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# CHIC Technical Brief on Country Decision-Making Factors: Expanding the Target Population for HPV Vaccination

## Purpose of this Document

From conversations across the CHIC Community of Practice, CHIC has noted an increasing number of countries, particularly across the African region, that are adopting, or actively considering, expanding their target population for HPV vaccine beyond the standard target recommended by the WHO (girls aged 9-14) – for older girls aged 15-18 (Cape Verde); for young women up to the age of 26 (Cape Verde); or for boys (Cameroon<sup>1</sup>, Cape Verde; Seychelles). Others have expanded age cohorts for girls as a short-term catch-up strategy, as previous supply constraints have resolved (Côte d'Ivoire, Burkina Faso, Liberia, Sierra Leone).

**Our starting point for this technical brief is that the primary aim of HPV vaccination remains the elimination of cervical cancer in women**, rather than the reduction of the relatively rarer other HPV diseases. This is in alignment with the 90-70-90 goals of the 2020 WHO global strategy<sup>2</sup>. Gavi-eligible countries have been encouraged to first focus on cervical cancer elimination above other aims<sup>3</sup>. The WHO position is that the priority aim of HPV vaccination programmes is to prevent cervical cancer<sup>4</sup>. This emphasis is further supported by the fact that if vaccine programme investments do not achieve high coverage, those same health systems will need to spend more on additional screening efforts in low-coverage cohorts.



In order to advance the application of the evidence that exists, and show where more evidence is needed, this brief considers the state of existing evidence relevant to three common questions.

### Two of these questions relate to impact on health outcomes for various vaccine allocation strategies:

1. After achieving high coverage (>80%) in the primary target of girls 9-14, what is the most efficient allocation of additional HPV vaccine doses, in terms of numbers needed to be vaccinated\* to prevent a case of cervical cancer?
2. What vaccination strategy (age, biological sex) delivers the quickest path to cervical cancer elimination?

### One question relates to demand generation and trust:

3. Might expanding to males, , reduce barriers to sustainable high coverage, such as specific fears, stigma or distrust of vaccines that a girls-only programme may generate?

\* The number of people who must receive a vaccine in order to prevent one case of cervical cancer; a lower number indicates a more effective vaccine.



## The World Health Organization Position on Choosing Cohorts

**First, let us re-orient ourselves in the context of the current WHO recommendations:** The WHO's position is that the primary goal of an HPV vaccination programme is "to attain the highest possible population protection among girls by the time they reach 15 years of age"<sup>4</sup>. The WHO-recommended primary vaccination target population is girls aged 9-14, because the vaccine's protective effectiveness is maximized by giving it before any exposure to an HPV virus<sup>5,6</sup>. An individual's immune response is also stronger at younger ages: the younger the age of vaccination within this age range, the better the recipient is protected against infection with the high-risk types of HPV that cause cervical cancer<sup>7,8</sup>. Also important is that living with HIV or other immunocompromise increases the risk of developing HPV-related disease, and WHO recommends that routine programmes place a priority on vaccinating people in this risk group.

For countries considering broadening eligibility, WHO recommends expanding programming to include a secondary target population, for example to older girls aged 15-18, to young women up to age 26, or to boys or young men, *only* if it is "feasible and affordable" to do so, and "does not divert resources from vaccination of the primary target population or effective cervical cancer screening programmes."<sup>4</sup> Funding policies encourage Gavi-eligible countries to devote vaccine supplies, staff time and other programme resources to the vaccination of girls aged 9 to 14 to reach cervical cancer elimination goals<sup>3</sup>.

### A few selected factors, highlighted in the current WHO Position Paper, inform Country decisions on expanding target cohorts:

**Epidemiological Context:** In the vast majority of settings, and almost all Gavi-eligible countries, cervical cancer takes priority, accounting for 80% or more of all HPV-related cancers<sup>9</sup>. In countries where other HPV-related cancers are increasing, HPV vaccination and screening programmes are often well-established.

**Cost and Cost-Effectiveness:** Countries must consider the potential cost of vaccinating an expanded target cohort, including current and projected prices of the intended vaccine product, as well as incremental programmatic costs of expanding services to the expanded target.

**Programmatic Feasibility:** The earliest countries to expand routine HPV vaccination to females over 15, boys, and other target groups have been high-income countries (such as USA,



England, Australia, Canada)<sup>10</sup>. Decisions to expand to females over the age of 15 have often been grounded in a focus on cervical cancer elimination, while decisions to expand to boys have often taken into account the perception of increased acceptability or gender equity. In a budget-constrained setting, local decision-makers may determine that other competing priorities offer higher value for money compared to potential gains in acceptability from expanding the target cohort.

**Political Will:** WHO's position is that countries should use HPV vaccination approaches that, among other factors, are "affordable and sustainable" and "capable of achieving the highest possible coverage"<sup>4</sup>. The SAGE framework for making this decision explicitly takes values, preferences, and acceptability into account<sup>10</sup>. There may be cases where expanding the target cohort to a secondary group will indeed facilitate a country attaining the highest possible coverage.



