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Human Papillomavirus Vaccine: Supply and Demand Update

UNICEF Supply Division

December 2019

Human Papillomavirus Vaccine Supply and Demand Update - December 2019

This update provides information on human papillomavirus vaccine, including supply, demand, and pricing trends. It highlights continued supply constraints foreseen over 2020, which also affect countries procuring through UNICEF. UNICEF requests self-financing middle-income countries to consolidate credible multi-year demand and to submit multi-year commitments through UNICEF.

A more recent note covering human papillomavirus vaccines exists. Please visit <https://www.unicef.org/supply/market-notes-and-updates>

1. Summary

- UNICEF's strategic plan for 2018-2021 seeks to ensure that at least 24 countries nationally introduce human papillomavirus (HPV) vaccine.¹ As of to date, 18 countries supplied through UNICEF, of which 14 supported by Gavi, the Vaccine Alliance (Gavi) and four countries having transitioned from Gavi support and self-finance their procurement have introduced HPV vaccine since the inception of Gavi's HPV programme in 2013. Four middle-income countries (MICs): the Maldives, Seychelles, Turkmenistan, and Vanuatu are also procuring HPV vaccines through UNICEF. From 2013 to 2018, UNICEF's total HPV vaccine procurement reached 18.9 million doses in support of girls. There is currently no gender-neutral programmes in countries supplied through UNICEF. Of the 18.9 million doses, UNICEF procured 16.1 million doses (85 per cent) for countries supported by Gavi, including those that transitioned from Gavi support and still access Gavi prices, and 2.8 million doses (15 per cent) on behalf of self-financing MICs.
- In December 2016, Gavi revised its programme strategy to support full-scale national HPV vaccine introductions with multi-age cohort (MAC) vaccinations, which substantially increased HPV vaccine demand through UNICEF from 2017. By end of 2019, Gavi had approved applications from 24 countries for HPV vaccine national introduction and anticipates additional countries to submit applications in 2020.
- Global HPV vaccine supply availability is currently insufficient to meet the aggregate demand. Consequently, HPV vaccine supply through UNICEF is also constrained and not sufficient to meet the increased requirements, which it projects could reach up to 35.8 million doses in 2020. As a result, countries introducing the vaccine with the support of Gavi will need to postpone their plans for MAC vaccinations. Self-financing MICs for which UNICEF does not have a long-term arrangement (LTA) with suppliers will not be able to access supply through UNICEF until supply availability improves.
- Currently, only two manufacturers have WHO prequalified HPV vaccines. UNICEF extended its LTA with Merck through to 2020, and its LTA with GlaxoSmithKline (GSK) through to 2022 to secure supply for countries that have introduced HPV programmes in their national immunization schedule. UNICEF issued a tender in December 2019 to existing manufacturers with WHO prequalified vaccines and future pipeline manufacturers to secure additional supply for 2021 and beyond.
- HPV vaccine pricing remains high and varies significantly between different country income levels. Vaccine affordability is a concern for most self-financing MICs considering HPV introduction, as well as for many Gavi-supported countries seeking to sustain HPV vaccination once they transition from Gavi support and self-finance their HPV procurement.

2. General Brief and Background

Human papillomavirus is a group of more than 100 viruses, of which 14 can cause cancer. Nearly all cases of cervical cancer are attributed to HPV.² Cervical cancer is the second most common form of cancer in women living in less developed regions,³ with an estimated 570,000 new cases a year resulting in an estimated 311,000 deaths. Eighty-five percent of cervical cancer cases occur in low-income countries (LICs) and MICs, with sub-Saharan Africa and Asia accounting for the highest incidence rates.⁴ Globally, two HPV strains (HPV-16 and HPV-18) cause about 71 per cent of all cases of invasive cervical cancer (Figure 1, next page).⁵

¹ United Nations, *Final Results Framework of the UNICEF Strategic Plan, 2018-2021*, UN, New York, July 2017, p. 19.

² World Health Organization, *Human Papillomavirus and Cervical Cancer*, WHO, Geneva, January 2019.

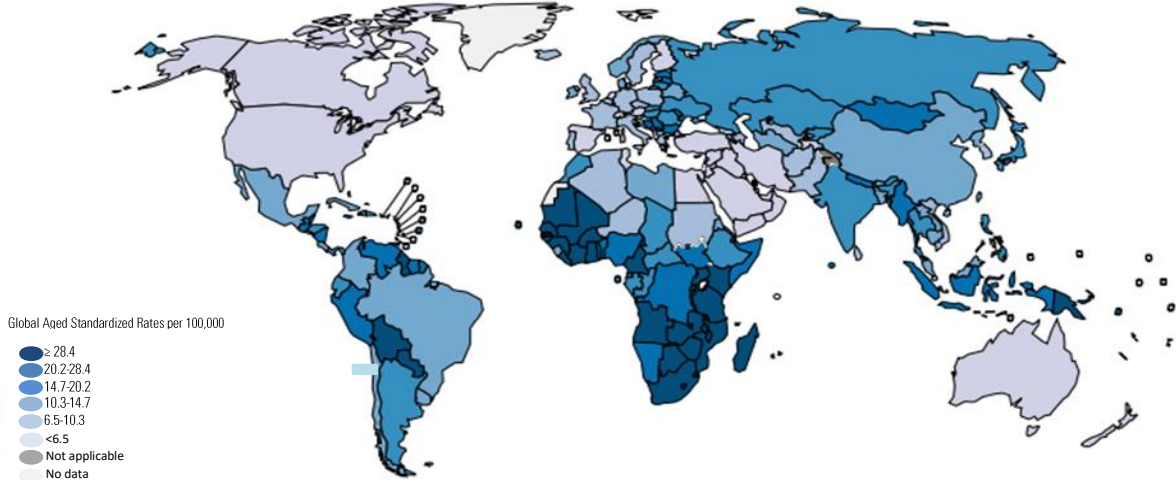
³ Ibid.

⁴ International Agency for Research on Cancer, *Cervix Uteri*, IARC, Lyon, 2018, p. 2.

