Public Health Scotland

Shingles vaccination: Screening tool for identifying contraindications including severe immunosuppression

For patients

This screening tool will be used by your healthcare practitioner to help determine whether you may receive your shingles vaccine today and to identify the most suitable shingles vaccine based on any pre-existing medical conditions. There are two licensed shingles vaccines available in the UK with the non-live vaccine suitable for people who have severely weakened immune systems.

Please complete the following. If a question is not clear, please ask your healthcare provider to explain it.

If you have brought a list of your medications, please show this to your healthcare practitioner.

Patient's details

Name

Address

Date of birth

DD - MM - YYYY

The questions below are for completion by the patient or by the healthcare practitioner in a structured interview with the patient.

Q1 Do you feel unwell today? Yes ☐ No ☐

Q2 Do you have active shingles or post-herpetic neuralgia (PHN, nerve pain following shingles), or have you had shingles or PHN in the past year? Yes ☐ No ☐

Q3 Have you had a serious allergic reaction (anaphylaxis) to a previous dose of shingles or varicella (chickenpox) vaccine or any of the vaccine components including neomycin or gelatin? Yes ☐ No ☐

Q4 Have you ever had a medical condition or medical treatment that resulted in immunosuppression (such as cancer, leukaemia, lymphoma or chemotherapy/radiotherapy treatments)? Yes ☐ No ☐

Q5 Have you ever had an organ or bone marrow transplant? Yes ☐ No ☐

Q6 Do you have HIV/AIDS or any other health condition that weakens your immune system or active untreated tuberculosis (TB)? Yes ☐ No ☐

Q7 Do you have rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis or inflammatory bowel disease? Yes ☐ No ☐

Q8 In the last 12 months, have you taken or been given any medicine that weakens your immune system? Yes ☐ No ☐

Examples may include: oral steroids, anti-cancer drugs, biological therapy, radiotherapy or chemotherapy. These may be taken/given as oral medication, injections or infusions/drips. These may be taken/given in any healthcare setting, such as GP, hospital or specialist clinic or at home.

Questions continue on the next page.

Q9 Have you attended hospital to see a specialist in the last year? Or are you receiving any medicines or therapy that is prescribed and/or administered outside the GP practice, for example at a hospital, specialist clinic or unit? Yes ☐ No ☐

Q10 Have you had a COVID-19 or flu vaccine in the previous seven days or are you due to receive a COVID-19 or flu vaccine in the next seven days? Yes ☐ No ☐

Q11 In the previous four weeks have you had, or in the next four weeks are you due to have, any other vaccines? Yes ☐ No ☐

Q12 Have you been treated recently with oral antivirals such as aciclovir? Yes ☐ No ☐

If a patient has answered yes to any of the questions, then further guidance MUST be read as Zostavax® may be contraindicated.

For healthcare practitioners

Background

There are two licensed shingles vaccines available in the UK. This tool can be used to aid identification of patients who may be contraindicated to the live shingles vaccine (Zostavax®). Some individuals who are eligible for vaccination but contraindicated to Zostavax®, due to conditions that result in severe immunosuppression (see **Appendix 1: Definition of severe immunosuppression**), may be indicated for the non-live shingles vaccine (Shingrix®). A clinical risk assessment should be undertaken to identify individuals who are severe immunosuppressed and the administration of Shingrix® be considered.

The supply of Shingrix® is currently limited and so individuals aged 70 to 79 years with no or lower levels of immunosuppression should be offered Zostavax®.

Healthcare practitioners should ensure that their knowledge is current via:

- **The Green Book (Chapter 28a)**
- The relevant Patient Group Direction (PGD): **Zostervax®** and **Shingrix®**
- The **August 2022 CMO letter**
- **NHS Education Scotland Shingles Vaccine Training Slides for Registered Healthcare Practitioners and Notes for Registered Healthcare Practitioners**

Please refer to this documentation and this screening tool when making your assessment.

Specialists with responsibility for patients in the vaccine eligible cohorts who are immunosuppressed should include a statement of their opinion on the patient's suitability for Zostavax® in their correspondence with primary care.

Guidance

If a patient has answered yes to any of the questions, then further guidance MUST be read as Zostavax® may be contraindicated. The Zostavax® vaccine is a live attenuated vaccine. If there is any doubt to the person's suitability due to severe immunosuppression, then **do not vaccinate** and consider the administration of Shingrix® where indicated (see **Appendix 2: Algorithm to aid clinical decision-making regarding vaccination with shingles vaccine**) or seek further advice.

