WHC/2022/15

WELSH HEALTH CIRCULAR

Issue Date: 1 June 2022

Llywodraeth Cymru
Welsh Government

STATUS: ACTION

CATEGORY: PUBLIC HEALTH

Title: : Changes to the vaccine for the HPV immunisation programme

Date of Expiry / Review N/A

For Action by:
Immunisation Leads, Health Boards/Trusts
School nurses, Health Boards/Trusts
Chief Executives, Health Boards/Trusts
Medical Directors, Health Boards/Trusts
Nurse Executive Directors, Health Boards/Trusts
Directors of Public Health, Health Boards
Chief Executive, Public Health Wales
Executive Director of Public Health Services, Public Health Wales
Nurse Director, Public Health Wales
Head Vaccine Preventable Disease Programme, Public Health Wales
NHS Wales Informatics Service

For information to:

Directors of Workforce and Organisational Development
Finance Directors
Health Boards/Trusts
Directors of Primary, Community and Mental Health, Health Boards
Chief Pharmacists, Health Boards/Trusts
Chief Executive, Welsh Local Government Association

General Practitioners

Sender:
Sir Frank Atherton, Chief Medical Officer/Medical Director NHS Wales

HSSG Welsh Government Contact(s) :
Vaccination Programme Team, Health and Social Services Group, Welsh Government, Cathays Park, Cardiff. CF10 3NQ Email: wg.vaccinationsprogrammeteam@gov.wales

Dear Colleague,

This letter provides information on the forthcoming changes to the human papillomavirus (HPV) immunisation programme. This letter is aimed at health professionals who are responsible for delivering the programme. I encourage you to share this guidance with all those who are involved in delivering the national HPV vaccination programme in your area.

Key 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 2022/23 academic year.

The UK Health Security Agency 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 in the second quarter of 2022.

Eligibility

There is no change to the eligibility criteria for this vaccine, and the change of vaccine will affect all parts of the HPV programme (adolescents aged 12-13 years, those who remain eligible until their 25th birthday, and individuals from the MSM community 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 2022/23 academic year.

Further detailed information and guidance for healthcare professionals is set out in *Annex A*.

Annex C includes a question and answer sheet to help you deal with questions that patients and their parents may ask about these changes.

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 and18 in 16-18 year old women in England who were offered vaccination at age 12-13 years had reduced substantially to less than 2% (compared to over 15% prior to the vaccination programme in 2008).

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, a recently published Cancer Research UK-funded study found that cervical cancer rates in women offered the vaccine between the ages of 12 and 13, and now in their 20s, were 87% lower than in an unvaccinated population.

HPV vaccine coverage rates have recently fallen compared with previous years, with a variable picture across health boards. Of all the teenage vaccines, HPV uptake appears to have been the most impacted by school closures, due to the pandemic.

The 2020/21 academic year cohort included the first group of boys to be offered the HPV vaccine in addition to girls. HPV vaccine uptake in the full 2020/21 Year 9 group (reaching their 14th birthday between 01/09/20 and 31/08/21) was 67.4% (71.1% for girls and 64.0% for boys). This is a decrease compared to the previous years' girls only cohort where uptake was 87.3%. Coverage of two doses of HPV vaccine in girls in the 2020/21 Year 10 group is currently 56.5%, this is a significant decrease from the previous year which had an uptake of 83.5%.

Catch-up immunisations will be required for those in these cohorts who did not receive immunisations as scheduled and health boards should make plans for such if they have not already done so. The efficacy evidence is clear, and we must do all we can to make the vaccine accessible and boost uptake.

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

Further information and guidance can be found in the attached Annexes.

Yours sincerely,

Sir Frank Atherton
Chief Medical Officer / Medical Director NHS Wales

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, Gardasil®9).

For the 9-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 in line with official recommendations: adolescents aged 12-13 years and those who remain eligible until they turn 25 years of age, and individuals from the MSM community 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. The JCVI has not made any statements or given any advice about the vaccine of choice for a gender-neutral programme.

Vaccine supply

The vaccine for the HPV programme will continue to be supplied in the usual way via ImmForm and the remaining central supplies of Gardasil® will be issued before the switch to Gardasil®9, which will occur at some point in the second quarter of 2022. ImmForm customers should refer to the ImmForm website for updates on timing of the switch.

Gardasil®9 will be supplied for all parts of the HPV programme (adolescents aged 12-13 years and those who remain eligible until they turn 25 years of age, and individuals from the MSM community 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 ring-fenced 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 have been published and are available from the PGD intranet page.

Service arrangements

There are no changes to the eligibility criteria for the HPV vaccination programme. The adolescent programme will continue to be offered in Years 8 and 9 in schools.

GP practices are required to provide (HPV) vaccinations to adolescent girls and boys who have missed the opportunity to be vaccinated in school (including via catch up programmes). 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.

Funding

Funding for the HPV vaccination programme is contained within health boards' core budgets. However, due to the significant difference in vaccine price between Gardasil® and Gardasil®9, additional funding will be made available to cover the increased cost of delivering the programme. Details of funding allocations will be issued shortly via a separate letter. There will be no changes to funding for any other aspect of the programme.

Information for healthcare professionals and patients

Detailed clinical guidance on HPV immunisation is contained in chapter 18a of Immunisation against Infectious Disease (the Green Book).

Healthcare professional information and guidance to support the HPV programme has been updated to reflect the above changes, including a training slide set, and will be available from the HPV vaccine - Information for health professionals

Updated public information materials will be available from the Health Information Resources page on the Public Health Wales website.

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, in particular given the change in vaccine. Guidance on consent can be found in the HPV vaccination: guidance for healthcare practitioners and Chapter 2 in the Green Book.

The consent form template will be updated and will be available from the HPV vaccine - Information for health professionals

Annex B – Programme resources available / being updated

Health Professional guidance for HPV for all (universal programme)

Green Book HPV chapter 18a

HPV Patient Group Direction (PGD)

HPV vaccination guidance for HCP

HPV **Factsheet for health professionals, parents and young people**

Patient facing resources

HPV vaccination Protecting against HPV infection to help reduce your risk of cancer leaflet

Protecting you from HPV cancers poster

Template letter for parents

Accessible format resources

HPV for MSM community programme

HPV Patient Group Direction (PGD) for MSM

HPV vaccination guidance for HCP

Resources for the MSM programme will be available from the HPV vaccine - Information for health professionals

Annex C - 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 types 16 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®.