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The effectiveness of seasonal trivalent inactivated influenza vaccine in preventing influenza hospitalisations and primary care visits in Auckland, New Zealand in 2013: provisional results

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Abstract

We present provisional estimates of influenza vaccine effectiveness (VE) for the NZ 2013 season. A case test-negative study was used to estimate propensity adjusted vaccine effectiveness. Influenza vaccination provided 52% (95% confidence interval (CI): 27% to 68%) protection against laboratory-confirmed influenza hospitalisation and 53% (95% CI: 28% to 70%) against laboratory-confirmed influenza in patients presenting to general practice.

Keywords

Influenza Vaccine; Vaccination; Immunization; Vaccine Effectiveness

Background

Influenza infection causes a significant burden of illness in adults and children [1, 2]. Seasonal trivalent influenza vaccines (TIV) are effective in preventing a range of laboratory confirmed outcomes [3], but effectiveness varies by severity and season, the presence of comorbidities and age [4, 5].

The SHIVERS study (Southern Hemisphere Influenza Vaccine Effectiveness, Research and Surveillance) has allowed estimation of vaccine effectiveness (VE) against hospitalised

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influenza since 2012 and against influenza presenting to primary care (general practice) since 2013.

In New Zealand (NZ) seasonal unadjuvanted inactivated TIV is available 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 on the private market for all others over 6 months of age. Two commercial vaccine products were available on the NZ market in 2013: Fluarix® (GlaxoSmithKline) and Fluvax® (bioCSL). Both vaccines contained A/California/7/2009 (H1N1)-like virus, A/Victoria/36/2011 (H3N2)-like virus and B/Wisconsin/1/2010-like virus (belonging to B/Yamagata/16/88 lineage).

Using the case test-negative design we estimated the effectiveness of these two seasonal TIV products in preventing laboratory-confirmed influenza in patients hospitalised with severe acute respiratory infections (SARI) and in patients presenting to general practice with an influenza-like illness (ILI) during the 2013 season.

Methods

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

Study Design

In both hospital and community settings, we conducted a standard case test-negative design [6] drawing on an urban population of approximately 838,000 people in Central, South and East Auckland,.

For community cases we undertook purposeful recruitment of 18 general practices, covering 103,884 enrolled patients representative of the population of the area. The practices recruited individuals aged 6 months and older who presented to a general practitioner or practice nurse with an ILI, defined as a history of fever or measured fever of ≥38°C and cough, with onset during the preceding 10 days [7].

For hospitalised patients we enrolled individuals aged 6 months and older who were admitted with SARI to one of the four public hospitals, Middlemore, Kidz First Children's, Auckland City and Starship Children's. Based on the World Health Organization definition, SARI was defined as hospitalisation with a patient-reported history of a fever or a measured temperature ≥38°C, cough, and onset within the past 10 days [8].

Recruitment was undertaken from 29 April to 29 September 2013.

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

All patients presenting to one of the sentinel general practices with suspected respiratory infections were screened by the general practitioner or nurse for ILI. All identified ILI cases were entered on an electronic form in the practice management system and a nasopharyngeal or throat swab was collected for influenza testing from all consenting patients.

SARI patients were identified following screening of admissions for respiratory disease by dedicated research nurses. Overnight admissions of patients with respiratory symptoms were screened the following day. All patients satisfying the SARI case definition were invited to participate. Patients who gave verbal consent completed a case report form and provided a nasopharyngeal swab or aspirate for influenza testing.

Excluded from the analysis were patients with incomplete data for vaccination status or age, children under 9 years who were only given one dose of TIV, patients who were vaccinated less than 14 days before admission, or patients who were swabbed more than 10 days after the onset of symptoms. For patients with multiple episodes the first influenza positive episode was used for analysis, or the first illness episode if there was no influenza positive episode.

Participant information

For all ILI cases, variables extracted from the electronic form and patient management system included age, sex, ethnicity, socioeconomic status as identified by the NZ deprivation status (a meshblock measure reflecting eight dimensions of deprivation distributed into deciles) [9], a subjective assessment of obesity by the clinician, chronic medical conditions and current smoking status.

