Premium Sponsor

ViiV Healthcare

Changes in the Model of Care

Chairs:

Chris Hodgson, Blackpool Teaching Hospital NHS Foundation Trust

Helen Reynolds, University of Liverpool

Update on DoxyPEP, MenB vaccine for gonorrhoea and MPOX

Rachel Morgan

Blackpool Teaching Hospital NHS Foundation Trust

DOXY PEP, 4CMENB VACCINE, MPOX

Rachel Morgan – Nurse Consultant – Sexual Health

DOXY POST EXPOSURE PROPHYLAXIS

- Four randomised controlled trials (RTC) took place to assess if it reduced bacterial STIs. Three involving GBMSM and TGW. One involving Cisgender women. All these patients were taking PrEP.

- The studies involving GBMSM and TGW showed that DoxyPEP effectively prevented chlamydia and syphilis.

- The study involving cisgender women did not find an effect of DoxyPEP on reducing the incidence of bacterial STIs. This could be due to poor adherence
- There have been other RCT's and all have concluded the results provide clear evidence of the efficacy of DoxyPEP in reducing chlamydia and syphilis in GBMSM and TGW compared to standard care.

STATISTICS

- Significant declines in Chlamydia and Syphilis has been observed, with a reduction rate of up to 89%.
- Chlamydia: 70-89%
- Syphilis: 73-87%
- New data published on the 2nd June 2026 from UKHSA - syphilis diagnoses in gay and bisexual men have fallen to their lowest level since 2016 and an 18.7% decline from 6, 349 in 2024 to 5,164 in 2025
- Although, infectious syphilis diagnoses fell overall, diagnoses in heterosexual women increased 4.8% - from 838 in 2024 to 878 in 2025
- Chlamydia - there was a 9.4% decrease in the number of chlamydia tests carried out, from 604,143 in 2024 to 547,308 in 2025, and a 13.6% decrease in chlamydia diagnoses, from 53,408 in 2024 to 46,122 in 2025 – these stats are only for girls/women aged 15 to 24.

ANTIMICROBIAL RESISTANCE

- To date, resistance to doxycycline has not been observed in Treponema pallidum and Chlamydia trachomatis.
- But DoxyPEP users had higher rates of Group A Streptococcus colonisation and it was found that DoxyPEP users had lower rates of S. aureus colonisation, but S. aureus tetracycline resistance was higher.
- Experts believe that this is unlikely to be a problem as doxycycline is already used long-term for acne and malaria prophylaxis.
- There is also a cause for concern with studies coming forward that although Doxycycline doe not cause direct resistance to ceftriaxone (1st line treatment for Neisseria gonorrhoeae), as they are different antibiotic classes – taking doxy pep repeatedly can select for tetracycline resistant to gonorrhoea, which can cluster with – or make bacteria more prone to developing resistance to cephalosporins

ASSESSMENT

- Since most chlamydial infections among GBMSM and TGW are not associated with harmful clinical manifestations, the major physical health benefit of DoxyPEP in these key populations is likely the prevention of syphilis.
- BASHH recommends DoxyPEP for:
- Cisgender GBMSM and TGW at elevated risk of acquiring syphilis

  Individuals who may be at increased risk of acquiring syphilis include those with a recent (in the last year) bacterial STI diagnosis and those with a recent history (in the last 3 months) of multiple new, occasional, or one-off sexual partners, including reporting group-sex and chemsex.

CISGENDER WOMEN AND TGM

- At the time of writing, there is no clinical trial evidence to support a recommendation of DoxyPEP for cisgender women and other people assigned female at birth
- Whilst available data suggests good protection in cisgender men and TGW engaging in oral and anal sex, it is not yet known whether this intervention protects from infection and potential ongoing problems (for example, pelvic inflammatory diseases and congenital syphilis) in cisgender women, transgender men and other individuals with a vagina who only engage in oral and/or anal sex.
- However, clinicians may consider DoxyPEP for people assigned female at birth at elevated risk of acquiring syphilis (this may include sex workers and transgender men who have sex with men), on a case-by-case basis, and in discussion with the patient. This would be a prescribed course.

