

# Welsh Government Integrated Impact Assessment

## Section 1 and 8

<b>Title of proposal:</b>	<b>The introduction of Mpox and Gonorrhoea routine vaccination programmes.</b>
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## Section 1. What action is the Welsh Government considering and why?

There are two separate but related issues which have prompted the Welsh Government to take action to establish new routine vaccination programmes for tackling mpox and gonorrhoea.

**Mpox** is a rare disease caused by infection with the mpox virus. The virus is related to but distinct from the ones that cause smallpox and cowpox. Most individuals experience a mild illness, with spontaneous and complete recovery within 3 weeks. However, severe illness can occur and sometimes results in death. The risk of severe outcomes from disease is higher in young children, pregnant women and immunosuppressed individuals. Following an mpox outbreak in Spring 2022, a UK wide outbreak response vaccination programme was developed, targeted at individuals most at risk of mpox infection - largely gay, bisexual and other men who have sex with men (GBMSM). Aside from some targeted activity in London and Manchester, this reactive vaccination offer was ended in England in the summer of 2023. However, in Wales that offer has continued to present day, operating on an opportunistic basis in terms of both identification and vaccination.

There are two known clades of mpox: clade I and clade II. The disease, which has been endemic in certain countries globally since 2022, has been linked to infections with clade II. In November 2023, the World Health Organisation (WHO) reported concerns about a further spread of mpox in the Democratic Republic of the Congo (DRC), and in August, determined that the upsurge of clade I mpox in the DRC and a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC). A more virulent clade of the virus, infection with clade I may lead to an increased risk of severe illness. The UK 4 nations public health agencies include mpox clade I in their list of high consequence infectious diseases. The WHO's risk assessment notes a significant risk of mpox further spreading to neighbouring countries and worldwide, with potentially more severe consequences than the current global outbreak.

**Gonorrhoea** is a bacterial sexually transmitted infection (STI) caused by the *Neisseria gonorrhoeae* bacterium. It causes significant morbidity and remains a public health concern globally. Infection is transmitted through condomless vaginal, oral or anal sex, or genital contact with an infected partner and may result in complications including chronic pelvic pain, pelvic inflammatory disease, ectopic pregnancy and infertility in women. Even if an infected person has no symptoms the infection can still be transmitted.

Public Health Wales data shows there was a 127% increase in gonorrhoea diagnoses in Wales in 2022 compared to 2021. 2023 data shows gonorrhoea diagnosis are at a 10 year high with a 27% increase in cases since 2022, reaching 5,292 diagnoses. The majority of cases are male and in the 15-24 age group. Reporting from the Gonococcal Resistance to Antimicrobial Surveillance Programme

(GRASP) for England and Wales shows gonorrhoea has developed resistance to all classes of antibiotics used to treat it; therefore, alternative courses of prevention need to be found. There is currently no vaccination undertaken in Wales to protect against gonorrhoea.

The Joint Committee on Vaccination and Immunisation (JCVI) has recommended a [routine targeted vaccination programme for the prevention of Gonorrhoea](#), alongside advising on a [routine vaccination programme against Mpox](#) for those at highest risk. The Committee advises both programmes should be offered on an opportunistic basis through specialist sexual health services, who have the experience in assessment and identification of those who are at increased risk of infection with bacterial sexually transmitted infections (STIs).

Welsh Government, along with the other 4 nations, proposes to introduce separate vaccination programmes for mpox and gonorrhoea from spring 2025, delivered on an opportunistic basis through Sexual Health Services.

This policy relates to four of the goals under the Well-being of Future Generations (Wales) Act namely:

- A more prosperous Wales – a highly vaccinated population is healthier, which in turn leads to higher employment and greater productivity.
- A healthier Wales – through contributing to people’s physical and mental well-being.
- A more equal Wales – where a healthier population can go on to reach their potential regardless of their background/ circumstances.
- A globally responsible Wales – where vaccination is key to global health security, in an interconnected world where disease outbreak can spread very quickly. A highly vaccinated country can respond better to public health outbreaks and emergencies.

In terms of the five ways of working, this policy considers:

### **Long term**

- These vaccination programmes would limit the infection rate and reduce the number of severe cases in those immunised. This will have a positive health effect for those vaccinated and will reduce the impact of both mpox and gonorrhoea on public health services, specifically sexual health services, in 2025 and beyond.
- Vaccination programmes provide a degree of social mobility, as poverty and the associated ill-health and mortality from infectious diseases are no longer the

determinants of one's life chances. Vaccine recipients have the potential for improved quality of life and life-expectancy.

