The introduction of a vaccine to protect against shingles
An update for registered healthcare practitioners

October 2014
Acknowledgments

This resource was based on work prepared by Public Health England to support vaccination against shingles (herpes zoster).

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

Title slide image source: Centers for Disease Control and Prevention (CDC).
Key Messages

• Shingles can lead to a severe painful illness in older people which can persist for several months or even years
• The severity of the illness increases with age and older people aged 70 years and over are at an increased risk
• An estimated 7000 cases of shingles occur in people aged 70 years and over each year in Scotland with approximately five cases resulting in death
• To reduce the incidence of shingles and shingles related complications in Scotland, the shingles vaccination programme was introduced to adults aged 70 years from 1 September 2013
Key Messages (cont.)

- In conjunction with the routine vaccination of adults aged 70 years, a catch-up programme was commenced.
- It is important that registered healthcare practitioners encourage vaccination in this age group.
Aims of Resource

- To support registered healthcare practitioners involved in discussing vaccination against shingles with individuals
- To raise awareness of shingles aetiology, current epidemiology and the impact of shingles on older people
- To provide guidance on the administration of this vaccine, including how to administer the vaccine, contraindications, precautions and potential adverse reactions
- To promote uptake of the shingles vaccine through increasing awareness amongst registered healthcare practitioners
Learning Outcomes

On completion of this programme, registered healthcare practitioners will be able to:

- **Describe** the aetiology and epidemiology of shingles
- **Describe** the relationship between shingles and chickenpox (varicella zoster) and the severity of the disease in older people
- **Discuss** the important role of vaccination against shingles in older people
- **Explain** their role in raising the issue of vaccination against shingles with older people with evidence based information about the vaccine
- **Know** the contraindications for vaccination against shingles
Learning Outcomes (cont.)

- **Safely** administer the vaccine
- **Recognise** the potential adverse reactions and how to report these
- **Identify** sources of additional information
Contents

1. Shingles vaccination programme
2. What is shingles?
3. Why vaccinate older adults against shingles?
4. Vaccination against shingles and the use of Zostavax®
5. Resources
Who is eligible in year two 2014/15 (from September 2014)

Routine Programme
• Those who are 70 years of age on 1 September 2014 (those born between 02/09/1943 and 01/09/1944)

Catch-up programme
• Those who are 78 years of age on 1 September 2014 (those born between 02/09/1935 and 01/09/1936)
• Those who are 79 years of age on 1 September 2014 (those born between 02/09/1934 and 01/09/1935)
• Those individuals who were 70 years of age on 1 September 2013 (those born between 02/09/1942 and 01/09/1943) who were not vaccinated in year one of programme.
What is shingles?

• Shingles is a viral infection of the nerve cells and surrounding skin. It is caused by the (herpes) varicella zoster virus that also causes chickenpox.

• After a person recovers from chickenpox infection, the virus remains dormant in the nerve cells and can reactivate at a later stage when the immune system is weakened.

• Reactivation can be associated with older age, immunosuppressant therapy or HIV infection.
What is shingles? (cont.)

- An estimated 7000 cases of shingles occur in people aged 70 years and above each year in Scotland
- Of these, between 700-1400 develop a very painful and long lasting condition called post-herpetic neuralgia (PHN)
- Around 600 hospitalisation episodes are recorded per year
- 1 in 1000 cases of shingles are estimated to result in death

Source: CDC / Dr. Erskine Palmer
Clinical presentation of shingles

Initial prodromal stage

The first signs of shingles may include:

- Headache
- Feeling generally unwell
- Myalgia
- Malaise
- High temperature (38°C) (although this is less common)

A prodromal illness is experienced by 80% of individuals with shingles and can last up to 72 hours before the rash appears.
Clinical presentation of shingles (cont.)

Acute stage

- A rash of fluid filled blisters develops after a few days and commonly occurs either on one side of the face or body, usually within the distribution of a dermatome.
- The rash often causes pain, itching or tingling sensation in the area of the affected nerve.
- The rash forms blisters that typically scab over in 7-10 days and this eventually clears within 2-4 weeks.
- In individuals with weakened immune systems, a more disseminated rash covering multiple dermatomes may occur and this may appear similar to the chickenpox rash.
Transmission of shingles

- Shingles can **not** be transmitted from one person to another.
- A person exposed to shingles will not develop shingles.
- However, a person who has not had chickenpox previously may develop chickenpox as a result of exposure to the shingles virus through direct contact with the fluid filled blisters.
- The varicella virus that causes shingles (herpes zoster) is the same virus that causes chickenpox (varicella zoster).

*Shingles is not spread through coughing, sneezing or casual contact.*
Infectious period

- A person with shingles is only infectious when the rash is present and fluid filled.
- A person is not infectious
  - Before the rash is present OR
  - When the rash has crusted.
- Shingles is less infectious than chickenpox and covering the rash will greatly reduce the risk of exposure to those non immune to chickenpox.

