Statistical Analysis Plan (SAP)

Improving HPV Immunization Coverage Among Adolescent Girls in Mali and Côte d'Ivoire Through an Innovative Community-Based Follow-Up

Protocol for a Randomized Controlled Trial (RCT) with a Waitlist

Field	Details
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Background

This Statistical Analysis Plan (SAP) describes the pre-specified statistical methods that will be applied to evaluate the effectiveness of a community-based follow-up intervention for improving human papillomavirus (HPV) immunization coverage among adolescent girls in Mali and Côte d'Ivoire. The SAP is written in accordance with best practices for randomized evaluations and adaptive trial reporting (CONSORT, SPIRIT-AI). It should be read alongside the full study protocol (Version 2.1, October 2026).

Cervical cancer is the leading cause of cancer-related mortality among women in Sub-Saharan Africa. HPV vaccination is the most cost-effective preventive measure. Despite availability, coverage in Mali and Côte d'Ivoire remains well below the WHO target of 90% coverage by age 15. Muso Health has developed an innovative community-based follow-up intervention in which professional Community Health Workers (ProCHWs) proactively identify and follow up with unvaccinated eligible girls using a digital tool integrated into the Community Health Toolkit (CHT) platform. This study evaluates this intervention using a randomized controlled trial (RCT) design with a waitlist.

The primary objective of this document is to define, in advance of the availability of study outcome data, the statistical analyses that will be used to assess the impact of the intervention on HPV vaccination coverage and time-to-vaccination. Any deviations from this pre-specified plan will be documented and clearly described in the study report.

Study Objectives and Hypotheses

Primary Objective

To evaluate the effectiveness of the community-based CHW follow-up intervention in increasing HPV vaccination coverage among eligible adolescent girls, compared to the standard community mobilization approach, at the phase 1 endline (12 weeks after launch, 1 July 2026).

Secondary Objective

To evaluate whether the intervention reduces the time elapsed from study initiation to HPV vaccination among eligible adolescent girls, relative to the control arm.

Hypothesis Testing Framework

Statistical testing will follow a two-sided hypothesis framework at a significance level of $\alpha = 0.05$. The primary hypothesis is tested once, on the complete phase 1 dataset (see Type I Error Control).

Primary Hypothesis

H_0: The HPV vaccination coverage in the intervention arm is equal to the coverage in the control arm at the phase 1 endline, 12 weeks after launch ($\theta_{intervention} = \theta_{control}$).

H_1: The HPV vaccination coverage in the intervention arm differs from the coverage in the control arm at the phase 1 endline, 12 weeks after launch ($\theta_{intervention} \neq \theta_{control}$).

Secondary Hypothesis

H_0: The mean time from study initiation to HPV vaccination within 12 weeks is equal in both arms ($\mu_{intervention} = \mu_{control}$).

H_1: The mean time from study initiation to HPV vaccination within 12 weeks differs between arms ($\mu_{intervention} \neq \mu_{control}$). The test is two-sided, consistent with the General Principles; the expected direction (a shorter time in the intervention arm) is stated for interpretation only.

Study Design

Design Summary

The study is a multi-site, pragmatic, two-arm, parallel-group randomized controlled trial (RCT) with a waitlist (delayed-intervention) design and a 1:1 allocation ratio, stratified by country. Eligible adolescent girls within Muso Health catchment areas in Mali and Côte d'Ivoire are randomly assigned to one of two arms:

- Control arm: Standard community mobilization with routine HPV vaccination follow-up (identification and vaccination-status verification only).

- Intervention arm: CHW home visits with proactive invitation and follow-up of unvaccinated girls, guided by real-time data visualization and digital task reminders via the CHT platform.

The phase 1 evaluation measures each girl's vaccination status 12 weeks after launch (1 July 2026). On 2 July 2026, the control arm crossed over to receive the full intervention package (waitlist crossover). The phase 2 evaluation measures vaccination status on 1 October 2026, about 25 weeks after launch, by which time both arms have received the intervention (the intervention arm from launch, the former control arm from 2 July 2026).

Timeline

Version 1.0 of the protocol (March 2026) planned a nominal launch on 1 April 2026, with phase 1 through 1 July 2026 and phase 2 from 2 July to 1 October 2026. In practice, the intervention launched on 8 and 9 April 2026 in Mali and Côte d'Ivoire, respectively, and the digital intervention package was deployed in two stages. The realized timeline, which this SAP uses for all analysis windows and censoring rules, is summarized below.

Milestone	**Date**	**Description**
Trial launch / Randomization	8–9 April 2026	Randomization and launch of CHW workflows in Mali (8 April) and Côte d'Ivoire (9 April)
Intervention package stage 1	Launch – 19 May 2026	Intervention arm: identification, status verification, invitation, and follow-up. Control arm: identification and status verification only.

Intervention package stage 2	From 19 May 2026	Supervisor dashboard activated in the intervention arm
Waitlist crossover	2-Jul-26	Former control arm begins receiving the full intervention package, irrespective of individual assessment status
Phase 1 verification window (both arms)	2 July – 1 October 2026	Rolling verification of each girl's vaccination status as of the phase 1 endline (1 July 2026, 12 weeks after launch), based on the documented vaccination date. Each girl's status is verified at her own CHW visit within this window, not on a single common date. Verification continued after the nominal endline, until 1 October 2026, to maximize the number of girls with a known status and preserve the pre-specified MDE.
Phase 2 endline (both arms)	1-Oct-26	Phase 2 outcome: each girl's vaccination status on 1 October 2026 (about 25 weeks after launch), based on

		the documented vaccination date recorded at her last CHW visit on or before that date

Phase 1 Endline and Verification Window

The phase 1 outcome is each girl's HPV vaccination status on 1 July 2026, 12 weeks after launch. Because CHWs could not verify every girl's status by that date, verification continued through a rolling window from 2 July to 1 October 2026. At each verification visit, the CHW records whether the girl had been vaccinated and, if so, the date of vaccination. A girl counts as vaccinated in the phase 1 analysis only if her documented vaccination date is on or before 1 July 2026; vaccinations given after that date are not counted, whichever arm the girl belongs to. The same visits also provide each girl's status for the phase 2 analysis, which considers vaccination status on 1 October 2026 (see Phase 2 Analysis).

