

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



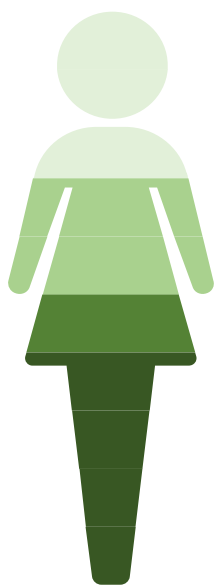
Background



Demography¹

- Population 204,461,575
- Women at risk of Cx 56 million
- Girls 9-14 12,372,066
- Out of school population 10.5 Million

Disease Burden in Nigeria



34.2%

Breast cancer

20.8%

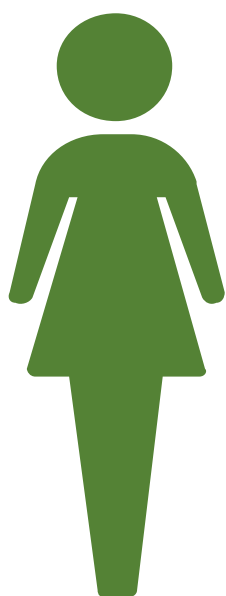
Cervical cancer

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

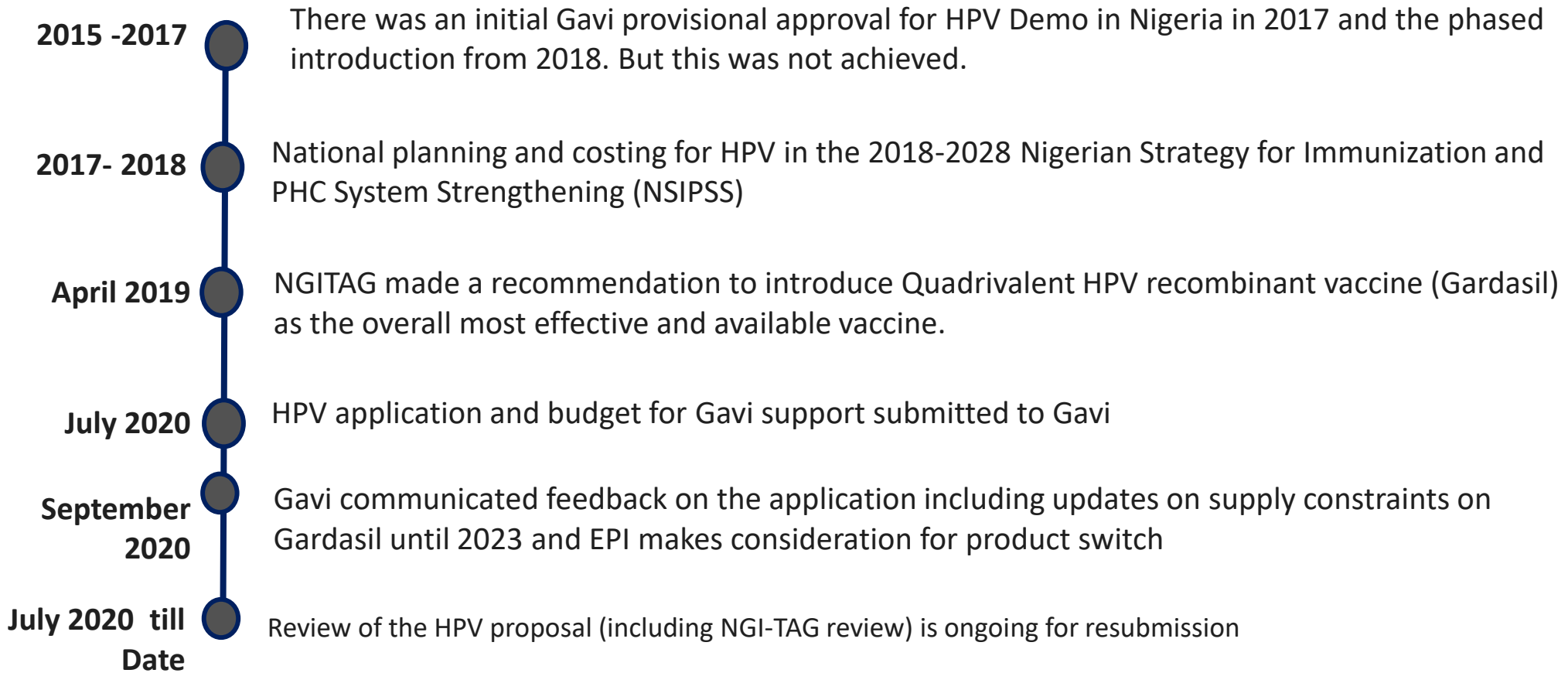
80% do not have access to preventive services



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:





Background...3



In line with NSIPSS(2018-2028), Nigeria planned to introduce HPV vaccine in 2021¹, 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 NGITAG recommendation of Gardasil-4 as choice for Nigeria, “Should Inovax Cocolin Vaccine be considered for introduction into Nigeria’s Routine Immunization (RI) schedule?”



