Health Protection Scotland

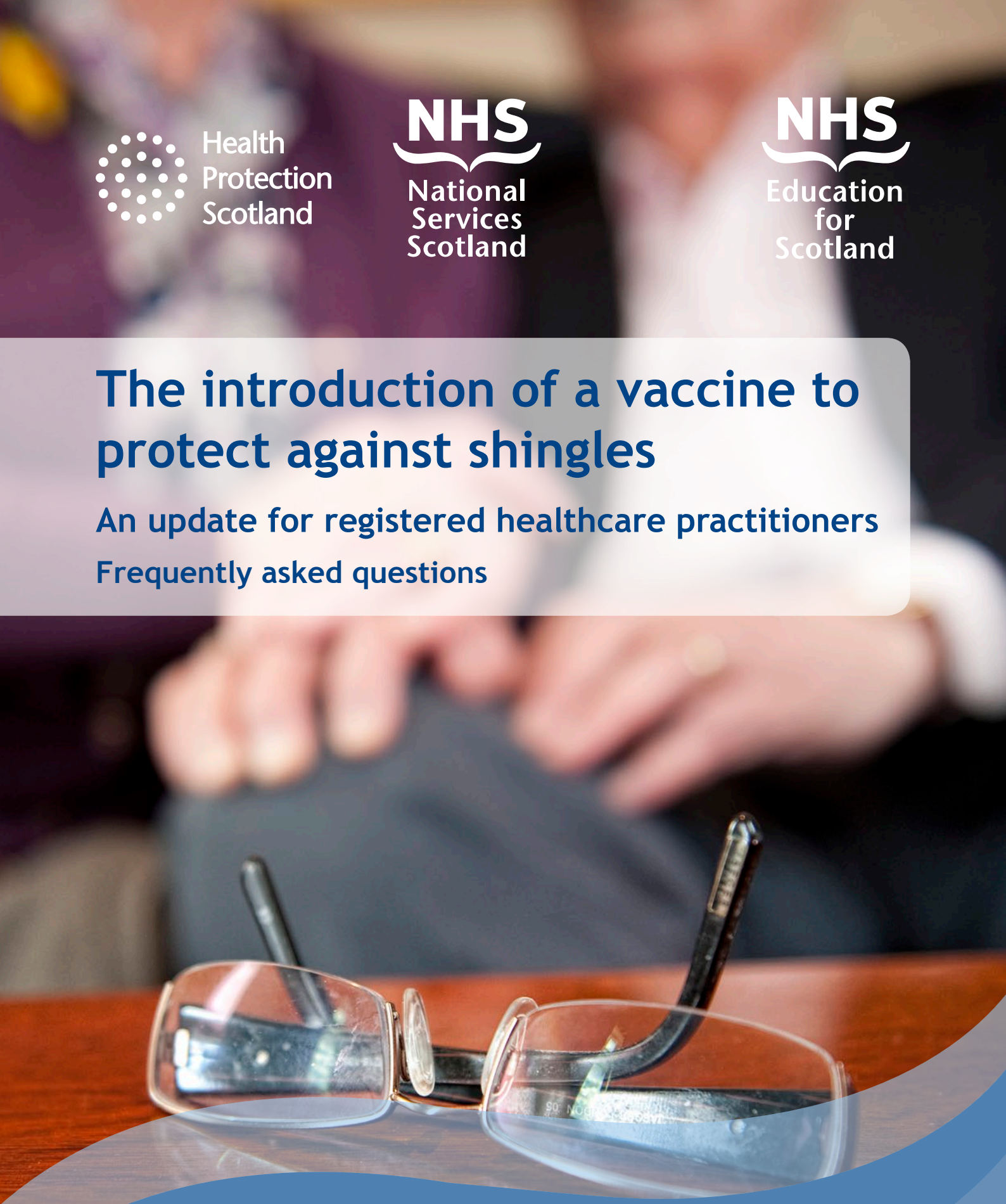
NHS National Services Scotland

NHS Education for Scotland

The introduction of a vaccine to protect against shingles

An update for registered healthcare practitioners

Frequently asked questions



Version 4.0 October 2014

Acknowledgements
This resource was based on work prepared by Public Health England to support vaccination against shingles (Herpes Zoster).

