GlobalResearch
Center for Research on Globalization

“Safe and Effective” – Understanding Vaccine Clinical Trials. The Placebos

By Health Freedom Defense Fund
Global Research, July 13, 2023
Region: USA
Theme: Science and Medicine

***

“Safe and effective,” the foundational creed of the vaccine orthodoxy, is enshrined by government health officials and medical professionals and is widely accepted by a largely under-informed public.

Aided by a compliant media, the vaccine industry itself relies on this mantra being accepted universally and unquestioningly.

Public health bureaucrats insist upon our obeisance to this medical catechism, demanding that we faithfully “follow the science and trust the experts.”

Yet, the specific methodologies used to determine the professed safety and efficacy of vaccines are little understood.

It is long past time to ask and answer: **Are the testing protocols scientifically sound? Are the practices used in vaccine clinical trials trustworthy? How exactly is “safe and effective” determined?**

We will examine the veracity of the “safe and effective” shibboleth by taking a critical look at one of the key elements of these testing procedure- the clinical trials themselves.

Randomized placebo-controlled clinical trials are considered, the “gold standard for evaluating the safety and efficacy of a new vaccine.”

The idea is to have participants in the trial randomized receive either the vaccine under investigation or a placebo.

How a placebo is defined and how the placebo is applied in practice are two points that, as we shall see, are crucial to the validity of any clinical trial.

The idea behind randomization and the use of a placebo is, “to control for confounding

effects, such that significant differences in disease incidence or adverse effects between the vaccine and control groups can likely be attributed to the vaccine."

What is a placebo?

The US Centers for Disease Control and Prevention (CDC) defines a placebo as, "a substance or treatment that has no effect on living beings, usually used as a comparison to vaccine or medicine in clinical trials."

A placebo can be either an inert substance, such as a saline solution that is injected or a sugar pill that can be taken orally.

The importance of using a true placebo to get an accurate assessment of vaccine safety cannot be overstated.

In a 2018 letter, the legal team at the nonprofit Informed Consent Action Network (ICAN) challenged the US Department of Health and Human Services as to how HHS can justify,"licensing any pediatric vaccine without first conducting a long-term clinical trial in which the rate of adverse reactions is compared between the subject group and a control group receiving an inert placebo."

Curiously, HHS defended its position, first by asserting that,

> "many pediatric vaccines have been investigated in clinical trials that included a placebo" [a false claim in and of itself] and then by adding, in the very next paragraph, "Inert placebo controls **are not required** to understand the safety profile of a new vaccine, and are thus not required." [Emphasis added.]

This convoluted language not only raises questions about the consistency of the HHS' position on placebos but it is patently absurd as it negates the possibility of knowing the true side-effects profile.

In that same paragraph, on page 2, HHS goes on to defend its position by claiming, "In cases where an active control is used, the adverse event profile of that control group is usually known and the findings of the study are reviewed in the context of that knowledge."

This specious claim sidesteps the fact that knowing the adverse event profile of an active control group holds little meaning at best and is often outright deceptive in practice.

In an 88-page comprehensive follow-up to this dissembling, ICAN called into question the integrity of HHS:

> The fact that HHS does not and apparently will not require pharmaceutical companies to use a placebo control in pediatric vaccine clinical trials evidences HHS's lack of confidence in the safety profile of these products. If HHS had confidence in their safety profiles, it would require that vaccine clinical trials —– as is typical for drug clinical trials —– include a placebo-control group.

A clear example of this manipulation is illustrated by the clinical trial of Gardasil and its subsequent licensure.

In the Gardasil trial, 10,706 women received Gardasil; 9,092 women received Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS), an "active control" used in the control group. Aluminum adjuvants, such as AAHS are known to induce autoimmunity in lab animals.

A small subset of participants, 320 women did receive a saline placebo. This smaller group was mixed in with the AAHS control group to form a "combined control group."

In the six month study, 2.3% of the women receiving Gardasil and 2.3% of the women in the "combined control group" reported developing a systemic autoimmune disorder.

Based on these similar rates of systemic autoimmune disorders in both the "test group" and the "combined control group," the vaccine was deemed safe and so was licensed by HHS.

What was not disclosed is that there were no autoimmune disorders among the 320 women who received the saline placebo. The reason this fact could be obfuscated was that the two control groups were combined.

Clearly, it is illogical, if not fraudulent, to claim a product is "safe" when it has an adverse event profile similar to an "active control" that has a poor adverse event profile.

Why was the safety profile of this product not directly compared to the women in the study who *did* use a genuine placebo?

Shouldn't this information have triggered a larger follow-up study with a control group that used *only* the saline placebo?

The answer may lie in a 1998 article titled, "Drug Study Designs Guidance for Institutional Review Boards and Clinical Investigators," in which the FDA points to issues that arise when active controls are used.

One of the problems the FDA cites is that there are, "numerous ways of conducting a study that can obscure differences between treatments adding that Active-control studies **which are intended to show no significant difference between treatments**." [Emphasis added.]

