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## Background

In 2010, the Joint Committee on Vaccination and Immunisation (JCVI) was asked by the Secretary of State for Health to review all the available evidence relevant to offering a universal vaccination programme for shingles. 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. Based on the findings of the cost-effectiveness analysis, the JCVI recommended a universal routine herpes zoster (shingles) vaccination programme for adults aged 70 years, with a catch-up programme for those aged 71 to 79 years, which commenced in September 2013.

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

In February 2018, the JCVI recommended that the Shingrix® inactivated shingles vaccine should be offered to all immunocompromised individuals for whom Zostavax® is contraindicated but who are eligible for vaccination under the current programme, so that they can gain a similar level of protection to those who are not immunocompromised. The committee noted that vaccination in this group was particularly important, due to the higher incidence of herpes zoster. This advice was consistent with the original recommendation for vaccination of all adults aged 70 to 79 years with herpes zoster vaccine. At this time, there were insufficient supplies of Shingrix® vaccine to be able to implement this recommendation.

From September 2021, Shingrix® vaccine is available as an alternative shingles vaccine for use in patients where Zostavax® is clinically contraindicated.

Shingles vaccine is available through GP surgeries in primary care, and GPs are encouraged to identify and offer the shingles vaccination to eligible patients.

It is important that Shingrix® is given only to those who are clinically contraindicated for Zostavax® (for example due to severe immunosuppression) in order to have sufficient vaccine supply for those who need to receive it. Immunocompetent eligible patients should continue to be offered Zostavax®.

Any individual who reaches their 80th birthday is no longer eligible for a shingles vaccination due to the reducing efficacy of the vaccine as age increases. This reflects the recommendation made by JCVI in 2010.

## 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. 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.

## 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 among adults aged 70 and above is considerably greater than younger adults.

Individuals in this age group can 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.

## 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. 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, while significantly reducing the incidence of PHN.

### Who is the vaccine recommended for?

All patients aged 70 will be offered a shingles vaccine. Patients remain eligible until their 80th birthday as part of a catch-up scheme. After the age of 80, the vaccine is not offered due to the decreasing efficacy of the vaccine as age increases. However, where an individual has had a single dose of Shingrix® and subsequently turned 80 prior to their second dose, they should be provided a second dose to complete the two dose schedule for Shingrix®.

### What are the recommended vaccines for the programme?

Zostavax® is a live attenuated vaccine that contains a high antigen level of varicella zoster virus (derived from Oka/Merck Strain), which is offered to everyone from 70 to 79 years of age (unless contraindicated due to underlying medical condition or immunosuppressive treatment).

Shingrix® is an inactivated recombinant adjuvant subunit shingles vaccine containing varicella zoster virus glycoprotein E antigen produced by recombinant DNA technology, adjuvanted with AS01B, which is available for individuals 70 to 79 years of age who are clinically contraindicated to receive Zostavax®.

### Prescription only medicines

Both Zostavax® and Shingrix® are prescription only medicines and must be administered using a prescription,

Patient Group Direction (PGD) or Patient Specific Direction (PSD). The Health and Social Care Board in collaboration with Public Health Agency have developed PGD templates for Zostavax® and Shingrix® to support the delivery of the shingles vaccine programme.

## 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.

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

While 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. 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.

### How will individuals receive the vaccine?

Both Zostavax® and Shingrix® are available from GP practices. GPs are encouraged to identify and offer the shingles vaccination to eligible patients. For convenience, the Zostavax® vaccine can routinely be administered at the same time as the seasonal

influenza vaccine. Routine administration of Shingrix® and adjuvanted influenza vaccine is not recommended at this time. Both shingles vaccines can be administered outside of the influenza vaccine season.

If required, the 23-valent pneumococcal polysaccharide (PPV23) vaccine can be co-administered with Zostavax® and flu vaccines. PPV23 vaccine can also be co-administered with Shingrix® for those eligible; however, the adverse reactions of fever and shivering were more frequent when PPV23 vaccine is co-administered with Shingrix®.

