Title	Section 13: Human Papilloma Virus Vaccination (HPV) for MSM patients
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Borders Sexual Health

Protocols

Section 19: Human Papilloma Virus Vaccination (HPV) for MSM patients

What's new in Version 4 of the HPV vaccination protocol?

- **The HPV vaccine used in national programmes will be changing from the quadrivalent Gardasil^{R} vaccine to the nonavalent Gardasil^{R}9 vaccine**
- **The two Gardasil vaccines can be used interchangeably for completion of any vaccine schedules already commenced.**
- **For HIV negative and otherwise immunocompetent MSM, the vaccine schedule is reduced to two doses, administered at least 6 months apart**
- Once started, a vaccine course should just be completed (using a Gardasil vaccine) even if the 24-month recommended period has elapsed, rather than restarting a new course
- If a patient is HIV negative and immunocompetent and has had **two doses of HPV vaccination at least 6 months apart** at some point in the past, a third dose is now no longer required.
- **HIV positive or immunocompromised MSM should continue to receive a three-dose vaccination schedule, with the 3 doses timed at 0, 1 month and 4-6 months.** (It is recommended that there is at least 1 month period gap between the first and second dose and at least 3 months between the second and third dose).

What is HPV?

HPV is a double stranded DNA virus which infects squamous epithelia, including skin and mucosal surfaces of the upper respiratory and ano-genital tract. Of the > 100 types of HPV present, about 40 infect the genital tract.

Genital HPV are transmitted primarily via sexua**l** contact, including penetrative sexual intercourse, oral intercourse and non –penetrative genital contact. Studies have demonstrated that incident genital HPV infection occurs soon after sexual debut, with almost 40% of women having at least one HPV type within 2 years of coitarche. Infection with multiple HPV types is common. Condoms reduce, but do not completely prevent, the transmission of genital HPV.

While most HPV infections are asymptomatic and self limiting, genital HPV infection may be linked with genital warts or anogenital cancers in both men and women. HPV types are classified as high or low risk based on their association with the development of cancer. The low risk HPV types 6 and 11are commonly associated with genital warts whilst high risk HPV types, most commonly 16 and 18, can lead to cervical, anal, penile, vulvo-vaginal and oropharyngeal cancers. Around 70% of cervical, 80-90% of anal, 50% of penile, 40% vulvo-vaginal and 50% oropharyngeal cancers are considered associated with high risk HPV infection.

Why vaccinate MSM?

- The UK HPV vaccination programme initially started in 2008 and covered secondary school girls only (the bivalent Cevarix vaccine was used Sept 2008 – Aug 2012, following which period it was switched to the quadrivalent Gardasil vaccine).
- This vaccination programme has subsequently been shown to be extremely effective, with vaccinated young women having significant reduction of HPV type 16 and 18 infections, cervical pre-cancerous lesions and cancer. First episode genital wart incidence also declined dramatically, in young heterosexual males as well as females, signifying a substantial herd immunity effect.
- However, MSM were unlikely to be protected to any significant extent by the herd immunity extending to heterosexual boys. In addition, the MSM population has been shown to have a significantly higher burden of baseline HPV related cancers in comparison to heterosexual men. Therefore, following detailed review of evidence and cost-effectiveness considerations, the Joint Committee on Vaccination and Immunisation (JCVI) recommended targeted vaccination of MSM attending specialist sexual health and HIV services **up to and including the age of 45 years.**
- Since Sept 2019 the national HPV school vaccination programme has been extended to include adolescent boys as well as girls. **MSM who have been vaccinated as part of this new universal school vaccination programme do not require additional HPV vaccination within sexual health services.**

Which HPV vaccination and how should it be administered?

- The current HPV vaccine available in Scottish sexual health services is Gardasil^{R} - a quadrivalent vaccine protecting against HPV types 6, 11, 16 and 18. **During 2022, the**

quadrivalent Gardasil^{R} vaccine will be replaced by the nonavalent Gardasil^{R}9 vaccine on the UK national vaccination programmes, including for both MSM and adolescents. Gardasil^{R}9 protects against high risk HPV types 31, 33, 45, 52 and 58, in addition to 6, 11, 16 and 18 infections.