Anchoring the outcome to a fixed date means that the timing of verification affects only whether a girl's status is known, not how long she had to become vaccinated. A girl verified in September and one verified in early July are classified against the same 12-week period, so the differential follow-up bias that would arise from comparing status at different verification dates does not apply. This holds under three conditions, each addressed in this SAP: (1) the vaccination date must be documented, so girls reported as vaccinated without a verifiable date are classified as having unknown status at 1 July (cause 2, no information source); (2) later verification must not reduce the accuracy of the recorded date, which is examined in the verification-timing sensitivity analysis; and (3) control-arm verification visits after the 2 July crossover are carried out under the intervention workflow, but they record status before the crossover and therefore do not contaminate the phase 1 comparison.

Eligibility and Age Criteria

Eligible participants are adolescent girls who are, or will become, eligible for HPV vaccination during the study period, per national guidelines: 10 years of age in Mali; 9 to 14 years of age in

Côte d'Ivoire. Girls not yet age-eligible at randomization but expected to become eligible during the study period are included and allocated per the rule in Section Randomization.

Randomization

Randomization is performed centrally using a computer-generated allocation sequence, stratified at the country level (Mali and Côte d'Ivoire analyzed separately). Within each country, eligible girls are randomized 1:1 to control and intervention arms, with additional stratification by site, catchment area, and CHW supervision zone. Girls expected to age out of HPV vaccination eligibility within the first three months of the study (i.e., before the phase 1 evaluation) are systematically allocated to the intervention arm rather than randomized, to avoid assigning girls with a limited remaining eligibility window to the delayed-intervention (waitlist) arm. These 2,110 girls (1,945 in Mali and 165 in Côte d'Ivoire) are included in the primary analysis, which is read together with an analysis restricted to randomized girls (see Girls Allocated by the Age-Out Rule).

Sample Size and Attrition Targets

The trial includes 17,188 adolescent girls: 8,823 in Mali (5,365 intervention; 3,458 control) and 8,365 in Côte d'Ivoire (4,185 intervention; 4,180 control). The intervention-arm totals include 2,110 girls (1,945 in Mali and 165 in Côte d'Ivoire) who were expected to age out of eligibility within the first three months and were therefore allocated to the intervention arm without randomization (see Sequence generation); they are included in the calculations below, consistent with the primary analysis. Because the number of girls was fixed by the eligible population of the catchment areas rather than chosen to reach a target power, we report the minimum detectable effect (MDE): the smallest true difference in coverage the trial can detect with 80% power, using a two-sided test at $\alpha = 0.05$.

Baseline HPV vaccination coverage differs sharply between the two countries, so the MDE is estimated separately for each country rather than from a single pooled baseline. Baseline coverage is 4.95% in the Mali study population. In Côte d'Ivoire, the April 2025 national multi-age campaign reached about 93% of eligible girls (10), so baseline coverage is assumed to be 93%. For each country, the MDE is the absolute difference $\Delta = p_1 - p_0$ that solves $\Delta = z_{1-\alpha/2}\sqrt{[\bar{p}(1-\bar{p})(1/n_1 + 1/n_0)]} + z_{1-\beta}\sqrt{[p_1(1-p_1)/n_1 + p_0(1-p_0)/n_0]}$, where p_0 is baseline coverage, p_1 is coverage in the

intervention arm, n_1 and n_0 are the numbers of girls in the intervention and control arms, and $\bar{p}$ is the average of p_1 and p_0 weighted by arm size.

The MDE is 1.42 percentage points in Mali (from 4.95% to 6.37%, a 29% relative increase; odds ratio 1.31) and 1.48 percentage points in Côte d'Ivoire (from 93.0% to 94.5%; odds ratio 1.29). Because about 93% of girls in Côte d'Ivoire are expected to have been vaccinated already, the intervention can raise coverage there only among the remaining 7%: an increase of 1.48 points corresponds to vaccinating an additional 21% of the girls who were unvaccinated at baseline. In the sensitivity analysis restricted to randomized girls (excluding the 2,110 girls allocated by the age-out rule), the MDEs are 1.57 points in Mali and 1.50 points in Côte d'Ivoire.

The primary analysis pools both countries in a model adjusted for country. Assuming a common intervention odds ratio in both countries and combining the country-specific variances of the log odds ratio by inverse-variance weighting, the trial has 80% power to detect an odds ratio of 1.20, equivalent to an increase of about 0.9 percentage points in Mali and 1.1 points in Côte d'Ivoire. Because randomization is individual and stratified by CHW supervision zone, no design effect for clustering is applied. These estimates replace the earlier calculation (MDE of 0.94 percentage points, a 19% relative increase), which applied the Mali baseline of 4.95% to the full sample of 17,188 girls.

Because the high baseline in Côte d'Ivoire dilutes any effect on coverage, a pre-specified supplementary analysis compares vaccination uptake by 12 weeks among girls unvaccinated at launch. Its MDE depends on uptake in the control arm, which is not known in advance. Assuming that about 95% of girls in Mali and 7% in Côte d'Ivoire were unvaccinated at launch, the MDE in Mali ranges from 1.5 to 2.6 percentage points for control-arm uptake between 5% and 20%. In Côte d'Ivoire, with about 590 unvaccinated girls, only increases of 6 to 10 percentage points could be detected, so the country-specific uptake estimate there will be imprecise. The observed baseline coverage in each country's trial cohort will be reported, and the MDEs recalculated with it.

Figure 2 shows how the MDE in each country changes with the proportion of girls whose vaccination status is unknown, assuming status is missing at random within each arm. At the attrition targets of 10% in the control arm and 20% in the intervention arm, the MDE rises to 1.54 percentage points in Mali and 1.61 points in Côte d'Ivoire, about 8% above its value with complete data. The MDE stays within 15% of its complete-data value as long as unknown status is below about 22% in both arms in Mali and 25% in Côte d'Ivoire. In Mali, unknown status in the control

arm costs more precision than in the intervention arm, because the control arm is smaller. The attrition targets of 10% (control) and 20% (intervention) are therefore retained. The extended phase 1 verification window (to 1 October 2026) is the primary operational mechanism for meeting these targets.