⁵ World Health Organization, *Human Papillomavirus Vaccines, WHO Position Paper*, WHO, Geneva, May 2017, p. 244.

The HPV vaccine is the first vaccine developed specifically targeting the prevention of cervical cancer. HPV vaccines do not prevent all forms of cervical cancer, and as such, they do not replace the need for cervical cancer screening. The World Health Organization (WHO) recommends countries to include HPV vaccination into national immunization programmes as part of a coordinated and comprehensive strategy that includes education, access to quality screening, and treatment. Immunization should primarily target girls aged 9 to 14 years of age, prior to becoming sexually active; and secondarily, to target girls aged 15 and above.⁶ WHO recommends a two-dose schedule for girls aged 9 to 14 years, and a three-dose schedule for girls 15 years of age and above, in accordance with manufacturer guidance.⁷

Figure 1 WHO Age Standardized Rate Estimates for Cervical Cancer Incidence Worldwide - 2018



Source: World Health Organization

WHO has at present prequalified three vaccines from two manufacturers, which all protect against the main strains causing cervical cancer including HPV-16 and HPV-18 (Table 1).

Table 1 WHO Prequalified HPV Vaccines

Manufacturer	Type	WHO PQ	Formul	Vial	Shelf Life	VVM	Cold Chain Volume
GlaxoSmithKline (Belgium)	Bivalent	2009	Liquid	1 dose	60 months	Type 30	9.7 cm ³
		2009	Liquid	2 dose	60 months	Type 30	4.8 cm ³
Merck (USA)	Tetravalent	2009	Liquid	1 dose	36 months	Type 30	15.0 cm ³
	Nonavalent	2018	Liquid	1 dose	36 months	Type 30	15.1 cm ³

Source: World Health Organization

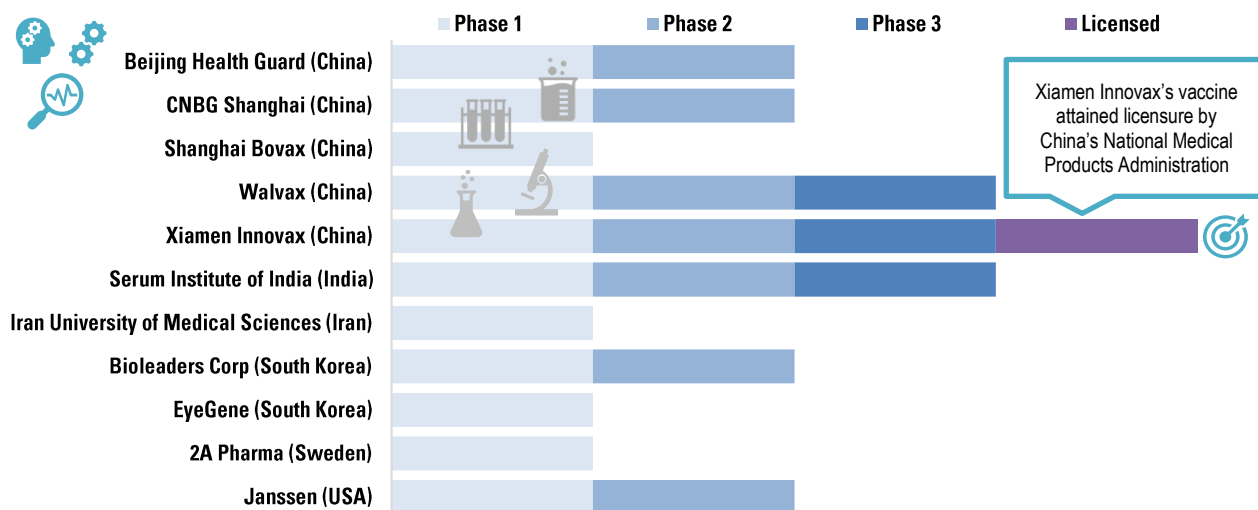
3. Innovation

There is currently only one other licensed HPV vaccine from Xiamen Innovax (China) that is not WHO prequalified and only for local markets.⁸ Several manufacturers are developing HPV vaccines, including tetravalent vaccines from CDIBP (China), Serum Institute of India, and Shantha Biotech (India),⁹ as well as bivalent vaccines from Walvax (China), amongst others, all in different stages of development. Of the 27 new generation vaccine candidates under development that UNICEF is aware of, 60 per cent are in discovery or preclinical stage, with the other 40 per cent being in different phases of clinical development, including two candidates in phase 3 (Figure 2, page 3). The success of ongoing research and development efforts and the timelines for new products to reach the market will be critical to alleviate current supply constraints and

⁶ WHO, *Human Papillomavirus Vaccines, WHO Position Paper*, p. 266.
⁷ Ibid., p. 249.
⁸ Innovax, *NMPA Announce the Approval to Bivalent HPV Vaccine Type 16&18 (Cecolin®)*, Innovax, Xiamen, December 2019.
⁹ **Note:** Shantha Biotech became a subsidiary of Sanofi Pasteur in July 2009.

improve market health. However, UNICEF does not expect any new HPV vaccines to be prequalified by WHO before 2021/2022 at the earliest. More information on some of the HPV vaccines targeting capsid antigens that are either licensed or in different stages of clinical trials can be accessed [here](#).¹⁰

Figure 2 Global HPV Pipeline – Non-exhaustive



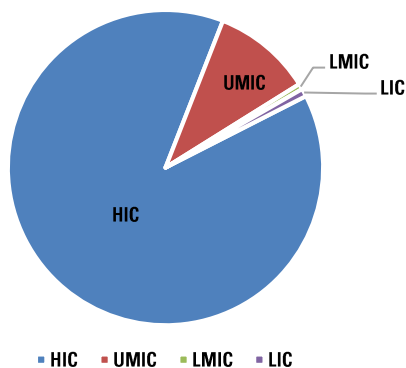
Source: GVMM

PATH, an international, non-profit global health organization focusing on product, service, and system innovation, is coordinating a consortium of nine research institutions that are undertaking the evaluation of evidence for a possible single-dose HPV vaccination schedule. The Single-Dose HPV Vaccine Evaluation Consortium, funded by the Bill and Melinda Gates Foundation (BMGF), is reviewing the effectiveness of such a single-dose schedule to inform policy discussions, which will impact demand and supply requirements.¹¹