- **The two different Gardasil vaccines should be considered interchangeable for the purposes of completing any already started vaccine courses** (i.e. a patient who started a vaccination course with Gardasil^{R} can complete the remaining doses with the Gardasil^{R}9 vaccine, instead of restarting a new course.)
- HPV vaccines are NOT live and cannot cause any HPV disease themselves.
- HPV vaccination should be offered **opportunistically to MSM patients attending sexual health and HIV services, up** t**o and including the age of 45 years. Once started, the vaccination schedule can be completed beyond the age of 45.** Transgender individuals with a similar risk profile to MSM can also be offered vaccination under this programme.
- Individuals who completed vaccination under the national school HPV vaccination programme do not require any further vaccination within sexual health.
- **The JCVI have now noted that a two dose schedule is adequate for HPV vaccination of both adolescents and adults, except in individuals living with HIV or immunosuppression at the point of vaccine offer.**
- **The two vaccine doses should be given AT LEAST <u>6 MONTHS APART</u> and preferably within 24 months of each other,** However, once started, a vaccine course should just be completed (using a Gardasil vaccine) even if the 24 month recommended period has elapsed, rather than restarting a new course.
- If a patient is HIV negative and immunocompetent and has had two doses of HPV vaccination at least 6 months apart at some point in the past, a third dose is now no longer required.
- **A three dose vaccine schedule is still recommended for HIV positive or immunocompromised individuals, with the 3 doses timed at 0, 1 month and 4-6 months.** (It is recommended that there is AT LEAST 1 month period gap between the first and second dose, and AT LEAST 3 months between the second and third dose). The JCVI guidance <u>states that all three doses should be ideally given within12 months and a 24-month period is clinically acceptable</u>. If the vaccine course is interrupted, it should be resumed (using another Gardasil vaccine) but not repeated, ideally allowing the appropriate interval between the remaining doses.
- Vaccination should be administered via <u>i</u>ntramuscular injection in the deltoid area of the upper arm, similar to Hepatitis A and B vaccinations.
- It is safe <u>t</u>o give the HPV vaccine with other vaccines such as for Hepatitis A and B and Monkeypox but the different vaccines should preferably be administered at different limbs. If vaccines are given in

the same arm, they should be given at least 2.5cm apart. Document the sites of administration for each vaccination,

- HPV vaccination should not be given to individuals who have had a confirmed anaphylactic reaction to a previous dose or a confirmed anaphylactic reaction to any component of the vaccine.

Vaccination Schedules:

For HIV negative and immunocompetent MSM (and suitable transgender) patients aged 45 years and under, who have not been previously vaccinated against HPV infection:

- Offer the two dose Gardasil vaccination schedule at 0 and 6 months (prescribe the full schedule on NASH at initial consultation). **There should be a MINIMUM of 6 months between the two doses** and it is recommended that both doses are given within 24 months
- If required, the HPV vaccination doses can coincide with Hepatitis vaccinations (for example the two Gardasil doses can usually be given at the same time as the 1st and 3rd doses of a Twinrix 0,1 and 6 months three dose course). Similarly, if tolerated, the HPV and Hepatitis vaccinations can be given at the same time as the Monkeypox vaccinations. The different vaccines should preferably be administered at different limbs. If vaccines are given in the same arm, they should be given at least 2.5cm apart. Document the sites of administration for each vaccination.

For HIV positive or immunocompromised MSM (and eligible transgender) patients aged 45 years and under, who have not been previously vaccinated against HPV infection:

- Offer the three dose Gardasil vaccination schedule at 0, 1 and 6 months (prescribe full schedule on NASH at initial consultation). **It is recommended that there is AT LEAST 1 month period gap between the first and second dose, and AT LEAST 3 months between the second and third dose).** The JCVI guidance states that all three doses should be ideally given within 12 months and a 24-month period is clinically acceptable.
- If required, the HPV vaccination doses can coincide with hepatitis (i.e. Twinrix, Havrix or Engerix) vaccinations. Similarly, if tolerated, the HPV and Hepatitis vaccinations can be given at the same time as the Monkeypox vaccinations. The different vaccines should preferably be administered at different limbs. If vaccines are given in the same arm,

