

Why the swine flu isn't a major threat

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For the last 15 years, physician and epidemiologist Tom Jefferson, MD, has made it his mission to conduct extensive reviews of all studies of seasonal influenza vaccines. With colleagues at the [Cochrane Collaboration](#), Dr. Jefferson has co-authored over [10 Cochrane reviews](#) to answer a wide range of questions such as: do these vaccines reduce the chance of getting influenza or reduce the risk of complications, hospitalizations and deaths in elderly people, children, healthy adults and asthmatics? Based in Rome, Italy, Dr. Jefferson has published extensively and is, arguably, the world's leading authority on the quality of the evidence supporting [seasonal influenza](#) vaccines. As we head into winter, the U.S. media is reporting a new, more ominous viral threat that may well become a pandemic. It is, of course, the swine flu, now known as the H1N1 virus or the 2009 H1N1 virus. Dr. Jefferson is interviewed by [Maryann Napoli](#).

MN: Thanks for sending me that September 16, 2009 letter from the Health Protection Service of Australia. It made me turn my attention to that part of the world. Now that winter is ending in the southern hemisphere, what has happened in Australia doesn't appear to be a pandemic. There were 131 H1N1 deaths out of a population of nearly 22 million people. Is it fair to conclude that the H1N1 virus did not turn out to be a pandemic in Australia?

TJ: Yes, you may conclude that the H1N1 virus is not the threat that it has been portrayed to be.

MN: And no H1N1 vaccine was available to Australians in time for their winter season.

TJ: Yes, that's right. But notice that I did not answer the second part of your initial question about whether Australia experienced a pandemic. That's because the definition of pandemic has changed on the World Health Organization's (WHO) website since May 2009. The [earlier version defines pandemic](#) as: "An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide **with enormous numbers of deaths and illness** [emphasis in the original document]." In [the lookalike document](#) that currently appears on the WHO Web site, the definition of pandemic has changed to: "A disease epidemic occurs when there are more cases of that disease than normal. A pandemic is a worldwide epidemic of a disease. An influenza pandemic may occur when a new influenza virus appears against which the human population has no immunity."

MN: The phrase "enormous numbers of deaths and illness" is gone. And we now have a lower threshold for calling something a pandemic

TJ: The definition we're left with makes the difference between seasonal influenza and pandemic influenza a matter of debate.

MN: What do you think is going on?

TJ: I am wondering if this means that the world will always be in a pandemic. The world will always have to be doubly vaccinated and the world will always be spending a huge amount of money for vaccines, and of course, buying anti-viral drugs by the barrel load. Journalists and others have contacted WHO to find out why the change in definition, and they are always told that someone will get back to them, which never happens.

MN: What about funding? The WHO funded the osteoporosis meeting in 1993 where [the definition of osteoporosis was expanded](#). Do you know whether the same thing may have happened here?

TJ: No, I don't, but when you look at the WHO pandemic preparedness document, which is 62 pages long, you see in the citation count only 2 references for hand washing, 3 for masks, 1 for gloves, 23 for vaccines and 18 for anti-viral drugs. What WHO should be pushing worldwide, especially for poor countries, are these public health interventions; instead, it's pushing pharmacologic interventions. We now have clear evidence from our reviews that pharmaceutical industry-sponsored influenza vaccine studies have risen in importance and visibility, considerably more than non-pharmaceutical industry-sponsored studies. However, this is not explained either by size or quality of the studies which is the same. The likely, and very unpalatable, explanation for this finding is that the most prestigious scientific journals are more likely to print pharmaceutical industry-sponsored studies probably because of the money they make out of selling reprints of the studies and advertising space.

MN: But Tom, many who read this will say, "Yes, maybe a lot of people are going to make money from our fear, but I'll still get the vaccine."