## **Prevention**

- Vaccination is one of the most important actions we can take for our own health, and it's one of the most important preventative measure NHS Wales can offer to people in Wales. The primary aim of the roll out of both these programmes is to offer individuals protection against severe illness from mpox and gonorrhoea, specifically hospitalisation and death, and to prevent future outbreaks, protecting those most at risk of exposure.

## **Integration**

- The impact of these programmes and their integration with other routine vaccination programmes in 2025 is being fully considered. Welsh Government officials will continue to work closely with Vaccine Programme Wales (VPW) and Public Health Wales (PHW) to minimise disruption to the NHS delivery and the wider work of sexual health services. VPW project managers have been working to evaluate options to plan for an efficient and effective rollout in Wales.

## **Collaboration**

- Welsh Government will continue to act in collaboration with VPW and PHW in planning the implementation of these vaccination programmes through regular meetings and communications. Policy officials continue to engage with the Sexual Health and Equalities teams on the deployment aspects of the programmes and how to best inform those eligible for vaccination, in order to maximise uptake.

## **Involvement**

- Relevant stakeholders (sexual health LGBTQ+ charities and Health Board Clinical Leads) were asked for their views to inform this integrated impact assessment and will be kept up to date as the policy develops. Feedback was received from clinical leads who liaise directly with service users. As sexual health services are a confidential service the feedback will be relating to a range of backgrounds/ages including those with protected characteristics. Seeking targeted feedback to understand the views of certain groups of people who are eligible – such as young people that may use sexual health services – is a challenge due to the sensitivities of discussing sexual health, sexuality and the confidential nature of this service, which is why representative bodies were consulted. Welsh Government will use the insights from the stakeholders' groups consulted,

who engage directly with service users, to inform decisions on how such programmes are stood up in Wales.

## **Impact**

### Positive –

- The purpose of establishing both the vaccination programmes (like all vaccination) is as a preventative measure to provide protection against mpox and gonorrhoea – with the aim of keeping individuals safe from severe disease, hospitalisation and death, and to limit transmission within communities, preventing future outbreaks.
- The vaccination programmes would limit the infection rate and reduce the number of severe cases in those immunised. This will have a positive health effect for those vaccinated and will reduce the impact of mpox and gonorrhoea on public health services, especially sexual health services.
- Potential to learn from the Covid-19 vaccination programme, which was promptly stood up in response to the pandemic, to inform deployment. Health boards would be expected to share innovation, learning and best practice with each other, to improve service provision and boost uptake, in line with the National Immunisation Framework.
- The vaccine advised to be used for the prevention of gonorrhoea (MenB) is already given to young children as part of the routine childhood schedule. This presents no licensing or safety issues as the vaccine is routinely used by the NHS. For most people this programme will just be providing additional doses of a vaccine they have already received when infants.
- As the recipients of both vaccines would need detailed risk assessments to ensure their clinical suitability there would be enhanced conversations with specially trained sexual health colleagues which adds additional opportunity for education and awareness about other matters relating to sexual health.
- Drop-in sexual health clinics for young people are currently established within health boards who run sexual health services. The provision of additional funding to undertake these new programmes should ensure a more resilient sexual health service is offered.

### Negative

- There is a risk in terms of acceptability and take up. There is a stigma attached to sexually transmitted infections which may impact the number of people attending sexual health services.

- Both vaccination programmes being delivered via Sexual Health Services, which could have a negative impact on their capacity and ability to deliver other routine services. In evidence considered by the Joint Committee on Vaccination and Immunisation (JCVI) it was noted that the mpox outbreak response had caused a significant disruption in sexual health services, impacting on their ability to continue with routine work. Although it is expected that a routine mpox programme will have less of an impact than the outbreak response, and the provision of additional funds to support the programmes should minimise this potential disruption.

### **Costs and Savings**

- The Welsh Government's Science Evidence Advice (SEA) Division reviewed the modelling of the impact and cost-effectiveness of an mpox vaccination programme undertaken by UKHSA and the University of Bristol. SEA concluded that continuing to vaccinate high risk GBMSM is cost effective in Wales, with a routine strategy likely to be more efficient and cost-effective than a reactive one. SEA also reviewed evidence presented to the JCVI and modelling conducted by Imperial College London on the cost effectiveness of vaccination for gonorrhoea, which found the value of vaccination increased over time, due to the accumulation of cases averted.
- The modelling also considered the wider cost savings, alongside the health benefits for individuals, in terms of the benefit vaccination programmes can provide businesses through limiting the economic impact of productivity losses and absenteeism.

