



Available evidence insufficient to assess safety and effectiveness of flu vaccines for older people

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Commentary on: **Jefferson T, Di Pietrantonj C, Al-Ansary LA, et al.** Vaccines for preventing influenza in the elderly. *Cochrane Database Syst Rev* 2010;**2**:CD004876.

10.1136/ebn1064

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Vaccines for preventing flu in older people

Flu is a major cause of morbidity and mortality, and one of the cornerstones of its control is annual vaccination. This Cochrane Review looks at the prevention of seasonal flu in people aged over 65 years. Despite finding a large number of studies, the authors were unable to come to a conclusion about the effect of vaccination in this group, in part because of the low methodological quality of the studies reviewed.

Vaccine research is complex, and the complexities are multiplied when disparate studies are combined, which also probably accounts for some of the lack of effect seen. First are the general research issues of defining variables, in particular which outcomes should be measured. The primary outcomes were those related to the number of cases of flu or flu-like illness and flu-related complications. As the authors note, there are a variety of case definitions of flu, making direct comparison extremely difficult and potentially misleading.¹ In addition, a variety of designs can be used, including randomised controlled trials, cohort studies and case-control studies, each of which has a valid, but different, place in vaccine research.

The purposes of vaccination also need to be considered. All vaccines aim to prevent or reduce disease severity in the recipient, but sometimes the additional effect of herd immunity is required. Flu is not particularly infectious in comparison with many other viruses,² so herd immunity should be relatively easy to achieve. However, this is clearly not possible if vaccination is restricted to particular groups, unless the infection is found only in those groups, which is not the case in the studies reviewed here.

An adverse event is not necessarily a side-effect

The secondary outcome of the review concerned adverse events. It is good to note that the term 'side-effects' was not used, as many apparently adverse events, including local tenderness and fever, may be the result of stimulating the immune system and are therefore a good if unpleasant outcome. Although it is important to be vigilant, miscategorisation of a normal response or chance happening as an adverse effect may have a damaging influence on vaccine uptake.³

Immunity to flu

One key issue specific to flu vaccination is variation in the circulating viruses. Flu changes in two ways – antigenic

drift and antigenic shift – and it is the latter that leads to epidemic and pandemic strains.⁴ Because vaccines have to be produced and distributed before they can be administered, a judgement has to be made about the composition of the vaccine some months before the flu season.⁵ The accuracy of the forecast about which strains are likely to circulate is therefore crucial to the effectiveness of flu vaccines.

In the review, the authors variously refer to 'efficacy' and 'effectiveness'. It is important to differentiate these two terms: efficacy refers to the effect that the intervention has in the study, and effectiveness refers to its effect in the clinical situation.⁶ An added complexity is that there then has to be a decision about efficiency: is the vaccine worth giving, and is it affordable? This is a value judgement based on a number of considerations, only one of which is effect, and this often accounts for the differences in vaccination schedules.⁷

Importance of vaccination

Although the authors of this study were unable to come to an overall conclusion, this was, as they note, probably due in large part to methodological limitations, many of which are inherent in vaccine research and are exacerbated in the case of flu. However, within the literature there is good evidence for the beneficial effect of flu vaccination, and there are likely to be moves to increase the recommended groups in most countries in the future.

Competing interests None.

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