

FALSE
NARRATIVE

No vaccines have been tested in placebo-controlled clinical trials

The False Narrative

Vaccines are never tested against placebos, or inactive agents, to determine safety and efficacy.

The Facts

As evidenced by published, peer-reviewed research, many vaccines — including influenza, HPV (human papillomavirus), Tdap (tetanus, diphtheria, and pertussis), MMR (measles, mumps, and rubella), and COVID-19 vaccines — have undergone and continue to undergo placebo-controlled trials as part of the vaccine research and development process.

On its website, the U.S. Food and Drug Administration (FDA), whose Center for Biologics Evaluation and Research oversees vaccine safety and efficacy in the U.S., explains that newly developed vaccines undergo three main phases of clinical trials, the second and third of which can include a placebo intervention. (In a vaccine trial, a placebo is an inactive agent, such as a saline injection, that mimics the real vaccine. Giving some study subjects a true vaccine and others a placebo allows researchers to better evaluate the safety and efficacy of an experimental shot.)

The U.S. Centers for Disease Control and Prevention (CDC) notes on its website that if a vaccine is ultimately approved for use by the FDA, the research enters a fourth phase — “a formal, ongoing study to evaluate the new vaccine’s safety and effectiveness over a longer period of time.”

It is true that, for ethical reasons, some new versions of vaccines are not tested against inert placebos, but rather against existing versions of vaccines proven to be safe and effective in protecting against the same diseases. For example, the FDA approved the Prevnar 13 vaccine, which protects against certain types of pneumonia, meningitis, and sepsis, in 2010 based on a clinical trial comparing the new vaccine to the existing Prevnar 7 vaccine.

An August 2014 guidance document from the World Health Organization (WHO), published in the journal *Vaccine*, said it is “unacceptable” to use a placebo in a vaccine trial when “a highly efficacious and safe vaccine exists” and available in the area where the trial is planned.

The guidance explained, “In this situation, a placebo-controlled trial would not address a question that is relevant in the local context, namely how the new vaccine compares to the one that is currently in use, and participants would be exposed to unacceptable levels of risk from delaying or foregoing a safe and effective vaccine that is accessible through the public health system.”

Debate during the COVID-19 pandemic — particularly in the early stages of COVID-19 vaccine development — focused on the question of whether it was ethical to use placebo injections in a setting where researchers could be denying subjects access to a potentially life-saving vaccine. In June 2020, the International Coalition of Medicines Regulatory Authorities (ICMRA), which is co-chaired by the FDA and European Medicines Agency, released a policy brief advising that phase three clinical trials of COVID-19 vaccines “should be randomized, double-blinded and controlled with a placebo or active comparators.” Several months later, in December 2020, a WHO expert panel

stated that as safe, authorized vaccines became available, researchers should notify potential trial subjects of their eligibility for a vaccine, adding, “Participants may elect to receive the authorized vaccine at any point in the trial.”

Where the False Narrative Spread

NewsGuard has found this claim repeated on websites that regularly spread vaccine misinformation, including [ChildrensHealthDefense.org](https://www.childrenshealthdefense.org), [ICANDecide.org](https://www.ICANDecide.org), and [Ratical.org](https://www.Ratical.org).

The claim gained traction when, in a July 10, 2023 interview on “Jesse Watters Primetime” on Fox News, Democratic presidential candidate Robert F. Kennedy Jr. — also the chairman of the anti-vaccination nonprofit Children’s Health Defense — claimed that “vaccines are exempt from pre-licensing controlled placebo trials.”

Background

While placebo-controlled studies are often a standard part of the vaccine development process, the medical ethics surrounding the topic remain a subject of debate. In the August 2014 WHO guidance document mentioned above, the WHO acknowledged that “there is insufficient and inconsistent guidance on how to evaluate the use of placebo controls in vaccine trials,” stating that ethics guidelines from organizations such as the Council for International Organizations of Medical Sciences, World Medical Association, and Council of Europe “offer conflicting guidance on the use of placebo controls.”

“Randomisation and the use of placebo interventions are designed 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,” the WHO stated. “However, randomised, placebo-controlled trial designs often raise ethical concerns when participants in the control arm are deprived of an existing vaccine.”

Editor's Note: This Misinformation Fingerprint was updated on Sept. 15, 2023, to add information about why some new versions of existing vaccines are not tested against placebos.

