

Vaccination against shingles for adults aged 70 or 78.

Information for healthcare professionals



Public Health
Agency

Background

In 2010, the Joint Committee on Vaccination and Immunisation (JCVI) were asked by the Secretary of State for Health to review all the available evidence relevant to offering a universal vaccination programme for shingles.¹

The JCVI reviewed all the available evidence on the disease epidemiology, vaccine efficacy and safety and cost effectiveness of introducing a routine shingles vaccination programme in the UK. The JCVI concluded that the incidence of shingles increases with age, 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 commenced in September 2013.

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

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.² Reactivation of the virus 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.³

Who does it affect?

Shingles can develop at any time following a chickenpox infection and can occur in individuals of any age. However, risk and severity of shingles increases with age. Thus the burden of disease amongst adults aged 70 and above is considerably greater than younger adults.⁴ Individuals in this age group experience a severe form of the disease often resulting in secondary complications such as post herpetic neuralgia (PHN) and secondary bacterial skin infections that may require hospitalisation.⁴

The shingles vaccination 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 to 79 years of age.³ Offering the shingles vaccine routinely to individuals at the age of 70 years aims to boost immunity to prevent the development of shingles in later years, whilst significantly reducing the incidence of post herpetic neuralgia.

Who is the vaccine recommended for?

This year the vaccine will be offered routinely to adults aged 70 years old on 1 September 2017, ie those born between 2 September 1946 and 1 September 1947. In conjunction with the routine vaccination of adults aged 70 years, a catch-up programme, for 2017/18, will also be available for adults aged 78 years on 1 September 2017, ie those born between 2 September 1938 and 1 September 1939.

What is the recommended vaccine for the programme?

Zostavax® is the recommended vaccine for the programme and is the only authorised shingles vaccine in the UK.

Zostavax® is a live attenuated vaccine that contains a high antigen level of varicella zoster virus (Oka/Merck Strain, not less than 19400PFU).⁵

The vaccine is recommended for the routine vaccination of individuals aged 70, and those in the 78 years old catch-up cohort, for the prevention of shingles and shingles related post herpetic neuralgia (PHN) from 1 October, 2016/17.

Vaccine eligibility

Vaccine from programme stocks **MUST** only be used for the defined age cohorts, because of vaccine supply constraints. Use will be carefully monitored to ensure there is adequate supply for the programme cohorts.

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 shingles disease is generally not as severe compared with older ages, the duration of protection and need for reinforcing doses of vaccine are not known and the most cost effective age to offer the vaccine therefore is to individuals aged 70 to 79 years.⁴ If offered outside the specified age cohorts, vaccine must be prescribed separately and programme vaccine must not be used.

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

The vaccine is not currently recommended in the programme for adults aged 80 years and above as the efficacy of the vaccine is reduced in this age group. Offering the vaccine to individuals in this

age group is not considered to be cost effective. If offered outside the specified age cohorts, the vaccine must be prescribed separately and programme vaccine must not be used.

What if someone was eligible for the vaccine in 2013/14, 2014/15, 2015/16, 2016/17 in the 70 years cohort and are now 71, 72, 73, 74 or were 78 in the 2015/16 cohort and are now 79, and so are no longer in the specified age cohort?

People who were eligible in the cohorts in 2013/14, 2014/15, 2015/16, 2016/17 but have now turned 71, 72, 73, 74 or 79 (but not 80) may still be given the vaccine this year.

What if someone was eligible for the vaccine in the 79 year old catch-up cohort in 2016/17 (DOB 2/9/36–1/9/37), have now turned 80 years old and are no longer in the specified age cohort?

People in the 79 year old cohort in 2016/17 and who have now turned 80 years old should **NOT** be given the vaccine if they request it after 1 September 2017. This is because the efficacy of the vaccine is reduced in people aged 80 years and above. If offered outside the specified age cohorts, vaccine must be prescribed separately and programme vaccine must not be used.

