

V3P: Key Findings for HPV



HPV

Highlights

- At present, only 41% of all countries, predominantly higher income countries, have introduced HPV;
- Nevertheless, HPV is the second highest value vaccine reported to the V3P, given the relatively high price (global median US\$17.69);
- High income countries (HICs) account for 81% of the value of the HPV market whereas non-Gavi, non-PAHO MICs account for 59% of the HPV volume;
- A total of seven products from four companies were available in 2016. Single-dose presentations was the most used;
- Despite the current oligopoly, the average price of HPV in USD has fallen over the last three years (current global median \$17.69);
- HPV prices are tiered by income/procurement segment, but there is considerable range within each segment, particularly for higher income groups;
- In non-Gavi, non-PAHO MICs, HPV represents an important share of country vaccine immunization expenditure (22% on average).

Analysis

Income/procurement segments are categorised as:

- HICs not procuring through the PAHO revolving fund (RF) (HICs);
- MICs not eligible or not receiving Gavi support, and not procuring through the PAHO RF (non-Gavi, non-PAHO MICs);
- PAHO countries of any income, procuring through the PAHO RF (PAHO), excluding two countries from AMRO classified as Gavi; and,
- All countries that were ever eligible to receive Gavi support, independent of transition status (Gavi).

Vaccine Introduction Status

As of January 2018, 79 countries (41%) had introduced HPV¹. In 2016, 41 countries reported use of HPV to the V3P.

By income/procurement segment, use of HPV ranges from 15% in Gavi to 80% in HICs (see chart 1, page 2). By region, the proportion ranges from 5% in EMR countries to 64% in EUR.

This product fact sheet is intended for use by global and regional vaccine policy makers. The product fact sheet provides information on HPV procured by V3P reporting countries, including analyses of:

- value to the market of HPV reported globally and in each WHO region;
- the distribution of available presentations globally and in each WHO region;
- the procurement methods used globally and in each WHO region;
- prices paid globally and in each WHO region, by income segment.

The Vaccine Product Price & Procurement (V3P) initiative was launched to provide all countries with a platform for greater vaccine price & procurement transparency. The initiative collects data through the WHO and UNICEF Joint Reporting Form, analyses and distributes information to relevant stakeholders to inform policy making and procurement processes. As of July 2017, the database contained data from 144 countries.

The fact sheet is exclusively based on the data reported through the JRF & V3P initiative, as of July 2017.

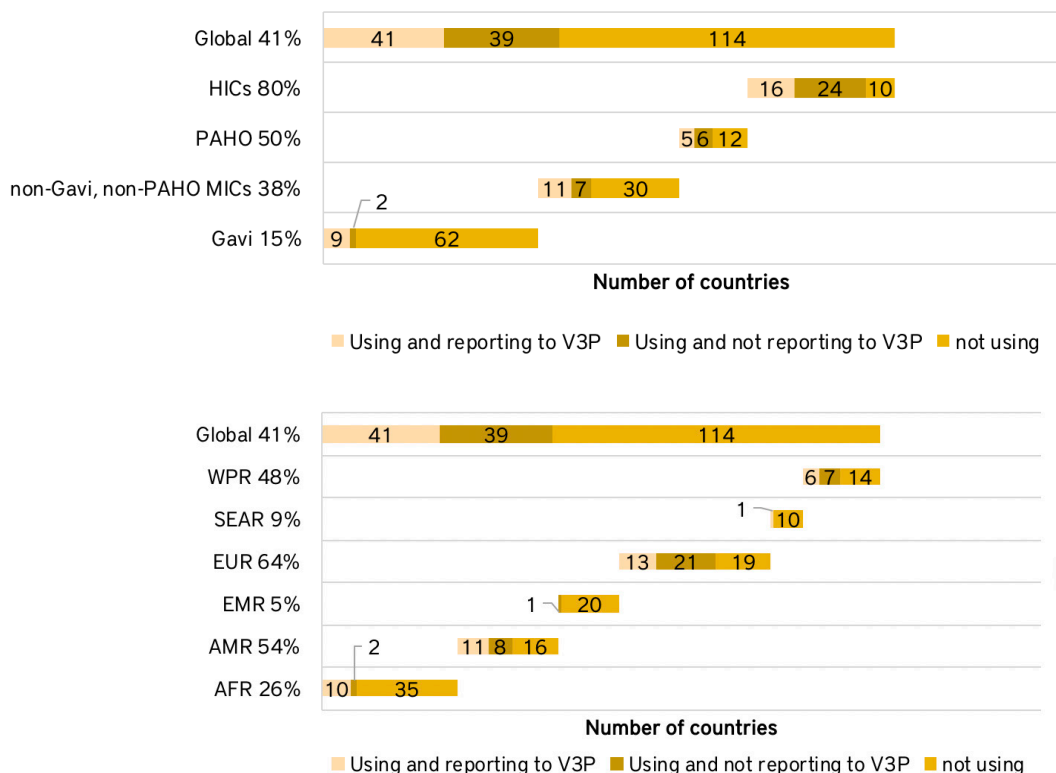
Pool-procurement refers to vaccines procured through UNICEF SD and the PAHO Revolving Fund.

