STATISTICAL ANALYSIS PLAN

THE IMPACT OF DIGITALLY ENABLED DISTRICT (DED 2.0) IMPLEMENTATION ON MATERNAL AND NEONATAL SERVICES IN PRIMARY HEALTH CARE: A STEPPED WEDGE CLUSTER RANDOMISED TRIAL

SUMMIT INSTITUTE FOR DEVELOPMENT

Jalan Sultan Hasanuddin No.10-137 Lingkungan Karang Jero, Kelurahan Karang Taliwang, Nusa Tenggara Barat, Indonesia

Ket640/UN2.F10.ETK/PPM0002/202
NCT Number: NCT07842224
Date of document: 8 October 2026

INTRODUCTION

Background, Objectives, and Hypotheses

Background

Maternal and neonatal health remain major challenges in Indonesia. The maternal mortality ratio was estimated at 249 deaths per 100,000 live births, still far above the SDG target of 70 by 2030 (Syairaji, 2024; United Nations, 2020). In addition, adolescent births and unmet family planning needs remain significant concerns. These conditions highlight the need to strengthen maternal and child health services.

In West Java, Garut District recorded the second-highest maternal mortality burden, with 50 maternal deaths and 330 neonatal deaths in 2024 (Dinas Kesehatan Garut, 2024). Direct causes of maternal deaths include hemorrhage, preeclampsia/eclampsia, and infection, while neonatal deaths are mainly linked to low birth weight, prematurity, asphyxia, and infection (Nuryanti, 2025). Direct causes of maternal death include bleeding, preeclampsia/eclampsia, infection, and premature rupture of membranes (Maryuni and Kurniasih, 2017). Indirect causes include pre-existing health conditions, such as heart disease, HIV/AIDS, and diabetes, that pre-existing maternal conditions (Supriyanti et al., 2016). Limited access to quality antenatal care (ANC), socioeconomic barriers, and delayed referrals contribute to the high maternal mortality rate (Rahim et al., 2024).

At the same time, local health information systems face fragmentation, with multiple disconnected applications causing duplicate data entry, inconsistent indicators, and delayed decision-making. To address this, digital transformation has emerged as a key strategy. The Digitally Enabled District (DED) initiative was developed to strengthen primary healthcare through digital infrastructure, interoperable data systems, and service monitoring dashboards. Early implementation (DED 1.0) in Garut showed improved ANC coverage and better service monitoring in intervention Puskesmas compared with controls.

However, evidence on whether digital health ecosystems improve maternal and neonatal outcomes remains limited, as most evaluations focus only on service coverage indicators. Therefore, a stepped wedge cluster randomised trial is needed to examine the relationship between digital health service utilization and maternal and neonatal outcomes. By leveraging the DED ecosystem, this study aims to generate evidence on how digital optimization can improve service quality and reduce maternal and neonatal mortality at the district level.

Rational for the stepped wedge design

Three features of the intervention make a stepped-wedge cluster randomised design the appropriate choice, and each also constrains the analysis. The intervention is a facility-level system change and cannot be individually randomised. DED alters the digital infrastructure, workforce capability and data-use practices of an entire Puskesmas. Randomising women within a facility is impossible without contaminating the comparison.

District policy requires universal roll-out. Withholding DED permanently from a control group is neither politically nor ethically sustainable. A stepped wedge delivers the intervention to every facility while preserving randomised comparison, and is the design

recommended when the question is one of implementation timing rather than of whether to implement at all.

Implementation capacity is limited. Only about 15 Puskesmas can be onboarded per quarter. A phased roll-out is therefore an operational necessity, and randomising the phase order converts that necessity into the basis of causal inference.

The design purchases statistical efficiency relative to a parallel cluster randomised trial of the same size, because every cluster contributes both control and intervention observations. That efficiency is bought at the price of complete confounding between intervention status and calendar time at the cluster level, which is why period effects must be modelled and cannot be omitted.

Aims

To evaluate the impact of the phased implementation of the DED ecosystem at Community Health Centers (Puskesmas) on the utilization of maternal and neonatal health services and pregnancy outcomes, compared to the control period.