What if someone aged 75 to 77 years of age requests vaccination in 2017/18?

Vaccine supply from the manufacturer is still somewhat limited, and between 1 September 2017 and 31 August 2018, there will only be enough vaccine to fully vaccinate two birth cohorts - the routine cohort, and one catch-up cohort (those aged 78 on 1 September 2017).

This situation should be explained to patients and they should be reassured that those aged 75-77 years will be offered the vaccine in the future. Details of future catch up campaigns will be issued in due course.

What if someone was aged 70 (or 78) years on 1 September 2017 but by the time they attend for vaccination they have turned 71 (or 79) years?

They should still be offered the vaccine – eligibility is determined by their age on 1 September 2017.

What if someone was aged 69 (or 77) years on 1 September 2017 but by the time they attend for vaccination they have turned 70 (or 78) years?

They should NOT be offered the vaccine – eligibility is determined by their age on 1 September 2017. It should be explained to them that they will be offered the vaccine next year.

How will individuals receive the vaccine?

Zostavax® will be available from 1 October 2017 via GP surgeries. GPs are encouraged to identify and offer the shingles vaccination to eligible patients. For convenience, the shingles vaccine can routinely be administered at the same time as the seasonal influenza vaccine. However some patients eligible for flu vaccine will be immunosuppressed and so should not be given the shingles vaccine. In this circumstance it would be important to only invite them for the flu vaccine and not the shingles vaccine and to ensure checks are made before the administration of the shingles vaccine that there are no contraindications.

Most patients by this age will have received the 23-valent pneumococcal polysaccharide vaccine (PPV), as it is normally offered at 65 years of age, however if some patients are due PPV then it can also be given with shingles and flu vaccines. However, scheduling of the appointment should not delay the administration of any of these vaccines. The shingles vaccine can be administered outside of the influenza vaccine season where the two vaccines have not been given together.

Care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The preferred route for administering the shingles vaccine is now intramuscularly, unless the person has a bleeding disorder. Additionally, given that some individuals eligible for seasonal influenza vaccination may be immunosuppressed, it is important to check that there are no contraindications to administering a live vaccine to these at risk groups.

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®.

Although an individual may present without a clinical history of chickenpox, many such patients would have had a subclinical infection without being aware. Therefore, the vaccine should still be offered to individuals without a clinical history of chickenpox to ensure protection against zoster.⁵

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. People can get shingles more than once and the vaccine will reduce the risk of further attacks.

Zostavax® is highly immunogenic in individuals who have had a history of shingles infection prior to vaccination and boosts immunity to shingles significantly in this age group.⁵

Can Zostavax® be given to an individual who is currently diagnosed with shingles infection?

No. Zostavax® is not licensed for the treatment of shingles or shingles related post herpetic neuralgia (PHN). Individuals presenting with an acute illness such as shingles infection should defer immunisation until they are fully recovered and treatment with antiviral drugs such as Aciclovir are completed as they may reduce the response to the vaccine. In immunocompetent individuals, it is recommended that vaccination is deferred until one year after their shingles infection. (Green Book Chapter 28a page 10).

What are the contraindications for receiving Zostavax®?

As Zostavax® is a live attenuated vaccine, it should not be given to a person who:

1. Has primary or acquired immunodeficiency states due to conditions including:

- acute and chronic leukaemias, lymphoma (including Hodgkin's lymphoma);
- immunosuppression due to HIV/AIDS (see later);
- cellular immune deficiencies;
- those remaining under follow up for a chronic lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (N.B: this list not exhaustive);
- those who have received an allogenic stem cell transplant (cells from a donor) in the past 24 months (it can only be given after 24 months if the person is demonstrated not to have ongoing immunosuppression or graft versus host disease (GVHD)).

- those who have received an autologous (using their own stem cells) haematopoietic stem cell transplant in the past 24 months (it can only be given after 24 months if the person is in remission).

