Public Health England

NHS

NHS Publishing Approval Reference: PAR779
PHE Gateway Number: GOV-8908

NHS England - NHS Improvement Regional Directors
NHS England - NHS Improvement Directors of Commissioning
NHS England - NHS Improvement Directors of Public Health and Primary Care
NHS England - NHS Improvement Heads of Public Health Commissioning
NHS England - NHS Improvement Heads of Primary Care
NHS England - NHS Improvement / Public Health England Screening and Immunisation Leads
Clinical Commissioning Groups Clinical Leaders
Clinical Commissioning Groups Accountable Officers
General Practitioners
Local Medical Committees
Local Authority Chief Executives
Local Authority Directors of Public Health

For information:
Chief Pharmacists of NHS Trusts
NHS Foundation Trusts
NHS Trusts

27 July 2021

Changes to the vaccine of the HPV immunisation programme

Dear Colleague,

This letter provides information about forthcoming changes to the HPV immunisation programme. This letter is aimed at health professionals who are responsible for commissioning and delivering the programme. We encourage you to share this guidance with all those who are involved in delivering the national HPV vaccination programme in your area.

Main points about the changes to the programme:

- **Change to the vaccine:** the vaccine supplied for the programme will change from Gardasil® to Gardasil® 9 during the 2021 to 2022 academic year. PHE will continue to supply vaccine for the HPV programme in the usual way and will issue the remaining

central supplies of Gardasil® before the switch to Gardasil® 9, which will occur at some point between late 2021 and early 2022. This change will affect both arms of the HPV programme (adolescents aged 12 to 13 years and those who remain eligible until their 25th birthday, and MSM up to 45 years of age). For the school-based programme in particular, there will need to be clear communication with parents and eligible adolescents and robust arrangements in place to ensure the consent process is adequate for this transition period during the 2021 to 2022 academic year. Further details on supply can be found in **Annex A.**

- Further detailed information and guidance for healthcare professionals is set out in **Annex A**.
- Details on ImmForm vaccine coverage data collection are set out in **Annex B**.
- **Annex C** includes information on vaccination records and data capture.
- Available programme resources to support the change have been set out in **Annex D**.
- **Annex E** includes a question and answer sheet to help you deal with questions that patients and their parents may ask about these changes.

If you have any queries about the content of this letter please contact immunisation@phe.gov.uk.

Update on the UK programme

There is growing evidence of the success of the programme so far. In 2018, ten years after the introduction of the programme, the prevalence of HPV types 16/18 in 16 to 18 year old women in England who were offered vaccination at age 12 to 13 years had reduced substantially to less than 2% (compared to over 15% prior to the vaccination programme in 2008)[1].

A 2018 Scottish study showed that the vaccine has reduced pre-cancerous cervical disease in 20 year old females by up to 71%. In England, diagnoses of genital warts have declined by 91% and 81% between 2015 and 2019 in 15 to 17 year old girls and boys, respectively (the latter demonstrating herd protection)[2].

From September 2019 the adolescent HPV vaccination programme became universal with 12 to 13 year old males becoming eligible alongside females.

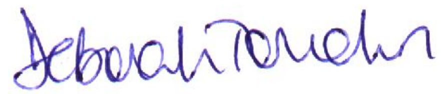
In June 2020, following the impact of the first wave of the Covid-19 pandemic NHSE-commissioned, school-aged immunisation providers were able to implement their restoration and recovery plans to commence catch-up of partially or incomplete programmes during the summer period. This included delivery of programmes in school and community settings. During the 2020 to 2021 academic year, school aged providers have continued to catch up the 2019 to 2020 academic year pupils, alongside the current year.

We would like to take this opportunity to thank all involved for their hard work to continue to deliver the HPV immunisation programme during this challenging time.

---

[1] Surveillance of type-specific HPV in sexually active young females in England to end 2018
[2] Sexually transmitted infections and screening for chlamydia in England,2019

Yours faithfully,



Deborah Tomalin
NHS England and NHS Improvement
Director of Public Health
Commissioning and Operations

Dr Mary Ramsay
Public Health England,
Head of Immunisation

Annex A - Detailed information and guidance for healthcare professionals

Why has the vaccine been changed?

The 9-valent vaccine Gardasil® 9 (manufactured by MSD) received licensing approval from the European Medicines Agency (EMA) for a two dose schedule in adolescent girls in April 2016 and is licensed for individuals aged 9 up to and including 14 years of age (SPC, Gardasil9).

For the nine-valent vaccine the indication is based on non-inferiority with the 4 vaccine types in the 4-valent vaccine for girls, women and men; demonstration of efficacy against HPV Types 31, 33, 45, 52 and 58 in girls and women and; demonstration of non-inferior immunogenicity against the Gardasil 9 HPV types in boys and girls aged 9 to 15 years and men aged 16 to 26 years, compared to girls and women aged 16 to 26 years. Gardasil® 9 can be used for all those eligible: adolescents aged 12-13 years and those who remain eligible until they turn 25 years of age, and MSM up to 45 years.