Objectives

1. To evaluate the impact of the DED ecosystem on the completeness and timeliness of maternal healthcare services, including antenatal care (ANC), ANC 12T services, and postnatal care (PNC), as well as to assess PNC standards compared to the control period.
2. To evaluate the impact of the DED ecosystem on the completeness and timeliness of neonatal healthcare services, including neonatal visits and examinations, compared to the control period.
3. To evaluate the impact of the DED ecosystem on pregnancy and delivery outcomes, including birth outcomes, place of delivery, and the healthcare personnel attending the delivery, compared to the control period.
4. To evaluate the impact of the DED ecosystem on reducing the risk of adverse pregnancy outcomes (APOs) such as hypertension in pregnancy, preterm birth, preeclampsia, small for gestational age, gestational diabetes, and pregnancy loss, compared to the control period.
5. To evaluate the cost-effectiveness of the DED ecosystem in improving maternal-neonatal healthcare services and outcomes compared to the control period.

Hypotheses

Main Hypothesis

a. **Null hypothesis (H0):**
   The implementation of the DED ecosystem does not improve the completeness and timeliness of maternal healthcare services (ANC and ANC 12T) compared to the control period.
b. **Alternative hypothesis (H1):**
   The implementation of the DED ecosystem improves the completeness and timeliness of maternal healthcare services (ANC and ANC 12T) compared to the control period.

Supporting Hypotheses

Maternal Services

a. **Null hypothesis (H0):**
   The implementation of the DED ecosystem does not improve the completeness and timeliness of PNC and standard PNC assessments compared to the control period.
b. **Alternative hypothesis (H1):**
   The implementation of the DED ecosystem improves the completeness and timeliness of PNC and standard PNC assessments compared to the control period.

Infant Services

a. **Null hypothesis (H0):**
   The implementation of the DED ecosystem does not improve the completeness and timeliness of neonatal healthcare services, including neonatal visits and examinations, compared to the control period.
b. **Alternative hypothesis (H1):**
   The implementation of the DED ecosystem improves the completeness and timeliness of neonatal healthcare services, including neonatal visits and examinations, compared to the control period.

Birth Outcomes

a. **Null hypothesis (H0):**
   The implementation of the DED ecosystem does not improve pregnancy and delivery outcomes, including birth outcomes, place of delivery, and healthcare personnel attending the delivery, compared to the control period.
b. **Alternative hypothesis (H1):**
   The implementation of the DED ecosystem improves pregnancy and delivery outcomes, including birth outcomes, place of delivery, and healthcare personnel attending the delivery, compared to the control period.

Risk of Pregnancy Complications

a. **Null hypothesis (H0):**
   The implementation of the DED ecosystem does not reduce the risk of adverse pregnancy outcomes (APOs) compared to the control period.
b. **Alternative hypothesis (H1):**
   The implementation of the DED ecosystem reduces the risk of adverse pregnancy outcomes (APOs) compared to the control period.

Cost-Effectiveness

a. **Null hypothesis (H0):**

The implementation of the DED ecosystem is not cost-effective in improving maternal-neonatal healthcare services and outcomes compared to the control period.

b. **Alternative hypothesis (H1):**
The implementation of the DED ecosystem is cost-effective in improving maternal-neonatal healthcare services and outcomes compared to the control period.

METHOD

Study design

Design Summary

This study used a stepped-wedge cluster randomized trial design, in which community health centers (Puskesmas) served as the unit of intervention. In this design, all Puskesmas begin in the control condition as baseline and cross over to the intervention condition at randomly assigned waves: by the end of the trial all Puskesmas have received the DED ecosystems. In total, 45 Puskesmas are designated to participate in the DED 2.0 program, selected from the 67 Puskesmas in Garut Regency, excluding the nine Puskesmas previously exposed to DED 1.0 activities.

45 Puskesmas allocated to 3 waves of 15, and 4 cluster-periods. One shared baseline period in which all clusters are in the control condition, followed by three steps at each of which one wave crosses over to DED implementation. The trial calendar is fixed as follows. Period 1, the shared baseline, is August-October 2026 (three months) and is ascertained retrospectively from routine registers; no cluster has crossed over during it. After the baseline, one wave crosses over to the intervention condition at the beginning of each subsequent three-month phase: Period 2 in November 2026, Period 3 in February 2027, and Period 4 in May 2027. All Puskesmas will have received the DED ecosystem by May 2027. Outcome ascertainment continues to 31 July 2027 to allow third-trimester windows, postnatal contacts (to 42 days) and neonatal visits (to 28 days) arising from Period 4 to close, no new exposure occurs in that close-out window and it constitutes no additional period. All 45 clusters have received DED by the end of the trial. What is randomised is the timing of crossover, not whether a cluster is ever exposed.

