



## Influenza vaccine in Hajj pilgrims: Policy issues from field studies

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### ABSTRACT

In pilgrims returning to the UK from the Hajj in 2005 and 2006, protection from PCR-confirmed influenza by influenza vaccine was estimated using verified vaccination histories from those with symptoms consistent with influenza. Of 538 patients whose nasal swabs were analysed and immunisation histories confirmed 115 (21%) were in a high-risk group for influenza; half of these (58/115) were immunised against influenza, compared with a fifth (90/423) of those not at high risk. Five percent of vaccinated 'at risk' pilgrims compared with 14% of unvaccinated (RR 0.37, 95% CI 0.1–1.4) had confirmed influenza. Rates of influenza in vaccinated and unvaccinated 'not at risk' pilgrims were similar (10% vs. 11%). Seasonal influenza vaccine was insignificantly protective against influenza in Hajj pilgrims.

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### 1. Introduction

Influenza is the commonest vaccine preventable infection among travellers to the tropics and subtropics [1]. With an incidence of one influenza-associated events per 100 person months abroad, it accounts for 38% of the viruses causing respiratory infections among travellers [1,2]. Transportation, prolonged air terminal waits, long haul flights, close contact in tour groups and shared accommodation contribute to the spread of influenza among travellers, but tourists who attend mass gatherings are at exceptionally high risk of the infection due to the extended close contact and overcrowding [3–5].

The Hajj pilgrimage in Mecca, Saudi Arabia is the largest annual congregation on the earth and has been occurring at the same venue and at the same time of lunar calendar for the last 14 centuries. The attack rate of influenza at the Hajj is reported to be as high as 38% despite vaccination [6].

As Saudi Arabia is in the tropical sphere, influenza is expected to occur in two different peaks corresponding to the winter seasons of northern and southern hemispheres or even throughout

the year [7]. As separate influenza vaccines are formulated for each hemisphere of the globe in accordance with the information of the commonest circulating strains, vaccinated pilgrims from northern hemisphere to Saudi Arabia could still be at risk of exposure to the southern strains and vice versa.

Qureshi et al. demonstrated that vaccinated pilgrims had lower frequency of influenza-like illnesses (ILIs) as compared to their unvaccinated counterparts, but because their study was without virologic confirmation efficacy of the vaccine could not be proven [8]. We therefore estimated the capacity of influenza vaccine to prevent PCR-confirmed influenza infections among Hajj pilgrims in a series of surveillance studies conducted during the winters of 2005 and 2006.

### 2. Methods

Fine details of patient selection, ethical background, data collection and diagnostic methods have been described elsewhere [9]. Briefly, the study was an enhanced surveillance for serious infections project, especially ILIs that was established at the Hajj during the previous years with prior ethical approval from Multi-centre Research Ethics Committee (Ref: MREC 02/2/12), UK. Patients with respiratory symptoms such as cough, sore throat, fever and rhinorrhoea attending or returning from the Hajj in 2005 and 2006 were invited to participate. The Hajj took place during the northern hemisphere winter months (December–January) of those years

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and therefore the pilgrims received the northern seasonal vaccine of 2004–2005 and 2005–2006, respectively.

After obtaining clinical and vaccination details, nasal swabs were collected from pilgrims in Mecca during the Hajj or in UK mosques after the Hajj for influenza RT-PCR tests which were carried out at the Health Protection Agency (HPA) laboratories in London using their standard protocols. Vaccination data including the dates of immunisations were subsequently verified by primary care providers.

Pilgrims with underlying immunosuppressive medical conditions and those over the age of 65 years were grouped as 'at risk' and the remainders as 'not at risk' and the data from studies in two Hajj years were stratified into these two groups. Attack rates of influenza among vaccinated 'at risk' pilgrims were compared with those of unvaccinated 'at risk' pilgrims. Similarly the attack rates of influenza among vaccinated 'not at risk' pilgrims were compared with those of unvaccinated 'not at risk' pilgrims.

Efficacy estimates against virologically confirmed influenza (as well as antibiotic use and hospital visits during the Hajj) were summarised as relative risk (RR) with 95% confidence intervals (95% CI) and proportions were compared using Chi-square test.

### 3. Results

#### 3.1. Demography

A total of 567 pilgrims were recruited during the two Hajj seasons, 51% (292/567) in 2005 during and immediately after the Hajj, and the rest 49% (275/567) in 2006. British travellers comprised 76% (432/567) of the recruits followed by Saudi Arabian pilgrims (20%, 113/567). The remaining pilgrims (4%, 22/567) came from several other countries notably Bangladesh, Pakistan, Canada and the USA; thus all our recruits were from northern hemisphere. They stayed at the Hajj for 12–52 days (mean 33 days). The major presenting symptoms of the patients were sore throat 75% (428/567), cough 72% (411/567), rhinorrhoea 64% (364/567) and fever 46% (263/567). All but nine consented to having nasal swabs taken and three swabs were lost, so that a total of 555 swabs were analysed (Fig. 1).

