Policy Notes

Technical and Implementation Guidelines for the Introduction of Human Papillomavirus Vaccine into China's National Immunization Program

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ABSTRACT

Human papillomavirus (HPV) vaccination administered before viral exposure (i.e., prior to sexual debut) effectively prevents infection with vaccine-type HPV strains and associated diseases, including cervical cancer. To advance HPV vaccination efforts and cervical cancer prevention, China has incorporated the bivalent HPV vaccine (types 16/18) into its National Immunization Program (NIP) as a program vaccine. This Policy Note presents comprehensive technical and implementation guidelines for HPV vaccine deployment, encompassing guidance development methodology, target population definition, routine vaccination schedules, catch-up vaccination protocols, implementation strategies, vaccine coverage and adverse event monitoring plans, and anticipated implementation challenges with proposed mitigation measures. The Vaccine Technical Working Groups of the China CDC developed relevant technical recommendations and guidelines, which were officially issued in November 2025.

INTRODUCTION

Burden of Cervical Cancer in China

China faces a substantial burden of cervical cancer, with rising incidence and mortality rates and a decreasing average age of onset (*1*). In 2023, the country recorded 155,700 new cervical cancer cases and 55,700 deaths from the disease (*2*). A recent national study estimated the average total cost of cervical cancer treatment at 105,000 to 191,000 Chinese yuan (CNY) [approximately 14,500 to 26,400 US Dollars (USD)] (*3*). Persistent infection with high-risk human papillomavirus (HPV) types causes nearly all cervical cancers (*4*), with HPV types 16 and 18 accounting for 70% to 75% of cases (*5*). HPV vaccination generates high-titer, long-lasting neutralizing antibodies that effectively prevent HPV infection and associated diseases.

HPV Vaccines Available in China

All currently available HPV vaccines utilize virus-like particles composed of the HPV L1 major structural protein as antigens. By valency, these vaccines are classified as: bivalent (targeting types 16/18), quadrivalent (types 6/11/16/18), or nonavalent (types 6/11/16/18/31/33/45/52/58). Seven HPV vaccines have been approved for use in China, comprising three bivalent, two quadrivalent, and two nonavalent formulations. The HPV vaccines incorporated into the National Immunization Program (NIP) are bivalent vaccines targeting HPV types 16 and 18.

METHODS

China CDC issued the *Technical and Implementation Guidelines for the Introduction of Human Papillomavirus Vaccine into China's National Immunization Program*. The HPV Vaccine Technical Working Group (TWG) and other implementation groups within China CDC developed these guidelines based on comprehensive evidence including the burden of HPV infection and HPV-related diseases, pre-market clinical trial data, and post-marketing real-world data on HPV vaccine immunogenicity, effectiveness, safety, and health economics. The TWGs consulted extensively with experts and government officials to incorporate lessons learned from HPV vaccination programs implemented in various municipalities and provinces. The TWGs finalized the recommendations and guidelines, which were officially issued in November 2025.

Rationale and Evidence

Cervical cancer ranks second in both morbidity and mortality among gynecological cancers in China (*6*). HPV vaccination effectively prevents infection from vaccine-covered HPV types and associated HPV-related diseases, including cervical cancer. Real-world international studies have demonstrated significant protection conferred by bivalent HPV vaccines. Health economic evaluations consistently show favorable cost-effectiveness for vaccinating adolescent girls. Vaccination administered before sexual debut provides maximum protection (*7*). Immune response induced by a two-dose schedule in girls aged <15 years is non-inferior to a three-dose schedule in 15-26-year-old women and provides durable protection (*8*–*10*).

HPV vaccination represents a fundamental pillar of the World Health Organization's *Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem*. Similarly, vaccination of girls constitutes a core prevention measure in the Chinese government's *Action Plan for Accelerating the Elimination of Cervical Cancer (2023–2030)*. Free and subsidized HPV vaccination pilot programs implemented across various municipalities and provinces have generated critical evidence regarding public acceptance, effective school-based vaccination delivery models, adverse event surveillance systems, cost-effectiveness, and inter-sectoral coordination mechanisms. As a program vaccine, government provision ensures equitable, convenient, and free access to HPV vaccines for all eligible girls.

