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12th July 2013

NHS England Area Directors
Clinical Leaders of Clinical Commissioning Groups
General Practices
Screening and Immunisation Leads
Directors of Public Health
Local Authority Chief Executives
PHE Centre Directors

For information via NHS News:
Chief Pharmacists of NHS Trusts
NHS Foundation Trusts
NHS Trusts
Community pharmacies

Dear Colleague,

Introduction of shingles vaccine for people aged 70

You will be aware from our letters regarding rotavirus vaccine and MenC vaccine¹ that, following recent advice and recommendations by the Joint Committee on Vaccination and Immunisation (JCVI), and in line with our standing commitments on patient rights under the NHS Constitution on implementing such recommendations, a series of changes to England's national immunisation programme is being introduced over the course of 2013-14.

¹ <https://www.gov.uk/government/publications/national-immunisation-programme-planned-changes-for-2013-to-2014>; <https://www.gov.uk/government/organisations/public-health-england/series/meningococcal-c-menc-vaccination-programme>

A table providing a summary of these changes to the immunisation programme can be found in **Annex A**.

This letter provides details of the programme for the introduction of shingles vaccine from September 2013. Detailed clinical guidance for healthcare professionals is set out in **Annex B** to this letter.

These planned changes have the support of the Department of Health's Chief Medical Officer, Chief Pharmaceutical Officer and Director of Nursing.

The introduction of a vaccine for people aged 70 years (routine cohort) and 79 years (catch-up cohort) to protect against shingles

Shingles is a debilitating condition, which occurs more frequently and tends to be more severe in older people. It is estimated that around 250,000 people are affected in England and Wales each year, including 30,000 people in their 70s. Around one in 1,000 people over 70 who get shingles dies of the infection.

We plan to offer routine vaccinations to people aged 70 years old to provide protection against shingles. We also plan to introduce a catch-up immunisation programme in 2013 for people aged 79 years. The efficacy of the vaccine declines with age and so it is not recommended for people aged 80 years or older.

The programme will begin from 1 September 2013 and will become a part of the routine vaccination programme for people aged 70 years. The catch-up campaign for those aged 79 will also begin from 1 September 2013.

A new chapter on shingles, including clinical advice and information about the herpes zoster vaccine, has been included in *Immunisation against infectious disease 2006 (the Green Book)*, available to read at

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147832/Green-Book-updated-140313.pdf

JCVI's statement about shingles and herpes zoster vaccine is available at:
http://webarchive.nationalarchives.gov.uk/20120907090205/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_133599.pdf

Colleagues will be aware that responsibility for the national immunisation programme changed from 1 April 2013. Colleagues are referred to the letter issued by the Department of Health on 23 August 2012, which sets out the roles and respective accountabilities of the Department of Health, Public Health England, NHS England and Local Authority Directors of Public Health with regard to immunisation in the new system from 1 April 2013.

<http://www.dh.gov.uk/health/2012/08/screening-immunisation-programmes/>

Shingles is a significant cause of morbidity in older people. We do not underestimate the additional work brought about by this change to the vaccination programme in addition to the other new programmes communicated in recent letters about rotavirus and MenC vaccination. However, we hope colleagues will recognise the benefits shingles vaccine will bring to older people and we would like to take this opportunity to thank all involved in delivering the programme for their continuing hard work.

For further information please contact Public Health England at:

immunisation@phe.gov.uk

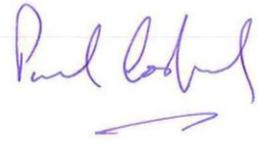
Yours sincerely

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



*From NHS England, Public Health England and,
the Department of Health*

PHE, Medical Director and Director of Health Protection (Paul Cosford)

A handwritten signature in blue ink, appearing to read "Paul Cosford", with a horizontal flourish underneath.

DH, Director General, Public Health (Felicity Harvey)

A handwritten signature in black ink, appearing to read "Felicity Harvey", with a long horizontal flourish extending to the right.

Summary of planned changes to the immunisation schedule in 2013/14

Programme	June 2013	July 2013	August 2013	Sept 2013
MenC vaccine: remove one dose	√			
Rotavirus vaccine introduced		√		
MenC vaccine: adolescent dose introduced through schools				√*
Shingles vaccine: programme begins (including catch-up)				√
Flu vaccine for 2 and 3 year olds introduced				√**

* This can take place at any point in the 2013/14 academic year. In practice, it is most likely to be administered in schools in the spring 2014 term.

