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Understanding the decline in HPV vaccination in Colombia: A population-based analysis of girls and parents in early rollout cohorts

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ABSTRACT

Many countries in the world are facing challenges to reach the WHO proposed target of HPV vaccination of 90 % of girls by the age of 15. A population-based cross-sectional survey was conducted in Manizales, Colombia to identify sociodemographic factors and components of the health belief model related to HPV vaccination in the 2003, 2004, and 2005 birth cohorts of girls and their parents targeted by the national HPV vaccination program in 2012, 2013, and 2014. Complementary log-log generalized linear models were used to obtain adjusted Prevalence Ratios (aPR) and 95 % confidence intervals (CI). A lower prevalence of HPV vaccination was observed in girls of the 2004 (aPR 0.82; 95 % CI 0.71–0.92) and 2005 (aPR 0.61; 95 % CI 0.52–0.71) cohorts compared to the 2003 cohort. The higher scores of perceived benefits by girls (aPR 1.06; 95 % CI 1.05–1.08) or their parents (aPR 1.05; 95 % CI 1.03–1.06) were associated to a higher prevalence of HPV vaccination of the girls. Conversely, this prevalence decreased with perceived barriers by girls (aPR 0.94; 95 % CI 0.91–0.96) and parents (aPR 0.91; 95 % CI 0.88–0.94). Parent's education lower attainment, lower socioeconomic stratum, and subsidized (public) health insurance were related to decreased likelihood of HPV vaccination. The results suggest that campaigns for HPV vaccination require effective education strategies to improve public perception of the vaccine's safety and benefits. Decision-makers and implementers must address also other social determinants such as disparities in access to education by parents, the SES, and the type of health insurance to improve HPV vaccination coverage.

1. Introduction

Evidence-based interventions like HPV vaccinations, HPV testing, and "screen and treat" approaches can effectively prevent cervical cancer (CC) [1]. However, over 600,000 women were diagnosed with CC worldwide in 2022, and 350,000 died from it [2]. This global burden

Abbreviations: AIC, Akaike Information Criterion; CC, cervical cancer; DANE, National Administrative Department of Statistics, for the initials of Departamento Administrativo Nacional de Estadística; ELISA, Enzyme-Linked Immunosorbent Assay; EPI, National Expanded Programme on Immunization; HBM, Health Belief Model; HICs, High-income countries; HPV, Human Papillomavirus; hrHPV+, high-risk HPV-positive; HSSS, Health and Social Security System; LMICs, Low-Middle-Income countries; MHSP, Ministry of Health and Social Protection; PR, Prevalence Ratios; SES, socio-economic strata; VIHOPE, Viviendas, Hogares y Personas; VLP, Virus-Like Particle; WHO, World Health Organization.

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is attributed to gaps in knowledge and practice in low-resource settings of High-Income Countries (HICs) and Lower-Middle-Income Countries (LMICs) [3]. The WHO's global strategy to eliminate cervical cancer by 2030 sets out the 90–70-90 targets: 90 % HPV vaccination of girls by age 15, 70 % screening coverage by age 35 and 45, and 90 % treatment coverage for cervical disease [4].

WHO recommends one or two doses of HPV vaccine, which could facilitate 90 % vaccination coverage by 2030 [5]. However, in 2022, only 21 % of countries had achieved one-dose coverage by age 15, and only 15 countries had over 90 % coverage [6]. Latin America leads in HPV vaccine introduction, with an average one-dose coverage of 69 % by age 15. However, 11 countries in Latin America have coverage between 70 and 90 %, while others have coverage below 70 % or no reported data. This highlights the challenges in introducing and achieving high HPV vaccine coverage globally.

In Colombia, the Ministry of Health and Social Protection (MHSP) introduced the HPV vaccine into the National Expanded Programme on Immunization (EPI) in 2012 [7]. The initial goal of vaccinating 80 % of nine-year-old girls in the fourth grade of primary education was achieved for two of the intended three doses. In 2013, the schedule was modified to two doses and extended to all 9–17-year-old girls and adolescents ("catch up" strategy) [8], reaching a coverage for the second dose below 70 %. In 2014, a major psychogenic event, a type of functional disorder resembling a seizure precipitated by psychological distress that occurred in El Carmen de Bolívar, a town located in the Caribbean region, was inaccurately attributed to the HPV vaccine by mainstream media. This propagated misinformation led to dramatic and sustained loss of public confidence and significant decline in program coverage, with first and second doses dropping to 63.6 % and 1.4 %, respectively [9,10] The current average of HPV vaccination coverage with one dose by age 15 is 52 % with wide regional inequalities [6].

Understanding the factors hindering or facilitating large-scale HPV vaccine implementation is crucial for achieving the WHO's goal of cervical cancer elimination. Sociodemographics, healthcare systems, beliefs, and perceptions about the HPV vaccine are key factors influencing vaccination. These factors may include race/ethnicity, income, insurance status, education level, knowledge of HPV, perceived safety and benefits of HPV vaccination, beliefs in conspiracy theories, vaccine availability, accessibility, cost, and healthcare provider recommendations [11–16]. In Colombia, the lack of information and safety concerns are barriers, while medical recommendations and disease prevention awareness are facilitators for HPV vaccination decisions [17–20].

However, the investigation of these factors especially in LMICs is very limited, and studies using evidence-based theoretical frameworks specifically tailored to identify factors that influence the behaviors to opt for HPV vaccination in the context of social health determinants are also scant.

The Health Belief Model (HBM) [21] is a conceptual model that helps explain the individual drivers to opt for health interventions. Studies on the HBM in the context of HPV vaccination in different cultural contexts have found that people's decisions about getting vaccinated are influenced by perceived susceptibility to getting CC and HPV infection, perceived severity of CC and HPV infection, perceived benefits of the HPV vaccine, perceived barriers to HPV vaccine application, and knowledge about CC, HPV, and the HPV vaccine [11–15,22]. Even further, the HBM has guided the design of strategies that promote vaccine application, and school-based interventions tailored in this framework have shown positive effects on improving knowledge and health beliefs about this vaccine in adolescents and parents [23,24].

This study aimed to identify sociodemographic factors and health beliefs related to HPV vaccination in a Colombian town using the HBM [21]. The study focused on the 2003, 2004 and 2005 birth cohorts of girls and their parents who were the target of vaccination program rollout phases in 2012, 2013, and 2014. The use of HBM in the context of an abrupt interruption of the vaccination program can be a valuable tool to understand public perception and improve communication surrounding the HPV vaccine, ultimately contributing to the fight against cervical cancer worldwide.