Of 555 pilgrims whose swabs were analysed 498 (90%) were men, aged 1–85 (median 41) years, 51 (9%) were over 65. Ethnically 172 (31%) were Bangladeshi, 166 (30%) Pakistani, 68 (12%) Saudi Arabian, 47 (8%) Indian, 40 (7%) 'African', 24 (4%) other Asian and 17 (3%) belonged to other ethnicities. Ethnic background was unknown in the rest 21 (4%).

One hundred and twenty pilgrims (21%) were categorised at risk of influenza; one-third ( $n=40$ ) solely because of old age ( $\geq 65$  years) and the rest ( $n=80$ ) due to chronic medical conditions (at any age) such as diabetes (37%,  $n=44$ ), lung diseases including bronchial asthma (17%,  $n=20$ ), and heart (13%,  $n=15$ ) and kidney diseases 1 (1%). Of 80 pilgrims with chronic medical conditions 11 (14%) were also aged  $\geq 65$  years.

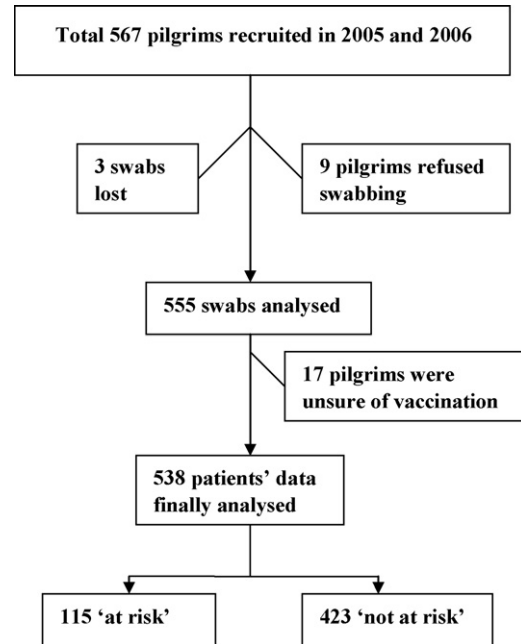


Fig. 1. Flow chart showing the recruitment of the pilgrims.

Of 120 'at risk' pilgrims 58 (48%) received the seasonal influenza vaccine 3–17 weeks (mean 8 weeks) before travelling on the Hajj, 57 (48%) did not and 5 (4%) could not recall if they had received the vaccine. Of 435 'not at risk' pilgrims 90 (21%) received the vaccine 4–20 weeks (mean 8 weeks) before travel, 333 (77%) did not and 12 (3%) could not recall if they had received the vaccine. Therefore, of total 555 pilgrims who underwent virological surveillance 148 (27%) received influenza vaccine and 390 (70%) did not. Except two physicians who received the vaccine from their own hospitals, all other pilgrims had it given by their primary care providers (e.g., GPs). Vaccination status of the remaining 17 (3%) pilgrims was unknown and therefore excluded from further analysis (Fig. 1).

Characteristics of 'at risk' and 'not at risk' vaccinated and unvaccinated pilgrims were similar except that more females among 'not at risk' pilgrims were vaccinated (19% vs. 8%,  $P=0.004$ ) (Table 1).

#### 3.2. Protectiveness of influenza vaccine

Eleven percent (30/282) pilgrims in 2005 and 10% (28/273) in 2006 had influenza ( $P=0.883$ ). Of a total of 58 virus detections, 45 (78%) were influenza A and 13 (22%) influenza B.

On the whole, the proportion of influenza infection among vaccinated and unvaccinated pilgrims was 8% (12/148) and 12% (45/390), respectively ( $P=0.255$ ).

Table 1

Characteristics and the proportion of influenza infections, antibiotic use and hospital visits in vaccinated unvaccinated pilgrims

	At risk group				Not at risk group			
	Vaccinated $n$ (%)	Unvaccinated $n$ (%)	RR	95% CI (LL–UL)	Vaccinated $n$ (%)	Unvaccinated $n$ (%)	RR	95% CI (LL–UL)
Sample size	58	57			90	333		
Mean age	56	55			44	37		
Male:female	10:1	10:1			4:1	11:1		
Influenza	3 (5)	8 (14)	0.37	0.1–1.4	9 (10)	37 (11)	0.90	0.41–1.8
Antibiotic use	19 (33)	12 (21)	1.56	0.8–3.1	26 (29)	79 (24)	1.22	0.81–1.8
Hospital visit	8 (14)	1 (2)	7.86	1.1–169.9	12 (13)	24 (7)	1.85	0.9–3.7

RR: relative risk, 95% CI: 95% confidence interval, LL: lower limit of the confidence interval, UL: upper limit of the confidence interval.

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