### **Mechanism**

- No new legislation is required to introduce these vaccination programmes in Wales.
- The [National Immunisation framework](#) was published in October 2022 and sets out our plans to transform the provision of vaccination services to ensure they are fit for the future, part of which includes helping people become informed about the vaccinations for which they are eligible for and how to receive them.
- The deployment of these programmes will be the responsibility of NHS Wales, with health boards in Wales developing local plans and impact assessing these.
- The establishment of mpox and gonorrhoea vaccination programmes will be communicated at the appropriate time to NHS via a Wales Health Circular and a written statement will be published to inform members of the Senedd.

- PHW will develop a communications strategy targeted at the eligible cohorts, to raise awareness of mpox and gonorrhoea, inform eligible individuals of the benefits of having the vaccination and how they can access vaccination.
- This comms strategy would develop a range of materials which are suitable for service users, for example, younger adults under the age of 18 years, who are understood to be accessing sexual health services.

## Section 8. Conclusion

### 8.1 How have people most likely to be affected by the proposal been involved in developing it?

The Joint Committee for Vaccination & Immunisation (JCVI) has recommended a routine targeted vaccination programme for the prevention of Gonorrhoea, alongside advising on a routine vaccination programme against Mpox for those at highest risk.

The JCVI advice is that both programmes should primarily target GBMSM who are at increased risk of becoming infected, though the advice is explicit in stating efforts should be made to ensure that the vaccine is offered to those at similar risk as GBMSM, including but not limited to transgender women, gender-diverse people assigned male at birth, and (for gonorrhoea) any other people, irrespective of gender, who may be heterosexual or identify otherwise and who have equivalent markers of increased risk.

In developing these vaccination policies, the views of relevant stakeholders and representatives of the targeted cohorts, who directly engage with service users, have been sought, including health board Sexual Health clinical leads, the British Association of Sexual Health & HIV (BASHH), Terrence Higgins Trust (THT) Wales and Fast Track Cymru (FTC). Their insights have helped inform this impact assessment and should the programmes be implemented, these stakeholders will continue to be involved in the promotion of the vaccinations and overall offer of sexual health services.

Public Health Wales (PHW) has a role in engaging with the public and a range of statutory and third sector organisations to gain behavioural insights on the barriers, perceptions and experiences of the vaccination programmes in Wales. The organisation uses various tools and methods to engage directly with groups to inform and influence national strategies and service improvements. The aim is to actively involve the different sections of the public, such as ethnic minority groups<sup>1</sup> in the development of resources and interventions, with the aim of informing and building trust. Should the programmes be implemented, PHW plans to develop a comprehensive communications plan and social media toolkit to encourage individuals to come forward, that can be shared with GBMSM networks and organisations, and via Health Board's local sexual health channels, as well as materials to publicise the programmes to specific groups, at events including Pride.

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<sup>1</sup> [phw.nhs.wales/topics/immunisation-and-vaccines/engagement-insights/evaluation-of-information-resources-ethnic-minorities-summary-report-2023/](https://phw.nhs.wales/topics/immunisation-and-vaccines/engagement-insights/evaluation-of-information-resources-ethnic-minorities-summary-report-2023/)

## **8.2 What are the most significant impacts, positive and negative?**

The implementation of the mpox and gonorrhoea vaccination programmes would have a positive impact on individuals considered most at risk, by offering protection against severe illness, hospitalisation and death.

Both mpox and gonorrhoea infections can impact an individual's health with severe illnesses occurring for some individuals. Gonorrhoea can cause significant morbidity and remains a public health concern globally, and the UK 4 nations public health agencies include mpox Clade I in their list of high consequence infectious diseases (HCID).

One of the main benefits of the vaccination programmes is expected to be at a community level with a significant reduction in the number of cases overall, helping to prevent future outbreaks.

Both programmes should primarily target GBMSM who are at increased risk of becoming infected, though efforts should be made to ensure that the vaccine is offered to those at similar risk, including but not limited to transgender women, gender-diverse people assigned male at birth, and (for gonorrhoea) any other people, irrespective of gender, who may be heterosexual or identify otherwise and who have equivalent markers of increased risk. If the vaccination programmes are implemented, then people eligible in Wales would receive the same protection as in other nations of the UK.

The proposed vaccination programmes will have a significant positive impact on business and the public, through helping to prevent future outbreaks and protecting those at risk of exposure. Individuals who contract either infection may need to take time off work as a result, with a longer recovery time needed for severe cases. Alongside the health benefits for individuals, the vaccination programmes can benefit businesses through limiting the economic impact of productivity losses and absenteeism.