Q1. Do you feel unwell today?

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. Immunisation of individuals who are acutely unwell should be postponed until they have recovered fully. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any sign or symptoms to the adverse effects of the vaccine.

Q2. Do you have active shingles or active post-herpetic neuralgia (PHN, nerve pain following shingles), or have you had shingles or PHN in the past year?

Zostavax® and Shingrix® are not recommended for the treatment of shingles or post herpetic neuralgia (PHN). Individuals who have active shingles or PHN should wait until symptoms have ceased before being considered for shingles immunisation. The natural boosting that occurs following an episode of shingles, however, makes the benefit of offering zoster vaccine immediately following recovery unclear. Therefore, vaccination should be delayed for one year to optimise response. This interval can be reduced to ensure vaccine is offered before age 80.

Patients who have two or more episodes of shingles in one year should have immunological investigation prior to vaccination to identify any underlying immunosuppressive conditions. Healthcare practitioners may wish to discuss such cases with local specialist teams.

Q3. Have you had a serious allergic reaction (anaphylactic) to a previous dose of shingles or varicella (chickenpox) vaccine or any of the vaccine components including neomycin or gelatin?

Anaphylaxis following vaccination is rare. Zostavax® should not be given to an individual who has had a confirmed anaphylactic reaction to a previous dose of the shingles or varicella virus – containing vaccine or to any component of the vaccine including neomycin or gelatin. Shingrix® should not be administered to an individual with a confirmed anaphylactic reaction to any component of the vaccine.

Q4. Have you ever had a medical condition or medical treatment that resulted in immunosuppression (such as cancer, leukaemia, lymphoma or chemotherapy/ radiotherapy treatments)?

Zostavax® should not be given to individuals with severe immunosuppression, including those who:

- have acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure.
- remain under follow up for a chronic lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B this list is not exhaustive).
- are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication.

The decision to administer Zostavax® to immunosuppressed individuals should be based on a clinical risk assessment. If healthcare professionals administering the vaccine have concerns about the nature of therapies (including biologicals) or the degree of immunosuppression, they should consider the administration of Shingrix® or contact the relevant specialist for advice.

Q5. Have you ever had an organ or bone marrow transplant?

Zostavax® should not be given to:

- those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant.
- those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months.
- those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD).

Administration of Shingrix® where individuals are severely immunosuppressed should be considered.

Q6. Do you have HIV/AIDS or any other health condition that weakens your immune system?

As Zostavax® is a live vaccine it should not be given to an individual who has immunosuppression due to:

- HIV/AIDS with a current CD4 count of below 200 cells/µl.
- primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (lymphopaenia (<1,000 lymphocytes/µl) or with a functional lymphocyte disorder.

Administration of Shingrix® where individuals are severely immunosuppressed should be considered.

Individuals with lower levels of immunosuppression can receive Zostavax®. Primary humoral immunodeficiencies, such as X-linked agammaglobulinemia, are not of themselves a contraindication for Zostavax® unless associated with T cell defects.

Q7. Do you have rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis or inflammatory bowel disease?

This question is included as many individuals with these conditions may be on some form of immunosuppressive therapy (e.g. biological therapy) but may not realise. Awareness of their condition is not necessarily a contraindication for vaccination but should prompt further questions based on information from question 8 (overleaf).

Q8. In the last 12 months, have you taken or been given any medicine that weakens your immune system?

Examples may include: oral steroids, anti-cancer drugs, biological therapy, radiotherapy or chemotherapy. These may be taken/given as oral medication, injections or infusions/ drips. These may be taken/given in any healthcare setting, such as GP, hospital or specialist clinic or at home.

Individuals may still be eligible despite taking these medications in the last 12 months and the health practitioner should check detailed criteria. Specific details are provided in the Green Book and summarised below. Please ask about all medications including infusions/ drips, injections and oral medications. If the individual has brought their medicines list, this should be reviewed. Please be aware that a GP repeat prescription slip may not contain details of medicines prescribed elsewhere.

If healthcare professionals administering the vaccine have concerns about the nature of therapies (including biologicals) or the degree of immunosuppression, they should consider the administration of Shingrix® or contact the relevant specialist for advice. Zostavax® should not be given to individuals who:

- are receiving immunosuppressive or immunomodulating therapy including;
    - those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication
    - those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant
    - those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors, IL-17 inhibitors, IL-12/23 inhibitors, IL-23 inhibitors (N.B: this list is not exhaustive). There are now many biological therapies, some (but not all) with names ending in "...mab" or "...cept"). These are commonly given by injection in a healthcare setting (GP, specialist clinic or other acute centre), or at home where it would be kept in a fridge.
- have chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy
    - moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month
    - long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months

- any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months
- certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months.