Amended for use in Scotland by NHS Education for Scotland and Health Protection Scotland.

Health Protection Scotland (HPS) is a division of NHS National Services Scotland.
NHS Education for Scotland (NES) is a division of NHS Scotland.

HPS website: http://www.hps.scot.nhs.uk.
NES website: http://www.nes.scot.nhs.uk.

Published by Health Protection Scotland and NHS Education for Scotland.

First published August 2013.
Version 2.0 published December 2013.
DRAFT Version 3.0 published August 2014.
Version 4.0 published October 2014.

Reference this document as:
Health Protection Scotland and NHS Education for Scotland. The introduction of a vaccine to protect against shingles, An update for registered healthcare practitioners. Frequently asked questions. Health Protection Scotland and NHS Education for Scotland. 2014.

Health Protection Scotland
NHS National Services Scotland
Meridian Court
5 Cadogan Street
Glasgow G2 6QE
Tel: +44 (0) 141 300 1100
Email: nss.hpsenquiries@nhs.net

NHS Education for Scotland
102 Westport
West Port
Edinburgh EH3 9DN
Tel: +44 (0) 131 656 3200
Website: http://www.nes.scot.nhs.uk

Designed and typeset by:
Graphics Team, Health Protection Scotland

Table of Contents

Background

The Joint Committee on Vaccination and Immunisation[1] reviewed all the available medical, epidemiological and economic evidence as well as vaccine safety and efficacy and concluded that the incidence of shingles is closely associated with older age groups, with the severity and disease burden increasing as the individual gets older. As a result, the JCVI recommended a universal routine herpes zoster (shingles) vaccination programme for adults aged 70 years to commence in September 2013.

As a result, in Scotland, the vaccine was introduced routinely to adults aged 70 years old from the 1 September 2013. In conjunction with the routine vaccination of adults aged 70 years, a catch-up programme was commenced.[2]

In the first year of the programme (from 1 September 2013) the catch-up included those aged 79 years on 1 September 2013.

In the second year of the programme (from 1 September 2014) the following groups will be eligible:

- Routine programme:
  - Those aged 70 years of age on 1 September 2014.
- Catch-up programme:
  - Those aged 78 and 79 years of age on 1 September 2014.

The aim of the universal vaccination programme is to reduce the incidence and severity of shingles disease in older people.

Shingles

What is shingles?

Shingles is a viral infection of the nerve cells that develops as a result of a chickenpox infection (varicella zoster). Once a person has recovered from chickenpox, the varicella zoster virus lies dormant in the nerve cells and can reactivate at a later stage when the immune system is weakened.[3] It is unclear what causes the reactivation of the virus, but it is thought to be associated with immunosuppression as a result of a decline in cell mediated immunity due to old age, immunosuppressant therapy or HIV infection.[4]

The clinical presentation of shingles (acute stage) includes a rash of fluid filled blisters and commonly occurs either on one side of the face or body, usually within the distribution of a dermatome. The rash often causes pain, itching or tingling sensation in the area of the affected nerve.

Shingles can cause a number of secondary complications and the severity of these can be dependant on how weak the individual's immune system is.

Most commonly reported complications in the older age group include secondary bacterial infections at the site of the rash and post herpetic neuralgia.

Who does it affect?

Shingles can develop at any time following a chickenpox infection and can occur in individuals of any age. However, as the reactivation of the virus is thought to be associated with immunosuppression, the disease is largely seen in older adults whereby the severity of the disease increases with age. Medical and epidemiological data shows the burden of the disease to be more severe in adults aged 70 years and above compared to younger adults.[5]

The vaccination against shingles programme

What is the purpose of the programme?