** Subject to conclusion of negotiations with GPC

CLINICAL GUIDANCE ON IMMUNISATION AGAINST SHINGLES

1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI)², the UK's independent panel of immunisation experts. Full guidance can be found in the new chapter on shingles now included in *Immunisation against infectious disease* ('the Green Book')³

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147832/Green-Book-updated-140313.pdf

2. It is important that the full guidance is always reviewed carefully in addition to the information in this letter. The guidance in the Green Book will be kept up to date.

Background to the introduction of shingles vaccine

3. Shingles (herpes zoster) is caused by the reactivation of a latent varicella zoster virus (VZV) (chickenpox) infection, sometimes decades after initial infection.

4. Shingles can occur at any age, with the highest incidence seen in older people. The incidence of shingles increases with age and around one in four adults will experience shingles in their lifetime. Increasing incidence with age is thought to be associated with age related immune senescence and waning immunity.

5. Data from GP-based studies in England and Wales suggest that over 50,000 cases of shingles occur in older people aged 70 years and above annually. The severity of shingles generally increases with age and can lead to Post Herpetic Neuralgia that can require hospitalisation. Around one in 1,000 shingles cases is estimated to result in death in people aged 70 years and above, although due to the population group involved, and the risk of co-morbidities, it is possible that a

² JCVI statement:

http://webarchive.nationalarchives.gov.uk/20120907090205/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_133599.pdf

³ The shingles chapter can be found in *Immunisation against infectious disease* at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147832/Green-Book-updated-140313.pdf

proportion of deaths recorded as being shingles related are not directly attributable to the disease.

6. Ophthalmic zoster develops when the viral infection is localised in or around the eye and this condition is also often associated with long-term pain. Studies have estimated ophthalmic zoster to occur in 10-20 per cent of shingles cases with around four per cent of the cases resulting in long-term sequelae.

7. Plans to add a vaccination against shingles to the immunisation schedule were recommended by JCVI in 2009, if it could be bought at a cost effective price.

8. Until recently, vaccine supplies have not been available in the quantities needed for this programme. We have now secured sufficient supplies of the vaccine at a cost-effective price to begin the programme. The vaccine, Zostavax®, will be supplied by Sanofi Pasteur MSD.

9. The aim of the routine programme is to offer shingles vaccine to all those aged 70 years. We will also run a catch up programme for those aged 79 during 2013.

Timing

10. The shingles vaccination programme will begin on 1 September 2013.

11. To ensure adequate supplies of vaccine for each year of the programme, and given the short shelf life of the product, the vaccine has been purchased centrally to ensure enough vaccine is available to deliver to one routine cohort each year, and for the catch-up cohort in 2013, depending upon uptake.

Catch-up programme

12. The catch-up cohort for those aged 79 in 2013 is defined by the patient's age on 1st September. Those born between 2 September 1933 and 1 September 1934 should be offered vaccine in the 2013 catch-up programme.

Recommendations for use of the vaccine

13. Zostavax® is the only shingles vaccine with market authorisation available in the UK. It contains live, attenuated virus derived from the Oka/Merck strain of varicella zoster virus.

Administration

14. The Zostavax® vaccination consists of a single dose (0.65mL), which should be administered by **subcutaneous** injection.

Dosage

15. Adults should receive a single **0.65ml** dose of Zostavax®. It is likely that the vaccine confers protection against shingles for at least seven years for many people. The need for, or timing of, a reinforcing dose has not yet been determined.

Contraindications

16. The vaccine should not be given to a person who:

- has primary or acquired immunodeficiency state due to conditions such as:
 - o acute and chronic leukaemias;
 - o lymphoma;
 - o other conditions affecting the bone marrow or lymphatic system;
 - o immunosuppression due to HIV/AIDS (see below);
 - o cellular immune deficiencies;
- is receiving immunosuppressive therapy (including high-dose corticosteroids); however, Zostavax® is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or in patients who are receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency;
- has an active untreated TB infection;
- has had a confirmed anaphylactic reaction to a previous dose of varicella vaccine;
- has had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or gelatin.

