The incidence of shingles and its implications for vaccination policy
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
A vaccine programme for shingles (herpes zoster), which was dependent upon the efficacy of the dose and the administration of the drug, was investigated.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised males and females over the age of 45 years. It was obtained from secondary data.

Setting
The setting was primary care. The economic study was carried out in the UK (England and Wales).

Dates to which data relate
Annual and weekly incidence data for herpes zoster virus (HZV) were from 1994 to 2001. Government Actuaries Department life expectancy at 5-year intervals from 45 year upwards was applicable as at 2000 (1998-based population for the UK). The cost data were not derived, but were based on an assumption made by the authors (as yet no cost is known for the vaccine).

Source of effectiveness data
The effectiveness data were derived from a review of existing data sources and estimates of effectiveness based on opinion.

Modelling
A model was used to calculate the potential number of cases saved per 100,000 population, the cost per case saved, and the number of cases saved in persons aged 70 years and older, for three efficacy models for the vaccine. The models were based on the following efficacy assumptions made by the authors:

- the vaccine would be effective in 100% of the population for 20 years only, and thereafter would be ineffective;
- the vaccine would be effective in 70% of the population for 20 years only, and thereafter would be ineffective; and
- the vaccine would be fully effective in 100% of the population for 10 years, and would then be subject to a linear decline in efficacy to zero over 10 years.
Three single vaccine scenarios were modelled, a single dose at one of three ages (55, 60 and 65 years). Two dual vaccine scenarios were modelled, two doses in the age combinations 45 and 65 years, or 50 and 70 years. The type of model used was not stated.

Outcomes assessed in the review
The outcomes assessed in the review were:

- the annual and weekly incidence data for HZV for 1994 to 2001 for six age groups (15-24, 25-44, 45-64, 65-74, and 75 years and over) for all patients and males and females separately; and
- life expectancy at 5-year intervals from 45 years upwards, applicable at 2000 (1998-based population for the UK) for males and females.

Study designs and other criteria for inclusion in the review
The data were taken from two databases. The incidence data were estimated from the weekly returns service of the Royal College of General Practitioners. This collates returns from general practice-based consultations in a population (approximately 650,000) nationally representative by the age and gender of England and Wales. Life expectancy data were taken from the Government Actuary(s Department (1998-based population for the UK).

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Two main studies were used in the review.

Methods of combining primary studies
Not applicable as the results were not combined.

Investigation of differences between primary studies
Not applicable.

Results of the review
The mean annual incidence of shingles was 395 per 100,000 population (range: 369 - 421, all ages, males and females). The mean annual incidence by age group was displayed as a graph in the original paper.

For females, the future life expectancy was 39.2 years at age 45, 34.3 years at age 50, 29.5 years at age 55, 24.9 years at age 60, 20.3 years at age 65, 15.8 years at age 70, 12 years at age 75, 8.8 years at age 80, and 6.4 years at age 85.

For males, the future life expectancy was 35.5 years at age 45, 30.6 years at age 50, 25.8 years at age 55, 21.3 years at age 60, 17.2 years at age 65, 13.1 years at age 70, 9.8 years at age 75, 7.2 years at age 80, and 5.2 years at age 85.
Methods used to derive estimates of effectiveness
The authors made assumptions about the effectiveness of the vaccine, based on expert opinions.

Estimates of effectiveness and key assumptions
For the efficacy models for the vaccine, the authors assumed that:

the vaccine would be effective in 100% of the population for 20 years only, and thereafter would be ineffective;

the vaccine would be effective in 70% of the population for 20 years only, and thereafter would be ineffective; and

the vaccine would fully effective in 100% of the population for 10 years, and would then be subject to a linear decline in efficacy to zero over 10 years.

Measure of benefits used in the economic analysis
The measure of benefits used was the number of cases saved.

Direct costs
The cost of the vaccine (including administration) was the only cost used in the model. The authors estimated this cost since the cost of the vaccine was not available. The costs were not discounted although discounting was methodologically relevant. No cost dates were reported as the cost was an estimate.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were reported.

Currency
UK pounds sterling (§).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
The potential number of cases saved per 100,000 population in the scenario vaccinate aged 55 years was 13,266 males and 16,954 females if the vaccine were fully effective in all patients for 20 years. The corresponding values were 9,286 males and 11,868 females if the vaccine were fully effective in 70% patients for 20 years, and 9,099 males and 11,949 females if the vaccine were fully effective in all patients for 10 years then declined to zero effectiveness over 10 years.

