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The tense standoff between Catholic bishops and the Kenyan government over tetanus vaccines

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That accusation, which was made [in a public statement](#) last week, carried the signature of about two dozen Kenyan Catholic leaders, including Cardinal John Njue, the archbishop of Nairobi. The controversy has since been [taken up by the Kenyan parliament](#).

The accusations are the latest to target a long-running vaccination program, sponsored by WHO and UNICEF, which inoculates women of reproductive age against tetanus. Despite several controversies over the past few decades, there's no definitive proof that the current or previous tetanus inoculation campaigns have produced mass sterilizations in inoculated women as charged.

But the bishops' conference believes it finally has that proof and has come out swinging against the government-run program with a litany of accusations and charges about science and secrecy. "We shall not waver in calling upon all Kenyans to avoid the tetanus vaccination campaign laced

with Beta-HCG, because we are convinced that it is indeed a disguised population control programme," the bishops said.

In a joint statement e-mailed to reporters this week, WHO and UNICEF said the "grave allegations" were "not backed up by evidence." The Kenyan government has also denied that the vaccination program is a secret mass sterilization effort.

At stake is the WHO- and UNICEF-sponsored Tetanus Toxoid, or TT, vaccination program, [one that focuses on inoculating against a severe form of tetanus](#) found in newborns by vaccinating women of reproductive age. The WHO says it concentrates these efforts on women who might become pregnant because inoculation can pass along antibodies to newborn infants.

The Kenyan initiative began earlier this year. Kenya is one of a couple dozen countries where tetanus remains a deadly health problem, particularly among newborns.

The science here is a little complex, but in short: Critics believe that the vaccines contain the Beta-hCG hormone, which in high doses, and administered in a particular way, may cause complications in pregnancy.

Both the bishops and health officials agree that if present, the hormone has no business being in the vaccine doses. But it's unclear whether the results of the tests ordered by the bishops are correct — and if they are, whether the samples contain enough of the hormone to have a contraceptive effect.

Earlier this year, the bishops and the Catholic Doctors

Association in Kenya decided to test several samples of the vaccine at four different labs for the presence of the hormone, [according to their statement](#). The results indicated that the samples were "laced with the Beta-hCG hormone."

The two sides have very different explanations as to how and why the hormone may have been present in the vaccine. UNICEF spokesman James Elder told The Post in an e-mail that its presence in a TT vaccine dose would represent an "extremely rare contamination." The bishops believe it was put there deliberately as part of a secret population-control program.

The issue is far from settled: The government says it tested the same vaccine for the presence of the hormone and found none. The government and the Catholic leadership group even used one of the same labs to test the samples, apparently receiving different results.

The Kenyan government, UNICEF and the WHO have questioned whether the testing used adequate samples and methods. "We have taken note of test results claiming to show levels of hCG in samples submitted to some clinical laboratories," the joint WHO-UNICEF statement reads. "However, it is important to note that testing for the content of a medicine e.g. TT Vaccine need to be done in a suitable laboratory, and from a sample of the actual medicine/vaccine obtained from an unopened pack and not a blood sample."

In an effort to end the controversy, Kenya's parliamentary health committee is asking for a [third round of testing](#), this time sponsored jointly by the government and the Catholic

bishops. UNICEF said in response to a question from The Post that it has "offered to support the Ministry to arrange for additional testing in a reference laboratory."

Although the actual test results haven't been released to the public by the bishops, the [Catholic News Agency](#) says it has seen a copy. And, the wire service writes, while "copies of the lab results obtained by CNA do show positive test results for the presence of the beta-hCG, reference levels given on the lab reports show that levels present in the vaccines are within 'normal values' for healthy men and women."

UNICEF, [which also says it's seen the results](#), added another note of caution, arguing that the labs testing the samples for the Catholic groups were not informed that they were testing a vaccine and used "analyzers used for testing human samples like blood and urine for pregnancy" to look for the presence of the hormone, which happens to be the very same one detected by pregnancy tests.