Randomization will be conducted using a permutation approach, specifically, Covariate-Constrained Randomization (CCR), to control for baseline covariate imbalances that are critical in cluster-randomized trials. First, CCR selects 45 of the 58 eligible Puskesmas for inclusion; the remaining 13 are excluded entirely and do not form a comparison or control group. The 45 included Puskesmas are then allocated to three crossover waves of 15 each. All 45 begin in the control condition (baseline period). At the first wave (month 1-3), approximately 33% of Puskesmas (15 Puskesmas) will gradually transition from the control phase to the intervention phase through the implementation of the DED ecosystem (KuApps, PWS Dashboard, AI OCR, and health communication). This process continues for 9 months. Therefore, by the end of the period, all Puskesmas will have received the DED ecosystem.

Outcomes will be evaluated using data from routine health service records, drawn from KuApps, Legacy Apps (including ASIK, SIGIZI, and Electronic Medical Record), and supplemented by the PWS monitoring dashboard. These data sources capture antenatal care (ANC), postnatal care (PNC), and neonatal care service utilization, as well as pregnancy and birth outcomes, for pregnant women who meet the study's inclusion criteria within each Puskesmas's catchment area. Given the stepped wedge cluster randomized trial design, outcome data will be extracted at each measurement period across all clusters, regardless of whether a given Puskesmas is currently in the control or intervention condition, allowing outcomes to be compared both within clusters over time and across clusters at the same time point.