Humoral deficiencies affecting IgG or IgA antibodies are not themselves contra-indications unless associated with T cell deficiencies. If there is any doubt (eg common variable immune deficiency), immunological advice should be sought prior to administration.

2. Is on immunosuppressive or immunomodulating therapy including:

- those who are receiving or have received in the past six months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders;
- those who are receiving or have received in the past six months immunosuppressive therapy for a solid organ transplant (depending upon the type of transplant and the immune status of the patient);
- those who are receiving or have received in the past 12 months biological therapy (eg anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist;
- those who are receiving or have received in the past three months immunosuppressive therapy including:
 - i) short-term high-dose corticosteroids (>40mg prednisolone per day for more than 1 week);

ii) long-term lower dose corticosteroids (>20mg prednisolone per day for more than 14 days);

iii) non-biological oral immune modulating drugs eg methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day.

For more details please see 'Special considerations'.

Zostavax® is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or corticosteroid replacement therapy.

3. Has had a confirmed anaphylactic reaction to a previous dose of varicella – containing vaccine or any component of the vaccine, including neomycin or gelatin.
4. Is pregnant. Zostavax® is not indicated in women of childbearing age. Women who are pregnant should not receive Zostavax®.

Special considerations

To support the assessment of patients with underlying conditions/on immunosuppressive therapy who are eligible for vaccination in the national programme, the following information may be used as a guide in determining patients suitability for the vaccine.

The decision to administer Zostavax® to such individuals should be based on obtaining complete clinical information to undertake the assessment. If the individual is under highly specialist care, and it may not be possible to obtain full information on that individual's treatment history, then vaccination should not proceed until the advice of the specialist or a local immunologist has been sought.

1. Malignancy

Eligible individuals who have undergone immunosuppressive chemotherapy or radiotherapy for malignant and non-malignant disorders (other than lymphoproliferative disorders, see section on haematological disorders) should not receive Zostavax® until six months after the end of treatment and they are demonstrated to be in remission. Primary healthcare professionals managing such patients may wish to discuss the patient's eligibility to receive the vaccine with the secondary care specialist or immunologist prior to administration.

2. Haematological disorders including haemopoietic stem cell transplants

Patients with chronic lymphoproliferative malignancies eg indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (abnormalities) should not receive Zostavax®.

Patients who have received an allogenic haematopoietic transplant (using stem cells from a donor) should not receive Zostavax® until at least 24 months following transplantation and only then if they are demonstrated not to have ongoing immunosuppression or graft versus host disease (GVHD).

Those patients who have received autologous (using their own stem cells) haematopoietic stem cell transplant with curative intent eg for a high grade lymphoma should not receive Zostavax® until 24 months after transplant and only then if they are in remission. Patients with Hodgkin's lymphomas should not receive Zostavax®.

For patients with autoimmune haematological disorders receiving immunosuppressive therapy, please see 'What are the contraindications for receiving Zostavax®?'.

3. Solid organ transplants

Those who are receiving, or have received in the past six months, immunosuppressive therapy for a solid organ transplant should not receive Zostavax®. The decision to vaccinate eligible patients should depend upon the type of transplant and the immune status of the patient. Primary healthcare professionals may wish to discuss the patients eligibility with a secondary care specialist or immunologist when making a decision whether to give the vaccine.

The decision to vaccinate should depend upon the type of transplant and the immune status of the patient.

4. Chronic inflammatory disorders on immunosuppressive or immunomodulating therapies eg rheumatoid arthritis, inflammatory bowel disease, psoriasis, glomerulonephritis (see 'What are the contraindications for receiving Zostavax®?')