2. Methods

2.1. Study design and context

A population-based cross-sectional study was conducted between September 2017 and February 2019 in Manizales, Colombia. Manizales, the capital of the state of Caldas, is a town located in the Central Andean region of Colombia and has an approximate area of 571.8 km^2. At the time of recruitment, there were 103,978 households, and the total population was 400,436 with 52.8 % women (211,430) and 47.2 % men (189,006). Most of the population (93.8 %) lived in the urban area, and 48.5 % of them were of medium socio-economic stratum (SES). Schooling among children under 17 years old was 92.2 % [25] at the time of this study. Manizales, a mid-sized, socially and economically developed city of the populated Andean region, is home to one of Colombia's five population cancer registries, allowing future monitoring of intervention impact.

2.2. Sample size

The sample size of girls to be surveyed was calculated assuming 65 % vaccine coverage in 2014, as reported by the Colombian MHSP, with a 95 % confidence level, a 5 % standard error, and a design effect of 2.0. The required number of households (selection unit) to visit to identify at least 1584 potentially eligible girls (analysis unit) was 5688.

2.3. Study sampling

Multistage sampling was conducted by randomly selecting blocks proportional to the area of residence (urban and rural) and SES (high, medium, and low). All blocks of Manizales were identified using the Housing, Homes and People database (Viviendas, Hogares y Personas-VIHOPE) [26], the census of the state of Caldas, and cartography provided by the National Administrative Department of Statistics (Departamento Administrativo Nacional de Estadística- DANE) [25]. Cartographic inconsistencies were corrected using the OpenStreetMap (version 474, 2012) software and Google Street View (accessed in June 2017). The number of blocks randomly and proportionally allocated to the area of residence, and SES, was projected using the DANE and VIHOPE databases, the updated user interface for Rural and Urban Projection Program (RUPEX, version 1, 2014) [27] and the Power Analysis and Sample Size (PASS version 14) [28] software. The selected blocks were numbered and assigned randomly to interviewers/recruiters who visited assigned neighborhoods weekly. To increase the probability of reaching the required sample size, additional blocks were selected around each of the initially selected blocks and visited only when the number of girls in that block was insufficient. All residential households within selected blocks were visited to identify eligible girls.

2.4. Participants and recruitment visit

Eligible girls were those born in the years 2003, 2004, and 2005, living in the city of Manizales between 2012 and 2014. Parents or a legal guardian (18 of age or older) residing in the same home as the girl at the time of the recruitment were also invited to participate. More than one eligible girl in the same household was surveyed if the legal guardians had no family relationship between them. The study excluded households where no legal guardian was present during any of the three recruitment visits. Trained interviewers systematically visited residential households on assigned blocks, starting at a previously defined point of the block in a clockwise direction. During the household visit, legal guardians/parents were informed first of the study and asked to sign an informed consent for they and their girl's participation in the study after it was reported that girls aged 12–14 were living in the household. The girls were informed of the study and provided informed assent, only if the adult had already given consent and they agreed to participate. Eligible girls were recruited by checking their identification document (ID) to confirm their year of birth. After the survey was completed, finger prick blood samples were collected on Whatman 903 Protein Saber Cards by saturating five 1.2-cm-diameter Dried Blood Spot (DBS) circles (GE Healthcare Bio-Sciences, Pittsburgh, PA) and allowed to dry at room temperature for 4 to 24 h. Recruitment continued until the required number of blocks by SES and area of residence were reached.

2.5. Variables

2.5.1. HPV vaccination status in girls

This is the primary outcome and was defined as the application of at least one dose of the HPV vaccine verified by at least one of three sources of information. The vaccination record was first searched on the Expanded Program on Immunization (Programa Ampliado de Inmunizaciones- PAIWEB) platform using the ID of the girls. The serology of IgG antibodies against HPV genotypes 16/18/11/6 was used to assign the vaccination status of girls not registered on the PAIWEB platform [29]. Concordant self-report between the adult and the girl was used for girls without assigned vaccination status with the two previous methods. Finally, girls with no information in any of the sources to define HPV vaccination status were excluded from the analysis.

2.5.2. Sociodemographic variables

Variables collected from girls included if she attended school, school grade, whether the school was public or private, and religious or secular, age, and who was the provider of financial support (both parents, only father, only mother, other). Variables from legal guardians included sex, age, educational level, marital status, religion, and type of health insurance (Colombia has two types of health insurance: contributive (people with the capacity to pay, retired and their families who could be considered as having a private form of insurance), and subsidized (people without the capacity to pay, classified as poor or vulnerable according to the system for identifying potential beneficiaries of social programs-SISBEN, who could be considered as having a public form of insurance). The SES was defined according to DANE's urban socioeconomic stratification for residential public services [30] as low, medium and high. In its absence, it was assigned by georeferencing.

2.5.3. Health belief model (HBM)

The HBM questions were based on the questionnaire developed by Kim et al. [31], Guvenc et al. [32], and Bowyer et al [33], and a previous qualitative study that included girls and parents from schools of Manizales purposeful sampled to capture maximum variation [17]. The surveys included five HBM constructs: *perceived susceptibility* to get CC and HPV infection, *perceived severity* of CC and HPV infection, *perceived benefits* of the HPV vaccine, *perceived barriers* to HPV vaccine application, and *knowledge* about CC, HPV, and the HPV vaccine. The reliability of the scales of the HBM constructs measured with Cronbach's alpha, was greater than 0.66 (acceptable), except for the construct of perceived susceptibility in girls, which had a value of 0.56. Supplementary Table 1 shows the HBM constructs with their questions and Cronbach's alphas. Three response options were used: "yes," "no," or "don't know" for the questions of each of the HBM constructs. One score was assigned to affirmative answers (in perceptions) or to correct answers (in knowledge); no score was assigned when the answers were negative, incorrect, or "don't know." The total score for everyone was the sum of the points in each of the five constructs (Supplementary Table 1). Scales were normalized in a range of 0–10, multiplying the score of each construct by ten and dividing the product by the total number of questions of each construct.

2.5.4. HPV vaccine acceptability

Among those legal guardians or girls who self-reported not being vaccinated against HPV ever or that she has received two doses or less, we asked about the intention to be vaccinated or to complete the vaccination schedule.