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Examples of this False Narrative ^①

- https://allnewspipeline.com/MOST_Vaccines_ARE_NOT_TESTED_For_Safety.php

“His match with Offit, along with what we know about the limitations of Congress’ 1986 National Childhood Vaccine Injury Act and its removal of liability for childhood vaccine injury; Big Pharma’s lack of incentive to understand the safety profile for their vaccines before they are licensed; and the problems behind establishing ...

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 7.5 / 100 allnewspipeline.com (en_US)

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- <https://skeptics.stackexchange.com/questions/55743/did-hhs-admit-that-mandated-childhood-vaccines-had-not-been-tested-for-safety-in>

“55743/did-hhs-admit-that-mandated-childhood-vaccines-had-not-been-tested-for-safety-in

Did HHS admit that mandated childhood vaccines had not been tested for safety in pre-licensing inert placebo tests?”

[VIEW ARCHIVED](#)

- <https://www.daystar.com/news-updates/general-updates/vaccines-fact-vs-fiction-with-robert-f-kennedy-jr/>

“But today, children are mandated to take 72 doses of 16 vaccines before the age of 18. None of them have ever been tested against placebo. Nobody knows what the risk profile is of those vaccines. ”

[VIEW ARCHIVED](#)

- <https://www.foxnews.com/video/6330950198112>

“We should have the same kind of testing, placebo-controlled trials. Vaccines are exempt from placebo-controlled trials.”



Jesse Watters Primetime (en_US)

VIEW ARCHIVED

- <https://icandecide.org/press-release/fda-emails-show-that-agency-could-not-address-serious-safety-gaps-in-clinical-trials-of-childhood-vaccines/>

“Despite that, the FDA’s incredible response was to lie and claim many of the vaccines did undergo placebo control studies even though the FDA’s own licensure documents for each childhood vaccine show otherwise!”



12.5 / 100 icandecide.org (en_US)

VIEW ARCHIVED

- <https://popularrationalism.substack.com/p/vaccine-makers-do-not-use-placebos>

“Vaccine makers do not use placebos to test the safety of their vaccines for kids.”

VIEW ARCHIVED

- <https://ratical.org/PandemicParallaxView/RFKvsDershowitzVaccineDebate.html>

“Not a single one of the vaccines—the 72 vaccines now administered to our children—have ever been tested against a placebo. ”



25 / 100 ratical.org (en_US)

VIEW ARCHIVED

- <https://childrenshealthdefense.org/vaccine-secrets/video-chapters/vaccine-makers-do-not-use-placebos-to-test-the-safety-of-their-vaccines-for-kids/>

“Vaccine makers do not use placebos to test the safety of their vaccines for kids.”



17.5 / 100 childrenshealthdefense.org (en_US)

VIEW ARCHIVED

- https://www.americanthinker.com/articles/2023/08/a_renowned_vaccinologist_and_the_placebocontrolled_clinical_trials_that_werent.html

“The list of licensed vaccines without placebo control is staggering.”

 12.5 / 100 [americanthinker.com \(en_US\)](https://www.americanthinker.com/en_US)

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Reliable Sources ⓘ

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<https://www.cdc.gov/vaccines/basics/test-approve.html>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4157320/>

<https://publications.aap.org/pediatrics/article-abstract/134/3/e657/74155/Long-term-Study-of-a-Quadrivalent-Human?redirectedFrom=fulltext>

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<https://thedispatch.com/article/fact-checking-claims-about-vaccine-testing-by-robert-f-kennedy-jr/>

Risk of Harm ⓘ

High

Categories ⓘ

[Vaccines](#)

[Health](#)

Myth Locations ⓘ

United States

Myth Spread Locations ⓘ

United States

Subject Tags ⓘ

[Clinical trial](#)

Search Terms ⓘ

("not placebo controlled" OR "not tested against placebo") AND (study OR trial) AND vaccine* -fact-check -myth

"no placebo" AND (study OR trial) AND vaccine* AND Robert Kennedy

Associated Labels ⓘ

[allnewspipeline.com \(en_US\)](#)

[americanthinker.com \(en_US\)](#)

[childrenshealthdefense.org \(en_US\)](#)

[icandecide.org \(en_US\)](#)

[Jesse Watters Primetime \(en_US\)](#)

[ratical.org \(en_US\)](#)

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