Nigerian Immunization Technical Advisory Group (NGI-TAG)



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

NGI-TAG MEMBERS

Prof. Mairo Hassan (Chairman)
Prof. Augustine I Omoigberale
Dr. A .D Tswana

Non-Core Members/Liaison Officers

Kofi Boateng (WHO)
Shola Dele-Olowu (CHAI)

Secretariat

Dr. Amina Abdul-One(NPHCDA)
Abubakar Mohammed(CHAI)
Adeyelu Asekun(CDC)
Adebisi Adenipekun(Sidani)
Sheriff Muhammad(CHAI)
Somto Keluo-Udeke(IVAC/DCL)
Aisha A. Umar(CHAI)
Mr. Ganiyu Salau (NPHCDA)
Temidayo Ogunrinu(CHAI)
Christiana Fashola
Dr. Bakunawa Garba (NPHCDA)



NGI-TAG Updated Recommendation (Feb, 2021)



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.



NGI-TAG HPV Recommendation (2019/2020)



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 – 14years.**
 - 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)



Strategies for cervical cancer elimination



Elimination of cervical cancer is possible through



#Vaccineswork

#EndCervicalCancer

#CervicalCancerForum2020



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



Reasons for Nationwide Introduction

- ✓ Country is experienced with new vaccine introduction and has the capacity
- ✓ High demand for HPV vaccine nationwide
- ✓ High disease burden in all the states
- ✓ Lessons learned and best practices from other countries on nationwide introduction
- ✓ Improved cold chain capacity at all levels
- ✓ Fear of multiple new vaccines to be introduced in 2021 so its important that health workers are not overwhelmed

Reasons for Phased Introduction

- ✓ HPV introduction involves new cohorts and new platform for delivery
- ✓ Limited experience on delivering vaccination to the new cohort (no demonstration project done)
- ✓ Limited global supply of the NITAG recommended HPV vaccine (availability)
- ✓ HPV Vaccines to be introduced in girls first due to high burden of cervical cancer. Introduction to be conducted in 2 phases (March & Sept. 2020)
- ✓ HPV Vaccines to be introduced in boys after further review in 5 years of introduction in girls





Phasing approach is based on 3 requisite criteria (Program Capacity, indicators associated with HPV disease burden and Special Considerations) to ensure equity

Phasing Criteria:

a. Program Capacity

1

State Level Cold Chain Capacity Sufficiency

2

Penta 3 Coverage (2018 NHDS)

3

Penta 3 Coverage (2019 Admin)