DOSAGE AND ADMINISTRATION

- Recommended dosing regimen: BASHH recommends taking a **single dose of 200 mg (2 x 100 mg capsules)** of doxycycline, within 24 hours and no later than 72 hours after sex.
- No more than 200 mg of doxycycline should be taken in each 24 h period.
- There is no evidence to guide whether the effectiveness of DoxyPEP varies depending on when it is taken in the 72-hour period after sex.
- Acknowledging this lack of evidence, individuals having sex on more than one occasion over a 72-hour period may consider taking a single 200 mg dose of doxycycline at the end of the 72-hour period, rather than multiple doses, to cover the entire period of risk.
- In Blackpool sexual health services, we give boxes of 50 100mg capsule boxes
- GUMCAD code is DPEP
- There is a national PGD for DoxyPEP

SYPHILIS

- The impact of DoxyPEP on the need for treating contacts of syphilis and chlamydia is not known.
- We recommend offering epidemiological treatment to DoxyPEP users who are contacts of syphilis, in line with current BASHH guidelines due to the long potential time between exposure and reliably ruling out infection by serology.
- However, asymptomatic contacts who consistently use DoxyPEP following sex or confirm that they took DoxyPEP within 72 h of the potential exposure, may choose not to receive epidemiological treatment, opting for a ‘watch and wait’ approach instead.
- We recommend that all contacts of syphilis should be supported to attend if they develop symptoms of potential syphilis infection and have serological testing at appropriate time points.

CHLAMYDIA

- We recommend that asymptomatic DoxyPEP users who are contacts of chlamydia and took DoxyPEP within 72 hours of exposure, do not require epidemiological treatment.

- If the individual attends within 72 hours of exposure but has not yet taken DoxyPEP, then consider taking a dose of DoxyPEP instead of offering standard epidemiological treatment.

- If the individual is in the clinical service, then consider offering a test for chlamydia. If this test is positive for Chlamydia, then offer treatment in line with the BASHH guideline on the management of Chlamydia.

MENINGOCOCCAL GROUP B (4CMENB) VACCINE

- It is important to understand the background information:
- Neisseria gonorrhoeae has developed resistance to every class of antibiotics used to treat it, and cephalosporins are the last remaining class of antibiotics available for use as empirical monotherapy
- Ceftriaxone-resistant Neisseria gonorrhoeae (the bacterium that causes gonorrhoea) was first detected in England in 2015. By May 2025, a total of 52 cases had been reported in England, 18 of which were extensively drug-resistant.
- Most ceftriaxone resistant cases are associated with travel to or from the Asia-Pacific region, where the prevalence of ceftriaxone resistance is high
- Gonococcal infections can also increase the risk of acquiring HIV