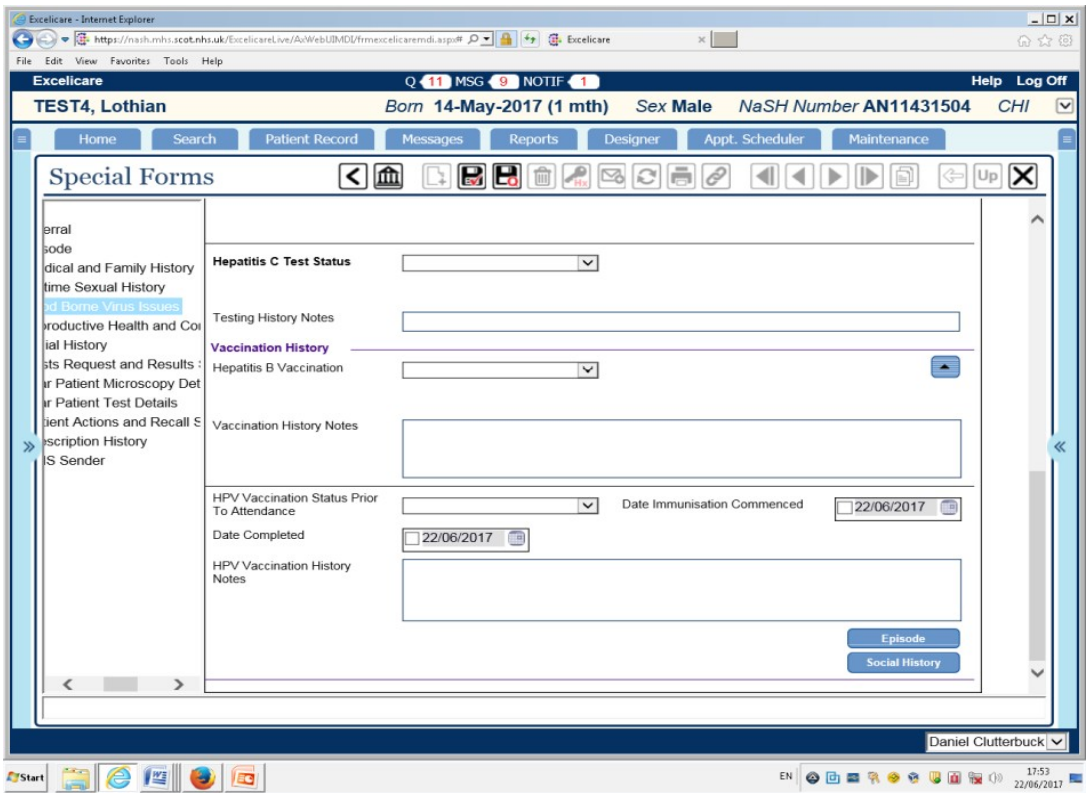
they should be given at least 2.5cm apart. Document the sites of administration for each vaccination.

