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Effectiveness of herpes zoster vaccination in an older United Kingdom population

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ABSTRACT

Background: Vaccination against herpes zoster was introduced in the United Kingdom in 2013 for individuals aged 70 years, with a phased catch-up campaign for 71–79 year olds. Vaccine introduction has resulted in a marked fall in incident herpes zoster and in post-herpetic neuralgia (PHN), but formal evaluation of vaccine effectiveness is needed.

Methods: In a population-based cohort study of older individuals born between 1933 and 1946, we used linked UK anonymised primary care health records for the first three years of the vaccination programme (01/09/2013–31/08/2016) and multivariable Poisson regression to obtain incidence rates and vaccine effectiveness (VE) against zoster and PHN.

Results: Among 516,547 individuals, 21% were vaccinated. Incidence of zoster was 3.15/1000 person-years in vaccinees and 8.80/1000 person-years in unvaccinated individuals. After adjustment, VE was 64% (95%CI = 60–68%) against incident zoster and 81% (95%CI = 61–91%) against PHN, with very similar VE estimates in the routine and catch-up cohorts. VE against zoster was lower in those with a previous history of zoster: 47% (95%CI = 31–58%) versus 64% (95%CI = 60–68%) in those without previous zoster. There was evidence of waning VE over time, from 69% (95%CI = 65–74%) in the first year after vaccination to 45% (95%CI = 29–57%) by the third year.

Conclusion: This first formal assessment of VE in the UK zoster vaccination programme demonstrates good effectiveness of zoster vaccine, and very good protection against PHN. The findings provide evidence that VE is similar across the age groups targeted for vaccination in the UK, and on duration of protection of the vaccine in public health use. The study provides key information for decision-makers about the future direction of UK zoster vaccination programme, indicating that the live zoster vaccine may be more cost-effective than estimated previously. It also supports efforts to communicate the benefits of zoster vaccination to address the declining coverage observed across the UK.

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1. Introduction

Herpes zoster occurs following reactivation of latent varicella zoster virus (VZV) infection. It results in a painful unilateral dermatomal rash and appreciable short- and long-term morbidity, notably prolonged pain (post-herpetic neuralgia, PHN). Reactivation of VZV as zoster is prevented by specific cell-mediated immunity, and thus those who are immunosuppressed are at increased zoster risk [1]. Zoster incidence also rises markedly with age, due to immunosenescence and loss of specific immunity to VZV, with rates of 8–12 per 1000 person-years in individuals aged 80+ years [2,3]. Older individuals are also more likely to develop PHN following zoster [4].

In 2006, a live attenuated vaccine against zoster (Zostavax; Zoster Vaccine Live; Merck & Co) was licensed for use and introduced in the USA for older individuals. The large US pre-licensure trial of the vaccine in individuals (median age: 69 years) followed up for a mean of 3.13 years demonstrated vaccine efficacy against incident zoster of 51%, with 67% efficacy against PHN [5]. Subsequent US post-licensure studies of older individuals, with maximum follow-up of 2–5.8 years, have reported estimates of vaccine effectiveness (VE) against incident zoster [6–11]. In those with

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estimates in the first three years of follow-up VE has varied from 33% to 55% [6,7,9]. Three post-licensure studies also reported VE against PHN, with estimates of 55% and 59% in the first three years [6,9] and 61% in a case-control study which included individuals vaccinated up to 4.8 years before their zoster diagnosis [10].

Zoster vaccination was introduced in the UK in September 2013, targeted at individuals aged 70 years (the routine cohort) on 1st September of that year, and those aged 70 years on 1st September 2014 and 1st September 2015 in the second and third year of the programme [12,13]. There was also a phased introduction of a catch-up campaign for older individuals, with the vaccine offered to those aged 79 years on 1st September 2013 (in the first year); 78 and 79 years on 1st September 2014 (second year), and 78 years on 1st September 2015 (third year). For both the routine and catch-up cohorts, unvaccinated individuals continued to be eligible for vaccination until their 80th birthday [12]. As a live vaccine, the vaccine is contraindicated for individuals with specific immunosuppressive conditions or receiving immunosuppressive therapy as defined in national guidance [12]. The vaccine is offered in general practice throughout the year, although practices are encouraged to administer it alongside the annual seasonal influenza vaccination programme. Vaccine uptake in England has declined over time, from 61.8% (first year) to 54.9% (third year) in the routine cohort, and from 59.6% to 55.5% in the catch-up cohort [14,15].

