

# Cardiovascular Risks from Swine Flu Vaccines

*Overstimulation of the immune system may trigger acute heart disease and sudden deaths in the increasing number of people with atherosclerosis; this hidden risk of mass vaccination programmes against swine flu could far outweigh the benefits*

[Dr. Mae-Wan Ho](#)

**This report has been submitted to the US FDA and Sir Liam Donaldson, UK Chief Medical Officer. Please circulate widely. You have permission to repost this article provided you leave it unchanged and with all links intact.**



## Mass vaccinations amid mounting safety concerns

Mass vaccinations for the pandemic H1N1 'swine flu' have begun in Britain, the United States, Sweden and elsewhere, targeting hundreds of millions around the world as concerns mount over the safety of the fast-tracked vaccines [1-3] ( [Fast-tracked Swine Flu Vaccine under Fire](#) , *SiS* 43; [Swine Flu Pandemic - To Vaccinate or Not to Vaccinate?](#) , [Flu Vaccines and the Risk of Cancer](#) , *SiS* 44). The risks identified so far include neurological damage, developmental defects, and autoimmune diseases from vaccine adjuvants; the potential for generating more virulent disease agents from live attenuated viral vaccines, and cancer from contaminants of cultured cells used to grow the vaccine viruses, or from chemical agents employed in killing the vaccine viruses.

Now, researchers at Mainz University Medical Center in Germany led by Sucharit Bhakdi have added cardiovascular risks that are not generally appreciated. Animal experiments and epidemiological data suggest that over-stimulation of the immune system may accelerate atherogenesis (the build-up of fatty deposits or plaques on the inner wall of arteries) [4]. They are especially concerned about vaccines containing adjuvants

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to boost immune response, which could aggravate the formation of plagues and atherosclerosis disease. The risks of other widespread diseases due to deregulated immune systems are also possible. Safety trials of vaccines conducted so far have not specifically taken those possible side-effects into account, and "unexpected serious adverse effects" may follow in the wake of mass vaccination programmes. This proved prophetic.

### Four deaths in less than two weeks

Less than two weeks into its mass vaccination, Sweden reported four deaths [5], among which were at least two with underlying heart condition. According to the Svenska Dagbladet newspaper, there were also 350 side effects recorded [6]. The Swedish Institute for Infectious Disease Control denies that the deaths are connected with the vaccine.

But this possibility was predicted in the paper published by Bhakdi and colleagues [4].

### Two vaccines with adjuvants

There are two main vaccines with adjuvants. One, modeled after Flud and widely used in European countries including Germany contains the adjuvant MF59 made by Novartis, and is also deployed worldwide mainly for people over 65 years of age. MF59 is a squalene oil-in-water emulsion; but its mechanism of action is still poorly understood. It appears to induce recruitment of macrophages (white blood cells that ingests foreign material and dead cells) to the injection site and promote uptake of antigen by macrophage and dendritic cells that process antigens to promote production of specific antibodies. Injection of flu vaccines with the adjuvant frequently causes local pain and occasionally fever, indicating that pro-inflammatory cytokines (signaling molecules produced by immune cells) are generated [7]. There is further evidence that injection of squalene can provoke autoimmune responses [1, 2].

Flu vaccines with MF59 adjuvant have been given to children, but there is little experience with their use in pregnant women who are currently in the priority group for vaccination [1, 2].

Another H1N1 vaccine with adjuvant is developed by GlaxoSmithKline (GSK). The adjuvant is AS03 [1], similar to MF59 in that it contains squalene, and in addition, the non-ionic detergent polysorbate 80 (Tween 80)., which is yet uncharacterized in terms of pharmacokinetic and immunological properties [4]. Studies with vaccines containing AS03 in infants, young children or pregnant women have not been published. And current clinical studies are being conducted with children

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## Hidden dangers of H1N1 vaccines with adjuvants

Immune mechanisms are now implicated in such a diversity of chronic diseases that no common denominator would have come to mind before the advent of modern immunology [4]. That is why the potential dangers of vaccine adjuvants such as those used with the current H1N1 swine flu vaccines are still not adequately addressed.

A major hurdle to addressing the dangers is the lack of specificity in the self-destructive processes perpetrated by an over-stimulated immune system. It is now recognized that the innate, relatively non-specific immune mechanisms are just as culpable as the specific, adaptive immune mechanisms in the pathology of some of the most widespread human diseases including atherosclerosis, inflammatory bowel disease, demyelinating disease and non-infectious arthritis; and the list is ever growing.

More baffling still is that such pathological processes sometimes have their roots in normal physiological events that serve useful biological functions.

For example, macrophages are involved in clearing tissues of cholesterol, which is poorly soluble. Atherosclerosis disease becomes manifest only when this cholesterol clearing role breaks down through overload, and lesions develop in the artery wall. The macrophages then cease to perform their physiological function and become the perpetrator of disease (see box).