At its meeting in June 2016, the Chair of the Joint Committee on Vaccination and Immunisation (JCVI) summarised that the 9-valent vaccine was the preferred vaccine for the girl's programme because of the additional health benefits that it provided in protecting against the 5 additional cancer causing HPV types[3]. The JCVI has not made any statements or given any advice about the vaccine of choice for a gender-neutral programme.

Vaccine supply

PHE will continue to supply vaccine for the HPV programme in the usual way and will issue the remaining central supplies of Gardasil® before the switch to Gardasil® 9, which will occur at some point between late 2021 and early 2022. ImmForm customers should refer to the ImmForm website for updates on timing of the switch.

Gardasil® 9 will be supplied for both arms of the HPV programme (adolescents aged 12 to 13 years and those who remain eligible until they turn 25 years of age, and MSM up to 45 years). As the programme transitions to Gardasil® 9, some individuals will receive a mixed schedule during the switch. The two vaccines should be considered interchangeable and vaccination should not be delayed due to preference for either vaccine.

Local supplies of Gardasil® should not be ringfenced for those who have already received a first dose of Gardasil®. Local supplies of Gardasil® should be used up prior to switching to Gardasil® 9.

Patient Group Directions (PGDs)

New PGD templates to support the provision of Gardasil® 9 will be published from July 2021.

Funding and service arrangements

From 1 April 2021 all provision of vaccination and immunisation services in general practice are essential services (with the exception of childhood and adult seasonal flu). A single item of service fee has been implemented for all doses delivered in vaccination programmes funded through the GMS contract, including where additional doses are

[3] Minutes of JCVI main committee meeting June 2016

required to meet clinical need and where children are vaccinated outside the routine schedule.

GP practices are required to provide (HPV) vaccinations to adolescent girls and boys who have attained the age of 14 years but who have not attained the age of 25 years who have missed vaccination under the schools' programme. Those eligible who missed vaccination in schools will be able to receive the vaccination opportunistically, or if requested, until the age of 25. Eligibility for boys include males born on or after 1 September 2006. An item of service fee will only be applicable for those vaccinations administered by the GP practice.

Payment for HPV will not be supported with an automated data extraction and monthly payment via CQRS for 2021 to 2022 and will remain a manual service for this year.

School aged providers are commissioned on the basis of 100% offer to all those eligible, including those who are home-schooled. Routine offer of vaccination is made for those eligible aged 12 or 13 years in School Year 8. Funding arrangements with commissioned providers remain unchanged.

Information for healthcare professionals and patients

Detailed clinical guidance on HPV immunisation is contained in chapter 18a[4] of Immunisation Against Infectious Disease (the Green Book). Please note a revised HPV chapter is due to be published shortly.

Healthcare professional information and guidance to support the HPV programme will be updated to reflect the above changes, including a training slide set, and become available on the HPV immunisation programme webpage[5] from July 2021.

Updated public information materials will be available on the HPV immunisation programme webpage[6] and to order from the Health Publications website[7] before September 2021.

Consent

There will need to be a clear communication with parents and eligible adolescents and robust arrangements will be needed to obtain consent for immunisation. Guidance on consent can be found in the guidance for health professionals[8] and Chapter 2[9] in the Green Book.

The consent form template will be updated:

HPV vaccination programme - GOV.UK (www.gov.uk)

[4] Human papillomavirus (HPV) chapter, chapter 18a of the Green Book
[5] HPV vaccination programme webpage
[6] HPV universal vaccination guidance for health professionals
[7] Health Publications website
[8] HPV universal vaccination guidance for health professionals
[9] Consent: the Green Book, chapter 2

Annex B - Vaccine coverage data collection

The routine HPV vaccine coverage collection for the adolescent programme will not be impacted by the changes announced in this letter.

Dose 1 and Dose 2 coverage of HPV vaccine will continue to be evaluated for both males and females in school Year 8 (ages 12 to 13 years old) and Year 9 (ages 13 to 14 years old) as part of the routine universal programme.

HPV coverage is based on aggregated school level data. The data is entered manually on a secure web platform called ImmForm. Vaccination type is not recorded.

Guidance for the 2020 to 2021 annual survey will be updated and available here:
https://www.gov.uk/government/publications/adolescent-vaccine-coverage-user-guidance

Annual HPV coverage reports are available here:
https://www.gov.uk/government/collections/vaccine-uptake#hpv-vaccine-uptake

MSM HPV immunisation programme - vaccine coverage collection

HPV vaccination uptake collections for the MSM programme will not be significantly impacted by the changes announced in this letter.

Vaccine coverage (uptake and completion) will continue to be evaluated for MSM aged up to and including 45 years attending specialist sexual health services (SSHS) and HIV clinics.

