

Exclusivo: NIH financia projeto piloto para promover vacina contra HPV em alunos sul-africanos da quinta série

Os Institutos Nacionais de Saúde concederam 340 mil dólares para testar táticas psicológicas destinadas a persuadir os alunos e pais sul-africanos do quinto ano a aceitarem a controversa vacina contra o HPV, de acordo com documentos obtidos pela Children's Health Defense através de um pedido da Lei da Liberdade de Informação.

By Dr. Brenda Baletti

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Os Institutos Nacionais de Saúde (NIH) estão financiando pesquisas sobre como aumentar a aceitação da vacina contra o papilomavírus humano (HPV) entre meninos e meninas do quinto ano na África do Sul, <u>a partir de documentos</u> obtidos pela <u>Children's Health</u> <u>Defense</u> (CHD) através de um pedido de um Freedom of Information Act revelado.

O NIH concedeu aproximadamente US\$ 340.000 aos investigadores principais, <u>Dra. Ingrid Katz</u>, médica do Brigham and Women's Hospital em Massachusetts, e <u>Lisa Michelle Butler</u>, <u>Ph.D.</u>, epidemiologista da Universidade de Connecticut.

A subvenção financia um projeto para desenvolver e testar estratégias de comunicação escolar dirigidas às crianças e aos seus pais nas escolas da província de <u>KwaZulu-Natal</u>, na África do Sul, para determinar que tipos de comunicação têm maior probabilidade de resultar em mais crianças a receberem a vacina contra o HPV.

O financiamento cobre um estudo piloto de viabilidade de um ano em cinco escolas para testar estratégias que os investigadores irão então refinar e testar em centenas de crianças num "ensaio híbrido tipo 2 maior, em grande escala".

Os investigadores esperam que as estratégias de comunicação escolar que desenvolvem ajudem a aumentar a vacinação contra o HPV em crianças e adolescentes na África do Sul, da taxa atual de 37% das raparigas para a taxa alvo de mais de 80% de todas as crianças com idades entre os 9 e os 12 anos.

Esperam utilizar mais tarde a mesma estratégia noutros países de baixo e médio rendimento para aumentar também as suas taxas.

"As vacinas contra o HPV não foram avaliadas de forma independente em termos de segurança e eficácia", disse o <u>Dr. Shankara Chetty</u>, clínico geral e cientista natural de KwaZulu-Natal. "Como tal, nenhuma estratégia de marketing coercitiva será suficiente para informar honestamente os destinatários sobre a sua decisão de consentimento."

"Vendo que os menores estão sendo alvo, é imperativo que os tutores destes menores

recebam todas as informações atuais e, mais importante, sejam informados da falta de informações sobre segurança e eficácia para fazer uma escolha informada", disse Chetty. "Isso não pode ser feito pela indústria lucrando com sua implementação."

Parte de uma iniciativa de subsídio de US\$ 40 milhões para promover vacinas contra o HPV

O CHD identificou em junho de 2023 quase 50 subsídios concedidos pelo Departamento de Saúde e Serviços Humanos (HHS) dos EUA e suas subagências, incluindo o NIH. As subvenções, totalizando mais de 40 milhões de dólares, foram destinadas a universidades, sistemas de saúde e departamentos de saúde pública para utilizarem estratégias de psicologia comportamental para <u>aumentar a adesão à vacina contra o HPV</u> entre os adolescentes.

Esta é a primeira subvenção identificada pelo CHD que utiliza os mesmos métodos para atingir crianças na África.

A pesquisa se enquadra em um programa mais amplo entre instituições do HHS, que inclui centenas de milhões de dólares em subsídios para desenvolver e testar estratégias para aumentar a aceitação de todas as vacinas entre comunidades de baixa renda e comunidades de cor, hesitantes em vacinas, usando mensagens "culturalmente adaptadas" em nome da "equidade na saúde".

Está também em linha com um esforço para fornecer <u>financiamento substancial</u> para aumentar as taxas de vacinação contra o HPV, "aumentando a consciencialização" e combatendo a "desinformação".

Além de satisfazer os objetivos do HHS, o projeto da África do Sul responde a um programa global estabelecido em 2020 pela <u>Assembleia Mundial da Saúde</u> da Organização Mundial da Saúde (OMS) para <u>erradicar o câncer do colo</u> do útero como um problema de saúde pública em todo o mundo, em grande parte através da vacinação contra o HPV.

A Gavi, a Vaccine Alliance, apoiada pela Fundação Bill & Melinda Gates, anunciou no ano passado que investiria mais de 600 milhões de dólares para atingir o seu <u>objetivo de vacinar 86 milhões de meninas</u> contra o HPV em países de baixa e média renda até 2025, em grande parte através de campanhas nacionais de vacinação.