17. Therapy with low-doses of methotrexate (<0.4 mg/kg/week), azathioprine (<3.0 mg/kg/day), or 6mercaptopurine (<1.5 mg/kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions are not considered sufficiently immunosuppressive and are not contraindications for administration of zoster vaccine.

18. **The use of topical acyclovir is not a contraindication to vaccination.**

19. Further information on contraindications and special considerations for vaccination can be found in Chapter 6 of *Immunisation against Infectious Disease*.

Concomitant administration with other vaccines

20. Zostavax® can be given at the same time as inactivated influenza vaccinations. If given at the same time as influenza vaccinations, care should be taken to ensure that the appropriate route of injection is used for both vaccinations and to check there are no contraindications to administering a live vaccine to individuals in at risk groups presenting for seasonal influenza vaccination.

21. Despite the advice in the Summary of Product Characteristics (SPC), new evidence suggests that Zostavax® can also be given at the same time as 23 valent pneumococcal polysaccharide vaccine (PPV23) for those who are eligible for both vaccines.⁴

Consent

22. See Chapter 2 of *Immunisation against infectious disease* ('the Green Book') <http://immunisation.dh.gov.uk/green-book-chapters/chapter-2/>

Pharmacy issues

Vaccine brand name and manufacturer

⁴ Although the Summary of Product Characteristics for Zostavax® indicates that PPV23 should not be administered concomitantly due to reduced immunogenicity, there is no established correlation between antibody titres to VZV and protection from herpes zoster. Furthermore a more recent observational study showed that herpes zoster vaccine was equally effective at preventing herpes zoster whether it was administered simultaneously with PPV23 or 4 weeks apart ([Tseng et al Vaccine 2011](#))

23. The vaccine is Zostavax® and it is manufactured by Sanofi Pasteur MSD.

Presentation

24. The vaccine is presented as a powder and solvent for suspension for injection in a pre-filled syringe.

25. The powder is a white to off-white compact crystalline plug.

26. The solvent is a clear, colourless fluid.

Vaccine supply (including ImmForm registration)

27. The shingles vaccine should be ordered online via the ImmForm website (www.immform.dh.gov.uk); it will be distributed by Movianto UK (Tel: 01234 248631) as part of the national immunisation programme.

28. Centrally purchased vaccines are provided free to NHS organisations for the national immunisation programme and are available to order via ImmForm. Vaccines can be ordered for delivery to appropriate locations such as GP practices and hospital pharmacies. Delivery of vaccines will be on the scheduled delivery day set by the distributor Movianto for delivery Monday to Friday. Orders need to be placed two working days prior to the scheduled delivery day to receive the order on the next scheduled delivery day. NHS organisations should be aware of their scheduled delivery days and can view this information on the ImmForm order page. However, if this information is not available please contact the ImmForm Helpdesk on Tel: 0844 376 0040. The vaccine will be available to order from August.

29. Most NHS organisations have an ImmForm account for ordering vaccines for the national immunisation programme. If a NHS organisation does not have an ImmForm account they will need to e-mail the ImmForm Helpdesk at helpdesk@immform.org.uk, with the following information:

- The full address of the NHS Organisation
- The full delivery address (if different)
- The NHS organisation code
- Contact telephone number

- First Name
- Surname
- NHS email address

30. If ImmForm do not have a NHS Movianto account number for the organisation (NOTE: a private Movianto account number is not suitable, as these are for billable private purchases only) or if the Movianto account number is not known, please email the details requested above to the helpdesk@immform.org.uk mailbox. Setting up a new Movianto account can take up to two days.

31. NHS organisations which have a NHS Movianto account can self-register on ImmForm by going to the following URL:

<https://vaccinesupply.immform.dh.gov.uk/Registration/Registration.aspx>.

They will need a NHS Movianto account number at hand and a NHS email address.

This process should take less than one day

32. Further information and help-sheets about ImmForm are available at on the Inside Government website at www.gov.uk/government/organisations/public-health-england/series/immform or from the ImmForm helpdesk at

helpdesk@immform.org.uk, or Tel: 0844 376 0040.

Storage

33. Store and transport refrigerated (2°C - 8°C).

34. Do not freeze.

35. Store in the original package in order to protect from light.

36. The vaccine should ideally be used immediately after reconstitution, and certainly within 30 minutes. The in-use stability has been demonstrated for 30 minutes when stored at 20°C - 25°C. It is strongly recommended that the vaccine is not reconstituted in advance of the patient presenting to the clinician.

