

# Letter to Hospital Authorities on Mandatory Influenza Vaccination

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This article is derived from a letter I sent to officials at my hospital concerning mandated influenza vaccination, asking them to consider whether vaccination is medically warranted, and whether the mandate is ethically correct.

## Magnitude of the Problem

Between 1979 and 2001, on average 36,000 people per year in the U.S. died from complications of influenza. Based on the number of hospital beds in acute and chronic care facilities, and spreading that risk evenly across all facilities, one person every three years, on average, would die at our hospital from influenza sequelae. This number is probably a significant overestimate since proof of influenza from positive viral cultures is rarely obtained (in most cases, 1,000–4,000 samples are submitted before a single positive viral culture is obtained), and deaths from influenza B and other influenza-like diseases, which would not be prevented by vaccination, may be included in these statistics. And, as noted below, vaccination does not clearly reduce these deaths.

## The Evidence for Benefit of Influenza Vaccine in General

It is important to understand that vaccination is a statistical gamble. Every year, based on viral sampling, the CDC (Centers for Disease Control and Prevention) decides which viral antigens to include in the vaccine for that year. It is possible—but highly unlikely—in the best-world outcome, that the vaccine targets 100% of influenza virus in circulation that year. It is also possible—and again unlikely—that it may target 0% of the viruses, thereby helping no one avoid the flu. The truth is somewhere between those two extremes, but varies year to year. For the 2007–2008 year, the vaccine effectiveness ranged from 44% to 86%.<sup>1</sup> Also, studies done by the Food and Drug Administration (FDA) prior to release of the Fluarix vaccine, as reported in the *Physician's Desk Reference* (PDR), show that 49.5%–68.9% of people were already immune at the time of vaccination.<sup>2</sup> These figures mean that the majority of people receiving the vaccine do not benefit from it. Furthermore, in a large meta-analysis of influenza vaccine the authors conclude: "Influenza vaccines have a modest effect in reducing influenza symptoms and working days lost. There is no evidence that they affect complications, such as pneumonia, or transmission."<sup>3</sup> Of trials included in this review, 15 out of 36 were funded by industry, and four had no funding declaration.

## Benefit to Hospitalized Patients

When considering mandatory staff vaccination, it would be important to demonstrate that doing so decreased the risk of

influenza transmission to hospitalized patients. However, I was unable to find any evidence that this is true. A study done in 40 French nursing homes looked at this question in a setting of the most vulnerable patients. In one arm of the study, nurses were strongly encouraged to be vaccinated, and achieved rates of 69.9%. In the control arm no vaccines were given, but the nurses nevertheless had a vaccination rate of 31.8%. They found that in facilities in the study arm, sick leave by nurses was 42% lower and, for the patients, there was decreased all-cause mortality. However, rates of these patients' hospitalization, influenza, or respiratory illness were not lower.<sup>4</sup> The French authors had no cause-and-effect explanation for the decreased mortality, but it might be suggested that, in a marginally functioning state-run system, the loss of nursing manpower resulted in the excess mortality in the control arm.

Even these modest results must be interpreted with caution as there is a disturbing pro-vaccine bias in the literature. For example, in another study by Munoz et al. in 1999,<sup>5</sup> based only upon the low vaccination rate and work absences of the staff nurses, the researchers concluded that nurses were the probable cause of an influenza outbreak. Drawing such a conclusion violates every epidemiologic principle, and does not even begin to meet Koch's postulates.

To bring in a little common sense: at our hospital we do not limit access of visitors to the hospital on the basis of vaccination status. Ironically, although unvaccinated employees cannot get near a patient while on duty, they are allowed to visit, hug, and kiss patients they may visit as friend or family in their off-duty hours! And, since most hospitals including ours do not have actual hermetically sealed isolation rooms, the airborne viral particles from a sick influenza patient will not be contained—in other words, we do not even truly quarantine patients with influenza who are known to be infectious.

## Risk of Vaccination

There are very few risk-free medical therapies, and no one—not even the most ardent vaccination supporter—believes that the influenza vaccine is risk free. In reviewing data from the previously cited studies submitted for FDA approval of Fluarix and Flulaval, common side effects reported were: 1.6% vomiting, 1.6% nausea, 1.4% influenza-like illness, one in 11,000 cases of anaphylaxis, and a smattering of other minor complaints. From 5% to 11% of children became febrile after vaccination. Importantly, the studies of 10,000 people on which approval was based only looked at a 21-day window after the vaccination. Other problems self-reported via the vaccine registry include Stevens-Johnson's syndrome, encephalomyelitis, neuritis, facial

palsy, meningitis, myelitis, Guillain-Barré syndrome, and other neurologic sequelae. There is general agreement that neurologic problems can occur after immunizations of various sorts, and that these neurologic changes are of an acute and unpredictable nature. Guillain-Barré is perhaps the best known of the risks. The incidence is unknown because of the sometimes delayed onset and the need for self-reporting, but is common enough that during my career I have seen a handful of cases that occurred after vaccination. This ascending paralysis can be fatal or leave permanent movement and sensory deficits. A study of 10,000 people may not be large enough to capture the incidence in controlled studies, and cases will be missed in studies looking at only a 21-day postvaccination window.