Esse anúncio coincidiu com campanhas nacionais de vacinação apoiadas pela Gavi na <u>Indonésia</u>, <u>Nigéria</u>, <u>Bangladesh</u>, <u>Zâmbia</u>, <u>Serra Leoa</u> e <u>Eritreia</u> nos últimos dois anos.

A África do Sul foi um dos primeiros países africanos a lançar uma <u>campanha nacional de</u> <u>vacinação</u> nas escolas, dirigida às meninas de 9 anos ou mais que frequentam o quarto ano nas escolas públicas.

Katz e Butler relataram no seu pedido de subvenção que a campanha foi inicialmente "bemsucedida", mas as taxas caíram desde então, especialmente durante e após a pandemia da <u>COVID-19</u>.

<u>A Merck</u>, que fabrica a <u>vacina Gardasil HPV</u>, disse que doará vacinas para o novo estudo. A Merck é <u>um dos principais parceiros da Gavi</u> na distribuição de vacinas em países de baixa e média renda em todo o mundo.

<u>Shabnam Palesa Mohamed</u>, diretora executiva do CHD África, disse <u>ao The Defender</u> que ficou desapontada ao ver investigadores sul-africanos colaborarem no projeto.

Ela disse:

"É difícil compreender porque é que os investigadores da UKZN [Universidade de KwaZulu-Natal] não consideram esta experiência manipulativa com crianças racista e desumanizante. A <u>indústria farmacêutica</u> tem um histórico terrível na África, onde a farmacovigilância é fraca ou inexistente, em grande parte devido ao financiamento farmacêutico de cientistas, autoridades reguladoras e departamentos de saúde. UKZN não é exceção. Seus financiadores incluem a <u>Fundação Bill e Melinda Gates</u>.

"Lembro-me dos <u>cientistas comportamentais</u> que ajudaram o governo do Reino Unido a manipular o público [durante a pandemia de COVID-19] e mais tarde disseram que ficamos sistematicamente 'atordoados com a transformação da psicologia comportamental em arma' durante a pandemia."

South Africa project 'smacks of pharmaceutical imperialism'

Under the \$340,000 grant awarded to Katz and Butler, principal investigators will collaborate with a team of psychologists, an education specialist, an epidemiologist and a biomedical engineer from U.S. universities and the UKZN, along with the local department of health and elementary schools in an urban setting in the KwaZulu-Natal province.

The name of the city and schools where the project will be implemented were redacted from the FOIA documents provided to CHD.

Researchers will specifically target "diverse populations" and integrate "the voices of individuals living in low-resource settings" as they try to understand why children don't take the HPV vaccine and in particular why those numbers declined after the COVID-19 pandemic.

"Health equity is at the core of our research," they wrote.

However, Mohamed said, "Manipulating children and families from underprivileged backgrounds is the essence of medical colonialism."

She added:

"Not for the first time, there will be <u>no proper informed consent</u> with these children or their families, and there will be no compensation for harms or death caused.

"The role of the controversial NIH in behavioral manipulation — the same NIH that did not expose the WHO facilitating <u>fertility experiments</u> on Kenyan girls and women — smacks of pharmaceutical imperialism."

The researchers hypothesize declining HPV vaccination rates may be linked to COVID-19related program interruptions, "increased medical mistrust, and vaccine hesitancy related to misinformation spread on social media," which they seek to correct.

They are expanding the HPV vaccine target population to include boys and children in private schools who were not initially included in South Africa's national <u>school-based</u>

vaccination program.

Currently, <u>GSK's bivalent Cervarix vaccine</u> is administered at no charge by school nurses in public schools on two designated days per year. Boys and private school children must pay for the shot.

The HPV vaccine has not previously been made widely available to boys in the country, and most low- and middle-income national vaccination campaigns target girls only.

However, since the U.S. Food and Drug Administration in 2009 expanded the license for use in males ages 9-26 for the prevention of genital warts, and in 2011 the CDC's Advisory Committee on Immunization Practices recommended it for routine use in boys, vaccination campaigns, at least in the U.S. and Europe, have also targeted boys.

The WHO noted that <u>market sustainability for the drug</u> will require also targeting boys.

To develop the communication materials for testing, researchers held initial meetings with school principals and teachers, nurses and parents of boys and girls enrolled in public and private schools in the study area. They reported respondents expressed a desire to "center community knowledge."

Respondents also indicated they wanted to make the vaccine program "inclusive" of boys and private school children and to have access to "culturally tailored education materials" to address persistent misunderstandings about vaccination — a set of goals that mirrors those of all other NIH-funded HPV uptake research programs in the U.S.

The pilot project will convene a "Stakeholder Working Group" with representatives from government, civil society, academia and those with legal, financial or ethical stakes in the HPV vaccination program. The group will meet periodically to discuss the research.

