

Pandemic flu vaccine campaigns may be undermined by coincidental medical events

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The effectiveness of pandemic flu vaccination campaigns - like that now underway for H1N1 - could be undermined by the public incorrectly associating coincidental and unrelated health events with the vaccines.

This is the conclusion of a paper published online Oct. 31 by the *Lancet* and authored by an international team of investigators led by Cincinnati Children's Hospital Medical Center.

"Regardless of whether someone gets the vaccine, bad things happen to people every day and generally occur at fairly predictable rates," said Steven Black, M.D., lead author and a physician in the Center for Global Health and Division of [Infectious Diseases](#) at Cincinnati Children's.

"Identifying real safety concerns with new vaccines means we have to untangle actual safety signals from background medical events, which are those that would happen without vaccination."

The team of investigators from 13 global medical institutions and health agencies reviewed medical data from prior studies and from hospital databases to identify background rates of health events that occurred without any vaccine. Their review showed the rates of adverse events varied by year, country, age and sex of the population.

The problem the authors identified is that public concern regarding medical events can interfere with important vaccine programs, even if the vaccine is not the cause. One example they cited is the interruption of a 2006 seasonal influenza campaign in Israel, where four deaths

occurred within 24 hours of immunization. The clustering of fatalities and close timing of vaccination resulted in global news coverage, public trepidation and compromised the inoculation campaign.

In actuality, the four patients who died all were in a group already at high risk for sudden death from age and underlying medical conditions. Their deaths were consistent with a cardiac cause of death, and the number of deaths was lower than would be expected normally for such a high risk population. Further analysis of the fatalities in Israel showed death normally occurs in this high risk group at a rate greater than one per 1,000 individuals in the same time period. Based on this, the researchers said 20 coincidental deaths among that group could be expected to occur by chance within 24 hours of an immunization.

The authors also revisited one of the concerns raised during the 1976-77 swine [flu vaccination](#) program. The vaccine in that campaign was associated with an increased number of Guillian-Barre Syndrome cases, in which the body's immune system mistakenly attacks part of the nervous system. Guillian-Barre normally affects about one out of every 100,000 people a year. Based on this Guillian-Barre background rate, if 100 million people in the United States are inoculated in a [pandemic flu](#) vaccination campaign, the researchers said one would expect 215 new cases of the disease within six weeks of vaccine. These cases would be expected to occur whether or not the vaccine had been given.

"The reporting of even a fraction of such a large number of case as adverse events following immunization, with attendant media coverage, would likely give rise to high levels public concern, even though the occurrence of such cases was completely predictable and would have happened in the absence of a mass campaign," according to the paper.

To help address these concerns, the U.S. Centers for Disease Control and Prevention (CDC) and other health agencies have been creating systems

to gather and accurately assess data on background health events when evaluating vaccine safety. The current paper presents some new data but also puts existing data into context for the public, said Dr. Black, who also serves as a pandemic flu vaccine safety consultant to the National [Vaccine](#) Program Office at the Department of Health and Human Services.

"In the heat of the moment of a pandemic [vaccination campaign](#), the public isn't good at evaluating comparative risk or realizing that obviously some people die or develop serious illnesses every day," Dr. Black said. "By putting background rate data into proper context, we want to help people make an informed decision about pandemic flu vaccinations."

Source: Cincinnati Children's Hospital Medical Center ([news](#) : [web](#))

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