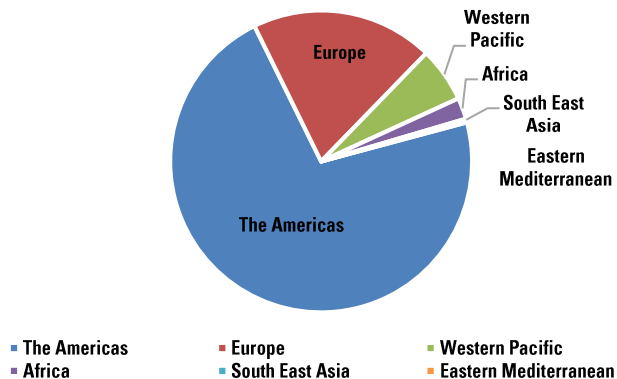
4. Current Market Situation

Figure 3 HPV Total Market Value in USD 2018

Share per World Bank Income Group
Total Revenues: USD 2.23 Billion



Share per Region
Total Revenues: USD 2.23 Billion



Source: GVMM

¹⁰ Roden, Richard, Peter Stern, *Opportunities and Challenges for Human Papillomavirus Vaccination in Cancer*, Nature Reviews Cancer, London, March 2018.

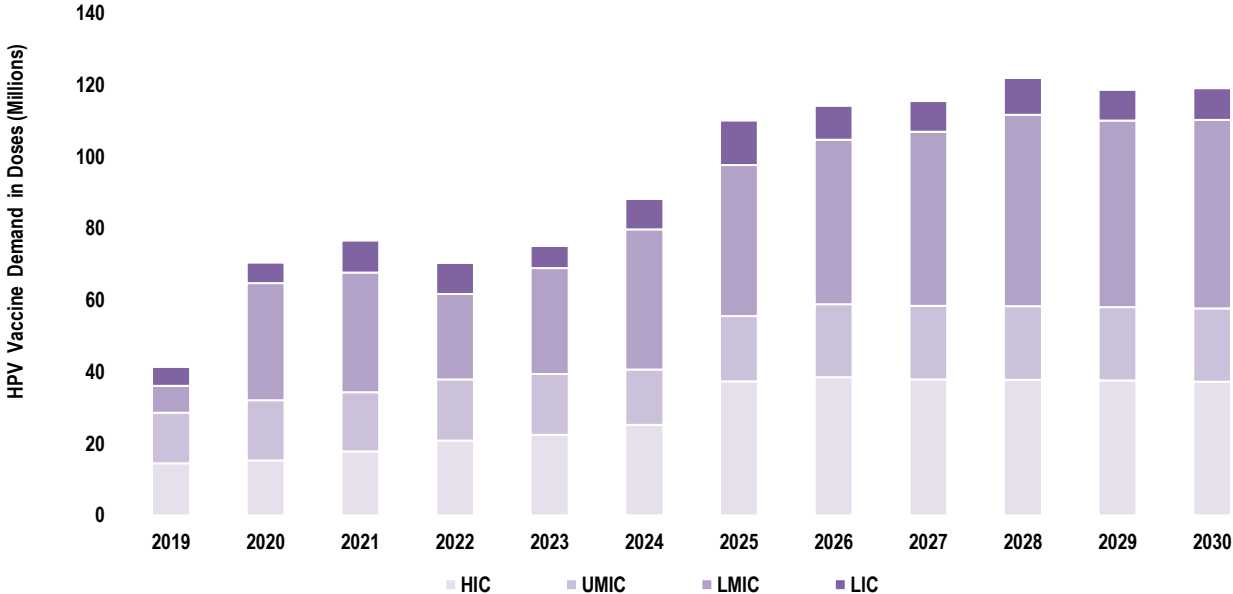
¹¹ PATH, *New Research Consortium to Evaluate Evidence for Single-dose HPV Vaccination*, PATH, Seattle, January 2018.

In 2018, the value of the global HPV vaccine market was estimated to reach USD 2.23 billion,¹² with some market reports estimating that it could reach USD 3.5 billion by 2025, based on an estimated compound aggregate growth rate (CAGR) of five per cent per year.¹³ High-income countries (HICs) will make up most of this growth, as they represent approximately 90 per cent of the market value (Figure 3, previous page). Even though geographically the Americas represent currently 72 per cent of the value, most revenue increases are anticipated to come from the Asia Pacific region.

In 2019, the global market volume for HPV vaccines reached approximately 41.4 million doses (Figure 4),¹⁴ having increased from an average of 30-35 million doses a year over 2010 to 2016,¹⁵ representing an increase of 18 per cent. HICs and upper middle-income countries (UMICs) make up 69 per cent of the global market share, while lower middle-income countries (LMICs) and LICs account for 18 per cent and 13 per cent respectively. Currently, the estimated market share by volume is 23 per cent for bivalent, 52 per cent for tetravalent, and 25 per cent for nonavalent HPV vaccines.

Global country demand for HPV could increase substantially over the next ten years to possibly reach 120 million doses a year by 2030 (Figure 4). Some significant increases in demand will be due to the introduction of the vaccine in China and India, and the adoption of gender neutral immunization policies, as well as growing interest in preventing cervical cancer through immunization, spearheaded by WHO's global call to action to end cervical cancer, which remains one of the gravest threats to women.¹⁶ However, as supply availability from manufacturers is constrained, UNICEF anticipates that it will not be sufficient to meet countries' demand through UNICEF in the near to medium term.