Many adults with chronic inflammatory diseases may be on stable long term low dose corticosteroid therapy (defined as $\leq 20\text{mg}$ prednisolone per day for more than 14 days) either alone or in combination with other immunosuppressive drugs including biological and non-biological therapies. Therapy with stable long-term low-dose corticosteroid therapy, either alone or in combination with low-dose non-biological oral modulating drugs are not contraindications for administration of Zostavax®. These include methotrexate ($\leq 25\text{mg}$ per week), Azathioprine ($\leq 3.0\text{mg/kg/day}$), or 6-mercaptopurine ($\leq 1.5\text{ mg/kg/day}$).

Those who are receiving or have received in the past 12 months biological therapies (eg anti-TNF therapy) should not receive Zostavax® unless otherwise directed by a specialist.

Specialists with responsibility for patients in the vaccine eligible cohorts should include a statement of their opinion on the patient's suitability for Zostavax® in their correspondence with primary care. If primary healthcare professionals administering the vaccine have concerns about the nature of therapies (including biologics) or the degree of immunosuppression they should contact the relevant specialist for advice.

5. Patients anticipating immunosuppressive therapy

The risk and severity of shingles is considerably higher amongst immunosuppressed individuals and therefore eligible individuals anticipating immunosuppressive therapy should ideally be assessed for vaccine eligibility before starting treatment that may contraindicate future vaccination.

Eligible individuals who have not received Zostavax® should receive a single dose of vaccine at the earliest opportunity and at least 14 days before starting immunosuppressive therapy, although leaving one month would be preferable if a delay is possible.³

6. HIV infection

The decision to administer Zostavax® to immunosuppressed individuals should be based on clinical risk assessment (see above).

The safety and efficacy of Zostavax® have not been conclusively established in adults who are known to be infected with HIV with or without evidence of immunosuppression. On the basis of limited Phase II trial data (Benson et al) and extrapolation from other live vaccines (Koenig et al) a CD4 count of 200 cells/ μl may be a suitable cut off value below which vaccination should not be given. Immunosuppressed patients who require protection against shingles should seek advice from a specialist.

7. Cellular immune deficiencies other than HIV infection

Patients with cellular immune deficiencies should not receive Zostavax®. However, humoral deficiencies affecting IgG or IgA antibodies are not themselves a contraindication unless associated with T cell deficiencies. If there is any doubt (eg common variable immune deficiency), immunological advice should be sought prior to administration.

Can Zostavax® be administered to patients with rheumatoid arthritis?

Patients with rheumatoid arthritis are at an increased risk of developing shingles infection compared to the general population. It is therefore important that all eligible patients with rheumatoid arthritis are clinically assessed for their suitability to receive Zostavax® as they have significant ability to benefit. Where possible, eligible patients with rheumatoid arthritis should be offered the vaccine prior to commencing treatment with non-biological or biological therapies, ie recombinant monoclonal antibody therapy.

Eligible patients who have already commenced treatment with non-biological therapies may also be considered for shingles vaccination. However, for those patients who have already commenced biological therapy, Zostavax® should not be administered.

As patients receiving immunosuppressive therapy for rheumatological conditions will usually be under the care of a rheumatologist, the British Society of Rheumatology recommends that eligible patients are clinically assessed by their specialist and that the specialist then liaises with primary care to advise on individual patient suitability for the vaccine.

Can Zostavax® be administered to patients with inflammatory bowel disease?

Patients with inflammatory bowel disease (IBD) are at an increased risk of developing shingles as compared to the general population. Where possible, eligible patients with IBD should be offered the vaccine prior to commencing treatment with immunomodulating or biological therapies.

It is recommended that eligible patients receiving immunosuppressive therapy for IBD should be assessed by their gastroenterologist who should then liaise with primary care to advise on individual patient suitability for the vaccine.

Can Zostavax® be administered to patients with dermatological conditions, eg Psoriasis?

The risk of shingles infection is increased with advancing age, prolonged treatment with oral corticosteroid, and with immunosuppressive and biological agents. As these therapeutic agents may be used in the management of dermatological conditions, patients eligible for the national programme should be clinically assessed for their suitability to receive Zostavax® prior to commencing treatment, as they may benefit significantly from receiving it.

