



Public Health
England

Protecting and improving the nation's health

Vaccination against Shingles

Information for healthcare professionals

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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Executive summary

This guidance document was first published in 2013 to support healthcare practitioners involved in the implementation of the shingles (herpes zoster) vaccination programme for older adults in England.

In response to a large number of clinical enquiries regarding the use of the live attenuated shingles vaccine in certain clinical risk groups, in 2016, the Immunisation department at Public Health England convened an expert working group (appendix 1) to review the available evidence and liaise with international colleagues to provide specific guidance for people with an underlying immunocompromising condition or who are taking immunosuppressant medication. This document has subsequently been revised to include updated information on the current eligibility for the national shingles vaccination programme.

Background

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

The JCVI considered a range of issues including disease epidemiology, vaccine efficacy and safety and cost effectiveness of introducing a routine shingles vaccination programme in the UK. Based on the findings of the cost-effectiveness analysis, the JCVI recommended a universal routine herpes zoster (shingles) vaccination programme using a single dose of Zostavax for adults aged 70 years with a catch up programme for those aged 71-79 years.

The shingles vaccination programme

The purpose of the shingles vaccination programme is to reduce the incidence and severity of shingles disease in adults aged 70 years and above, in whom the risk and severity of disease and of subsequent post herpetic neuralgia (PHN) is higher.

Offering a single dose of the shingles vaccine (Zostavax) routinely to individuals at the age of 70 years aims to boost immunity in individuals with pre-existing varicella zoster virus (VZV) immunity to prevent the development of shingles in later years and significantly reduce the incidence of PHN.

Prior to April 2017, shingles vaccine was offered routinely to individuals aged 70 years with a phased catch up programme based on age as of 1 September that year.

From 1 April 2017, it was agreed that patients could be opportunistically immunised at any time of the year once they reached the eligible age (70 or 78 years), but in order to ensure appropriate vaccine supply, the majority of patients continued to be immunised during the autumn months.

As sufficient vaccine is now available and in order to improve vaccine uptake, from 1st April 2018, practices are encouraged to opportunistically immunise patients who

¹ Joint Committee on Vaccination and Immunisation Statement on varicella and herpes zoster vaccines 29 March 2010. Available at:
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_133599.pdf

become 70 or 78 years of age **at any point in the year following their 70th or 78th birthday.**

Patients previously eligible who have not yet received the shingles vaccine, remain eligible up until their 80th birthday and can be offered immunisation on an opportunistic basis.

Shingles vaccine should be offered to:

- patients aged 70 years, on or after their 70th birthday
- patients aged 78 years, on or after their 78th birthday
- patients who were eligible for immunisation in the previous programme years but have not yet been vaccinated against shingles.

These are:

- anyone in their 70s who was born on or after 2/9/1942
- 79 year olds (until their 80th birthday).

Care must be taken to ensure that the patients who have already turned 70 or 78 years of age since 2 September 2017 are offered the vaccine.

Patients remain eligible until their 80th birthday. The programme does not offer patients the vaccine after they become 80 due to the reducing efficacy of the vaccine as age increases.

GPs are able to apply their clinical discretion and provide the vaccine, following a clinical assessment, to those who are not currently eligible for the national programme but who would benefit medically, for example those with underlying conditions which increase their risk of shingles. Please note that vaccine supplied free of charge to practices via Immform cannot be used for this purpose.

Programme delivery

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

Although, 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), **the shingles vaccine can be administered at any time of year and does not need to be administered during the influenza vaccine season.**

As some individuals eligible for seasonal influenza vaccination may be immunosuppressed, it is important to check that there are no contraindications to administering the live shingles vaccine to these individuals.

Shingles infection

Shingles (herpes zoster) is a viral infection of an individual nerve and the skin surface that is served by the nerve. Shingles infection develops as a result of a reactivation of latent varicella zoster virus, the same virus that causes chickenpox.