Figure 4 HPV Projected Global Demand by World Bank Country Income Group



Source: GVMM

4.1 Overall HPV Demand through UNICEF

UNICEF's strategic plan for 2018-2021 includes a target that at least 24 countries have introduced HPV into their national immunization programmes.¹⁷ As of to date, 18 countries supplied through UNICEF, of which 14 supported by Gavi, and four countries that have transitioned from Gavi support and self-finance their procurement, have introduced HPV vaccines since

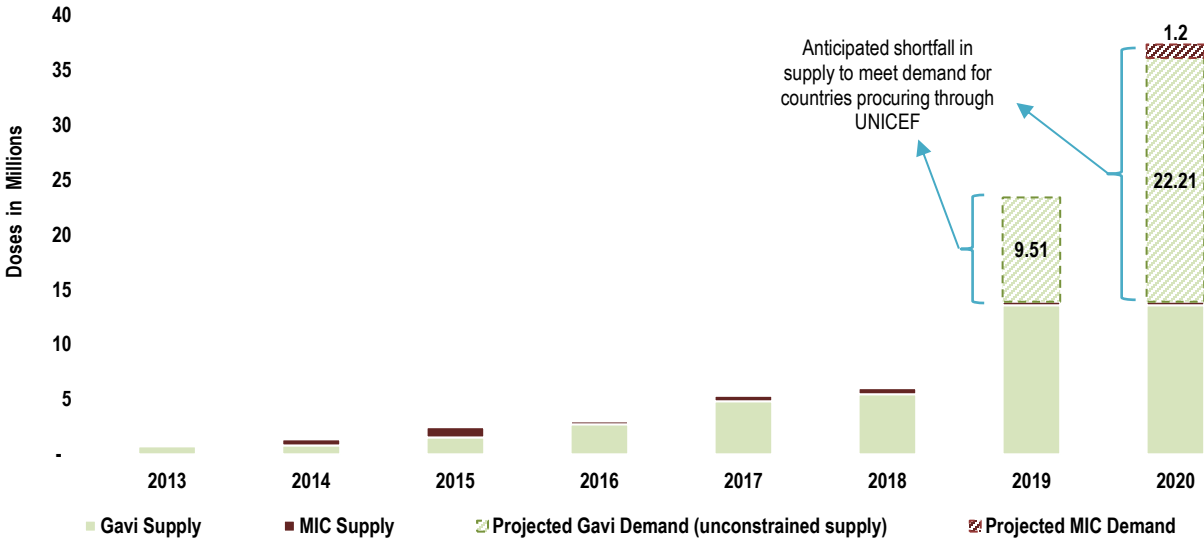
¹² Linksbridge, *The Global Vaccine Market Model*, Linksbridge, Seattle, 2019.
¹³ Transparency Market Research, *Human Papillomavirus Vaccine Market-Global Industry Analysis, Size, Share, Growth, Trends, and Forecast 2017-2025*, Transparency Market Research, Pune, March 2018.
¹⁴ Linksbridge, *The Global Vaccine Market Model*.
¹⁵ Gavi, the Vaccine Alliance, *Human Papillomavirus Vaccine Roadmap: Public Summary*, Gavi, Geneva, December 2017, p. 1.
¹⁶ The International Papillomavirus Society, *WHO Is Calling for Global Action to End Cervical Cancer*, IPVS, Geneva, May 2018.
¹⁷ United Nations, *Final Results Framework of the UNICEF Strategic Plan, 2018-2021*, p. 19.

the inception of Gavi’s HPV programme in 2013. Four MICs: the Maldives, Seychelles, Turkmenistan, and Vanuatu are also procuring HPV vaccines through UNICEF.

From 2013 to 2018, UNICEF procured 18.9 million doses of bivalent and tetravalent HPV vaccines for both Gavi-supported countries and self-financing MICs totalling USD 105.7 million.¹⁸ In 2018, UNICEF procured six million doses at a value of USD 30 million, which represents a market share of approximately 14 per cent of the global volume and 1.4 per cent of the value. Countries have not yet procured any nonavalent vaccine through UNICEF to date (Figure 5).

UNICEF’s current total projected demand for 2019 and 2020 could reach up to 60.8 million doses, mostly (97 per cent) on behalf of Gavi-supported countries, with 23 million doses for 2019, and 35.8 million for 2020. However, based on suppliers’ indications on short-term supply availability, UNICEF was only able to secure 13.58 million doses a year for 2019 and 2020, resulting in an anticipated shortfall of 31.7 million doses, which is more than half of the projected demand (Figure 5).

Figure 5 UNICEF HPV Supply and Projected Demand 2013-2020



Source: UNICEF Supply Division

4.2 Gavi-supported Country Demand

Gavi country demand refers to the demand from the 73 countries that are either eligible for funding support through Gavi or have transitioned from Gavi support. Gavi has supported HPV vaccine introduction since 2012, and initially offered eligible countries two introduction pathways, either through small-scale demonstration projects, or by directly rolling-out national introduction. Gavi had initially identified 47 countries as meeting the criteria to apply for HPV support and had set a target to vaccinate 30 million girls by 2020, with a demand forecast to reach approximately 63 million doses over the period 2013-2017.

However, by 2016, total HPV vaccine procurement through UNICEF for Gavi countries had only reached 5.8 million doses. In 2014, UNICEF’s demand forecast had been reduced by one third after WHO recommended to reduce the HPV vaccine dose regimen for girls aged 9 to 14 years from three to two doses. Countries were also taking longer than expected to transition from demonstration projects to national introductions. Even though 23 Gavi-supported countries had conducted HPV vaccine demonstration programmes, only three countries: Honduras, Rwanda, and Uganda had by then introduced HPV into their national immunization programmes (Figure 6).¹⁹

The programme’s initial design delayed national scale-up as demonstration projects did not encourage countries to identify cost-effective, sustainable delivery strategies, and were not integrated into many countries’ expanded programmes on

¹⁸ UNICEF, [Price Data Overview](#), UNICEF, Copenhagen, March 2018.

