



Public Health
England

Protecting and improving the nation's health

Changes to the Human papillomavirus (HPV) vaccine schedule 2014/15

Advice for healthcare professionals

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Published March 2015 v2.

PHE publications gateway number: 2014814.



Background

The human papillomavirus (HPV) national childhood vaccination programme was introduced in 2008 for secondary school year 8 girls (12 to 13 years of age) as a three-dose schedule given within a six-month period.

In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation on the HPV vaccination programme for adolescent girls to change from a three-dose to a two-dose schedule. Emerging evidence from evaluations of the programme around the world has shown that the number of young women with pre-cancerous lesions is falling and all the current indications are that this protection will last for many years. More recent research shows that the antibody levels provided by two doses of the vaccine in young adolescent girls is very good and therefore protection from this schedule is also likely to be long lasting.

For girls aged less than 15 years of age JCVI recommended that for both HPV vaccines a schedule of 0 and 6-24 months is clinically acceptable. For planning purposes, PHE is recommending a schedule at 0 and 12 months, but local needs should be considered in planning the programme. Girls who have not had their first dose of HPV vaccine by the age of 15 years should be offered the three-dose schedule – this is because the response to the two-dose schedule is not quite as high in older girls.

The HPV vaccine coverage in England for 2012/13 for at least one dose was 90.9%, at least two doses 89.6% and three doses 86.1%. It is anticipated that with the two-dose schedule, coverage will be maintained at these high levels.

The HPV vaccination programme

Change to the HPV vaccination programme

From September 2014, the number of doses of HPV vaccine that is given to teenage girls will be reduced from three to two.

The key changes to the programme are as follows:

- the first dose can be given at any time during school year 8
- the minimum time between the first and second dose should be six months where the priming dose is received at less than 15 years of age
- the maximum time between the first and second dose is 24 months
- for operational purposes, PHE recommends around a 12-month gap between the two doses which would reduce the number of HPV vaccination sessions. However, local needs should be considered when planning the programme

Why is the vaccination programme changing?

In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation on the HPV vaccination programme for adolescent girls to change from a three-dose to a two-dose schedule. Emerging evidence from evaluations of the programme around the world has shown that the number of young women with pre-cancerous lesions is falling and all the current indications are that this protection will last for many years.

More recent research shows that antibody response to the two-dose schedule in adolescent girls is equivalent to the response that correlated with protection against persistent infection and pre-cancerous lesions in the initial vaccine trials for the three-dose course. Therefore, the protection provided by two doses of the vaccine in adolescent girls is likely to be good and long-lasting. The long-term effectiveness of the vaccine will continue to be monitored carefully.

When will the change to the HPV vaccination programme start?

The change to the programme will start in September 2014 at the beginning of the academic year.

When should the first dose be given?

This has not changed. As part of the routine HPV vaccination programme, the first dose can be given at any time during school year 8, to girls who are usually 12 to 13 years old.

When should the second dose be given?

For operational purposes, PHE recommends that the second dose of the HPV vaccine is scheduled to be given around 12 months after the first; some local areas may choose to schedule the second dose from six months after the first. To allow for mop-up of any girls who may miss appointments any gap between six months and 24 months is acceptable.

Is there a cut off age for when you can start the two-dose schedule?

Yes. The two-dose schedule should only be started in girls up to (and including) 14 years of age.

What if a girl has not had her first HPV vaccine dose by the age of 15 years?

Girls who have not had their first dose of HPV vaccine by the time they are 15 years old should be offered the three-dose schedule. This is because the response in older girls is not quite as good, so it has been agreed that they should be offered three doses at zero, one and six months.

What if a girl has had the first two doses of the current three-dose schedule – does she still need the third one now?

Girls who commenced a three-dose schedule either before or after their fifteenth birthday and who have received two doses of vaccine less than six months apart should complete the three-dose schedule as originally planned.

For those girls who commenced a three-dose schedule before the age of 15 years and who received the first two doses of vaccine at least 6 months apart do not require a third dose and should be considered to have completed the full course.

What if a girl receives two doses less than six months apart?

Two doses less than six months apart should not be considered adequate to provide long-term protection and a third dose should be given according to the guidance on dosage and schedule in the Green Book HPV chapter

What happens if the two-dose course is interrupted?

If the two-dose course is interrupted, it should be resumed (using the same vaccine) but not repeated, even if more than 24 months have elapsed since the first dose and regardless of the age at which the girl presents.