Readers may access additional vaccine price and procurement information from reporting countries and procurement agencies (UNICEF and PAHO) on the V3P website: www.who.int/immunization/v3p or by contacting v3p-project@who.int

¹WHO IVB database on HPV introductions.



Chart 1. The number of countries, by income/procurement segment and WHO region, using HPV in 2016, showing number of user countries reporting to V3P.

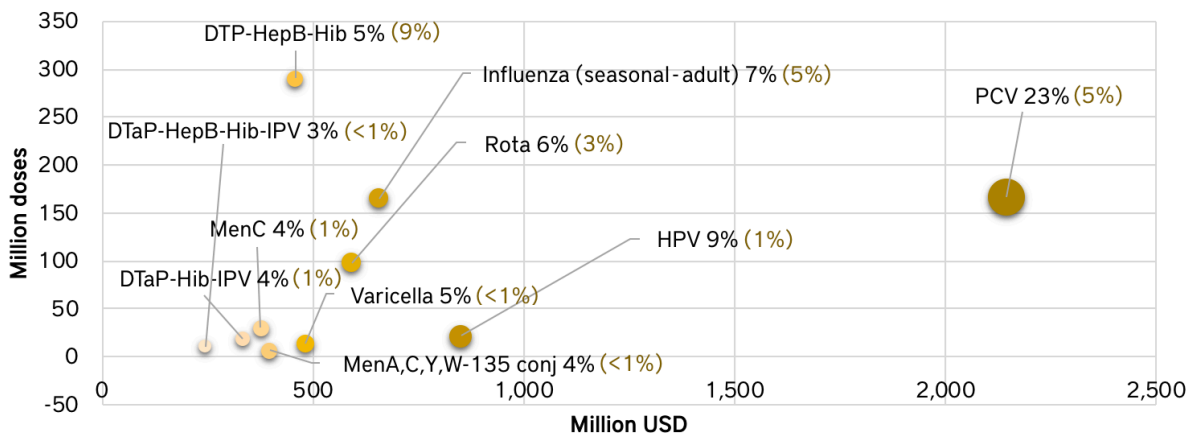


Market Value & Volume

HPV constitutes the second largest vaccine market, in value, of any vaccine. Of all vaccines reported to the V3P for 2016, HPV accounted for \$850 million (9%) of the

\$9.3 billion in vaccine purchases, but about 2.5 times less value than the highest value vaccine (PCV) reported to the V3P (see chart 2).

Chart 2. The global top 10 vaccines, by value, reported to the V3P for 2016, with bubble size showing the % value of the global vaccine market (corresponding global proportion in volume) for each vaccine.





Due to price tiering and introduction status, the contributions of each income segment to the global HPV market are highly heterogeneous (Chart 3). The HIC segment is by far the largest contributor to the value of the global HPV market (81%), whereas the non-Gavi, non-PAHO segment is by far the largest contributor to the total volume (59%).

