14 May 2014

Dear Colleague,

**Change in schedule from three to two doses in the HPV vaccination programme**

This letter provides information on forthcoming changes to the human papillomavirus (HPV) vaccine programme. The HPV vaccine, introduced in 2008, is part of the NHS national childhood vaccination programme. It is currently routinely offered to secondary school girls aged 12 to 13 in school year 8.

In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation to change from a **three to a two dose schedule**. Recent research shows that antibody response to two doses in adolescent girls is as good as a three dose course in the age group where efficacy against persistent infection and pre-cancerous lesions has been demonstrated. Emerging evidence from evaluation of HPV programmes around the world has shown that the number of young people with pre-cancerous lesions is falling and protection is expected to be long term.

**Key points about the changes to the programme:**

- we plan to introduce the change in September 2014, at the beginning of the academic year
- 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
- 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 antibody response in older girls is not quite as good
Further information on the range of delivery options is available in Appendix A.

The vaccine used for the current three-dose programme is Gardasil and is suitable for the new two-dose schedule. Gardasil is available from ImmForm website. See https://www.immform.dh.gov.uk/SignIn.aspx?ReturnUrl=%2f.

Both Gardasil and Cervarix have been approved for use in a two-dose schedule. The patient information leaflet (PIL) included in the packaging may still refer to a three-dose schedule, or give different recommended timings between doses. The PIL will be updated by the vaccine manufacturer as soon as possible. In the meantime, the guidance in the updated HPV chapter of the Green Book and in this letter should be followed. The Green Book states:

Recommendations on immunisation procedures are based on currently available evidence and experience of best practice. In some circumstances, this advice may differ from that in vaccine manufacturers’ Summaries of Product Characteristics (SPCs). When this occurs, the recommendations in this book (which are based on current expert advice received from the Joint Committee on Vaccination and Immunisation (JCVI)) should be followed. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf

Additional information:

- An updated Q&A for health professionals will be available in mid-June to reflect the programme changes.
- A revised information leaflet is being developed to reflect the changes which can be used as part of the consent process.
- Vaccine coverage data will continue to be collected via ImmForm but will move to an annual collection only from 2014/15, collected at beginning of the 2015/16 academic year. See Appendix B for details.
- 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 the vaccine to year 8 girls. This may provide an opportunity to reinforce other adolescent programmes such as MenC, Td/IPV and MMR where needed. For further information see: https://www.gov.uk/government/publications/menc-vaccination-schedule-planned-changes-from-june-2013
If you have any further queries please email them to immunisation@phe.gov.uk

Yours sincerely,

Dame Barbara Hakin  
NHS England,  
Chief Operating Officer and Deputy Chief Executive

Dr Paul Cosford  
Public Health England,  
Medical Director and Director for Health Protection

Dr Felicity Harvey  
Department of Health,  
Director General  
Public Health
Appendix A: Options for the delivery of the HPV vaccine programme
2014/2015

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. Please be aware that any gap between doses of between six and 24 months is clinically acceptable.

<table>
<thead>
<tr>
<th>Option</th>
<th>Dose 1: Year 8 girls</th>
<th>Dose 2: Year 8 girls</th>
<th>Dose 2: Year 9 girls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1</td>
<td>Autumn term</td>
<td>n/a</td>
<td>Autumn term</td>
</tr>
<tr>
<td>Option 2</td>
<td>Spring term</td>
<td>n/a</td>
<td>Spring term</td>
</tr>
<tr>
<td>Option 3</td>
<td>Summer term</td>
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<td>Summer term</td>
</tr>
<tr>
<td>Option 4</td>
<td>Autumn term</td>
<td>Summer term</td>
<td>n/a</td>
</tr>
</tbody>
</table>

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 Men C and Td/IPV clinics are delivered in the spring term; therefore the 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 suggests that it would not 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.
Appendix B: Data collection

Suggested approach for HPV vaccine programme data collection from 2014/15

Vaccine coverage data will continue to be collected via ImmForm but will move to an annual collection only from 2014/15, collected at the beginning of the following 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

<table>
<thead>
<tr>
<th>Birth cohorts</th>
<th>Year 8</th>
<th>Year 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Born 01/09/01 to 31/8/02</td>
<td>2014/15</td>
<td>2015/16</td>
</tr>
<tr>
<td>Born 01/09/02 to 31/8/03</td>
<td>2015/16</td>
<td>2016/17</td>
</tr>
</tbody>
</table>

For the first year of the programme:

<table>
<thead>
<tr>
<th>2014/15</th>
<th>School year offering HPV vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Priming dose 1 (HPV1)</td>
</tr>
<tr>
<td></td>
<td>Boosting dose 2 (HPV2)</td>
</tr>
<tr>
<td>Areas offering two doses in one year</td>
<td>Year 8</td>
</tr>
<tr>
<td>Areas offering two doses in two years</td>
<td>Year 8</td>
</tr>
</tbody>
</table>

For the second year of the programme:

<table>
<thead>
<tr>
<th>2015/16</th>
<th>School year offering HPV vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Priming dose 1 (HPV1)</td>
</tr>
<tr>
<td></td>
<td>Boosting dose 2 (HPV2)</td>
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<td>Year 8</td>
</tr>
<tr>
<td>Areas offering two doses in two years</td>
<td>Year 8</td>
</tr>
</tbody>
</table>
To:

For action:
NHS England Area Team Directors
Accountable Officers of Clinical Commissioning Groups
General Practitioners
Screening and Immunisation Leads
NHS Foundation Trusts
NHS Trusts
School Nursing Teams
Directors of Public Health
Local Authority Chief Executives
Regional Heads of Public Health and Primary Care
Area Team Heads of Public Health Commissioning

For information:
PHE Centre Directors
Chief Pharmacists of NHS Trusts
NHS Foundation Trusts
NHS Trusts
Community Pharmacies
Royal College of Physicians
Royal College of General Practitioners
British Medical Association
Royal Pharmaceutical Society
Faculty of Pharmaceutical Medicine
Royal College of Paediatrics and Child Health
Faculty of Public Health
Royal College of Nursing
Community Practitioners and Health Visitors Association
Chairs Infection Control Committees
Consultants in Communicable Disease Control
Health Visitors
NHS Employers