## Technical Considerations on an Expansion Decision

**The CHIC Community of Practice notes a need to clearly articulate the rationale that a country may use to make a well-reasoned decision on whether or not to expand their target population.** This includes making it clear whether decisions are based on accelerating to cervical cancer elimination, and/or the desire to optimize acceptability by including broader population targets. The following questions aim to help countries work through decisions about expanding the target cohort for HPV vaccination.

### Questions related to impact on health outcomes for various vaccine allocation strategies:

**Number Needed to Vaccinate to Prevent Cervical Cancer:** After achieving high coverage (>80%) in girls 9-14, what is the most efficient allocation of additional HPV vaccine doses, in terms of numbers needed to be vaccinated to prevent a case of cervical cancer?

The WHO position is that a programme focused on vaccinating pre-adolescent girls is usually a cost-effective approach to prevent cervical cancer, particularly when resources are constrained and screening and other control and prevention measures are limited<sup>4</sup>. We reference guidance from the multigovernmental International Agency for Research on Cancer (IARC), the WHO Immunization Vaccines and Biologicals department, and their Strategic Advisory Group of Experts (SAGE). The modelling they report suggests a step-wise allocation of vaccines to expanded cohorts. This considers each of the following groups in sequence: first **a**) girls up to 18, then **b**) women up to age 25, (or 30, dependent on local context) then **c**) boys, and potentially then **d**) young men (Table). The modeling studies used by IARC, WHO and SAGE to shape policy on this topic<sup>10</sup> showed that, when HPV vaccine



coverage is  $\geq 80\%$ , expanding the target to include women up to age 18 or to include adolescent boys<sup>11,12</sup> is less efficient and cost-effective, in terms of the ratio of dollars spent per disability-adjusted life years gained (DALY), than a strategy that ensures high coverage vaccination of girls between the ages of 9 to 14<sup>11,13</sup>. This finding is likely to remain true even at slightly lower levels of coverage<sup>10,13</sup>, even down to the sub-national level, as has been recently supported in IARC work for countries with lower coverage<sup>14</sup>. These considerations apply to long-term expansions of target populations; noting that some countries do temporarily expand age eligibility simply to allow catch-up of clients who missed vaccination at earlier ages, with WHO and (where applicable).

The “number needed to vaccinate” (NNV\*) to prevent one case of cervical cancer can also help understand the most effective use of HPV vaccine. Precise estimates will vary with local context, and modelling has examined this question in low-resource settings<sup>11,13,14</sup>. Because vaccinating at a younger age provides protection earlier in life, the NNV to prevent a case of cervical cancer is lower (that is: more efficient) for girls (9-14) compared to older girls (15-18)<sup>7,11,14</sup>, which is lower again for young women up to age 25<sup>11,15</sup>.

Target group	Efficiency in terms of NNV to prevent a case of cervical cancer
Girls 9-14	Top priority
Girls 15-18	Next most efficient
Women 19-25 (or 30)	Next most efficient
Boys, then men	Least efficient

**Greatest Health Impact:** What vaccination strategy (age, biological sex) delivers the quickest path to cervical cancer elimination?

The WHO Cervical Cancer Elimination Modelling Consortium (CCEMC) has shown that a strategy focused on vaccinating the majority of girls in the primary WHO target (aged 9-14) can eliminate cervical cancer in most LMICs: if 90% coverage of that primary target group can be reached, such a strategy can prevent 61 million cervical cancer cases over the next 100 years<sup>16</sup>. To maximize health gains, CCEMC models all include screening programmes in assessing feasibility of elimination: Adding twice-lifetime screening can prevent an additional 12 million diagnoses, speed up the time to elimination – and make elimination possible in many of the highest-burden countries<sup>16</sup>. Expanding vaccination to include older girls and women decreases the rate of new cervical cancer cases in the CCEMC models, but does not ultimately speed up elimination<sup>16</sup>. Expanding to vaccinate boys has even smaller effects on time to reach elimination thresholds<sup>16,17</sup>: Vaccinating boys can prevent a case of cervical cancer only indirectly, through herd immunity effects.

\* The number of people who must receive a vaccine in order to prevent one case of cervical cancer; a lower number indicates a more effective vaccine.

## Question related to demand generation & trust:

**Acceptance:** Might expanding to males, reduce barriers to sustainable high coverage, such as specific fears, stigma or distrust of vaccines that a girls-only programme may generate?