Likewise, the contributions of the WHO regions to the value and volume of the global HPV market are highly varied (Chart 4). AMR alone accounts for 88% of the total value of the HPV market, and 68% of the volume.

Chart 3. The contributions of income/procurement segments to the global HPV market, showing the absolute value and volume of HPV-2 and HPV-4, by income group (proportion of HPV-2 / HPV-4).

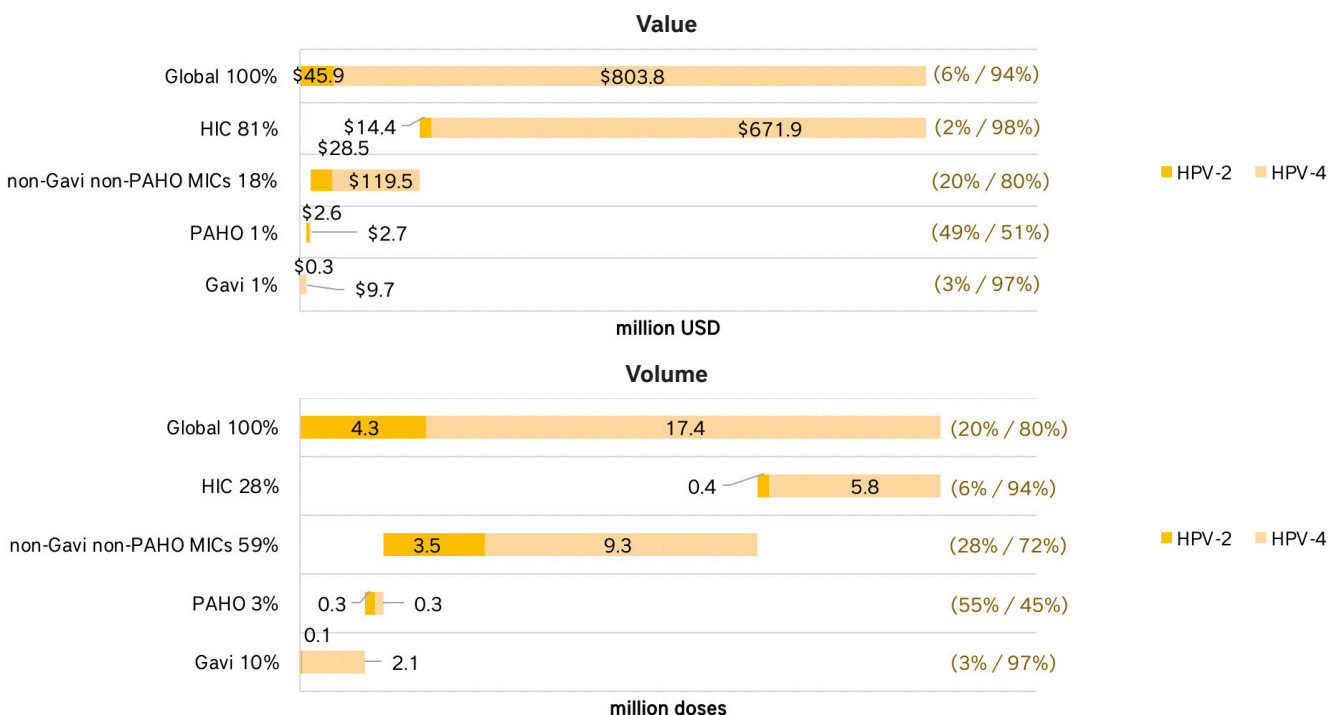
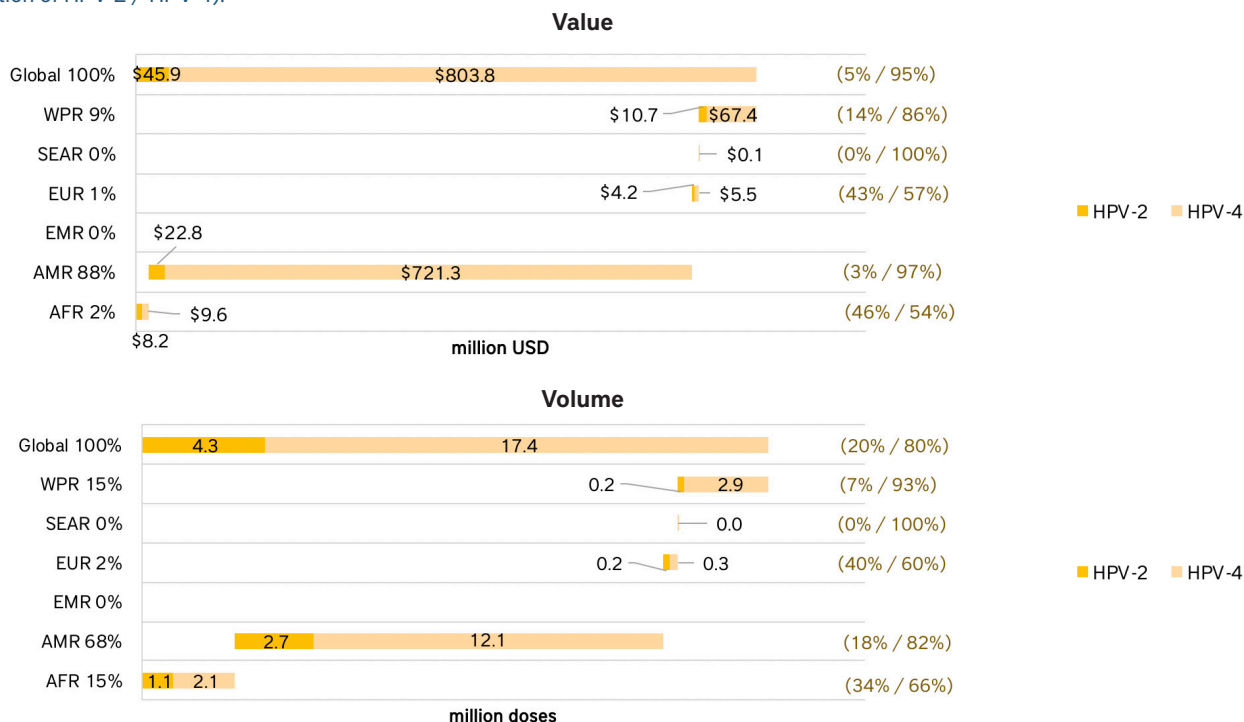