The researchers also plan to survey and interview children, families, teachers and school nurses about their ideas and behaviors related to the vaccine.

Based on information gathered in those meetings, they will develop a "multi-level communication strategy" for schools that includes promotional curricular material aimed at children and informational brochures to be distributed to parents.

They also will develop a "conversation map" strategy for teachers and nurses fluent in Zulu that they can use as a tool to "facilitate dialogue" around "misinformation" and vaccine efficacy.

<u>Jive Media Africa</u> will produce "entertaining" curricular materials. The company was selected based on its work producing <u>COVID-19 materials for schools</u>.

The study's success will be measured by how many children get vaccinated two months, six months and 12 months after the intervention and whether they get an initial dose or the full two-dose series. It also will measure whether the research subjects' knowledge, ideas and beliefs about the HPV vaccine change.

The project targets fifth-graders and their parents, the researchers wrote, because research has found <u>low coverage in South Africa</u> is primarily due to lack of parental consent. It also targets those who might be able to influence the parents, such as teachers and nurses.

The five-school randomized controlled pilot study funded by the grant will target 200 parents and children and 16 teachers and nurses.

In the Phase 2 trial, a 10-school randomized study will aim for about 1,500 participants.

Parents and students will be recruited in the selected schools through a letter sent home with the fifth-graders asking them to consent to participate in surveys and to share their children's immunization records. People interviewed will provide verbal consent to be interviewed.

After the pilot study, researchers will refine their materials and launch the Phase 2 randomized control trial in more schools.

The Phase 2 trial is scheduled to begin in January 2025, according to the U.S. government <u>clinical trials website</u>. It is unclear whether funding has already been secured for the Phase 2 trial.

Justification: cervical cancer eradication

According to Gavi, nearly 80-90% percent of the approximately 300,000 deaths per year from cervical cancer — the <u>fourth most common cancer</u> among women — occur in low- and middle-income countries and the majority occur in sub-Saharan Africa.

The higher rates of cancer in low- and middle-income countries are largely attributed to <u>low screening coverage for cervical cancer</u> and limited <u>treatment options</u> in the region, although actual numbers vary widely from country to country.

The HPV virus has been associated with cervical cancer, although the vast<u>majority of HPV</u> infectionsclear on their own.

There are more than 150 strains of HPV. High-risk HPV types can cause cervical cell abnormalities that are precursors to cancer, although HPV infection is not the sole risk factor for cervical cancer.

Regular <u>pap screening</u> has been found to reduce the incidence and mortality of cervical cancer among women by at least 80%.

However, <u>according to Gavi</u>, "Cervical cancer is almost entirely vaccine-preventable, which means that alongside screening for early detection, rolling out the <u>HPV vaccine is critical</u> to preventing infections."

The grant documents use this same language although they are less equivocal, stating that cervical cancer is "entirely preventable" with the HPV vaccine. This is despite the fact that the vaccines have not been tested for cancer prevention, only for their ability to suppress target strains of HPV.

Between 2007 and 2012, several low- and middle-income countries conducted small-scale <u>HPV vaccine demonstration projects</u> with vaccines provided by Merck's now-discontinued <u>Gardasil Access Program</u> or by the Bill & Melinda Gates Foundation through the <u>PATH initiative</u>.

In 2012, Gavi began supporting national HPV vaccine introductions in low- and middle-

income countries and it continues to do so today.

A total of 122 <u>WHO member states</u> have added the HPV vaccine to their routine immunization schedules.

However, according to research published in <u>Preventative Medicine</u>, vaccine uptake is highly uneven and researchers argue more "effective communication strategies" are needed.

When South Africa's program launched in 2012, 86.6% of age-eligible girls were vaccinated in the first year. But by 2019 the numbers were down to 69% and in 2021 they were down to 37%.

HPV vaccine dangers remain unaddressed by project proponents

The <u>Gardasil vaccine</u> has been linked to myriad adverse events worldwide. Some of the signature impacts observed following HPV vaccination include permanently disabling <u>autoimmune and neurological conditions</u>, such as <u>postural orthostatic tachycardia syndrome</u>, or POTS, <u>fibromyalgia</u>and <u>myalgic encephalomyelitis/chronic fatigue syndrome</u>.

Peer-reviewed scientific literature from the U.S., Australia, Denmark, Sweden, France and Japan, and statistics published by public health agencies in each of these countries, demonstrate plausible associations between <u>HPV vaccination and autoimmune conditions</u>.

According to an article in the <u>British Journal of Clinical Pharmacology</u>, most low- to middle-income countries have very low reporting rates for adverse events associated with vaccines or other pharmaceutical products, so it is difficult to track injuries related to previous vaccine rollouts.

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