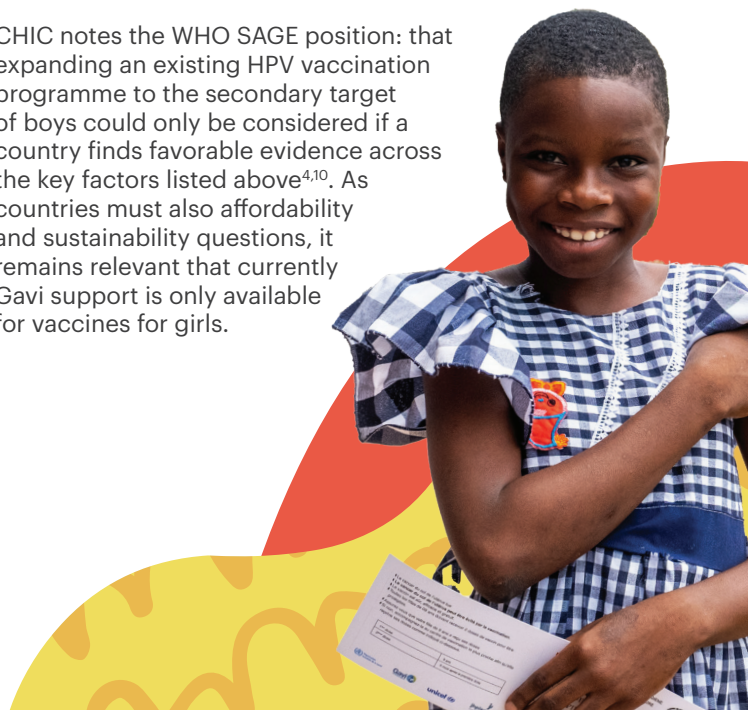
Across the CHIC Community of Practice, we have noted a frequently cited hypothesis: that expanding HPV vaccination services to boys may increase acceptability and decrease resistance, particularly among male heads of family, by lessening fears, stigma, and distrust. It is also possible, although not well-researched, that vaccinating older girls and women might reduce trust-related barriers to vaccine acceptance by parents of younger girls. Stakeholders also hypothesize that offering vaccination to boys and girls may improve delivery logistics and feasibility. In particular, where low coverage of girls is the baseline, adding boys is assumed anecdotally to increase likelihood of higher coverage among girls, through increased acceptance.

Although relevant research is underway, our CHIC experts have not been able to identify clear published evidence showing that expanding the HPV vaccine cohort to include boys has a reproducible effect on the uptake of or demand for HPV vaccine among girls of similar ages.

Discussions on vaccinating males continue<sup>23</sup>, based on assumptions of personal risk of HPV related disease beyond cervical cancer and barriers such as cost<sup>24</sup>. Those countries that do vaccinate older females and males are often high-income and with long-standing HPV vaccination programmes<sup>25</sup>, sometimes citing an equity basis, as in Australia<sup>26</sup>. Some discussions suggest vaccinating boys might help model the norm that both males and females share reproductive health responsibilities<sup>27</sup>. However, these assumptions around equity and acceptability have not yet been demonstrated in more resource-constrained settings, especially those receiving Gavi vaccine procurement support.

There is strong real-world data that males are protected by a successful girls-only strategy through herd immunity to other HPV-related diseases<sup>18</sup> (as predicted by earlier modelling<sup>10</sup>). Evidence for herd effects continues to grow, showing protection in unvaccinated females in the United States<sup>19,20</sup>, and strong herd immunity among unvaccinated men in Quebec<sup>21,22</sup>. This strong herd protection is strongest at high coverage, for example 80%<sup>10</sup>, but is also seen at lower coverage levels<sup>22</sup>.

CHIC notes the WHO SAGE position: that expanding an existing HPV vaccination programme to the secondary target of boys could only be considered if a country finds favorable evidence across the key factors listed above<sup>4,10</sup>. As countries must also affordability and sustainability questions, it remains relevant that currently Gavi support is only available for vaccines for girls.



## Gaps in the Evidence & Additional Programme Considerations

We highlight three particularly pressing gaps in evidence needed to inform programming decisions on expanding target cohorts for HPV vaccination. First, there is a need to better understand and quantify the nature of any change in acceptance and coverage following the expansion of HPV vaccination programmes to include boys, and even girls over the age of 15, in low-resource settings. Second, there is a need for real-world data in low-resource settings on the cost-effectiveness of adding new target populations: to confirm or challenge modelling predictions. Third, there is a need to build capacity to disaggregate coverage data across equity-related characteristics, so that expansion decisions first serve the most under-vaccinated and marginalized communities.

As country programmes consider expanding HPV vaccination to additional cohorts, it is important to consider what vaccine product the country is likely to purchase and stock in the near future. A competitively priced product may not be licensed for use in males: for example, among the WHO Prequalified vaccines, some bivalent vaccines are not licensed for males in some jurisdictions<sup>4</sup>. Expansion in the short term may create expectations among the public that expansion will be maintained in the long term. The incremental costs of such commitments may not be feasible within budget allocations year over year. And, as additional products enter the market and obtain WHO prequalification, staying current with emerging evidence related to HPV vaccines and their impact and cost remains ever important.



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