Eligible patients should be considered for vaccination prior to commencement of biological and non-biological therapies. Therapy with stable long-term low-dose corticosteroid therapy, either alone or in combination with low dose non-biological oral modulating drugs are not contraindications for administration of Zostavax®. These include methotrexate ($\leq 25\text{mg}$ per week), Azathioprine ($\leq 3.0\text{mg/kg/day}$), or 6-mercaptopurine ($\leq 1.5\text{ mg/kg/day}$).

However, patients already established on biological therapy, such as etanercept and infliximab, should not receive Zostavax®.

It is recommended that eligible patients receiving immunosuppressive therapy for a dermatological condition should be assessed by their dermatologist who should then liaise with primary care to advise on the individual patient's suitability for the vaccine.

Can Zostavax® be administered to patients with renal conditions eg glomerulonephritis or reduced renal function?

Patients with impaired renal function and/or receiving immunosuppression for inflammatory renal diseases will have an increased risk of shingles as well as reduced vaccine responses and may have reduced clearance of oral immunosuppressants and their active metabolites including azathioprine, methotrexate and 6-mercaptopurine.

Patients requiring low-dose oral immunosuppression for inflammatory renal disease with preserved kidney function who are in remission could be considered for Zostavax® if they are receiving long-term stable low-dose corticosteroid therapy (defined as $\leq 20\text{mg}$ prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (eg methotrexate $\leq 25\text{mg}$ per week, azathioprine $\leq 3.0\text{mg/kg/day}$ or 6-mercaptopurine $\leq 1.5\text{mg/kg/day}$).

Primary care physicians may wish to discuss the suitability of Zostavax® with the secondary care physician responsible for managing the immunosuppression for those patients with impaired, particularly severely impaired, renal

function who are also receiving long-term stable low-dose non-biological oral immune modulating drugs (eg methotrexate $\leq 25\text{mg}$ per week, azathioprine $\leq 3.0\text{mg/kg/day}$ or 6-mercaptopurine $\leq 1.5\text{mg/kg/day}$) alone or in combination with low-dose corticosteroid therapy (defined as $\leq 20\text{mg}$ prednisolone per day for more than 14 days).

Zostavax® is contraindicated for some patients with inflammatory renal disease including:

- those whose inflammatory disease is not in remission;
- those on current or recent immunosuppressive chemotherapy in the last six months;
- those who are receiving or have received in the past 12 months biological therapy (eg anti-TNF therapy);
- those who are receiving or have received in the past three months immunosuppressive therapy including:
 - i) short term high-dose corticosteroids ($>40\text{mg}$ prednisolone per day for more than 1 week);
 - ii) long term lower dose corticosteroids ($>20\text{mg}$ prednisolone per day for more than 14 days);
 - iii) non-biological oral immune modulating drugs e.g. methotrexate $>25\text{mg}$ per week, azathioprine $>3.0\text{mg/kg/day}$ or 6-mercaptopurine $>1.5\text{mg/kg/day}$.

Can Zostavax® be administered to patients with an absent or dysfunctional spleen?

Eligible patients who have an absent or dysfunctional spleen should be offered Zostavax®, unless otherwise contraindicated as they have a significant ability to benefit from the vaccine. While there is no evidence relating specifically to the use of Zostavax® in splenectomy patients, asplenia or a dysfunctional spleen is not considered a contraindication to receiving the vaccine.

Live and inactivated vaccines are safely administered to children and adults with an absent or dysfunctional spleen routinely in primary care to offer protection against a range of vaccine preventable diseases.

However, while asplenia itself is not a contraindication to receiving Zostavax®, it is important for healthcare professionals to be aware of the underlying cause that has resulted in the absent or dysfunctional spleen, as this may be a contraindication to receiving the vaccine. For example, leukaemic infiltration is a potential reason for splenectomy, and so the patient may have an acute leukaemia which is one of the specific contraindications to use of Zostavax®.

