Children's Health Defense

By the Children's Health Defense Team

Human papillomavirus (HPV) vaccines hit the global marketplace in the mid-2000s. From the start, public health agencies enthusiastically promoted HPV vaccination as the "best way to protect [young people] against certain types of cancer later in life." However, a blistering new study by British researchers—and new data showing that cervical cancer rates are surging in British 25- to 29-year-olds—raise numerous questions about officials' inflated claims. The study's results indicate, instead, that the jury is still out on whether HPV vaccination is effective.

The question is far from academic because, prior to Britain's introduction of HPV vaccination in 2008, cervical cancer rates had been trending sharply downward. In fact, between the late 1980s and mid-2000s, cervical cancer rates halved . Now, Britain's leading cancer research charity (Cancer Research UK) reports a steep 54% rise in cervical cancer in one of the very age groups that first received the vaccine.

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"Significant uncertainties"

The 2020 study, published in the *Journal of the Royal Society of Medicine*, critically appraises twelve published randomized controlled trials that HPV vaccine makers GlaxoSmithKline and Merck used to buttress assertions about their vaccines' efficacy (Cervarix and Gardasil). The British authors do not beat around the bush in presenting their conclusions, which include the following:

- The trials' **questionable methodology** generated "uncertainties" so significant that they undermine claims of efficacy.
- The ages of the women who participated in the trials **were not representative** of the younger adolescents who constitute HPV vaccination's primary target groups.

- The studies used highly restrictive criteria to exclude many potential participants, **li miting the trials' "relevance and validity for real world settings."**
(During Science Day presentations for the
Jennifer Robi vs. Merck and Kaiser Permanente
Gardasil lawsuit in January 2019, Robert F. Kennedy, Jr. made the same point, describing the "elite club of superheroes" who constituted the study group and noting that Merck purged anyone with the slightest vulnerabilities to the vaccine or its ingredients despite the fact that the vaccine would ultimately be marketed to girls
with the very vulnerabilities excluded during the clinical trials
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- The trials used **"composite and distant surrogate outcomes"** that essentially made it "impossible to determine effects on clinically significant outcomes." The authors explain that the surrogate outcomes used (forms of cervical dysplasia called CIN1 and CIN2) often regress on their own "and are of limited clinical concern." They also note that different forms of cervical dysplasia each have "their own different natural histories, prevalence and incidence and strength of association with cancer." Lumping together vastly different forms of dysplasia into the trials' composite surrogate endpoints, therefore, was "problematic."
- The trial investigators' unusually frequent cervical screening of study participants likely resulted in **overdiagnosis** of low-grade cervical changes while **overestimating** t he vaccines' efficacy in preventing them. The
Royal Society of Medicine
authors also note that vaccine efficacy against low-grade cervical changes is no guarantee of efficacy against the higher-grade abnormalities that may contribute,
along with other risk factors
, to cervical cancer.

- Most damningly, the authors argue that no certainty about whether HPV vaccination prevents cervical cancer is possible, because the trials " **were not designed to detect this outcome** , which takes
decades to develop."

a cervical cancer "peak" at ages 25-29 represents a "big change" from the pattern that prevailed in Britain in previous decades—when cervical cancer peaked in women aged 50-64.

High vaccine uptake . . . and rising cancer rates

Now consider these uncertainties against the backdrop of the United Kingdom's HPV vaccination program—launched with great fanfare in 2008 with the bivalent Cervarix vaccine (replaced by Gardasil in 2011). The UK's program rapidly achieved a high national uptake —on the order of 76% to 90%—making it "one of the most successful globally." Although the HPV vaccination program primarily targeted 12-year-olds, Britain also operated a "catch-up" program during the initial three-year period (2008-2011) that encouraged girls ages 13-18 to get vaccinated. By mid-2018, the UK government estimated that 80% of 15- to 24-year-old girls and women had received the vaccine.

