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CDC States H1N1 Vaccine May Maim and Kill 30,000 Americans, FDA Requires Minimal Efficacy

CDC says to assume 1 in every 100,000 vaccine recipients will suffer serious side effects, FDA only requires vaccine be effectiv

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Theme: Science and Medicine
In-depth Report: THE H1N1 SWINE FLU PANDEMIC

The Center for Disease Control and Prevention (CDC) has officially stated that there will be as many as 30,000 serious, potentially lethal adverse reactions to the novel H1N1 vaccine, while the FDA guidelines for the novel H1N1 vaccine only require that it work in 3 out of every 10 recipients.

Last Saturday, I attended one of 10 "public engagement" meetings the CDC is holding across the country, utilizing a new model of public engagement designed to provide a public viewpoint or societal perspective on the topic at hand (mass vaccination) to the sponsor (in this case, the CDC).

Part of the process entails the sponsor (CDC) providing the following: "Information on the many sides of an issue is provided to the participants in a fair and balanced manner so that all participants become well-informed, and the overall group process is convened and managed in a neutral, respectful fashion."

This requirement is met by providing an oral presentation in easy to understand language, a booklet summarizing the key facts needed and a discussion guide summarizing the choices faced.

The assembled group of 80 participants was shown a video, given a brief oral presentation and a printed discussion guide. We were asked to accept several **assumptions** in considering the topic. We were asked to assume that the severity would be similar to what had already been observed in the spring of 2009; we were told to assume that the vaccination program would be voluntary, not mandatory; we were told to assume that initial vaccine supplies will be available in October but supply would be limited through February 2010.

The most disturbing assumption we were asked to accept dealt with the safety of the novel H1N1 vaccine. In the video, the CDC spokesperson explained that during the 1976 mass vaccination campaign, 1 in every 100,000 recipients of the vaccine developed Guillain Barré syndrome (GBS), a disorder in which the body's immune system attacks the peripheral nervous system often leading to paralysis and death. There is no known cure for GBS.

In 1976 roughly 40 million Americans received the vaccine and some 4,000 developed GBS.

The printed material that was distributed reiterated these horrific statistics and we were

asked to **accept the assumption** that, “the estimated risk for more serious reactions (e.g. Guillain Barré syndrome) is between 1-10 per million persons vaccinated”.

This is a less direct way of stating that the risk is about the same as existed during the 1976 mass vaccination attempt and that as many as 1 in every 100,000 recipients will develop GBS or some other serious adverse reaction. The CDC is setting up a new intensive surveillance system with which to monitor and track GBS cases that result from the novel H1N1 vaccine.

Merriam-Webster defines assumption as a fact or statement taken for granted and assumed to be true. If we accept the documented assumption presented by the CDC, we are to consider it a fact that 1 in every 100,000 vaccine recipients will suffer a serious adverse effect such as GBS.

This means that if the entire U.S. population is vaccinated (a stated goal of the CDC), we are to **assume as a fact** that 30,000 Americans will suffer debilitating or lethal side effects. Apparently the CDC considers this an acceptable level of collateral damage.

As unthinkable as this is (destroying or ending the lives of as many as 30,000 Americans), that is only part of the story.

The novel H1N1 vaccine being developed must adhere to guidelines set forth by the U.S. Food and Drug Administration (FDA). The FDA has announced that a vaccine will be accepted if it creates antibodies in 4 out of 10 recipients (40%), with at least 70 percent of those 4 achieving an antibody level **believed** to provide benefit. This means that an acceptable vaccine candidate would provide “protection” for 28% of vaccine recipients (70% of the 40%), or less than 3 in 10 recipients. The requirement drops to 18% efficacy for those over 65 years of age (60% of 30%).

So here are the facts, as documented by the CDC and the FDA:

As many as 30,000 Americans will be harmed by the novel H1N1 vaccine.

The vaccine may be ineffective in more than 7 out of 10 recipients.

And in case you think I am alone in my concerns, here is what several vaccine experts associated with the CDC and the U.S. government say on the subject.

“I am very skeptical of finishing vaccine before we know the appropriate dose to be included in each inoculation, before immunogenicity studies are complete, or before safety assessments have been finished,” William Schaffner, MD, Chairman of the Department of Preventive Medicine at Vanderbilt University and a member of the CDC *Advisory Committee on Immunization Practices* (ACIP), wrote in an recent e-mail.

“We have assured both the profession and the public that the H1N1 vaccine will be evaluated with the same rigor that is applied to seasonal vaccine. We should NOT make vaccine available before the trials are complete and the results carefully assessed.”

Others are worried about a repeat of the last swine flu “pandemic,” now regarded as a public health and public relations debacle.

“I fear that a rush towards vaccinating the population without completing trials risks leading

to the harmful outcome that we witnessed during the 1976 swine flu scare, where the government advocated rapid production and vaccination of the population without adequate safeguards, which led to an unexplained increase in cases of Guillain Barré syndrome (GBS), amongst other complications, and massive liability for the government," wrote Amir Afkhami, MD, PhD, of George Washington University, an international expert on the 1918 Influenza pandemic and an advisor to the U.S. State Department, the U.S. military, and the World Bank on issues pertaining to infectious diseases, public health and, mental health.

"I think in this regard, we must learn from lessons of the past and be mindful of not jumping from the proverbial frying pan into the fire by putting people's health at risk without adequate production and safety monitoring of the vaccines."

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