STATISTICS

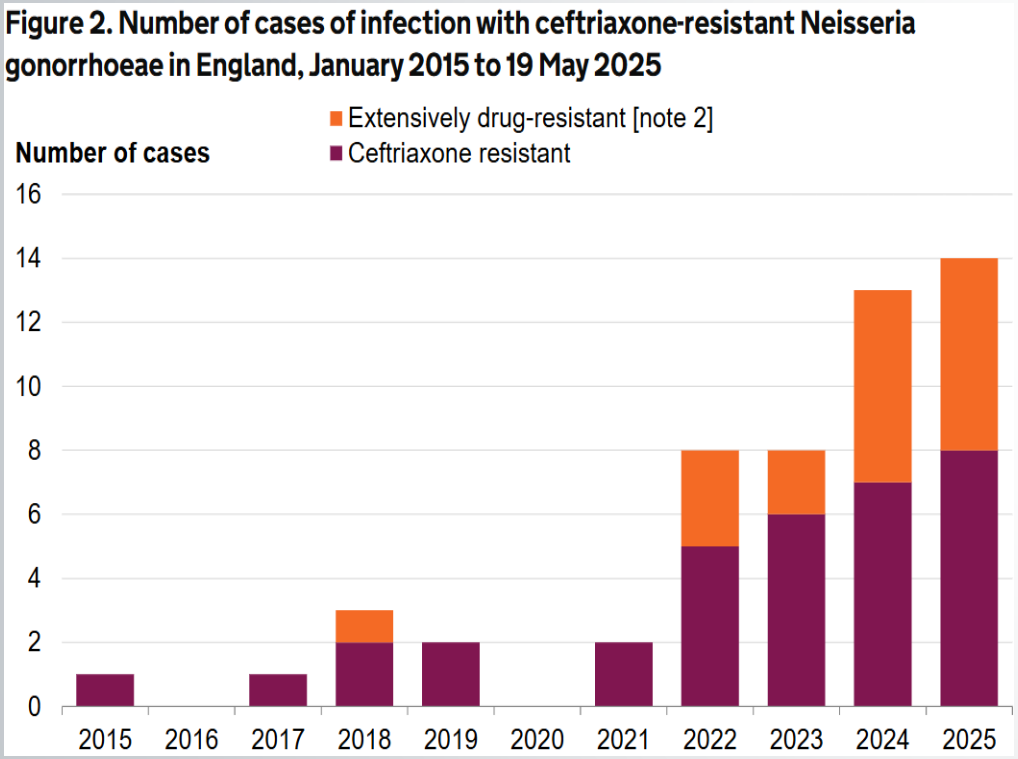


Figure 2. Number of cases of infection with ceftriaxone-resistant Neisseria gonorrhoeae in England, January 2015 to 19 May 2025
Extensively drug-resistant [note 2]
Ceftriaxone resistant
Number of cases
16
14
12
10
8
6
4
2
0
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025