TJ: First of all, it's not "maybe" a lot of people are going to make money. Here's [a swine and bird flu stocks index](#), which tells you just how much money vaccine companies made in the last six months. So if you want to know how the pandemic is going, you can consult this Web site. I call it a "pandemimeter," the barometer of the pandemic. Don't forget to read the comments at the end of the page and the insights from the contributing pundits.

MN: Don't you mean that this Web site is a barometer of the *fear* of the pandemic?

TJ: No, I think it is a reflection of what this pandemic really is: [a commercial operation](#). Why else would the Australian government plan to immunize millions of people after the epidemic with a partially evaluated vaccine?

MN: The Food and Drug Administration recently announced approval for four new vaccines against the H1N1 virus. They come with the usual warnings for people with allergies to eggs and possible "unexpected or rare serious adverse events." Do you have any other reservations about these vaccines?

TJ: Yes, I do. I am aware of only one published study. It appeared recently in the [online version \[September 11, 2009\] of the New England Journal of Medicine](#). I have four problems with this study, which was done in Australia. 1) It was tiny, only 240 adults. The authors made reassuring statements about [Guillain-Barré syndrome](#), which is ridiculous because GBS occurs in one out of 750,000 to 1 million vaccinations, and this study only had 240 participants; 2) one third of these volunteers had side effects that resembled influenza-like illness (headaches, sore throats, etc.), so they were vaccinating to prevent symptoms that they were causing; 3) there was no placebo arm in the study [a group that was injected with an inert vaccine], yet there's no ethical excuse for not having a placebo arm because these are experimental vaccines; and 4) the description of what additive substances [ingredients that boost the immune response] were in the vaccine was unclear. We know that there is thimerosal [mercury] in this H1N1 vaccine, but its manufacturer did not say whether there are additional substances like aluminum, which can be found in many other vaccines. We just don't know. And they are advising this vaccine for pregnant women and children over six months of age!

MN: Can you just back up and explain how vaccine studies determine whether a new vaccine should be approved?

TJ: In all our reviews of the studies involving seasonal influenza vaccines, we always looked for real outcomes, i.e., cases of influenza, bronchitis, pneumonia. [In other vaccine studies like this new one from Australia], researchers look at the quantity and quality of antibodies [in the bloodstream] of the volunteers once they are injected with an experimental vaccine. If they produce a pre-set quantity considered to be "protective," then it is assumed that once vaccinated, people will be protected. So the key question is how these laboratory markers relate to the protection of people. To answer the question we reviewed all influenza vaccines studies from 1948 to 2007. A straight answer is made difficult by the poor quality of these studies, but vaccines have performed very poorly especially in the elderly (for which they are universally recommended). So if this is the track record, why are researchers pursuing the same old tired and fruitless road?

MN: Yes, you made that so clear [when I interviewed you in 2006](#) after you published an extensive report in the British Medical Journal. What about that CDC-generated statistic that the media hauls out each year to scare us into getting vaccinated: [36,000 U.S. deaths](#) each year from influenza? It never changes. And when you think of it, 36,000 out of 300 million Americans is miniscule.

TJ: We know that in the last 20 years in the U.S., the seasonal influenza-related mortality rate is flat, despite the fact that over the years a higher and higher number of people have been getting influenza vaccines.

MN: Re the seasonal influenza vaccine which the CDC usually recommends for certain populations like children under age two and the elderly...

TJ: There is no evidence whatsoever that seasonal influenza vaccines have any effect, [especially in the elderly and young children](#). No evidence of reduced [number of] cases, deaths, complications.

MN: Obviously, there's no Cochrane review on the horizon for the H1N1 virus.

TJ: Of course not, there's no data yet to review. There is no problem with the H1N1 virus. It's no different from any other seasonal virus. In fact, it looks—from the Australian experience—like it's going to be milder and it can be handled with [public health measures, such as hand washing, masks](#).

At the end of this interview Dr. Jefferson was asked if he had any conflicts of interest to report about influenza vaccines. His response: "Yes: I am publicizing my work. But no, I have no financial conflicts."

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