Similar information was collected for all SARI patients but for this group we also collected a patient or caregiver reported measure of dependence (which assessed requirement for assistance with normal activity or full dependency on nursing care); a simple frailty measure based on use of long term oxygen; a history of chronic medical conditions; and a self-defined, standardised functional well-being health status score from a national survey [10], combining fair or poor well-being versus all others.

SARI case vaccination status for the 12 months prior to hospitalisation was determined by self-report with reliability assessed against electronic administrative records from nearly all general practices in the Auckland region. For ILI cases vaccination status was taken from the general practice record. In New Zealand almost all influenza vaccinations are administered in general practices.

Laboratory Methods

Nasopharyngeal swabs, aspirates and other respiratory samples were collected according to hospital or general practice standard procedures. Samples were tested using the United States Centers for Disease Control and Prevention real time RT-PCR protocol [11] or the AusDiagnostic PCR protocol.[12]. RT-PCR assays detected influenza virus types A and B and subtyping was performed for type A. All influenza positive PCR cases were forwarded to the National Influenza Centre and a convenience sample were characterised antigenically using established methods [13].

Statistical analysis

Univariate χ^2-tests were undertaken to compare characteristics of patients who were influenza positive (cases) and negative (controls). A multivariate logistic model was used to calculate an odds ratio (OR) for the propensity to bet vaccinated for a range of patient characteristic used in previous studies [13]. The results from the propensity model are presented as odds ratios and were used to adjust the VE estimate.

For both SARI and ILI, we calculated the crude VE, adjusting only for the timing of the presentation relative to the influenza season (defined as week from the peak), and the adjusted VE, which included the timing of the presentation and a variable calculated from the cubic spline of the fitted values of the propensity model. The season was defined as the period with continuous weeks with at least two laboratory-confirmed influenza cases. It began on the week of 10th June 2013 and was continuing at 27th September 2013 when the analysis period ended.

For all patient characteristics, other than age and vaccination status, each missing data point was imputed simply as the baseline (referent) value for that data point. The baseline values used were: non-Māori, non-Pacific ethnicity, female, not low income, not pregnant, non-smoker, without chronic disease, not obese, with self-rated health average or better, not on long term oxygen use and living without assistance. Sensitivity analyses were performed excluding individuals with missing data. VE estimates were calculated against both SARI and ILI, by influenza type and subtype and by age group (0–17, 18–64, 65+ years).

Results

A total of 886 SARI admissions and 1298 ILI patients were included in the analysis, of whom 182 (21%) and 391 (30%) were influenza positive, respectively. Of the 182 SARI admissions who tested inflenza positive, 67(38%) were vaccinated compared with 299/704 (42%) who tested negative. Of the 391 ILI admissions who tested inflenza positive 37 (9%) were vaccinated compared with 170/979(17%) who tested negative (Table 1).

Influenza positive cases and influenza negative controls were compared across a range of patient characteristics. Patients less likely to test influenza positive for SARI and ILI were vaccinated, aged 6 months to 5 years or over 80 years, or those presenting outside the influenza season. In comparision to the community patients, the hospitalised patients were more likely to be vaccinated, to be older, to live in a deprived area, to be of Māori or Pacific ethnicity, to be a current smoker and to be obese (Table 1).

Of the 573 influenza cases detected in both SARI and ILI patients, 357 (62%) were type A (252 H3N2, 40 H1N1 and 65 not subtyped) and 221 (39%) type B (55 B/Wisconsin/1/2010-like of the B/Yamagata lineage, 4 B/Brisbane/60/2008-like of the B/Victoria lineage and 162 where the B lineage was not determined) (Table 2). Five cases tested positive for both influenza A and B.