Source: CDC
Possible complications of shingles

Complications are more likely in adults aged over 50 years, with the severity of the illness increasing with age.

The most common complications are:

- Post-herpetic neuralgia (PHN)
- Secondary bacterial skin infections

Other less common complications include:

- Ophthalmic Zoster
- Peripheral motor neuropathy
- In severe cases shingles can lead to hospitalisation and death
Possible complications of shingles (cont.)

Post herpetic neuralgia (PHN)

- Is a common complication of shingles in older adults
- Defined as a pain that persists for, or appears more than 90 days after the onset of the shingles rash
- Specifically focused in the area affected by shingles
- More likely to develop and is more severe in people over the age of 50, with one third of sufferers over the age of 80 experiencing intense pain
- In 50% of those affected it can persist for 3 to 6 months
- The pain may be a constant burning, itching, stabbing or aching pain which is extremely sensitive to touch and is not routinely relieved by common pain killers
Why vaccinate older adults against shingles?
Why vaccinate older adults against shingles?

Epidemiology of shingles in Scotland in 2010-11

Consultation rate (per 1000 patients)

Age group (years)

Data source: ISD
**Epidemiology of shingles in Scotland**

**Rate of hospitalisation in 2011 by age group**

Data source: ISD
Why vaccinate older adults against shingles?

- The epidemiology of the disease shows that individuals over 70 years of age are not only at an increased risk of developing the disease, but they also suffer a more severe form of the illness resulting in complications such as PHN and an increase in hospital admissions.

- Analytical studies show that the most cost-effective age for offering vaccination to prevent and/or reduce the disease burden is for those aged 70 to 79 years.
The use of Zostavax®
The recommended vaccine: Zostavax®

- Zostavax® is the **only** vaccine recommended for the prevention of shingles and shingles related PHN
- It is **important** to familiarise yourself with the vaccine and its product information to avoid administration errors

Image courtesy of Sanofi Pasteur MSD
The recommended vaccine: Zostavax®

- **Brand name:** Zostavax®
- **Generic Name:** Shingles (herpes zoster) vaccine live
- **Marketed by Sanofi Pasteur MSD**
- **Live Attenuated** (i.e. a weakened live organism)
- Licensed for use from age of 50 years and above
- **Recommended** by JCVI for adults aged 70 (with a catch up programme up to 79 years)
- **Administered by subcutaneous injection. It should not** be given by intramuscular injection
- **Administered by subcutaneous injection. It should not** be given by intramuscular injection
- Powder and solvent for suspension for injection in a prefilled syringe
- **Container dimensions** 47 x 23 x 150mm
### Composition of Zostavax®

#### Composition
- Varicella-zoster virus, Oka/Merck strain (live, attenuated) not less than 19400 PFU
- produced in human diploid (MRC-5) cells
- PFU = Plaque-forming units

#### Residual substances
- This vaccine may contain traces of neomycin

#### Excipients

**Powder:**
- Sucrose
- Hydrolysed gelatin
- Sodium chloride
- Potassium dihydrogen phosphate
- Potassium chloride

**Solvent:**
- Water for injection
- Monosodium L-glutamate
- Anhydrous disodium phosphate
- Sodium hydroxide (to adjust pH)
- Urea
Storage of Zostavax®

Zostavax® must be stored in accordance with manufacturer’s instructions

- Cold chain must be maintained
  - Store between +2°C and +8°C
  - Store in the original packaging
  - Protect from light

Image courtesy of Sanofi Pasteur MSD
Presentation of Zostavax®

- The vial is a freeze dried preparation that appears as an off-white, crystalline plug
- The diluent in the pre-filled syringe is a clear colourless liquid
- When mixed together, Zostavax® should appear as a semi-hazy to translucent, off white to pale yellow liquid

Zostavax® contains:
- x1 Zostavax® vial
- x1 pre-filled syringe
- x2 separate needles in secondary packaging
Zostavax® reconstitution instructions

• Separate needles should be used for the reconstitution and administration of the vaccine

• To reconstitute the vaccine, inject all the solvent in the pre-filled syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly

• Withdraw the entire contents into a syringe for injection

• Two separate needles are available with the pre-filled syringe

• Select the needle required for injection

• The needle should be pushed into the extremity of the syringe and rotated a quarter of a turn (90°) to secure the connection
• It is recommended that the vaccine be administered immediately after reconstitution
• Discard reconstituted vaccine if it is not used within 30 minutes
• Do not use the reconstituted vaccine if you notice any particulate matter or if the appearance of the solvent or of the reconstituted vaccine differs from that described above

(Zostavax® reconstitution instructions courtesy of Sanofi Pasteur®)
Zostavax® dosage and schedule

- Adults should receive a single dose of 0.65ml
The recommended vaccine: Zostavax®

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 by 38% and provided protection for a minimum of seven years
- For those vaccinated but who later developed shingles, the vaccine:
  - **Significantly** reduced the burden of illness by 55%
  - **Significantly** reduced the incidence of PHN by 66.8%
Administration of Zostavax®

- Given by subcutaneous injection into the upper arm (deltoid region) - 0.65ml (1 dose)
- Further information on vaccinations given by subcutaneous injection can be found in chapter 4 of the Green Book
Licensing of Zostavax®

The Green Book states:

“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 in those ages 50-69 years when compared with older ages. Furthermore, given that the duration of protection is not known, offering vaccination routinely below 70 years of age may not confer protection during the period where the burden of disease is highest. Administration after 80 years is less cost-effective due to the limited effectiveness of the vaccine beyond this age.”
Licensing of Zostavax® (cont.)

