GARDASIL®9
Human Papillomavirus 9-valent Vaccine
(Recombinant, adsorbed)

Increasing Human Papillomavirus (HPV) immunisation uptake with a focus on eligible 14 to 25-year-olds under the NHS National Immunisation Programme (NIP)

HPV Vaccination Best Practice Guide

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Prescribing information for Great Britain & Prescribing information for Northern Ireland

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Adverse event reporting is available on the next page.

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MSD

Gardasil 9 therapeutic indications

GARDASIL® 9 is indicated for active immunisation of individuals from the age of 9 years against the following HPV diseases:

- Premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccines HPV types.
- Genital warts (Condyloma acuminata) caused by specific HPV types.

The use of GARDASIL® 9 should be in accordance with official recommendation

HCPs must consult the SmPC for further information before making any prescribing decisions.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to MSD (Tel: 0208 154 8000).
By clicking the above link, you will leave the MSD website and be taken to the MHRA website.

Background

2007
HPV immunisation programme for girls recommended

In 2007 the Joint Committee for Vaccination and Immunisation (JCVI) met and recommended a Human Papillomavirus (HPV) immunisation programme for girls aged 12–13 years old with a catch-up programme instigated to immunise girls aged 13–18 years old[1]. In 2008, when this programme came into place the aim at that time was to reduce the risk of cervical cancer caused by the HPV types 16 and 18, which were included in the vaccines[2].

2014
Dose reduction for under 15s

Since its introduction the HPV immunisation programme has remained under review by JCVI, and the programme has changed over the intervening years. The initial 3 dose schedule was reduced to a 2 dose schedule for recipients under 15 years of age in May 2014[3].

2015
MSM up to and including age 45 became eligible for HPV vaccination

In 2015 the JCVI advised that all men who had sex with men (MSM) up to and including 45 years of age should be offered HPV vaccination[4], this programme is delivered via specialist sexual health and HIV services. Since the introduction of the programme for eligible girls in 2008 the JCVI continued to review evidence and data in consideration of extending the programme to other groups, including boys.

2018
Universal HPV programme announced for girls & boys

In 2018 the JCVI released a statement indicating that a combined girls' and boys' programme was likely to be cost-effective compared to no vaccination[5]. In 2018 a universal HPV programme was announced for eligible boys and girls which commenced in September 2019[6].

2021
2021 change from Gardasil to Gardasil 9 vaccine used in the NIP

In July 2021 it was announced that the vaccine used in the programme would change from Gardasil (Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed) to Gardasil 9 (containing HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58). Once the remaining central supplies of Gardasil had been issued Gardasil 9 would be issued in late 2021 or early 2022[7].

There may be slight differences between implementation of the HPV immunisation programme in Scotland, Northern Ireland and Wales. Immunisers working in nations other than England should ensure that they are following relevant guidance specific to the area in which they practice (The Scottish Government (2022)[8,32]; Public Health Agency Northern Ireland (2022)[9,33] and Welsh Government (2022)[10,34]).

Current programme in 2022

The HPV immunisation programme is delivered in all UK nations, with the same eligible groups being offered the vaccination [11, 12, 31,32, 33]. The HPV vaccination is recommended for all eligible girls and boys aged 12 and 13. The HPV programme for these adolescents is primarily delivered by School Age Immunisation Services (SAIS), however provision can vary from area to area (immunisers in general practice should establish the arrangements in their area).

For information on the NHS National Immunisation Programme please refer to the relevant UK Health Security Agency website.

Vaccine supply for both the adolescent (and catch-up groups) and MSM eligible groups is ordered by providers from the national supply via the ImmForm Platform. Orders can be placed weekly and delivered within a few days[35].

Rationale for the programme

Human Papillomavirus (HPV) is a very common virus that most people will be exposed to at some time during their lives.

There are approximately **100 types** of HPV with types being classed as 'high' or 'low' risk depending on their association with the development of cancer[11].

Persistent infection by high-risk HPV types has been detected in **more than 99%** of cervical cancers[11].

HPV types have also been causally associated with some less common anogenital cancers and other cancers[1].

The current programme aims to reduce HPV infections, HPV-associated cancers and genital warts caused by the HPV types contained in the vaccine supplied in the national programme[11].

Impact of the HPV NIP in the UK

HPV vaccines have been shown to be highly effective at preventing HPV infection for the serotypes contained in the vaccines.