Side effects of HPV vaccination

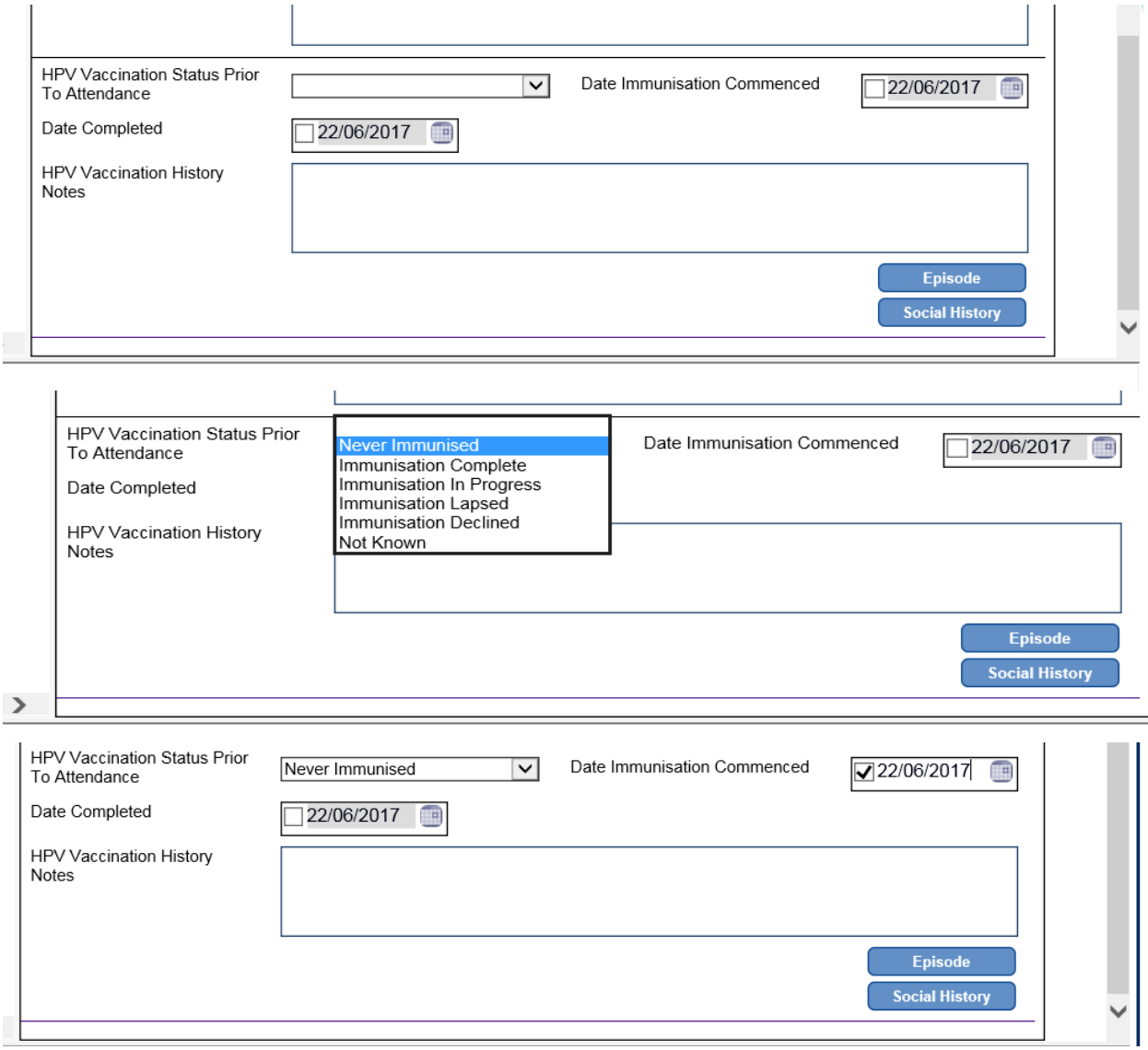
- Local site side effects are commonest: mild to moderate short-lasting pain at the injection site and/ or redness.
- Other commonly reported side effects include headache, myalgia, fatigue and low-grade fever.
- Fainting and panic attacks occurring before or shortly after vaccination are not considered direct side effects (adverse reactions) of the vaccine but are events associated with the injection process itself.
- Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the Yellow Card Scheme (www.mhra. gov.uk/yellowcard)

