

Vaccines Case Study: South Africa, 2014-2015

Protecting school girls from cervical cancer in Khayelitsha, South Africa



View of Khayelitsha, Western Cape, South Africa. ©Sydelle Willow Smith

Background

Khayelitsha is the largest township in Western Cape Province, South Africa and one of the poorest areas of Cape Town. Médecins Sans Frontières/Doctors Without Borders (MSF) began working in Khayelitsha in 1999 as one of the first providers of free antiretroviral treatment for people living with HIV in the public sector, with the project evolving to support the Department of Health (DoH) to deliver a variety of HIV treatment and care programmes. In 2010, MSF reported an antenatal HIV prevalence rate of 26.3% in Khayelitsha.¹

In South Africa, cervical cancer is the second most common cancer and the leading cause of cancer deaths in women.² Over 10,000 cases are diagnosed annually, and the disease kills over 5,800 women in the country every year, per 2021 data.² The human papillomavirus (HPV) is the primary cause of cervical cancer, and at least 14 strains of HPV are known to be carcinogenic. Of these, viral types 16 and 18 account for about 70% of all cervical cancers worldwide.³ Additionally, people living with HIV are more likely to be infected with multiple HPV types and have an increased risk of more aggressive, precancerous lesions at a younger age.³

HPV vaccines help prevent cervical and other HPV-related cancers. In 2009, the World Health Organization (WHO) recommended the inclusion of HPV vaccines in national immunisation programmes for girls aged 9-13 years, prior to the onset of sexual activity. In May 2013, the South African government announced that they would be introducing free HPV vaccination for all girls in grade four at public schools aged 9 years and older. The first round of the vaccination campaign in March 2014 aimed to reach around 520,000 girls with a two-dose vaccine schedule administered through the school health system. As MSF was already working in Khayelitsha, the organisation

partnered with the DoH and Department of Education (DoE) to support the implementation of the vaccination campaign in this sub-district.

Obtaining the HPV vaccine for school girls in South Africa

As an upper middle-income country, South Africa is ineligible for financial support for vaccines through Gavi, the Vaccine Alliance. The South African DoH was therefore required to negotiate directly with the manufacturers to agree on a price and preferred supplier for the HPV vaccine. At the time, only two manufacturers of HPV vaccines existed globally: GlaxoSmithKline (GSK) and Merck. GSK markets Cervarix, which protects against two types of HPV (16 and 18). Merck markets two vaccines: Gardasil, which protects against four types of HPV (6, 11, 16, and 18), and Gardasil9, a more recent product that was unavailable at the time of the vaccination campaign, which protects against nine types of HPV (6, 11, 16, 18, 31, 33, 45, 52, and 58).

The South African DoH eventually negotiated a public sector price of 157 South African Rand (ZAR) per dose (approximately US\$15*) for the GSK vaccine. Although this was substantially less expensive than the private sector prices in South Africa in 2014 (approximately ZAR 591 [US\$55.19*] per dose for the GSK vaccine and ZAR 613 [US\$57.27*] per dose for the Merck vaccine), it was still nearly three times more expensive than the lowest global price of approximately ZAR 48 (US\$4.50*) per dose⁷ paid by Gavi for low-income countries (LICs).

Implementation of the HPV vaccine campaign in Khayelitsha

MSF accessed HPV vaccine supplies directly from the South African government, with the DoH pharmacy team distributing vaccines to local primary care clinics for collection by MSF teams. In addition to directly supporting vaccination activities in Khayelitsha, MSF assisted in data collection and clinical training for health workers, explaining practical requirements for transport and administration of the vaccine. MSF also produced educational radio sessions and articles for local newspapers to provide information on the HPV vaccine, prevention of sexually transmitted infections, cervical cancer, and sexual violence.

The first round of South Africa's HPV vaccination campaign ran from mid-March to mid-April 2014. The overall coverage in Western Cape Province was 91%, with varying results in each of the five districts. In Khayelitsha, a coverage of 74% was achieved. Notably, girls missed during the first round of the vaccination campaign were not initially included in the second round. However, a decision was subsequently made at the national level to include girls who were both scheduled to receive their second dose and had not received the vaccine during the first round. The second round of vaccinations took place in early 2015, and overall coverage in Khayelitsha rose to 87%. The decision to include girls who were missed during the first round therefore represented a significant achievement and a success in terms of increasing the total number of girls vaccinated.