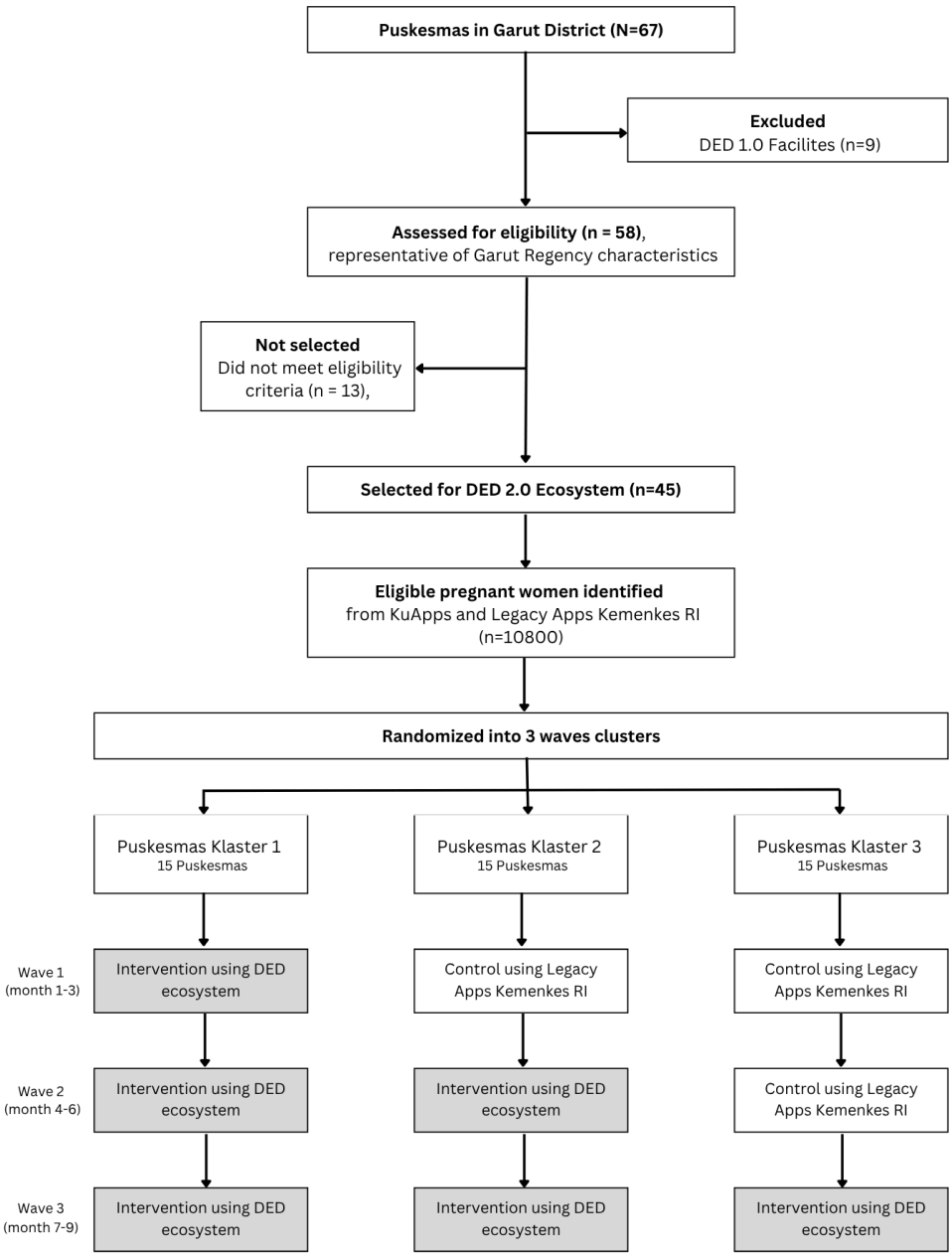


Figure 1. Study Flow of DED Programme

In addition, a prospective longitudinal cohort component (closed cohort) to complement the primary repeated cross-sectional, cluster-period analysis. The following pregnant women enrolled at ≤14 weeks gestational age and tracked through delivery and 42 day postpartum period. This enables assessment of within-individual changes in maternal and neonatal services utilization as each woman's assigned Puskesmas transitions from control to intervention status during her pregnancy. Each woman captures ANC visit completion, component documentation (12 T), and PNC service uptake. As women experience time-varying DED exposure, within-individual GEE analysis quantifies dose-response effects (weeks of DED exposure) and exposure timing

effects, patterns not captured by facility-level GLMM comparison. GEE models account for nested within-individual and intra-individual correlation using cluster-adjusted sandwich variance estimation. This individual-level longitudinal analysis complements the cluster-period primary analysis by detecting heterogeneous effects, selection bias, and implementation dosage requirements that aggregate analyses conceal. Additionally, while the primary analysis (GLMM on cluster-periods) evaluates the facility-level effects averaged across all pregnant women at each cluster-period, the closed cohort component enables:

1. Within-individual trajectories: Assessment of how service utilization patterns change for the same woman as her facility transitions from control to intervention
2. Exposure timing effects: Capture during pregnancy woman is exposed to DED implementation (early vs late in her pregnancy)
3. Dose-response patterns: Test whether longer duration of DED exposure within a single pregnancy is associated with greater service uptake
4. Selection effects: Identify whether observed facility-level improvements reflect true behaviour change vs preferential uptake by higher-engagement pregnant women

Design Matrix

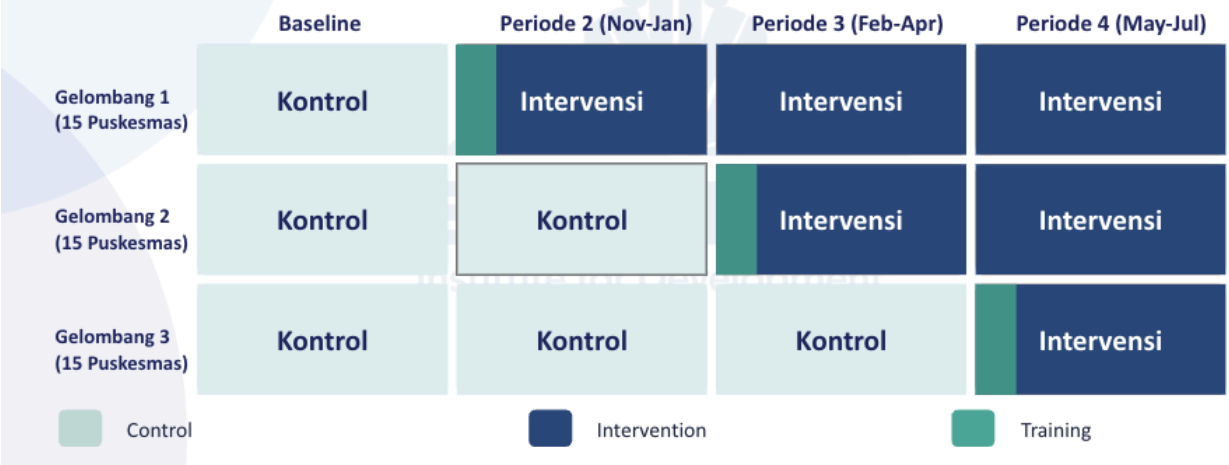


Figure 2. Design Matrix SW-CRT

Design summaries required by the Hussey–Hughes variance formula, with X_{ij} the intervention indicator for cluster i in period j:

$$U = \sum_i \sum_j X_{ij} = 90, \qquad W = \sum_j \left(\sum_i X_{ij}\right)^2 = 3150, \qquad V = \sum_i \left(\sum_j X_{ij}\right)^2 = 210.$$