2.6. Data sources

2.6.1. Expanded Program on Immunization information system (PAIWEB)

PAIWEB is an information system implemented in 2012 by the Colombian Ministry of Health and Social Protection to track the vaccination records of all citizens who are part of the Expanded Program on Immunization (EPI). Access to PAIWEB vaccination records for all girls of the state of Caldas was facilitated by departmental health authorities. All eligible girl IDs were searched on this platform between August and September 2019 for vaccinations registered from August 2012 to July 2019.

2.6.2. HPV serology

Serology was conducted to assign the vaccination status of girls without information about HPV vaccination on the PAIWEB. For this purpose, nine 2-mm circles were punched from DBSs, placed in Eppendorf tubes, and shipped dry to Queen Mary University of London (QMUL) where they were processed by eluting the DBSs in 200 μL of PBS containing 0.05 % Tween 20 and overnight incubation at 4 °C with gently shaking. After processing, the samples were sent frozen to the Virus Reference Department, UK Health Security Agency (London), where they were tested. The method used to estimate total human IgG has been previously described by Louie, K. et al. [29] NOR-01 (human IgG standard; Nordic-MUbio, The Netherlands) was used as the internal standard for the Human IgG ELISA. The mean (±SD) observed/expected concentration of this standard following five-parameter logistic equation (GraphPad Prism®, v8) was 100 % (±2 %) ($n = 22$) and DBS sample repeatability gave a mean (±SD) IgG concentration ratio of 1.1 ± 0.3 ($n = 80$). The median IgG content of the DBS samples in this study was 124 μg/mL (IQR 94 – 159 μg/mL). Levels of IgG serum antibodies against Virus-Like Particles (VLPs) of genotypes HPV 6/11/16/18 normalized to total IgG levels of the same individual DBS eluted sample were detected using a Multiplex Human Papillomavirus L1L2 virus-like particle antibody binding assay [34,35]. Pooled Gardasil® vaccinee sera [36] were used to make an internal standard which was calibrated to International Units/mL (IU/mL) using IS16/IS18 from the WHO/National Institute for Biological Standards and Control, United Kingdom for HPV16/18, while HPV6/11 are reported in AU/mL (arbitrary units). The mean (±SD; CV %) Units/mL of the internal quality control (IQC) used for this study was as indicated for HPV6 (45.6 ± 6.7; 15 %; $n = 21$), HPV11 (77.7 ± 12.3; 16 %), HPV16 (131.3 ± 18.1; 14 %) and HPV18 (73.7 ± 10.2; 14 %). Normalized unitage is reported for the DBS outcomes as Units/mg of IgG (IU/mg or AU/mg). A cutoff of 0.2 Units/mg (censored at 0.1 Units/mg, for calculation purposes) was used based upon the mean + 3SD HPV antibody levels and IgG content of pre-vaccine serum samples from 12 to 15-year-old girls ($n = 71$) [36]. DBS sample ($n = 40$) repeatability gave good agreement for assignment of serostatus (Agreement 93 %; Kappa = 0.826; 95 %CI 0.731–0.920) and pairwise HPV-specific IgG concentration ($R2 = 0.931$). Data from five girls who had no vaccination records on the PAIWEB, had no measurable IgG content, or were mislabeled were excluded from serology analysis. Girls with antibody levels >0.1 Units/mg against all the four vaccine HPV genotypes were considered vaccinated.

2.6.3. The survey instrument

Survey was created based on HPV-based HBM-validated surveys [31–33] and information collected in a previous qualitative phase conducted with parents and girls from schools of Manizales [17]. The questionnaires were translated independently by 2 researchers from English to Spanish, and the content of the finally reviewed translated version was validated by six experts in CC, HPV, public health, and adolescents' health. After corrections, the survey was applied to six non-experts, and language adaptations were made to some of the questions. The questionnaire was piloted before the study, with the interviewers (nursing assistants) and six individuals captured randomly in 14 blocks of a specific urban area of Manizales. The surveys were applied face-to-face in confidentially, and the interviewer recorded the responses on an electronic device. The information was digitized with licensed software for surveys on mobile devices (mSurvey, version 1.0.8). The data was provided in its entirety by the respondents, except for the SES and the area of residence, which in some cases were captured by the interviewer from public services invoices and verified through official government maps and registries.

2.7. Efforts to address potential sources of bias

The sampling generated representativeness of all households with the target population. Selection bias was controlled by GPS location verification, recontacting absent parents or adults, and replacing households in the next block after three recruitment attempts. Information biases were controlled by calling 10 % of the adults surveyed to verify the answers to the socio-demographic questions. To control for recall bias about self-reported vaccination status, legal guardians were instructed to check any available HPV vaccination records. To control for the measurement bias of the main outcome (vaccination status), three sources of information (PAIWEB, serology, and concordant self-report) were used, giving priority to those that were not biased by memory.

2.8. Statistical methods

Absolute and percentage frequencies were estimated for qualitative variables, and proportions were compared by the Chi-Squared test. The mean and standard deviation were estimated for quantitative variables, and the means were compared with the Student *t*-test. Considering an expected prevalence of the outcome greater than 20 %, we used complementary log-log generalized linear models to obtain crude and adjusted Prevalence Ratios (aPR) with their respective 95 % confidence intervals and *p*-values to avoid overestimating the association [37]. The standardized scales of the HBM constructs were considered independent variables, and the sociodemographic factors as adjustment variables. The Stepwise forward method following the Hosmer and Lemeshow criteria in the bivariate analyses was used to choose variables for the multivariate model, and the best model that explained the outcome was selected by choosing the lowest value with the Akaike Information Criterion (AIC). Additionally, an adjustment was made for the random cluster effect. There was no missing data in the variables analyzed. A significance value of $\alpha = 0.05$ was considered. The data were analyzed

