

(Some of these articles are lengthy offering only tidbits of information. To get the real “nuts and bolts” on vaccines, attend Dr. Shetlin’s “Vaccine Conundrum.” Workshop Or

Skip to the bottom for Dr. Shetlin’s and Dr. Dan Murphy’s Key points)

Influenza Vaccination Policy versus Evidence

British Medical Journal
October 28, 2006;333:912-915

Tom Jefferson
Coordinator, Cochrane Vaccines Field

THIS AUTHOR NOTES:

“Each year enormous effort goes into producing influenza vaccines for that specific year and delivering them to appropriate sections of the population.

Is this effort justified?”

The flu (influenza) is a viral respiratory tract infection. Flu vaccination campaigns claim the following benefits:

- Reduced flu cases.
- Reduced hospital admissions.
- Reduced mortality.
- Reduced antibiotic prescriptions. *[Ironic and sad, as flu is viral and antibiotics do not treat viruses].*
- Reduced school absenteeism.

“On the basis of single studies, the World Health Organization estimates that ‘vaccination of the elderly reduces the risk of serious complications or of death by 70-85%.’”

However, **WHERE IS THE EVIDENCE?**



Consider the following:

1) Influenza and Influenza-Like-Illness are two distinct, different diseases, yet their signs and symptoms are often identical. The influenza vaccine targets only influenza and NOT influenza-like-illness. Therefore, the influenza vaccine CANNOT reduce the incidence or severity of influenza-like-illness. Influenza-like-illness is more common than influenza, and it is the typical disease presented to doctor offices. Consequently, many with influenza-like-illness are wrongly diagnosed as having real influenza. This leads to a “gross overestimation” of the impact of influenza, and “impractical advice given by public bodies” concerning flu vaccinations.

2) The influenza virus is extremely variable, with essentially no carryover protection from one year's vaccine to future years.

3) “Single studies are also not reliable sources for generalizing and forecasting the effects of vaccines,” and there is misuse of studies assessing the effects of influenza vaccines.

4) “No one can forecast with precision the impact on next year's influenza.”

5) Studies that advocate flu vaccines rely heavily on non-randomized studies in the elderly. Many of these studies are of poor methodological quality in that they often fail to report on viral types and on vaccine content; they supply insufficient data “to allow reviewers to assess the author's claims,” or they contain data that is “both counterintuitive and implausible.” Therefore this author claims that these pro flu vaccine study findings are more likely the result of “selection bias.” This author notes that some of these pro flu vaccine studies are “badly executed, which introduces bias,” and that an “accurate interpretation of the data is difficult.” Therefore, “caution in interpretation should thus be the rule, not the exception.” This author further notes:

“The only way that all known and unknown confounders can be adequately controlled for is by randomization,” which is rarely done on flu vaccination studies.

“The influence of poor study quality is also seen in the outcome of a review of evidence supporting the vaccination of all children to minimize transmission to family contacts. Five randomized studies and five non-randomized studies were reviewed, but although data were suggestive of protection, its extent was impossible to measure because of the weak methods used in the primary studies.”

6) “In children under 2 years inactivated vaccines had the same field efficacy as placebo, and in healthy people under 65 vaccination

did not affect hospital stay, time off work, or death from influenza and its complications.”

7) There is very little data on the “safety of inactivated vaccines, which is surprising given their longstanding and widespread use.”

“The large gap between policy and what the data tell us (when rigorously assembled and evaluated) is surprising.”

SUMMARY POINTS FROM AUTHOR

1) “Public policy worldwide recommends the use of inactivated influenza vaccines to prevent seasonal outbreaks.”

2) “Evidence from systematic reviews shows that inactivated vaccines have little or no effect on the effects measured.”

3) “Most [pro flu vaccine] studies are of poor methodological quality.”

4) Little evidence on the safety of flu vaccines exists, especially the safety evidence of giving the flu vaccination over multiple consecutive years.

5) “The optimistic and confident tone of some predictions of viral circulation and of the impact of inactivated vaccines, which are at odds with the evidence, is striking.” The reasons are complex and may involve “a messy blend of truth conflicts and conflicts of interest making it difficult to separate factual disputes from value disputes or a manifestation of optimism bias (an unwarranted belief in the efficacy of interventions).”

THIS ARTICLE GENERATED THESE PUBLISHED RAPID RESPONSES, in part:

**Emperor's clothes exposed
Nick Hardwick,
Consultant Dermatologist
Mid Staffs General Hospitals ST16 3SA**

“Tom Jefferson's article raises concern about the situation in which an inadequate evidence base has become canonized into established guidelines, Government policy and incentivised practice. It takes a bold man indeed to challenge this set of Emperor's clothes.”