The purpose of the programme is to reduce both the incidence and severity of shingles disease in adults aged 70 years[4] and above. Individuals in this age group experience a severe form of the disease often resulting in secondary complications that may require hospitalisation.[5] Offering the shingles vaccine to individuals at the age of 70 years aims to boost immunity against the disease, therefore providing protection to individuals in later years. The primary purpose of the programme is to prevent the development of the disease in the first instance and secondly to reduce the severity of secondary complications associated with the disease.

Is Scotland the only country introducing the vaccine against shingles?

The shingles vaccination programme was introduced in all parts of the UK. Shingles vaccination has been used for some time in countries such as the USA.

Who is the vaccine recommended for?

As described above the vaccine was offered routinely to adults aged 70 years from 1 September 2013. In conjunction with the routine vaccination of adults aged 70 years, a catch-up programme was commenced.[4]

Can the vaccine be offered to individuals below the age of 70 years?

Whilst the vaccine is authorised for use from age 50 years and is effective in this age group the burden of singles disease is generally not as severe when compared with older ages. Furthermore, given that the duration of protection is not known to last for more that ten years (minimum seven years)[9] and the need for a second dose is not known, the vaccine is not recommended to be offered routinely below 70 years.

Can the vaccine be offered to individuals over the age of 80 years?

Administration after 80 years is less cost-effective due to limited effectiveness beyond this age and is not recommended.

The efficacy of Zostavax® in adults aged 70 years and above is low; why is the vaccine being offered to individuals in this age group?

A one dose schedule of Zostavax® was assessed in clinical trials using 17 775 adults aged 70 years and over. The vaccine was able to effectively reduce the incidence of shingles infection by 38%,[7] whilst significantly attenuating the disease. Zostavax® may not prevent the development of the disease in some cases; however, in those who later develop shingles following vaccination, the vaccine can significantly reduce the burden of disease by 55% and significantly reduce the incidence of post-herpetic neuralgia (PHN) by 66.8% in this age group.[7]

What if someone aged 70 years in 2013/14 requests vaccination in 2014/15?

Individuals who were 70 years of age on 1 September 2013 who did not take up their offer of vaccination in year one of the programme remain eligible for vaccination in year two. This decision is a one-off (for 2014-2015) and will be subject to review for future years.

What if someone aged 72 to 77 years requests vaccination in 2014/15?

Vaccine supply from the manufacturer is at present limited, and between 1 September 2014 and 31 August 2015, there will only be enough vaccine to fully vaccinate three birth cohorts – the routine cohort and two catch up cohorts (those aged 78 and 79 years on 1 September 2014).

What if someone aged 79 years in 2013/14 requests vaccination in 2014/15?

Individuals who were 79 years of age on 1 September 2013 who did not take up their offer of vaccination in year one of the programme are not eligible for vaccination once they become 80 years of age.

What vaccine is being given?

The vaccine that will be used is Zostavax®. It is the only shingles vaccine authorised for use in the UK.

Zostavax® is a live attenuated vaccine (a weakened form of virus which cannot cause disease but which protects against shingles and PHN).

How should the Zostavax® vaccine be stored?

Zostavax® must be stored in accordance with the manufacturer's instructions. As with most vaccines Zostavax® should be stored in a refrigerator between +2°C and +8°C.

The vaccine should be stored in the original packaging. This makes it easy to identify in the refrigerator and will protect the vaccine from light.

How is the vaccine ordered?

Zostavax® has been procured after a UK tendering exercise. It should be ordered from NHS board vaccine holding centres.

How is the vaccine presented?

The vaccine is presented as a vial containing freeze dried powder that appears as an off-white, crystalline plug and a prefilled syringe of clear colourless solvent. When mixed together, Zostavax® should appear as a semi-hazy to translucent, off white to pale yellow liquid.

The vaccine should not be administered if any particulate matter is noticed or if the appearance of the solvent or reconstituted vaccine is different to that described above.

It is recommended that the vaccine be administered immediately after reconstitution. Discard the vaccine if it is not used within 30 minutes.