These values are confirmed arithmetically: U = 15(3 + 2 + 1) = 90; W = 0^2 + 15^2 + 30^2 + 45^2 = 3,150; V = 15(3^2) + 15(2^2) + 15(1^2) = 210. Of the 180 cluster-periods, 90 are intervention and 90 are control, so the design is balanced with respect to exposure. Because the baseline period is ascertained retrospectively, it carries no risk of anticipatory behaviour change at clusters that already know their wave, provided the

allocation is not revealed until the baseline window has closed,a condition that interacts with the training schedule,

Implementation (transition) periods

Each wave is trained during the calendar month immediately before its crossover, September 2026, December 2026 and March 2027, and that training is conducted entirely in a development environment. No production instance of KuApps, the dashboard, AI-OCR, or health communication is deployed at the facility during its training month, and no DED-generated record enters the production registers from which every outcome in this trial is ascertained. Production deployment and utilisation begin on the first day of the intervention period. A facility in its training month is therefore, as a matter of fact and not merely of coding, still in the control condition, and it is analysed as such.

Crossover date for each cluster is defined as the date on which the DED implementation package is declared operational in the production environment (November 2026, February 2027 and May 2027 for waves 1, 2 and 3 respectively) recorded prospectively and frozen before analysis. Because training precedes crossover and is conducted in a development environment, the crossover month itself is a full production month and no part of it is excluded, whether performance in the first month nonetheless differs from later months is answered by the exposure-time analysis rather than assumed either way. Actual training dates, development-environment access dates and production go-live dates are recorded by cluster and reported. Because no month is excluded, the shared baseline is symmetric. All three waves contribute for August-October 2026 to Period 1, and baseline characteristics are tabulated on the full two-month baseline for all three waves.

Unit of Analysis

Puskesmas is the unit of randomization and the primary clustering unit. Even though the analysis is conducted at the level of the individual woman x gestational window, the unit of statistical independence is the Puskesmas because women receiving care within the same Puskesmas cannot be assumed to be statistically independent. Within-Puskesmas correlation (ICC) and correlation across periods within a Puskesmas (CAC) are modelled explicitly in every specification. In the primary GLMM, these are represented by three random effects, a random cluster intercept, a random cluster x period effect, and a random woman intercept nested within the cluster. Any analysis that treats individual women as independent observations understates the variance of the treatment effect and inflates the type I error rate, in cluster randomised trials with small to moderate numbers of clusters this inflation is well documented and substantial.

Randomization

With only 45 clusters and three waves, simple randomisation carries a material probability of chance imbalance on cluster-level prognostic factors, and such imbalance in a cluster randomised trial cannot be repaired by analysis in the way that individual-level imbalance can. Covariate-constrained randomisation (CCR) enumerates the space of possible allocations, computes a balance metric for each, discards those classified as unacceptably imbalanced, and draws at random from the acceptable

remainder. In parallel cluster randomised trials this has been shown to protect against substantial power loss relative to simple randomization.

Allocation, or randomisation, of Puskesmas into intervention periods or waves was determined through a two-stage lottery using a combinatorial approach (i.e., an exhaustive enumeration of possible combinations, not permutations). The first stage was conducted before 1 October 2026 and consisted of selecting 15 out of 45 Puskesmas to form Wave 1, drawing from a total of 344,867,425,584 possible combinations. This selection of 15 Puskesmas was verified to be balanced in characteristics relative to the remaining 30 Puskesmas that had not yet been grouped. Following this, a second lottery was conducted in December 2026, prior to the start of Wave 2, in which the remaining 30 Puskesmas were divided into Wave 2 and Wave 3, drawing from a total of 155,117,520 possible combinations, while accounting for the characteristics of Wave 1 so that balance was maintained across all three waves.

To safeguard transparency and prevent any changes once the lottery process had begun, all technical specifications were fixed in advance. These specifications included: the variables used as the basis for assessing balance, the tolerance threshold for acceptable imbalance, the order in which combinations were examined, and the acceptance criteria for the lottery outcome. All of these technical specifications were documented in writing and assigned a digital verification code (hash) to serve as evidence that the document had not been altered after being finalised.