Since the commencement of the programme, English sexually transmitted infection surveillance has shown a reduction in CIN (cervical intraepithelial neoplasia) and genital warts in both sexes[28]. Two systematic reviews and meta-analysis of global studies [25, 26] found reduction in HPV infections caused by type 16 and 18 (high risk types), significant reductions in genital warts and pre cancerous lesions among vaccinated cohorts. Additionally, there were significant reductions in genital warts in males and females who were not vaccinated indicating herd effects. In Scotland, a 7-year cross-sectional study evaluating the changes in the prevalence of HPV following a national bivalent HPV vaccination programme, showed substantial reductions in HPV 16 and 18 from 28·9% (95% CI 26·7–31·1) in 2009 to 4·8% (3·8–5·9) in 2015 (unadjusted OR 0·12, 95% CI 0·10–0·16; linear p value <0·0001)[27].

In 2020, the rate of first episode genital warts diagnoses among girls aged 15 to 17 years attending Sexual Health Services, was 95% lower compared to 2016 (6.6 vs 129.7 per 100,000 population). Most of these girls would have been offered the quadrivalent HPV vaccine (Gardasil) when aged 12 to 13 years old[28].

An 89% decline (3.5 vs 32.5 per 100,000 population) in the incidence of genital warts was seen in heterosexual boys of the same age over the same period, suggesting substantial herd protection. A more modest, but still substantial decline of 58% was seen in MSM of the same age, though numbers of diagnoses among young MSM remain small[28].

In a 2021 study it's estimated that cervical cancer rates have been reduced by almost 90% in women in their 20s who were offered the vaccine at age 12 and 13 years in England, when compared to an unvaccinated population[29]

This observational study uses modelling data from a total of 13.7 million years of follow up of women aged 20 to younger than 30 years old, across 4 different cohorts[29].

The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination. For more information on the safety profile and vaccine effectiveness of Gardasil 9 please click here to be taken to the SmPC.

This link will direct you to a third-party website.

The full impact of the national HPV immunisation programme on cervical cancer is yet to be fully realised. As more women who have been vaccinated since 2008 enter the cervical screening programme, at age 25 years, more evidence of prevention of HPV infection is likely to become evident.

Estimates suggest that the HPV universal immunisation programme will save hundreds of lives by preventing tens of thousands of cervical and non-cervical HPV related cancers in the UK over the coming years[30].

Improving uptake

In the early years of the programme (2008–2013/14) national uptake in England for 3 doses of HPV for girls aged 12–13 years was consistently over 86%, with over 40% of Primary Care Trusts in England achieving at least 90%[13]. Assessing uptake and coverage of HPV vaccination, and comparing one year with another, has been complicated by changes in the programme and different delivery models across the country. Uptake varies by area with some areas in England showing increasing uptake between 2015 and 2019 and other areas seeing declining uptake[14]. Uptake in Scotland[8] has historically been slightly higher than England, Northern Ireland and Wales over the years [9,10], however all four UK nations have reported a drop in uptake since the start of the SARS-CoV-2 pandemic[8,9,10,16].

The SARS-CoV-2 pandemic in early 2020 has had a major impact on coverage of the HPV immunisation programme delivery in 2019-20 and 2020-21[8,9,10,15,16]. National reports reveal declines in uptake in 2019–20 and 2020–21 of the order of 20-30% when compared with the pre-pandemic years, with large variations by region within each country [8,9,10,15,16]. Closure of schools and a requirement for students to stay home if they tested positive has meant that some young people were unable to receive their immunisation at school, as planned. School Age Immunisation Teams continue to work hard to offer catch-up immunisations to eligible students who missed it [16,17,18].

Although SAIS teams will endeavour to catch-up missed immunisations, there is a low likelihood of young people being offered the vaccination by these teams, once they move into higher school cohorts or leave school. This is where the involvement of primary care can contribute significantly to help protect these young people with HPV immunisation.

In England, the GP contract letter of 10th March 2021[19] detailed GP contract changes pertaining to vaccination and immunisation. This letter states that...

> ***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.***

Vaccines given to these eligible young people in General Practice will attract an item of service fee of £10.06 per dose administered[19]. The changes to the GP contract and payment arrangements support the importance of General Practice participation in the catch-up efforts within the HPV immunisation programme.

General Practice in England are only required to offer HPV vaccination to young people aged over 14 and less than 25 years of age opportunistically or when it is requested[19]. GP practices are not expected to proactively offer the immunisation to patients since the service is commissioned to be delivered through SAISs[20]. Immunisers in Scotland, Northern Ireland and Wales should familiarise themselves with the relevant contracts and financial arrangements in their nations.

This document provides a summary of strategies that General Practices can employ in order to increase HPV immunisation uptake opportunistically or when requested. Strategies for improving immunisation uptake are drawn from studies of other immunisation programmes, especially influenza immunisation delivery[21,22,23]. Many of the strategies to increase vaccine uptake are transferrable across all the immunisation programmes, including HPV.

