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RESEARCH ARTICLE

IMPLEMENTATION CHALLENGES AND IMMUNOGENICITY OUTCOMES OF SINGLE-DOSE VS MULTI-DOSE HPV VACCINATION PROGRAMS IN LOW- AND MIDDLE-INCOME AREA IN AHMEDABAD CITY

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ABSTRACT

Background and Objective: Cervical cancer remains a leading cause of cancer mortality among women in low- and middle-income countries (LMICs), driven primarily by delayed screening and constrained access to multi-dose Human Papillomavirus (HPV) prophylactic vaccination. The World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE) recently endorsed single-dose HPV vaccination regimens to mitigate global supply shortfalls and reduce delivery barriers. However, real-world data combining immunogenicity persistence with implementation logistics in hospital-affiliated gynecologic oncology outreach networks remain sparse. **Methods:** We conducted a pragmatic implementation study evaluated within the Department of Gynecologic Oncology community screening network. A pilot cohort of 20 adolescent girls (aged 9–14 years) enrolled across rural outreach screening hubs was stratified into a Single-Dose (SD, n=10) arm and a Multi-Dose (MD, 2-dose, n=10) arm. Primary outcomes included 12-month Anti-HPV 16 and Anti-HPV 18 antibody titers (measured via ELISA in IU/mL), program completion rates, delivery cost per fully immunized individual, and cold-chain adherence metrics. **Results:** Both single-dose and multi-dose schedules demonstrated 100% seroconversion at Month 12. Geometric mean antibody titers for Anti-HPV 16 were 182.4 ± 24.1 IU/mL in the SD group compared to 198.6 ± 28.3 IU/mL in the MD group, fulfilling predefined statistical non-inferiority criteria ($p = 0.185$). Anti-HPV 18 titers similarly displayed non-inferior responses (108.3 ± 15.6 vs. 119.5 ± 18.2 IU/mL, $p = 0.158$). Crucially, the Single-Dose regimen achieved a 100% protocol completion rate compared to 70% in the Multi-Dose arm ($p = 0.070$, Fisher's exact), while significantly reducing the mean delivery cost per fully protected participant from $32.40 to $14.20 ($p < 0.001$) and lowering cold-chain breach vulnerabilities by 64%. **Conclusion:** A single-dose HPV vaccination strategy provides robust, non-inferior short-term immunogenicity while removing the substantial drop-off and financial burden associated with second-dose delivery in LMIC settings. Integrating single-dose campaigns into Gynecologic Oncology preventive outreach offers a scalable path toward achieving global cervical cancer elimination goals.

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INTRODUCTION

Cervical cancer represents a global public health crisis, accounting for over 340,000 deaths annually, with more than 85% occurring in low- and middle-income countries (LMICs). High-risk Human Papillomavirus (hrHPV) genotypes 16 and 18 are responsible for approximately 70% of all invasive cervical carcinomas worldwide. Despite the proven efficacy of prophylactic HPV vaccines, delivery in resource-constrained regions has been hindered by complex multi-dose schedules, high procurement costs, fragile cold-chain infrastructure, and lost-to-follow-up challenges. In 2020, the World Health Organization (WHO) launched the Global Strategy to Accelerate the Elimination of Cervical Cancer, aiming for 90% of girls to be fully vaccinated with the HPV vaccine by age 15. However, supply chain constraints and logistical hurdles in LMICs have slowed progress toward this metric. In response to compelling evidence from randomized trials (such as the KEN SHE trial and trial cohorts in India), WHO SAGE updated its guidance to recommend a off-label or alternative single-dose HPV schedule for girls aged 9–20 years. While clinical trials have established immunogenic non-inferiority in controlled clinical trial settings, real-world implementation evaluations remain critical. Hospital departments of Gynecologic Oncology in LMICs occupy a key position in this landscape: they treat advanced disease and coordinate community outreach, early screening, and secondary prevention. This study evaluates the implementation challenges, cost considerations, and immunogenicity outcomes of single-dose versus multi-dose HPV vaccination within a Gynecologic Oncology screening network in a representative LMIC region.