Why does the JCVI recommendation about the upper age limit for the two-dose schedule differ from the information included in the Summary of Product Characteristics (SPC) for Gardasil®?

In 2013/14, both Gardasil® and Cervarix® received licensing approval from the European Medicines Agency (EMA) for a two-dose schedule in adolescent girls. The two-dose schedule for Gardasil® is licensed for individuals aged nine up to and including 13 years of age and Cervarix® is licensed for individuals aged nine up to and including 14 years of age. JCVI has agreed, however, to recommend a two-dose schedule up to (and including) 14 years of age for both Cervarix® and Gardasil®. The WHO's Strategic Advisory Group of Experts (SAGE) on immunisation also recently reviewed the evidence on HPV immunisation schedules. Upon review of the evidence, SAGE also recommended a two-dose schedule for girls if vaccination is

initiated prior to 15 years of age. A three-dose schedule remains necessary if immunisation is initiated after the girls' 15th birthday.

Patient group directions (PGDs) and off-label use of Gardasil[®] and Cervarix[®]

Off-label use of licensed products can be permitted under a PGD. The off-label use of Gardasil[®] and Cervarix[®] as recommended by JCVI and WHO, should be included in PGDs together with a reference of where there is a deviation from the Summary of Product Characteristics (SPC).

Patient information leaflets (PILs)

Both Cervarix[®] and Gardasil[®] have updated their PILs following licensing approval from the European Medicines Agency (EMA) for a two-dose schedule in adolescent girls. These are available online (see useful links at the end of this document). The Vaccine Supply team will be issuing up-to-date PILs with each order of HPV vaccine to replace any out-of-date PILs that will be contained in the box.

If you still hold stock of the vaccine which contains the out-of-date PIL please refer patients to the [link](#) to the up-to-date PIL (also included in the *Your guide to HPV vaccination from September 2014* leaflet for girls and their parents).

Previous incomplete vaccination with Cervarix[®] – advice for girls and young women covered by the national HPV vaccination programme

There is no longer a supply of Cervarix[®] available in the UK. For girls who started the schedule with Cervarix[®], but did not complete the vaccination course, the course can be completed with Gardasil[®]. The course should be completed according to a vaccination schedule of 0, 1, 4-6 months or 0, 6-24 months, depending on the age of the girl when she received the first dose and whether one or two doses have already been given. If the course is interrupted, it should be resumed but not repeated.

Previous incomplete vaccination with Gardasil[®] – advice for girls and young women covered by the national HPV vaccination programme

The course should be completed according to a vaccination schedule of 0, 1, 4-6 months or 0, 6-24 months, depending on the age of the girl when she received the first dose and whether one or two doses have already been given. If the course is interrupted, it should be resumed but not repeated.

Vaccination of females with incomplete immunisation status

Where a female in the target cohort aged over 12 and under 18 years presents with an incomplete vaccination history, every effort should be made to clarify what doses she has had and when she received them. A female who has started but did not complete the schedule

before reaching the age of 18 years, should complete the vaccination course at the minimum interval where possible (see Green Book). If the course is interrupted then it should be resumed but not repeated.

Immunosuppression and HIV infection

There is no data for two-dose schedules for immunocompromised individuals. Therefore, a three-dose schedule should be offered to individuals who are HIV-infected or are known to be immunocompromised at the time of immunisation. This recommendation is endorsed by WHO SAGE. Re-immunisation should be considered after treatment is finished and/or recovery has occurred. Specialist advice may be required (see Green Book).

Can the HPV vaccine be given at the same time as other vaccines?

HPV vaccines can be given at the same time as other vaccines such as Td/IPV, MMR, Influenza, MenC and hepatitis B. A trend of lower anti-HPV titres has been observed when Gardasil® is administered concomitantly with dTaP, dT/IPV and dTaP/IPV vaccines, though the clinical significance of this observation is unclear. The vaccines should be given at a separate site, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Are any other changes being made to the programme?

No, everything else stays the same.

Will the vaccine that is being saved by this change be used to protect men against HPV and genital warts?

All vaccination programmes are kept under constant review so they can be improved in the light of experience. The routine use of HPV vaccine in boys, and men who have sex with men, is something that has been raised at JCVI and will continue to be taken into consideration in their future deliberations.

What are the options for implementation of the routine HPV programme for adolescent females in England?

For planning purposes, PHE is recommending a schedule at 0 and 12 months but local needs should be considered when planning the programme; some local areas may choose to schedule the second dose from six months after the first. To allow for mop-up of girls who may miss appointments, any gap between 6 and 24 months is acceptable.