Additionally, offering the shingles vaccine to eligible patients who are asplenic or who have a dysfunctional spleen provides an opportunity for the clinician to ensure the patient is up-to-date with all the recommended vaccines for asplenic patients, as documented in chapter 7 of the Green Book.

What is the efficacy of Zostavax® in adults aged 70 years and above?

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%, however it is more effective at reducing the severity of the illness in those for whom it does not completely prevent it. 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 PHN by 66.8% in this age group.⁵

Vaccine administration

How is the vaccine administered?

Zostavax® is administered by intramuscular or subcutaneous injection into the upper arm (deltoid region). One dose contains 0.65ml. Intramuscular injection is the preferred route of administration. Individuals with a bleeding disorder should have shingles vaccine administered subcutaneously to reduce the risk of bleeding.

The vaccine comes in a box that contains a vial and pre-filled syringe for reconstitution. Once reconstituted, the mixture should form a semi-hazy to translucent, off white to pale yellow liquid that should be administered immediately.

Healthcare professionals are encouraged to read the Summary Product of Characteristics (SPC) to ensure accurate reconstitution of the product.

Can Zostavax® be administered at the same time as other vaccines?

Yes. Zostavax® can be administered concomitantly with other vaccines such as inactivated influenza and 23-valent pneumococcal polysaccharide vaccine (PPV) and live vaccines such as Yellow Fever.^{3, 6}

Based on evidence that MMR vaccine can lead to an attenuation of the varicella vaccine response it is recommended that, a four-week interval is observed between administration of MMR and Zostavax® vaccines to ensure adequate protection.

In line with JCVI advice (JCVI February 2014), there are no other restrictions for timing between Zostavax® and other live vaccines.

General practitioners are encouraged to offer the shingles vaccination when patients are called for the seasonal influenza vaccine. The 23-valent pneumococcal polysaccharide vaccines (PPV) can also be given at the same time if a patient is due it.

However, scheduling of the appointment should not delay the administration of any of the vaccines. The shingles vaccine can be administered outside of the influenza vaccine season where the vaccines have not been given together.

If given at the same time as influenza vaccinations, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.

Additionally, given that some individuals eligible for seasonal influenza vaccination may be immunosuppressed, it is important to check that there are no contraindications to administering a live vaccine to these at risk groups.

Where more than one vaccine is administered at the same time, the vaccines should be given at a separate site, preferably in a different limb. If more than one vaccine is given in the same limb, they should be given at least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual's health records.

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 (PPV) for those who are eligible for both vaccines. Although a manufacturer conducted trial showed inferior VZV antibody responses in those receiving zoster vaccine and PPV-23 concomitantly than in 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 whether it was administered simultaneously with PPV or four weeks apart.⁶

Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book 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.

What adverse reactions are commonly associated with the administration of Zostavax®?

The most commonly reported adverse reactions affecting 1 in 10 of those receiving the vaccine include, headaches, erythema (redness), pain, swelling and pruritus (itching) at the injection site. Other less commonly reported reactions affecting 1 in 100 include haematoma, induration and warmth at the injection site.

Serious suspected adverse reactions to Zostavax® should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the yellow card reporting scheme.

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 to establish the degree of immunosuppression and the need for prophylactic acyclovir. As all individuals of this age group should be VZV antibody positive, varicella-zoster immunoglobulin is unlikely to be of benefit but prophylactic aciclovir 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 should be urgently assessed and offered prompt treatment with aciclovir, given the risks and severity of disseminated zoster.

As a precautionary measure, any person who develops a vesicular rash after receiving Zostavax® should ensure the rash area is kept covered when in contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted. If the person who received the vaccine is themselves immunosuppressed, they should ensure the rash area is kept covered when in contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted.