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 weakened². Reactivation of the virus is thought to be associated with immunosuppression as a result of a decline in cell mediated immunity.

Increasing age, immunosuppressant therapy or HIV infection are all thought to increase the risk of developing shingles³.

Shingles can develop at any time following a chickenpox infection and can occur in individuals of any age. However, the risk and severity of shingles increases with age. Consequently the burden of disease amongst adults aged 70 and above is considerably greater than for younger adults³. Older adults tend to experience a severe form of the disease which can result in secondary complications including persistent pain or postherpetic neuralgia (PHN) and secondary bacterial skin infections that may require hospitalisation.

Shingles vaccine

Zostavax is a live attenuated vaccine that contains a high antigen content of varicella zoster virus (Oka/Merck Strain, not less than 19400PFU)⁴ and is the recommended vaccine for the national shingles programme. It is currently the only market-authorized shingles vaccine in the UK, and can be ordered via the [ImmForm website](#).

² NHS Choices. Shingles. Available at: <http://www.nhs.uk/Conditions/Shingles/Pages/Introduction.aspx>

³ van Hoek AJ, Gay N et al. (2009) Estimating the costeffectiveness of vaccination against herpes zoster in England and Wales. *Vaccine* 2009 Feb 25;27(9): 1454-67.

⁴ Merck Sharp and Dohme Limited. Zostavax SPC. Available at: <http://www.medicines.org.uk/emc/medicine/25927>

Shingrix is a recombinant (non-live) shingles vaccine and is not currently licenced in the UK. The Joint Committee on Vaccination and Immunisation (JCVI), an independent committee that advises the Government on all aspects relating to immunisation, currently has this vaccine under consideration for potential future use in the national programme.

Healthcare professionals should subscribe to [Vaccine Update](#) and also refer to the [ImmForm website](#) on a regular basis for up to date information on the programme and vaccine availability.

Vaccine excipients

Zostavax does not contain latex or thiomersal but it does contain hydrolysed gelatine derived from pork as one of its additives.

Zostavax is the only vaccine recommended by the Department of Health for the prevention of shingles and shingles-related PHN. At this time, there is no alternative shingles vaccine available. Public Health England's statement⁵ on vaccines and gelatine can be found [here](#).

Vaccine efficacy

A one dose schedule of Zostavax was assessed in clinical trials using 17,775 adults aged 70 years and over. The study demonstrated that the vaccine reduced the incidence of shingles by 38% and boosted immunity for at least 5 years. For those immunised with Zostavax but who later developed shingles, the vaccine significantly reduced the burden of illness by 55% and significantly reduced the incidence of PHN by 66.8%.

A recent evaluation of the impact of the first three years of the shingles vaccination programme⁶ described reductions in GP consultations consistent with a short term vaccine effectiveness of about 62% against herpes zoster and 70 to 88% against PHN in the year of vaccination. This equates to 17,000 fewer zoster consultations among the 5.5 million individuals eligible for vaccination in the first three years of the programme.

⁵ Public Health England. Vaccines and Gelatin: PHE's response. Last updated 2014. Available at: <https://www.gov.uk/government/news/vaccines-and-gelatine-phe-response>

⁶ Amirthalingam G, Andrews N et al. Evaluation of the effect of the herpes zoster vaccination programme 3 years after its introduction in England: a population-based study. *Lancet Public Health* 2018; 3: e82–90 [http://www.thelancet.com/pdfs/journals/lanpub/PIIS2468-2667\(17\)30234-7.pdf](http://www.thelancet.com/pdfs/journals/lanpub/PIIS2468-2667(17)30234-7.pdf)

Vaccine supply

Vaccines for the national shingles vaccination programme should be ordered from **ImmForm**. As the programme is a year round programme and not a seasonal programme, vaccines should be ordered regularly throughout the year and can be requested when placing orders for other routine vaccines such as those vaccines used in the childhood programme.