Recording Vaccination

Use the Blood Borne Virus page on NaSH, scroll to the bottom

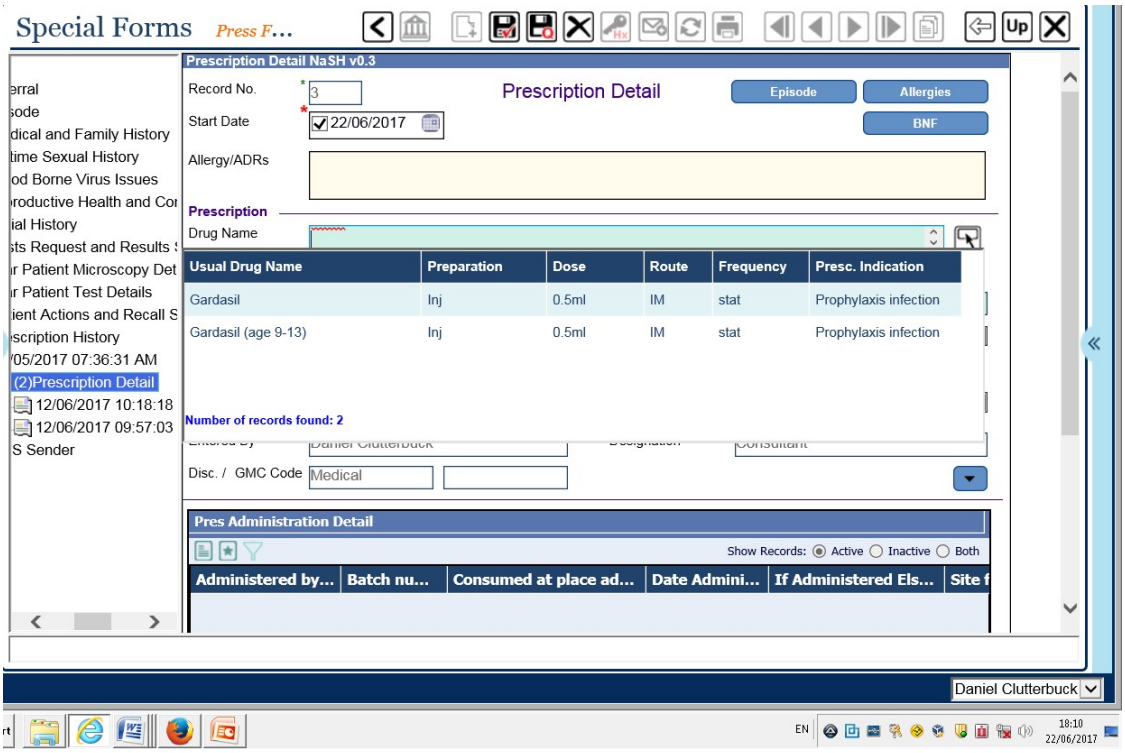


- Complete HPV vaccination status prior to attendance
- If vaccination declined, choose ‘immunisation declined’ from dropdown
- Check box ‘Date Immunisation commenced’ if starting vaccination course
- Check box ‘Date completed’ when giving final vaccination