How many doses are required?

A single dose of 0.65ml of Zostavax® is required. The need for, and timing of, receiving a reinforcing dose has not yet been determined. Current recommendations are based on a one dose schedule of the vaccine with no plans for a second/booster dose.

How is the vaccine given?

Zostavax® is administered by subcutaneous injection preferably in the deltoid region of the upper arm. It must not be given by intramuscular injection as there are few data on the effectiveness of Zostavax® given by this route.

How will individuals receive the vaccine?

Zostavax® became available from the 1 September 2013 as per local arrangements including GP surgeries.

Does Zostavax® contain latex?

No, Zostavax® does not contain any latex.

Does Zostavax® contain thiomersal?

No, Zostavax® does not contain any thiomersal.

Does Zostavax® contain pork (porcine) gelatin?

Yes. Gelatin is an essential ingredient in many medicines, including some vaccines. Many faith groups have approved the use of gelatin-containing vaccines. It is, however, an individual choice whether or not to receive this vaccine and we recognise there will be diversity of thought within different communities. There is no alternative shingles vaccine available that does not contain porcine gelatin. The following statements from representatives of the Jewish and Muslim communities may help individuals reach a decision about having this vaccine.

Rabbi Abraham Adler from the Kashrus and Medicines Information Service, said:

> "It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, including those administered via the nose, injections, suppositories, creams and ointments."

In 2001, The World Health Organization published a letter reporting the findings of a seminar involving more than 100 Islamic legal scholars to clarify Islamic purity laws on the use of medicinal products containing gelatin which stated that:

> "Transformation which means the conversion of a substance into another substance, different in characteristics, changes substances that are judicially impure into pure substances, and changes substances that are prohibited into lawful and permissible substances".

This means that gelatin made of unclean animal's bones, skin and tendons is clean and permissible for consumption.

Vegetarians should also note that pork gelatin is an ingredient in the vaccine.

Can Zostavax® be administered at the same time as the influenza vaccine?

Yes. Zostavax® can safely be administered concomitantly with inactivated influenza vaccine.[4] If given at the same time as influenza vaccine, care should be taken to ensure that the appropriate route of administration is used.

Zostavax® is a live attenuated vaccine and registered healthcare practitioners should check there are no contraindications to administering a live vaccine to individuals in at risk groups presenting for seasonal influenza vaccination.

The vaccine Summary of Product Characteristics (SPC) states that Zostavax® should not be administered at the same time as 23-valent pneumococcal polysaccharide vaccine (PPV); why does your advice differ?

Zostavax® can be given at the same time as 23-valent pneumococcal polysaccharide vaccine for those who are eligible for both vaccines. Although a manufacturer conducted trial[6] showed inferior VZV antibody responses in those receiving zoster vaccine and PPV-23 concomitantly than those receiving the vaccines four weeks apart, 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 or four weeks apart.[8]

Registered healthcare practitioners are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book chapters may differ from those in the Summary of Product Characteristics (SPC) for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed.

Are there individuals who cannot receive Zostavax®?

Zostavax® should not be given to a person who:

- Has primary or acquired immunodeficiency state due to conditions such as: acute and chronic leukaemia; lymphoma; immunosuppression due to HIV/AIDS; cellular immune deficiencies.
- Is receiving immunosuppressive therapy. This includes high-dose corticosteroids, biological therapies or combination therapies.
    - People who have undergone immunosuppressive chemotherapy or radiotherapy for malignancy should not receive the vaccine until 6 months after the end of treatment, and they are demonstrated to be in remission. Clinicians may wish to discuss with the specialist caring for the patient prior to administration.
    - People receiving 40mg Prednisolone per day for more than one week should not receive the vaccine until at least 3 months after cessation of therapy. A longer delay, up to 6 months, may be appropriate for the age cohorts included in the national vaccination programme. The vaccine is not contraindicated for use in individuals who are receiving topical / inhaled corticosteroids and in people who are recieving corticosteroids as replacement therapy (e.g. for adrenal insufficiency).
    - Therapy with a single low-dose non-biological oral immune modulating drug, either alone or with low dose steroids, for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions, are **not** necessarily sufficiently immunosuppressive and maynot be contraindications for administration of zoster vaccine. The degree of immunosuppression should be assessed on a case by case basis. Specialists with responsibility for patients in the vaccine eligible age cohorts should include a statement of their opinion on the patient's suitability for Zostavax® in their correspondence with primary care.
- Is pregnant.
- 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.
- Is being treated with either oral or intravenous aciclovir or is within 48 hours of cessation of treatment due to the potential to lower effectiveness of the vaccine.