Chart 4. The contributions of WHO regions to the global HPV market, showing the absolute value and volume of HPV-2 and HPV-4, by region (proportion of HPV-2 / HPV-4).





Inherent differences in the income segments and WHO regions, and price differentiation, account for the varied contributions to the global HPV market. The AFR market is dominated by LMIC-Gavi supported and UNICEF-procuring countries, characterised by high purchase volumes and relatively low prices. The HIC market is characterised by relatively low purchase volumes but the highest prices in the market.

It is also important to note contribution of large countries to specific markets. For reporting countries to the V3P in 2016², almost a third of the volume (32%) and 84% of the value of the HPV market in AMR is constituted by the USA public market alone, where vaccine prices are at their highest. Brazil is also a major contributor in AMR (40% by volume, 10% by value). In other regions, large contributing countries include Malaysia in WPR (50% by volume, 20% by value), and South Africa in AFR (32% by volume, 42% by value)³. EUR, due to under-reporting to the V3P by large HICs, accounts for the relatively small contributions in value (1%) and in volume (2%).

Products and Presentations

Seven products are available from four manufacturers:

- HPV-2 (Cervarix® - GSK) is available in 1- and 2-dose vials, and a 1-dose prefilled syringe (WHO pre-qualified);
- HPV-4 (Gardasil® - Merck) is available in a 1-dose vial and a 1-dose prefilled syringe (WHO pre-qualified);
- HPV-4 (Butantan) is available in a 1-dose vial (not WHO pre-qualified);
- HPV-4 (Silgard - Sinergium) is available in a 1-dose prefilled syringe (not WHO pre-qualified).