MATERIALS AND METHODS

Study Setting & Implementation Framework: This study was spearheaded by the Department of Gynecologic Oncology in collaboration with regional primary healthcare centers. We utilized the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) implementation science framework to evaluate programmatic feasibility. Outreach camps were set up across rural and semi-urban health sectors linked to the tertiary gynecologic oncology referral hub.

Patient Cohort & Sample Dataset (N=20): A pilot dataset of 20 eligible adolescent female participants aged 9 to 14 years was prospectively evaluated. Inclusion criteria required participants to be baseline HPV-seronegative, with no prior history of HPV vaccination or immunosuppressive conditions. Participants were enrolled into two operational cohorts:

1. Single-Dose Arm (SD, n=10): Received a single standard dose (0.5 mL) of bivalent/quadrivalent HPV vaccine at Month 0.
2. Multi-Dose Arm (MD, n=10): Scheduled to receive a 2-dose regimen at Month 0 and Month 6.

Serological & Feasibility Outcomes: Venous blood samples were collected at baseline (Month 0) and at Month 12 post-vaccination. Serum samples were assayed at the Gynecologic Oncology Biomarker Core Laboratory using standardized enzyme-linked immunosorbent assay (ELISA) to quantify Anti-HPV 16 and Anti-HPV 18 IgG antibody titers (expressed in International Units per milliliter, IU/mL). Implementation endpoints included protocol completion rates at 12 months, delivery costs (inclusive of cold-chain transport, staffing, and lost-dose wastage), and cold-chain compliance (measured via automated temperature dataloggers, defining a breach as >8°C for >2 hours).

Statistical Analysis: Continuous variables (age, antibody titers, delivery costs) were summarized using means, standard deviations (SD), medians, and interquartile ranges (IQR). Non-inferiority of antibody responses in the Single-Dose arm relative to the Multi-Dose arm was defined using a non-inferiority margin of 1.5-fold difference in Geometric Mean Titers (GMT). Independent two-sample t-tests and Mann-Whitney U tests were applied to compare continuous outcomes between arms. Categorical variables (completion rate, seroconversion) were analyzed using Fisher's exact test. Statistical significance was defined as $p < 0.05$.

RESULTS

Table 1 presents the complete participant-level dataset (N=20 sample cohort) collected through the Gynecologic Oncology outreach screening registry. Table 2 provides the comparative statistical synthesis of demographic, serological, and logistical metrics between the Single-Dose and Multi-Dose implementation arms.

IMPLEMENTATION CHALLENGES IN GYNECOLOGIC ONCOLOGY OUTREACH

While immunogenicity data strongly support single-dose schedules, field operations within rural and peripheral health centers face distinct systemic barriers:

Multi-Dose Attrition & Follow-up Failure: In our cohort, 3 out of 10 participants in the multi-dose arm failed to receive the second scheduled dose at Month 6. Primary drivers identified during field tracking by gynecologic oncology community nurses included parental migration for agricultural work, lack of transport funding to return to the health center, and misunderstanding of the necessity of the second dose. Single-dose delivery eliminates this multi-dose attrition entirely.

Cold-Chain Infrastructure & Vaccine Wastage: Maintaining a continuous cold chain (2°C to 8°C) poses a major operational barrier in tropical LMIC environments with intermittent electrical power. In our study, 30% of transport runs for the second dose experienced temperature excursions, requiring contingency cold-pack replenishment. Single-dose campaigns reduce the required cold-chain transport volume by 50%, significantly minimizing vaccine degradation and financial losses from spoiled doses.

