Effectiveness of the Trivalent Seasonal Influenza Vaccine of Hong Kong Institutionalized Elderly: A 12-month Retrospective Cohort Study

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Background

- Since the 2009 H1N1 influenza pandemic
- Influenza A/H1N1 2009 was included in Trivalent influenza vaccine in subsequent year
- Low vaccination rate
  - Fear of side effects
  - Unsure clinical effect
- No previous study conducted in Residential Care Homes for the Elderly (RCHEs).

Objective

- To investigate the effects of Trivalent influenza vaccine used in annual vaccination program 2010/2011 in RCHEs elderly in Hong Kong
  - Major adverse effect
  - Laboratory confirmed seasonal influenza infection
  - Influenza-like illnesses (ILI)
  - Mortality
  - Hospitalization

Methodology

12-month retrospective cohort study
- December 2010 to December 2011

Methodology

- Inclusion criteria
  - Elderly aged 65 or above
  - One RCHE which is under care of Community Geriatric Assessment Team (CGAT)
- Exclusion criteria
  - Advanced stage malignancy

Methodology

- Sample size
  - 183 residents

- Setting
  - 1 RCHE covered by HKWC CGAT

Methodology

- 2 groups of residents
  - Vaccinated group
    - Vaccinated using the vaccine in annual vaccination program 2010/2011
    - 119 (65%) received the vaccine
- Unvaccinated group / control group
  - Not vaccinated
  - 64 (35%) refused to receive

Vaccination done by Visiting Medical Officer (VMO) under Residential Care Home Vaccination Programme (RVP) (Department of Health) with consent

Data collected

- Vaccination status
- Gender
- Age
- Frailty of elderly
  - Charlson Co-morbidity index (CCI)

Data Collection

Through computer management system (HA) and medical/nursing record of RCHE

- Major adverse effect

- Laboratory confirmed influenza infection

- Influenza-like illnesses infection

- Mortality
  - All cause mortality

  - Mortality due to pneumonia

- Hospitalization
  - All cause hospitalization

  - Hospitalization due to pneumonia

Results

Table 1. Baseline characteristics of participants

	Influenza vaccine 2010		
	Vaccinated (n*=119)	Not vaccinated (n*=64)	P value
Gender*			
Male	36 (30.3%)	32 (50%)	0.008**
Female	83 (69.7%)	32 (50%)	
Age†			
Mean $\pm$ SD	84.7 $\pm$ 7.7	84.9 $\pm$ 7.1	0.81
Range	65-106	65-102	
Charlson Comorbidity Index‡	2.78 $\pm$ 2.08	3.11 $\pm$ 2.43	0.34

n = number of person
** p<0.05 significant at 95% confidence level

† Independent t-test was used.
* Chi-square test was used.
‡ Mann-Whitney U-test

Adverse effect

- Among all recipient
    - No major adverse effect detected

Table 2. Laboratory confirmed Influenza infection and Influenza-like illnesses for all participants in different vaccination groups