Overall, HPV-2 accounts for about 20% of the global volume of HPV, but only 5% of the value. This is explained by the fact that in the HIC market, which accounts for 81% of the value, HPV-2 accounted for only 6% of the volume.

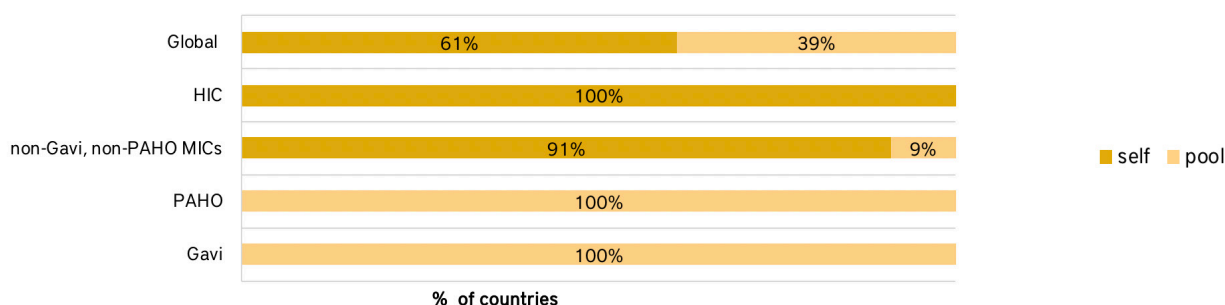
The single dose presentation size constitutes the vast majority of product choice (93% of countries reporting HPV to V3P for 2016). Only three pool-procuring Gavi countries (all in AFR) reported the purchase of the 2-dose presentation in 2016.

Globally, only 46% of countries use prefilled syringes. Since prefilled syringes are not currently UN pre-qualified they are unavailable to countries procuring through UNICEF SD. The highest number of countries using pre-filled syringes by income/procurement level is HICs (88%) and by region is EUR (92%).

Procurement Method

Globally, the majority of countries self-procure HPV, yet an important share - 39% - use pool-procurement (chart 5). By WHO region, self-procurement for HPV ranges from 0% in SEAR to 92% in EUR. Regional variations are primarily accounted for by differences in income levels between regions. Regions with a higher concentration of UMICs and HICs tend to have higher rates of self-procurement than regions with fewer.⁴ At present, non-Gavi, non-PAHO MICs mainly self-procure (91% of countries).

Chart 5. Prevalence of procurement method for HPV, for countries reporting to V3P, by global and income/procurement segments.



²Data reported to V3P is for public markets only, i.e. vaccines purchased by governments.

³These proportions are a function of the mix of the reporting and non-reporting countries to the V3P, and may not accurately represent the impact of specific countries in their respective regional markets.

⁴The exception is AMR, where pool procurement dominates, independent of income level, because of the Revolving Fund.