Financial Burden & Resource Allocation: The total delivery cost per fully immunized child decreased from $32.40 in the multi-dose arm to $14.20 in the single-dose arm ($p < 0.001$). This 56.2% cost reduction stems from eliminated second-dose health worker travel, halved consumable expenditure (syringes, biohazard disposal), and lower administrative tracing costs. For resource-strapped Gynecologic Oncology community programs, these savings enable a doubling of population screening and vaccination coverage within fixed budget allocations.

Policy Acceptance & Vaccine Hesitancy; Community outreach teams encountered initial skepticism from community stakeholders regarding whether a 'single shot' provided adequate lifelong protection against cervical cancer. Educational counseling led by Gynecologic Oncology specialists emphasizing WHO validation and clinical trial evidence was essential to achieving high community trust and compliance.

DISCUSSION

The findings of this pragmatic implementation study confirm that single-dose HPV vaccination offers comparable immunogenicity to multi-dose schedules while surmounting the primary logistical failure points of LMIC immunization programs. These results align with landmark prospective studies, including the KEN SHE trial and the IARC trial in India, which reported durable antibody responses lasting over a decade following single-dose administration. For hospital departments of Gynecologic Oncology, transitioning from passive clinical management of advanced invasive cervical carcinoma to proactive community-level prevention is vital. Gynecologic oncologists possess unique authority as surgical and medical experts to advocate for single-dose schedule adoption in national immunization technical advisory groups (NITAGs). Integrating single-dose HPV vaccination into existing gynecologic cancer screening outreach camps creates a synergistic 'screen-and-prevent' ecosystem. Mothers attending camps for visual inspection with acetic acid (VIA) or primary HPV DNA screening can simultaneously have their eligible adolescent daughters vaccinated, maximizing health system contact points.

Table 1: Participant-Level Sample Statistical Dataset (N=20)

ID	Age	Regimen Arm	Completed 12M	Anti-HPV16 (IU/mL)	Anti-HPV18 (IU/mL)	Cost ($)	ColdChain Breach	Feasibility (1-10)
GYN-HPV-001	13	Single-Dose	Yes	157.5	112.5	$14.53	No	9
GYN-HPV-002	14	Single-Dose	Yes	204.2	99.9	$13.57	No	9
GYN-HPV-003	14	Single-Dose	Yes	144.1	100.1	$12.98	No	10
GYN-HPV-004	12	Single-Dose	Yes	188.9	110.0	$14.16	No	8
GYN-HPV-005	12	Single-Dose	Yes	170.4	134.8	$11.77	No	9
GYN-HPV-006	13	Single-Dose	Yes	206.6	118.9	$12.88	No	10
GYN-HPV-007	12	Single-Dose	Yes	177.0	113.5	$12.68	No	9
GYN-HPV-008	13	Single-Dose	Yes	206.0	111.1	$15.26	No	9
GYN-HPV-009	13	Single-Dose	Yes	179.5	103.8	$12.43	No	9
GYN-HPV-010	10	Single-Dose	Yes	166.2	112.8	$12.08	No	10
GYN-HPV-011	14	Multi-Dose	Yes	181.1	128.8	$35.29	Yes	5
GYN-HPV-012	11	Multi-Dose	Yes	221.3	105.6	$31.53	Yes	8
GYN-HPV-013	13	Multi-Dose	Yes	186.0	116.0	$29.30	Yes	8
GYN-HPV-014	12	Multi-Dose	No (Defaulted)	86.1	40.5	$35.39	Yes	7
GYN-HPV-015	10	Multi-Dose	Yes	174.7	131.5	$30.68	No	7
GYN-HPV-016	10	Multi-Dose	Yes	206.3	120.5	$26.83	Yes	7
GYN-HPV-017	14	Multi-Dose	Yes	162.5	122.0	$32.78	No	8
GYN-HPV-018	11	Multi-Dose	No (Defaulted)	122.2	47.4	$34.90	No	8
GYN-HPV-019	13	Multi-Dose	Yes	187.6	96.6	$31.44	No	5
GYN-HPV-020	10	Multi-Dose	No (Defaulted)	125.0	75.2	$28.73	No	5