b. 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

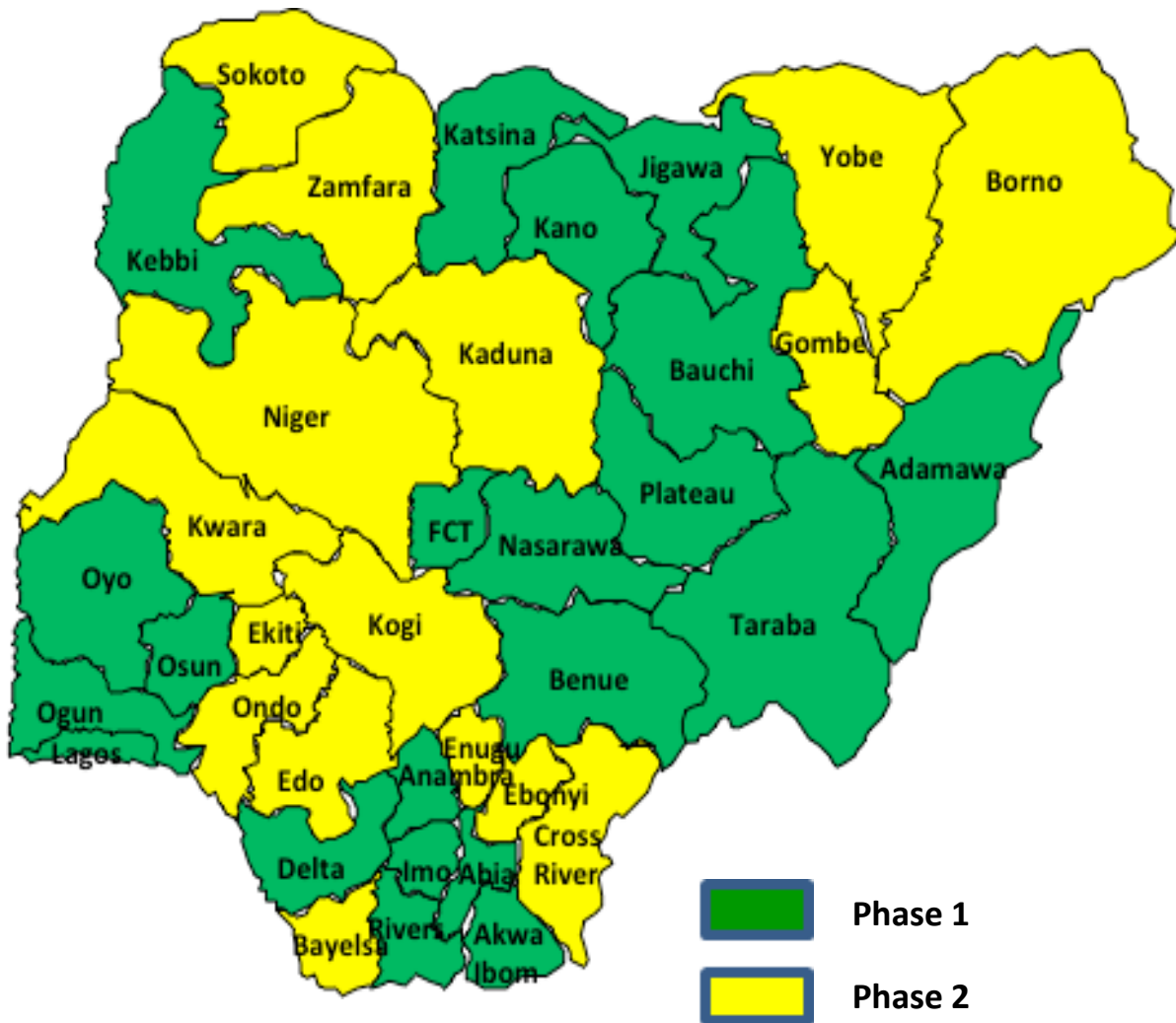
9

HIV Prevalence

c. Special Considerations for 3 states



The nationwide introduction will be in 2 phases: (2022/2023)



Phasing Criteria:

a. Phase 1 states: 20 states + FCT

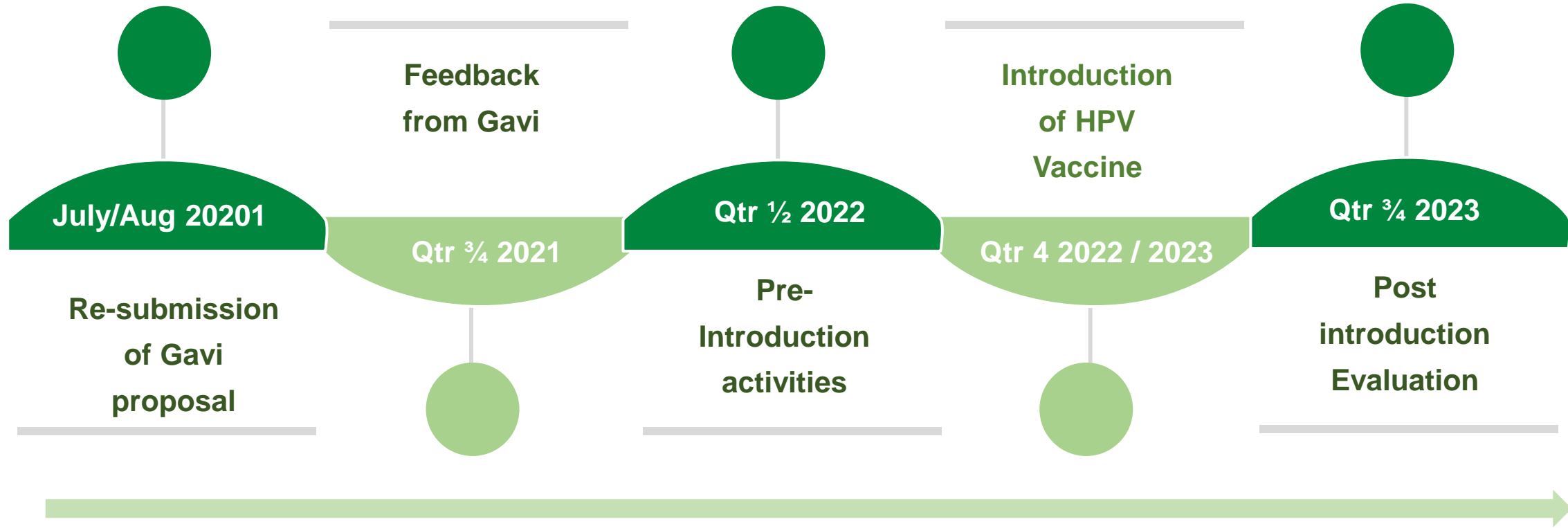
Kano, Katsina, Jigawa, Kebbi, Bauchi, Adamawa, Taraba, Plateau, Benue, Nasarawa, FCT, Lagos, Oyo, Osun, Ogun, Rivers, Delta, Akwa Ibom, Anambra, Abia & Imo