Administration of Zostavax® should be postponed in individuals:

- Who are acutely unwell. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any signs and symptoms to adverse effects of the vaccine.

What is an individual has asplenia/splenectomy?

Asplenia/splenectomy is **not** of itself a contra-indication, though the underlying cause may be (such as leukaemia or lymphoma infiltration).

Can Zostavax® be given to an individual who currently has shingles or PHN?

No. Zostavax® is not recommended for the treatment of shingles or PHN. Individuals who have PHN should wait until symptoms have ceased before being considered for shingles immunisation. In immunocompetent individuals who develop shingles, vaccination should be delayed for one year as the natural boosting that occurs following an episode of shingles makes the benefit of offering zoster vaccine immediately following recovery limited.

What if an individual is taking antiviral drugs such aciclovir?

Zostavax® should be delayed for 48 hours following the end of treatment with antiviral drugs such as aciclovir as they may reduce the response to the vaccine.

The use of topical aciclovir is not a contraindication to vaccination.

What if an individual does not have a previous history of chickenpox; should they still be offered the vaccine?

Yes, a previous clinical history of chickenpox infection is not a pre-requisite for receiving Zostavax®.

An individual presenting without a clinical history of chickenpox should still be offered the vaccine. Individuals in this age group may have been exposed to varicella zoster without being aware and developed a sub-clinical infection as a result of the exposure. Therefore, the vaccine should still be offered to individuals without a clinical history of chickenpox to ensure protection against zoster.[6]

What if an individual presents with a previous history of shingles infection; should they still be offered the vaccine?

Yes, the individual should still be offered the vaccine despite presenting with a previous history of shingles infection.

Zostavax® is highly immunogenic in individuals[6] who have had a history of shingles infection prior to vaccination and boosts immunity to shingles significantly in this age group.

What are the potential side effects of this vaccine?

The most commonly reported side effects of Zostavax® affecting one in 10 of those receiving the vaccine includes injection site reactions such as redness, pain, swelling and itching at the injection site.

Other less commonly reported reactions affecting one in 100 includes are haematoma, induration and warmth at injection site. Other reactions include pain in the arm or leg and headache.

The full list of adverse reactions associated with Zostavax® is available in the marketing authorisation holder's summary of product characteristics.

Can anaphylaxis occur with zoster?

As with all vaccines, there is a very rare possibility of this vaccine causing a severe allergic reaction called anaphylaxis. All registered healthcare practitioners responsible for vaccination should be trained to recognise and treat anaphylaxis.

As Zostavax® is a live vaccine, can it be passed to others?

Post marketing experience with varicella vaccines suggests that transmission of vaccine virus may occur rarely between those vaccinated who develop a varicella-like rash and susceptible contacts. As a precautionary measure, any person who develops a varicella-like rash after receiving Zostavax® should avoid direct contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted.

Should contacts of immunosuppressed individuals receive Zostavax®?

Yes, contacts of immunosuppressed individuals should be offered the vaccine if they are eligible.

What should you do if you inadvertently administer Zostavax® to an individual who is immunosuppressed in error?