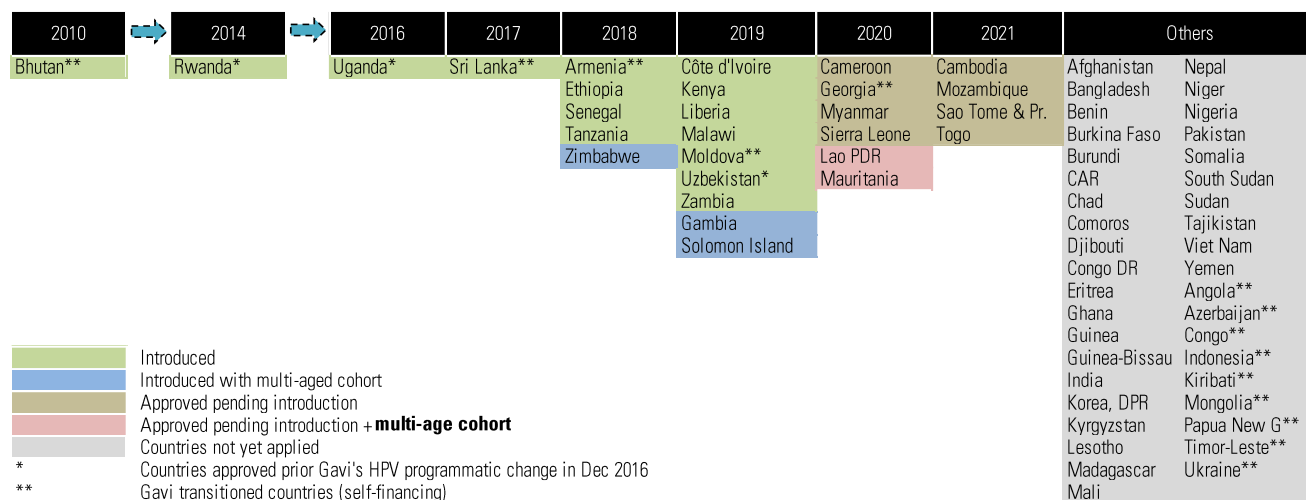
¹⁹ Figure 6 excludes Honduras, as the six Gavi-eligible/transitioned countries from Latin America and the Caribbean (Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua) access HPV through the Pan American Health Organization’s (PAHO) Revolving Fund.

immunization (EPI). Countries were also hesitant because they perceived programmatic and co-financing costs to be high, in addition to having pressure from other competing health and vaccine priorities.

To overcome some of these challenges, in December 2016, Gavi redesigned its HPV programme so that national introductions would no longer require prior evidence of experience in delivering HPV vaccines to adolescent girls. They also encouraged countries to immunize MACs from 9 to 14 years of age in the first year of their programme. As part of the redesign, Gavi also increased its target to vaccinate 40 million girls against HPV by 2020.

As of end of 2019, Gavi has approved 24 countries, of which 15 countries have introduced the vaccines, and nine countries are pending introduction under the redesigned programme to support HPV vaccine introduction, including support for MACs in the first year of introduction (Figure 6). The other countries: Armenia, Bhutan, Georgia, and Moldova introduced HPV after transitioning from Gavi support. Thirty countries remain eligible to apply to Gavi for HPV support, but which have not yet done so, while nine countries having transitioned from Gavi support are yet to make a decision on HPV introduction.

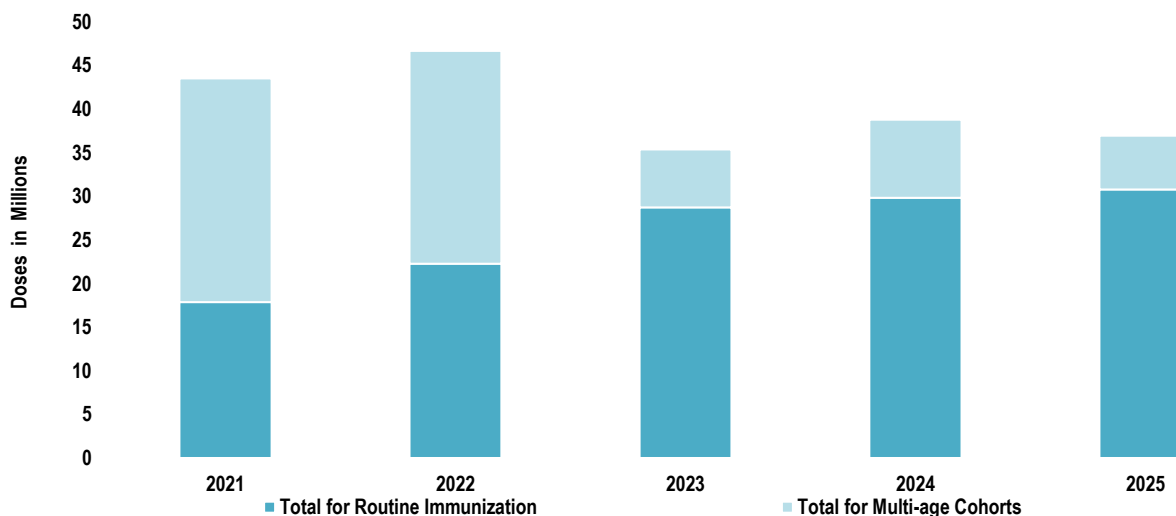
Figure 6 HPV Gavi Country Introduction Status through UNICEF 2019



Source: UNICEF Supply Division

UNICEF anticipates total unconstrained HPV vaccine country demand for Gavi-supported countries could reach up to 35.8 million doses in 2020, which includes MACs, but also previous MAC vaccination deferments combined with additional country applications in 2018 and 2019 (Figure 5, page 5).

Figure 7 Unconstrained UNICEF HPV Projected Demand 2021-2025 (Excluding India, Indonesia, and PAHO)



Source: Gavi

Manufacturers only allocated a limited supply of HPV vaccine to Gavi eligible countries reaching a total of 27.2 million doses for 2019 and 2020, which is only sufficient to support the existing programmes in 18 countries, and the introduction of HPV vaccines for routine immunization in an additional five countries during the same time period. To date, three countries have introduced HPV with a MAC strategy and an additional two countries will introduce by 2020. In the context of limited HPV vaccine supply, WHO's Strategic Advisory Group of Experts (SAGE) on Immunization recommends that:

*“all countries should temporarily pause implementation of boy, older age group (>15 years) and MAC HPV vaccination strategies until vaccine supply allows equitable access to HPV vaccine by all countries”.*²⁰

Therefore, until supply availability improves, future Gavi-supported MAC will be deferred. UNICEF anticipates that beyond 2020, Gavi supported demand through UNICEF could average at approximately 40 million doses a year over 2021-2025, depending on vaccine supply availability from manufacturers to support vaccine introduction and MAC campaigns (Figure 7).

