Vaccination against shingles for adults

Questions and Answers

Background

Shingles (herpes zoster) is caused by the varicella zoster virus (VZV), the same virus that causes chickenpox. The virus lies dormant following chickenpox infection, and may reactivate, sometimes decades after the primary infection. The risk, and severity of shingles and post herpetic neuralgia increases with age.

In 2010, the Joint Committee on Vaccination and Immunisation (JCVI) reviewed all the available evidence relevant to offering a universal vaccination programme for shingles¹.

The JCVI reviewed evidence on disease epidemiology, vaccine efficacy and safety and the cost effectiveness of introducing a routine shingles vaccination programme in the UK. The incidence of shingles increases with age, with the severity and disease burden also increasing as the individual gets older. A universal routine herpes zoster (shingles) vaccination programme for those age 70-79 years was recommended. The programme will commence in September 2013.

The aim of the vaccination programme is to reduce the incidence and severity of shingles 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 (VZV) lies dormant in the nerve cells and can reactivate at a later stage when the immune system is weakened². Reactivation of the virus is thought to be associated with immunosuppression as a result of a decline in cell mediated immunity in old age, immunosuppressive therapy or HIV infection³.

Who does shingles 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. The burden of disease amongst adults aged 70 and above is considerably greater than younger adults⁴. It is estimated that around 250,000 people are affected in England and Wales each year, including 30,000 people in their 70s. Individuals over 70 years of age are

more likely to 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 hospitalisation⁴. Around one in 1,000 people over 70 who get shingles dies of the infection.

The shingles vaccination programme

What is the purpose of the programme?

The aim of the shingles vaccination programme is to reduce both the incidence and severity of shingles disease in older adults³. Offering the shingles vaccine to individuals from the age of 70 years aims to boost immunity to prevent the development of shingles in later life, whilst significantly reducing the incidence of post herpetic neuralgia.

Who will be offered the shingles vaccine?

From 1 September 2013, the vaccine will be offered routinely to adults aged 70 years but not yet 71 years on 1 September 2013 (those born between 2 September 1942 and 1 September 1943). In addition adults aged 79 years on 1 September 2013 will be offered the vaccine as part of a catch-up programme (those born between 2 September 1933 and 1 September 1934).

What is the recommended vaccine for the shingles programme?

Zostavax[®] is the recommended vaccine for the programme and is the only authorised shingles vaccine in the UK. It is a live attenuated vaccine that contains a high antigen level of varicella zoster virus (Oka/Merck Strain, not less than 19400 plaque forming units per dose)⁵.

The Welsh Government has secured sufficient supplies of this vaccine for the routine vaccination of adults in the target group. The vaccine can be ordered in the same way as childhood vaccines are currently ordered.

Vaccine eligibility

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

Whilst the vaccine is licensed for use from the age of 50 years, and is effective in this age group, the burden of shingles disease is generally not as severe when compared with older people. The duration of protection

and need for reinforcing doses of vaccine are not known. Limited supplies of vaccine have been available. The most cost effective age to offer the vaccine programme is to individuals aged 70 to 79 years⁴.

Can the vaccine be offered to individuals over the age of 79 years?

In adults aged 80 years and above the efficacy of the vaccine is reduced. Offering the vaccine programme in this age group is not considered to be cost effective.

How will individuals receive the vaccine?

Zostavax[®] will be available from the 1 September 2013 through GP surgeries.

General Practitioners (GPs) are encouraged to identify and offer the shingles vaccination to eligible patients. The shingles vaccine can be given at the same time as the seasonal influenza vaccine or pneumococcal polysaccharide vaccine (PPV). However, scheduling of the appointment should not delay the administration of either vaccine. The shingles vaccine can be administered outside of the influenza vaccine season where the two vaccines have not been given together.

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

Yes, a previous clinical history of chickenpox infection is not a requirement for receiving Zostavax[®].

Although an individual may present without a clinical history of chickenpox, almost all adults have serological evidence of previous infection 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 shingles⁵.

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

Yes, individuals should still be offered the vaccine if presenting with a previous history of shingles infection. $Zostavax^{(R)}$ is highly immunogenic in individuals who have had a history of shingles infection prior to vaccination and boosts immunity to shingles significantly in the target age group⁵.

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 $^{\mbox{\tiny \$}}$ 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 reduced the incidence of shingles infection by 38%, whilst also reducing the severity of illness. In those who later developed shingles following vaccination, the vaccine significantly reduced the burden of disease by 55% and significantly reduced the incidence of PHN by 66.8%⁵.

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, or within 30 minutes.

Healthcare professionals should 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[®] is safe to be administered at the same time as other vaccines such as the flu vaccine, the 23-valent pneumococcal polysaccharide vaccine (PPV) ^{3, 6} and live vaccines such as yellow fever vaccine.

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 (GPs) are encouraged to offer the shingles vaccination when patients are called for the seasonal influenza vaccine and PPV. However, scheduling of the appointment should not delay the

administration of either vaccine. Shingles vaccine can be administered at any time of year.

If given at the same time as other vaccinations, care should be taken to ensure that the appropriate route of injection is used for each vaccination. Zostavax[®] should be given by subcutaneous injection.

As a live vaccine, Zostavax[®] is contraindicated in immunosuppressed individuals. Given that 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 the 23-valent pneumococcal polysaccharide vaccine (PPV); why does your advice differ?

Zostavax[®] can be given at the same time as PPV. Although a manufacturer conducted trial showed inferior varicella zoster virus (VZV) antibody responses in those receiving zoster vaccine and PPV together compared with 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 apart⁶.

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?

Familiarity with the Zostavax[®] packaging will reduce administration errors: <u>Zostavax[®] Packaging</u>

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 acyclovir³.

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.

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 vaccine status. Eligible individuals who have not previously 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 a one month interval would be preferable if a delay is possible³.

What should you do if you inadvertently administer Zostavax[®] to a child?

Familiarity with the Zostavax[®] packaging will reduce administration errors: <u>Zostavax[®] packaging</u>

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[®]?

Familiarity with the Zostavax[®] packaging will reduce administration errors: <u>Zostavax[®] packaging</u>

Varicella vaccines contains a significantly lower antigen content than Zostavax[®] and is 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 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 Book³.

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, theoretically suggest that rarely transmission of vaccine virus may occur from an individual who has received the shingles vaccine who develops a varicella-zoster virus (VZV)-like rash to susceptible close contacts (for example, an infant without a history of chickenpox)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.

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 (bruising), induration (a hard lump) and warmth at the injection site, also headache and pain in vaccinated limb may also occur. Other side effects are rare.

What are the contraindications for Zostavax[®]?

The vaccine should not be given to a person who:

- has primary or acquired immunodeficiency state due to conditions such as: acute and chronic leukaemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS (see below); cellular immune deficiencies,
- is receiving immunosuppressive therapy (including high-dose corticosteroids); however, Zostavax[®] is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or in those who are receiving corticosteroids as replacement therapy, e.g., for adrenal insufficiency,
- 3. has an active untreated TB infection,
- 4. has had a confirmed anaphylactic reaction to a previous dose of varicella vaccine,
- 5. 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 to be contraindications for administration of zoster vaccine³.

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 Book³.

References

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