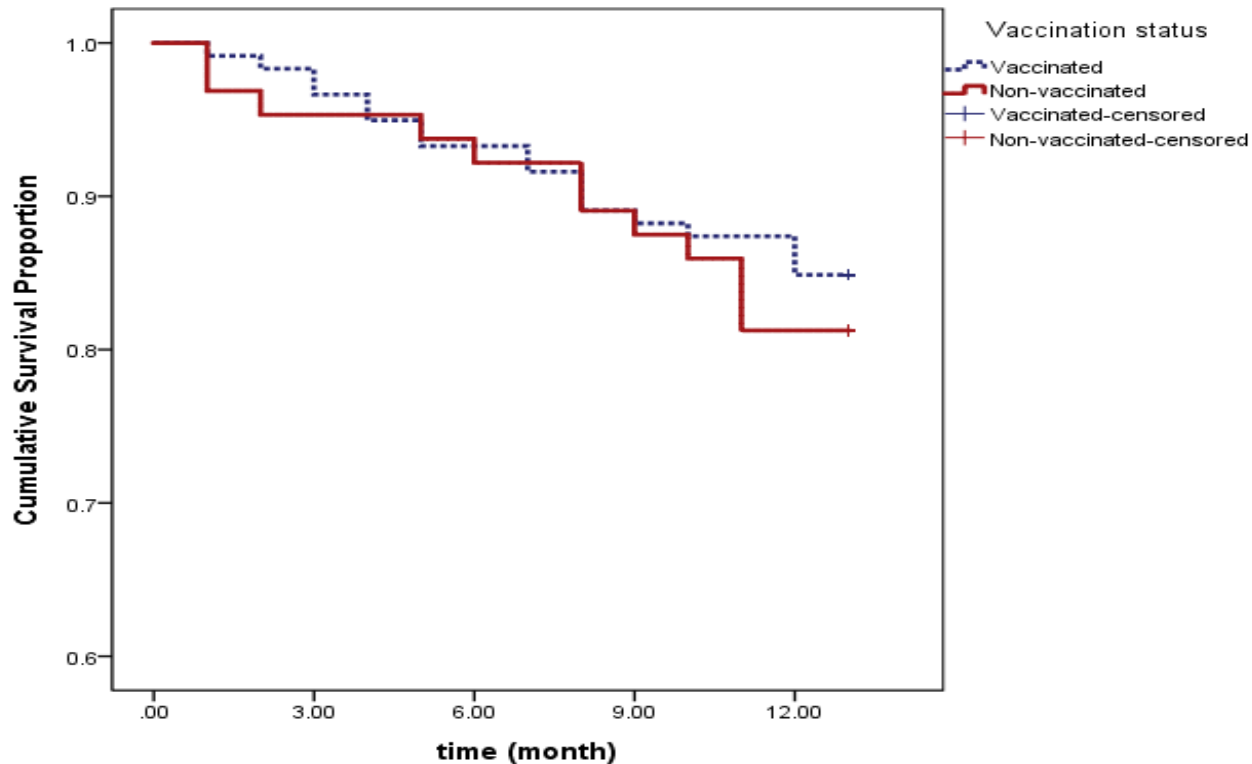|	Influenza vaccine 2010		
	Vaccinated (n*=119)	Not vaccinated (n*=64)	P value‡
Laboratory confirmed Influenza infection	3 (2.5%)	1 (1.6%)	1.0
Influenza-like illnesses	18 (15.1%)	6 (9.4%)	1.0

n = number of person
‡ Mann-Whitney U-test

Table 3. Hospitalization for all participants in different vaccination groups

Hospitalization	Influenza vaccine 2010		
	Vaccinated (n*=119)	Not vaccinated (n*=64)	P value‡
Influenza infection	3 (2.5%)	1 (1.6%)	1.0
Influenza-like illnesses	3 (2.5%)	1 (1.6%)	1.0
Pneumonia	37 (31.1%)	17 (26.6%)	0.611
All cause	75 (63.0%)	37 (57.8%)	0.527

n = number of person
‡ Mann-Whitney U-test

# Figure 1. Kaplan-Meier Curve of 12-month all cause mortality for participants in different vaccination groups

	Influenza vaccine 2010	
	Vaccinated	Not vaccinated
Death at 12 months (number / %)	18 (15.1)	12 (18.8)
Survival at 12 months (number / %)	101 (84.9)	52 (81.2)
Total (number / %)	119 (100)	64 (100)
Comparison by Log-Rank test: p=0.54		