4.3 Gavi-supported Country Supply

UNICEF's last HPV vaccine tender for Gavi supported countries secured supply to enable HPV demonstration projects and national introductions by establishing two five-year LTAs with two manufacturers covering 2013-2017. During this period, UNICEF procured 10.4 million doses of HPV vaccine for Gavi-eligible countries. As the demand from countries did not materialize in line with the level originally anticipated, manufacturers curtailed their production capacity through UNICEF to reflect its actual level. The increase in HPV vaccine demand, following Gavi's HPV vaccine programme redesign, has now surpassed total supply availability from both manufacturers.

UNICEF extended its current LTAs with both manufacturers based on confirmed supply availability. UNICEF extended its LTA with Merck to 2020 and GSK to 2022, as well as having increased the total number of awarded doses for the period 2013-2022 to 42.7 million doses, from 14.3 million by 28.3 million doses (Table 2).

Table 2 UNICEF HPV Vaccine LTA Awards for Gavi-Eligible Countries 2013-2022

Manufacturer (Country)	Type	Price per Dose	LTA Duration	LTA Duration	Dose Increase	Total Awards
GSK (Belgium)	Bivalent	USD 4.60	10 years	2013-2022	2,320,000	4,830,660
Merck (USA)	Tetravalent	USD 4.50	8 years	2013-2020	26,000,000	37,822,820
Total					28,320,000	42,653,480

Source: UNICEF Supply Division

Whereas UNICEF had previously made incremental awards to manufacturers during 2013-2016 based on the forecast demand of approved country programmes, UNICEF's limited awarded quantities in 2017-2022 were based on manufacturers' supply availability. Those countries that have transitioned from Gavi support and now have to self-finance their vaccine procurement (i.e. Armenia, Bhutan, Georgia, Moldova, and Sri-Lanka) can access HPV vaccines at the prices for Gavi-eligible countries and supply through UNICEF's LTA awards with manufacturers for Gavi-eligible countries subject to the agreement of the manufacturer.

As current supply from manufacturers through UNICEF is constrained, UNICEF and countries had to review their HPV vaccine introduction plans and MAC timing schedules against the timing of manufacturers' supply availability. MAC vaccinations in countries that will be introducing HPV vaccine into their national programmes in 2018-2021 will need to be postponed until supply availability improves.

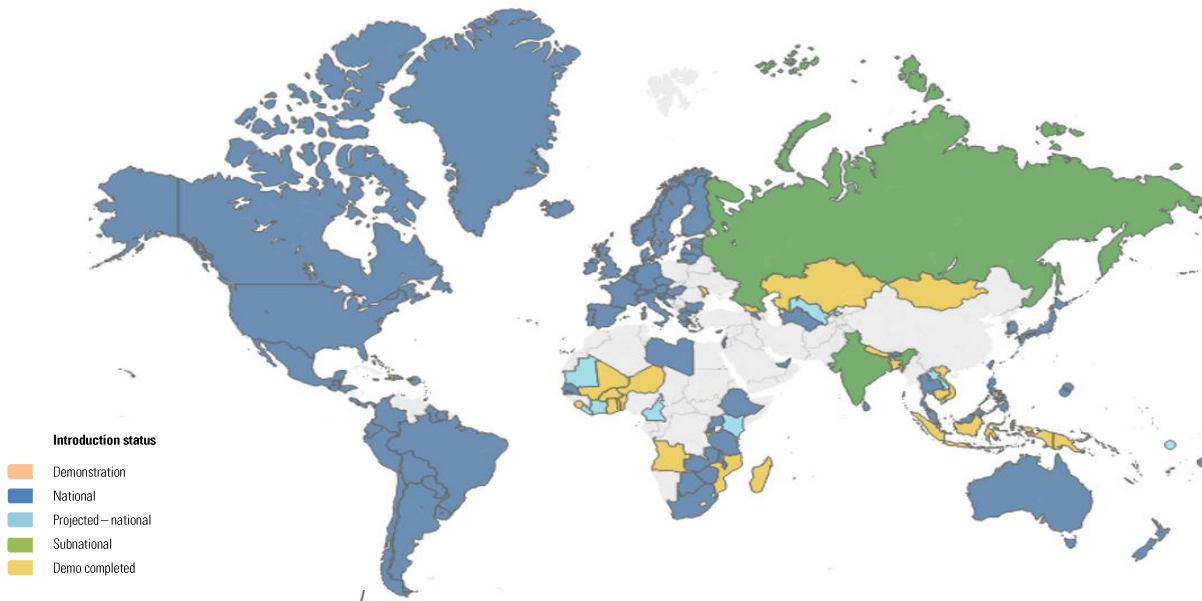
UNICEF is engaging with manufacturers and advocating for them to rapidly scale-up their production capacity to meet UNICEF's demand forecast. However, UNICEF anticipates that the supply constraints from manufacturers may likely last through 2024. As such, UNICEF encourages countries that are considering applying to Gavi for HPV vaccine support, to do so nevertheless, bearing in mind that there could be a 24-month lead time for vaccine delivery, and to plan their introduction timing accordingly.

²⁰ World Health Organization, [Meeting of the Strategic Advisory Group of Experts on Immunization, October 2019: Conclusions and Recommendations, No 47](#), WHO, November 2019, p. 550.