Vaccines required for individuals that are not in the eligible cohort, for example where the practice has decided that it is clinically appropriate to vaccinate the patient but they are under the age of 70 years, would require the GP practice to purchase the vaccine directly from the manufacturer.

Vaccine storage

Zostavax should be stored between 2°C and 8°C in a vaccine / medicines fridge. The vaccine should be stored in the original packaging to protect it from light. After reconstitution, the vaccine should be used immediately.

Vaccine eligibility for the national programme

It is recommended that the shingles vaccine is routinely offered to people aged 70 years of age. A catch up programme is offered for those aged 78 years of age. All those eligible to receive the vaccine remain eligible until they become aged 80 years. This means that patients who were eligible for immunisation in the previous programme years but have not yet been vaccinated against shingles (anyone in their 70s who was born on or after 2/9/1942, and 79 year olds until their 80th birthday) should be offered the vaccine.

Patients remain eligible until their 80th birthday. The programme does not offer patients the vaccine after they become 80 due to the reducing efficacy of the vaccine as age increases.

Individuals outside of the national programme

Those who are not eligible to receive the vaccine as part of the national programme but who wish to pay for the vaccine privately should discuss their request with a private provider.

GPs are not able to charge their own patients registered at their practice a private fee for the vaccine and should not use centrally procured stock for the national programme to vaccinate private patients.

Patients seeking the vaccine privately should be made aware that they will be liable for the full cost of the vaccine and any additional administration charges that the private provider may apply.

Contraindications and special considerations for receiving Zostavax

Immunisers should refer to the [shingles PGD](#)⁷ when discussing vaccination with their patients and checking their medical history. This will allow easier identification of patients for whom the vaccine may be contraindicated.

As Zostavax is a live attenuated vaccine, it should not be given to any patient in the following groups:

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

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

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

2. Patients taking immunosuppressive or immunomodulating therapy including:

- those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders
- those who are receiving or have received in the past 6 months immunosuppressive therapy for a solid organ transplant (depending upon the type of transplant and the immune status of the patient).

⁷ Public Health England. Shingles vaccine (Zostavax®) patient group direction (PGD) template. Available at: <https://www.gov.uk/government/publications/shingles-vaccine-zostavax-patient-group-direction-pgd-template>

- those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist
- those who are receiving or have received in the past 3 months immunosuppressive therapy including:
 - i) short term high-dose corticosteroids (>40mg prednisolone per day for more than 1 week);
 - ii) long term lower dose corticosteroids (>20mg prednisolone per day for more than 14 days)
 - iii) non-biological oral immune modulating drugs e.g. methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day

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

Long term stable low dose corticosteroid therapy (defined as ≤ 20 mg prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate ≤ 25 mg per week, azathioprine ≤ 3.0 mg/kg/day or 6-mercaptopurine ≤ 1.5 mg/kg/day) are not considered sufficiently immunosuppressive and these patients can receive the vaccine.

Specialist advice should be sought for other treatment regimes to determine if the patient is considered to be immunosuppressed. The prescribing consultant may be able to convert other treatment regimes to the prednisolone equivalent dose.

3. Patients with a previous confirmed anaphylactic reaction to a previous dose of varicella containing vaccine or any component of the vaccine, including neomycin or gelatin.

4. Patients that are pregnant

Zostavax is not indicated for women of childbearing age and pregnant women should not receive Zostavax.

Imminent general anaesthesia and recent or imminent elective surgery are NOT contraindications to routine immunisation.

Special considerations for vaccination of eligible individuals in clinical risk groups

To support the assessment of **patients eligible for the national programme in clinical risk groups**, the following information may be used as a guide in determining patients suitability for the vaccine.

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

Immunosuppressed individuals who are inadvertently vaccinated with Zostavax should be urgently assessed to establish the degree of immunosuppression. As all individuals of this age group should be VZV antibody positive, varicella-zoster immunoglobulin is unlikely to be of benefit but prophylactic aciclovir may be considered in those for whom the attenuated vaccine virus poses a significant risk.

Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with aciclovir, given the risks and severity of disseminated zoster (see page 20 for further information on action to take in the event of development of a vesicular rash following Zostavax administration).

Malignancy

Eligible individuals who have undergone immunosuppressive chemotherapy or radiotherapy for malignant and non-malignant disorders (other than lymphoproliferative disorders, see section on haematological disorders below) should not receive Zostavax until 6 months after the end of treatment AND they are demonstrated to be in remission.

Primary healthcare professionals managing such patients may wish to discuss the patient's eligibility to receive the vaccine with the secondary care specialist or immunologist prior to administration.

Haematological disorders including haemopoietic stem cell transplants

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

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

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

For patients with autoimmune haematological disorders receiving immunosuppressive therapy, please see contraindications on page 12-13.

Solid Organ Transplants

Those who have received a solid organ transplant and are currently on immunosuppressive therapy should not receive Zostavax. The decision to vaccinate eligible patients should depend upon the type of transplant and the immune status of the patient. Primary healthcare professionals may wish to discuss the patient's eligibility with a secondary care specialist or immunologist prior to administration.

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

Chronic inflammatory disorders on immunosuppressive or immunomodulating therapies e.g. rheumatoid arthritis, inflammatory bowel disease, psoriasis, glomerulonephritis

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

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

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

Patients with Rheumatoid Arthritis (RA)

Patients with rheumatoid arthritis (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 Zostavax as they have significant ability to benefit. Where possible, eligible patients with RA should be offered the vaccine prior to commencing treatment with non-biological or biological therapies, i.e. 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

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 the 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 it.

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

However, patients already established on biological therapy, such as Etanercept and Infliximab, should not receive Zostavax.

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

Patients with renal conditions such as glomerulonephritis or reduced renal function

Patients with impaired renal function and/or receiving immunosuppression for inflammatory renal diseases will have an increased risk of shingles as well as reduced vaccine responses and may have reduced clearance of oral immunosuppressants and their active metabolites including azathioprine, methotrexate and 6-mercaptopurine. Patients requiring low dose oral immunosuppression for inflammatory renal disease with preserved kidney function who are in remission could be considered for Zostavax if they are receiving long term stable low dose corticosteroid therapy (defined as ≤ 20 mg prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate ≤ 25 mg per week, azathioprine ≤ 3.0 mg/kg/day or 6-mercaptopurine ≤ 1.5 mg/kg/day).

Primary care physicians may wish to discuss the suitability of Zostavax with the secondary care physician responsible for managing the immunosuppression for those patients with impaired, particularly severely impaired, renal function who are also receiving long term stable low dose non-biological oral immune modulating drugs (e.g. methotrexate ≤ 25 mg per week, azathioprine ≤ 3.0 mg/kg/day or 6-mercaptopurine

≤ 1.5 mg/kg/day) alone or in combination with low dose corticosteroid therapy (defined as ≤ 20 mg prednisolone per day for more than 14 days).

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

- those whose inflammatory disease is not in remission
- those on current or recent immunosuppressive chemotherapy in the last 6 months
- those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy)
- those who are receiving or have received in the past 3 months immunosuppressive therapy including:
 - short term high-dose corticosteroids (>40 mg prednisolone per day for more than 1 week);
 - long term lower dose corticosteroids (>20 mg prednisolone per day for more than 14 days)
 - non-biological oral immune modulating drugs e.g. methotrexate >25 mg per week, azathioprine >3.0 mg/kg/day or 6-mercaptopurine >1.5 mg/kg/day

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 contra-indicate future vaccination.