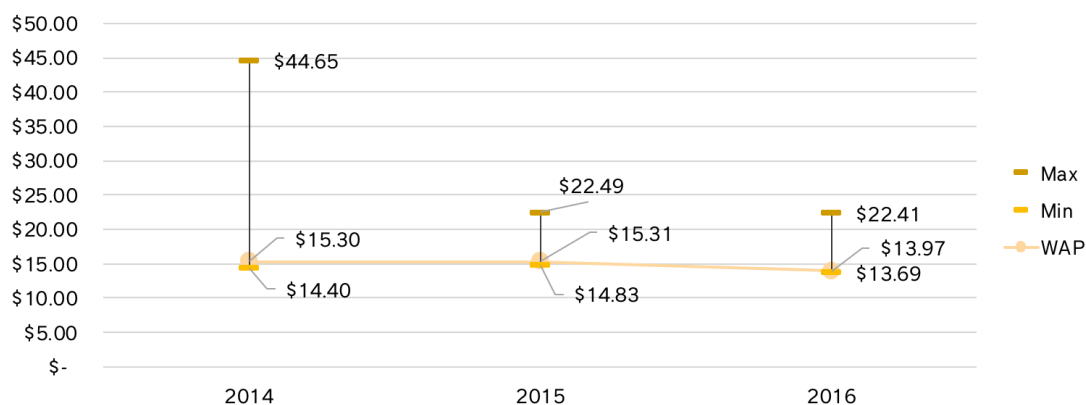
Prices

Price over time

For self-procuring countries, the limited historical data from V3P for the period 2013 to 2016 shows that for a total of up to nine countries with at least three years of data, seven of which are HICs, WAP of HPV (in USD) has declined by about 65% between 2013 and 2016⁵.

For the two non-Gavi, non-PAHO MICs with at least three years of historical data, the WAP has fallen by about 9% between 2014 and 2016 (chart 6), in spite of the limited number of participants in the market.

Chart 6. Weighted Average Price (WAP) of HPV for self-procuring non-Gavi, non-PAHO MICs with three consecutive years of data, showing maximum and minimum prices.



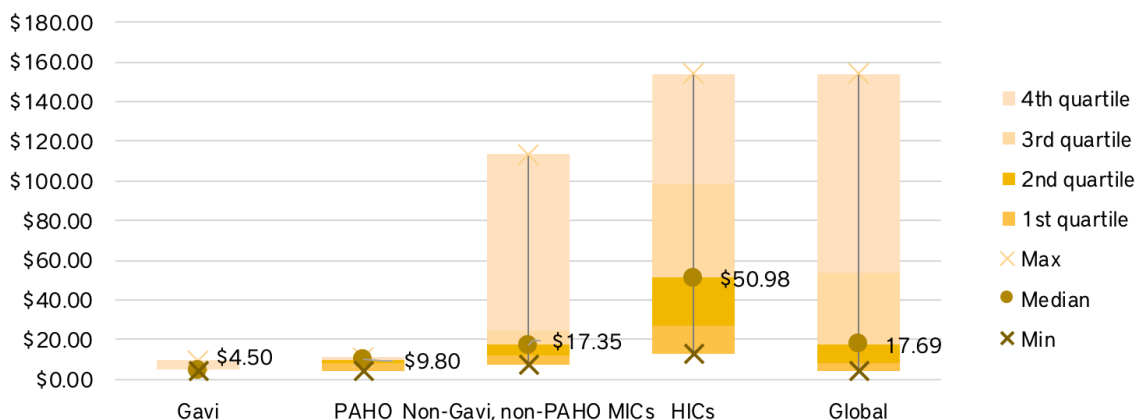
Price by income/procurement

As noted for other vaccines reported to V3P, prices vary according to income/procurement segment. The global median price reported to V3P for 2016 is \$17.69, which is slightly higher than the median for non-Gavi, non-PAHO MICs (chart 7), but almost three times lower than the median for HICs.

Median prices are lowest for Gavi (\$4.50) and progressively increase for PAHO (\$9.80), non-Gavi,

non-PAHO MICs (\$17.35), and HICs (\$50.98), although considerable variation exists within each income/procurement group. Price ranges progressively increase with increasing income/procurement level, and the highest price in non-Gavi, non-PAHO MICs is as much as 6.5 times the median, and in HICs 3 times the median (15.4 times the lowest price of the non-Gavi, non-PAHO MICs and 11.8 times the lowest prices in HICs).

Chart 7. Min, median, and max prices for HPV, by income/procurement segment, showing quartiles for price range.



⁵The same price trend may not be observed with all local currencies.



