Department of Health & Social Care

Independent report

# JCVI statement on the shingles (herpes zoster) vaccination programme

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# Advice

The Joint Committee on Vaccination and Immunisation (JCVI) previously recommended that the universal shingles vaccination programme should be updated to offer 2 doses of Shingrix® at 60 years of age. This was to replace the previous programme which offered Zostavax® at 70 years of age. JCVI also recommended offering 2 doses of Shingrix® to severely immunosuppressed individuals aged 50 years and older.

During 2024 JCVI have formed further advice for the vaccination of additional cohorts who remain at risk from severe shingles disease and resulting post-herpetic neuralgia.

JCVI advises that Shingrix® programme eligibility should be expanded to include all severely immunosuppressed adults aged 18 years and over.

JCVI advises that the offer of vaccination should also expanded to include older adult cohorts aged 80 and over. There is a clear cost-effective benefit from offering a single dose of Shingrix® to this age group.

JCVI considers that there is likely to be additional benefit from a second dose offered to adults over the age of 80 years for the prevention of cases of shingles and secondary outcomes such as post-herpetic neuralgia. Should Shingrix® be available at the cost-effective price determined for the second dose, a 2-dose programme should be offered for adults aged 80 years and older.  This would also bring the offer in line with the other groups offered Shingrix®.

The long-term vaccine effectiveness from a single dose of Shingrix® in adults aged 80 years and over is still uncertain.

Individuals should be eligible regardless of whether they have previously been eligible for, or have been vaccinated with, Zostavax®.

# Background and previous Zostavax® programme

JCVI is an expert scientific advisory committee which advises the UK government on vaccination and immunisation matters.

Shingles, also referred to as herpes zoster, is caused by the reactivation of a latent varicella-zoster virus in a previously infected person. Varicella-zoster virus infects, and then becomes latent in nerve cells. This reactivation generally occurs decades after primary infection with varicella (commonly known as chickenpox) which typically occurs in childhood. There

is no evidence that shingles can be acquired from exposure to another individual infected with varicella.

The onset of shingles is commonly associated with a blistered rash and pain, with the rash typically lasting between 2 to 4 weeks. In some cases, shingles-associated pain may persist for more than 3 months. This is known as post-herpetic neuralgia (PHN).

Other complications from shingles depend on the nerves affected and include motor weakness, facial palsy and herpes zoster ophthalmicus (which may lead to complications resulting in impaired vision). Zoster infection may disseminate, affecting other organs to cause pneumonia, hepatitis, or encephalitis.

In general, the incidence and severity of shingles increases in older age cohorts, as does the risk of PHN. Suppression of the immune system is associated with an increased risk of shingles, from either immunosuppressive treatment, underlying medical conditions or age-related immunosenescence. Studies have also shown that the risk of PHN is also higher in individuals with immunosuppression (see reference 5).

## Previous shingles vaccination programme

In 2009, JCVI recommended the implementation of a herpes zoster vaccination programme based on modelling that indicated that such a programme would be cost-effective (see reference 1 and 9). A universal national vaccination programme using a single dose of live zoster vaccine (brand name Zostavax®) commenced in September 2013.

This programme was introduced to the routine schedule at 70 years, with a phased catch-up programme for 71 to 79 year olds. The choice of age group was based on the evidence of cost-effectiveness of Zostavax® and this group was considered likely to have the greatest benefit due to the burden of disease and the estimated effectiveness of Zostavax® in this age group, and the expected duration of protection.

Data for Zostavax® showed that vaccine effectiveness declined with age at vaccination. Therefore, individuals only remained eligible until they turned 80 years old (see reference 10). Individuals who were born on or before 1 September 1933 have therefore never been eligible for a routine shingles vaccination programme.

As a live attenuated vaccine, Zostavax® is contraindicated in individuals who are immunosuppressed. These individuals were therefore unable to receive vaccination under the previous programme despite their increased risk from shingles.

Study data has shown that the protection offered by vaccination with Zostavax® declines over time, with estimates suggesting that vaccine effectiveness against disease 8 years after vaccination is not statistically significant (see references 7 and 8).

## Impact of the Zostavax® programme

Prior to the introduction of a shingles vaccination programme, it was estimated that there were over 4,500 hospital admissions per year attributable to zoster, mostly occurring in those over the age of 60 years. The majority of hospitalisations were considered to be vaccine-preventable (see reference 3).

Population based cohort studies showed that vaccine effectiveness from the routine programme was good and was higher than had been predicted based on clinical trial data. Effectiveness was similar between routine age cohort and the older catch-up cohorts (see reference 12).