Data Sources and Variable Definitions

Data Source

All data will be extracted from the Community Health Toolkit (CHT) platform, which collects routine programmatic data from CHW mobile applications. Data are synchronized in near real-time into a Looker Studio dashboard. The extraction will cover the period from the country-specific launch dates (8 April 2026 in Mali; 9 April 2026 in Côte d'Ivoire) to 1 October 2026. Because verification of phase 1 vaccination status continued until 1 October 2026, the analysis extract will be pulled after that date, once the eligibility review is complete.

Key Variables

Variable	Type	Source	Definition
HPV_vaccinated	Binary (0/1)	CHT	1 = documented HPV vaccination dated on or before the phase 1 endline (1 July 2026, 12 weeks after launch); 0 = not vaccinated by that date
HPV_vaccinated_phase2	Binary (0/1)	CHT	1 = documented HPV vaccination dated on or before the phase 2 endline (1 October 2026, about 25 weeks after

			launch); 0 = not vaccinated as of the last CHW visit on or before that date
arm	Binary (0/1)	Randomization list	0 = Control; 1 = Intervention
country	Categorical	CHT	Mali or Côte d'Ivoire
site	Categorical	CHT	Health area/catchment area name
chw_zone	Categorical	CHT	CHW supervision zone
age_years	Numeric (continuous)	CHT	Age at randomization (years)
age_group	Categorical	Derived	Age category per country eligibility criteria (Mali: 10 years; Côte d'Ivoire: 9–14 years)
days_to_vacc	Numeric (continuous)	CHT	Days from country-specific study launch (8 April 2026 Mali; 9 April 2026 Côte d'Ivoire) to vaccination date

assess_date_phase1	Date	CHT	Date of the CHW visit at which the girl's vaccination status as of 1 July 2026 was verified, within the 2 July – 1 October 2026 window
verification_lag	Numeric (continuous)	Derived	Days from the phase 1 endline (1 July 2026) to assess_date_phase1; describes how late status was verified and is used in the verification-timing sensitivity analysis
status_known_phase1	Binary	CHT	1 = vaccination status as of 1 July 2026 verified during the 2 July – 1 October 2026 window; 0 = unknown

status_known_phase2	Binary	CHT	1 = vaccination status as of 1 October 2026 documented at the last CHW visit on or before that date; 0 = unknown
prior_vacc	Binary	CHT	1 = documented HPV vaccination dated before the country-specific launch date; 0 = not vaccinated at launch
unknown_reason	Categorical	CHT; eligibility review log	Cause of unknown status, recorded for every girl with status_known = 0: (1) deactivated or deceased; (2) no information source (e.g., lost vaccination card); (3a) not visited, aged out of eligibility; (3b) not visited, age/sex data correction; (3c) not visited, not reached in time

eligible_final	Binary	Derived (eligibility review)	1 = eligible after review of age/sex data corrections; 0 = not eligible at randomization once corrected data are applied (removed from the analysis denominator)
last_status_date	Date	CHT	Last date on which the girl's vaccination status was documented; censoring date for girls with unknown status

Derived Variables

- Vaccination coverage per arm: proportion of girls with HPV_vaccinated = 1 among those with known status (status_known = 1).
- Log-transformed duration: log(days_to_vacc + 1) for the secondary analysis to stabilize variance and handle near-zero observations.
- Country-specific age group indicator: girls aged 10 years (Mali) or 9 to 14 years (Côte d'Ivoire) at randomization.
- Verification lag (verification_lag): computed for every girl with status_known_phase1 = 1 and summarized by arm. Because the outcome refers to status on 1 July 2026, verification timing does not change the period in which a girl could be counted as vaccinated; it is reported for transparency and used in the verification-timing sensitivity analysis. Girls reported as vaccinated without a documented vaccination date are classified as having unknown status at 1 July (cause 2).

- Unvaccinated at launch (prior_vacc = 0): girls with no documented HPV vaccination dated before the country-specific launch date. This group defines the population for the supplementary uptake analysis and for the time-to-event analyses; girls whose status at launch cannot be established are excluded from these analyses and counted in the missing-data summary.
- Cause of unknown status (unknown_reason): assigned to every girl with unknown status before any outcome analysis, from CHT deactivation records, CHW visit logs and the data-correction audit trail. Each girl receives a single category, applied in the order 3b, 1, 3a, 2, 3c, so that traceable and structural causes take precedence over the residual "not reached in time" category.

Analysis Populations

Intent-to-Treat (ITT) Population-Primary

The ITT population includes all adolescent girls allocated to either the intervention or control arm, whether by randomization or by the age-out rule (see Randomization), regardless of actual receipt of the CHW intervention, vaccination outcome, or subsequent loss to follow-up. This is the primary population for all primary and secondary analyses. For randomized girls, ITT analysis preserves the integrity of randomization and provides an unbiased estimate of the treatment effect under real-world implementation conditions. The only post-randomization exclusions permitted are girls found, through the eligibility review below, not to have met the age or sex criteria at randomization; the analysis population is therefore a modified ITT population and will be reported as such.

Post-Randomization Eligibility Review (Age/Sex Data Corrections)

Some girls recorded as "not visited" were not visited because a correction to their recorded age or sex showed that they were not eligible. These cases are not missing outcome data: the reason is fully traceable in the CHT audit trail, and the question they raise is whether the girl belonged in the trial denominator at all. They are therefore handled through an eligibility review rather than through the missing-data methods described under Handling Missing Data.