However, scheduling of the appointment should not delay the administration of any of these vaccines. When co-administering vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.

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

A previous clinical history of chickenpox infection is not a pre-requisite for receiving Zostavax® or Shingrix®.

Although an individual may present without a clinical history of chickenpox, the majority of adults in the UK are immune and many would have had a subclinical infection without being aware. The vaccine should therefore still be offered to individuals without a clinical history of chickenpox to ensure protection against shingles.

Individuals who have been tested for chickenpox and are negative for varicella zoster (VZV) on a quantitative test should not be offered shingles vaccine but should be assessed on an individual basis to decide on the best course of action.

#### 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.

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

Neither Zostavax® nor Shingrix® is recommended for the treatment of shingles or shingles related post herpetic neuralgia (PHN). For individuals presenting with an acute illness, vaccination should be postponed until they have recovered fully. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any sign or symptoms to the adverse effects of the vaccine. Individuals who have shingles should wait until symptoms have ceased before being considered for shingles immunisation. The natural boosting that occurs following an episode of shingles, however, makes the benefit of offering zoster vaccine immediately following recovery unclear. Patients who have two or more episodes of shingles in one year should have immunological investigation prior to vaccination.

## Contraindications

### Zostavax®

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

- 1. Is immunosuppressed due to an underlying condition or treatment as defined in the [Green Book Shingles Chapter 28a](#). If there is any doubt, individual patients should be discussed with their specialist.**
- 2. Has had a confirmed anaphylactic reaction to a previous dose of varicella-containing vaccine or any component of the vaccine, including neomycin or gelatin.**
- 3. Is pregnant. Zostavax® is not indicated in women of childbearing age. Women who are pregnant should not receive Zostavax®.**

## Shingrix®

Shingrix® should not be administered to an individual with a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a dose of Shingrix® or any component of the vaccine.

## Precautions

Immunisation of individuals who are acutely unwell should be postponed until they have recovered fully. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any sign or symptom to the adverse effects of the vaccine.

## Vaccination of eligible individuals in clinical risk groups

The section below provides information about different conditions and treatments that affect the immune system and may make the live shingles vaccine Zostavax® unsuitable. If primary healthcare practitioners administering the vaccine have questions or concerns about the nature of therapies or the degree of immunosuppression, they should contact the individual's relevant specialist team for advice.

### Patients with Rheumatoid Arthritis (RA)

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

### Patients with Inflammatory Bowel Disease (IBD)

Patients with inflammatory bowel disease (IBD) are at an increased risk of developing shingles 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 Zostavax® vaccine.

### Patients prescribed mesalazine

On its own, mesalazine is not considered highly immunosuppressive so does not contraindicate Zostavax® vaccine. The patient should be assessed to identify if they are taking any other prescribed medication that may be immunosuppressive and therefore contraindicate Zostavax® vaccine.

### Patients with dermatological conditions

The risk of shingles infection is increased with advancing age, prolonged treatment with oral corticosteroids, 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 the vaccine. 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 suitability for Zostavax® vaccine.

#### Patients with renal conditions such as glomerulonephritis or reduced renal function

Patients with impaired renal function 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 – see [Green Book Chapter 28a](#) for full details, doses and definitions. Zostavax® is contraindicated for some patients with inflammatory renal disease.

#### 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. Whilst 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 unless it is contraindicated due to their underlying medical condition or treatment. Live and inactivated vaccines are safely administered to many children and adults with an absent or dysfunctional spleen 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 the patient may therefore have an acute leukaemia, which is one of the specific contraindications to use of Zostavax®. 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 the [Green Book Chapter 7](#).

#### Vaccination of individuals receiving palliative care (cancer diagnosis)

Some individuals may be receiving medication following a cancer diagnosis that does not contraindicate receipt of Zostavax®. An example would be Prostag for prostate cancer. This drug is not in itself immunosuppressive but the patient should be assessed for evidence of immunosuppression from disease or other medications before administration of a live vaccine.