The more controversial vaccine issues involve potential long-term sequelae that may be related to the adjuvants used in the vaccine to stimulate the immune response, the risk of vaccines containing small SNPs (single nucleotide polymorphisms) of oncogenes from the media in which they are grown, and the overall risk-to-benefit ratio of multiple vaccinations.

In our very specialized medical world we sometimes fail to look at the big picture. For example, although statins have decreased death from myocardial infarction, we have seen an increase in heart failure, and the all-cause mortality is not lowered. In the case of influenza vaccine, are we interfering with our natural immune function by trying to eliminate all disease? What is the function of natural infection in overall health? We know, for example, that since the introduction of childhood vaccination, asthma and other autoimmune phenomena in children have risen. Some researchers attribute this to altering the natural “learning process” of the immune system. I attended a cancer seminar in which the researcher from the University of Texas MD Anderson Cancer Center noted that people who took the influenza vaccine eight out of ten years were more apt to get cancer. The lecture was about the effect of febrile illness on cancer, and the researcher hypothesized that febrile illness in general causes temporary hypervigilance of the immune system, which wipes out incipient cancer cells during that period. In any case, it must be conceded that the issues are complex, and the effect of altering the interaction of the human immune system with the natural world is not completely understood.

One of the ways we alter the immune system in vaccination is by the use of adjuvants—chemicals that boost the immune system response to an antigen. Some of these materials, specifically squalene, have been shown in animal studies to cause autoimmune responses some time after the exposure. This tends to support the concern by some researchers that squalene may increase the risk for autoimmune disorders in humans.

Another adjuvant is aluminum. In 1998 Dr. Romain Gherardi, a French specialist in neuromuscular diseases, described a new syndrome of severe muscle pain, cognitive impairment, and debilitating weakness following vaccination with one of three different vaccines, all containing aluminum.<sup>6</sup> He found that macrophages in muscles were filled with aluminum from the adjuvant. This was confirmed later in patients in America. Yet aluminum is still used in vaccines. It should be noted that the

maximum accumulation of the aluminum-filled macrophages occurred 5 years after receiving the vaccine. In later (unpublished) animal experiments by the same researcher, aluminum-containing adjuvants injected into muscle resulted in 31% of animals developing aluminum deposits in the brain.

Adjuvants are necessary because elderly people—those we are targeting with the influenza virus—do not respond well to the “unboosted” influenza antigens. The scientific argument is beyond the scope of this letter, but consider this observation regarding one of the adjuvants:

MF59, an oil-in-water emulsion, is currently licensed for use in the elderly as an adjuvant in seasonal influenza vaccines. *Its mechanism of action is not fully understood, but enhancement of the interaction between the antigen and the dendritic cell seems to be involved. When used with seasonal influenza vaccines, an increase occurs in the hemagglutination inhibition antibody titers against some, but not all, seasonal vaccine influenza strains.... The use of the adjuvant is associated with an increase in the frequency of local and systemic early post-vaccine adverse events (3–7 days), but no increase in adverse events was observed thereafter*<sup>7</sup> [emphasis added].

In other words, according to the researcher, adjuvants affect the immune system in a very basic way that scientists do not fully understand, yet they can nevertheless guarantee the absence of long-term problems although they only looked at relatively small groups of people over short periods of time. Science is an ever changing field, and I admit there is no perfect safety for any treatment, but I am not comfortable with this level of certainty.

Vaccines are big business. Unfortunately, with enough money on the table, safety can take a back seat. It turns out that the government does not require vaccine manufacturers to submit to independent safety studies, but allows them do their own. Recently Pfizer pharmaceutical company was ordered to pay \$2.3 billion for “felony with intent to defraud,” and the *Journal of the American Medical Association (JAMA)* revealed that drug companies pay for ghostwriting scientific papers. In Britain, during a court investigation concerning vaccines, it was revealed that the a major drug company was publishing a journal, taking care to make it appear as peer reviewed, but in reality selecting articles favorable to its vaccines. Danish police are investigating Dr. Poul Thorsen, a leading “researcher” whose group wrote papers supporting vaccine safety. These are still the bulwark of safety claims in the popular press. After his major papers were questioned for authenticity, and after having been paid more than \$14 million by the CDC since 2002, he has absconded with \$2 million. His partner Kreesten Madsen was found to have e-mails that showed him colluding with CDC officials to cherry pick studies to defend the role of and safety of vaccines.