Kevin Donovan, director of the Pellegrino Center for Clinical Bioethics at Georgetown University, seemed to cautiously agree in an interview with CNA. "I suspect that the tests that the hospital labs tried to do for the Catholic bishops weren't really designed to test the way that they did, maybe giving them erroneous results," he said.

So far, the bishops are standing by their results, even going so far as to call the government's negative tests a "false and a deliberate attempt to distort the truth and mislead 42 million Kenyans." At least one Catholic charity, Matercare, [has backed the bishops' claims](#), issuing a statement from the Kenya Catholic Doctors Association calling the vaccination

program "evil."

It's easy to see why the accusations from the Kenyan Catholic groups have attracted so much attention: Reproductive health, fertility and sterilization are fraught international issues. As the Kenyan controversy rages, authorities in India are [investigating 13 deaths](#) at sterilization camps in the country.

Forced, involuntary sterilization — particularly targeting certain groups, such as the poor, the mentally ill or the HIV-positive — has a long and shameful history, [including in the United States](#).

The question, then, is whether the bishops' accusations will hold up to continued scrutiny.

Several Western Catholic groups, along with organizations identifying as "pro-life," have waded into the matter, as has online [debunking site Snopes](#), which rated the claim "false."

But some aren't ready to leave the issue entirely, including Donovan of Georgetown's Pellegrino Center for Clinical Bioethics, who told the CNA that "there are aspects of this that need to be raising red flags because of history and because of the way it was all being done. But raising red flags doesn't mean that there's something that actually has occurred."

He urged the Kenyan government, along with the WHO, to be more transparent in responding to the bishops' complaints. "The way you prove that's not the case is by not being arrogant, but responding to it and being transparent," he said.

To settle the matter once and for all, he said, the parties involved should move forward with "a test designed to test for what they're testing for."

Some who are skeptical of the bishops' claims have pointed to a controversy over the very same program in 1994, when the WHO was vaccinating women in Mexico, Nicaragua, the Philippines and Tanzania.

As the Catholic bishops have done this year, concerned officials at the time demanded that the vaccines be tested for safety. Then, as now, the vaccines tested positive for hCG. Except there was a problem: The results were likely false positives.

The vaccines were sent to hospital laboratories and tested using pregnancy test kits which are developed for use on serum and urine specimens, and are not appropriate for a vaccine such as TT (tetanus toxoid), which contains a special preservative (merthiolate) and an adjuvant (aluminum salt.)

When the vaccines were tested in laboratories which used properly validated test systems, the results clearly showed that the vaccines did not contain hCG. The results found in six laboratories in five countries on tetanus toxoid vaccines from seven manufacturers are available on request. The low levels of HCG like activity seen in some samples were the result of false positive reactions. In fact, in a laboratory in Hungary, it was shown that the sterile water supply from the local hospital gave a higher false positive level of HCG than did the TT vaccine.

While the controversy in Kenya remains unresolved, the

bishops' accusations are having their desired effect, according to Elder, the UNICEF spokesman. "The vaccination campaign was adversely affected by the negative publicity," Elder said in an e-mailed statement. "It is an extremely disappointing situation, none more so than for those the vaccine is there to protect -- once again, the most marginalized."

According to Elder, the vaccine's manufacturer is Serum Institute India, the manufacturer "pre-qualified by WHO to manufacture and supply vaccines." A Kenyan regulatory body also "ensures registration and quality before use," Elder said.

World Vision Kenya National Health Coordinator Margaret Njenga said Kenya ranks 121st out of 147 countries in the Christian charity organization's "Killer Gap" report, which measures the gap in care between the country's "health rich" and "health poor." In an e-mailed statement, Njenga said that the gap "means reaching the most vulnerable children with life-saving health care can be difficult, and we are often battling low awareness, lack of physical access, consistency and quality in our efforts to overcome this."

She wouldn't comment on the specific allegations against the Kenyan government, UNICEF and the WHO. But, she said, there are "a number of barriers" World Vision and other aid groups face in overcoming that "killer gap," including differences in education and understanding and perceptions of life-saving health-care programs.

World Vision, she said, works on these issues at the community level, with a "focus on raising awareness and

understanding of the importance of approved vaccines.”