There is a risk that the programmes will have a negative impact on the capacity of SHS, potentially affecting their ability to deliver other routine services, though with the provision of additional funding, this impact is expected to be minimal. Producing all the necessary vaccination literature and guidance from a PHW perspective is also a challenge, as is standing up the necessary digital systems necessary to record vaccination uptake, though if the policy is agreed, plans will be drawn up to ensure these challenges are overcome. PHW and Digital Health Care Wales have the experience and capability to take this work forward, having done this previously on other vaccination programmes established.

### **8.3 In light of the impacts identified, how will the proposal:**

- **maximise contribution to our well-being objectives and the seven well-being goals; and/or,**
- **avoid, reduce or mitigate any negative impacts?**

Due consideration has been given to how the vaccination policies relate to the goals under the Well-being of Future Generations (Wales) Act and the five ways of working. A highly vaccinated population is healthier, physically and mentally, which contributes to the healthier Wales goal, and healthier people mean a more productive workforce and higher productivity which lends itself to a more prosperous Wales. Vaccination is key to global health security, in an interconnected world where disease outbreak can spread very quickly. A highly vaccinated country can respond better to public health outbreaks and emergencies, which results in a more globally responsible Wales.

#### **In terms of the five ways of working, these policies consider:**

Vaccination programmes in the long term provide a degree of social mobility, as poverty and the associated ill-health and mortality from infectious diseases are no longer the determinants of one's life chances. Vaccination is one of the most important actions we can take for our own health, and it's the most important preventative action NHS Wales can offer to people in Wales. These vaccination programmes will consider how to integrate with the wider work of sexual health services. Welsh Government officials will continue to work closely with Vaccine Programme Wales (VPW) and Public Health Wales (PHW) to minimise disruption to the NHS delivery and sexual health. The Welsh Government has and will continue to act in collaboration with VPW and PHW in planning the implementation of the vaccination programmes and monitoring their success, through regular engagement. Relevant stakeholders were involved to inform this integrated impact assessment and will be kept up to date as the policies develop. Subject to Ministerial agreement, the Welsh Government will work with clinical and operational colleagues to inform decisions on how both mpox and gonorrhoea vaccination programmes would be delivered in 2025.

In order to maximise the benefits described, vaccination must be accessible to all who are eligible.

To maximise uptake for both programmes in hard-to-reach groups, NHS Wales, through Sexual Health Services (SHS), will be implementing the principles of the National Immunisation Framework, published by the Welsh Government in 2022<sup>2</sup>, which aims to transform and improve the delivery of vaccination and immunisation

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<sup>2</sup> <https://www.gov.wales/national-immunisation-framework-wales>

programmes for the people of Wales, with an emphasis on increased uptake and with equity at its core.

The vaccines will be offered on an opportunistic basis through SHS which have the experience in assessment and identification of those who are at increased risk of infection with bacterial sexually transmitted infections (STIs).

SHS will be expected to offer tailored support to enable and encourage under-served groups to take-up the offer of the vaccination. This requires a proactive approach to ensure that:

- Equitable access to vaccination is given to those considered most at risk
- Everyone is supported with the information that they need to make an informed decision on vaccination based upon reliable sources.

The introduction of both vaccination programmes should be supported by a tailored communications campaign targeted at reaching the GBMSM community and to those with equivalent risk factors, to promote the benefits of vaccination and address the associated stigma.

Person centred, accessible deployment options are critical to maximising uptake. It is proposed that both vaccination programmes will be delivered via SHS, with a minority of those eligible identified and vaccinated via other routes, such as GP surgeries. Bringing vaccines as close to individuals as possible improves uptake – SHS operate clinics throughout Wales, with eligible individuals able to access vaccination at clinics outside of their local health board.

#### **8.4 How will the impact of the proposal be monitored and evaluated as it progresses and when it concludes?**

The implementation of the mpox and gonorrhoea vaccination programmes will be monitored by VPW who will report back to Welsh Government via the Vaccine Oversight Board as part of the national governance arrangements.

A four-nation project board has been set up to discuss implementation and align deployment to ensure consistency across the UK and NI. These meetings will continue to monitor progress along with meetings at official level. Regular, quarterly surveillance reporting will be established by the Vaccine Preventable Diseases Programme (VPDP), utilising existing sexual health systems. These surveillance reports will help inform health boards and sexual health clinics plans in promoting equity and ensuring the eligible cohorts are targeted to maximise vaccine uptake.

Welsh Government will continue to liaise with all relevant stakeholders beyond the implementation phase to monitor progress and evaluate the initial rollout. Officials will continue to attend JCVI vaccination meetings, as observers, to monitor any future discussion on mpox and gonorrhoea and any changes they might advise.