Immunosuppressed individuals who are inadvertently vaccinated with Zostavax® should be urgently assessed by a clinician to establish the degree of immunosuppression. As all individuals in the eligible cohort should be VZV antibody positive, varicella-zoster immunoglobulin is unlikely to be of benefit but prophylactic acyclovir may be considered in those for whom the attenuated vaccine virus poses a significant risk. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination can be offered treatment with aciclovir.[4]

Registered healthcare practitioners should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

Should Zostavax® be administered to an individual due to receive immunosuppressive therapy in the near future?

The risk and severity of shingles is considerably higher amongst immunosuppressed individuals and therefore individuals anticipating immunosuppressive therapy should be assessed prior to commencing treatment in relation to their vaccination status. Eligible individuals who have not received zoster vaccine should receive a single dose of vaccine at the earliest opportunity at least 14 days prior to commencing immunosuppressive therapy, although leaving one month would be preferable if a delay is possible.[9]

Can Zostavax® be used as an alternative to Varivax® or Varilrix® for the prevention of chickenpox infection (varicella zoster)?

No. Zostavax® is licensed for the immunisation of individuals aged 50 years and above for the prevention of shingles (herpes zoster) and shingles related post herpetic neuralgia. Varivax® and Varilrix® are licensed vaccines for the prevention of varicella (chickenpox) infection and should continue to be administered as recommended in the Department of Health, Green Book Chapter 34.

What should you do if you inadvertently administer Zostavax® to a child in error?

Although Zostavax® is similar to the varicella vaccine, it has significantly higher antigen content. Early trials in susceptible children used vaccine at doses approaching the range used in Zostavax®. The high dose formulation was well tolerated and efficacious. Inadvertent vaccination with Zostavax® in varicella naïve children is unlikely to result in serious adverse reactions and should count as a valid dose of varicella vaccine.[4]

Registered healthcare practitioners should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

Where can I get more information?

CMO Letter
http://www.sehd.scot.nhs.uk/cmo/CMO(2014)21.pdf

Green Book
https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

NHS Education for Scotland and Health Protection Scotland training resources
http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/shingles.aspx

Sanofi Pasteur MSD Limited - Zostavax® SPC
http://www.medicines.org.uk/emc/medicine/25927

More information on the clinical presentation of shingles from NHS Inform
http://www.immunisationscotland.org.uk

NHS Health Scotland immunisation website
http://www.nhsinform.co.uk

References

1. Joint Committee on Vaccination and Immunisation (2010) Statement on varicella and herpes zoster vaccines 29 March 2010. [accessed 01 March 2013] http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/ab/JCVI/DH_094744

2. Chief Medical Officer for Scotland (2013) 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. Available at: http://www.sehd.scot.nhs.uk/cmo/CMO(2014)21.pdf

3. NHS Choices (2012). Shingles. [accessed 14 April 2013] http://www.nhs.uk/Conditions/Shingles/Pages/Introduction.aspx

4. Public Health England, 2013, Immunisation against infectious disease: the Green Book. Shingles Chapter 28a. [accessed on 29 July 2013] Available at: https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

5. van Hoek AJ, Gay N, Melegaro A et al. (2009) Estimating the cost-effectiveness of vaccination against herpes zoster in England and Wales. *Vaccine* **27**(9): 1454-67. Cited in Joint Committee on Vaccination and Immunisation (2010)

6. Sanofi Pasteur MSD Limited (2013). Zostavax SPC. [accessed on 14 April 2013] http://www.medicines.org.uk/emc/medicine/25927

7. Oxman MN, Levin MJ, Johnson GR et al. (2005) A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. *N Engl J Med* **352**(22): 2271-84.

8. Tseng HF, Smith N, Sy LS, Jacobsen SJ. Evaluation of the incidence of herpes zoster after concomitant administration of zoster vaccine and polysaccharide pneumococcal vaccine. *Vaccine* 2011;**29**(20):3628–32

9. Public Health England and Department of Health. Vaccination against shingles for adults: Q&As for healthcare professionals. [accessed 30 July] https://www.gov.uk/government/publications/vaccination-against-shingles-for-adults-qas-for-healthcare-professionals