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

The risk and severity of shingles is considerably higher amongst immunosuppressed individuals and people in the eligible cohorts anticipating immunosuppressive therapy should be assessed prior to commencing treatment in relation to their vaccination status. Eligible individuals who have not received Zostavax® 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.³ People who are not aged 70 or 78 are not included in the shingles vaccination programme in 2017/18.

What action should be taken in the event that Zostavax® is inadvertently administered during pregnancy?

As a precautionary measure, health professionals should treat the inadvertent administration of Zostavax® vaccine in a pregnant woman in the same way as a natural exposure to chickenpox infection and should urgently assess the woman's susceptibility to chickenpox.

Those women who give a reliable history of chickenpox infection or who have documented evidence of receiving two doses of varicella vaccine should be reassured that they are immune and that the inadvertent administration of Zostavax® will boost their existing antibodies against varicella zoster virus (chickenpox). These women should be provided with information on the safety of varicella vaccines when given in pregnancy leaflet and advised that no further action is required.

For those women who are unable to give a reliable history of chickenpox infection or documented evidence of varicella vaccination, an urgent varicella antibody test (VZV IgG) should be performed using either the women's booking bloods or arrange a blood sample to be taken. It is important for healthcare professionals to liaise directly with the local microbiologist to arrange urgent testing and timely reporting of results. Those women who are found to be VZV

IgG positive should be reassured that they are immune and that the inadvertent administration of Zostavax® will boost their existing antibodies against varicella zoster virus (chickenpox). These women should be provided with information on the safety of varicella vaccines when given in pregnancy leaflet and advised that no further action is required. For those women with a VZV IgG equivocal result, we recommend that the local laboratory re-test the sample using a more sensitive assay eg binding site to confirm the result.

For those women who are found to be VZV IgG negative on testing, please contact the duty room at Public Health Agency 0300 555 0119 for further advice and consideration of the use of VZIG within 10 days of inadvertent vaccination. Ideally, VZIG should be administered within seven days where practically possible but can be offered up to 10 days following vaccination. Further guidance on the management of pregnant women exposed to a vesicular rash can be found in the viral rash in pregnancy guidance document.

All incidents of inadvertent administration of Zostavax® during pregnancy should also be reported to Public Health England using the vaccines administered in pregnancy reporting form (VIP). This national surveillance collects additional information on such exposures so that we can better inform health professionals and pregnant women in the future.

Inadvertently administering Zostavax® during pregnancy is a serious clinical incident that should be reported immediately via the local governance system(s), so that appropriate action

can be taken, lessons can be learnt and the risk of future errors minimised.

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

Please ensure that all relevant staff are familiar with the Zostavax® packaging. 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.³

Healthcare professionals 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.

What should you do if you inadvertently administer varicella vaccine (Varivax® or Varilrix®) to an adult instead of Zostavax®?

Please ensure that all relevant staff are familiar with the Zostavax® packaging. Varicella vaccines contain a significantly lower antigen content than Zostavax® and are unlikely to provide the same level of protection against herpes zoster. Therefore, the varicella vaccine should be discounted and a further dose of Zostavax® should be offered.

Varivax®, Varilrix® and Zostavax® are all live attenuated vaccines. Therefore, Zostavax® should be administered at the same visit following the inadvertent administration of

varicella or, if this is not possible, allowing a four week interval between doses. Healthcare professionals 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.

Can Zostavax® be used to 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 Varicella 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 Green Book.

What action should a person take if they develop a shingles like rash after receiving Zostavax®?

Transmission of the Zostavax® vaccine virus (Oka/Merck strain) has not been reported during clinical trials.

However, experience with varicella (chickenpox) vaccines, which use a lower dose of the same virus strain, suggest that transmission of vaccine virus may occur rarely between vaccinees that develop a varicella-zoster virus (VZV)-like rash and susceptible close contacts.⁵

As a precautionary measure, a person who develops a shingles like rash after receiving Zostavax® should restrict contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted.

Contact tracing is not required if an immunocompetent person develops a localised vesicular rash following vaccination.

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