Figure 2. Kaplan-Meier Curve of 12-month mortality due to pneumonia for participants in different vaccination groups
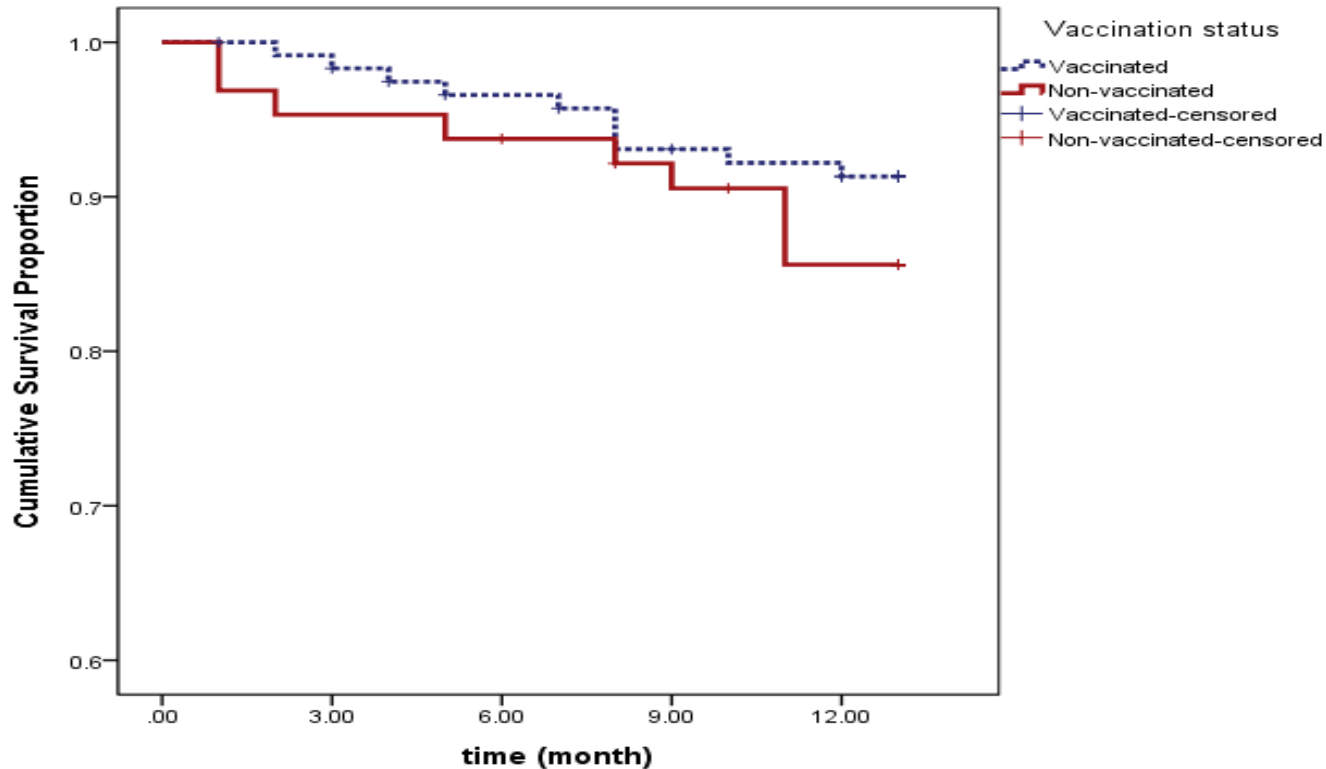
	Influenza vaccine 2010	
	Vaccinated	Not vaccinated
Death at 12 months (number / %)	10 (8.4)	9 (14.1)
Survival at 12 months (number / %)	109 (91.6)	55 (85.9)
Total (number / %)	119 (100)	64 (100)
Comparison by Log-Rank test: p=0.25		

Discussion

- All outcome differences between the two groups were not statistically significant.

- By observation of the Kaplan-Meier Curve, survival rate of vaccinated group is higher than non-vaccinated group

Limitations of the study

- Sample size is too small
  - Data collection was performed in one RCHE
- Not double blind controlled trial -- participants were not randomized
- No adjustment of pneumococcal vaccination

Conclusion

- Trivalent influenza vaccine 2010/2011 is safe
- However, its efficacy in reducing laboratory confirmed seasonal influenza infection, influenza-like illnesses (ILI), mortality and hospitalization has not been demonstrated in this study

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- HKWC Sub-vented Home in charge

