

T: 0131-244 2241 F: 0131-244 2157
E: Jacqueline.campbell@scotland.gsi.gov.uk

Dear Colleague

IMPORTANT CHANGES TO THE SCOTTISH IMMUNISATION PROGRAMME IN 2013/14 - THE INTRODUCTION OF A VACCINE FOR PEOPLE AGED 70 YEARS (ROUTINE COHORT) AND 79 YEARS (CATCH-UP COHORT) TO PROTECT AGAINST SHINGLES

1. This letter provides details of the shingles immunisation programme, which will be introduced into the Scottish Immunisation Programme from 1 September 2013.

2. Shingles is a debilitating condition, which occurs more frequently and tends to be more severe in older people. It is estimated that around 7,000 people aged 70 years and above are affected in Scotland each year. Of these, between 700-1,400 develop a very painful and long lasting condition – Post Herpetic Neuralgia (PHN). Around 600 hospitalisation episodes are recorded per year, with approximately 5 cases resulting in death each year.

3. Colleagues will recognise the significant benefits the vaccine will bring to their patients, and we would like to take this opportunity to thank all those involved in delivering the programme for their continued hard work.

4. 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.

From the Chief Medical Officer
Chief Nursing Officer
Chief Pharmaceutical Officer
Sir Harry Burns MPH FRCS(Glas)
FRCP(Ed) FFPH
Ros Moore RGN, RNT, BSc
(Hons) Nursing, MA
Professor Bill Scott BSc MSc DSc
(Hons) FRPharmS

13 August 2013

SGHD/CMO(2013)15

Addressees

For action

NHS Board Chief Executives
NHS Board Immunisation
Coordinators
NHS Board Medical Directors
NHS Board Nursing Directors
NHS Board Directors of Public
Health
Infectious Disease Consultants
Practice Nurses
Health Visitors
CPHMs
Scottish Prison Service
Scottish Ambulance Service

For information

NHS Board Chairs
General Practitioners
Directors of Pharmacy
Consultant Paediatricians
Consultant Physicians
Health Protection Scotland
Chief Executive, NHS Health
Scotland
NHS 24
Scottish General Practitioners
Committee

Further Enquiries

Policy Issues

Jacqueline Campbell
3EN St Andrews House
Jacqueline.campbell@scotland.gsi.gov.uk
www.scotland.gsi.gov.uk

Medical Issues

Dr. Nicola Steedman
3E.05 St Andrews House
Nicola.steedman@scotland.gsi.gov.uk

Pharmaceutical and Vaccine Supply

William Malcolm
Health Protection Scotland
w.malcolm@nhs.net

5. The programme will begin from 1 September 2013 and will become a part of the routine vaccination programme for people aged 70. The catch-up campaign for those aged 79 will also begin from 1 September 2013.
6. A new chapter on shingles, including clinical advice and information about the shingles vaccine, has been included in *Immunisation against Infectious Disease 2006* (the Green Book), available to read at: <https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a>. It is important for all staff to ensure that they always refer to the most recent online version of the Green Book, in addition to this letter.
7. JCVI's statement about shingles and herpes zoster vaccine is available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_co_nsum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_133599.pdf

Background to the Introduction of Shingles Vaccine

8. Shingles (herpes zoster) is caused by the reactivation of a latent varicella zoster virus (VZV) infection, sometimes decades after initial infection.
9. 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 4 adults will experience shingles in their lifetime. Increasing incidence with age is thought to be associated with age related immune senescence and waning immunity.
10. The severity of shingles generally increases with age and can lead to Post Herpetic Neuralgia (PHN) 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 proportion of deaths recorded as being shingles related are not directly attributable to the disease.
11. 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 4 per cent of the cases resulting in long-term sequelae.
12. 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.
13. 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.
14. 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 2013/14.

Timing

15. The shingles vaccination programme will begin on 1 September 2013.
16. 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 2013/14.

Eligibility

17. The routine cohort for those aged 70 in 2013/14 is defined by the patient's age on 1st September 2013. Those born between **2 September 1942 and 1 September 1943** should be offered the vaccine in the 2013/14 routine programme.

18. The catch-up cohort for those aged 79 in 2013/14 is defined by the patient's age on 1st September 2013. Those born between **2 September 1933 and 1 September 1934** should be offered vaccine in the 2013/14 catch-up programme.

19. NHS Boards and GP practices are reminded of their responsibilities in the vaccination of eligible persons in care homes and long-term hospital care.

20. Central vaccine supply should only be used for the patients in the programme. It is recognised, however, that there may rarely be patients outwith the national programme, that clinicians think may benefit from receiving the shingles vaccination i.e. patients in whom the clinician thinks the occurrence of shingles could cause a significant deterioration in their health. Under these circumstances, prescribers will have the discretion to provide the shingles vaccination to these individuals via a NHS prescription, and outwith the national programme.

Process for Call Up

21. Call up for the shingles programme will be through GPs only; there will be no central call or recall for this programme. GPs are reminded that they are required to develop a proactive and preventative approach to offering immunisations by adopting robust call and reminder systems to contact all eligible patients. We would encourage all GP practices to provide call and recall by way of a letter, as recent experience has indicated that such letters can have a very positive impact on vaccine uptake. Template letters will become available nearer the time, if practices wish to make use of them. These will be available on the Health Scotland website: www.healthscotland.com/topics/immunisation/agegroups.aspx

Recommendations for Use of the Vaccine

22. 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.

23. Adults should receive a single **0.65ml** dose of Zostavax®, which should be administered by **subcutaneous injection**. It should **not** be given by intramuscular injection. It is likely that the vaccine confers protection against shingles for at least 7 years for many people. The need for, or timing of, a reinforcing dose has not yet been determined.

