



## Vaccination against shingles for adults aged 70 and 79 years of age- Q&A's for healthcare professionals

### Background

In 2010, the Joint Committee on Vaccination and Immunisation (JCVI) <sup>1</sup> were 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. As a result, the JCVI recommended a universal routine herpes zoster (shingles) vaccination programme for adults aged 70 years to commence 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<sup>2</sup>. 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<sup>3</sup>.

### 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<sup>4</sup>. 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<sup>4</sup>.

### 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<sup>3</sup>. 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?**

In England, the vaccine will be offered routinely to adults aged 70 years on or after the 1 September 2013<sup>3</sup>.

In conjunction with the routine vaccination of adults aged 70 years, a catch-up programme will also be available for adults aged 79 years on or after the 1 September 2013 for the 2013/14 year.

Please refer to “The introduction of a shingles vaccine for people aged 70 years (routine cohort) and 79 years (catch up cohort) to protect against herpes zoster” letter for further details.

### **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)<sup>5</sup>.

The vaccine is recommended for the routine vaccination of individuals aged 70 (and 79 years catch-up cohort) for the prevention of shingles and shingles related post herpetic neuralgia (PHN) from 1 September 2013.

The Department of Health have secured sufficient supplies of this vaccine for the routine vaccination of adults aged 70 years of age and adults identified in the catch-up cohort. The vaccine can be ordered via [Immform Website](#).

### **Vaccine eligibility**

#### **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<sup>4</sup>.

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

The vaccine is licensed for use in those aged 50 years and over, but 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.

#### **What if someone aged 71 to 78 years of age requests vaccination in 2013/14?**

Vaccine supply from the manufacturer is at present limited, and between 1 September 2013 and 31 August 2014, there will only be enough vaccine to fully vaccinate two birth cohorts - the routine cohort, and one catch-up cohort (those aged 79 on 1 September 2013).

JCVI recommended that everyone aged 70 to 79 should be offered shingles vaccine; therefore, under the NHS constitution everyone aged 70 to 79 years has a right to receive the vaccine. Given the amount of vaccine available, the most equitable



approach is to vaccinate 79-year-olds first, in addition to the routine cohort, as 79-year-olds will be too old to be eligible for vaccination in 2014/15, when more vaccine becomes available.

Because of the limited supply of vaccine, vaccinating patients earlier than indicated could result in those aged 79 being unable to receive vaccine while eligible. Vaccine stock will however be carefully monitored, and if any age cohort can be vaccinated earlier than set out in the public health information letter on shingles vaccination this will be communicated through the usual channels.

### **How will individuals receive the vaccine?**

Zostavax® will be available from the 1 September 2013 via GP surgeries. General Practitioners (GP's) are encouraged to identify and offer the shingles vaccination to eligible patients. For convenience, the shingles vaccine can be administered at the same time when patients are called for the seasonal influenza vaccine and or 23-valent pneumococcal polysaccharide vaccine (PPV). 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.

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.

### **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, the majority of adults are immune and many 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<sup>5</sup>.

### **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 who have had a history of shingles infection prior to vaccination and boosts immunity to shingles significantly in this age group<sup>5</sup>.



### **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.

### **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%, whilst reducing the severity of the illness. 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 PHN by 66.8% in this age group<sup>5</sup>.

## **Vaccine administration**

### **How is the vaccine 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.

### **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)<sup>3, 6</sup> and live vaccines such as Yellow Fever.

Zostavax® should ideally be given at the same time as other live vaccines. If live vaccines cannot be administered simultaneously, a four week interval is recommended.

General Practitioners (GP's) are encouraged to offer the shingles vaccination when patients are called for the seasonal influenza vaccine and 23-valent pneumococcal polysaccharide vaccines (PPV). 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 4 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 4 weeks apart<sup>6</sup>.

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 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 and the need for prophylactic acyclovir. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination can be offered treatment with acyclovir<sup>3</sup>.

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

**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<sup>3</sup>.



### **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<sup>3</sup>.

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 contains 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 4 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 (Orka/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<sup>5</sup>.

As a precautionary measure, the 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.



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

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

### **What are the contra-indications for receiving Zostavax®?**

The vaccine should not be given to a person who:

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

Therapy with low-doses of methotrexate (<0.4 mg/Kg/week), azathioprine (<3.0 mg/Kg/day), or 6mercaptopurine (<1.5 mg/Kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions are not considered sufficiently immunosuppressive and are not contraindications for administration of zoster vaccine<sup>3</sup>.

The use of topical acyclovir is not a contraindication to vaccination. Further information on contraindications and special considerations for vaccination can be found in Chapter 6 of the Green Book.

### **References**

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