#### Patients receiving antiviral agents (oral or intravenous)

Zostavax® should be delayed for eligible patients currently receiving oral or intravenous antivirals (such as aciclovir) until 48 hours after cessation of treatment – see [Green Book Chapter 28a](#) for further details. This also applies to individuals receiving aciclovir prophylaxis which should be ceased for 48 hours before vaccination and individuals who have received high dose IVIG or VZIG in the previous six weeks. This is due to the potential to lower effectiveness of the vaccine as the therapy may reduce response to the vaccine. The use of topical aciclovir is not a contraindication to either Zostavax® or Shingrix® vaccination. Where possible, antiviral therapies should not be started within two weeks after receiving Zostavax® as this may adversely affect the effectiveness of the vaccine.

### Topical or inhaled corticosteroids or corticosteroid replacement therapy

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

### 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 Zostavax® vaccination. Such individuals are not currently eligible for pre-treatment vaccination with Shingrix®. Supply of Shingrix® is currently limited and so vaccine supplied via the national programme should not be used for this indication. 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.

### Who should be offered Shingrix® instead of Zostavax®?

The decision as to which shingles vaccine should be administered to an individual should be based on a full clinical assessment.

Shingrix® should only be offered to those who are aged 70 to 79 and contraindicated to receive Zostavax® due to immunosuppression caused by their underlying condition or treatment.

Full details about which conditions and medications or therapies would require that an individual be offered Shingrix® instead of Zostavax® are available in the [Green Book Chapter 28a](#).

## Administration

### How is Zostavax® administered?

Zostavax® is administered by subcutaneous injection into the upper arm (deltoid region). One dose contains 0.65ml. 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.

Deep subcutaneous injections should be given with the needle at a 45 degree angle to the skin and the skin should be bunched, not stretched. It is not necessary to aspirate the syringe after the needle is introduced into the tissue.

### How is Shingrix® administered?

Shingrix® should be given by intramuscular injection, preferably in the deltoid region of upper arm. Subcutaneous administration is not recommended. Adults should receive two doses of 0.5ml of Shingrix® a minimum of two months apart. Shingrix® is available as a white powder for reconstitution with diluent and is injected as a suspension. After reconstitution, the suspension is an opalescent colourless to pale brownish liquid.

Intramuscular injections should be given with the needle at a 90 degree angle to the skin and the skin should be stretched to aid dispersal of subcutaneous tissue. It is not necessary to aspirate the syringe after the needle is introduced into the tissue.

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

Zostavax® can be administered concomitantly with other vaccines such as inactivated influenza and PPV23 vaccines and live vaccines such as Yellow Fever.



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 Zostavax® when patients are called for the seasonal influenza vaccine. PPV23 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.

Zostavax® 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 severely immunosuppressed, it is important to check that there are no contraindications to co-administration of Zostavax®.

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.

#### Can Shingrix® be given at the same time as other vaccines?

Shingrix® can be given concomitantly with inactivated influenza vaccine. However, routine administration of Shingrix® and the adjuvanted influenza vaccine is not recommended at this time, because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine. Based on current information, scheduling should ideally be separated

by an interval of at least seven days to avoid incorrect attribution of potential adverse events. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered.

As Shingrix® is an inactivated vaccine, where individuals in an eligible cohort present having received another inactivated or live vaccine (other than COVID-19 vaccine), Shingrix® vaccination should still be considered. In most cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.

#### Can shingles vaccine be given at the same time as COVID-19 vaccine?

Immunisation with Zostavax® and Shingrix® should ideally be delayed for seven days after COVID-19 vaccination and vice versa. Neither vaccine has been tested for routine co-administration; there is potential for the side effects of Shingrix® to be confused with those of COVID-19 vaccines, and there may be a reduced response to Zostavax®. However, where individuals attend requiring both vaccines, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered.

#### What if an individual has inadvertently received one dose of Shingrix® when Zostavax® would have been suitable?

The current programme recommendation is to only offer Shingrix® vaccine to individuals for whom Zostavax® is clinically contraindicated. If a dose of Shingrix® vaccine has inadvertently been given to an individual who did not have any contraindications to receiving Zostavax® then Zostavax®, rather than Shingrix®, should be given at the time the second dose of Shingrix® would have been scheduled.