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



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

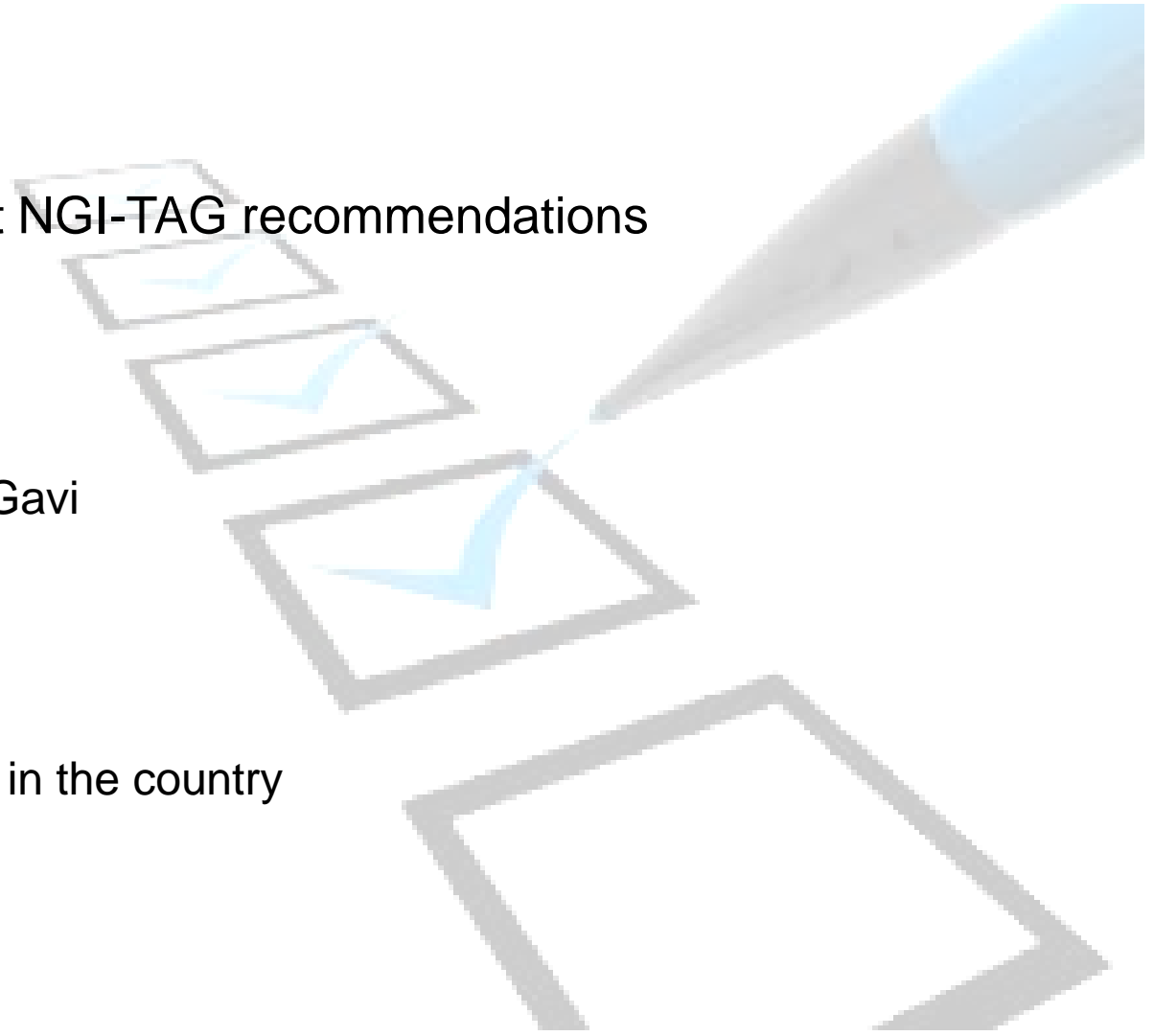
However, efforts are ongoing by Government and partners to ensure the HPV vaccine introduction in 2022 or 2023 at most



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 Inovax -Cecolin is expecting WHO PQ in 2021¹

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