

Improving public health information for patients: shared decision making and influenza vaccination

INTRODUCTION

Shared decision making (SDM) is a process that every health professional should apply when there is scientific uncertainty between several care strategies.

Papers have established quality criteria and tools to help in SDM.¹ In 2012, the International Patient Decision Aids Standards (IPDAS) updated its quality criteria at an international expert consensus conference. The changes were published in a supplement in *BMC Medical Informatics and Decision Making*.²

In this field, patients and doctors expect SDM to be done from the best available research evidence.³ IPDAS recommends that shared decision tools are comprehensive and up-to-date summaries of scientific data, and that the evidence itself should be subject to critical appraisal.³

In this context, we analysed annual influenza vaccination in the over-65s. This is a typical example of where shared medical decision making is of major importance, because it deals with prevention in an asymptomatic population. The aim is to discuss the situation with the patient so that they can make their own decision, not only from objective information given by the doctor, but also from their own subjective viewpoint.

INFLUENZA VACCINATION

With regards to influenza vaccination in the over-65s, scientific facts on the benefits are uncertain and communication of facts has caused controversy.^{4,5} Thus far, no randomised controlled trial (RCT) has rigorously analysed the clinical efficacy of the vaccine in the over-65s on clinically pertinent outcomes, such as mortality or hospitalisation.

INFORMATION GIVEN TO THE GENERAL PUBLIC BY THE NATIONAL FRENCH AND BRITISH AUTHORITIES

Our aim was to analyse the content of the documents made available on the web by French and British health authorities, on the Assurance Maladie⁶ and NHS Choices⁷ websites.

We analysed thoroughly the quality of the information and the quality criteria of the SDM based on the level of evidence defined by IPDAS of the content of the websites according to the five following decision criteria.

The scientific level of evidence of the studies

Neither source gave any information on the level of evidence of the studies the information was based upon. Therefore we cannot discuss the value and confidence level of the scientific data.

Nowhere is it mentioned that, at present, no RCT has proven the efficacy of the influenza vaccination in terms of reduction of mortality/morbidity in the over-65s.⁸

Neither the French nor the British authorities give 'comprehensive' or 'critically appraised' information on their websites. However, the NHS website specifies the date of the last update and the next update. On the French website, only one page mentions an update and there seems to be no update policy.

Prevalence of the disease

Neither website specifies the prevalence of the disease in the general population or in the over-65s.

Risks of complications

For both websites, it is stated only that influenza can be unpleasant for the general population and can be more severe and dangerous in populations at risk; the complications are loss of autonomy, pneumonia, and worsening of pre-existing chronic diseases (respiratory failure, diabetes, and heart disease). In addition, death can result from complications.

Neither of these statements takes into account the reference class of the target population of the over-65s.

Efficacy of the vaccination and expected benefit reduction of absolute risk

Both websites mention the annual variability of the efficacy of the vaccine due to viral mutation. However, neither specifies the absolute risk reduction due to the vaccine.

The vaccine is portrayed as the best protection against the virus and a way to reduce the complications of the viral infection. It mentions a reduction in the

prevalence, and in the risk of hospitalisation.

Some figures are found on the French website. However, the risks are expressed in relative risk only: over the age of 65 years the risk of hospitalisation due to influenza is multiplied by three and the vaccine reduces the risk of death by 35%.

Risks linked to the vaccine (expressed in absolute risk)

Neither source mentions risks linked to the vaccine in absolute risk. The NHS website simply states that, 'Serious side effects of the injected flu vaccine are very rare.'⁹

SHORTCOMINGS IN SHARED MEDICAL DECISION MAKING

For a decision to be well informed, it is important that the information be delivered according to quality standards, especially when the information is issued by national institutions. The information must be reliable, truthful, and transparent.

The information presented in patients' decision aids should include not only evidence-based estimates of the effects of the various relevant options, but also an indication of the extent to which this evidence is protected from error. This is not found on institutional websites that advocate vaccinating the over-65s.

Neither of these two websites gives any information on the five points we have indicated. The prevalence of influenza and its complications are not given. Words like 'can be' and 'dangerous' do not enable patients to get a clear and rational picture of the situation. These words use people's emotions, specifically fear, to persuade them to be vaccinated.

Furthermore, the benefit/risk ratio is not clearly presented in a way that could promote true decision making, that is, respecting the fact that a patient could refuse vaccination.

IMPORTANT MISSING DATA

Neither source mentions assessment of

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absolute risk. This is partly because, thus far, only one RCT has been carried out and has not shown any reduction in mortality in vaccinated patients. However, this RCT was not designed to analyse this endpoint. The trial was not powerful enough to study the morbidity linked to the disease.⁹ Currently we have no scientific data that enable us to conclude with a high level of evidence that vaccination is effective in the over-65s.⁸

As there are no RCTs, we can only suggest that vaccination may be beneficial. As risks linked to the vaccination are rare, it is legitimate to suggest vaccination. However, it is ethically debatable to promote vaccination with studies that have a low level of evidence and not to inform patients about the uncertainty of the data.

THE PLACE OF LOW-LEVEL EVIDENCE STUDIES

Despite the absence of RCTs, the existing observational studies remain useful for SDM. We could assess the absolute risks on the basis of relative effect estimated from observational studies. However, even if we use those studies, they will be assessed as a moderate-quality level with respect to the GRADE approach.¹⁰

Furthermore, although SDM is not only based on the level of evidence of the studies, it does not seem ethically acceptable to use data from observational studies to assess clinical efficacy in therapeutics. These observational studies have biases that can be difficult to quantify and analyse, selection biases in particular. Therefore, integrating these biases introduces unknowns into the scientific findings that the decision-making tools are based on. However, the scientific findings are the absolute prerequisite for the tool.^{4,11}

PERSPECTIVES ON IMPROVEMENT

There is room for improvement for both the French and British websites. Indeed, it would be more ethically acceptable to inform patients that there is no definite proof that vaccination is effective, but that, according to observational studies with a lower level of evidence, vaccination seems to be effective. In the same way, risks and benefits should be expressed

in absolute values so that patients can make a more independent decision. Without this information, risk assessment is approximate.

In this context, we suggest adding this information to all the tools designed to help decision making with regards to influenza:

*'The available evidence is of poor quality and provides no guidance regarding the safety, efficacy, or effectiveness of influenza vaccines for people aged 65 years or older.'*⁸

Our point is not to oppose influenza vaccination, but that currently available scientific data should be analysed and that the right information be given to patients. This is why, in agreement with other authors,¹² we believe that the responsibility for health programmes must be separated from the responsibility for making information tools. Furthermore, patients should always be included in the creation of communication tools in health care.

Patients must have access to reliable and up-to-date scientific data, so that they can make informed decisions about their own health. Because the benefit of influenza vaccination is not only individual, doctors must let patients consider different possibilities and express their preferences.

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Competing interests

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