Thank you

Influenza Vaccine Composition

The viral-strain composition recommended by the Scientific Committee on Vaccine Preventable Diseases in 2010-2011 (northern hemisphere winter) contains the followings:
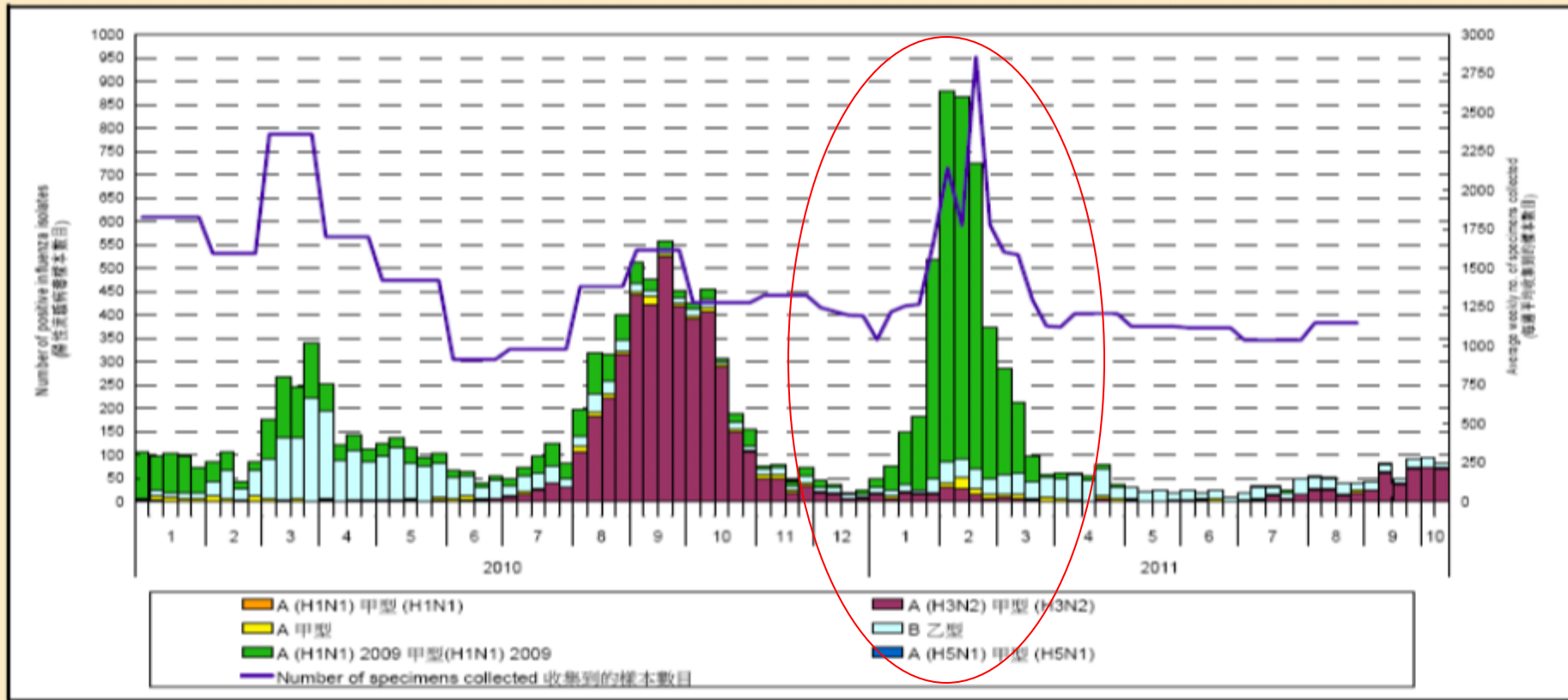
- A/California/7/2009 (H1N1)-like virus
- A/Perth/16/2009 (H3N2)-like virus
- B/Brisbane/60/2008-like virus

Ethics

- Formally approved by IRB HA HKWC

Influenza virus detections (Laboratory surveillance), 2010-11
流行性感冒病毒化驗數目 (實驗室監測), 2010-11

H1N1 (2009)