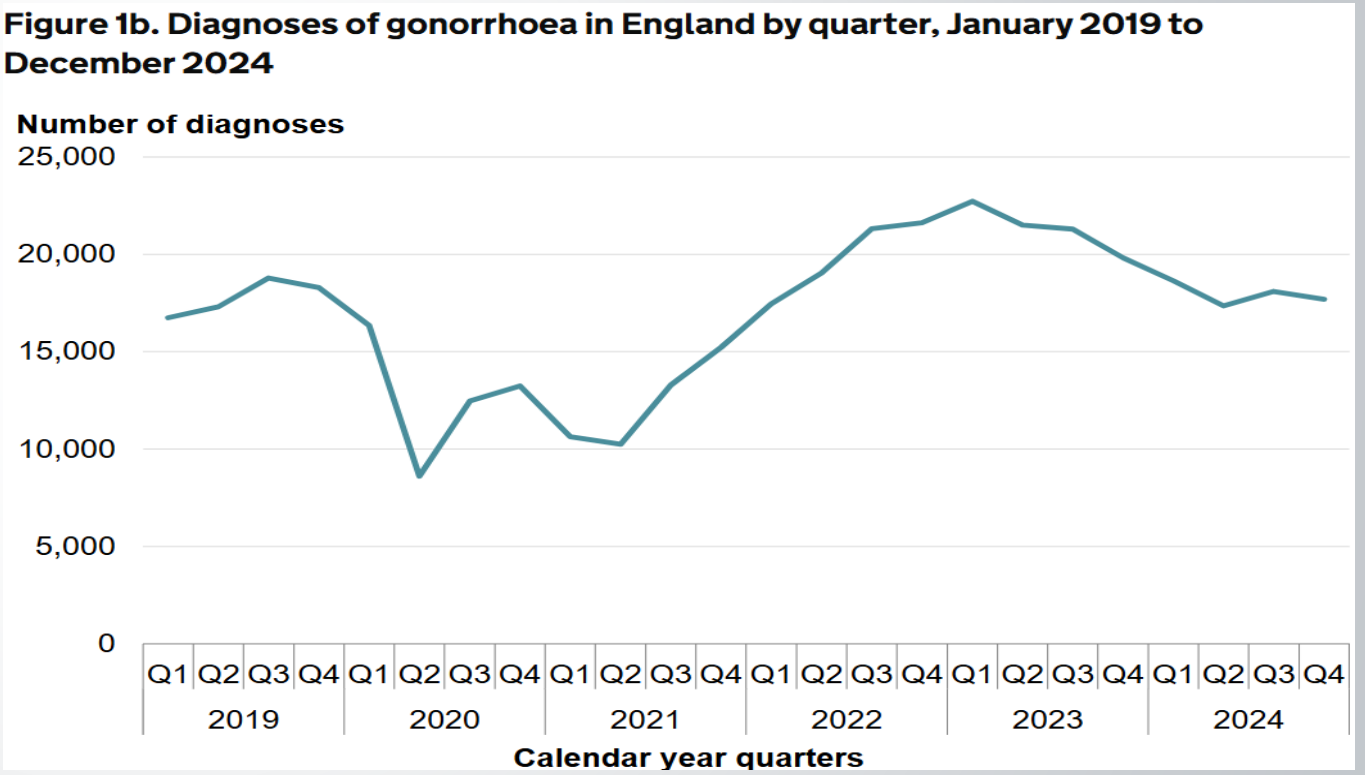


Figure 1b. Diagnoses of gonorrhoea in England by quarter, January 2019 to December 2024
Number of diagnoses
25,000
20,000
15,000
10,000
5,000
0
Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4
2019
2020
2021
2022
2023
2024
Calendar year quarters

WHY USE A VACCINATION PROGRAMME

- The programme is national and uses the 4CMenB (Bexsero) vaccine – starting in August 2025 following advice from the joint committee on vaccination and immunisation (JCVI)
- The vaccine is an inactivated, recombinant vaccine which provides high protection against MenB invasive meningococcal disease.
- The vaccine became available in 2013 and in 2015 the UK became the first country to implement a publicly funded immunisation programme to infants – within 3 years, there was a 75% reduction in invasive MenB disease
- N. gonorrhoeae the bacteria which cause gonorrhoea is genetically highly related to MenB disease with 80-90%similar virology factors
- Several observational studies have reported a 33% to 47% reduction in gonorrhoea among those immunised
- Around half of gonorrhoea diagnoses in England are GBMSM, which accounted for 36,833 in 2025 (total 63,943)
- Those who identify as GBMSM have a 24 times higher incidence risk compared to heterosexual men
- Gonorrhoea is classed as a major global public health concern

RECOMMENDATIONS AND ELIGIBILITY

- A targeted opportunistic vaccine programme was endorsed in 2023
- Not currently licensed for protection against N. gonorrhoeae – it is being used off-label
- A two-dose vaccine is recommended – in South Australia they have estimated effectiveness to be 34.9% during the first 6-36 months after vaccination – some evidence suggests that protection wanes after this time
- A booster dose is not yet recommended but a number of RCTs are currently in progress to evaluate its effectiveness
- For cost-effectiveness it is advised we offer 4CMenB to GBMSM at increased risk who access sexual health services – increased risk is defined as GBMSM diagnosed with gonorrhoea and those who report high-risk sexual behaviour
- For operational purposes this is defined further as, 1. those with a bacterial STI in the previous 12 months and, 2. Those reporting at least 5 sexual partners in the previous 3 months
- Professionals may perform an individual risk assessment for those who also have an incidence of gonorrohoea approaching the criteria set above – such as sex workers engaging in condomless sex

DOSAGE AND SCHEDULE

- Administer a course of two dose (0.5ml IM/SC injection) at least 4 weeks apart
- There is no maximum time interval limit between the two vaccine doses
- This allows for a more pragmatic use of the vaccine – for e.g. the next PrEP appointment
- For those attending services with active gonorrhoea, these patients can still be offered the vaccine at the same clinic attendance
- 4CMenB does not clear acute gonorrhoea infection and patients should be managed in-line with BASHH guidance
- 4CMenB can be administered before, at the same time as, or after other vaccines currently being offered in sexual health clinics

PRECAUTIONS AND SIDE EFFECTS

- Immunosuppression and HIV infection eligible individuals, regardless of CD4 count, should be given the vaccine in accordance with the same advice as on the previous slides