We recently showed that general practice consultations for zoster and for PHN in the first three years of the programme decreased by 35% and 58% respectively in the routine cohorts, and by 33% and 38% in the catch-up cohorts [16]. However, this ecological study assessed vaccine impact and did not use patient-level data to formally estimate VE. Therefore, in this study we used linked individual-level electronic health records to estimate effectiveness of the zoster vaccine in the first three years of the UK programme against incident zoster and PHN.

2. Methods

2.1. Data sources

We used anonymised data from the Clinical Practice Research Datalink (CPRD), which comprises the primary care records from a representative 7% sample of the UK population [17]. Approximately 58% of the practices have consented to taking part in the CPRD linkage scheme, and patients' records from these practices are linked to hospitalisation data (Hospital Episode Statistics, HES), and to patient-level deprivation data (Index of Multiple Deprivation for the postcode of the patient's residence) [17].

2.2. Study population

We selected individuals who had at least one year's prior registration with a CPRD practice on 1st September 2013. For reasons of confidentiality, CPRD patients' month and day of birth are not available to researchers. We therefore chose individuals born in the years 1933–1946, to ensure that we included those eligible for vaccination in the routine programme (individuals born 2/9/1942–1/9/1945, aged 68–70 years in September 2013) and those eligible for the catch-up programme (born 2/9/1933–01/09/1937, aged 76–79 in September 2013). Inclusion of the remaining individuals in the study added statistical power for determining age effects and extra person-time. In addition, including unvaccinated individuals who were ineligible (not of eligible age) for vaccination helped to mitigate potential confounding by health-seeking behaviour. This is because our unvaccinated group comprised not only those who were eligible for vaccination but did not come forward (who may be at different risk of zoster to eligible individuals who accepted vaccination), but also those who were similar in age but ineligible for vaccination (who would be less likely to be at different baseline risk of zoster to vaccinated individuals).

We excluded from the study population those who had no contact with their practice (a consultation or prescription) or other evidence of ongoing care (e.g. recording of test results) at any time from one year prior to 1st September 2013 until the end of the follow-up, to remove individuals who were inactive in the database. We also excluded those who had received zoster vaccine before the start of the national vaccination campaign, and those who at any point during the study period had an immunosuppressive condition or therapy that was a contraindication for zoster vaccination (Appendix A details how these conditions/therapies were identified).

2.3. Outcomes

Incident zoster diagnoses were identified using Read codes in the CPRD data, supplemented in those with linked hospitalisation data by diagnoses identified using ICD-10 (International Classification of Diseases, 10th revision) codes in the primary or secondary diagnosis fields of a hospitalisation (code lists are in Appendix B). If zoster codes occurred in both the CPRD and HES data, the earlier code was taken as the incident date. Individuals with ongoing zoster episodes at the start of the study period were not considered at risk of zoster for 365 days after their zoster incident date, or (for individuals with ongoing zoster consultations extending beyond a year) until 90 days after their last zoster code. Episodes beginning with a PHN code were also not included in analyses, as we could not ascertain whether these individuals had past zoster with ongoing PHN rather than an incident zoster episode; these individuals also started follow-up at the end of the episode.

We defined PHN as pain persisting $\geq$3 months after the zoster diagnosis [5]. Although there are specific Read and ICD-10 PHN codes, general practitioners often do not use them, instead recording consultations for pain or prescribed pain medications. We therefore used an update of our PHN algorithm, based on a validated algorithm developed for US administrative health data [18,19]. Briefly, we looked in the 90–365 days after the zoster diagnosis for evidence of: PHN codes; combinations of zoster codes, neuralgia codes and medications used to treat PHN; and referrals to pain clinics (full definitions are in Appendix C). As anticonvulsant drugs and codes for neuropathic pain/neuralgia comprised part of our PHN algorithm, we excluded from the PHN analysis patients with a history of epilepsy, other specific conditions that cause neuropathic pain, or trigeminal neuralgia. We also restricted patients to those with at least 365 days follow-up after a zoster diagnosis (or, for those who did not develop zoster, at least 365 days follow-up in the study period) to enable full assessment of PHN.

2.4. Vaccination status

This was determined from patients' immunisation, clinical, therapy and referral files in CPRD. Those with conflicting vaccination status on the same day (for example records indicating that the vaccine was both refused and given) were dropped from our study. Patients were considered fully vaccinated 42 days after the vaccine was given.

2.5. Covariates

A priori confounders of the relationship between vaccination status and the outcomes of interest included age, study year and calendar month. Further potential confounders included sex,

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