Update on Human Papillomavirus Vaccine (HPV) Introduction in Nigeria

Presented during

Coalition to Strengthen the HPV Immunization Community (CHIC) Online Technical Meeting

24th June, 2021
### Background

<table>
<thead>
<tr>
<th>Demography¹</th>
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<tbody>
<tr>
<td>Population</td>
<td>204,461,575</td>
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<tr>
<td>Women at risk of Cx</td>
<td>56 million</td>
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<tr>
<td>Girls 9-14</td>
<td>12,372,066</td>
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<tr>
<td>Out of school population</td>
<td>10.5 Million</td>
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### Disease Burden in Nigeria

- 34.2% Breast cancer
- 20.8% Cervical cancer
- 10.8% Liver Cancer
- 34.9% others
- 14,943 New cervical Cases annually
- 10,403 Annual deaths due to cervical cancer

### Justification For HPV Introduction

1. **Increasing cases of cervical cancer which can be prevented**
   - 19% of women initiate sexual intercourse by age 15 increasing risk of HPV infection (NDHS report, 2018)

2. **Slow momentum of secondary and tertiary prevention and treatment options**
   - Limited platform for vaccination of adolescents hence the need for HPV Vaccine introduction
   - About 80% of cervical cancer cases present with advanced disease
   - About 80% will die when clinical disease is discovered in advance stage
   - 80% do not have access to preventive services

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**SOURCE:** WHO International Agency for Research on Cancer, 2018
UNICEF Statistics on Education in Nigeria, 2018
2006 Projected Census population

NPHCDA – National Primary Health Care Development Agency
With the support of Gavi, Nigeria plans to introduce the HPV vaccine nationwide using a phased approach to sustain the country’s focus on reducing morbidity and mortality from cervical cancer.

The planning process is underway/ongoing and has been a long one, including the application for Gavi support:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>2015 - 2017</td>
<td>There was an initial Gavi provisional approval for HPV Demo in Nigeria in 2017 and the phased introduction from 2018. But this was not achieved.</td>
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<tr>
<td>April 2019</td>
<td>NGITAG made a recommendation to introduce Quadrivalent HPV recombinant vaccine (Gardasil) as the overall most effective and available vaccine.</td>
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<tr>
<td>July 2020</td>
<td>HPV application and budget for Gavi support submitted to Gavi</td>
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<tr>
<td>September 2020</td>
<td>Gavi communicated feedback on the application including updates on supply constraints on Gardasil until 2023 and EPI makes consideration for product switch</td>
</tr>
<tr>
<td>July 2020 till Date</td>
<td>Review of the HPV proposal (including NGI-TAG review) is ongoing for resubmission</td>
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1. Lives Saved Analysis with NSIPSS Coverage  
3. Nigeria Human Papillomavirus and Related Cancers, Fact Sheet 2018  
4. NSIPSS projected growth rate  
5. Review of the HPV proposal (including NGI-TAG review) is ongoing for resubmission
In line with NSIPSS(2018-2028), Nigeria planned to introduce HPV vaccine in 2021, however update from Gavi and the vaccine suppliers indicate that the vaccine of choice Gardasil-4 will be available earliest in 2023.

Based on Gavi feedback, NPHCDA made a request to the NGITAG to review the available information on HPV and provide recommendation to the Country on the vaccine product selection and other scenario.

Question:
Given the prevailing HPV vaccine shortages and the existing NGI-TAG recommendation of Gardasil-4 as choice for Nigeria, “Should Innovax Cecolin Vaccine be considered for introduction into Nigeria’s Routine Immunization (RI) schedule?”
Draft – Reviewed Recommendation on Human Papillomavirus Vaccine introduction into Routine Immunization (RI) in the light of supply constraints and new pipeline vaccines

22nd February 2021

HPV Working Group

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NPHCDA – National Primary Health Care Development Agency
The NGI-TAG substantially retains its previous recommendation with minimal amendments to the timelines of introduction and certainties about availability and supplies. The previous recommendations are substantially maintained due to the following:

❖ That there is no significant difference in the immunogenicity and safety of Innovax-Cecolin when compared with Gardasil or other HPV candidates, data on effectiveness post licensure is not available.

❖ Evidence about the production capacity of Innovax-Cecolin vaccines and availability of same is very scanty.

❖ Though the Innovax-Cecolin vaccine appears to be readily affordable, and there is evidence of its safety and efficacy, it has not received WHO prequalification, which is a critical requirement for NGI-TAG’s vaccine recommendation.

❖ Furthermore, this vaccine has only been introduced in China, and though the immunogenicity and safety are commendable, review demonstrated that Innovax-Cecolin use, and performance has been limited in scope. More comprehensive and broader geographical based clinical data will be required for more robust evidence-based findings to dictate recommendations for use.
Evidence show that the prevalence of cervical cancer and other cancers in Nigeria remains high and pose greater socio-economic risk to the population especially women. Review of available literature on profiles of HPV vaccine products demonstrates opportunity to reduce morbidity and mortality due to cervical cancers in the population. Therefore, the following draft recommendations are being tabled for consideration:

- Nigeria should introduce the **HPV vaccine in its immunization programme in line with the proposed 2021 timelines** in the Nigeria Strategy for Immunization and PHC System Strengthening 2018 – 2028. The HPV introduction should target age **group 9 – 14 years**.
  - The country should consider introduction of the HPV vaccine in both sexes (boys and girls) **with a phased approach initially targeting girls**
  - In the medium to long term (5 – 10 years) the country should **improve on its immunization financing status and consider inclusion of HPV schedules for boys**.