POTENTIAL PROBLEMS

- Clinical trial evidence from the GoGoVax trials in Feb 2026 – showed concerns about the evidence base
- It was a double-blind, randomised, placebo-controlled trial in Australia involving 587 GBMSM – the study team found no evidence of protection – people in both arms of the study had the same incidence of gonorrhoea
- There are other trials which also found no or minimal evidence, MenGO trial, DOXYVAC study
- The JCVI has not recommended stopping the vaccine and has advised there is a body of evidence from observational studies
- The UK health Security Agency (UKHSA) is monitoring the impact and effectiveness of the vaccination programme and plans to share these findings with the JCVI in 2026 to 2027

MPOX

- 2 major types, which are called clades – clade I and clade II – subtypes of each clade have been identified
- It is an infectious disease – first discovered in 1958 – in monkeys kept for research
- First human case 1970 in the Democratic Republic of the Congo
- More recently, since May 2022, it has spread to multiple countries, including the UK
- This ongoing outbreak is mostly caused by clade IIb – is spread mostly by sexual contact
- Since August 2024, clade I has also been reported and is spread mostly through close physical contact
- Clade I has a significantly higher mortality rate – 1.4% to 10% - with the sub type Clade Ib having a lower mortality rate of 0.5%
- Clade 11 – estimated case fatality rate of less than 3% - with the sub-type Clade IIb – has a mortality rate 0.1% to 0.5%

TRANSMISSION

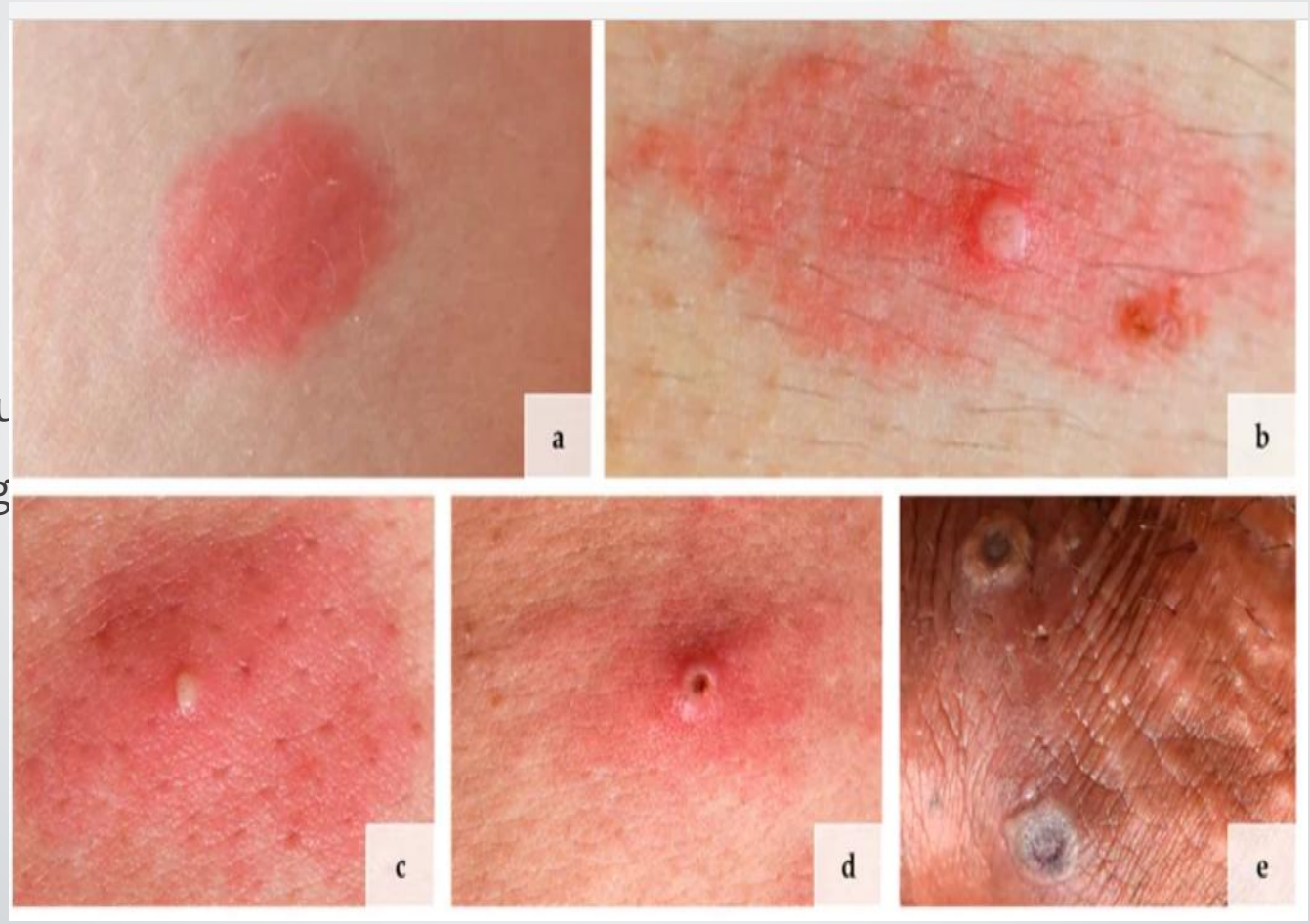
- MPOX does not spread easily between people unless there is close contact
- Direct contact with rash, skin lesions or scabs – including during sexual contact, kissing, cuddling
- Contact with bodily fluids such as saliva, nasal mucus or semen/vaginal fluids
- Contact with clothing, linen (bedding/towels)
- It is possible that MPOX may spread between people through close and prolonged face-to-face contact such as talking, breathing, coughing or sneezing – limited evidence
- For healthcare professionals – if a suspected patient has respiratory symptoms – a fluid-resistant surgical mask is acceptable when providing care within 1-metre of a patient, eye/face protection is also advised. The patient should be advised to also wear a FRSM. Routine cleaning – use of detergent wipes is acceptable for cleaning surfaces/frequently touched sites