The review follows the accepted conditions for excluding participants after randomization (Fergusson et al., 2002): (1) only corrections to baseline characteristics (date of birth or age, and sex) recorded in the CHT audit trail are considered, so the decision cannot depend on allocation or outcome; (2) the review is carried out by a data manager blinded to arm and to vaccination status, applying a pre-specified rule (not eligible if the corrected age falls outside the national eligibility range for the entire study period, or if the corrected sex is male); and (3) the review is completed, and the list of exclusions frozen, before the phase 1 analysis dataset is locked. Girls whose corrected data still meet the criteria remain in the analysis with the corrected values and are reassigned to the appropriate cause of unknown status if their status is unknown. Exclusions will be reported by arm and by type of correction in the CONSORT flow diagram. A sensitivity analysis will retain excluded girls as randomized, with their status bounded as described under Bounding Analysis, to confirm that the exclusions do not drive the result.

Randomized-Girls Population

All girls allocated by randomization: 15,078 girls (6,878 in Mali; 8,200 in Côte d'Ivoire), excluding the 2,110 girls allocated to the intervention arm by the age-out rule. Every primary, secondary and supplementary analysis is repeated in this population and read together with the ITT result (see Girls Allocated by the Age-Out Rule).

Complete-Case Population-Sensitivity

Girls with known HPV vaccination status at the relevant evaluation point (phase 1 or phase 2 endline), among girls who remain eligible after the eligibility review. This population will be used in the primary complete-case analysis and the corresponding sensitivity analysis for missing data.

Country-Specific Populations

Analyses will be performed separately for Mali (girls aged 10 years) and Côte d'Ivoire (girls aged 9 to 14 years) as pre-specified subgroups, given the distinct eligibility criteria, health systems, and programmatic contexts in each country.

Statistical Methods

General Principles

All statistical analyses will be conducted using R (version ≥ 4.3). Reporting will follow the CONSORT 2010 checklist for randomized controlled trials. All tests are two-sided at $\alpha = 0.05$, unless otherwise stated. Confidence intervals are reported at the 95% level. All primary analyses are pre-specified. Post hoc analyses will be clearly labelled as exploratory.

Continuous variables will be described by mean (standard deviation, SD) or median (interquartile range, IQR) as appropriate. Categorical variables will be described by counts and proportions. Baseline comparability between arms will be assessed using standardized mean differences (SMD); formal significance testing of baseline variables is not recommended for randomized designs and will not be performed.

Primary Analysis: HPV Vaccination Coverage

Descriptive Estimates

HPV vaccination coverage in each arm at baseline and at the phase 1 endline (1 July 2026) will be estimated as the proportion of girls with known vaccination status who received the HPV vaccine. Coverage estimates will be reported with 95% Wilson score confidence intervals (preferred over the Wald interval for proportions near 0 or 1). The absolute difference in coverage between arms will be computed as:

$$\Delta = \text{Coverage_intervention} - \text{Coverage_control}$$

with 95% CI derived using the Newcombe method (without continuity correction) for the difference between two proportions.

Verification timing: the distribution of verification dates (verification_lag) will be reported by arm. Because the outcome refers to status on 1 July 2026, differences in verification timing between arms do not bias the coverage comparison directly; they are reported for transparency and examined in the verification-timing sensitivity analysis.

Primary Regression Model: Mixed-Effects Logistic Regression

The primary analytic model for the binary primary outcome (HPV_vaccinated) is a mixed-effects logistic regression (multilevel model), specified as follows:

$$\text{logit}[P(Y_{ij} = 1)] = \beta_0 + \beta_1 \cdot \text{Arm_i} + \beta_2 \cdot \text{Country_i} + \beta_3 \cdot \text{Age_i} + u_j$$

Where:

- Y_{ij} = HPV vaccination status on 1 July 2026 (1 = vaccinated by that date) for girl i in CHW zone j
- Arm_i = binary indicator for intervention arm (1 = intervention, 0 = control)
- Country_i = binary indicator for country (1 = Mali, 0 = Côte d'Ivoire)
- Age_i = age at launch, modelled as months remaining in the national eligibility window at launch (restricted cubic spline with three knots). Whole-year age cannot separate girls close to ageing out from younger girls in Mali, where eligibility covers a single year of age.
- u_j = CHW supervision zone random intercept ($u_j \sim N(0, \sigma^2_u)$), accounting for clustering

The parameter of primary interest is β_1, which represents the log-odds of being vaccinated by 1 July 2026 in the intervention arm relative to the control arm, adjusting for country, age, and clustering within CHW zones. This will be reported as an Odds Ratio (OR) with 95% CI and two-sided p-value. Because the outcome is anchored at a fixed date, no adjustment for individual verification timing is needed; the follow-up-time covariate included in versions 2.0 has been removed.

In addition to the OR, the Absolute Risk Difference (ARD) and Relative Risk (RR) will be estimated using marginal standardization (G-computation / average marginal effects) from the fitted model, as these are more interpretable on the public health scale. The intraclass correlation coefficient (ICC) at the CHW zone level will be reported to characterize clustering.

Covariate Adjustment and Model Selection

The pre-specified adjusted model includes country (Mali/Côte d'Ivoire) and age (months remaining in the national eligibility window at launch, restricted cubic spline) as fixed-effect covariates, and CHW supervision zone as a random effect. No further covariate selection will be

performed to avoid post-hoc model fishing. A sensitivity analysis will include site and the interaction term Arm × Country to assess effect modification by country.

Model fit will be assessed using the Area Under the ROC Curve (AUC/c-statistic), and calibration will be evaluated using the Hosmer-Lemeshow test (10 groups). Variance Inflation Factors (VIF) will be checked to detect multicollinearity (VIF > 10 triggers investigation).

Girls Allocated by the Age-Out Rule

The 2,110 girls expected to age out of eligibility within the first three months (1,945 in Mali, 36% of the Mali intervention arm; 165 in Côte d'Ivoire) were allocated to the intervention arm without randomization. They are included in the primary analysis and analysed in the intervention arm. Because they are older than randomized girls and had less time left to be vaccinated through the national programme, their outcomes may differ systematically; the primary model therefore adjusts for age as months remaining in the eligibility window.