- The vaccine marketing authorisation holder’s Summary of Product Characteristics (SPC) for Zostavax® states that the vaccine is licensed for immunisation of individuals 50 years of age or older.
- Whilst the SPC indication allows for use from 50 years of age, JCVI recommendation is that it should be used from 70 to 79 years.
- The recommendations for use of the vaccine detailed within the Green Book are based upon JCVI’s expert opinion after reviewing all the available evidence and these recommendations should be followed.
Administration of Zostavax® with other vaccines

- Zostavax® can be given at the same time as inactivated influenza vaccination. If given at the same time as influenza vaccination, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.
- 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.
- Zostavax® can be administered at the same time as 23-valent pneumococcal polysaccharide vaccine (PPV).
Administration of Zostavax®

Zostavax® should only be administered:

- Against a prescription written manually or electronically by a registered medical practitioner or other authorised prescriber
- Against a Patient Specific Direction
- Against a Patient Group Direction
Administration of Zostavax® and pork gelatin

- Zostavax® contains pork (porcine) gelatin which is an essential ingredient in many medicines, including some vaccines.
- Many faith groups have approved the use of gelatin-containing vaccines. It is, however, an individual choice whether or not to receive this vaccine and we recognise there will be diversity of thought within different communities.
- There is no alternative shingles vaccine available that does not contain porcine gelatin.
Administration of Zostavax® Contraindications and Precautions

Contraindications

The vaccine should not be given to an individual who:

- Has primary or acquired immunodeficiency state due to conditions such as:
  - acute and chronic leukaemias
  - lymphoma
  - immunosuppression due to HIV/AIDS
  - cellular immune deficiencies
Contraindications and Precautions

Contraindications (cont.)

The vaccine should not be given to an individual who:

- is receiving immunosuppressive therapy. This includes high-dose corticosteroids, biological therapies or combination therapies.
Administration of Zostavax® Contraindications and Precautions

Contraindications (cont.)

The vaccine should not be given to an individual who:

- has had a confirmed anaphylactic reaction to a previous dose of varicella vaccine
- has had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or gelatin
- is being treated with either oral or intravenous aciclovir or is within 48 hours of cessation of treatment due to the potential to lower effectiveness of the vaccine
- is pregnant
Administration of Zostavax® Contraindications and Precautions

Precautions

- Acute illness - defer immunisation until recovered
- Immunosuppressed patients who require protection against shingles should seek advice from a specialist
- Transmission of vaccine virus may rarely occur between those vaccinated who develop a varicella like rash and susceptible contacts.
- Zostavax® is not recommended for the treatment of shingles or post-herpetic neuralgia (PHN)
Administration of Zostavax® Possible adverse reactions

**Most commonly** reported (1:10 of people vaccinated)
- Erythema (redness), pain, swelling and pruritus (itching) at the injection site

**Less commonly** reported (1:100 of people vaccinated)
- Haematoma, induration and warmth at the injection site, pain in arm or leg and headache

**Very rarely reported** (1:10,000 of people vaccinated)
- Varicella (chickenpox) infection
Administration of Zostavax®

Reporting suspected adverse reactions

- Yellow card scheme
- Voluntary reporting system for suspected adverse reaction to medicines/vaccines
- Success depends on early, complete and accurate reporting
- Report even if uncertain about whether vaccine caused condition
- See http://mhra.gov.uk/yellowcard
- See chapter 8 of Green Book for details
Key Messages

• Shingles can lead to a severe painful illness in older people which can persist for several months or even years.

• The severity of the illness increases with age and older people aged 70 years and over are at an increased risk.

• An estimated 7000 cases of shingles occur in people aged 70 years and over each year in Scotland with approximately five cases resulting in death.

• To reduce the incidence of shingles and shingles related complications in Scotland, was introduced to adults aged 70 years from September 2013.
Key Messages (cont.)

• In conjunction with the routine vaccination of adults aged 70 years, a catch-up programme was commenced.
• It is important that registered healthcare practitioners encourage vaccination in this age group.
Resources

NHS Choices
• http://www.nhs.uk/conditions/shingles/pages/Introduction.aspx

CMO Letter

Green Book

NHS Education for Scotland and Health Protection Scotland training resources

Shingles Support Society
• http://www.shinglessupport.org