### What if the second dose of Shingrix® is delayed by more than 6 months after the first dose?

The vaccine schedule does not need to be restarted if more than 6 months have elapsed since the first dose of Shingrix®. The second dose should be given as soon as possible to provide protection and complete the schedule.

### What if the second dose of Shingrix® vaccine is given early?

The recommended schedule for Shingrix® vaccine is two doses, with the second dose given two months after the first dose. If the second dose is given earlier than four weeks from the first dose, then the dose should be repeated with an interval of at least eight weeks from the last dose.

### Patients eligible for shingles vaccine (70 to 79 years of age) for whom Zostavax® has been previously contraindicated

Patients between 70 and 79 years of age who were not given shingles vaccination previously because it was contraindicated due to an underlying medical condition or treatment, should be re-assessed for vaccine suitability and offered Shingrix® if Zostavax® is still contraindicated.

### 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.

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

In the phase 3 randomised placebo controlled clinical trials of 15,411 participants, vaccine efficacy in the 6,950 immunocompetent adults  $\geq 70$  years, administered with two doses of Shingrix® two months apart was estimated at 91.2%.

### Vaccination of individuals with a current chickenpox infection

It is very unlikely that someone in the eligible age range has never previously had chickenpox. Individuals presenting aged 70 years or over with a first time chickenpox infection should be assessed to determine whether or not they are immunosuppressed as it is possible that they may have disseminated zoster. If found to be immunosuppressed following clinical review, follow the advice in the [Green Book Chapter 28a](#) for eligibility for Shingrix®.

### Interval after exposure to a person with chickenpox or shingles

Zostavax® and Shingrix® vaccine can still be offered if an individual has been exposed to another person with chickenpox or shingles without any interval providing the patient is well and there are no known contraindications to the vaccine.

Neither Zostavax® nor Shingrix® is recommended for use as post-exposure prophylaxis for chickenpox or shingles. Zostavax® and Shingrix® are not recommended for the treatment of shingles or post herpetic neuralgia (PHN).

### Individuals with a history of shingles

Individuals with a previous history of shingles infection are still eligible for shingles vaccine.

Individuals who have shingles should wait until symptoms have ceased before being considered for shingles immunisation. The natural boosting that

occurs following an episode of shingles, however, makes the benefit of offering zoster vaccine immediately following recovery unclear.

Immunocompetent individuals who present with a recent history of shingles infection should ideally have their vaccination delayed for one year as boosting from natural infection is likely to offer protection at least until this time.

For immunocompetent individuals aged between 79 and 80 years at the time of natural shingles infection, it is acceptable to reduce the interval from recovery to vaccination to less than one year to enable Zostavax® vaccine to be administered as part of the national programme before the 80th birthday.

As there is very little data on waning antibodies following natural infection, particularly beyond six months, there is currently no recommendation for revaccination if shingles vaccine is administered with a less than one year interval from natural infection.

For immunosuppressed individuals being offered Shingrix® vaccine, it can be given as long as the individual has recovered from acute infection and they have no active vesicles. There is no additional wait period for these individuals since they are at higher risk of recurrent episodes of shingles.

Individuals who have had two or more episodes of shingles in one year should have immunological investigation prior to vaccination. Clinicians may wish to discuss such cases with local specialist teams.

### Vaccination of individuals under 70 years of age with a previous history of shingles infection (including recurrent shingles infections)

Individuals within this age group who present with a previous history of shingles should be reassured

that having natural infection will help to boost the individual's immune response to the virus. Therefore, such individuals should wait until they become eligible for the national programme. Patients who have had two or more episodes of shingles in one year should have immunological investigation prior to vaccination. Clinicians may wish to discuss such cases with local specialist teams.

