) vaccine, based on evidence of crossprotection.

Real-world data from multiple countries estimate vaccine effectiveness of approximately 33–47% for 4CMenB against gonorrhoea in high-risk groups. Although 4CMenB is only currently licensed for meningococcal B disease, this is considered an appropriate off-label use. The JCVI considers a programme targeting high risk GBMSM individuals, as well as those who clinicians assess to be at equivalent risk. to be cost effective, and should reduce the overall number of cases of gonorrhoea.

Delivery Model

Vaccination will be delivered through specialist sexual health services which are best placed to identify those eligible for vaccination, and to discuss with the patient the risks and benefits of the programme both to themselves and the wider community.

The first dose should be discussed offered and opportunistically when an eligible patient presents in clinic.

Background

The number of gonorrhoea infections has been rising over recent years across the UK, and it is now the second most common bacterial STI in Scotland. Gonorrhoea can cause significant morbidity, and serious longer term complications in some individuals if untreated. These include pelvic inflammatory diseases and, in rare cases, disseminated systemic infection. Gonorrhoea currently remains a public health concern globally. Having had one infection is the most likely indicator of risk of subsequent infection as prior infection provides no ongoing protection or immunity.

The majority of cases of gonorrhoea in Scotland over the most recent ten-year period are in men, notably gay, bisexual, and other men who have sex with men (GBMSM).





In 2023, there were 5,999 diagnoses of gonorrhoea in Scotland. This was higher than in 2022 and represents a 6% increase.

Neisseria gonorrhoeae, the bacterium which causes gonorrhoea, has developed resistance to every class of antibiotic used for treatment, with cephalosporins as the last remaining class of antibiotics available for use as empirical monotherapy. Whilst there has been no increase in the number of ceftriaxone-resistant gonorrhoea cases in Scotland, there are an increasing number of cases being detected in England. Most cases with ceftriaxone-resistant N. gonorrhoeae are linked to international travel, particularly to and from the Asia-Pacific region, where ceftriaxone resistance is reported in up to 30% of isolates in some countries.

Action

Health Boards are requested to action this letter and ensure that their sexual health services, vaccination teams, public health and primary and secondary care colleagues are aware of the new programme. Health Boards are asked to ensure that they support provision of this important vaccine to those eligible via their sexual health services.

We are grateful for your continued support and hard work in delivering the broader Scottish Vaccination and Immunisation Programme to the people of Scotland.

Yours sincerely,

Gregor Smith Alison Strath

Professor Sir Gregor Smith Professor Alison Strath

Chief Medical Officer Chief Pharmaceutical Officer





ANNEX

Vaccine Schedule and Administration

The recommended vaccine schedule is two doses:

- Dose 1: At first visit
- Dose 2: Minimum interval: 1 month

The vaccine is given intramuscularly into the upper arm or anterolateral thigh. This is to reduce the risk of localised reactions, which are more common with subcutaneous injection. However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.

As efficacy estimates are based on receipt of the full two-dose schedule, eligible individuals should be strongly encouraged to complete the schedule.

There is no maximum time interval limit between the two vaccine doses. Pragmatically and opportunistically the second dose can be scheduled for the next clinic attendance, which may be after 3, 6 or 12 months. There is no need to recommence the primary immunisation schedule even after a prolonged interval between the two doses.

There are no data on the immunogenicity or protection offered when 4CMenB is administered during active or recent gonorrhoea infection. Eligible individuals attending sexual health clinics for testing and/or management of bacterial STIs, including gonorrhoea, should be offered 4CMenB at the same clinic attendance. This is to avoid delay in offering potential protection to those at highest risk of gonorrhoea who may be reinfected before their next visit to the clinic.

It is unlikely that acute gonorrhoea will affect immune responses to vaccination since natural infection does not confer protection against reinfection. Even if some attenuation in vaccine response did occur with the first dose, eligible individuals will receive a second dose of the same vaccine after the infection is treated

The vaccine can be co-administered with other vaccines such as hepatitis A/B, HPV, and mpox.

A prioritisation document to aid conversations with individuals to inform their own decisions about the vaccines available and when to offer will be available for sexual health services.

Vaccine Product and Dosage

4CMenB (Bexsero®) vaccine is supplied as a white opalescent liquid suspension (0.5ml) in a pre-filled syringe (single pack size) for injection via intramuscular/subcutaneous injection. One dose (0.5ml) contains 50 micrograms each of NHBA, NadA and fHbp and 25 micrograms of OMV.

Vaccine Supply

Bexsero® for use in the gonorrhoea programme will be available to order through vaccine holding centres from July 2025. The vaccine is the same as is used in the childhood programme. Vaccine Holding Centres should ensure only vaccines used in the gonorrhoea programme area ordered and used for eligible adults.







Vaccine Storage and Disposal

Vaccines should be stored in their original packaging at +2°C to +8°C and stored in the original packaging to protect from light. Do not freeze.

In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal

Vaccine Stock Management

Please ensure sufficient fridge space is available for the vaccine and enough is held to be able to offer opportunistically. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.

Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to minimise vaccine wastage, as even small percentage reductions in waste have a major impact on the financing of vaccine supplies.

Patient Group Directions (PGD)

A national specimen Patient Group Direction (PGD) for administration of Bexero® for the gonorrhoea programme will be produced by Public Health Scotland (PHS).

Communications Materials for Patients

PHS, in partnership with stakeholders, are developing communications materials for patients. An information leaflet to support informed consent will be available at Sexual Health Clinics. This information will also be available on NHS Inform.

Workforce Education Resources for Healthcare practitioners

NHS Education for Scotland (NES), in partnership with PHS and stakeholders, are developing educational resources for healthcare practitioners in relation to the introduction of the gonorrhoea vaccination programme. These will include a vaccine specific slide set and a webinar and will be available on Immunisation | Turas | Learn

The Green Book

Full details on use, dosage, administration, concomitant administration with other vaccines, contraindications, consent and reporting of adverse reactions with Bexero® will be included in the Green Book chapter.

Information on consent for vaccination can also be found in chapter two of the Green Book.

Vaccine Safety and Adverse Reactions

For 4CMenB (Bexsero®), the most common local and systemic adverse reactions observed in adolescents and adults were pain at the injection site, malaise and headache.

Suspected vaccine related adverse drug reactions should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).







Vaccination Adverse Events

Vaccination adverse events should continue to be managed in accordance with current local and national protocols and standards and escalated as appropriate. Further details can be found in the existing publication PHS Vaccination Adverse Event Management Protocol, version 2.0, published 04 March 2024.

Vaccine Uptake

Vaccination should be recorded via NaSH. For those boards who do not routinely use NaSH, a manual process will be communicated and regular submissions should be sent to PHS.

Health Boards are expected to participate in quality improvement activity led by PHS, with an inclusion and equity lens applied to the programme. All programmes must include an element of proactive inclusion work in an effort to reduce health inequalities, with a particular focus on areas of highest deprivation and certain ethnicities who may have lower uptake of vaccines.

Funding Arrangements

Scottish Government will pay for the vaccine centrally, as is done for the childhood programme. Delivery costs are to be covered through Health Board baseline budgets.