Although vaccination was more common in SARI patients, the same factors affected the propensity to be vaccinated in persons with ILI or SARI. The adjusted odds ratios for the

association of various patient characteristics with the likelihood of vaccination showed that older age groups and those with chronic diseases were most likely to be vaccinated (Table 3). In contrast, there was no statistically significant difference in the likelihood of vaccination by ethnicity, gender, income, pregnancy, obesity, self-rated health, smoking, assisted living or the timing of the admission relative to the influenza season (Table 3). Administrative GP records of vaccination were found for 215 (59%) and 33 (6%) SARI patients who reported being vaccinated and unvaccinated, respectively. Of the 151 SARI patients with unconfirmed self-reported vaccination, 112 (74%) reported they were vaccinated at their genearl practice.

Vaccine Effectiveness

The VE against all circulating strains, adjusted only for week from the peak of the season, was 28% (95% confidence interval (CI): −5;47) for influenza-confirmed SARI and 53% (95% CI: 29;68) for influenza-confirmed ILI (Table 4). After also adjusting for the propensity to be vaccinated, the estimated VE was 52% (95% CI: 27;68) for SARI and 53% (95% CI: 28;70) for ILI. Adjusting for the propensity to be vaccinated had more effect on the VE estimate for SARI than adjusting for week of onset. For ILI the VE crude and adjusted point estimates were the same. There was no significant change to these estimates when excluding patients with missing values (data not shown) or when a logistic regression model was constructed and directly adjusted for all the covariates in table 2. For example, for SARI patients the VE was 56% (95% CI: 28;73) using this model. Adjusting for only the variables that were significant in the model ($p<0.05$) resulted in a VE estimate of 55% (95% CI: 27,52).

The vaccine was significantly protective among patients aged 18–64 years. Specifically VE was 60% (95% CI: 26;78) against influenza-confirmed SARI and 60% (95% CI: 29;77) against influenza-confirmed ILI. In the 1,005 patients in this age group, 7 were pregnant and 241 had co-morbidities. VE point estimates for those aged 0–17 and 65+ years were similar (45% and 40%, respectively), although confidence intervals included zero (Table 4).

For ILI patients, VE against influenza A was 55% (95% CI: 24;74) and against influenza B was 53% (95% CI: 13;75). For SARI patients VE against influenza A was 42% (95% CI: 6;64) and against influenza B was 70% (95% CI: 40;84) (Table 4).

Most of the 40 A(H1N1) viruses characterized were closely related to A/California/7/2009 virus. Almost all of the 252 influenza A(H3N2) viruses characterized were similar to A/Victoria/361/2011-like virus. B/Yamagata lineage viruses were the predominant B viruses in New Zealand in 2013. Although this lineage was included in the 2013 Southern Hemisphere vaccine formulation, antigenic drift was observed in these viruses as they reacted better with ferret sera raised against B/Massachusetts/2/2012-like virus (selected for the Southern Hemisphere 2014 vaccine) than B/Wisconsin/1/2010 virus (included in the Southern Hemisphere 2013 vaccine).

Discussion

The 2013 NZ influenza season was characterised by low incidence and a late peak, with virus circulation continuing at the time of this analysis. Influenza A(H3N2) and influenza B predominated. The circulating influenza A sub-types were antigenically similar to the H1 and H3 components of the 2013 vaccine, while the predominant circulating B viruses were lineage matched, although antigenic drift was observed.

This is the first study comparing VE against medically attended ILI and hospitalised SARI due to laboratory confirmed influenza in in the same season in New Zealand. We have demonstrated moderate VE, around 50%, against both outcomes. There was unlikely to be a substantial difference in VE by severity of influenza illness, represented by ILI or SARI, although the study was not powered to test for this. Our estimates were made before the season had finished but they are late season estimates and are likely to be predictive of the final VE [14].

VE estimates were similar for all types and sub-types, with a tendency towards lower VE for H1N1, but based on small numbers. Except for the 18 to 64 year age group, where the vaccine prevented about 60% of both ILI presentations and SARI hospitalisations, the sample size was too small to make definitive VE estimates by age group. Our point estimate for VE against medically attended influenza-confirmed ILI was very similar to northern hemisphere estimates for the 2012/13 influenza season, with interim adjusted estimates of 56% from the US [15], a UK mid-season estimate of 51% (95% CI: 27;68) [16] and a Canadian interim estimate of 45% (95% CI: 13;66) [17].