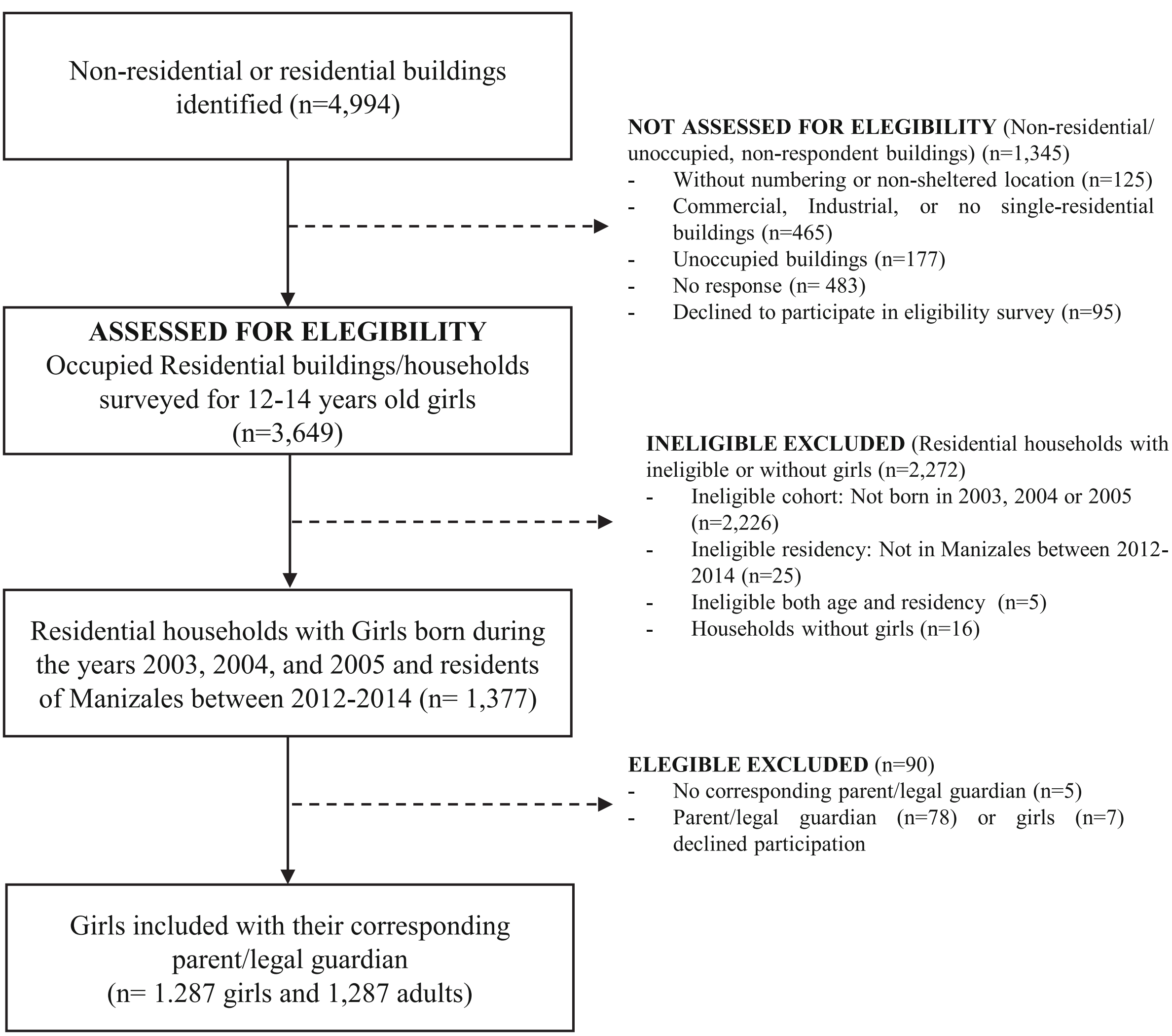

Fig. 1. Flowchart of participants selection. Recruiters visited 4994 buildings/households finding 3649 occupied residential buildings/households that were surveyed for 12–14 years old girls. After excluding 2272 ineligible girls, 1377 eligible girls remained. Of these, 90 eligible participants were excluded, leading to a final sample of 1287 girls and their parents/responsible adults that signed assent and informed consent and answered the surveys.

using R version 4.3.2 and R Studio 2023.10.31.

2.9. Ethics statement

The study was approved by the Bioethics Committee of the University Research Headquarters of the University of Antioquia, (Act 15–40-667, 2015). Legal guardians signed an informed consent, and the girls signed an informed assent after a brief mental evaluation to verify their ability to assent. The recruitment, informed assent, and data collection were supervised by a psychologist with experience in research with adolescents.

3. Results

3.1. Recruitment of participants

Fig. 1 shows the flowchart for the participant selection. Recruiters visited 4994 buildings/households finding 3649 occupied residential buildings/households that were surveyed for 12–14 years old girls. After excluding 2272 ineligible girls, 1377 eligible remained. Of these, 90 declined participations, leading to a final sample of 1287 girls and their parents/responsible adults that signed assent and informed consent and answered the surveys.

3.2. HPV vaccination status of girls

Table 1 shows the vaccination status based on three sources: PAIWEB records (778 girls) and, serology (465 girls). Forty-four did not provide (n = 38) or did not have quality-approved samples (n = 6) in the serology test. These 43 girls had vaccination status defined by concordant self-report. One girl was excluded from the analysis because no information in any source. Among the 1286 girls 947 (73.6 %) were assigned as vaccinated with at least one dose, 88.6 %, 77.6 %, and 55.5 % from the 2003, 2004, and 2005 cohorts, respectively.

3.3. Sociodemographic characteristics

The sociodemographic characteristics by HPV vaccination status of the girls and responsible adults are presented in Supplementary Table 2 and Supplementary Table 3, respectively. The survey reveals that most girls (92.5 %) were between sixth and ninth grades, attending public schools (81.9 %) and secular education (78.1 %). There were significant differences in vaccination status based on school grade and birth cohort. Unvaccinated girls were more frequent in sixth and seventh school grades and recent cohorts. Most parents/responsible adults were women (94.0 %), with a mean age of 42.5 years. Most resided in urban areas (96.7 %), of low SES (58.2 %), and were affiliated with the contributing regimen of HSSS (68.7 %). Sixty-six point seven % of responsible adults were married or cohabitating with a partner, and the Christian religion was predominant (96.7 %). The percentages of parents/responsible adults that have no education or incomplete primary education were higher in unvaccinated (15.3 %) than in vaccinated girls (8.7 %).

3.4. HBM constructs scores (health beliefs and knowledge)

Compared with vaccinated girls, unvaccinated girls tended to have lower scores for perceived susceptibility to HPV infection and perceived severity for cervical cancer, perceived benefits of HPV vaccination, and knowledge about HPV; meanwhile, their scores for perceived barriers were higher (Supplementary Table 2). Parents/Responsible adults of unvaccinated girls had lower scores for perceived benefits and higher scores for perceived barriers to HPV vaccination. There were no differences in the other HBM constructs between parents of vaccinated and unvaccinated girls (Supplementary Table 3). Overall, the medians for perceived barriers and benefits scores of girls and their parents/ responsible adults were higher and lower in 2005 and 2004 than in the 2003 cohort respectively, whereas (Supplementary fig. 1) lower perceived benefits were observed in vaccinated girls of the 2005 cohort (Supplementary fig. 2).