– The major isolated strain of influenza in 2010 to 2011

– Jan to March 2011: more than 80% isolated strain in laboratory was H1N1 (2009)

Charlson Comorbidity Index (ICD-9-CM)

Scoring	Comorbidity
1	Myocardial Infraction
	Congestive Heart Failure
	Peripheral Vascular Disease
	Cerebrovascular Disease
	Dementia
	Chronic Pulmonary Disease
	Chronic Rheumatic Disease
	Peptic Ulcer Disease
	Mild Liver Disease
	Diabetes without Chronic Complication

Scoring	Comorbidity
2	Diabetes with Chronic Complication
	Hemiplegia
	Renal Disease
	Tumor without Metastasis
3	Moderate or Severe Liver Disease
6	Metastatic Solid Tumor
	AIDS

Proper sample size

- The most important limitation in this study is the sample size is too small.

- Power analysis and sample size 2008 (windows version 2008) was used in sample size calculation.

- It showed that a group **sample size of 1004** and **502 in treatment and control** group respectively **with 2:1 ratio** would be able to achieve a 80% power to detect a difference in proportion of 0.05 over 1 year between the null hypothesis and the alternative hypothesis using a two side chi square test with continuity correction and with significance level of 0.05.
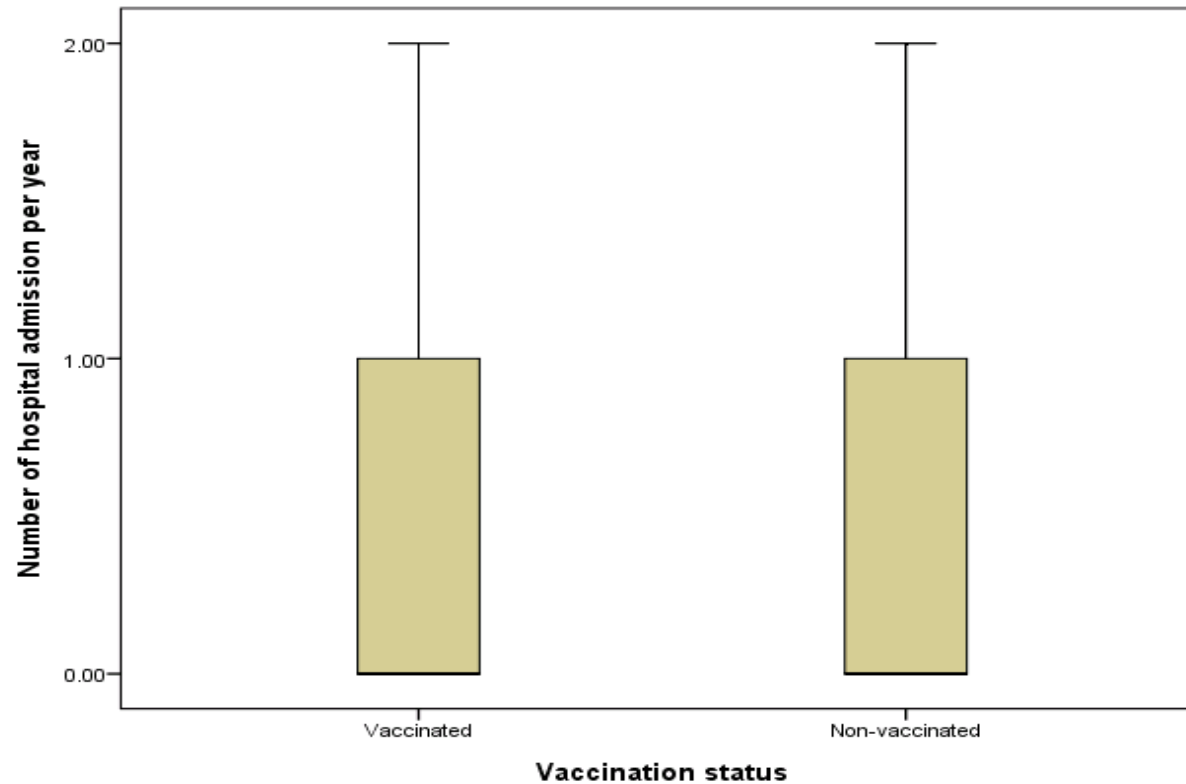
Figure 3. Boxplot diagram for number of all cause hospitalization in different vaccination status
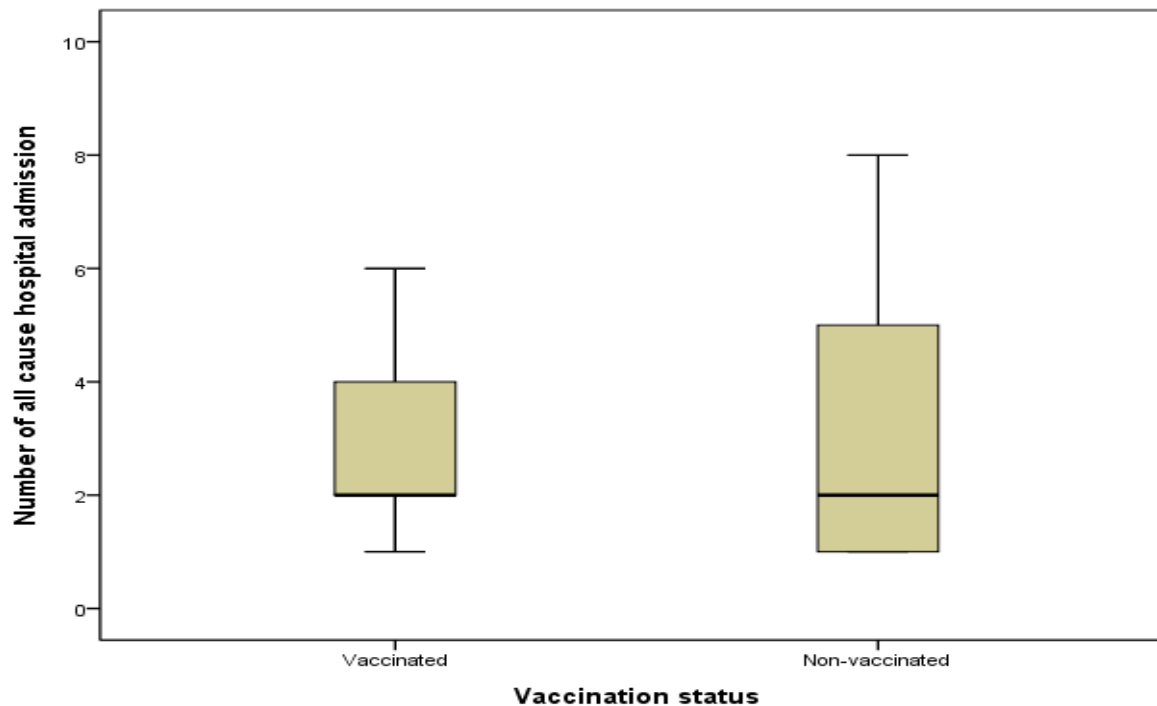
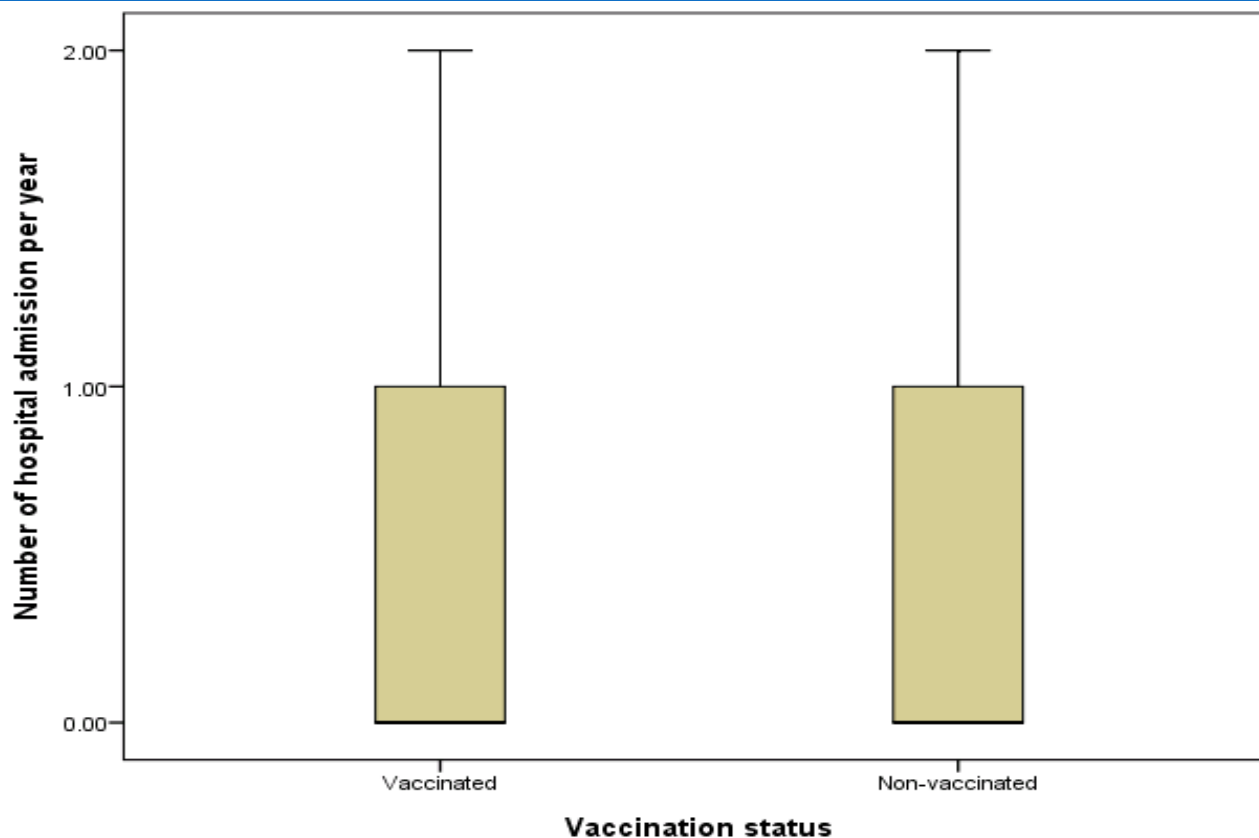|	Influenza vaccine 2010		
	Vaccinated (n=119)	Not vaccinated (n=64)	P value‡
Number of hospitalization per year	2 (2-4)	2 (1-5)	0.447