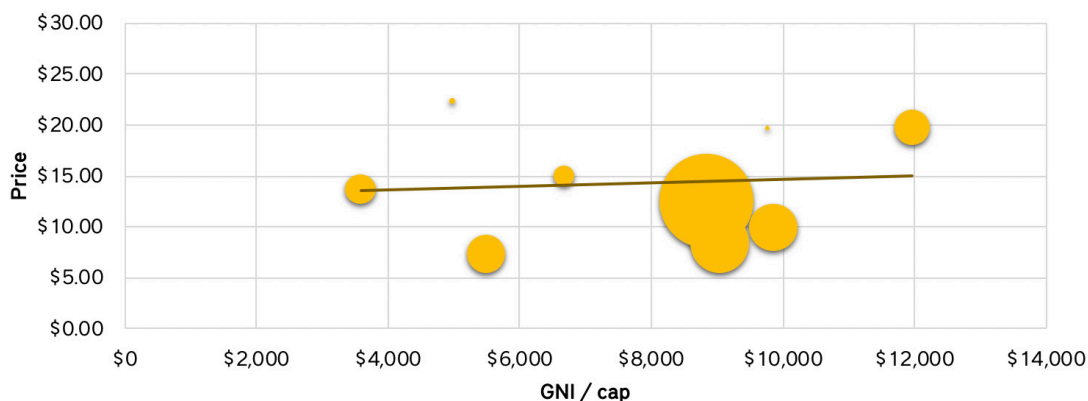
Prices for non-Gavi, non-PAHO MICs

From chart 1 it is apparent that HPV introduction is lower in non-Gavi, non-PAHO MICs than in the PAHO and HIC market segments. Introductions in Gavi countries are expected to rapidly increase, leaving the non-Gavi, non-PAHO MIC segment lagging behind. Thus, potential pricing obstacles in this income group were further explored.

Analysis shows that for non-Gavi, non-PAHO MICs purchasing at least a thousand doses of HPV annually, there is no correlation between vaccine price and GNI per capita in this market segment ($r=0.08$) (chart 8). Instead, lower purchase volumes appear to be moderately correlated with higher pricing ($r=0.42$).

The estimated value and volume of the HPV market for all 48 non-Gavi, non-PAHO countries (using and reporting, using and not reporting, and not using countries)⁶, under the assumption of full immunisation (2 doses) of a total birth cohort of girls of 20 million would amount to \$465 million, at the currently reported WAP, and 40 million doses. Assuming that the current HPV market remained constant in other income/procurement segments, the full non-Gavi, non-PAHO MIC segment would then represent as much as 40% of value and 82% of volume of the adjusted global market, up from 17% of the value and 59% of the volume.

Chart 8. Relationship between price of HPV and GNI/capita and annual number of doses purchased in non-Gavi, non-PAHO MICs. Bubble sizes represent annual purchase volumes of HPV.

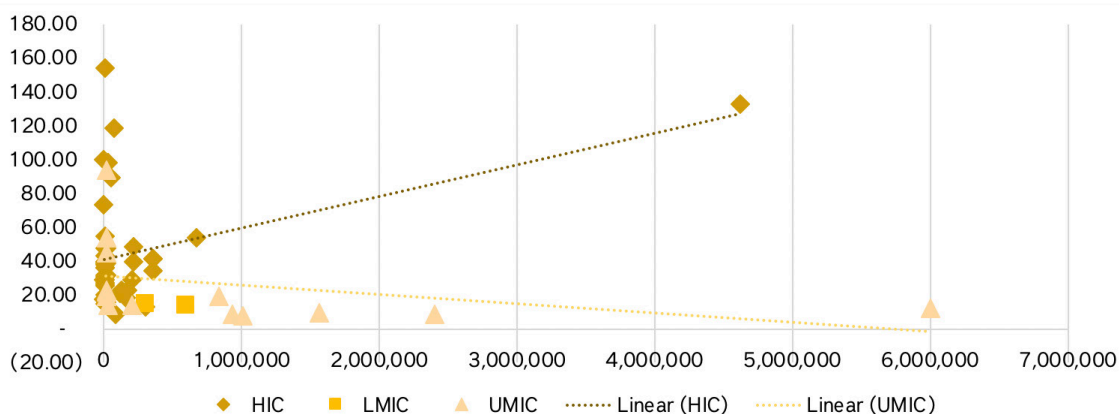


Price and volume

As observed above, there is some evidence that for non-Gavi, non-PAHO MICs very high and very low purchase volumes are related to price of HPV. However, the

evidence is weak and does not hold across all income groups (Chart 9).