3.5. Multivariate analysis

The results of the complementary log-log regression analysis (Table 2) showed that the vaccination against HPV was more prevalent in girls of eighth and ninth grades (aPR 1.22; 95 % CI 1.13–1.32) than those in sixth and seventh grades while it was less prevalent in girls of the 2004 (aPR 0.82; 95 % CI 0.71–0.92) and 2005 (aPR 0.61; 95 % CI 0.52–0.71) compared to the 2003 birth cohort. On the other hand, the girls with higher scores of perceived benefits (PRa 1.06; 95 % CI 1.05–1.08) had higher, while those with higher scores of perceived barriers had lower (PRa 0.94; 95 % CI 0.91, 0.96) prevalence of HPV vaccination. Similarly, to the observed in girls, higher prevalence of HPV vaccination of girls was observed in parents with higher than in parents with lower perceived benefits scores (aPR 1.05; 95 % CI 1.03–1.06, Table 3) while this prevalence was lower in those parents with higher as compared to those with lower scores of perceived barriers (aPR 0.91; 95 % CI 0.88–0.94). The girls of parents/responsible adults with some secondary school (aPR 1.21; 95 % CI 1.03–1.37), complete secondary education (PRa 1.26; 95 % CI 1.09–1.42), or higher education (PRa 1.24; 95 % CI 1.06–1.42), had a higher prevalence of HPV vaccination than those without education.

Table 1
Vaccination status assigned to girls by the three sources of information (n = 1287).

Source of information	Assigned Vaccination status	Total (n = 1287)		Birth cohort					
				2003 (n = 422)		2004 (n = 424)		2005 (n = 441)	
		n	(%)	n	(%)	n	(%)	n	(%)
PAIWEB[a] (n = 778)	Vaccinated	778	(60.5)	301	(71.3)	264	(62.3)	213	(48.3)
Serology[b] (n = 465)	Vaccinated	155	(12.0)	69	(16.4)	60	(14.1)	26	(5.9)
	Unvaccinated	310	(24.0)	42	(9.9)	90	(21.2)	178	(40.4)
Self-report of girls and parent/legal guardian[c] (n = 43)	Vaccinated	14	(1.1)	4	(0.9)	5	(1.2)	5	(1.1)
	Unvaccinated	29	(2.3)	6	(1.5)	5	(1.2)	18	(4.1)
None (n = 1)	Undefined	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.2)
Final vaccination status[d] (n = 1286)	Vaccinated	947	(73.6)	374	(88.6)	329	(77.6)	244	(55.5)
	Unvaccinated	339	(26.3)	48	(11.4)	95	(22.4)	196	(44.5)

[a] **PAIWEB:** National vaccine registration of the Expanded program of Immunization of Colombia. Vaccinated with at least one dose: records for first or second or third dose or with any combination or with all three doses.
[b] **Serology for the HPV 16/18/11/6 genotypes:** Vaccinated = titers >0.1 Units /mg against each of the four VLPs (VLP-16, VLP-18, VLP-11, and VLP-6.
[c] **Self-report by parents/responsible adults and the corresponding daughter girl:** Vaccinated = Both the parent and the girl self-reported girl was vaccinated.
[d] **Final Vaccination status**: Defined by PAIWEB or serology for HPV HPV 16/18/11/6 VLPs (on girls with no information in the PAIWEB) or concordant self-report between girls and parent/legal guardian (girls with no information in the PAIWEB or serology). Undefined = vaccination status was not possible to be assigned.

Table 2
Association among sociodemographic characteristics, knowledge, and Human Papillomavirus health beliefs with HPV vaccination status of girls (n = 1286).

Variables	Vaccinated n = 947	Unvaccinated n = 339	PRc	CI 95 %	p-value	PRa	CI 95 %	p-value
	n (%)	n (%)						
School grade[a]								
Sixth-Seventh	382 (40.3)	212 (62.5)	Ref			Ref		
Eighth-Ninth	511 (64.0)	85 (25.1)	1.35	1.28–1.41	<0.001	1.22	1.13–1.32	**<0.001**
Other level	43 (4.5)	38 (11.2)	0.81	0.64–1.00	0.048	0.80	0.62–1.00	**0.048**
Not enrolled in school	11 (1.2)	4 (1.2)	1.11	0.74–1.42	0.580	0.95	0.60–1.31	0.777
School funding								
Private	788 (83.2)	265 (78.2)	Ref					
Public	148 (15.6)	70 (20.6)	0.91	0.81–1.00	0.061			
Not enrolled in school	11 (1.2)	4 (1.2)	0.97	0.66–1.22	0.839			
School character								
Religious	753 (79.5)	252 (74.3)	Ref					
Secular	183 (19.3)	83 (24.5)	0.91	0.82–1.00	0.044			
Not enrolled in school	11 (1.2)	4 (1.2)	0.97	0.66–1.22	0.820			
Birth cohort (year)								
2003	374 (39.5)	48 (14.2)	Ref			Ref		
2004	329 (34.7)	95 (28.0)	0.87	0.81–0.93	<0.001	0.82	0.71–0.92	**0.001**
2005	244 (25.8)	196 (57.8)	0.62	0.55–0.70	<0.001	0.61	0.52–0.71	**<0.001**
Provider of financial support								
Both parents	372 (39.3)	145 (42.8)	Ref					
Only father	220 (23.2)	63 (18.6)	1.07	0.98–1.15	0.123			
Only mother	299 (31.6)	115 (33.9)	0.99	0.91–1.07	0.881			
Other relatives[b]	56 (5.9)	16 (4.7)	1.08	0.93–1.21	0.279			
Constructs of HBM (standardized scales in range 0–10) [Mean/SD]								
Perceived susceptibility	2.06 (3.36)	1.31 (2.85)	1.02	1.01–1.03	<0.001			
Perceived severity	2.08 (3.13)	1.40 (2.54)	1.02	1.01–1.04	<0.001			
Perceived benefits	7.40 (2.76)	5.09 (3.45)	1.11	1.09–1.13	<0.001	1.06	1.05–1.08	**<0.001**
Perceived barriers	1.47 (1.77)	2.42 (2.34)	0.95	0.93–0.96	<0.001	0.94	0.91–0.96	**<0.001**
Knowledge[c]	1.82 (2.43)	1.20 (1.89)	1.04	1.02–1.05	<0.001			

cPR: Crude Prevalence Ratio.
aPR: Adjusted Prevalence Ratio. **SD**: Standard Deviation. Model adjusted by background variables with $p < 0.25$ in bivariate analysis and random cluster effect (p = 0.006).
[a] **School grade:** The Colombian education system consists of preschool, primary school (first to fifth grade), secondary school (sixth to eleventh grade) and higher education (technician, technologist, professional or postgraduate).
[b] **Other relatives**: grandparents, siblings, uncle, aunts.
[c] **Knowledge** about cervical cancer, HPV and HPV vaccine. **HBM**: Adapted Constructs of the Health Belief Model.