Main Contents of the Technical Recommendations

The technical recommendations for HPV vaccination establish comprehensive guidance for proper use of program HPV vaccines. These guidelines address eligibility criteria, dosing specifications, administration routes, routine and catch-up vaccination schedules, product interchangeability considerations, co-administration with other vaccines, and vaccination approaches for special populations.

Girls born after November 10, 2011, become eligible for vaccination upon reaching 13 years of age. The program HPV vaccine follows a two-dose schedule with a 6-month interval between doses. The second dose should be administered within 12 months of the first dose. Each 0.5 mL dose is administered by intramuscular injection into the deltoid muscle. Girls born after November 10, 2011, who have not completed the two-dose routine schedule should receive missed doses as soon as possible before their 18th birthday. Immunocompromised individuals or those living with human immunodeficiency virus (HIV) should follow a three-dose schedule as specified in the prescribing information. HPV vaccines may be co-administered with other vaccines when given at different injection sites.

The two-dose schedule should be completed using bivalent HPV vaccine from the same manufacturer. Substituting subsequent doses with vaccines from different manufacturers is not recommended. However, when completing the schedule with the same manufacturer's vaccine is not feasible, remaining doses may be administered using a bivalent HPV vaccine from a different manufacturer following informed consent. Age-eligible girls who previously received a dose of non-program HPV vaccine and desire to receive the second dose with program HPV vaccine may do so, after informed consent. Individuals who complete a full vaccination course with any licensed HPV vaccine, regardless of valency, require no additional doses and are considered fully vaccinated.

Province-level immunization programs are encouraged to expand the target population to include multi-age cohorts of girls over 13 years of age for HPV vaccination.

Main Contents of the Implementation Guidelines

The implementation guidelines establish procedures to promote smooth, full vaccination of the target population. These guidelines address vaccine procurement, target population enumeration, mobilization and organization of vaccination activities, public communications, adverse event monitoring and management, use of Immunization Information Systems (IIS) for recording vaccinations, and monitoring of vaccine supply, demand, and coverage over time.

Province-level immunization programs formulate procurement plans, while China CDC organizes centralized tender procurement. Local CDCs and vaccination units should evaluate vaccine storage and transportation capacity to ensure proper management of HPV vaccines.

CDCs and vaccination units should record vaccine inventory movements in their provincial IIS, monitor vaccine supply and demand to ensure balanced distribution, and exchange vaccine distribution data with both the vaccine traceability collaborative service platform and the National IIS.

Local departments of disease control and prevention, education, and health should collaborate to conduct a census of the target population and develop coordinated plans for school engagement, public outreach, and social mobilization. They should maintain regular communication regarding the number of eligible girls and those vaccinated to enable timely remobilization efforts when needed. For age-eligible girls not enrolled in schools, township and street-level government departments should identify these individuals within their jurisdictions and conduct appropriate outreach and mobilization activities.

County-level CDCs should integrate target population lists from both in-school and out-of-school sources into the IIS and share these data with vaccination units. Any individuals not yet included in the IIS should be added promptly.

All vaccination units providing routine immunization services should offer HPV vaccination. Vaccination units should provide convenient appointment scheduling options, such as smartphone-based vaccination applications. When vaccination services in schools are desired, temporary vaccination sites may be established in schools upon approval by county or district disease control and prevention departments and health authorities.

All regions and localities must adhere to standard informed consent principles. For in-school vaccination, schools should distribute informed consent forms in advance, and eligible girls must present identification documents and guardian-signed consent forms before vaccination. For out-of-school vaccination, guardians must accompany the girl to the vaccination unit with appropriate documentation.