### Vaccination of individuals with post herpetic neuralgia or residual nerve pain

Shingles vaccine is not licensed for the treatment of shingles or shingles related post-herpetic neuralgia (PHN). Individuals who have active PHN should wait until the symptoms resolve. In some cases PHN can be persistent and the patient may experience residual nerve pain that may be permanent. These patients should be assessed and vaccination offered as appropriate.

### Vaccination of individuals who have received a shingles vaccine before age 70

#### *Individuals vaccinated with Zostavax® before 60 years of age*

These individuals should be reassessed for any contraindications and offered another dose of the appropriate shingles vaccine once they reach 70 years of age. It does not matter how long the interval between doses of Zostavax® has been.

One trial that looked at revaccination in individuals vaccinated with Zostavax® more than 10 years previously found no increase in local or systemic reactions.

#### *Individuals vaccinated with Zostavax® between 60 and 70 years of age*

Individuals who received a dose of Zostavax® between 60 and 70 years of age should be assessed on an individual basis for recommendation on further doses of shingles vaccine.

### *Vaccination of individuals who received Shingrix® before 70 years of age*

If a healthy individual has received a single dose of Shingrix® vaccine before 70 years of age, they would be eligible for a dose of Zostavax® (if there are no contraindications to the vaccine) when they turn 70 years of age.

If an individual eligible for Shingrix® has already received a single dose of Shingrix® vaccine before 70 years of age and is still immunosuppressed when they turn 70 years of age then a second dose of Shingrix® vaccine should be given to complete the two-dose course regardless of the interval between doses. The course does not need to be restarted.

If two doses of Shingrix® vaccine have been administered to an individual over 50 years of age, with an interval of at least two months, no further vaccine is required, regardless of the interval or number of years since administration of Shingrix® vaccine. At present, the recommendation for a booster dose after the primary schedule has not been established.

## **Adverse effects**

### **Zostavax®**

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

### **Shingrix®**

The most commonly reported side effects were pain at injection site, myalgia, fever headache, fatigue, and gastrointestinal upset. These were mostly short-lived with a median duration of 2-3 days. Reactions can occur following first, second or both doses of

Shingrix®. Reactions are reportedly lower in the over 70 years of age cohort.

### **Development of a vesicular rash after receiving Zostavax®**

Transmission of the Zostavax® vaccine virus (Oka/Merck strain) has not been reported during clinical trials; however, any person developing a vesicular rash following administration of Zostavax® should be tested with a vesicle fluid sample sent for analysis to confirm the diagnosis and determine whether the rash is vaccine associated or wild type.

Manufacturer experience with varicella (chickenpox) vaccines that use a lower dose of the same virus strain, suggests that transmission of vaccine virus may occur rarely between vaccine recipients who develop a varicella-zoster virus (VZV) like rash and susceptible close contacts.

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 avoid contact with susceptible people until the rash is dry and crusted, due to the higher risk of virus shedding.

*Immunosuppressed individuals who develop a rash following inadvertent vaccination with Zostavax® should be urgently assessed and offered prompt treatment with aciclovir – see the guidance in the section titled Inadvertent administration of Zostavax® to an individual who is immunosuppressed.*

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

### Development of a rash after Shingrix® vaccine

As Shingrix® vaccine is not a live vaccine, it should not cause the development of a vesicular rash. If a vesicular rash does develop after Shingrix® vaccine, the patient should be referred for prompt assessment and management as it is likely that they have developed shingles naturally (not due to the vaccine) and are at risk of disseminated zoster.

### Inadvertent vaccine administration errors

Where there are errors in vaccine administration, health professionals should report these via their local governance system so appropriate action can be taken. This way lessons may be learnt and risk of repeat errors reduced.

### Administration of Zostavax® to an individual who is immunosuppressed

Immunosuppressed individuals who are inadvertently vaccinated with Zostavax® should be urgently assessed to establish the degree of immunosuppression and the need for prophylactic aciclovir. 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 IV aciclovir, given the risks of disseminated zoster.

### Inadvertent administration of Zostavax® during pregnancy

Inadvertently administering Zostavax® during pregnancy is a serious clinical incident and should be reported immediately.

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. See '[Varicella zoster immunoglobulin](#)' guidance.