While we collected information on most known potential confounding variables, we could not control for residual confounders. In future years we will collect data on previous presentations with respiratory illnesses and previous vaccination. New Zealand intends to add influenza vaccination to the national immunisation register in 2014. This will provide more accurate vaccination history than patient reported status for SARI patients.

In conclusion this study shows a moderate protective effectiveness of influenza vaccine against medically-attended and hospitalised influenza, supporting the current national immunisation strategy in New Zealand. The similarity of the VE estimates, obtained in the same population and at the same time, suggests that influenza vaccine has similar protective benefit against more severe hospitalised disease as against illness of mild to moderate severity. Pooled data from future SHIVERS years will allow more precise VE estimates for high risk subgroups and will also allow more extensive comparisons between VE estimates in primary care (general practice) and hospital settings.

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Appendix

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Table 1

Influenza-like illness and Severe Acute Respiratory Illness patient characteristics

	Hospitalised with Severe Acute Respiratory Illness		General Practice visit for influenza-like illness	
	Cases n=182	**Controls n=704**	**Cases n=391**	**Controls n=979**
Vaccinated n (%)	67(36.8%)	299(42.5%)	37 (9.5%)	170(17.4%)
Median Age (years)	49	40	27	23
Age Group 0 to 5 years	36(19.8%)	239(34%)	55(14.2%)	235(24.0%)
6 to 17years	10(5.5%)	27(3.8%)	116(29.7%)	209(21.4%)
18 to 45 years	39(21.4%)	116(16.5%)	146(37.3%)	333(34.0%)
46 to 64 years	41(22.5%)	129(18.3%)	58(14.8%)	153(15.6%)
65 to 79 years	42(23.1%)	120(17.1%)	14(3.6%)	43(4.4%)
80+years	14(7.7%)	73(10.4%)	2(0.5%)	6(0.6%)
Male	83(45.6%)	353(50.1%)	175(44.8%)	399(40.8%)
Maori	25(13.7%)	143(20.3%)	13(3.3%)	53(5.4%)
Pacific	62(34.1%)	206(29.3%)	82(21%)	201(20.5%)
Mean NZDep score (by decile)[1]	7	7.1	5	5
Pregnant	4(2.2%)	3(0.4%)	Not collected	Not collected
Smoker	21(11.5%)	76(10.8%)	23(5.9%)	58(5.9%)
Chronic Disease	110(60.4%)	435(61.8%)	Not collected	Not collected
Obese	30(16.5%)	103(14.6%)	17(4.4%)	42(4.3%)
SF36- (poor or fair)[2]	23(12.6%)	115(16.3%)	Not collected	Not collected
Long Term Oxygen use	4(2.2%)	19(2.7%)	Not collected	Not collected
Dependence	8(4.4%)	41(5.8%)	Not collected	Not collected
Pre-Season	8(4.4%)	184(26.1%)	25(6.4%)	374(38.2%)

[1] A meshblock measure reflecting eight dimensions of deprivation distributed into deciles

[2] A self-defined, standardised functional well-being health status score

Table 2

Types and subtypes of influenza positive cases by vaccination status in hospitalised and community study participants*

Influenza type	Hospitalised with Severe Acute Respiratory Illness (SARI)		General Practice visit for influenza-like illness (ILI)	
	Vaccinated (%)	Unvaccinated (%)	Vaccinated (%)	Unvaccinated (%)
All	67	115	37	354
A(H1N1)	6 (9%)	6 (5.2%)	3 (8.1%)	25 (7.1%)
A(H3N2)	37 (55.2%)	49 (42.6%)	15 (40.5%)	151(42.7%)
All A	53 (79.1%)	71(61.7%)	23 (62.2%)	210 (59.3%)
All B	14 (20.9%)	45 (39.1%)	14 (37.8%)	148 (41.8%)

* SARI case and 4 ILI cases tested positive for both influenza A and B. Not all cases of influenza A were sub-typed. Sub-types do not add to all influenza A.