Continues the FDA:

> "In the absence of a placebo group, a finding of no difference in an active-control study therefore can mean that both agents are effective, that neither agent was effective in that study, or that the study was simply unable to tell effective from ineffective agents. **In other words, to draw the conclusion that the test article was effective, one has to know with assurance that the active-control would have shown superior results to a placebo**, had a placebo group been included in the study." [Emphasis added.]

Using genuine placebos in safety studies is essential to demonstrate the true side effect profile of any drug. Absent a genuine placebo, it's not possible to make precise claims about the *actual* risks of the drug being tested.

Clinical trials testing for efficacy that do not use a genuine placebo only tell us something about the efficacy of the product *relative* to the other product rather than the product's *absolute* effectiveness. This allows for claims to be made that may be factually true but may

misrepresent the overall impression.

So, when we see the word "placebo" mentioned in a study, it's vital to ask

- "Does this mean that an *inert* substance was used in the study?"
- "Are the tests using *real* placebos or are they using placebos *engineered* to suit the objectives of the study?"
- "If a proper placebo is not being employed, will this lead to comparative distortions of adverse effects?"

To get an accurate picture of how placebos are defined and materially implemented in practice, we will explore three further examples of clinical trials that studied the safety and efficacy of the vaccines highlighted:

(1) In the largest of the clinical trials for GlaxoSmithKline's (GSK) pediatric vaccine Pediarix, a 5-1 vaccine designed to protect against diphtheria, tetanus, pertussis, hepatitis B and polio, the placebo used by the control group was the pediatric DTaP vaccine Infanrix.

In 14 additional trials in that study (see page 8), the placebos received by the control groups are simply referred to as "comparator vaccines."

Infanrix itself was tested using the older generation DTP vaccine (a vaccine known to cause serious side effects in infants) as the placebo for one control group in a clinical trial. No control group was used in another trial.

For Pediarix, no control group received a proper placebo.

(2) Our next example highlights Merck's hepatitis 'A' vaccine VAQTA. The safety profile for this vaccine also did not include a true placebo control.

Neither of the two clinical trials for VAQTA used a proper control group. In the first trial, the "Monroe" study, it was acknowledged (see page 11) that the placebo utilized the aluminum adjuvant contained in the vaccine as well as thimerosal, a mercury- based neurotoxin phased out in the early 2000's.

Neither of these substances can be considered inert or safe.

The second trial administered the vaccine alongside two other vaccines- called "historical control groups."

This practice is widely considered unscientific, as it eliminates randomization. On page 62 of the Final Clinical Review (cited above) it is noted, Again, the use of historical controls is not the preferred trial design method."

(3) Our third example is Merck's VARIVAX, the first vaccine licensed for chicken pox. The safety section of the package insert for this vaccine stated that the product was tested using- "a double-blind, placebo-controlled study among 914 healthy children and adolescents who were serologically confirmed to be susceptible to varicella."

Was this small study in fact "placebo-controlled" with a proper placebo?

As it turns out, the control group, for VARIVAX, was given a placebo described as being,

“identical in appearance to the vaccine in both lyophilized and reconstituted forms, but contained no virus material. The placebo consisted of lyophilized stabilizer containing approximately 45 mg of neomycin per milliliter.”

In short, this meant that the control group was given the test vaccine minus the viral component. Perhaps this explains why the rates of adverse reactions were similar between the groups.

These three examples are not exceptional cases in the large body of literature on vaccine clinical trials. Sadly, this is standard operating procedure for virtually all vaccine trials.

The reality is that vaccines are generally or always tested either against an older form of the vaccine or against another vaccine or against a solution made of everything in the vaccine except the antigen in question.

In light of the emerging body of evidence, we have to ask ourselves:

“First do the current methods of testing provide a reliable measure of the safety and adverse effects of vaccines or do these methods serve to obfuscate potential harm?”

“Second, do the current methods of evaluation provide concrete evidence for the efficacy of these products?”

Beyond the matter of improper controls there are a host of additional confounding factors that are prevalent in vaccine trials. Problematic issues such as unblinding in trials, erratic clinical case definitions, biased statistics and design protocols, lack of long- term studies, lack of data on combinative impacts of multiple vaccines, and many additional questions materialize throughout these studies.

A critical reader of the scientific literature would grasp the implications of all of this and posit that the “safe and effective” bromide appears to be built on a foundation of quicksand.

Indeed, acceptance of this unassailable doctrine of the soundness of vaccines depends on the public not knowing the particulars of how these trials are conceived and carried out.

As an antidote to this information vacuum, HFDF will be presenting a comprehensive expose’ of the United States childhood vaccination schedule over the course of the next few weeks.

We shall look at each vaccine to see if in fact the science is sound, the studies are adequate, and the established dogma is credible.

*

Note to readers: Please click the share button above. Follow us on Instagram and Twitter and subscribe to our Telegram Channel. Feel free to repost and share widely Global Research articles.

This article was originally published on Health Freedom Defense Fund.

Featured image is from HFDF

Articles by: **Health Freedom Defense Fund**