Impact of high vaccine prices

South Africa spent an estimated ZAR 70 million (approximately US\$6.5 million*) on vaccine products alone for the first round of the vaccination campaign. While the introduction of school-based administration of the HPV vaccine was and remains a progressive approach internationally, the high price of the vaccine placed certain limitations on the overall impact of the programme. First, while Gavi-eligible countries can select either HPV vaccine product for the same price, the South African DoH chose the HPV vaccine product that protects against fewer strains of HPV, likely due to its lower price. Second, at the time of this campaign, the WHO recommended a

^{*} Currency conversions are valid as of March 2014 to represent the prices at the time of the vaccination campaign, taken from https://www.oanda.com/currency/converter/.

three-dose HPV vaccine schedule.* However, South Africa chose to use a two-dose schedule, as emerging evidence at the time (now proven correct) suggested that this was sufficient to provide immunity, and it helped to reduce vaccine and implementation costs.

When the DoH introduced the HPV vaccine into the national immunisation programme, the total government purchase price for the vaccines to fully vaccinate a girl increased by 18%, from ZAR 1,115 (approximately US\$104*) for 12 other vaccines to ZAR 1,363 (approximately US\$127*) per girl.† If South Africa was able to purchase HPV vaccines at Gavi prices, it would have realised savings of ZAR 214 million (approximately US\$20 million*) every year using the two-dose vaccination schedule. These savings could have been invested into purchasing additional HPV vaccines to cover a broader age range of girls and women, vaccinating young men, or improving delivery services and conducting outreach to girls who were not in school or otherwise went unvaccinated. Alternatively, the cost savings could have been used to improve vaccine coverage overall, which was 65% nationally at the time of this analysis.

Conclusion and future solutions

The average global cost of fully vaccinating a child has increased 68-fold since 2001,⁸ and is in large part driven by the cost of new products like the HPV vaccine. Market prices for new vaccines remain high because of a lack of competition in the marketplace. While lower-cost manufacturers are in the process of developing more affordable versions of HPV vaccines, a broader base of products are several years away from reaching the market, in part due to multiple patent barriers along the development, manufacturing and administration processes.⁹ In the meantime, GSK and Merck's market dominance means they can charge excessively high prices. Between 2006 and the end of 2017, these companies had collectively made approximately US\$21 billion[‡] in sales from their respective HPV vaccine products. Middle-income countries (MICs) ineligible for Gavi support, such as South Africa, may struggle to introduce new vaccines due to high costs. As newer, more expensive products such as the HPV vaccine enter the market, a number of steps need to be taken to limit the increasing cost of fully vaccinating children.

Access to Gavi prices

Currently, LICs are offered the lowest global prices through Gavi, but most MICs are left out and assumed to be able to pay substantially more for the same vaccines. South Africa, for instance, contributes funds to Gavi, but, because of its MIC status, fails to benefit from Gavi support or prices. Offering countries like South Africa vaccine prices based solely on income level ignores the country's significant burden of cervical cancer and other vaccine-preventable diseases, and the need to optimise financial resources for the large cohort of eligible children requiring vaccination each year.

The South African government should demand and receive access from manufacturers to the lowest global prices paid by Gavi, and use its voice to champion access challenges for other MICs. Considering the burden of cervical cancer in South Africa, and high rates of cervical cancer/HIV co-infection, lower prices to expand access to HPV vaccination is a public health priority.

* In April 2014, the WHO Strategic Advisory Group of Experts recommended switching from a three-dose to a two-dose schedule for girls, provided that vaccination was started before 15 years of age.

[†] Cost projections based on prices provided in May 2014 by the National Department of Health to MSF. These prices are not inclusive of VAT or delivery charges. Vaccines include two doses of rotavirus, four doses of DTaP-IPV-Hib, three doses of HBV, three doses of PCV, two doses of measles and two doses of Td, to which the price of the HPV is added. Prices were not provided for the two doses of OPV or single dose of BCG that are also included in the South African EPI.

[‡] Approximate cumulative calculation from Merck and GSK quarterly revenue reports provided on their websites <u>here (Merck)</u> and <u>here (GSK)</u>.

Transparency on vaccine prices

All countries and vaccine purchasers, including South Africa, should publish in the public domain information on their volumes purchased and prices paid for vaccine products through WHO's Vaccine Product, Price and Procurement (V3P) platform.¹⁰ Greater transparency and sharing of information between countries will increase countries' bargaining power, and help more countries obtain a better deal on vaccine prices.

As Dr Yogan Pillay, Deputy Director General of the South African DoH, stated at the time, "We introduced two new vaccines recently [PCV and HPV] ... and because there are only two suppliers for each vaccine, there is no competition and we pay a premium ... To the extent that we know what other countries are paying, that would strengthen our arm [in negotiations with companies]".¹¹

Transparency on research and development costs

Transparency is also needed from vaccine manufacturers around research and development (R&D) and manufacturing costs. This would allow the global vaccine community to more accurately determine fair and affordable prices for new products based on meeting countries' public health needs.

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