HPV immunisation delivery arrangements

Each practice should decide how best to ensure all eligible young people who request missed HPV immunisation, or who are missing HPV vaccine doses and are attending the practice for other reasons, are offered HPV vaccine.

Strategies could include:

1

Ensuring a registered healthcare professional trained and competent in immunisation is available all or most of the time the General Practice is open.

2

Check in advance the HPV immunisation history of young people attending the practice for other vaccines (e.g., national immunisation programmes like COVID, flu, or travel vaccines).

3

Check in advance the HPV immunisation history of young people attending the practice for other healthcare provision (e.g., medication reviews, contraception advice, cervical screening, non-acute illness, counselling, or mental health support appointments).

Staff responsibilities

Identify a named lead member of staff with responsibility for the immunisation service (in England a GP contract requirement[19]).

Ensure all staff in the practice knows who the immunisation lead person is.

Ensure every member of the practice know their role and responsibilities with regard to HPV immunisation programme delivery.

Ensure 12-13 year old teenagers, and others who are not eligible for HPV immunisation at the practice, are signposted to relevant providers. Those aged 12 up to their 14th birthday should be referred to the School Age Immunisation Services. Groups eligible for vaccination via sexual health services should be informed of that arrangement.

Ensure all immunisers understand the rationale for the HPV programme and have access to HPV resources[11,12,32,33] and are skilled at addressing myths pertaining to HPV[24].

Get all staff involved in encouraging young eligible patients to discuss and consider HPV immunisation.

Keep requested and opportunistic HPV immunisation catch-up on the practice staff meeting agenda

Ensure the practice's ability to offer missing HPV vaccine doses to eligible young people aged between 14 and less than 25 years of age is known to other healthcare professionals who may engage with such young people: local pharmacists, physiotherapists, phlebotomists, opticians, dentists, contraception services or sexual health services. This will enable them to advocate HPV immunisation and signpost eligible patients to ask about HPV immunisation.

Practice goals

1. Set a goal of ensuring all eligible young people registered in the practice have received their HPV immunisation (either via another provider or if eligible via the practice).
2. Create computer searches to check immunisation status, measure uptake and progress towards the goal.
3. Maximise practice remuneration by ensuring systems are in place to claim payment for HPV immunisation activity[20].
4. Advertise the practice arrangements for young people to access missing HPV vaccines.

Identifying eligible patients

1. Create a system for identifying eligible patients who may attend the practice for other reasons; to see the GP, the phlebotomist, the physiotherapist etc. Use IT alerts, flags or sticky notes to alert staff to the opportunity to discuss immunisation with the patient.
2. If HPV immunisation is not recorded on an eligible patient's GP record check the HPV immunisation status with the local Child Health Information System (CHIS) or Child Health department.
3. Check that the correct codes to capture HPV immunisation data are in your system and that staff know which codes to use.

Clinics and appointments

- Ensure that there are some doses of HPV vaccine in the fridge for any opportunistic or requested immunisation activity. However, staff should take care not to over order to reduce the risk of vaccine expiry and subsequent wastage.
- Provide opportunistic HPV vaccine to eligible young people at other vaccine clinics (e.g., Flu, COVID, MMR vaccines or travel vaccines).
- Have mechanisms and reminders for offering HPV vaccine catch-up to young women who book for cervical screen appointments and are still under the age of 25 years (in England they will be sent their first invitation at age 24.5 years [31]. Staff in Scotland, Northern Ireland and Wales need to check invitation arrangements in their country.
- Consider checking young parents HPV eligibility and status when they attend for immunisations for their children and offer HPV vaccine opportunistically.
- For young people requesting HPV catch-up of missed vaccines allow variable methods for booking an appointment – online, by phone or via the NHS App.
- Make arrangements to immunise eligible young people who are unable to easily attend the practice such as those in care or with special needs.
- Consider appointment times convenient to young people in education or full-time work.
- Ensure all vaccinated patients have access to the patient information leaflet provided with the vaccine.

Highlight the vaccination offer to all practice users

- Display HPV immunisation information leaflets and posters in the reception and waiting rooms.
- Place prominent information about the HPV immunisation programme on the practice website, Facebook page and other social media.
- Consider advertising the practice offer and arrangements in local venues frequented by teenagers and young adults such as hairdressers, barbers, beauty salons, pubs and cafés.

Service provision at regular intervals in the year

(e.g. quarterly)

- Review HPV immunisation uptake against your goals; how many eligible teenagers and young adults in your practice seem to be unprotected against HPV?
- Review the provision of opportunistic immunisation; do your arrangements work for eligible groups? What lessons have been learnt? Does provision need to be adapted?
- Keep staff involved in service provision planning, informed of any changes to the arrangements or eligibility of teenagers and young adults.

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