## Macrophages and atherosclerosis

Macrophages are large white blood cells that have the ability to phagocytose (engulf) foreign materials such as bacteria and viruses and debris from dead cells. They are a very important component of innate immunity, not only in protecting the body against pathogens, but also in scavenging and tissue repair. However, macrophages are also involved in the development of atherosclerosis – hardening of the arteries due to fatty deposits (plaques) in the arterial wall – and especially in the acute clinical disease resulting from the rupture of the plaques [8].

Atherosclerosis is an inflammatory disease triggered by the over-stimulation of the immune system. It accounts for 39 percent of deaths in the UK, while 12 million in the USA have atherosclerosis-associated disease. Atherosclerosis results in narrowing the arteries, producing stable angina (chest pains due to blockage of arterial blood flow) or else

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dramatic rupture, producing acute syndromes such as unstable angina, myocardial infarction (heart attack, when the blood supply to part of the heart is interrupted causing some heart muscle cells to die), or sudden death . Macrophages are abundant in ruptured atherosclerotic plaques and are suspected of causing the rupture. As they belong to the innate immunity branch that does not require specific recognition, macrophages may damage tissues indiscriminately. Macrophages are recruited and activated by many signals and they have an impressive arsenal of molecules to promote tissue damage.

Macrophage recruitment to the developing atherosclerotic plaques is aided by the expression of special inflammatory adhesion molecules in the abnormal lining of the arterial wall over the plaques, which are up-regulated by multiple atherosclerosis risk factors including oxidized low density lipoprotein (oxLDL, bad cholesterol), smoking, hypertension and diabetes. The activated macrophages express effector molecules that kill cells and degrade the extracellular matrix. These include Fas-L and nitric oxide (NO). Macrophage NO up-regulates vascular smooth muscle cell (VSMC) surface Fas (the binding partner for Fas-L) priming the VSMC for apoptosis (programmed cell death). As VSMCs promote plaque stability, their apoptosis may contribute to plaque rupture. Macrophages also express multiple metalloproteinases ( *e.g.* stromelysin) and serine proteases ( *e.g.* urokinase) that degrade the extracellular matrix, weakening the plaque and making it prone to rupture. In addition, macrophages secrete numerous other effectors including reactive oxygen species that kill bacteria under normal conditions [9] (see [The Body Does Burn Water](#), *SiS* 43) , but will cause oxidative damage to cells when overproduced as the result of environmental stress.

## **Macrophages a major culprit**

A key question is whether self-destructive processes perpetrated by the immune system can be influenced by unrelated immunological events. Again, atherosclerosis serves as a case in point, and the answer is yes [4]. There is a current debate over whether innate or adaptive immunity is more important in accelerating and aggravating atherosclerosis. But there is broad agreement that pathology is driven by diverse conditions that stimulate the immune system, such as acute and chronic infections, stress, smoking and diabetes.

While macrophages normally perform their cholesterol scavenging function in the absence of inflammation, they readily induce immune-mediated collateral damage by moving to sites of atherosclerotic lesions that become unstable when activated by immune stimulation. Rabbits on a high blood cholesterol diet injected with an endotoxin that caused a brief rise in body temperature of only 1° C developed markedly larger

atherosclerosis lesions than controls. Thus, immune stimulation in the absence of any infection can accelerate atherogenesis via the activation of macrophages. If, at any stage, vaccination drives macrophages into their inflammatory state, the effects will be unpredictable and "acute clinical events could be precipitated." It might be caused by "the adjuvant or another ingredient, a combination of both, or any other inflammatory events provoked by intramuscular injection of the vaccine."

### **No trial data available on cardiovascular risks**

There is simply no relevant clinical data that could rule out such immunological adverse effects resulting from vaccination. Trials would have to be conducted in individuals with identified risk factors - but these are just the subjects usually excluded from the trials [1, 2]; moreover, the follow up observations would have to be made over extended periods of time.

These risks do not just apply to people with identified risk factors, but may also apply to healthy young individuals repeatedly challenged with vaccines that contain adjuvants over years or decades. To make matters worse, the GSK flu vaccine with its novel combination of adjuvants and additives has not ever been given to a large number of recipients.

The GSK vaccine was assessed in 400 volunteers [10]. Fever developed in 4 out of 200 participants that received the vaccine without adjuvant compared with 15 out of the 200 that received the vaccine with adjuvant. The group receiving the vaccine with adjuvant also showed marked increases in the incidence of all other registered symptoms including local redness, swelling, muscle aches, all signs of inflammation.

Bhakdi and colleagues pointed out that in 2003, smallpox vaccine was administered to 36 000 civilians aged 46–65 in the USA, and five myocardial infarctions (MI) occurred within 3 weeks of vaccination. Five cases of MI were higher than the two that would have been expected in the period within this age-group, although it just missed being significant at the 5 percent probability level.

The authors did not question the need for effective vaccine strategies against H1N1, only the possibility that the risks of mass vaccinations at this stage might outweigh the benefits. H1N1-related mortality is very low in Europe, and nowhere near that due to seasonal flu [1, 2].

Why not hold mass vaccination in reserve, as we have already won the first round; and if mass vaccination is implemented, at risk individuals

should be given vaccines without adjuvants.

The same arguments against mass vaccinations would extend to the many other diseases with immunopathological components.

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