3.6. Sociodemographic characteristics of HPV unvaccinated girls open to vaccination

We asked about the intention to be vaccinated or to complete the vaccination schedule to the 1107 girls that self-reported not being vaccinated against HPV ever or that she has received two or less doses of the vaccine (data not shown). Ninety-seven of these girls have not been vaccinated ever despite their willingness to get vaccinated (Acceptors/unvaccinated), while 143 have received at least one dose despite reporting that they were not willing to get vaccinated (Refusers/vaccinated). The distribution of sociodemographic factors and HBM scores between these two groups is shown in Table 4. Higher percentages of girls of low socioeconomic stratum (74.2 % vs. 58 %), affiliated with the subsidized health insurance (40.2 vs. 28 %), and of the 2005 cohort (44.3 vs. 29.4 %) were observed among the HPV unvaccinated girls that were open to be vaccinated. These unvaccinated girls had lower scores for knowledge about HPV, HPV vaccine, and cervical cancer (1.19 vs. 1.31), for perceived susceptibility (1.29 vs. 1.40), and for perceived barriers (1.71, vs. 3.34,) but higher scores for perceived benefits of the HPV vaccine (mean 6.87 vs. 5.09).

4. Discussion

A cross-sectional survey was conducted in Manizales, Colombia, among girls born 2003–2005 and their parents. Multivariate analysis identified sociodemographic factors and HPV-related beliefs influencing HPV vaccination decisions. Data was collected from a representative sample using the DANE Census as a frame. The data regarding school enrolment, and area of residence [38,39] is within the expected distributions described for this population. Socioeconomic stratification projected by the DANE in 2019 was 40,75 % for Low (strata 1 and 2), 48,48 % for Middle (strata 3 and 4) and 10,77 for high (strata 5 and 6). The respective percentages in the study sample were 58.2 %, 35.2 %, and 6.5 %. Lower recruitment probability in the middle and high socioeconomic strata led to an overrepresentation of the low stratum.

We used a robust approach to determine vaccination status in our study. HPV vaccination status was determined using PAIWEB registries (n = 778, 60.5 %), HPV validated serology (n = 465, 36,2 %), and self-reporting (3.3 %). Coverage rates for cohorts 2003, 2004, and 2005 were 88.6 %, 77.6 %, and 55.5 %, respectively. PAIWEB is a mandatory tool for registering vaccination in Colombia, but its effectiveness has been the subject of much debate and analysis within the health sector. Using as gold standard 330 randomly selected girls with at least one dose in the PAIWEB, the sensitivity to identify vaccinated girls by serology was 83 % and this test was positive in all the 25 girls with records for all three HPV vaccine doses. PAIWEB data would not be reliable for estimating specificity, as it only captures individuals at the time of vaccination, but the serology test used in this study, exhibited a 96 % specificity in sexually active, self-reported unvaccinated women (18–30) recruited from a sexual health clinic in England [29]. The vaccination status of the remaining 43 (3.3 %) girls was determined by the concordant self-reporting between the adult and the girl, which had a 93 % overall agreement and a kappa coefficient of 0.74 (95 % CI 0.69–0.80).

Although the proportions of vaccination are 10 % lower than reported by the Colombian MHSP [40] (Supplementary Table 4) they show the same trend in the reduction of vaccinated girls in subsequent cohorts. The differences could be explained because MHSP estimates coverage by dividing the total number of vaccinations registered in the PAIWEB, by the total number of children in the target cohort projected by the DANE. Given that many eligible girls were not registered on the

Table 3
Association among sociodemographic characteristics, knowledge, and Human Papillomavirus health beliefs of parents/responsible adults with HPV vaccination status of girls (n = 1286).

Variables	Vaccinated n = 947	Unvaccinated n = 339	PRc	CI 95 %	p-value	PRa	CI 95 %	p-value
	n (%)	n (%)						
Residence area								
Rural	33 (3.5)	9 (2.7)	Ref					
Urban	914 (96.5)	330 (97.3)	0.93	0.73–1.10	0.442			
Socioeconomic stratum[a]								
Low (1–2)	544 (57.4)	205 (60.5)	Ref					
Middle (3–4)	347 (36.6)	106 (31.3)	1.06	0.98–1.13	0.167			
High (5–6)	56 (5.9)	28 (8.3)	0.94	0.77–1.10	0.458			
Health insurance[b]								
Subsidized (Public)	285 (30.1)	117 (34.5)	Ref					
Contributive (Private)	662 (69.9)	222 (65.5)	1.05	0.97–1.12	0.186			
Sex								
Male	57 (6.0)	20 (5.9)	Ref					
Female	890 (94.0)	319 (94.1)	0.99	0.85–1.12	0.904			
Age (years old)								
18–37	354 (37.4)	130 (38.3)	Ref					
38–47	328 (34.6)	116 (34.2)	1.02	0.94–1.10	0.623			
48–57	188 (19.9)	61 (18.0)	1.03	0.94–1.12	0.466			
≥58	77 (8.1)	32 (9.4)	0.98	0.84–1.10	0.748			
Educational level[c]								
None/some primary school	82 (8.7)	52 (15.3)	Ref			Ref		
Complete/some secondary school	295 (31.1)	102 (30.1)	1.21	1.06–1.34	0.007	1.21	1.03–1.37	**0.019**
Complete secondary school	341 (36.0)	99 (29.2)	1.25	1.11–1.38	<0.001	1.26	1.09–1.42	**0.003**
Higher education	229 (24.2)	86 (25.4)	1.18	1.02–1.33	0.027	1.24	1.06–1.42	**0.009**
Marital status								
Single	207 (21.9)	77 (22.7)	Ref					
Married/Cohabiting	637 (67.3)	224 (66.1)	1.02	0.94–1.10	0.592			
Separate/Divorced/Widowed	103 (10.9)	38 (11.2)	1.01	0.88–1.13	0.930			
Religion								
None	26 (2.7)	16 (4.7)	Ref					
Christians	921 (97.3)	323 (95.3)	1.18	0.94–1.24	0.135			
Constructs of HBM in parents/legal guardians (standardized scales in range 0–10) [Mean/SD]								
Perceived susceptibility	5.28 (4.11)	4.95 (4.22)	1.00	1.00–1.01	0.268			
Perceived severity	5.10 (3.93)	5.03 (4.05)	1.00	0.92–1.01	0.906			
Perceived benefits	7.07 (2.82)	5.35 (3.38)	1.07	1.05–1.09	<0.001	1.05	1.03–1.06	**<0.001**
Perceived barriers	1.74 (1.49)	2.63 (1.97)	0.94	0.92–0.95	<0.001	0.91	0.88–0.94	**<0.001**
Knowledge	4.44 (3.14)	4.31 (3.28)	1.00	0.99–1.01	0.644			