No girl in the control arm was within three months of ageing out, so age adjustment cannot compare these girls with control girls of the same age: it relies on extending the age relationship observed in randomized girls. The primary analysis will therefore be read together with the same model fitted in the randomized-girls population, which is a purely randomized comparison. Both estimates will be reported side by side (Table 3), overall and by country, for the primary outcome, the secondary outcome and the supplementary uptake analysis. If they agree in direction and approximate size, the result will be considered robust to the allocation rule. If they diverge, the randomized-girls estimate will take precedence for causal interpretation, and the difference will be reported and discussed. The minimum detectable effects in the randomized-girls population are 1.57 percentage points in Mali and 1.50 in Côte d'Ivoire (see Sample Size and Attrition Targets).

Unadjusted (Marginal) Analysis

A chi-squared test (or Fisher's exact test if any expected cell count < 5) will compare the proportion vaccinated between arms. This serves as a pre-specified unadjusted comparison and will be presented alongside the regression-based estimate.

Sensitivity Analysis: Kaplan-Meier Coverage Estimate at 12 Weeks

The primary analysis uses only girls whose status on 1 July 2026 is known. As a sensitivity analysis, coverage at 12 weeks will also be estimated with the Kaplan-Meier method, which keeps partial information from girls whose status at 1 July is unknown but who were documented as unvaccinated at an earlier contact. For each arm, a Kaplan-Meier estimator $\hat{S}(t)$ of the probability of remaining unvaccinated by day t since launch will be fitted using:

- Event time: days from country-specific launch to vaccination date, for girls with a documented vaccination on or before 1 July 2026 (event = 1).
- Censoring time: day 84 (1 July 2026) for girls known to be unvaccinated on that date; for girls whose status on 1 July is unknown, the last date before 1 July on which they were documented as unvaccinated (event = 0).

The Kaplan-Meier estimator is fitted among girls unvaccinated at launch. Coverage at 12 weeks for each arm is then $\pi + (1 - \pi)[1 - \hat{S}(84)]$, where π is the proportion of girls in that arm vaccinated before launch, and the between-arm difference is estimated with a 95% CI from Greenwood's formula (bootstrap percentile CI as a cross-check). Covariate adjustment, if needed, will use pseudo-value regression (Andersen & Perme, 2010). If deaths are not negligible in number, cumulative incidence will be estimated with the Aalen-Johansen estimator, treating death as a competing event.

Close agreement between this estimate and the complete-case estimate will be read as evidence that restricting the analysis to girls with known status does not drive the result; a material difference will be investigated and reported in the limitations.

Sensitivity Analysis: Verification Timing

To check that later verification did not affect how accurately vaccination dates were recorded, the primary model will be refitted (a) restricted to girls whose status was verified by 30 August 2026, the originally planned close of the verification window, and (b) in the full complete-case population with verification_lag added as a covariate. A material change in the OR (more than 10% or a change in statistical significance) will be reported and discussed.

Supplementary Analysis: Vaccination Uptake Among Girls Unvaccinated at Launch

In Côte d'Ivoire, about 93% of girls are expected to have been vaccinated before launch, so any effect of the intervention on coverage is confined to the remaining girls and is diluted in the coverage comparison. To measure the effect where it can occur, the primary model will be refitted among girls unvaccinated at launch (prior_vacc = 0), with vaccination by 1 July 2026 (12 weeks) as the outcome. Results will be reported as OR, ARD and RR with 95% CIs, overall and separately by country, with an arm × country interaction to assess whether the effect differs between countries.

Because prior_vacc is determined by vaccination dates before launch, restricting the analysis to girls unvaccinated at launch is a restriction on a baseline characteristic and preserves the randomized comparison. This analysis is supplementary: it does not replace the registered primary endpoint and is reported with 95% CIs without adjustment for multiplicity. Its expected precision is described under Sample Size and Attrition Targets; the country-specific estimate for Côte d'Ivoire will be imprecise because few girls there were unvaccinated at launch. The same uptake measure at 25 weeks (1 October 2026) is analysed as an exploratory phase 2 outcome (see Phase 2 Analysis).

Secondary Analysis: Time to HPV Vaccination

Kaplan-Meier Survival Analysis

The time-to-event outcome (days from the country-specific study launch, 8 April 2026 in Mali and 9 April 2026 in Côte d'Ivoire, to HPV vaccination) will be analysed over the registered 12-week time frame (84 days, to 1 July 2026) using standard survival methods, which handle right-censoring of girls not vaccinated within that period. These analyses include only girls unvaccinated at launch (prior_vacc = 0), since girls vaccinated earlier have no event during follow-up.

Censoring rules:

- Girls vaccinated on or before 1 July 2026: event time = days from the country-specific launch date to vaccination date (event = 1).
- Girls not vaccinated by 1 July 2026, with known status: censored at day 84, the end of the 12-week time frame (event = 0).

- Phase 2 analyses (see Phase 2 Analysis) follow the same rules with follow-up to 1 October 2026: girls not vaccinated at their last CHW visit on or before 1 October 2026 are censored at the date of that visit.
- Girls with unknown vaccination status: censored at the last date before 1 July 2026 on which their vaccination status was documented (last_status_date). Because the independent-censoring assumption behind the Kaplan-Meier and Cox methods holds only for some causes of unknown status, the time-to-event analyses will be repeated with censoring handled by cause (see Disaggregation of Unknown Status by Cause): deaths treated as a competing event, with cumulative incidence estimated by the Aalen-Johansen estimator, if they are not negligible in number; girls who aged out (category 3a) bounded as described under Bounding Analysis; and girls excluded at the eligibility review (category 3b) removed from the analysis.

Because the time frame ends at day 84 for all girls, censoring of girls with known status is administrative and identical across arms. Only girls whose status at 1 July is unknown are censored earlier, and their handling is conditioned on the cause of unknown status, as described above.

Kaplan-Meier (KM) survival curves (time to vaccination) will be plotted for each arm, stratified by country. The log-rank test will be used to compare time-to-vaccination distributions between arms (two-sided, $\alpha = 0.05$). Median time to vaccination with 95% CI (Brookmeyer-Crowley) will be reported for each arm where it is reached; because coverage at 12 weeks is expected to be low, the median is unlikely to be reached, and the cumulative proportion vaccinated at 4, 8 and 12 weeks will be reported instead.