Analysis of the first 3 years of the shingles vaccination programme estimated that the population impact in England was equivalent to about 17,000 fewer episodes of shingles and 3,300 fewer episodes of post-herpetic neuralgia among the eligible population (see reference 13).

An ecological study showed substantial reductions in the number of shingles hospitalisations and PHN consultations in the first 5 years of the shingles vaccination programme. Over the whole 5-year period it was estimated that there have been 40,500 fewer shingles consultations and 1,840 fewer shingles hospitalisations attributable to the vaccination programme (see reference 11).

Although the impact of the programme has been significant, based on coverage data, there is likely to be a number of individuals who have aged out of vaccine eligibility who have never been vaccinated. In addition, based on the expected waning patterns of protection against shingles disease there is likely to be little vaccine protection remaining in these older age groups.

# Current shingles vaccination programme

Following the availability of a new recombinant shingles vaccine, Shingrix®, JCVI reviewed and updated its advice on the national programme.

Shingrix® is authorised as a 2-dose schedule, whereas Zostavax® was authorised as one dose.

Following review of available data on Shingrix® use in immunocompromised individuals, in February 2018 JCVI advised the use of this vaccine in those who were eligible for the shingles vaccination programme but contraindicated for live zoster vaccine (Zostavax®).

In 2019, JCVI updated its recommendation for the shingles vaccination programme having reviewed cost-effectiveness modelling on a routine Shingrix® vaccination programme. The committee recommended that the Zostavax® programme should be replaced with a 2-dose Shingrix® programme offering vaccination routinely at 60 years of age. It was advised that those aged between 60 and 70 years should also be offered vaccination with Shingrix®.

At this time, JCVI also recommended that all severely immunosuppressed individuals over the age of 50 years should be offered Shingrix® vaccination. This recommendation reflected the authorised product indication at the time, which indicated the vaccine for use in individuals over the age of 50 years who were at increased risk of shingles.

A phased introduction of the Shingrix® vaccination programme commenced from 1 September 2023 in England, offering vaccination to those turning 65 years and 70 years.

This operational delivery approach was agreed between the Department of Health and Social Care (DHSC), UK Health Security Agency (UKHSA) and NHS England. This approach aimed to maintain the existing offer of vaccination at 70 years previously put in place for the Zostavax® programme and adding a new cohort to be vaccinated as they turn 65 years. As the programme progresses, this will then shift to offering vaccination to those turning 60 years and 65 years.

Similar programmes have been implemented in Scotland, Wales and Northern Ireland.

# Further considerations for the Shingrix® vaccination programme

JCVI varicella-zoster sub-committee met multiple times during 2018 and 2019 to consider the initial advice on the Shingrix® vaccination programme.

Following the initial advice, further work was identified as being needed to address outstanding questions related to the shingles vaccination

programme. This included the potential vaccination of:

- severely immunosuppressed individuals to include adults 18 to 49 years
- older individuals who have never been eligible for a shingles vaccination programme
- individuals who received Zostavax® vaccination in the previous routine programme
- older individuals (80 years and over) who never received Zostavax® although they were previously eligible

The varicella-zoster sub-committee met between 2022 and 2024 to discuss these outstanding questions. Updated modelling and analyses were presented to JCVI in 2024.

# Expansion of eligibility: immunosuppressed people

Since the initial Shingrix® programme recommendations in 2019, the licensed indication for Shingrix® has been expanded for the prevention of shingles in adults 18 years and older at increased risk of shingles.

In October 2022, JCVI advised that it would be reasonable to offer individuals aged 18 to 49 years who had received a stem-cell transplant or CAR-T therapies vaccination with 2 doses of Shingrix® due to their significantly increased risk from shingles (see reference 4). This advice was added to the shingles chapter (chapter 28a) of ‘Immunisation against infectious disease’, also referred to as The Green Book.

In its February 2024 meeting, JCVI reviewed analysis undertaken by UKHSA to determine the risk of hospitalisation and PHN in younger (18 to 49 years) severely immunosuppressed individuals and how this compares to the risk in cohorts already eligible for vaccination. This analysis concluded that the risk of hospitalisation in younger immunosuppressed age groups from shingles or resulting PHN was similar to other cohorts who were already eligible for vaccination.  JCVI advised that this group should be considered for vaccination based on their equivalent risk. This advice has been passed to DHSC whose role it is to set vaccination policy.

# Cost-effectiveness modelling

## 2019 modelling

In February 2019, JCVI reviewed modelling work undertaken by the London School of Hygiene and Tropical Medicine (LSHTM) (see reference 15).