cPR: Crude Prevalence Ratio.
aPR: Adjusted Prevalence Ratio. **SD**: Standard Deviation. Model adjusted by background variables with p < 0.25 in bivariate analysis and random cluster effect (p = 0.006).
[a] **Socioeconomic stratum:** The stratification based on the residential public services developed by the Departamento Administrativo Nacional de Estadística (DANE), was used as follows: 1) low-low, 2) low, 3) medium-low, 4) medium, 5) medium-high, and 6) high.
[b] **Health insurance:** Colombia has two types of health insurance: contributive (people with the capacity to pay, retired and their families), and subsidized (people without the capacity to pay, classified as poor or vulnerable by the system for identifying potential beneficiaries of social programs-SISBEN).
[c] **Educational Levels:** The Colombian education system consists of preschool, primary school (first to fifth grade), secondary school (sixth to eleventh grade) and higher education (technician, technologist, professional or postgraduate). **Christians**: Catholics, Evangelicals, Protestants and Adventists) **Knowledge** = knowledge about cervical cancer, HPV, and HPV vaccine. **HBM**: Adapted Constructs of the Health Belief Model.

PAIWEB and that seven years elapsed between the start of the vaccination program and the completion of enrolment in this study, using serology was extremely useful to obtain complete study outcome measurement and study results. Nonetheless, our data strengthens global observations about the challenges faced by countries to achieve the goal of 90 % HPV vaccination coverage with one dose by age 15 [40].

In addition to the anticipated cohort effect (Table 2), the higher education level of parents (Table 3) were the only sociodemographic factors related to the likelihood that the girls were vaccinated in the linear regression models. Low parental education and socioeconomic level have been negatively associated with childhood vaccination [41,42]. However, in the application of the HPV vaccine, the association of this variable varies between studies, as higher educational levels in parents have been associated both against [43,44] and in favour of vaccination [45]. In the Colombian context, families with higher educational and socioeconomic levels have been also described as more aware of vaccines [17] [46], but it is important to consider that these individuals may have more access to various sources of information, where there is a lot of misinformation about the benefits and adverse events of this vaccine.

Among the various Health Belief Model (HBM) constructs considered, only the perceived barriers or benefits were consistently identified by both girls (Table 2) and their parents (Table 3) as factors influencing negatively or positively the likelihood of vaccination. Barriers and benefits scores increased and decreased between the 2003 and 2005 cohorts respectively (Supplementary Fig. 1) and vaccinated girls of later cohort reported lower perceived benefits (Supplementary Fig. 2). Many policy changes occurred during the three years of the roll-out phases of the vaccination program in Colombia. The program was launched in 2012 for 9-year-old schoolgirls (cohort 2003), in 2013 MHSP guidelines changed to include girls up to the age of 17, regardless of whether they were schooled. Carmen de Bolívar psychogenic event [10] occurred mostly in 13–15-year-old girls during the implementation of the first and second doses of the 2014 campaign. The data of the MHSP and this study confirms the observation that vaccination in Colombia declined to around 30 % in the national territory after this event (Supplementary Table 4). The nature of this study does not allow us to suggest that altogether these events are directly related to the decline of HPV vaccination. However, points out that the perceptions about the benefits and barriers declined and increased respectively, as well as the HPV

Table 4
Sociodemographic characteristics, knowledge, and Human Papillomavirus health beliefs of girls by HPV vaccination status and acceptability of HPV vaccine ($n = 240$).

Variables	Refusers Vaccinated (n = 143)	Acceptors Unvaccinated (n = 97)	p-value
	n (%)	n (%)	
Residence area			
Rural	6 (4.2)	2 (2.1)	0.366[a]
Urban	137 (95.8)	95 (97.9)	
Socioeconomic stratum[c]			
Low (1–2)	83 (58.0)	72 (74.2)	**0.010**[a]
Middle and High (3–6)	60 (42.0)	25 (25.8)	
Health insurance[d]			
Subsidized (Public)	40 (28.0)	39 (40.2)	**0.048**[a]
Contributive (Private)	103 (72.0)	58 (59.8)	
School grade[e]			
Sixth-Seventh	51 (35.7)	58 (59.8)	**<0.001**[a]
Eighth-Ninth	85 (59.4)	27 (27.8)	
Other level	4 (2.8)	10 (10.3)	
Not enrolled in school	3 (2.1)	2 (2.1)	
School funding			
Private	121 (84.6)	82 (84.5)	1.000[a]
Public	19 (13.3)	13 (13.4)	
Not enrolled in school	3 (2.1)	2 (2.1)	
School character			
Religious	107 (74.8)	80 (82.5)	0.328[a]
Secular	33 (23.1)	15 (15.5)	
Not enrolled in school	3 (2.1)	2 (2.1)	
Birth cohort (year)			
2003	55 (38.5)	19 (19.6)	**0.005**[a]
2004	46 (32.2)	35 (36.1)	
2005	42 (29.4)	43 (44.3)	
Provider of financial support			
Both parents	57 (39.9)	38 (39.2)	0.117[a]
Only father	35 (24.5)	20 (20.6)	
Only mother	42 (29.4)	38 (39.2)	
Other [grandparents, siblings, uncle, aunt, etc.]	9 (6.3)	1 (1.0)	
Constructs of HBM in girls (standardized scales in range 0–10)			
Perceived susceptibility [Mean/SD]	1.40 (2.87)	1.29 (2.82)	0.769[b]
Perceived severity [Mean/SD]	1.50 (2.73)	1.32 (2.48)	0.603[b]
Perceived benefits [Mean/SD]	5.09 (3.09)	6.87 (2.96)	**<0.001**[b]
Perceived barriers [Mean/SD]	3.34 (2.75)	1.71 (2.28)	**<0.001**[b]
Knowledge (cervical cancer, HPV and HPV vaccine) [Mean/SD]	1.31 (2.01)	1.19 (1.88)	0.631[b]