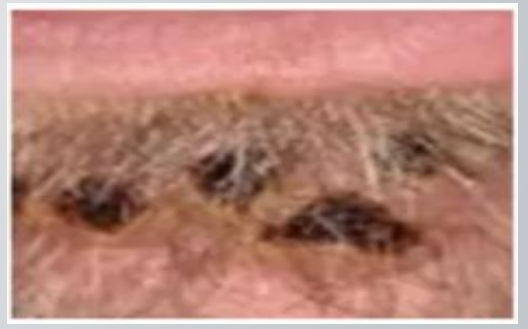
CLINICAL FEATURES

- The incubation period is between 5 and 21 days
- Most people who catch MPOX will recover within several weeks with out any treatment
- The illness begins with: fever, headache, muscle aches, backache, swollen lymph nodes, chills, exhaustion, joint pain
- Within 1-5 days after the initial symptoms, a rash develops, often beginning on the face and then spreading to other parts of the body including soles of the feet and palms of the hands. The rash can also affect the mouth, genitals and anus. Some individuals do not have a rash and only have genital lesions
- The rash is made up with a variable number of lesions. They go through various stages, 1. small vesticle, 2. small pustule, 3. Umbilicated pustule – pus filled with a central indentation, 4. Ulcerated lesion, 5. Crusting of lesions, 6. Fully scabbed and partially removed scabs
- A patient is contagious until all the scabs have fallen off and skin is intact

CLINICAL FEATURES

- A: macular
- B: papular
- C: pustular
- D/E: umbilicated pustu
- Crusting and scabbing



