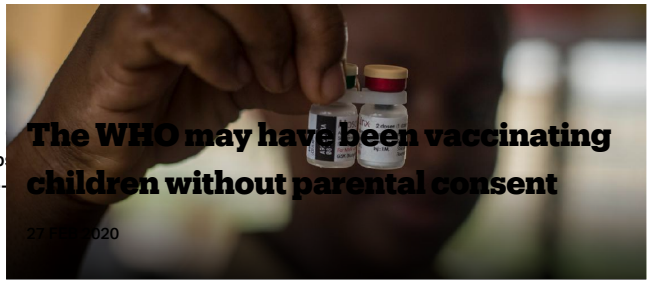
u=http
have-



The WHO may have been vaccinating children without parental consent

27 [illegible] 020

url=http
have-
con

The World Health Organization has vaccinated more than 15,000 children in Africa against malaria. But did they do so with consent, or were the children part of a research project?

url=http
have-
con
vac

An article published (https://www.bmj.com/content/368/bmj.m734) in the *BMJ* (formerly known as the *British Medical Journal*) points out the troubling aspects of a World Health Organization (WHO) malaria vaccination implementation programme (MVIP).

url=http
have-
con
vac

"Every year, malaria claims the lives of more than 400,000 people," the WHO says in a brochure (https://apps.who.int/iris/bitstream/handle/10665/272456/WHO-CDS-GMP-2018.05-eng.pdf?ua=1), adding: "Children under the age of five in sub-Saharan Africa are especially vulnerable; more than 250,000 children die from the disease every year. One child dies from malaria every two minutes."

subject=
WHO

https:
have-

A leading bioethicist speaking to the *BMJ*, Charles Weijer, of the Western University in Canada, calls the WHO trial a "serious breach" of international ethics standards.

text=htt
have-

Weijer is the lead author of the Ottawa Statement which is "a consensus statement on the ethics of cluster randomised trials" and he says the WHO's failure to obtain informed consent from parents of children in the malaria programme violates it, as it does the Council for International Organizations of Medical Sciences' International Ethical Guidelines.

"The failure to require informed consent is a serious breach of international ethical standards," Weijer says.

The World Health Organization carried out (https://www.who.int/malaria/mpac/proposed-framework-for-policy-decision-on-rtss-as01-malaria-vaccine.pdf) the MVIP phase three in Africa between 2009 and 2014. Using a vaccine called RTS,S/AS01 — known as Mosquirix (https://www.malariavaccine.org/files/content/page/files/RTSS%20vaccine%20candidate%20Fa — they have vaccinated 15,459 young children aged

6736(15)60767-X/fulltext) (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, and Tanzania) at 11 sites.

Now the programme is being offered in Malawi, Kenya and Ghana.

According to the WHO: "[A] four-dose schedule is required, with the first dose given as soon as possible after five months of age, doses two and three given at monthly intervals, and the fourth dose given 15–18 months after the third dose."

Dr Mary Hamel of the WHO explains (https://www.who.int/immunization/diseases/malaria/malaria_vaccine_implementation_programr "The vaccine pilot will help us learn more about the public health use of the vaccine and will inform WHO recommendations on broader use of the vaccine in sub-Saharan Africa." Yet not everyone is convinced.

The *BMJ*'s Peter Doshi points out "a rate of meningitis in those receiving Mosquirix 10 times that of those who did not, increased cerebral malaria cases, and a doubling in the risk of death (from any cause) in girls."

The WHO has defended itself by calling the study a "pilot introduction" and not a "research activity", the BMJ reports. The organisation has said that consent by parents of vaccinated children was implied.

"An implied consent process is one in which parents are informed of imminent vaccination through social mobilisation and communication, sometimes including letters directly addressed to parents. Subsequently, the physical presence of the child or adolescent, with or without an accompanying parent at the vaccination session, is considered to imply consent," said a WHO spokesperson.

For McGill bioethicist Jonathan Kimmelman, that's not good enough. "Unless certain conditions are met, human subjects must provide informed consent."

Kimmelman also disagrees with the WHO on whether the study is research: "The fact that the activity has been registered in clinicaltrials.gov [NCT03806465 (https://www.bmj.com/lookup/external-ref?link_type=CLINTRIALGOV&access_num=NCT03806465&atom=%2Fbmj%2F368%2Fbmj.m734. amounts to an open declaration that this is research."

Yet another article (https://www.bmj.com/content/368/bmj.l6920?ijkey=632fefa22e9c2ed1aaa0eb22d0f796f5d064afea&keytype2=tf_ipsecsha) published in the *BMJ* questions the WHO's decision to

The authors say: "An early decision after 24 months might be biased in favour of the vaccine, which was more efficacious in the first year of follow-up in the phase III trials; the relative risks of both cerebral malaria and female mortality increased after the booster dose at 20 months."

One of the authors of the study, Christine Stabell Benn of the University of Southern Denmark, tells the *BMJ*: "I think parents should be made aware of this doubled female mortality. Imagine that this mortality was a true finding ... If true, then how will this be perceived by the participants—that their children were unknowingly involved in a huge experiment by the authorities? This could be a disaster for public trust in vaccines and health authorities."

According to *BMJ*'s Doshi, participants in the WHO's MVIP are not being told they're in a study and whether the parents know about Mosquirix's safety concerns before their children are injected is uncertain.

"Information on vaccination is provided to the community and to parents through health talks and community outreach—among other methods, and parents who present for vaccination do so with the option to vaccinate their children or not," the WHO says.

However, according to Weijer: "Implied consent is no consent at all. We have no assurance that parents in fact received information about the study let alone that they understood it."

In a June 2019 article (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6697765/) written for *Ghana Medical Journal* titled 'Musings on malaria morbidity and mortality after the new Mosquirix vaccine', Dr Adziri H Sackey criticises the WHO programme and says: "When the existing malaria control measures are implemented more effectively, the vaccine in its current form does not offer any measurable mortality advantages," adding: "This means that if there were a willingness to implement malaria control measures intensively, there would be no need to expose our children to the unknown effects of a new vaccine."

Another article (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6842733/) in response to Dr Sackey's, written by several doctors, defends the WHO programme, saying: "The vaccine is not to replace the other malaria interventions but an

It must be noted that one of the doctors works for an institution that received research funds to conduct part of Phase II/III trials of Mosquirix while another doctor is the Programme Manager for Malaria Control in Ghana.

Related News

(/africa/malaria-immunisation-pilot-project-begins-in-ghana-26305)

Malaria immunisation pilot project begins in Ghana (/africa/malaria-immunisation-pilot-project-begins-in-ghana-26305)

(/africa/african-countries-seek-declaration-of-global-climate-emergency-at-un-summit-30033)

African countries seek declaration of global climate emergency at UN summit (/africa/african-countries-seek-declaration-of-global-climate-emergency-at-un-summit-30033)

(/life/malawi-pilots-groundbreaking-malaria-vaccine-26104)

Malawi pilots groundbreaking malaria vaccine (/life/malawi-pilots-groundbreaking-malaria-vaccine-26104)