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

- has primary or acquired immunodeficiency state due to conditions such as:
 - acute and chronic leukaemias;
 - lymphoma;
 - other conditions affecting the bone marrow or lymphatic system;
 - immunosuppression due to HIV/AIDS (see below);

- 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. Health professionals should consult the shingles chapter of the Green Book for clarification - <https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6>;
- 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.

25. 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.

26. 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.

27. 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.¹

28. These shingles, influenza, and PPV23 vaccines can all be administered on the same occasion. However, if 2 are being given in one limb, at least 2.5cm should be left between them.

29. Further information on dosage, administration, concomitant administration with other vaccines, contraindications, consent and reporting of adverse reactions is set out in the relevant chapters of the Green Book: <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Pharmacy Issues

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

31. The vaccine is presented as a powder and solvent for suspension for injection in a pre-filled syringe. The powder is a white to off-white compact crystalline plug and the solvent is a clear, colourless fluid.

¹ 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](#))

32. After reconstitution, the vaccine should be used immediately, but may be used for up to 30 minutes following reconstitution. It is strongly recommended that the vaccine is not reconstituted in advance of the patient presenting to the clinician.

Supply

33. Zostavax® should be ordered through NHS vaccine holding centres using the ordering system required by each NHS Board. GP practices and vaccine holding centres must liaise closely to ensure sufficient vaccine availability prior to the scheduling of immunisation appointments. Holding centres will order vaccines from ImmForm.

Storage

34. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Do not freeze. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents

Vaccine Stock Management

35. Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. No more than 2 to 4 weeks of stock 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.

36. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage, including the use of appropriate cool boxes/bags for transporting the vaccine during home/care home visits. 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.

Reporting of Adverse Reactions

37. Suspected adverse reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). Chapter 9 of the Green Book gives detailed guidance about which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation. Information on the side effects of Zostavax® is available in Chapter 28a of the Green Book. These chapters are available at: <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Patient Group Directions

38. The requirement for Patient Group Directions is described in HDL(2001)7 available from http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM. The use of PGDs for administration of vaccines is described in detail in chapter 5 'Immunisation against Infectious Disease' <http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf>

39. A national specimen Patient Group Direction (PGD) for administration of Zostavax® will be available on the Health Protection Scotland website.

Monitoring Vaccine Uptake: Data Extraction

40. Health Protection Scotland (HPS) will lead in monitoring vaccine uptake on behalf of the Scottish Government. This will be primarily managed by extracting uptake information from GP systems by age and gender. Estimated vaccine uptake rates will be published on a monthly basis in the HPS shingles report. The data made available will include vaccine uptake by month in the year 2013/14. In future, comparison data will be available to allow NHS Boards to monitor the success of their strategy to increase uptake.

41. The Scottish Clinical Information Management in Practice (SCIMP) website provides very good information and guidance on coding, recording of vaccinations and exceptions (e.g. where a vaccine is contraindicated), as well as links to relevant documents. Colleagues in primary care or within NHS Boards with general queries about data extraction and coding, should refer to the SCIMP website in the first instance: <http://www.scimp.scot.nhs.uk/>.

42. GP practices are requested to send to Practitioner Services Division (PSD) a single figure for the total number of people in the relevant age groups (70 year olds as of 1 September 2013, and 79 year olds as of 1 September 2013) within their practice, as well as separately the number of people in the practice population who are ineligible for the vaccine according to the criteria in paragraph 24, or have not responded or refused the vaccine by the end of August 2014. The denominator figure (size of the eligible populations in the two age groups) for percentage uptake calculations will be used for statistical purposes and is important as this information allows HPS to validate the estimated uptake figures collected throughout the year for those eligible to receive shingles vaccine.

43. For further information regarding the HPS vaccine uptake monitoring programme, please contact Nss.immunisation@nhs.net

GP Contractual Arrangements

44. A new DES will be issued to reflect the programme, which will come as a one-off vaccination for 70 year olds from September 2013 and a catch up programme for 79 year olds in 2013. Practitioner Services Division will provide the details of the process for claims for payment which can be made for shingles vaccination. We are happy for GP surgeries to decide, (subject to vaccine availability), on the exact timings of vaccinations throughout the year, and the **fee will be £7.67** per course (one dose) for this additional work.

45. As previously notified, SGHSCID is meeting the vaccine purchase costs (including delivery to vaccine holding centres) associated with this programme and Boards are meeting the service delivery costs, including GP costs, from their baseline resources.

46. We ask Boards to ensure that practice attached staff are appropriately engaged in assisting practices to deliver immunisations.

Communications and Information for Patients and Health Professionals

47. Further information about the full range of immunisations and vaccines in Scotland is available on the public information website: www.immunisationscotland.org.uk

48. An Information leaflet and poster for the eligible group will be available to support the introduction of the vaccine. These will be distributed locally by NHS Health Scotland before the programme commences and will also be available online via the national immunisation website: www.immunisationscotland.org.uk

49. The leaflet will also be available in Urdu, Chinese and Polish, and in Easy Read format. NHS Health Scotland is happy to consider requests for other languages and formats. Please contact 0131 536 5500 or email nhs.healthscotland-alternativeformats@nhs.net

50. NHS Education for Scotland in partnership with Health Protection Scotland has produced educational resources for registered healthcare practitioners including training slides and a question and answer resource. These will be available at: <http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/shingles.aspx>

51. The new Green Book chapter on shingles is available at: <https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a>

Action

52. NHS Boards are asked to note the arrangements outlined in this letter for the vaccination of those susceptible to shingles, including the catch-up campaign.

Yours sincerely

Harry Burns

Ros Moore

Bill Scott

HARRY BURNS
Chief Medical Officer

ROS MOORE
Chief Nursing Officer

BILL SCOTT
Chief Pharmaceutical Officer