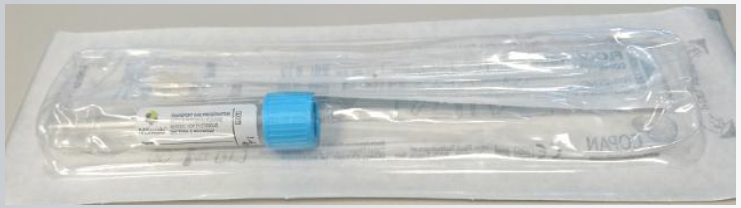


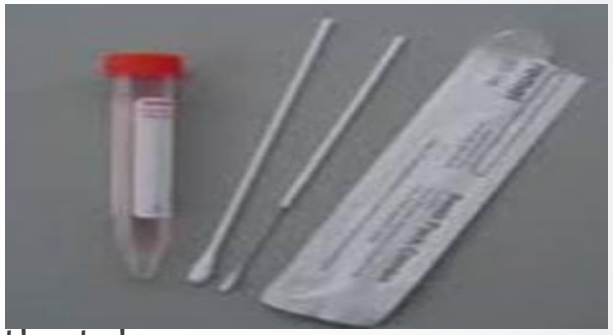
DIAGNOSIS

- Diagnosis can be difficult, as there can be many differential diagnoses, such as chicken pox/shingles, herpes simplex virus, syphilis, molluscum contagiosum. Also, consider staph and strep infections.
- What to consider:
- Does the patient have a prodrome? i.e. fever, swollen lymph nodes
- Is this an individual who has had contact with a confirmed or suspected case of mpox in the 21 days before symptom onset
- Or:
- Does the patient have a MPOX-compatible rash anywhere on the skin, or symptoms of proctitis and in the last 21 days have they had a recent new sexual partner, contact with a known or suspected case of mpox, a tavel history to a country where mpox is common: last updated data from Dec 2025 – DRC – 451, Guinea – 299, Liberia – 196, Spain – 137 (1 month data)
- Also consider if there is a rash, symptoms of proctitis, where there is no other risk factor and no alternative differential diagnosis can be made

TESTING

- Ensure you are wearing the minimum appropriate PPE – glove/apron/FRFM/face visor
- Testing the queried MPOX site is with a viral swab – either remel swab or blue coban





MPOX is still a notifiable disease

- Rub the swab over the lesion and place the swab in the tube
- Label the tube with the patient's name and date of birth, the date and the site of the sample
- The sample needs to be double bagged and placed in a bio-bottle or other appropriate container and this needs to be clearly labelled for the Virology department and write danger of infection on the box
- The RIPL diagnostic MPOX form needs to be sent with the sample https://assets.publishing.service.gov.uk/media/68134820ee9d78cbe60117fc/Microbiology_request_form_P7_v4.pdf
- Most labs conduct all testing, and all positives will be referred to RIPL, Porton Down for clade testing. Eash swab should be tested for MPOX, Syphilis, HSV, Varicella

VACCINE

- In November 2023, the JCVI recommended that a routine vaccination programme of GBMSM at highest risk of exposure to MPOX and offered through sexual health services, should be developed to prevent future outbreaks
- The JCVI used similar risk markers as those used for HIV PrEP but can be applied regardless of HIV status
- The risk criteria:
- A recent history of multiple partners
- Participating in group sex
- Attending sex-on-premises venues
- Diagnosis of bacterial STI within the last year

VACCINE

- Storage – frozen vials of Imvanex or Jynneos should be transferred to 2 to 8 degrees- vaccine then can then be stored for up to 8 weeks
- Vaccine to reach room temperature before use
- To be given IM or deep SC route
- Pre-exposure dosage – administer a course of two doses with a least a 28-day interval between doses
- Individuals who have previously been vaccinated with a live smallpox vaccination should only receive a single dose
- Post-exposure – low effectiveness but may lower disease severity – ideally administered within 4 days from exposure – can be extended to 14 days in those that are higher risk – children (below 5 years), pregnant people and those with severe immunosuppression, including HIV individuals, especially where CD4 count is less than 200 cells/mm3
- Can be given alongside other vaccines
- Observe patient for approx. 15 minutes
- Treatment is limited and so vaccination is the most effective way to protect against MPOX
- To add: It is not known if living with HIV increases the chances of getting MPOX but those with advanced HIV are at increased risk of severe disease and may require anti-viral treatment – which are usually given under medical supervision
- Positive patients are still being asked to isolate until the rash and lesions are healed – to separate themselves in their household and must avoid contact with pets – please see Mpox: isolating at home guidance

QUESTIONS