Chart 9. Relationship of price to purchase volume for HPV, for self-procuring countries purchasing at least one thousand doses between 2013 and 2016.



⁶ Analyses from the 48 countries does not include birth cohorts from Cook Islands, Marshall Islands, Niue, Palau, and Tuvalu due to lack of data from a same source.

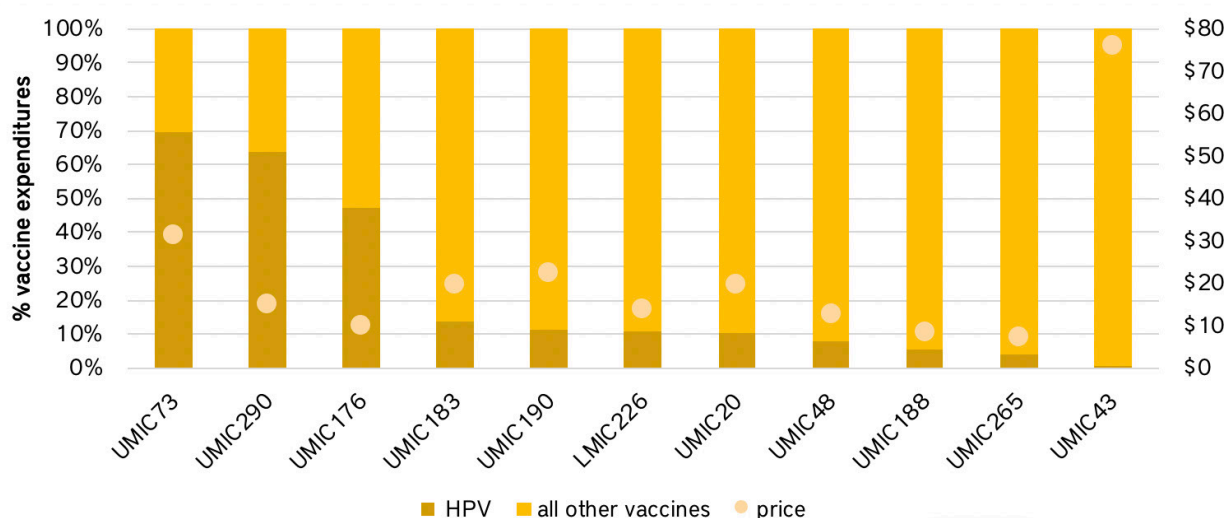


Proportion of vaccine expenditure on PCV

Analysis shows that non-Gavi, non-PAHO MICs' budgets increase drastically when they introduce a new vaccine. HPV on average represents 22% of non Gavi, non-PAHO

MICs vaccine budget and can account for as much as 70% of vaccine spending (Chart 10).

Chart 10. Share of HPV expenditure, out of all vaccine expenditure reported to V3P by non-Gavi, non-PAHO MICs, in 2016, showing prices paid in USD.



There is no apparent relation between the share of HPV in vaccine spending and the price of HPV (range \$7.38– \$75.91), the number of doses purchased (range 400 doses to 6 million doses), and the total vaccine expenditure, as reported to the V3P (range \$18,000 to \$929 million). Of note, higher prices of HPV were not associated with proportionally greater expenditure on HPV.

The proportion of HPV vaccine expenditure is instead related to the mix (mature vs new) and number of other vaccines purchased. A greater amount of other vaccines (in value and in quantity) reduces the proportion of HPV expenditure.

DISCLAIMER

Information contained in the V3P database is provided by participating countries and/or organizations procuring on behalf of countries that have agreed to share vaccine price and procurement data with V3P. Participating countries are solely responsible for the accuracy of the data provided.

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