Cox Proportional Hazards Model

A Cox proportional hazards regression model will be fitted as the primary regression approach for the time-to-event outcome over the 12-week time frame:

$$h(t \mid X_i) = h_0(t) \cdot \exp(\gamma_1 \cdot \text{Arm_i} + \gamma_2 \cdot \text{Country_i} + \gamma_3 \cdot \text{Age_i})$$

Where $h_0(t)$ is the baseline hazard. The parameter of interest is γ_1, reported as an Adjusted Hazard Ratio (aHR) with 95% CI, clustered robust standard errors at the CHW zone level (to account for

within-cluster correlation). A hazard ratio > 1 indicates faster time to vaccination (higher instantaneous vaccination rate) in the intervention arm.

The proportional hazards assumption will be tested using scaled Schoenfeld residuals and log-log survival plots for each covariate. If the PH assumption is violated for the arm variable, a time-varying coefficient model (using piecewise constant or penalized spline) or the restricted mean survival time (RMST) framework will be used as alternatives.

Restricted Mean Survival Time (RMST)

The secondary endpoint, the between-arm difference in mean time to vaccination within 12 weeks, will be estimated as the difference in restricted mean survival time (RMST) at $\tau = 84$ days. For each arm, the RMST is the mean number of days, out of the first 84, that girls remained unvaccinated; the difference (ΔRMST = RMST_intervention − RMST_control) is therefore the average number of days by which vaccination occurred earlier in one arm than in the other within the 12-week time frame. Unlike the mean time among vaccinated girls only, ΔRMST uses all randomized girls and so preserves the randomized comparison. It will be estimated with a 95% CI using the method of Uno et al. (2014) in the survRM2 R package. A smaller RMST in the intervention arm indicates earlier vaccination.

Phase 1 Analysis

Purpose and Timing

The waitlist crossover (control arm beginning to receive the full intervention package) took place on the fixed operational date of 2 July 2026. Verification of each girl's vaccination status as of 1 July 2026 continued until 1 October 2026. The phase 1 analysis dataset will be locked after that date, once the eligibility review is complete, and analysed once. The phase 1 analysis serves two purposes: (1) confirming whether the pre-specified attrition targets (below 10% control, below 20% intervention) were met, and (2) testing the primary hypothesis.

Type I Error Control

The primary hypothesis is tested once, on the complete phase 1 dataset, at a two-sided significance level of $\alpha = 0.05$. Version 2.0 of this SAP applied an O'Brien-Fleming alpha-spending function (O'Brien & Fleming, 1979) across the phase 1 and phase 2 analyses, treating phase 1 as an interim look. That framework no longer applies, for two reasons. First, because verification continued until 1 October 2026, the phase 1 analysis is carried out only after data collection has ended, so there is no earlier look at the primary outcome. Second, the phase 2 analysis does not test the primary hypothesis again. After the control arm crossed over on 2 July 2026, the comparison between the original arms on 1 October 2026 contrasts an early start with a delayed start of the intervention, which is a different question from the intervention-versus-control comparison at 12 weeks.

The phase 1 between-arm comparison at 12 weeks is therefore the trial's single confirmatory test, and the full α of 0.05 is available to it. The sample size calculation assumed a single test at $\alpha = 0.05$, so this specification is consistent with the planned power and MDE. Secondary outcomes, subgroup analyses and the phase 2 analyses are supportive or exploratory; they are reported with 95% CIs and are not adjusted for multiplicity.

Phase 1 Outcome Reporting

At the phase 1 analysis lock, HPV vaccination coverage at 12 weeks by arm will be reported with 95% CI (Wilson method), together with the OR, ARD and RR from the primary mixed-effects logistic model, the Kaplan-Meier coverage estimate at 12 weeks, the distribution of verification timing by arm, and the causes of unknown status by arm.

Phase 2 Analysis (Vaccination Status on 1 October 2026)

The phase 2 outcome is each girl's HPV vaccination status on 1 October 2026, about 25 weeks after launch (175 days in Côte d'Ivoire, 176 days in Mali). A girl counts as vaccinated if her documented vaccination date is on or before 1 October 2026, as recorded at her last CHW visit on or before that date. By 1 October, the intervention arm had received the intervention for the whole period and the former control arm since the 2 July crossover. Girls are analysed in the arm to which they were originally allocated. The following analyses are planned:

- Coverage on 1 October 2026 by original arm, with 95% Wilson CIs, and the between-arm difference estimated with the same mixed-effects logistic model as the primary analysis (OR, ARD and RR). Because allocation was randomized, this is a randomized comparison of an early start with a delayed start of the intervention; it shows whether the former control arm caught up after crossover.
- Kaplan-Meier estimate of coverage on 1 October 2026, computed as for the 12-week estimate, $\pi + (1 - \pi)[1 - \hat{S}(t)]$ at the country-specific day count, with girls not vaccinated at their last visit censored at that visit. Some girls were last visited, and found unvaccinated, before 1 October and may have been vaccinated afterwards; the complete-case proportion therefore tends to understate coverage on 1 October, and the Kaplan-Meier estimate corrects for this. Both are reported, with the number of girls still under observation near 1 October, and the distribution of the time between the last visit and 1 October is reported by arm.
- Vaccination uptake by 1 October 2026 (25 weeks) among girls unvaccinated at launch (prior_vacc = 0), by original arm, overall and by country. It is analysed with the same model as the supplementary 12-week uptake analysis and reported for all allocated girls and for randomized girls only. As for coverage, the between-arm comparison contrasts an early start with a delayed start of the intervention. A Kaplan-Meier estimate, $1 - \hat{S}(t)$ at the country-specific day count with girls not vaccinated at their last visit censored at that visit, is reported alongside, because some girls were last seen unvaccinated before 1 October. In Côte d'Ivoire, where only about 590 girls were unvaccinated at launch, the country-specific estimate will be imprecise.