Vaccine stock management

37. Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. Two to four weeks of stock holding is recommended, and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme. To ensure optimum management of vaccine supplies, colleagues are reminded not to order more vaccine than required.

38. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.

39. Any cold chain failures must be documented and reported to the local immunisation co-ordinator and PHE/ImmForm as appropriate.

Reporting of adverse reactions

40. The safety of Zostavax® has been extensively evaluated in clinical trials; the most commonly reported side effects for Zostavax®, occurring in at least one in ten people, were injection site reactions including erythema (redness), pain, swelling, and pruritis (itching). Other common reactions reported in at least one in 100 people were haematoma, induration and warmth at the injection site, pain in arm or leg and headache. Very rarely, varicella (chickenpox) was reported, in less than 1 in 10,000 people.

41. A full list of side effects can be found in the Zostavax® SPC.

42. Serious suspected adverse reactions to Zostavax® should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme (www.mhra.gov.uk/yellowcard).

43. [Chapter 9 of the Green Book](#) gives detailed guidance which ADRs to report and how to do so. Additionally, [Chapter 8 of the Green Book](#) provides detailed advice on managing ADRs following immunisation.

Funding and service arrangements

44. The Directions confirm that a payment of £7.63 will be made to the contractor in respect of each registered patient who has received the Shingles Vaccine during the financial year ending 31 March 2014, who on the 1st September 2013 attained the age of 70 years but not 71 years.

45. In regard to the catch up for 79 year olds, a payment of £7.64 will be made to the contractor in respect of each registered patient who has received the shingles vaccine during the financial year ending 31 March 2014.

Communications and information for health professionals

46. Information leaflets for patients will be produced to support the introduction of the vaccine. These will be available from the Publications Orderline in the usual way. In addition to the new Green Book chapter, there will be a factsheet for health professionals.

47. Materials for patients and health care professionals will be available via:

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation>

Surveillance

48. The programme will be carefully monitored by Public Health England and the Medicines and Healthcare products Regulatory Agency.

Vaccine uptake data collection

49. Subject to ROCR approval, data will be collected in two ways for each programme year (1 September to 31 August):

1. monthly automated 'sentinel' collections (September to July)
2. annual manual data collection (August)

50. In the eleven monthly 'sentinel' collections, collecting cumulative data for each month from September to July, the data will be collected through an automated process using ImmForm. These collections will allow the collection of monthly data

with minimal or no burden to the NHS and will give quick and timely cumulative uptake figures across the year.

51. In August each year a manual collection from all GP practices will be undertaken through ImmForm, allowing for validated annual data to be collected.

52. These collections will provide:

- monthly cumulative coverage;
- the ability to compare coverage;
- the ability to view data and export data into Excel, for further analysis.

53. This data will also allow the Department of Health, NHS England and Public Health England to assess the progress of the vaccination programme.

54. Data will be collected with the following numerator and denominator for the 2013/14 programme:

- Denominator – All registered patients in each birth cohort who have not received Zostavax® prior to 1 September 2013.
- Numerator – Number of registered patients in the denominator vaccinated from 1 September 2013.

55. A list of birth cohorts and data to be collected is set out in the table below:

List of birth cohorts numerator and denominator

Cohort	Number of patients	Number vaccinated
Registered patients aged 79 on 1 September	X patients	X vaccinated
Registered patients aged 78 on 1 September	X patients	X vaccinated
Registered patients aged 77 on 1 September	X patients	X vaccinated
Registered patients aged 76 on 1 September	X patients	X vaccinated
Registered patients aged 75 on 1 September	X patients	X vaccinated
Registered patients aged 74 on 1 September	X patients	X vaccinated
Registered patients aged 73 on 1 September	X patients	X vaccinated
Registered patients aged 72 on 1 September	X patients	X vaccinated
Registered patients aged 71 on 1 September	X patients	X vaccinated

Registered patients aged 70 on 1 September	X patients	X vaccinated
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56. Whilst data will be collected for all these cohorts, the target cohorts in the first year of the programme will be those identified at 70 years (routine cohort) and 79 years (catch-up cohort).