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).

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 woman's booking bloods or by arranging for 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).

For those women who are found to be VZV IgG negative on testing, please contact the duty room at Public Health Agency on 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.

All incidents of inadvertent administration of Zostavax® during pregnancy should also be reported to UK Health Security Agency 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.

#### [Inadvertent administration of Shingrix® during pregnancy](#)

There are no data on the use of Shingrix® in pregnant women but as a precautionary measure it is preferable to avoid the use of Shingrix® during pregnancy. If Shingrix® vaccine is inadvertently administered to a pregnant woman, the individual should be informed and reassured that there is no known risk associated with giving Shingrix® during pregnancy since as it is an inactivated vaccine, it cannot replicate and therefore cannot cause infection in the mother or foetus. They should be advised to seek medical advice for any concerns.

#### [Inadvertent administration of Zostavax® to a child](#)

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 naive children is unlikely to result in serious adverse reactions and should count as a valid dose of varicella vaccine. 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.

#### [Inadvertent administration of Shingrix® to a child](#)

Shingrix® is licensed from 18 years of age. Parents should be advised of the error and of possible side effects such as pain at the injection site, fatigue, myalgia, headache, fever, and to seek medical advice with any concerns.

If Shingrix® was inadvertently given to a child instead of varicella vaccine, the dose does not count and varicella vaccine should be administered as soon as possible after the error is realised. There is no recommended interval between inadvertent Shingrix® vaccine and varicella vaccine.

#### [Inadvertent administration of 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.

Zostavax® should be administered at the same visit following the inadvertent administration of varicella or, if this is not possible, it should be administered as soon as possible after the error is noted.

#### [Inadvertent administration of varicella vaccine \(Varivax or Varilrix\) to an adult instead of Shingrix®](#)

Immunosuppressed individuals who are inadvertently vaccinated with live varicella vaccine (Varivax or Varilrix) when they should have received inactivated shingles vaccine (Shingrix®) should be urgently assessed to establish the degree of immunosuppression and followed up on an individual basis.

As 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 in whom the attenuated vaccine virus poses a significant risk.

The individual would need protection from administration of the correct shingles vaccine after completion of aciclovir treatment.

#### Inadvertent administration of Zostavax® instead of varicella vaccine (Varivax or Varilrix)

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 for the prevention of primary varicella (chickenpox) infection. Zostavax® should not be used as a vaccination against chickenpox.

Although Zostavax® is similar to the varicella vaccine, it has significantly higher antigen content. Early trials of chickenpox vaccine in susceptible children used vaccine at antigen doses approaching the range used in Zostavax®. The high dose formulation was well tolerated and efficacious.

If Zostavax® has inadvertently been given (where there are no contraindications to the vaccine), it is unlikely to result in serious adverse reactions and should count as a valid dose of varicella vaccine.

#### Inadvertent partial or incomplete dose of Zostavax® or Shingrix® vaccine

If the patient is still in clinic, repeat a full dose immediately. If the dose cannot be given on the same day administer another dose four weeks after the invalid (incomplete or partial) dose. The wait period is because of the potential reactogenicity.

If an incomplete or partial dose 'first' dose of Shingrix® is given and a replacement dose is not administered until four weeks later, ensure a further dose (which will actually be the third dose) is given two months after the replacement dose to ensure the schedule is completed and that the patient will have received two valid doses of vaccine.

#### Inadvertent administration of Shingrix® diluent only

As the diluent contains the AS01B adjuvant suspension which can be highly reactogenic, it is recommended that an interval of four weeks is observed before giving the correctly reconstituted dose.

## Further resources

The Green Book: Chapter 28A Shingles (Herpes Zoster)

PHE Shingles: Guidance and Vaccination Programme

PHE Shingles Vaccination: Guidance for Healthcare Professionals

NHS Conditions - Shingles

The use of Human and Animal Products in Vaccines

Viral Rash in Pregnancy Guidelines

Varicella Zoster Immunoglobulin

Shingles Leaflets, Posters and Graphics



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