- Change in coverage between 1 July and 1 October 2026 within each arm, and whether the gap between arms narrowed after the crossover. Each girl contributes her status at both dates; the model includes arm, time point (1 July, 1 October) and their interaction, fitted with generalized estimating equations (exchangeable working correlation, robust standard errors clustered by CHW zone). The arm × time interaction estimates the change in the between-arm difference after crossover.
- Time to vaccination over the full follow-up to 1 October 2026: Kaplan-Meier curves by original arm with the 2 July crossover marked, RMST at the country-specific day count, and a Cox model with an arm × period interaction (period: before or after 2 July 2026). The hazard ratio before 2 July estimates the intervention effect; the hazard ratio after 2 July, when both arms received the intervention, is expected to move toward 1.
- Coverage gained by the former control arm during phase 2 (2 July – 1 October 2026), compared descriptively with the coverage gained by the intervention arm during phase 1, using the intervention arm's phase 1 performance as a historical comparator.

Phase 2 analyses are supportive or exploratory (see Type I Error Control). The randomized early-versus-delayed comparison is the most robust of them; the within-arm changes and the historical comparison cannot fully separate the effect of the intervention from time trends and from the staged rollout of the digital intervention package, and will be reported with that caveat. Unknown status on 1 October 2026 is classified and handled by cause, as described in Handling Missing Data.

Handling Missing Data

Sources of Missing Data and the Extended Verification Window as Mitigation

Missing vaccination status is distinct from not being vaccinated; girls with unknown status will not be assumed vaccinated or unvaccinated. Unknown status does not, however, arise from a single mechanism. Its causes differ in whether they are random or structural and in whether they fall evenly across arms. Treating them as one category would blend structural bias with random missingness inside methods, such as multiple imputation, that assume data are missing at random

(MAR). This SAP therefore classifies every girl with unknown status by cause and conditions the handling of each group on that cause (see Disaggregation of Unknown Status by Cause).

For the phase 1 evaluation specifically, the assessment window is deliberately extended from the nominal endline of 1 July 2026 through 1 October 2026, with CHWs continuing to attempt vaccination-status verification for any girl not yet assessed, rather than closing data collection on a single fixed date. This is the primary, protocol-level mitigation strategy for missing phase 1 data: it directly targets the "not reached in time" category (3c, defined below) by giving CHWs up to an additional three months to reach girls who were not available, not found, or not yet verifiable at the nominal 1 July endline. The window is expected to close later, on average, in the control arm than in the intervention arm, since intervention-arm CHWs are already conducting proactive follow-up visits that naturally accelerate ascertainment, while control-arm ascertainment (limited to identification and status-verification visits) may require more attempts to reach the same completeness. This extension is expected to bring realized attrition closer to, or below, the attrition targets (below 10% control, below 20% intervention) than would have been achieved under a single fixed endline date, thereby preserving the pre-specified MDE. Because the outcome is each girl's status on 1 July 2026, later verification does not lengthen the period in which she could be counted as vaccinated; its possible effect on the accuracy of recorded dates is examined in the verification-timing sensitivity analysis.

Disaggregation of Unknown Status by Cause

Each girl with unknown status at an evaluation point will be assigned one of five causes, using the variable unknown_reason. The causes, their expected pattern across arms, and the way each is handled are summarized below.

Cause of unknown status	Nature	Expected pattern across arms	Handling
1. Deactivated or deceased (moved out of the catchment area, record deactivated, or death)	Genuine attrition; outcome cannot be recovered	No asymmetry expected by design; reported by arm to confirm	Excluded from the complete-case analysis; not imputed; included in the bounding analysis; deaths treated as a competing event in time-to-event analyses
2. No information source (e.g., lost	Irrecoverable but not structural: the girl was	Not expected to differ by arm, but possibly related	Imputed in a second multiple-imputation analysis with a

vaccination card, no verifiable record, or vaccination reported without a documented date)	reached, but her status could not be verified	to vaccination status itself (girls never vaccinated may be more likely to have no record)	delta (tipping-point) adjustment for missingness not at random; included in the bounding analysis
3a. Not visited: aged out of eligibility	Structural: the girl passed the national eligibility age before a CHW reached her	Concentrated in the intervention arm, because girls expected to age out early were allocated to that arm by design	Not imputed; reported separately by arm; handled through the bounding analysis and the sensitivity analysis restricted to randomized girls
3b. Not visited: age/sex data correction	Not missing data: a traceable eligibility (denominator) question	No asymmetry expected; verified by arm	Resolved through the post-randomization eligibility review; girls found not eligible are removed from the denominator, others are retained with corrected data and reclassified
3c. Not visited: not reached in time	Operational: the CHW did not reach the girl before the verification window closed (1 October 2026)	May differ by arm (control-arm ascertainment is expected to be slower), but plausibly random given arm, site, CHW zone and timing	The only group treated as missing at random: target of the main multiple-imputation analysis; censored at last documented status in time-to-event analyses

The causes will be assigned before any outcome analysis, from CHT deactivation records, CHW visit logs and the data-correction audit trail, and the analyst assigning them will not have access to vaccination outcomes. Their distribution will be reported by arm and evaluation point (Table 6) and compared between arms with a chi-squared test. Attrition against the targets in Sample Size and Attrition Targets (below 10% control, below 20% intervention) will be computed on the denominator that remains after the eligibility review, with each cause shown separately, because the extended assessment window can recover only girls in category 3c.

Primary Approach: Complete-Case Analysis

The primary analysis will be performed on the complete-case population: girls with known HPV vaccination status at the relevant evaluation point, among those who remain eligible after the eligibility review. A complete-case analysis is unbiased when missingness is unrelated to vaccination status once the model covariates are taken into account. This assumption is most plausible for girls not reached in time (category 3c) and less plausible for girls with no information source (category 2) or who aged out (category 3a), which is why the sensitivity analyses below are conditioned on cause. Baseline characteristics will be compared between girls with and without

verified status, overall and by cause of unknown status, to assess potential informative missingness.