Table 3

Severe Acute Respiratory Illness and Influenza-like Illness patient characteristics and their association with influenza vaccination status*

	Hospitalised with Severe Acute Respiratory Illness		General Practice visit for Influenza-like illness	
Characteristic	OR (95% CI)	P	OR (95% CI)	P
Age 6 months to 5 yrs	0.05 (0.02–0.1)	<0.01	0.1(0.05 – 0.19)	<0.01
Age 6 to 17 yrs	0.07 (0.02 – 0.24)	<0.01	0.21 (0.13 – 0.34)	<0.01
Age 18 to 45 yrs	0.32 (0.19 – 0.52)	<0.01	0.3 (0.2 – 0.46)	<0.01
Age 65 to 79 yrs	2.6 (1.54 – 4.37)	<0.01	5.1 (2.66 – 9.79)	<0.01
Age 80 + yrs	2.36 (1.23 – 4.53)	0.01	12.43(1.48 – 104.34)	0.02
Maori	0.62 (0.36 – 1.04)	0.07	0.93 (0.43 – 2.01)	0.85
Pacific	1.05 (0.65 – 1.7)	0.85	0.69 (0.41 – 1.18)	0.18
Male	0.97 (0.82 – 1.13)	0.67	0.71 (0.5 – 1.01)	0.06
NZDep score	1.03 (0.96 – 1.11)	0.36	0.97 (0.91 – 1.04)	0.44
Pregnant	1.18 (0.21 – 6.72)	0.85	Not collected	
Smoker	1.03 (0.61 – 1.71)	0.92	0.61 (0.31 – 1.21)	0.16
Chronic disease	1.74 (1.08 – 2.82)	0.02	Not collected	
Obese	1.05 (0.65 – 1.72)	0.83	1.48 (0.72 – 3.05)	0.29
Sf36-	1.11 (0.67 – 1.84)	0.69	Not collected	
Frailty	3.32 (0.91 – 12.07)	0.07	Not collected	
Dependence	1.58 (0.67 – 3.73)	0.29	Not collected	
Early Season	0.72 (0.41 – 1.29)	0.27	1.06 (0.62 – 1.82)	0.83
Weeks from influenza peak	0.98 (0.92 – 1.03)	0.37	0.98 (0.93 – 1.03)	0.39

*Adjusted odds ratio compared to referent group: female, aged 46 to 64 years, non-Māori non-Pacific ethnicity, not low income, not pregnant, non-smoker, without chronic disease, not obese, with self-rated health average or better, not on long term oxygen use, living without assistance and admitted to hospital for SARI during the influenza season.

Table 4

Estimated vaccine effectiveness (VE), overall by age group and by influenza type and sub-type: crude and propensity adjusted models.

		Hospitalised with Severe Acute Respiratory Illness		General Practice visit for Influenza-like illness	
		Crude Model*	Propensity Adjusted Model*	Crude Model*	Propensity Adjusted Model*
		VE % (95%CI)	VE% %(95% CI)	VE % (95% CI)	VE %(95% CI)
	Overall	28 (−4, 51)	52 (27, 68)	53 (29, 68)	53 (28, 70)
Influenza type or sub-type	A(H1N1)	−35 (− 325, 57)	18 (−173, 75)	44 (−88, 83)	40 (−121, 84)
	A(H3N2)	10 (− 50, 46)	37 (− 11, 64)	54 (18, 75)	59 (23, 78)
	All A	7 (− 43, 40)	42 (6, 64)	50 (18, 70)	55 (24, 74)
	All B	60 (25, 79)	70 (40, 84)	57 (22, 76)	53 (13, 75)
Age Group (years)	0 to 17	52 (−131, 90)	69 (−59, 94)	42 (−31, 74)	45 (−24, 76)
	18 to 64	61 (29, 79)	60 (26, 78)	63 (35, 79)	60 (29, 77)
	65 +	46 (−22, 76)	47 (−21, 77)	41(−147, 86)	40 (−154, 86)

*All models were adjusted for the timing of the admission relative to the influenza season by including a term for a pre-season admission and for those admitted in the influenza season adjusting for the number of weeks from the influenza peak.