Vaccination must adhere to standardized protocols: Three Checks (check recipient's health status and absence of contraindications, vaccination certificates, vaccine appearance /lot number /expiration date); Seven Verifications (verify recipient's name, age, vaccine type, specifications, dosage, injection site, and administration route); and One Confirmation (confirm the correct vaccine is being administered and has not expired). All recipients must remain under observation for 30 minutes post-vaccination to enable prompt detection and management of immediate adverse reactions.

Following *Guidelines for Vaccination Practices (2023 Edition)*, vaccination clinic staff shall enter vaccination information into the IIS in a timely manner and provide printed vaccination certificates to guardians. Provincial CDCs are responsible for completing local IIS upgrades and conducting necessary professional training. In accordance with the *National Immunization Program Vaccination Coverage Monitoring Plan (Trial)*, localities should analyze and report vaccination coverage monthly, monitor HPV vaccination progress closely, and maintain active information sharing and collaboration with education departments. Vaccination units should regularly review the list of unvaccinated and under-vaccinated age-appropriate girls through the IIS, notify their guardians or provide feedback to the schools for encouraging guardians to catch-up vaccination of the girls.

All CDCs, vaccination units, and medical institutions shall strengthen training on adverse events following immunization (AEFI) monitoring, reporting, investigation, diagnosis, and data analysis according to their designated responsibilities, as mandated by the *Vaccine Administration Law of the People's Republic of China*, the *Measures for the Identification of Adverse Events Following Immunization*, and the *National Surveillance Guideline for Adverse Events Following Immunization (2022 Edition)*.

Vaccination should be scheduled to avoid examination periods and times when students may experience excessive stress, fatigue, or hunger. Following vaccination, all recipients should undergo a 30-minute on-site observation period to monitor for immediate reactions such as acute allergic reaction or fainting. AEFIs occurring during observation shall be managed properly, taking care to avoid mass psychogenic reactions. In case of a suspected mass psychogenic reaction, response measures should be taken immediately.

Provinces may conduct public communication and media engagement activities based on this technical plan and according to locality situations. Efforts should be made to promote public awareness of the rationale and significance of incorporating HPV vaccination into the National Immunization Program, distribute educational materials, and monitor and analyze public sentiment. Guidance on public media platforms should be strengthened to ensure dissemination of accurate, evidence-based information.

DISCUSSION

The introduction of HPV vaccine into China's NIP marks the first expansion of the program's protective scope since 2007. These technical and implementation guidelines define the target population for HPV vaccination and provide comprehensive

recommendations for both routine and catch-up vaccination, and provide recommendations for the special populations of immunocompromised individuals and individuals living with HIV. The implementation guidelines delineate the responsibilities of relevant entities and their specific tasks while offering practical strategies to ensure smooth program rollout.

The NIP's policy of providing two doses of bivalent HPV vaccine (types 16/18) to 13-year-old females aligns with current regulatory prescribing information and is grounded in robust evidence for cervical cancer prevention, supported by a sufficient and secure supply of affordable vaccines. The guidelines do not recommend vaccination using two different manufacturers' vaccines for an individual because of sparse data especially domestic evidences on interchangeability of vaccines with different valencies and same valencies from different manufacturers. With the current and impending availability of new domestic higher-valency HPV vaccines, evidences of additional evidence regarding the immunogenicity, effectiveness, and safety of vaccine interchangeability — as well as the potential efficacy of a one-dose regimen — will be needed for refining future HPV vaccination policies.

The anticipated impact of incorporating HPV vaccine into the NIP is marked reduction of infection and persistent infection of HPV types covered by the program vaccines and reduction in associated cervical cancer precursors and cervical cancer throughout the lifetimes of vaccinated cohorts. China maintains robust systems for monitoring vaccination coverage and AEFI. Moving forward, further research is needed to track HPV type prevalence shifts, pathogen-spectrum evolution, and other real-world evidence of vaccination impact. Establishing a comprehensive monitoring and evaluation framework will be essential for informing future updates to HPV vaccination policies, practices, and implementation strategies.

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