‡   Mann-Whitney U-test

Figure 4. Boxplot diagram for number of hospitalization for pneumonia in different vaccination status

	Influenza vaccine 2010		
	Vaccinated (n=119)	Not vaccinated (n=64)	P value‡
Number of hospitalization per year	0 (0-1)	0 (0-1)	0.88
‡ Mann-Whitney U-test			

Figure 5. Boxplot diagram for number of hospitalization for "influenza" + "influenza like illnesses" + "pneumonia" in different vaccination status

	Influenza vaccine 2010		
	Vaccinated (n=119)	Not vaccinated (n=64)	P value[‡]
Number of hospitalization per year	0 (0-1)	0 (0-1)	0.85

‡ Mann-Whitney U-test

Table 3. Hospitalization for all participants in different vaccination groups

Hospitalization	Influenza vaccine 2010		
	Vaccinated (n*=119)	Not vaccinated (n*=64)	P value‡
Influenza infection	3 (2.5%)	1 (1.6%)	1.0
Influenza-like illnesses	3 (2.5%)	1 (1.6%)	1.0
Pneumonia	37 (31.1%)	17 (26.6%)	0.611
Influenza + Influenza-like illnesses + Pneumonia	43 (36.1%)	19 (29.8%)	0.621
All cause	75 (63.0%)	37 (57.8%)	0.527

n = number of person
‡ Mann-Whitney U-test