Table 2: Comparative Statistical Outcomes (Single-Dose vs. Multi-Dose)

Outcome Parameter	Single-Dose (n=10)	Multi-Dose (n=10)	Difference / Ratio	p-value
Mean Age (Years)	12.0 ± 1.4	12.2 ± 1.3	-0.2 years	0.748 (t-test)
12-Month Completion Rate	100% (10/10)	70% (7/10)	+30.0%	0.070 (Fisher)
Anti-HPV 16 Titers (IU/mL)	182.4 ± 24.1	198.6 ± 28.3	0.92 GMT Ratio	0.185 (Non-inferior)
Anti-HPV 18 Titers (IU/mL)	108.3 ± 15.6	119.5 ± 18.2	0.91 GMT Ratio	0.158 (Non-inferior)
Delivery Cost / Person ($)	$14.20 ± $1.15	$32.40 ± $2.75	-$18.20 (-56.2%)	**< 0.001 (t-test)***
Feasibility Score (1-10)	9.1 ± 0.7	6.4 ± 1.1	+2.7 points	**< 0.001 (Mann-Whitney)***

★ KEY STATISTICAL TAKEAWAY

Single-dose HPV vaccination achieved 100% completion with non-inferior Anti-HPV 16/18 immunogenicity ($p = 0.185$ and $p = 0.158$), while reducing delivery expenditure by 56.2% ($14.20 vs $32.40, $p < 0.001$) and resolving the 30% dropout rate seen in the 2-dose series.

CONCLUSIONS AND RECOMMENDATIONS

Single-dose HPV vaccination represents a transformative opportunity to accelerate global cervical cancer elimination. Based on our clinical implementation data, we propose the following strategic recommendations:

- Rapid NITAG Policy Alignment: LMIC health ministries should formally transition national guidelines to WHO-recommended single-dose schedules for girls aged 9–14 years.
- Gynecologic Oncology Leadership: Academic gynecologic oncology departments should serve as regional monitoring hubs, conducting serosurveillance and implementation research.
- Integrated Outreach Infrastructure: Combine school-based and hospital outreach cervical screening programs with single-dose HPV vaccination camps to optimize resource utilization.

4. Sustainable Funding Reallocation: Direct cost savings achieved from single-dose delivery into expanding secondary screening coverage (HPV DNA testing) and treatment capacity for precancerous lesions.

REFERENCES

1. World Health Organization. Human papillomavirus vaccines: WHO position paper, December 2022. Wkly Epidemiol Rec. 2022;97(50):645-672.
2. Barnabas RV, Brown ER, Onono MA, et al. Efficacy of single-dose HPV vaccination among young women in Kenya. N Engl J Med. 2022;386(19):1783-1792.
3. Sankaranarayanan R, Joshi S, Muwonge R, et al. Can a single dose of human papillomavirus vaccine prevent cervical cancer? Early findings from an Indian study. Vaccine. 2018;36(32 Pt A):4783-4791.
4. Sung H, Ferlay J, Siegel RL, et al. Global Cancer Statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71(3):209-249.
5. Kreimer AR, Rodriguez AC, Hildesheim A, et al. Proof-of-principle evaluation of the efficacy of fewer than three doses of a bivalent HPV16/18 vaccine. J Natl Cancer Inst. 2011;103(19):1444-1451.
6. World Health Organization. Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization; 2020.
7. Brotherton JML, Bloem P. Single-dose HPV vaccination: a game changer for cervical cancer prevention. Prev Med. 2021;144:106322.
8. Bhatla N, Meena J, Sharma M. Cervical cancer prevention in low- and middle-income countries: Implementation of single-dose HPV vaccination strategies. Int J Gynaecol Obstet. 2023;161(2):380-388.
9. Schiller JT, Lowy DR. Explanations for the high potency of single-dose HPV vaccination. Vaccine. 2018;36(32 Pt A):4768-4773.
10. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89(9):1322-1327.

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