- Based on appraisal of the vaccine products on: **efficacy and prevalence of serotypes in Nigeria, added protection against genital warts, and duration of protection; cost per fully immunized and cold chain capacity** it is recommended that:
  - Quadrivalent HPV recombinant vaccine should be the vaccine of choice
  - The Nigeria Immunization Programme should use the following **strategies for HPV introduction**
    - facility based
    - outreaches (in schools and out of schools)
The three (3) key strategies for cervical cancer elimination included the following:

1. Primary: Vaccination
2. Secondary: Screening
3. Tertiary: Treatment
HPV Vaccination Strategy

Delivery

1. Health facility –based
   - Fixed sessions

2. Outreach
   - School
   - Out- of –school (Community)

Target Age group
- Girls aged 9-14

Scope
- Nationwide
- Phased Approach

Vaccine of choice
- Generic name: [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]
- Brand name: GARDASIL® (2 doses)
Scope: HPV introduction will be nationwide and in phases for several reasons

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<thead>
<tr>
<th>Reasons for Nationwide Introduction</th>
<th>Reasons for Phased Introduction</th>
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<tr>
<td>✓ Country is experienced with new vaccine introduction and has the capacity</td>
<td>✓ HPV introduction involves new cohorts and new platform for delivery</td>
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<td>✓ High demand for HPV vaccine nationwide</td>
<td>✓ Limited experience on delivering vaccination to the new cohort (no demonstration project done)</td>
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<td>✓ High disease burden in all the states</td>
<td>✓ Limited global supply of the NITAG recommended HPV vaccine (availability)</td>
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<td>✓ Lessons learned and best practices from other countries on nationwide introduction</td>
<td>✓ HPV Vaccines to be introduced in girls first due to high burden of cervical cancer. Introduction to be conducted in 2 phases (March &amp; Sept. 2020)</td>
</tr>
<tr>
<td>✓ Improved cold chain capacity at all levels</td>
<td>✓ HPV Vaccines to be introduced in boys after further review in 5 years of introduction in girls</td>
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<td>✓ Fear of multiple new vaccines to be introduced in 2021 so its important that health workers are not overwhelmed</td>
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Phasing approach is based on 3 requisite criteria (Program Capacity, indicators associated with HPV disease burden and Special Considerations) to ensure equity.

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<td>1. Program Capacity</td>
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<td>2. Indicators associated with high burden of HPV (NDHS based)</td>
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<td>3. Special Considerations for 3 states</td>
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### Program Capacity
1. State Level Cold Chain Capacity Sufficiency
2. Penta 3 Coverage (2018 NHDS)
3. Penta 3 Coverage (2019 Admin)

### Indicators associated with high burden of HPV (NDHS based)
4. Mean age at first Sexual Contact
5. Percent Teenage Pregnancy
6. Mean Number of Sexual Partners
7. STI Prevalence in last 12 months
8. Percentage Male Circumcision
9. HIV Prevalence
The nationwide introduction will be in 2 phases: (2022/2023)

Phasing Criteria:

a. **Phase 1 states**: 20 states + FCT
   - Kano, Katsina, Jigawa, Kebbi, Bauchi, Adamawa, Taraba, Plateau, Benue, Nasarawa, FCT, Lagos, Oyo, Osun, Ogun, Rivers, Delta, Akwa Ibom, Anambra, Abia & Imo

b. **Phase 2 States**: 16 States
   - Bayelsa, Cross River, Edo, Enugu, Ebonyi, Ekiti, Ondo, Kogi, Kwara, Kaduna, Niger, Yobe, Borno, Gombe, Sokoto, Zamfara
Proposed Timeline for HPV vaccine Introduction

- **July/Aug 2020**: Re-submission of Gavi proposal
- **Qtr 3/4 2021**: Feedback from Gavi
- **Qtr 1/2 2022**: Pre-Introduction activities
- **Qtr 4 2022 / 2023**: Introduction of HPV Vaccine
- **Qtr 3/4 2023**: Post introduction Evaluation

**SOURCE**: WHO International Agency for Research on Cancer, 2018
UNICEF Statistics on Education in Nigeria, 2018
2006 Projected Census population
Challenges in the planned HPV introduction

1. Global shortage of HPV vaccines, which has contributed to the delay in the planned HPV vaccine introduction in the country

2. Lack of clarity on the choice of vaccine that will be available for introduction in Nigeria; and actual date of implementation as the proposal review is still ongoing

3. Huge resources that would be needed for the planned HPV vaccine introduction in the country

However, efforts are ongoing by Government and partners to ensure the HPV vaccine introduction in 2022 or 2023 at most
Next steps

1. Update the HPV proposal based on recent NGI-TAG recommendations

2. Resubmission of the country HPV proposal to Gavi

3. Follow up for approval and introduction of HPV in the country
Thank you
Background

HPV is the **most common viral infection of the reproductive tract** and is the cause of a range of conditions in men and women, including precancerous lesions which if left untreated may progress to cancer. In women, specific HPV types with oncogenic strains (most frequently HPV-16 and HPV-18) may lead to precancerous lesions which, if untreated, may progress to cervical cancer.

The World Health Organization (WHO)\(^1\) recommends vaccinating girls aged **9-14 years old** before their first sexual activity, as a key preventive measure against cervical cancer.

There are three WHO Prequalified vaccines currently available globally for the prevention of Human papillomavirus (HPV) infections:
1. **Quadrivalent vaccine (Gardasil-4)** licensed in 2006
2. **Nonavalent vaccine (Gardasil-9)** licensed in 2015
3. **Bivalent vaccine (Cervarix)** licensed in 2007

However, a bivalent vaccine Innovax -Cecolin is expecting WHO PQ in 2021\(^1\)

Over 100 countries around the world have introduced the vaccines either routinely through various country immunization programs or through the private health sector.