HPV vaccination data for MSM is entered for all attendances via the GUMCAD and HARS mandatory reporting systems for SSHS and HIV clinics, respectively.
Annual reports of HPV vaccination uptake in MSM are available here:
https://www.gov.uk/government/publications/hpv-vaccination-uptake-in-men-who-have-sex-with-men-msm

Annex C – Vaccination records and data capture

Accurate recording of all vaccines given, and good management of all associated documentation is essential and as per the core elements set out in the core service specifications, Statement of Financial Entitlement (SFE) and contracts.

The provider must ensure that information on vaccines administered, including the name of the vaccine administered, that is, Gardasil 4 or 9 is submitted directly to the Registered General Practitioner and any relevant population immunisation registers, in most areas this is the Child Health Information System (CHIS).

Following an immunisation session/clinic or individual immunisation, local arrangements should be made for the transfer of data onto the relevant CHIS. Where possible this should aim to be within two working days.

Arrangements will also be required to inform neighbouring areas when children resident in their area are immunised outside their local area.

NHS England will continue to work with NHS X, NHS Digital and NHSE S7a regional commissioners to ensure robust data pathways are in place to enable the accurate recording and reporting of vaccines administered. This includes any additional reporting requirements to align vaccination status with screening programmes, for example, for young females who become eligible for the NHS Cervical Screening programme.

Annex D – Programme resources available / updated

Health Professional guidance for HPV for all (universal programme)

HPV universal factsheet for health professionals

HPV cervical cancer factsheet

Patient facing resources

HPV for all leaflet
This is also available translated into Arabic, Bengali, Chinese, Czech, Farsi, French, Pashto, Polish, Portuguese, Panjabi, Somali, Romanian, Russian, Tigran and Urdu

HPV for all record card – 2 dose schedule

HPV for all poster

HPV for MSM programme

Health Professional guidance for HPV for MSM programme

HPV for MSM clinical and operational guidance

HPV vaccination for MSM: posters and leaflets

Patient facing resources

HPV for MSM leaflet

HPV for MSM poster

Annex E - Question and answer sheet

Q. Is Gardasil® inferior to Gardasil® 9?

A. Gardasil® has been shown to be highly effective in preventing the types of HPV infection for which it is indicated. Evidence from clinical trials has shown that protection is maintained for at least ten years but is expected to last much longer and may be lifelong. Gardasil® has been shown to give good protection against HPV types16 and 18 which account for around 70% of all cervical cancers. and HPV6 and HPV11, the two HPV types that cause approximately 90% of all anogenital warts in males and females. In clinical trials in young women with no previous history of HPV infection, the vaccine was 99% effective at preventing pre-cancerous lesions associated with HPV types 16 and 18. Gardasil® is also 99% effective at preventing genital warts associated with vaccine types in young women.

Q. What should we say to those who request two doses of the same vaccine?

A. While the vaccine supplied for HPV vaccinations is changing from Gardasil® to Gardasil® 9, there will only be one type of vaccine available for the adolescent and MSM programmes at any given time. Therefore, depending on when the transition occurs for the respective programme, individuals may receive two doses of Gardasil®, two doses of Gardasil® 9, or a mixed schedule. The two vaccines should be considered interchangeable and vaccination should not be delayed due to preference for either vaccine.

Q. What do we say to those who have already been vaccinated?

A. They did exactly the right thing in being vaccinated. As a result of their vaccination, they are significantly less likely to be infected by HPV types 16 and 18 that cause over 70 per cent of cervical cancers in the UK – which is an excellent outcome.

Q. Should those who received Gardasil® now be boosted or revaccinated?

A. Gardasil® provides good protection against HPV-related cancers and boosters or revaccination after the initial course are not required.

Q. Is there something wrong with Gardasil®?

A. No. Gardasil® has an excellent safety record established after use of more than 7 million doses in the routine immunisation programme in the UK since it was first used in 2012, with more doses used in other countries. No serious new safety issues have been found with Gardasil® since it was introduced in the UK, and it has been shown to provide good protection against cervical and other HPV-related cancers.

Q. Is Gardasil® 9 a new vaccine? Do we know how safe it is?

A. Gardasil® 9 has been used extensively in other countries since it was first licensed in 2015 and its safety is well established. The Medicines and Healthcare Products Regulatory Agency and the JCVI keeps the safety of vaccines under review.

Q. How will you monitor if there are any adverse reactions when Gardasil® 9 starts to be used?

A. As with any vaccine or medicine newly introduced in the UK, the MHRA will closely monitor the safety of Gardasil® 9. Health professionals and those vaccinated will be asked to help confirm the safety profile by reporting any suspected side effects through the Yellow Card Scheme, and the MHRA will regularly review any such reports using statistical and epidemiological techniques.

Q. My child has completed the course of Gardasil® but I want them to be vaccinated with Gardasil® 9 so they are protected against these further strains.

A. The primary purpose of the national immunisation programme is to protect against HPV-related cancers. Gardasil® has been shown to give good protection against HPV-related cancers. It would not be appropriate therefore as part of the NHS programme to offer Gardasil® 9 to those who have had a full course of Gardasil®.