# Cost-benefit evaluation of routine influenza immunisation in people 65–74 years of age

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# **Executive summary**

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# **Objectives**

To determine the cost-effectiveness of influenza vaccination in people aged 65–74 years in the absence of co-morbidity.

# Design

Primary research: randomised controlled trial.

# Setting

Primary care.

# **Subjects**

People without risk factors for influenza (diabetes, asthma, chronic heart, lung or renal disease, immunosuppression or living in an institution) or contraindications to vaccination were identified from 20 general practitioner (GP) practices in Liverpool in September 1999 and invited to participate in the study. There were 5875/9727 (60.4%) people aged 65–74 years identified as potentially eligible for entry into the study and, of these, 729 (12%) were randomised. The remaining 39.6% of people in this age group had one or more risk factors for influenza making them eligible for vaccination according to guidance from the Department of Health and so could not be included in this study.

# Intervention

Participants were randomised in a ratio of 3:1 to receive either influenza vaccine or placebo (physiological saline solution), with all individuals receiving pneumococcal vaccine unless administered in the previous 10 years. Of the 729 people randomised, 552 received vaccine and 177 received placebo; 726 individuals were administered pneumococcal vaccine. Influenza vaccine was manufactured in accordance with the WHO recommendation (Northern Hemisphere) for 1999–2000 and contained the following antigens: A/Beijing/262/95 (H1N1), A/Sydney/5/97 (H3N2) and B/Beijing/184/93.

## Main outcome measures

GP attendance with influenza-like illness (ILI) or pneumonia (primary outcome measure); GP attendance with respiratory symptoms; hospitalisation with a respiratory illness; death; participant self-reported ILI; quality of life (QoL) measures (EuroQoL EQ-5D and Hospital Anxiety and Depression scale) at 2, 4 and 6 months poststudy vaccination; adverse reactions 3 days after vaccination. All outcome measures were recorded between 1 October 1999 and 31 March 2000.

# Methodology of economic evaluation

The economic analysis was undertaken from a societal perspective and incorporated both public and privately borne costs associated with the vaccination programme. A cost-effectiveness analysis was undertaken to identify the incremental cost associated with the avoidance of episodes of influenza in the vaccination population. As many episodes of influenza may not lead to a GP consultation (sufferers simply 'take to their bed'), a patient-held diary was employed to identify such 'invisible' episodes of ILI. An impact model was used to extrapolate the cost-effectiveness results obtained from the trial to assess their generalisability throughout the NHS.

# Results

#### Background influenza rate

The background influenza rate in Liverpool in 1999–2000 was very similar to the overall rate in England and Wales where weekly consultations for influenza and ILI remained at baseline levels (less than 50 per 100,000 population) until week 50/1999 and then increased rapidly, peaking during week 2/2000 with a rate of 231/100,000. This rate fell within the range of 'higher than expected seasonal activity' of 200–400/100,000. Rates then quickly declined, returning to baseline levels by week 5/2000. The predominant circulating strain during this period was influenza A (H3N2).

#### **Clinical outcome**

Five (0.9%) people in the vaccine group were diagnosed by their GP with an ILI compared to two (1.1%) in the placebo group [relative risk (RR), 0.8; 95% confidence interval (CI) = 0.16 to 4.1]. No participants were diagnosed with pneumonia by their GP and there were no hospitalisations for respiratory illness in either group. Significantly fewer vaccinated individuals self-reported a single ILI (4.6% vs 8.9%, RR, 0.51; 95% CI for RR, 0.28 to 0.96). There was no significant difference in any of the OoL measurements over time between the two groups. Reported systemic side-effects (feverishness, aching limbs, fatigue, rash, cough, runny nose, headache and sore throat) showed no significant differences between groups. Local sideeffects occurred with a significantly increased incidence in the vaccine group (11.3% vs 5.1%, p = 0.02).

#### **Economic evaluation**

Each GP consultation avoided by vaccination was estimated from trial data to generate a net NHS cost of £174.

## Conclusions

No difference was seen between groups for the primary outcome measure (GP attendance with ILI or pneumonia), although the trial was underpowered to demonstrate a true difference. Vaccination had no significant effect on any of the QoL measures used, although vaccinated individuals were less likely to self-report ILI.

# Implications for healthcare

Our analysis did not suggest that influenza vaccination in healthy people aged 65–74 years would lead to lower NHS costs. A significant protective effect of influenza vaccine was found for the reduction of self-reported ILI, but the study was not sufficiently powered to examine the effect of influenza vaccination on mortality, GP consultations for respiratory illness or hospital admissions for pneumonia- and influenzaassociated respiratory illness.

## **Recommendations for future** research

Following the introduction in 2000–1 of new Department of Health guidelines to include all people aged 65 years or more in the national vaccination programme, future research should look at ways to maximise vaccine uptake in people at greatest risk from influenza, especially older people (>80 years) and those living in nursing and residential accommodation. Research is also needed to investigate the level of vaccine protection afforded to people from different age and socio-economic populations.

# **Publication**

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