Current vaccines, in order to speed their production, are grown in media that incorporate viral DNA. The vaccines antigens are then harvested, and the DNA removed by various processes. But as any chemist knows, it is difficult to remove every bit of growth medium, and allowable levels are never given as zero but in “acceptable” parts per million. What is acceptable for an oncogene? This is not just a theoretical risk, as pointed out by the FDA, which wrote:

The experience in the early 1960s with SV40 contamination of poliovirus and adenovirus vaccines and the continuing questions regarding whether SV40 could be responsible for some human neoplasms underscores the importance of keeping viral vaccines free of adventitious agents.<sup>8</sup>

These viral fragment contaminants are a known problem, but we simply cannot check every batch of vaccine, so at best we spot check. As more vaccine manufacture has moved overseas, the problem of safety oversight is worsened. In China, plants are inspected by the FDA only every 12 years, and the FDA can't really enter the plant, but just takes the word of Communist officials.

In short, the risks and benefits of vaccination are murky at best. Science is not done by consensus but by honest research, reporting, and verification. What is generally glossed over or actually repressed when officials discuss vaccines is how little we clearly know. The level of uncertainty of safety and benefit should be honestly assessed—especially if mandating treatment with these substances.

### Alternatives to Vaccination

Before mandating a potentially risky medical treatment with limited effectiveness, we should ask, "Are there alternatives?" It turns out there are. A randomized clinical trial from Japan showed that Vitamin D supplementation was more effective than the influenza vaccine in preventing influenza in school children.<sup>9</sup> Vitamin D is a cheap, safe supplement. No overdose has ever been reported at 10,000 units a day, and it is generally conceded (except by the Institute of Medicine) that there is a worldwide deficiency of Vitamin D in temperate climates. This study has led to the suggestion that the seasonal nature of the influenza may be less attributable to confined winter quarters than to lack of sunlight and falling winter Vitamin D levels.

### Ethical Considerations

Most importantly, there is a grave ethical issue at stake here. Does any government or public agency have the right to force a medical treatment with its attendant risks on an individual or group of individuals? A private business can require that certain physical standards be met, even vaccination, but to do so it must bear the moral burden of potentially harming people.

According to a study by the American College of Cardiology, the half-life of medical truth is about 20 years. In other words, looking back at the literature, only about half of what was touted as true 20 years ago is still thought to be valid 20 years later. The other 50% has been supplanted by new evidence and ideas. It may well be that in 20 years we will determine that the adjuvants we gave as part of these vaccines were, as some suggest now, responsible for a long-term autoimmune reaction in genetically susceptible people. To give a vaccine to people on a voluntary basis is one thing, but to mandate such a treatment puts the hospital in a very different moral space. It is important to note that doctors—those theoretically with the most knowledge of such things—*never* mandate treatment. No matter how "critical" such

treatment may be, for ethical and legal reasons we always leave the ultimate choice of treatment to the patient. We can only advise as to the potential benefits and risks, and a wise physician makes sure his patients know that risks are never completely known.

Finally, the moral responsibility for potentially harming people cannot be avoided by deferring to a higher level of authority. The "I was just following orders" defense has been left on the doorstep at Nuremberg. If the hospital is honest in its approach, it has only two paths. We may say either: 1) "We are mandating a potentially hazardous treatment whose risks are truly unknown to our employees to be in compliance with the corporate guidelines" or 2) "The hospital system has mandated influenza vaccine for all employees, but we do not believe it is ethical or medically sound to do so. You, the employee, are free to choose to follow the guidelines or not, as you deem fit after reviewing the evidence."

Some nurses will choose to take the vaccine, as was shown in the study cited above in which 36% of nurses in the nursing homes chose to vaccinate voluntarily. And Iowa is in the top three states for voluntary influenza vaccination, ranging from 50% to 59% each year.

I personally prefer that our hospital not continue mandatory medical treatment of anyone as a requirement for continued unrestricted employment, and instead choose a principled stance, acting as a leader in this issue, not as a collaborator in an ill-conceived, scientifically unsound, and potentially harmful program.

Sincerely, Lee D. Hieb, M.D.

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