The potential number of cases saved per 100,000 population in the scenario vaccinate aged 60 years was 15,810 males and 19,160 females if the vaccine were fully effective in all patients for 20 years. The corresponding values were 11,067 males and 13,412 females if the vaccine were fully effective in 70% patients for 20 years, and 11,089 males and 13,769 females if the vaccine were fully effective in all patients for 10 years then declined to zero effectiveness over 10 years.

The potential number of cases saved per 100,000 population in the scenario vaccinate aged 65 years was 15,081 males and
and 20,692 females if the vaccine were fully effective in all patients for 20 years. The corresponding values were 10,556 males and 14,485 females if the vaccine were fully effective in 70% patients for 20 years, and 12,194 males and 15,215 females if the vaccine were fully effective in all patients for 10 years then declined to zero effectiveness over 10 years.

The potential number of cases saved per 100,000 population in the scenario vaccinate aged 45 and 65 years was 23,479 males and 32,614 females if the vaccine were fully effective in all patients for 20 years. The corresponding values were 16,436 males and 22,830 females if the vaccine were fully effective in 70% patients for 20 years, and 17,796 males and 23,360 females if the vaccine were fully effective in all patients for 10 years then declined to zero effectiveness over 10 years.

The potential number of cases saved per 100,000 population in the scenario vaccinate aged 50 and 70 years was 23,024 males and 31,414 females if the vaccine were fully effective in all patients for 20 years. The corresponding values were 16,116 males and 21,990 females if the vaccine were fully effective in 70% patients for 20 years, and 18,797 males and 24,951 females if the vaccine were fully effective in all patients for 10 years then declined to zero effectiveness over 10 years.

The model of efficacy that saved the greatest number of cases in both males and females was the dual vaccine at ages 45 and 65 years (23,479 males and 32,614 females).

Side effects were not considered.

**Cost results**
The total intervention cost was 40 for a single vaccine and 80 for the dual programme.

**Synthesis of costs and benefits**
The lowest cost per case saved for females was vaccination at 65 years, single vaccine, 100% efficacy for 20 years, saving 193. The lowest cost per case saved for males was vaccination at 60 years, single vaccine, 100% efficacy for 20 years, saving 253.

The highest cost per case saved was the dual vaccine (50 and 70 years) with 70% efficacy, with a saving of 496 for males and 364 for females.

**Authors' conclusions**
The authors stated that if a vaccine were available that gave lifelong protection, this would have the most impact if given at an early age, but no such vaccine is available. However, the authors concluded that, whichever vaccine efficacy model was chosen, a single vaccination policy at age 65 years was the most favourable option in both males and females.

**CRD COMMENTARY - Selection of comparators**
The use of a vaccine was compared with no vaccine, which was applicable. However, details of the vaccine dose were not provided.

**Validity of estimate of measure of effectiveness**
The analysis was based on comprehensive data sources. The duration of the model was based on life expectancy, which was appropriate for the study question. However, it was unclear if other data sources were available for the same measures of effectiveness (i.e. incidence of the disease) in order to allow comparison with other studies.

**Validity of estimate of measure of benefit**
The measure of benefit was the number of cases averted. This was appropriate given the study aim.

Validity of estimate of costs
The only cost included in the analysis was the assumed cost of the vaccine. This cost was not subject to a sensitivity analysis. The costs arising from complications of the disease were not considered. For example, shingles can cause severe illness in the elderly, but any potential benefits or cost-savings from reducing this were not considered.

Other issues
The authors made appropriate assumptions about the potential efficacy of the vaccine and carried out an appropriate sub-group analysis by age group and gender. The authors stated that more precise estimates of vaccine efficacy will be available from ongoing clinical trials. The authors do not appear to have presented the results selectively. A reported limitation of the study was that the data for incidence were based on the number of episodes of the disease rather than on the number of persons suffering. It is possible to suffer from more than one episode of shingles during a lifetime, although this is thought to be uncommon. Most of the published material was based on cases rather than persons. This limitation was discussed in detail, but the authors stated that the impact on the results is likely to have been minimal. Issues around how to implement such a vaccine strategy in practice were not addressed.

Implications of the study
The authors stated that, as the population ages, shingles will present an increasing problem for health care delivery. The estimate of vaccine efficacy from ongoing clinical trials should be used in the model to predict the optimal age for vaccination. The place of the vaccine in routine preventive care needs to be determined.

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