	Dose 1. Year 8 girls	Dose 2. Year 8 girls	Dose 2. Year 9 girls
Option 1	Autumn term	n/a	Autumn term
Option 2	Spring term	n/a	Spring term

Option 3	Summer term	n/a	Summer term
Option 4	Autumn term	Summer term	n/a

OPTION 1 Continue to offer the first HPV vaccine dose in the autumn and the second dose in the autumn of the following year (when student is in year 9). This allows teams to focus on the MenC and Td/IPV clinics and on any mop-up for HPV in the spring term, with minimal disruption to exam time in the summer term. This option will allow school nursing teams to focus on moving the adolescent MenC booster dose and Td/IPV to year 9 (in areas where this is still delivered in year 10).

OPTION 2 The MenC and Td/IPV clinics are usually delivered in the spring term; therefore, the second dose of HPV could be added to these clinics. However, the disadvantage of this option is that year 9 girls will be offered three injections in one session, which may not be acceptable and may reduce uptake.

OPTION 3 Delivering HPV in the summer term is unlikely to clash with any other immunisation programmes (flu, Men C, Td/IPV) and therefore will have less impact on provider capacity. However, currently the take-up of the third dose of HPV is always lower in the summer term because many children are out of school.

OPTION 4 Delivering the two HPV doses in one academic year reduces the impact on providers and schools because this is the option most similar to the current programme, essentially the only change will be dropping clinics for dose 2 in the spring term.

Obtaining consent

The giving and obtaining of consent is viewed as a process and not a one-off event. The two HPV doses are likely to be given across two different academic years (year 8 and year 9) in areas delivering a school-based programme. If written consent is sought from parents, this need only be done once for the full course.

How will vaccine coverage data for the HPV programme change?

Vaccine coverage data will continue to be collected via ImmForm but will move to an annual collection only from 2014/15, with data being collected at the beginning of the 2015/16 academic year. PHE will amend the data collection template to reflect these changes and will disseminate this to area teams in time for the 2014/15 academic year.

Denominator definition

Dose 1 Prime (HPV1) – Year 8 girls
 Dose 2 Boost (HPV2) – Year 9 girls

Birth cohorts	Year 8	Year 9
Born 01/09/01 to 31/8/02	2014/15	2015/16

Born 01/09/02 to 31/8/03 2015/16 2016/17

For the **first year** of the programme:

2014/15	School year offering HPV vaccine	
	Priming dose1 (HPV1)	Boosting dose 2 (HPV2)
Areas offering two doses in one year	Year 8	Year 8
Areas offering two doses in two years	Year 8	n/a

For the **second year** of the programme:

2015/16	School year offering HPV vaccine	
	Priming dose 1 (HPV1)	Boosting dose 2 (HPV2)
Areas offering two doses in one year	Year 8	Year 8
Areas offering two doses in two years	Year 8	Year 9

How will this change impact all the other adolescent vaccination programmes?

The reduction in the number of doses and immunisation clinics required, presents an opportunity for local providers to strengthen other school-based immunisation programmes. In the first year of implementation, those areas that choose to offer the two doses 12 months apart, will only be offering one dose of HPV vaccine to year 8 girls. This may provide an opportunity to reinforce other adolescent programmes such as MenC, Td/IPV and MMR where needed.

Where can I get more information?

Tripartite letter: Change in schedule from three to two doses in the HPV vaccination programme:

www.gov.uk/government/uploads/system/uploads/attachment_data/file/310958/HPV_Joint_Letter_14_May.pdf

For further information on the MenC adolescent vaccination programme see:

www.gov.uk/government/publications/mencvaccination-schedule-planned-changes-from-june-2013

Useful links

A range of resources available to the field to support the delivery of the existing programme is being updated to reflect the changes to the programme and is available from the PHE immunisation webpage under the HPV vaccination programme heading at:

www.gov.uk/government/collections/immunisation

The following are ready for download **here** and / or ordering for printing via the DH orderline:

www.orderline.dh.gov.uk/ecom_dh/public/home.jsf

- HPV consent form (Word and pdf versions only, for local downloading and printing)
- *Your guide to HPV vaccination from September 2014* (leaflet for girls and their parents)
- HPV vaccination record card
- Poster

Manufacturer patient information leaflets

Gardasil[®] <http://www.medicines.org.uk/emc/medicine/19033/pil/gardasil>

Cervarix[®] <http://www.medicines.org.uk/emc/document.aspx?documentId=20207>