

Evidence hunters versus public health workers

13 November 2006



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Though there is little new in this review article (much is reiterating previous publications by the same author [1-3]) and there are significant gaps in the data he presents [4] the views of the author require careful consideration. This is especially the case since the article appeared at a time when flu vaccination campaigns are at their peak in most European countries and the paper was interpreted by the media in some countries as meaning that immunisation of the recognised risk groups (the elderly, those with chronic diseases and health care workers) was of no value. We are really concerned about the conflicting views that sometimes exist between "evidence hunters" and public health workers, even though we are sure that a serene scientific discussion at the proper time can benefit prevention policies.

The author considers two issues which we wish to comment on:

Effectiveness. "The heavy reliance on non-randomised studies (chiefly cohort studies) especially in the elderly" ... "Either the absence of evidence or the absence of convincing evidence on most of the effects at the centre of campaign objectives". Placebo controlled randomised controlled trials (RCTs) are one gold standard, but in fact RCT data are available both on efficacy and effectiveness of flu inactivated vaccines, including in the elderly and these indicate a protective effect. [2,4-6]. Nevertheless they are few trials as performing RCTs is difficult, especially among particular higher risk populations. Even in the face of incomplete knowledge, many people would consider it unethical to allow high risk population groups to miss this opportunity of protecting themselves in order to generate RCT data. [4] Observational studies may be affected by bias and confounding but dealing with this is a large part of the science of epidemiological research and many studies have attempted to allow for it and still found protective effect. The bias also operates in both directions with tendencies for better off groups to be immunised counterbalanced by people with more severe underlying conditions being immunised preferentially.[4] While unknown sources of bias and confounding can never be absolutely ruled out, the large body of evidence points to immunisation is protective against influenza or influenza like illness). Even if it's incomplete, the list provided by the Author in his table 2 shows a majority of studies having positive (protective) outcomes, especially regarding the efficacy/effectiveness in the elderly who remain the principle target of the vaccination campaign in EU countries. Estimated point efficacy range from 23% to 95% in this age group, depending on the considered outcome and the study design. [1]

Safety. "The small and heterogeneous dataset on the safety of inactivated vaccines" – Inactivated influenza vaccines are widely used worldwide from decades and data on safety are available from routine adverse event surveillance systems and focused studies. These sufficient to assert that the current used inactivated vaccines are generally very safe and are among the safest vaccines used in the targeted population groups. The only serious enduring adverse effect being an increase of Guillan-Barre syndrome in older recipients at a rate of around one per million vaccine recipients. [7]

Hence it is important to underline that vaccination is the most effective available measure to lessen the burden of seasonal influenza. The current vaccination policy carried out in EU countries (mainly centred on the selective vaccination of high risk groups such as elderly people and persons with underlying chronic disease) is based on strong scientific evidence. Even if such evidence does not fit the gold standard placebo- controlled, double-blinded-RCT criteria "Lack of evidence" doesn't necessarily mean "evidence of lack of efficacy". Not every scientific question can be answered only by RCTs [8].

Nevertheless, this article shows that there is room for discussion and further investigation and development in influenza vaccination. Better and more universal vaccines are needed but presently the field efficacy of influenza vaccines is not routinely estimated in the European Union. This is an

important gap given that the mix of circulating viruses and the vaccine combination changes over time.[9] Also there is the issue of the vaccination children vaccination, where the lack of knowledge is particularly evident (and that's the reason why no EU country has started routine vaccination in children). Producing an expert independent opinion on childhood vaccination is a priority in ECDC's current (2006) work-plan and developing a plan for routine monitoring of vaccine efficacy in the EU is central in its proposed 2007 work-plan.

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Competing interests: None declared