**Vested interests will always
trump evidence
GH Hall, Retired Physician
EX1 2HW**

“5 years ago I asked my GP what the facts were about the pros and cons of flu vaccination, and I was referred to the propaganda hand outs from the Department of Health. These were long on assertion and short on facts. Perhaps unwisely I embarked on a literature search and running correspondence with various civil service mandarins with the limited ambition of getting data on what actual tests- of efficacy and safety were done on current vaccines and with what results. After much evasive action and stalling I was informed that such information was confidential. The Lancet (2001:357:2141) published my skepticism about the extra ordinary claims being made for the ability of flu vaccine to prevent not only the flu but death as well, whatever the cause. There have been a few papers expressing concern about the inconclusive nature of the evidence for its efficacy. On the other hand, there have been repeated exhortations to the public to ‘protect themselves’. The enormous expense of this futile exercise doesn’t seem to register- partly, I fear, because of payment inducements offered to GPs. They, perhaps, may claim they believed the recommendations of the DH and carried out the vaccination programs in good faith. This ‘only carrying out orders’ excuse is of doubtful validity. There can be no excuse for the harmful public health decisions and refusal to come clean about what precisely were the reasons for them. It is too much to hope for repentance and reversal, however.”

**Policy versus evidence: policy in the lead
Peter Doshi, Graduate student
Massachusetts Institute of Technology, Cambridge, MA**

“Tom Jefferson finds that there is a ‘large gap between [influenza vaccination] policy and what the data tell us’.” “What the data tell us, he writes, is that the inactivated vaccines have ‘little or no effect on the effects measured’ and the comparative evidence is insufficient to demonstrate the vaccines are safe.” “Jefferson's results are consistent with previous epidemiological reviews of the effects of influenza vaccination. A 2005 National Institutes of Health review of over 30 influenza seasons ‘could not correlate

increasing vaccination coverage after 1980 with declining mortality rates in any age group' and concluded 'observational studies substantially overestimate vaccination benefit'. “Annually, public health agencies in the US and UK launch massive campaigns aimed at convincing doctors of the importance of influenza vaccination.” “It is interesting to note here that not only is the evidence supporting the safety and effectiveness of influenza vaccination lacking, but there are also reasons to doubt conventional estimates of the mortality burden of influenza.” “Influenza-like-illness is not only indistinguishable from influenza, but far more common, leading to unrealistic expectations of influenza vaccination.” “While it is often said that influenza poses a serious burden to health, influenza vaccines impose their own particular burden--to the tune of billions of dollars annually. If policy is going to be driven by evidence, this requires us, first of all, to consider the evidence.”

Dan Murphy is one of my favorite doctors! He does a fantastic job finding key articles and summarizing them for the profession. He always has great comments. – Dr. Shetlin

KEY POINTS FROM DAN MURPHY

1) Influenza and Influenza-Like-Illness are two distinct, different diseases, yet their signs and symptoms are often identical. The influenza vaccine targets only influenza and NOT influenza-like-illness. Therefore, the influenza vaccine CANNOT reduce the incidence or severity of influenza-like-illness. Influenza-like-illness is more common than influenza, and it is the typical disease presented to doctor offices. Consequently, many with influenza-like-illness are wrongly diagnosed as having real influenza. This leads to a “gross overestimation” of the impact of influenza, and “impractical advice given by public bodies” concerning flu vaccinations.

2) Studies that public policy makers use to advocate flu vaccine are not reliable, are often misused, are of poor methodological quality, are badly executed and show evidence of selection bias. Therefore, “caution in interpretation should thus be the rule, not the exception.”

3) “In children under 2 years inactivated vaccines had the same field efficacy as placebo.”

4) In healthy people under 65 flu vaccination “did not affect hospital stay, time off work, or death from influenza and its complications.”

5) There is very little data on the “safety of inactivated vaccines, which is surprising given their longstanding and widespread use.”

6) “The large gap between policy and what the data tell us is surprising.”

7) The optimistic and confident tone of the impact of inactivated vaccines is “at odds with the evidence.”

8) Public health recommendations for flu vaccination may be driven by “a messy blend of truth conflicts and conflicts of interest.”

FROM RAPID CORRESPONDENCES:

- 1) Regarding flu vaccine, inadequate evidence has become canonised into established public health guidelines, Government policy and clinical practice.
- 2) The Department of Health in the UK flu vaccination information is “propaganda,” “long on assertion and short on facts.”
- 3) There is a large gap between flu vaccination policy and what the data tell us.
- 4) Inactivated flu vaccines have ‘little or no effect on the effects measured’ and the comparative evidence is insufficient to demonstrate the vaccines are safe.
- 5) “A 2005 National Institutes of Health review of over 30 influenza seasons ‘could not correlate increasing vaccination coverage after 1980 with declining mortality rates in any age group’ and concluded ‘observational studies substantially overestimate vaccination benefit’.”
- 6) “Not only is the evidence supporting the safety and effectiveness of influenza vaccination lacking, but there are also reasons to doubt conventional estimates of the mortality burden of influenza.”
- 7) “Influenza-like-illness is not only indistinguishable from influenza, but far more common, leading to unrealistic expectations of influenza vaccination.”
- 8) “While it is often said that influenza poses a serious burden to health, influenza vaccines impose their own particular burden--to the tune of billions of dollars annually. If policy is going to be driven by evidence, this requires us, first of all, to consider the evidence.”