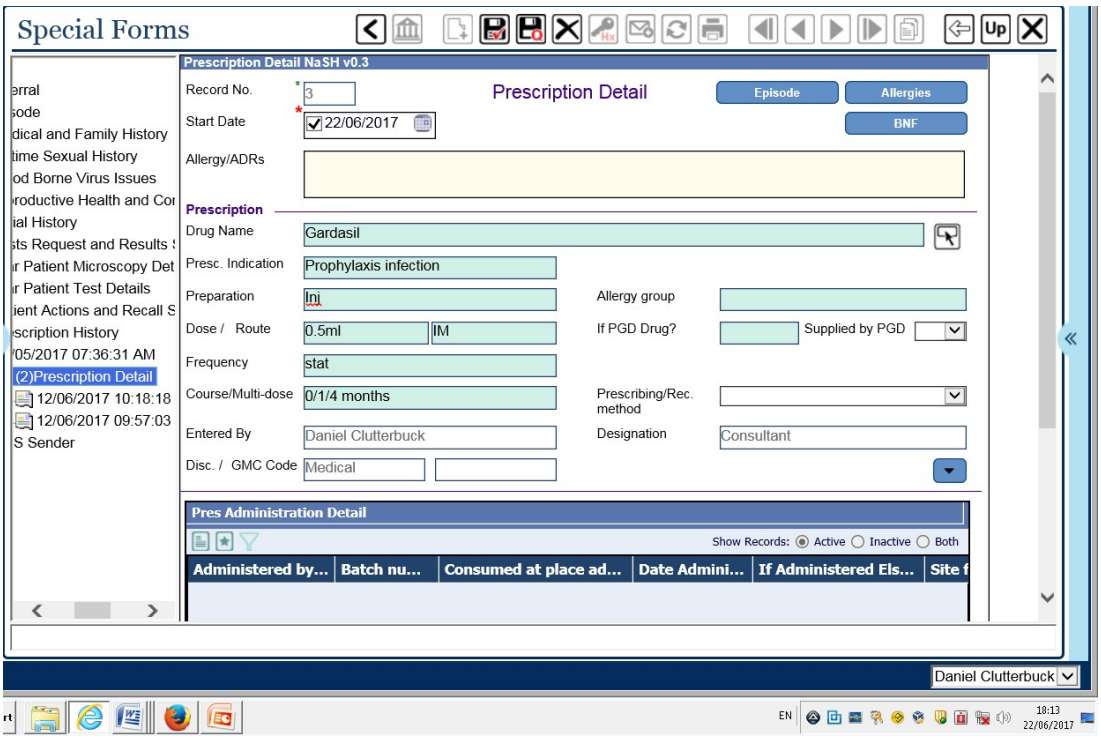


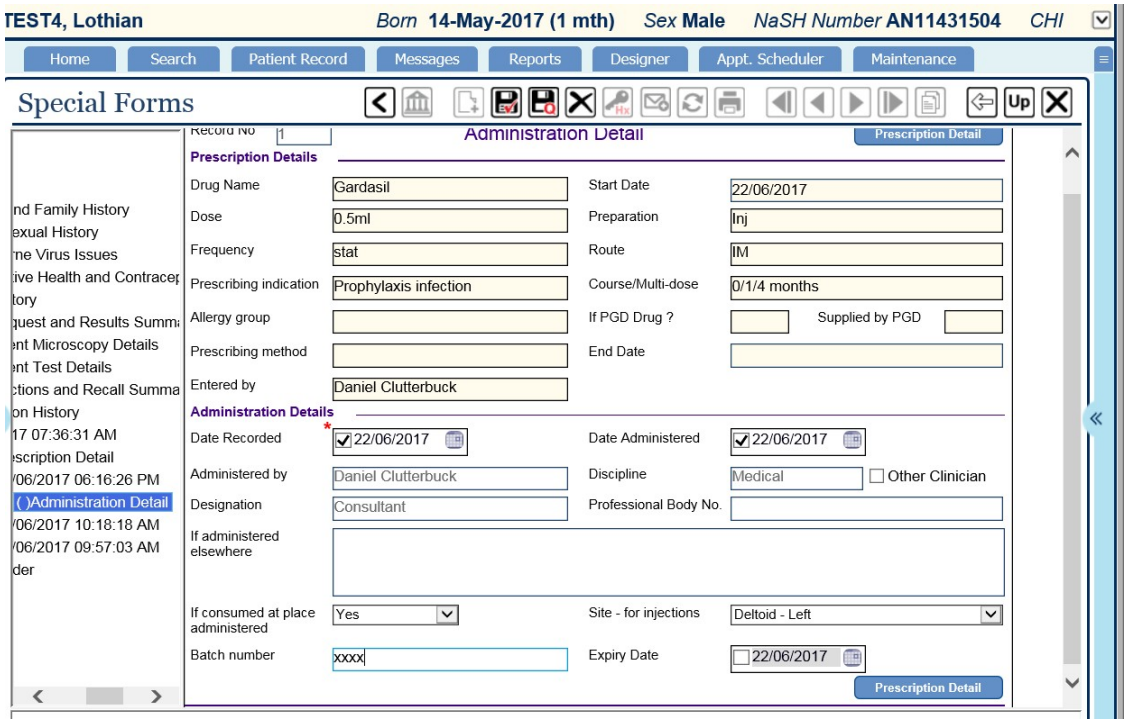
Prescribing Gardasil

Use the prescribing page on NaSH



Choose Gardasil from the drop-down menu (choose Gardasil^{R} or Gardasil^{R}9 as per availability in clinic).





Enter administration details in the usual way, as for hepatitis vaccination

- Date administered
- GMC/NMC number
- Site of injection
- Batch number
- Expiry date

More Information

- Human papillomavirus (HPV): the green book, chapter 18a - GOV.UK (www.gov.uk)
- http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/human-papillomavirus-msm.aspx

- FAQs sheet – very helpful
  - http://www.nes.scot.nhs.uk/media/3977006/HPV%20MSM%20FAQs%20Final%20080617.pdf

- CMO Letter 2 dose Schedule
  CMO_Letterhead.dot (scot.nhs.uk)

- CMO letter Gardasil 9
  CMO(2022)24.pdf (scot.nhs.uk)