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

HIV infection

The safety and efficacy of Zostavax have not been conclusively established in adults who are known to be infected with HIV with or without evidence of immunosuppression. On the basis of limited Phase II trial data⁸ and extrapolation from other live vaccines⁹, a

⁸ Benson C, Hua L, et al. ZOSTAVAX is generally safe and immunogenic in HIV+ adults virologically suppressed on ART: results of a phase 2, randomized, double-blind, placebo-controlled trial. Program and abstracts of the 19th Conference on Retroviruses and Opportunistic Infections; March 5-8, 2012; Seattle, Washington. Abstract 96

⁹ Koenig H, Garland J et al. Vaccinating HIV patients: focus on human papillomavirus and herpes zoster vaccines. AIDS Rev. 2013 Apr-Jun;15(2):77-86

CD4 count of 200 cells/ μ l may be a suitable cut off value below which vaccination should not be given. Immunosuppressed patients who require protection against shingles should seek advice from a secondary care specialist.

Cellular immune deficiencies other than HIV infection

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

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 (but see below).

Live and inactivated vaccines are safely administered to children and adults with an absent or dysfunctional spleen routinely¹⁰ in primary care to offer protection against a range of vaccine preventable diseases.

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

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

¹⁰ Davies J, Lewis M et al. Review of guidelines for the prevention and treatment of infection in patients with an absent or dysfunctional spleen: Prepared on behalf of the British Committee for Standards in Haematology by a Working Party of the Haemato-Oncology Task Force. *Br J Haematol*. 2011 Nov;155(3):308-17. Available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1365-2141.2011.08843.x>

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 Prostatin 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 not be administered to eligible patients currently receiving oral or intravenous (IV) antiviral agents (such as aciclovir) or who are within 48 hours after cessation of treatment as the therapy may reduce the response to the vaccine.

Where possible, antiviral therapies should not be started within two weeks after receiving Zostavax as this may adversely affect the effectiveness of the vaccine.

The use of topical antiviral agents such as aciclovir is not a contraindication to vaccination. Eligible patients currently receiving topical antiviral agents should be offered Zostavax as nationally recommended.

Adverse reactions commonly associated with the administration of Zostavax

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

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

Development of a vesicular rash after receiving Zostavax

Although transmission of the Zostavax vaccine virus (Orka/Merck strain) has not been reported during clinical trials, any person developing a vesicular rash after receiving Zostavax should be tested, as recommended below.

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 vaccinees that develop a varicella-zoster virus (VZV)-like rash and susceptible close contacts⁴.

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. N.B. Immunosuppressed individuals who develop a rash following inadvertent vaccination with Zostavax should be **urgently assessed and offered prompt treatment with acyclovir** - see the guidance below in the section titled “Inadvertant administration of Zostavax to immunosuppressed individuals”(p26).

In addition to the precautionary measures outlined above, a vesicle fluid sample should also be sent for analysis to confirm the diagnosis and determine whether the rash is vaccine associated or wild type. This service is available at the Virus Reference Department (VRD) at Public Health England, Colindale (T: 0208 327 6266). Please note sampling kits are not supplied by the Virus Reference Department at Public Health England. Health professionals are requested to obtain vesicle swabs from their local hospital laboratories. [Forms and instructions on how to take a vesicle fluid sample can be found here](#)

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

Vaccination of individuals with no previous history of chickenpox infection

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 in the UK 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 zoster⁴.

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 they may have disseminated zoster. If immunosuppressed the vaccine would be contraindicated.

Vaccination of eligible individuals with a previous history of shingles infection

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 those aged between 79 and 80 years at the time of natural shingles infection, it is acceptable to reduce the interval from recovery to vaccination from one year to enable Zostavax 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 6 months, there is currently no recommendation for revaccination if Zostavax is administered with a less than one year interval from natural infection.

Vaccination of individuals less than 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 (including recurrent shingles infections), 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, ideally allowing a one year interval period between vaccination and the last episode of infection if possible.

Patients who have 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 a current shingles infection

Zostavax is not licensed for the treatment of shingles or shingles related postherpetic neuralgia (PHN). Eligible individuals presenting with shingles infection should defer immunisation for a period of one year (or until just before their 80th birthday if this is sooner).