4.4 Middle-income Country Demand and Supply

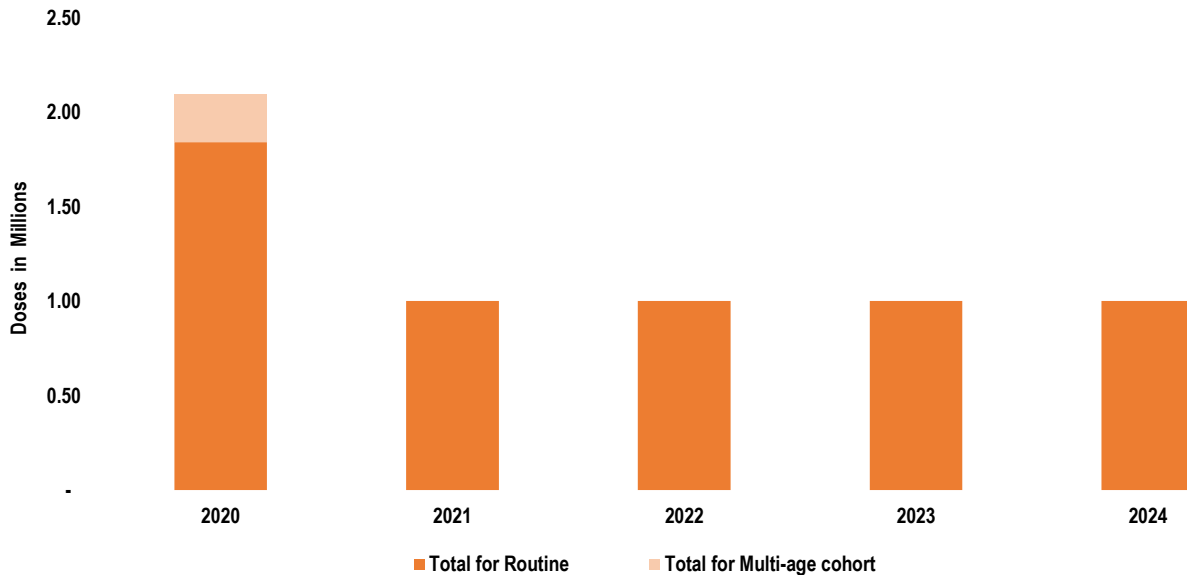
As of January 2019, 115 countries and territories currently have HPV vaccine in their national schedules. Most of these countries are HICs and UMICs, with many LICs and LMICs not yet having introduced the vaccine (Figure 8). Some MICs that are not eligible for Gavi support and self-finance their HPV vaccines procurement, channel their procurement through UNICEF. Since 2013 through the end of 2018, UNICEF procured 2.9 million doses on behalf of seven countries and territories not supported by Gavi or eligible to access Gavi prices through single-country tenders (Cook Islands, Fiji, Peru, the Philippines, Seychelles, Turkmenistan, and Vanuatu).

Figure 8 Status of HPV Vaccine Country Introductions Worldwide 2019



Source: PATH

Figure 9 HPV Projected Demand from MICs Indicating Interest to Procure through UNICEF 2020-2024



Source: UNICEF Supply Division

Several MICs have approached UNICEF to secure supply for introduction of HPV vaccine, but due to the constrained supply availability globally and through UNICEF, UNICEF may not be able to meet requests through 2020 from countries that do not have LTAs in place (Figure 9). UNICEF recommends all countries to forecast their HPV vaccine requirements for the next five years and make multi-year commitments to facilitate UNICEF’s engagement with manufacturers to secure supply through 2021 and beyond.

4.5 Pricing

Most countries considering HPV introduction, as well as those seeking to sustain HPV coverage after they transition from Gavi support, and have to self-finance their HPV procurement, are concerned about the high level of HPV vaccine pricing. Both GSK and Merck have agreed with conditions and for a limited timeframe, to continue to provide countries that have transitioned from Gavi support with vaccines at the same prices they accessed when supported by Gavi (Table 2).²¹ However, prices offered by manufacturers to MICs that self-finance their HPV vaccine purchases through UNICEF have been significantly higher, and have ranged from USD 10.25 to USD 31.50 (Table 3). These prices represent between two and half to seven times the lowest price offered to Gavi-supported countries at USD 4.50.

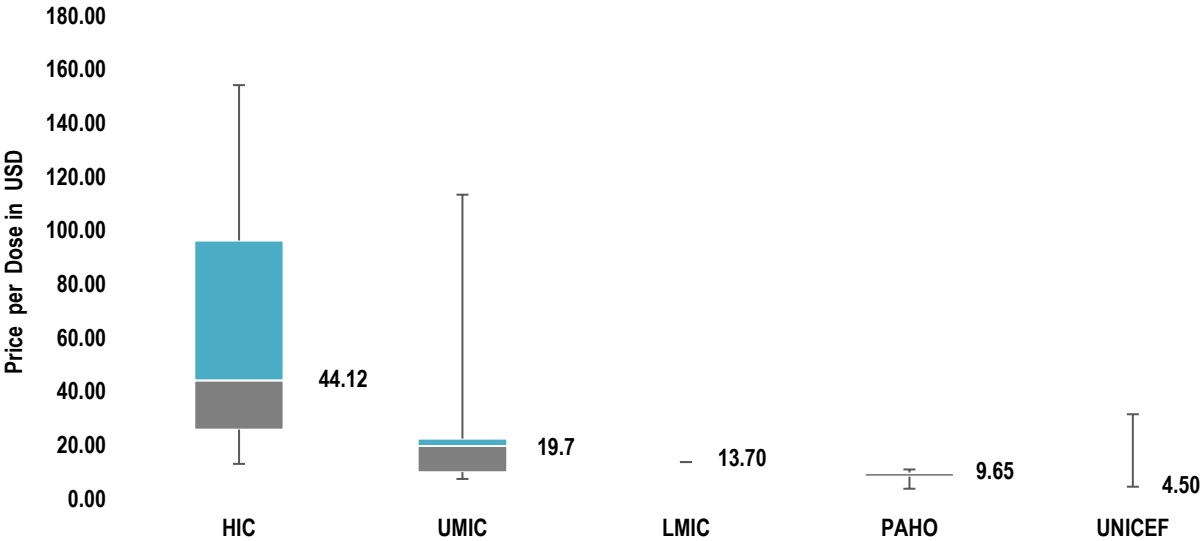
Table 3 UNICEF Middle-income Country HPV Vaccine Procurement 2013-2018

Vaccine	Manufacturer	Vaccine Price Range per Dose	Total Award in Doses
HPV	GSK (Belgium)	USD 10.25 - 31.50	8,800
HPV	Merck (USA)	USD 11.64 - 15.00	2,891,940
Total			2,900,740

Source: UNICEF Supply Division

Beyond procuring through UNICEF, Figure 10 highlights the notable variance in prices per dose offered to countries in different income classification tiers, as well as to countries in the same tier, and which is a growing concern for UNICEF and countries.²²

Figure 10 HPV Price per Dose Ranges per Income Group 2019 Showing Median Price²³



Source: World Health Organization, UNICEF Supply Division

²¹ Gavi, the Vaccine Alliance, [Vaccine Price Commitments for Countries Transitioning Out of Gavi’s Financial Support](#), Gavi, Geneva, November 2016.