This modelling updated and extended the cost-effectiveness modelling used to inform the advice for the Zostavax® programme (see reference 1 and 9). Using data from the clinical trials, it was estimated that Shingrix® would sustain higher vaccine efficacy for longer than Zostavax® had been shown to.

Results from cost-effectiveness modelling suggested that vaccination with Shingrix® was cost-effective for the immunosuppressed population for ages 50 to 90 years. These age parameters were chosen based on the vaccine authorisation at the time.

For the immunocompetent population, the modelling indicated that the highest net-monetary benefit from a routine Shingrix® programme was vaccination at 65 years of age. However, vaccination at 60 years of age was predicted to prevent more cases. This analysis determined that vaccination with Shingrix® was likely to be the optimal and most cost-effective strategy (when compared with Zostavax®, and no vaccination) for individuals between 56 and 71 years of age.

The committee recommended that the shingles vaccination programme should be changed to offer 2 doses of Shingrix® routinely at 60 years of age, and all individuals between 60 and 70 years of age should also be offered Shingrix®.

Due to the size of the potential expanded programme, and the potentially limited initial supply of vaccination, the committee agreed that severely immunosuppressed individuals who were eligible under the existing programme should be prioritised for receiving Shingrix®.

## 2024 modelling

In October 2024, JCVI reviewed modelling undertaken by modellers at the LSHTM (see reference 6). This cost-effectiveness modelling sought to determine whether offering recombinant zoster vaccine to those over 80 years would be cost effective. This analysis looked at cohorts who had previously been vaccinated during the Zostavax® programme, and those who had never received a vaccine.

This modelling included updated data on population demographics, epidemiology, and updated vaccine-effectiveness and modelled duration of protection from real world studies. It also included uptake data from the

previous programme, and updated estimates on loss of quality adjusted life years (QALYs) from shingles.

The key finding from the modelling was that an extra single dose of Shingrix® for individuals over the age of 80 years would be cost-effective. This additional dose would make the programme as a whole more cost-effective due to the greater cost-effectiveness of a single dose compared to 2 doses, even if there are fewer QALY losses to prevent in the oldest age groups.

There remains some uncertainty around the longer-term vaccine effectiveness in the oldest age groups, and the incremental increase in vaccine effectiveness that would be gained from a second dose.

# Additional advice for older adults

In October 2024, JCVI reviewed the updated cost-effectiveness modelling with a view to advising on whether additional older age cohorts, who may remain vulnerable to shingles, should be offered vaccination.

The committee concluded that based on modelling, there was a clear cost-effective benefit in offering a single dose of Shingrix® to all adults 80 years of age and older.

This would include offering a vaccine to individuals who had never previously been eligible for shingles vaccination, those who had been eligible for Zostavax® but didn’t take up vaccination, and those who have previously received Zostavax®.

There will be a small minority of eligible individuals who were vaccinated relatively recently with Zostavax®. However, the majority of the vaccinated cohort would have been immunised some time ago when becoming eligible at 70 years of age. Zostavax® has not been given routinely in the UK since August 2023. There would therefore be little benefit to operating a revaccination programme for which eligibility is determined on the amount of time since Zostavax® vaccination was given.

It has been established that the risk of severe shingles and resulting PHN is higher in the oldest age cohort. When establishing whether a programme is cost effective, the number of QALYs estimated to be gained from vaccination has to be evaluated for the relevant cohort.

Shingrix® has been shown to be more effective overall including in the oldest age cohorts than Zostavax®, the previously used vaccine. Data has also shown that vaccine effectiveness in the oldest age groups is lower than in younger eligible age groups. This difference by age has been seen for

both one dose and 2 dose vaccine effectiveness data. Some studies have been conducted on the long-term effectiveness of a single dose, however, there remains some uncertainty (see reference 14).

Offering a second dose of vaccine would prevent more cases of shingles and PHN overall, and therefore would be preferable epidemiologically. It would also mean that the same offer of 2 doses would be given across the entire shingles vaccination programme. The additional marginal benefit from a second dose would however be lower than the initial benefit offered from the first dose.

Although there would be some additional benefit from a second dose of vaccine in these groups, the additional willingness to pay for another dose related to this benefit to be gained may not be sufficient to represent a realistic procurement price for additional doses. As per its code of practice, JCVI is required to consider cost-effectiveness on an incremental basis, considering whether the additional benefits to be gained are worth the additional costs incurred.

# Future considerations

JCVI notes that it would be interested in further real world data on the longer term vaccine effectiveness of Shingrix®. Cohorts receiving vaccination at a relatively young age due to immunosuppression may benefit from revaccination later in life, however, this has yet to be evaluated.

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