Vaccination of individuals with post herpetic neuralgia or residual nerve pain

Zostavax is not licensed for the treatment of shingles or shingles related postherpetic 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 that have previously received Zostavax

Individuals vaccinated with Zostavax before 60 years of age should be offered another dose of shingles vaccine once they reach 70 years of age. The interval between these doses is not important.

One trial that looked at revaccination in individuals vaccinated more than 10 years previously (<https://www.ncbi.nlm.nih.gov/pubmed/26452397>) found no increase in local reactions.

Inadvertent administration of a repeat dose of Zostavax is unlikely to cause harm but the patient should be assessed to ensure that they have no contraindications.

Vaccine administration

Although initially licensed for subcutaneous injection, in January 2016, Zostavax was licensed for administration via the intramuscular (IM) or subcutaneous (SC) routes. As injection-site adverse reactions were significantly less frequent in those who received the vaccine via the IM route, IM administration is preferred for those who do not have bleeding disorders.

For eligible patients with a bleeding disorder such as thrombocytopenia, administration via the SC route is recommended.

Shingles vaccine reconstitution

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.

Each pack is a single dose with a volume of 0.65ml after reconstitution

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

Prescribing route for vaccine administration

Shingles vaccine is a prescription only medicine and must be administered using a prescription, Patient Group Direction (PGD) or Patient Specific Direction (PSD).

The following link to the Care Quality Commission website may be of use in differentiating between a PGD and a PSD: <http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-19-patient-group-directions-pgds-patient-specific-directions>

Inadvertent administration of Zostavax

Inadvertent oral administration of Zostavax vaccine

Inadvertently administering Zostavax via the oral route is unlikely to cause significant harm as it is expected that the attenuated virus will be neutralised by the gastrointestinal tract.

Health professionals should inform the patient of the administration error, provide reassurance where necessary and encourage the patient to seek medical assistance if they become unwell. If the patient was eligible to receive Zostavax, then an additional dose administered via the recommended route should be offered as soon as possible.

Inadvertently administering Zostavax via the oral route 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.

Administration of Zostavax during pregnancy

As a precautionary measure, health professionals should treat the inadvertent administration of Zostavax vaccine in a pregnant woman in the same way as a natural exposure to chickenpox infection and should urgently assess the woman's susceptibility to chickenpox. Please see "[Chickenpox immunoglobulin](#)" guidance and advice for "[Pregnant women who have received shingles \(Zostavax\)](#)" on the PHE website.

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

For those women who are unable to give a reliable history of chickenpox infection or documented evidence of varicella vaccination, an urgent varicella antibody test (VZV IgG) should be performed using either the women's booking bloods or 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). These women should be provided with [information on the safety of varicella vaccines when given in pregnancy leaflet](#) and advised that no further action is required. For those women with a VZV IgG equivocal result, it is recommended that the local laboratory re-test the sample using a more sensitive assay such as Binding Site to confirm the result.

For those women who are found to be VZV IgG negative on testing, please contact the duty doctor at Public Health England (PHE) Colindale (T: 020 8200 4400) for further advice and consideration of the use of VZIG if within 10 days of inadvertent vaccination. Ideally, VZIG should be administered within 7 days where practically possible but can be offered up to 10 days following vaccination. Samples from those pregnant women found to be VZV IgG negative on local testing will be requested to be sent to the Virus Reference Department for storage. These samples will not be routinely tested but may undergo further testing should the need arise later in pregnancy. Further guidance on the management of pregnant women exposed to a vesicular rash can be found in the [viral rash in pregnancy](#) guidance document.

