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The effectiveness of seasonal trivalent inactivated influenza vaccine in preventing laboratory confirmed influenza hospitalisations in Auckland, New Zealand in 2012

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ABSTRACT

Background: Few studies report the effectiveness of trivalent inactivated influenza vaccine (TIV) in preventing hospitalisation for influenza-confirmed respiratory infections. Using a prospective surveillance platform, this study reports the first such estimate from a well-defined ethnically diverse population in New Zealand (NZ).

Methods: A case test-negative design was used to estimate propensity adjusted vaccine effectiveness. Patients with a severe acute respiratory infection (SARI), defined as a patient of any age requiring hospitalisation with a history of a fever or a measured temperature ≥38 °C and cough and onset within the past 7 days, admitted to public hospitals in South and Central Auckland were eligible for inclusion in the study. Cases were SARI patients who tested positive for influenza, while non-cases (controls) were SARI patients who tested negative. Results were adjusted for the propensity to be vaccinated and the timing of the influenza season.

Results: The propensity and season adjusted vaccine effectiveness (VE) was estimated as 39% (95% CI 16;56). The VE point estimate against influenza A (H1N1) was lower than for influenza B or influenza A (H3N2) but confidence intervals were wide and overlapping. Estimated VE was 59% (95% CI 26;77) in patients aged 45–64 years but only 8% (−78;53) in those aged 65 years and above.

Conclusion: Prospective surveillance for SARI has been successfully established in NZ. This study for the first year, the 2012 influenza season, has shown low to moderate protection by TIV against influenza positive hospitalisation.

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1. Introduction

Influenza continues to cause a significant burden of illness in adults and children [1,2] despite vaccines having been used internationally for more than 60 years and being recommended by the World Health Organization [3]. Estimates of efficacy (from trials) and effectiveness (from observational studies) for seasonal trivalent inactivated vaccine (TIV) have been variable. An umbrella review of meta-analyses of community studies from 2005 to 2011 concluded that protection against laboratory-confirmed influenza (largely mild disease) by TIV ranged from 59 to 65% with estimates being similar in working age adults and children aged 2 years and above [4]. There have been too few trials in children under

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2 years for accurate estimates of efficacy in this age group [5,6]. Observational studies provide a range of effectiveness estimates from zero to approximately 60% protection in young children [7,8]. While studies specifically of older adults are less common, vaccine effectiveness (VE) has been reported to be as high as 57% in adults over 70 years [6], there are significant concerns over bias in studies in this age group [9] and other studies report much lower or even null estimates [10]. However significant variability by season is acknowledged [6] and increasing immunosenescence and the presence of comorbidities are likely to reduce effectiveness [6].

Results are more limited when reviewing protection against influenza-confirmed hospitalisation. No trials address this outcome. Estimates from observational studies include no protection by TIV against laboratory-confirmed influenza [11] to a protective range of 49% to 61% in adults [12–14]. Pooled European data for VE against A (H3N2) during 2011/2012 gave a point estimate for the target groups for vaccination of 29% with wide confidence intervals [15].

The antigenic composition of influenza vaccines is reviewed annually to predict the best match for a constantly evolving virus. The impact of vaccination is expected to be higher in the presence of a good antigenic match, although significant effectiveness has been shown even in seasons when the circulating strain is not a good match [16,17].

In New Zealand (NZ) seasonal unadjuvanted TIV is offered annually free of charge to all adults aged 65 years and over, pregnant women and all those over 6 months of age with chronic medical conditions that are likely to increase severity of infection. The vaccines are also available from early March on the private market for all others over 6 months of age. The influenza season usually occurs somewhere between early May and late September.

Using a case test-negative design (a modification to the case-control study design [18]), we aimed to estimate the effectiveness of seasonal TIVs in preventing hospitalised laboratory-confirmed influenza in persons aged at least 6 months who were admitted with an acute respiratory illness to public hospitals in Central, South and East Auckland between April 2012 and February 2013. The study reports results from the first year of a five year SHIVERS (Southern Hemisphere Influenza Vaccine Effectiveness, Research and Surveillance) project.