[a] Fisher Exact Test.
[b] Student t-test.
[c] **Socioeconomic stratum**: The stratification based on the residential public services developed by the Departamento Administrativo Nacional de Estadística (DANE), was used as follows: 1) low-low, 2) low, 3) medium-low, 4) medium, 5) medium-high, and 6) high.
[d] **Health insurance**: Colombia has two types of health insurance: contributive (people with the capacity to pay, retired and their families), and subsidized (people without the capacity to pay, classified as poor or vulnerable by the system for identifying potential beneficiaries of social programs-SISBEN).
[e] **School grades:** The Colombian education system consists of preschool, primary school (first to fifth grade), secondary school (sixth to eleventh grade) and higher education (technician, technologist, professional or postgraduate). **HBM**: Adapted Constructs of the Health Belief Model.

vaccination, from the cohorts (2003 and 2005) eligible for vaccination in 2012 and 2014, the period also of the psychogenic event. Several studies, including some conducted on Latin American women [41], have related the HPV vaccination with perceived barriers and benefits within the context of HBM [45]. This is the first study to confirm these observations in adolescent girls and their parents of Latin America. Even further, before the introduction of the HPV vaccination, Wiesner et al. [19] showed mistrust of Colombian family parents who expressed doubts about the scientific data supporting the vaccine efficacy and safety. Research conducted in other countries has shown the influence of doubts about the efficacy and safety of vaccines [15,47–49] on HPV vaccination.

Because our population was already exposed to the intervention at the time of the survey, we only determined the willingness to get vaccinated (acceptability) with the HPV vaccine in the subgroup of girls who self-reported not having been vaccinated or having not completed the vaccination schedule. We explored if sociodemographic factors maybe hindering HPV vaccination by comparing girls who were open to vaccination but unvaccinated (Acceptors/Unvaccinated) to those who were negative about the vaccine but vaccinated (refusers/vaccinated) (Table 4). Our findings highlight significant disparities in HPV vaccination coverage among girls from low socioeconomic strata and subsidized health insurance. Future studies should delve deeper into the factors contributing to these inequities.

Some limitations to this study must be considered when interpreting the findings. The distribution of socioeconomic strata may be biased because of the difficulties to contact residents in buildings of neighborhoods of high SES. The second issue was that HBM constructs on facilitators and self-efficacy were not included considering that the population has been already exposed to the vaccination program. Because of the study cross-sectional design, information was gathered at a single point in time. As a result, socio-demographic characteristics and individual beliefs may evolve or differ since the time of vaccination.

The outcome was defined first according to registration in the PAIWEB, followed by a serology measuring vaccine-specific antibodies [29], and a concordant self-reporting agreement between the girl and the adult. This strengthened the ability to determine the HPV vaccination status with a certain degree of accuracy despite the uncertainty of data available in the PAIWEB. As a result of the sampling strategy, a representative and random sample of the general population was obtained. As far as we are aware, there is no comparison of vaccination coverage between the government health statistics and independent population-based surveys. Although HBM targets individual change rather than community change [50], its use for measuring knowledge and beliefs about the HPV vaccine allows for further proper direction in the design of education tools that can have a positive impact on this population. It should also be noted that the survey quality assurance enabled reliable data collection while minimizing errors.

In conclusion, in addition to confirm the negative effect of the psychogenic event of 2014, this study informs the following reasons as barriers to achieving HPV vaccination rates of 90 % for girls by age 15 in Colombia: The wrong perception about potential negative aspects of the vaccine and vaccination process (The HPV vaccine is not safe or effective, needle fear) [17], lack of awareness about the benefits of HPV vaccination and misconceptions about promotion of earlier sexual activity [18]. Other social determinants such as disparities in access to education by parents, the SES, and the type of health insurance, seem also making it harder for some girls to receive the vaccine [19]. Improving socioeconomic conditions is a powerful strategy for improving population health including vaccination uptake [24]. Providing clear, science-based information about the HPV vaccine through public health campaigns, doctor's offices, schools, and parent-teacher organizations, highlighting the positive aspects of the vaccine, like preventing cervical cancer, encouraging open conversations between parents and children about sex and sexual health, educate doctors to address parental concerns about safety and the efficacy and partnering with community leaders and organizations to spread awareness about the vaccine have helped to address these barriers in other contexts [18–20].

CRediT authorship contribution statement

Karen Cárdenas-Garzon: Writing – review & editing, Writing –

original draft, Validation, Methodology, Formal analysis, Data curation. **María Cecilia Agudelo:** Writing – review & editing, Methodology, Investigation, Data curation. **Olga Lucia Tovar-Aguirre:** Writing – review & editing, Methodology, Investigation. **Caroline Reuter:** Writing – review & editing, Methodology, Investigation. **Nelson Enrique Arias-Ortiz:** Writing – review & editing, Methodology, Investigation. **Sandra Milena Franco:** Writing – review & editing, Methodology, Investigation. **Kelly Paola Valverde:** Writing – review & editing, Methodology, Investigation. **Samuel Agudelo:** Writing – review & editing, Formal analysis, Data curation. **Isabel C. Garcés-Palacio:** Writing – review & editing, Methodology, Investigation. **María Patricia Arbelaez:** Writing – review & editing, Methodology, Investigation. **Nilton Edu Montoya:** Writing – review & editing, Methodology, Investigation. **Difariney Gonzalez-Gómez:** Writing – review & editing, Methodology, Investigation. **Karly S Louie:** Writing – review & editing, Validation, Methodology, Investigation, Conceptualization. **Simon Beddows:** Writing – review & editing, Validation, Methodology, Investigation, Formal analysis, Conceptualization. **Gloria I. Sanchez:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2025.127507.

Data availability

The dataset excluding personal identifiers will be available to proper academic parties on request from the corresponding author under the data sharing policies of the University of Antioquia, Medellín, Colombia.

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