²² World Health Organization, [Vaccine Product, Price and Procurement \(V3P\) Web Platform](#), WHO, Geneva, March 2018.

²³ UNICEF uses a “box and whisker” chart to show data distributed per quartile. It highlights price data and ranges in sections each containing approximately 25 per cent. The “blue and grey” boxes span the interquartile range showing 50 per cent of the price data, with the median price marked by a vertical line inside the box separating the two shaded halves, each containing 25 per cent of the data. The “whiskers” show the minimum and maximum price range of the data set. Looked at overall, the chart shows you the spread of a product’s price range per country income classification tiers.

UNICEF advises self-financing MICs seeking to procure through UNICEF to forecast and plan their demand, and to consider longer-term commitments to achieve more affordable prices. Manufacturers may offer improved pricing and secure availability if the needs for vaccines are identified, planned, budgeted, and secured against longer timeline procurement commitments.

For example, UNICEF has procured ad hoc HPV vaccines on behalf of one self-financing MIC since 2016 and secured 280,000 doses at a cost of USD 15.00 per dose. To achieve more affordable, sustainable prices, UNICEF re-tendered for HPV vaccines in 2017 based on a multi-year commitment by the country to procure HPV vaccines through UNICEF until 2020, for an annual requirement of between 260,000 and 290,000 doses. UNICEF negotiated an LTA with the supplier to secure 1.2 million doses, and a price reduction of 11 per cent, to USD 13.40 per dose. In absence of a critical mass of self-financed MIC demand, based on country multi-year commitments, UNICEF negotiated tangible, albeit modest, price-reductions with manufacturers resulting in savings that may be used to further strengthen routine immunization programmes.

5. Healthy Market Framework

The Bill and Melinda Gates Foundation, Gavi, and UNICEF, developed the Healthy Markets Framework (HMF).²⁴ The HMF is a tool to support market shaping and is used to assess and articulate a market’s current and desired future state. UNICEF and partners use it to identify a set of attributes that measure the health of a particular market; to provide a process to value it specifically for vaccines; and to provide a framework to describe its desired healthy state. BMGF, Gavi, and UNICEF analysed the HPV vaccine market in 2017 (Figure 11).²⁵

Figure 11 Application of the Health Market Framework to HPV Vaccine Market

Total System Effectiveness	Long-term Competition	Product Innovation
Buffer Capacity	Individual Supplier Risk	NRA Risk
Meet Country Preferences		
Supply Meets Demand		

The HMF rates the HPV market health as being low in four of the eight attributes: i. supply meets demand, ii. country preferences, iii. buffer capacity, and iv. total systems effectiveness. The HMF rates it medium in three attributes: i. individual supplier risk, ii. long-term competition, and iii. product innovation, and only high in one attribute: national regulatory authority risk. Overall, the assessment based on the HMF indicated a low state of market health. UNICEF anticipates it will evolve towards a moderate state of health by 2024 with the entry of new suppliers and additional capacity from existing suppliers.

Source: Gavi

6. Issues and Challenges

- Short to medium-term supply to support new HPV introductions in Gavi-supported countries and MICs interested in channelling their procurement through UNICEF is constrained as manufacturers need to scale up production to meet the increase in demand. Based on manufacturers’ commitments, UNICEF anticipates that the shortfall in supply may improve by 2024 to meet the adjusted country demand for new HPV vaccine introductions supplied through UNICEF.
- One supplier, supplying 87 per cent of UNICEF’s supply, currently dominates the HPV vaccine market (Table 2). UNICEF does not anticipate any new market entrants with WHO prequalified products before 2021.
- The limited visibility on medium- or long-term demand from self-financing MICs through UNICEF disincentivizes manufacturers from offering, planning, and securing, sufficient supply availability at more affordable prices in response to UNICEF tenders.
- Current HPV vaccine pricing levels and variances also remain a significant concern for countries to budget the necessary funding for long-term sustainable financing of HPV programmes.

7. Steps Forward

UNICEF will prioritise the following actions to achieve a healthy and sustainable market for all countries:

²⁴ Gavi, the Vaccine Alliance, *Markets Shaping*, Gavi, Geneva, May 2017.
²⁵ Gavi, the Vaccine Alliance, *Human Papillomavirus Vaccine Roadmap: Public Summary*, Gavi, Geneva, December 2017, p. 2.

- UNICEF will work with Gavi, partners, and countries to adjust short- and medium-term plans for routine and MAC introductions in line with the timing of supply availability communicated by manufacturers.
- It will work with manufacturers of WHO prequalified products to review their production scale-up plans and supply lead times to deliver HPV vaccine for new country introductions, as well as to encourage potential new market entrants and pipeline suppliers to meet future demand at affordable prices.
- UNICEF launched a tender in December 2019, which will conclude in January 2020 to secure sufficient supply of HPV vaccines at affordable prices for Gavi-supported countries for 2021 and beyond.
- It will also collaborate with countries, partners and suppliers to improve access to affordable HPV vaccine supply for MICs, and to increase the transparency of prices secured for MICs. UNICEF will seek greater clarity on MIC requirements to provide industry with better visibility and predictability on the evolution of demand.
- For self-financing MICs that wish to channel their procurement through UNICEF, UNICEF will engage with them to consolidate credible multi-year HPV vaccine demand and encourage countries to submit multi-year commitments through UNICEF.
- UNICEF will also engage with manufacturers to explore and develop innovative and flexible contractual modalities and financing mechanisms to secure access to multi-year HPV vaccine supply for MICs.

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