2. Methods

Ethics approval for the study was obtained from the Northern A Health and Disability Ethics Committee (NTX/11/11/102 AM02).

3. Study design

We used the standard case test-negative design [19] and a similar analytic approach to a previous study of hospitalised patients, with adjustment for the propensity to be vaccinated [13]. From 30 April 2012 to 28th February 2013 we attempted to enrol all individuals aged 6 months and older who were hospitalised with a severe acute respiratory infection (SARI). Based on the World Health Organization definition, this was defined as a patient requiring hospitalisation with a patient-reported history of a fever or a measured temperature $\geq$38 °C, cough and onset within the past 7 days [20].

A confirmed case of hospitalised influenza was defined as a SARI patient with a positive laboratory result for any influenza virus detected by real time reverse transcription polymerase chain reaction (RT-PCR) or viral isolation, while non-cases (controls) were those who tested negative to all influenza viruses.

Eligible patients were those admitted to the public hospitals Middlemore, Kidz First Children's, Auckland City and Starship Children's which together serve a population of approximately 838,000 people in Central, South and East Auckland. Recruitment was undertaken by trained research nurses. The nurses recruited patients during the day and screened all overnight admissions of febrile patients with respiratory symptoms daily from Monday to Saturday. Sunday admissions were captured on Mondays if the patients were still hospitalised.

All identified SARI cases who gave verbal consent completed a case report form, administered by a research nurse, and provided a nasopharyngeal swab or aspirate for influenza testing by RT-PCR and/or viral isolation.

Excluded from the analysis were patients transferred from another hospital, those see outside the influenza season, children under 6 months of age, patients who had not provided consent, patients with incomplete data for vaccination status or age, or patients who were swabbed more than 7 days after the onset of symptoms. At the end of the season, people with multiple SARI hospitalisations were excluded if their vaccination status differed between hospitalisations, otherwise the first influenza positive admission was used. Only the first in season hospital admission was used if a person had multiple admissions but no influenza positive admission.

4. Participant information

Demographic data collected for all cases and non-cases included age; sex; ethnicity (Māori, Pacific, Asian, NZ European or other); and income, with low income defined as a household that received either a government benefit or held a community services card. The age data were cross validated with hospital held electronic data. Clinical information was obtained from both the case report form and electronic data extraction from hospital databases. These data included clinical symptoms and signs; influenza vaccination status recorded on the case report form; smoking status; body mass index based on either measured weight and height or a visual estimation by the research nurses (using the categories obese, overweight, normal weight, underweight or unsure); a patient or caregiver reported measure of dependence, assessing requirement for assistance with normal activity or full dependency on nursing care; a simple frailty measure based on use of long term oxygen; any chronic medical conditions; and a self-defined health status score using the general health question from the SF36 [21] and combining fair or poor versus all others (the SF-36 is a generic, multi-purpose, short-form health survey that generates a functional health and well-being score).

The chronic medical conditions examined were the following: asthma, with the need for preventative therapy; diabetes; chronic obstructive pulmonary disease (COPD); other chronic lung disease; cardiac disease; cerebrovascular disease; moderate to severe cognitive impairment; other chronic neurological disease; psychiatric disorder (psychotic or major affective disorder); current alcohol or drug dependence; active cancer (excluding non-invasive skin cancer); immune deficiency condition (including asplenia, HIV/AIDS); immune suppressive treatment; chronic renal disease; or chronic liver disease (including cirrhosis, chronic hepatitis, transplant).

Vaccination status was recorded as fully vaccinated if the patient or caregiver reported influenza vaccination given during the current season at least 14 days prior to the onset of symptoms for which they were hospitalised. All children less than 9 years of age were recorded as fully vaccinated if they had received a vaccination in the season at least 14 days prior to onset of symptoms, and had ever received an earlier vaccine at least one month prior to the current vaccine. Children under 9 years of age who had received only one dose of vaccine in the season and no previous vaccine were considered partially vaccinated but were analysed as non-vaccinated.

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