Sensitivity Analysis: Multiple Imputation (MI)

If the proportion of girls with unknown status exceeds 10% in either arm (as flagged in the protocol's power analysis heatmap), a Multiple Imputation by Chained Equations (MICE) analysis will be conducted as a pre-specified sensitivity analysis. Because MICE assumes data are missing at random, imputation is restricted to the causes for which that assumption is defensible: category 3c (not reached in time) in the main imputation analysis, and category 2 (no information source) in a second analysis that adds a delta adjustment. Categories 1 and 3a are not imputed, and category 3b is not treated as missing data. The imputation models will include country, age, site, CHW zone, number of CHW contacts, days from launch to last documented status, baseline vaccination status of household children, and arm allocation. A total of m = 50 imputed datasets will be generated using the mice R package; the primary model will be fitted to each and estimates pooled using Rubin's rules. For category 2, the imputed log-odds of vaccination will be shifted downward by a range of offsets (δ), reflecting the possibility that girls without any record are less likely to have been vaccinated, to identify the offset at which the conclusion would change (tipping-point analysis; Carpenter & Kenward, 2013). Results will be compared with the complete-case analysis; material differences (a change in OR exceeding 10% or a change in statistical significance) will be interpreted as evidence of informative missingness and discussed in the limitations.

Bounding Analysis

A bounding (Manski) analysis will assess robustness to the causes that cannot reasonably be imputed under MAR. In the worst case for the intervention, girls with unknown status in the intervention arm are assumed unvaccinated and those in the control arm vaccinated; the best case reverses these assumptions. The bounds will be reported in three versions: (a) categories 1, 2 and 3a together; (b) category 3a alone, so that the structural contribution of the age-out allocation rule, which concentrates these girls in the intervention arm, is visible separately; and (c) all unknown statuses, as in the original specification. If the treatment effect (OR) remains significant under both extreme scenarios in version (a), the findings are considered robust to missing data; version (c) is reported as the most conservative check.

Presentation of Results

Tables and Figures

The following tables and figures are planned for the final study report:

- Table 1: Baseline characteristics of enrolled girls by arm (ITT population)-proportions for categorical variables, means (SD) or medians (IQR) for continuous variables, and standardized mean differences (SMD).
- Table 2: HPV vaccination coverage by arm at baseline and at the phase 1 endline (12 weeks), with 95% CI and coverage difference (absolute and relative).
- Table 3: Primary analysis: adjusted and unadjusted OR, RR and ARD for HPV vaccination at 12 weeks (intervention vs. control) from the mixed-effects logistic regression model, for all girls (ITT) and for randomized girls only, with the supplementary uptake analysis among girls unvaccinated at launch, overall and by country.
- Table 4: Secondary analysis: cumulative proportion vaccinated at 4, 8 and 12 weeks, RMST at 12 weeks (estimate of the secondary endpoint), and Cox model adjusted HR, by arm.
- Table 5: Country-specific results (Mali and Côte d'Ivoire separately).
- Table 6: Unknown vaccination status by arm, evaluation timepoint and cause (categories 1, 2, 3a, 3b and 3c), including the number of girls excluded at the eligibility review.
- Table 7: Sensitivity analyses summary-key estimates under each scenario.
- Table 8: Phase 2 results: coverage on 1 October 2026 by original arm (complete-case and Kaplan-Meier), uptake by 1 October 2026 among girls unvaccinated at launch, overall and by country, change in coverage between 1 July and 1 October 2026 by arm, and hazard ratios before and after the 2 July crossover.
- Figure 1 (Protocol): CHW workflow diagram.
- Figure 2 (Protocol): MDE heatmap under varying attrition rates.
- Figure 3 (SAP): CONSORT flow diagram showing girls eligible, randomized, excluded at the eligibility review (by arm), analyzed, and with unknown status by cause.

- Figure 4 (SAP): Kaplan-Meier curves for time-to-vaccination by arm and by country, over the 12-week phase 1 time frame and over the full follow-up to 1 October 2026, with the 2 July crossover marked.
- Figure 5 (SAP): Forest plot of subgroup-specific ORs for primary outcome.
- Figure 6 (SAP): Caterpillar plot of CHW-zone random effects (u_j) with 95% CI.

Effect Measure Reporting

All regression-based primary results will report three complementary effect measures to maximize interpretability across audiences: the Odds Ratio (OR) from the logistic model, the Relative Risk (RR) derived via marginal standardization, and the Absolute Risk Difference (ARD). All three will be presented with 95% CI and two-sided p-value.

Roles, Governance, and SAP Amendments

SAP Governance

This SAP was developed by the principal investigator (Arsène Brunelle Sandie) in consultation with the co-principal investigators (Youssouf Keita, Ari Johnson) and statistical collaborators. The SAP will be finalized and date-stamped before any outcome data are accessed for the endline analysis. The locked SAP version will be deposited in the study's electronic repository.

Amendments

Any deviation from this pre-specified SAP must be documented as a protocol amendment with the following information: (i) the nature of the deviation; (ii) the date and rationale; (iii) whether the deviation was identified before or after data unblinding. Amendments identified after data access will be clearly labelled as post hoc in the study report.

Amendment record: version 2.1 (7 October 2026) were made before any outcome data were accessed. Version 2.1 classified unknown vaccination status by cause and introduced the post-randomization eligibility review; defined the phase 1 outcome as vaccination status on 1 July 2026 (12 weeks after launch), with verification continuing until 1 October 2026; set 12-week time frames for the primary and secondary outcomes; removed the follow-up-time adjustment and the

alpha-spending framework, which no longer apply; and specified the RMST difference at 12 weeks as the estimate of the secondary endpoint; specified the phase 2 analysis of vaccination status on 1 October 2026, including the randomized comparison of early and delayed start of the intervention; added a supplementary analysis of vaccination uptake among girls unvaccinated at launch, and specified that the primary analysis, which includes the 2,110 girls allocated by the age-out rule and adjusts for months remaining in the eligibility window, is read together with the same analysis restricted to randomized girls; and added uptake by 1 October 2026 (25 weeks) among girls unvaccinated at launch as an exploratory phase 2 outcome.

Data Access

The analytic extract of CHT data used for this evaluation will be accessed only after all pre-specified analysis scripts have been finalized; this restriction does not affect routine programmatic data, which continue to feed operational dashboards as usual.

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