- have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month. Individuals who received high dose short term immunosuppression at doses equivalent to ≤40mg prednisolone per day for an acute episode of illness such as asthma, chronic obstructive pulmonary disease (COPD) or COVID-19 may be vaccinated with Zostavax® when they have recovered. Zostavax® may also be offered to those on replacement corticosteroids for adrenal insufficiency, or to those topical or inhaled corticosteroids or corticosteroid replacement therapy. Zostavax® is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or corticosteroid replacement therapy.

Q9. Have you attended hospital to see a specialist in the last year? Or are you receiving any medicines or therapy that is prescribed and/or administered outside the GP practice, for example at a hospital, specialist clinic or unit?

This question aims to further identify any individuals with conditions resulting in immunosuppression or individuals receiving immunosuppression therapy. A variety of different clinical specialties may prescribe medicines that are immunosuppressive. The health professional should aim to confirm diagnosis and therapy. If in doubt, vaccination should be deferred and advice sought from hospital specialist/prescribing consultant, or the patient can be assessed for suitability of Shingrix® vaccine.

Q10. Have you had a COVID-19 or flu vaccine in the previous seven days or are you due to receive a COVID-19 or flu vaccine in the next seven days?

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

Shingrix® can be given concomitantly with inactivated influenza vaccine. Because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine, it should not be routine to offer appointments to give this vaccine at the same time as the

adjuvanted influenza vaccine. Based on current information, scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered.

Q11. In the previous four weeks have you had, or in the next four weeks are you due to have, any other vaccines?

Based on evidence that MMR vaccine can lead to an attenuation of the response to varicella vaccine, it is recommended that a four-week interval is observed between administration of MMR and Zostavax® vaccines to ensure adequate protection. Travel vaccines containing live attenuated virus e.g. yellow fever, may be given to the age group recommended for shingles vaccination. There is limited evidence on the timing of administration of Zostavax® and Yellow Fever vaccine, with a single case report demonstrating good response to Yellow Fever vaccine 21 days after receiving Zostavax®. Given the lack of data it would be appropriate to leave a four-week interval between administration of Yellow Fever vaccine and Zostavax®. In line with JCVI advice, there are no other restrictions for timing between Zostavax® and other live vaccines.

Q12. Have you been treated recently with oral antivirals such as aciclovir?

Immunisation with Zostavax® should be delayed in individuals who are being treated for non-varicella zoster infections with either oral or intravenous antivirals (such as aciclovir) until 48 hours after cessation of treatment. This also applies to individuals receiving aciclovir prophylaxis which should be ceased for at least 48 hours before vaccination and individuals who have received high dose IVIG or varicella zoster immunoglobulin (VZIG) in the previous 6 weeks. This is due to the potential to lower effectiveness of the vaccine by reducing replication. The use of topical aciclovir is not a contraindication to Zostavax® or Shingrix® vaccination.

Appendix 1: Definition of severe immunosuppression

Individuals with primary or acquired immunodeficiency states due to conditions including:

- acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure.
- individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B: this list not exhaustive).
- immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.
- primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder.
- those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months.
- those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD).

Individuals on immunosuppressive or immunomodulating therapy including:

- those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication.
- those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant.
- those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors, IL-17 inhibitors, IL-12/23 inhibitors, IL-23 inhibitors (N.B: this list is not exhaustive).

Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy:

- moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month.
- long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months.
- any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months.
- certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months.

Individual who have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month.

Appendix 2: Algorithm to aid clinical decision-making regarding vaccination with shingles vaccine

Is the individual eligible to receive a shingles vaccine?

Eligibility for the 2022/23 programme is as follows:

- Routine vaccination of 70 year olds (defined by age at 1 September 2022)
- Active call and recall of 71–79 year olds who have not previously been vaccinated (defined by age at 1 September 2022). People in this age group who were not vaccinated due to contraindication to the live vaccine should be identified from their clinical records and offered the Shingrix® vaccine.
- Vaccine should not be offered to anyone aged 80 years and over, even if they have previously been eligible (defined by age at 1 September 2022).