All incidents of inadvertent administration of Zostavax during pregnancy should also be reported to Public Health England using the [vaccines administered in pregnancy reporting form \(VIP\)](#). This national surveillance collects additional information on such exposures so that PHE 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 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 naïve 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 Zostavax to immunosuppressed individuals

Immunosuppressed individuals who are inadvertently vaccinated with Zostavax should be urgently assessed by a clinician to establish the degree of immunosuppression. 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.

Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed by a hospital specialist and offered prompt treatment with high dose iv aciclovir. Please refer to information above (p20) as to further action that should be taken if a patient develops a vesicular rash after receiving Zostavax.

Adverse events following administration of Zostavax should be reported to the MHRA via the [Yellow Card scheme](#).

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.

Inadvertent administration of varicella vaccine (Varivax or Varilrix) to an adult instead of Zostavax

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.

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

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.

Inadvertent administration of Zostavax instead of 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.

Administering Zostavax at the same time as other vaccines

Zostavax can be administered at the same time as any other vaccine. If MMR is required and this cannot be administered at the same time as Zostavax, a four week interval period is ideally recommended.

In 2015, the JCVI agreed that the previously recommended four week interval period between the administration of live vaccines is no longer applicable¹¹, except for Yellow Fever and MMR (these vaccines should **not** be administered at the same time; a four week interval period is recommended) and MMR and Varicella/Zoster (where these vaccines cannot be administered at the same time, a four week interval period is recommended). Therefore excepting these vaccines, live vaccines can be administered at any time before or after other live vaccines. It can also be offered at any interval before or after any inactivated vaccine.

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.

Administering Zostavax at the same time as 23 valent pneumococcal polysaccharide vaccine

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 trial conducted by the manufacturer showed inferior VZV antibody responses in those

¹¹ Public Health England. Immunisation against infectious disease: revised recommendations for the administration of more than 1 live vaccine. Last updated April 2015. Available at: <https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine>

receiving zoster vaccine and PPV23 concomitantly compared to those receiving the vaccines four weeks apart, there is no established correlation between antibody titres to VZV and protection against herpes zoster. Furthermore a more recent observational study showed that herpes zoster vaccine was equally effective whether it was administered simultaneously with PPV or four weeks apart.

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 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.

Gelatin content of Zostavax

Gelatine is commonly used in a range of pharmaceutical products, including many capsules and some vaccines. The gelatine used in Zostavax is a highly purified product used to stabilise live viral vaccines. A full list of vaccine excipients can be found in the [Summary of Product Characteristics \(SPC\)](#).

Vaccine acceptability for the Jewish and Muslim communities

Some patients may be concerned about the gelatin content of the vaccine. The statement below is from representatives of the Jewish community and may help patients to reach a decision about having the vaccine:

Rabbi Abraham Adler from the Kashrus and Medicines Information Service, said: “It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, including those administered via the nose, injections, suppositories, creams and ointments”.

However, PHE acknowledges that there is diversity within the British Muslim and Jewish communities and they, and some other groups, may consider medicines and vaccines containing any porcine product to be forbidden. In these circumstances, it is likely that the individual would be unable to accept many pharmaceutical products unless there was no suitable alternative and/or the product was considered life-saving. As Zostavax is the only shingles vaccine currently available, there is unfortunately no suitable alternative to this vaccine.

For further information, please see [“Vaccines and porcine gelatine”](#) information on the PHE website.

Further information

NHS Choices. Shingles. <http://www.nhs.uk/Conditions/Shingles/Pages/Introduction.aspx>

Public Health England. Shingles: guidance and vaccination programme. Available at: <https://www.gov.uk/government/collections/shingles-vaccination-programme>

Public Health England. Immunisation against infectious diseases (The Green Book): Chapter 28a Shingles (herpes zoster). Available at: <https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a>

Public Health England. Herpes zoster (shingles) immunisation programme: vaccine coverage data. Available at: <https://www.gov.uk/government/publications/herpes-zoster-shingles-immunisation-programme-2013-to-2014-provisional-vaccine-coverage-data>

Appendix 1

Members of the expert working group

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