Given that Britain's HPV vaccine uptake was high from the get-go, many of the women now in their mid to late twenties who are experiencing the spiking cervical cancer rate must have been among the UK's first HPV vaccine recipients. How does this uncomfortable fact square with Public Health England's sunny endorsement of HPV vaccination and its confident prediction (in 2018) that it would be able to "get an accurate picture of the impact this vaccine will have on this devastating cancer" as soon as vaccinated girls reached ages 25-29?

The public health agency classifies 25- to 29-year-olds as the age group most commonly affected by cervical cancer but does not mention that a cervical cancer "peak" at ages 25-29 represents a " big change " from the pattern that prevailed in Britain in previous decades—when cervical cancer peaked in women aged 50-64. In the United States, where HPV vaccine uptake has been considerably lower, women in their mid to late twenties have the second *lowest* cervical cancer rate , with a peak in women ages 40-44.

There are several plausible explanations for rising cervical cancer rates in the context of high vaccine uptake. One is the phenomenon known as "type replacement"—in which an HPV

vaccine that covers only four to nine of the 100-200 types of HPV "may lay bare an ecological niche for non-vaccine HPV types ," some of which may be high-risk for cervical cancer. A 2016 study that analyzed the prevalence of 32 types of HPV in women with cervical abnormalities acknowledged the potential for "a continuous shift in the prevalence of HPV types as a result of vaccination" as well as the potential for increased transmission of more virulent nonvaccine types. Another study published around the same time confirmed that vaccinated women "had a higher prevalence of high-risk nonvaccine types ."

Receiving the HPV vaccine when one already has HPV is another cause for concern. In his *Rob i vs. Merck* Science Day presentation , Robert F. Kennedy, Jr. noted that Merck's pre-clinical trial records for Gardasil "show that girls or women who already had HPV—had been exposed at some point in their life to it—actually had a negative efficacy of 44.6 percent. What is negative efficacy? It means those girls had a 44.6 increased risk of getting those precancerous lesions."

A third concern has to do with the decline in cervical cancer screening. Cancer Research UK is cognizant that "Cervical cancer is one of the few cancers that can be prevented through screening " and it is, therefore, a strong proponent of pap smear screening, but the organization's research shows that the number of UK women seeking screening has reached a "record low." One reason is because many women don't feel they are at risk . British cancer prevention experts have expressed worry that women may be lulled into complacency by the HPV vaccine's promises and " may stop going to screening because they think it's not important."

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A foundation of fraud

As frank as its conclusions are, the study in the *Journal of the Royal Society of Medicine*

barely scratches the surface of the dubious—and fraudulent, as the *Robi vs. Merck* lawsuit alleges—methodological shenanigans that manufacturers and industry-captured regulators deployed to fast-track HPV vaccines into worldwide use. Dr. Nicole Delépine—a French physician specialized in both pediatrics and oncology and a member of numerous professional associations devoted to cancer care and research—has written about the "paradoxical effect" of HPV vaccination on cervical cancer rates in Britain as well as other high-vaccine-uptake countries such Australia, Sweden and Norway. In all of these settings, where cervical cancer was declining prior to vaccination, Gardasil has reversed the trend, "with a *significant* increase *in the frequency of invasive cancers in the most vaccinated groups" [emphasis in original].*

These facts need to be brought to the attention of the U.S. legislators contemplating HPV vaccine mandates. For example, New York Senator Brad Hoylman (D) and Assemblywoman Amy Paulin (D) have co-sponsored legislation to mandate that all seventh graders in public and private schools receive the HPV vaccine, and additional proposed legislation in New York (again co-sponsored by Hoylman) would allow children ages 14 and above to receive vaccines without parental knowledge or consent. These legislators should keep Dr. Delépine's words of warning in mind: "It takes a long time to affirm that a preventive action really protects," but "Evidence that vaccination increases the risk of invasive cancer can be rapid if the vaccine changes the natural history of cancer by accelerating it." And this is exactly what we are seeing.