Prior DED Exposure and Contamination

DED 1.0 activities were implemented in nine pilot Puskesmas, distinct from the 58 Puskesmas eligible for DED 2.0. These nine pilot facilities were excluded a priori from the DED 2.0 randomisation frame before eligibility or covariate values were reviewed, leaving 58 eligible Puskesmas (67 total in Garut Regency minus the 9 pilots). No facility in the DED 2.0 control condition received any DED 1.0 intervention component, and control facilities receive no DED 2.0 access during their control period regardless of prior exposure. All control-period facilities are therefore DED-naive with respect to concurrent exposure, though prior DED 1.0 status is separately relevant as a covariate.

Puskesmas were randomly assigned using permutation-based covariate-constrained randomization (CCR). This method calculates the imbalance of cluster-level variables (covariates) at baseline using a predefined balance metric, then randomly selects one randomization scheme from a set of schemes classified as having "acceptable" balance (Ivers et al. 2012, Ciolino et al. 2019). Of the 58 eligible Puskesmas, 45 were selected for enrolment and 13 were not selected. For each scheme the baseline imbalance between the 45 selected and 13 non-selected Puskesmas is evaluated on the pre-specified covariates using a standardised balance metric, and a scheme is retained as "acceptable" if every covariate difference falls below the pre-set tolerance (a standardised mean difference below 0.25. The covariates in this case were (1) baseline ANC6/K6 coverage from 2023 field survey, (2) the ratio of medical personnel (health workers) per pregnant woman, (3) geographic access, (4) the number of pregnant women in the Garut Regency health center's coverage area, (5) prior KuApps training status before randomisation (18 of the 58 eligible facilities), which is a separate exposure from DED 1.0 pilot status. This approach aims to reduce the risk of covariate imbalance

between groups by eliminating the worst-balanced allocation from consideration (Kristunas et al., 2022).

Participants will be assigned to intervention or control groups after randomisation through permutation, according to the Puskesmas in which they were registered and identified within the study sampling frame. This assignment will remain fixed for the primary analysis, regardless of subsequent utilization of other health facilities during pregnancy, delivery, the postpartum period, or neonatal care. Transfers of care between Puskesmas, in either direction, are reported by status of origin and destination and by period, but are never excluded from the primary analysis. A sensitivity analysis restricted to non-transferring women is conducted separately and labelled as supportive, not confirmatory.

Theory of Change and Intervention Exposure

The Digitally Enabled District (DED) 2.0 program is a multi-component health system strengthening intervention implemented at the Puskesmas level. During the study period, intervention Puskesmas will receive a standardized DED package consisting of: (1) training and capacity building for frontline health workers, managers, and data personnel; (2) strengthening of digital infrastructure and interoperability across routine health information systems; (3) implementation and enhancement of operational and service-monitoring dashboards; (4) improvement of data visibility, quality, and utilization through integrated digital platforms; and (5) ongoing technical support, monitoring, and scale-up activities to strengthen adoption and sustainability.

The underlying theory of change is that improved digital infrastructure, interoperability, and workforce capacity will increase the completeness, timeliness, visibility, and use of routine health data. Improved data availability and utilization are expected to facilitate earlier identification of service gaps and high-risk cases, strengthen care coordination and follow-up, support more timely referrals, and improve monitoring of maternal and neonatal services. These improvements are hypothesized to increase the completeness and timeliness of antenatal care, postnatal care, and neonatal services, improve facility-based delivery and skilled birth attendance, and ultimately contribute to improved maternal and neonatal outcomes.

The primary evaluation will estimate the overall effect of exposure to care within a DED-implemented Puskesmas environment compared with care within a non-DED Puskesmas environment, leveraging the stepped-wedge cluster randomized trial design in which Puskesmas cross sequentially from control to DED-implemented status. The analysis is designed to estimate the total program effect of the DED intervention package and is not intended to identify the independent contribution of individual intervention components or formally evaluate mediation pathways.

The nine Puskesmas that participated in DED 1.0 pilot activities are excluded a priori from the DED 2.0 randomization frame and are not among the 45 Puskesmas enrolled in this evaluation, they do not appear as intervention facilities, control facilities, or in any analysis. Accordingly, the primary analysis will evaluate the overall impact of DED 2.0 as a facility-level intervention delivered within routine health system conditions.

Study population

The target population includes all pregnant women residing within the catchment areas of the 45 Puskesmas enrolled in the DED 2.0 stepped-wedge cluster, who are registered during the study period and meet the study's eligibility criteria. The contributing observations may differ across cluster periods, and the analysis does not require the same women to be observed repeatedly over time.

The source population will be identified through:

a. PHC maternal health registers (LegacyApps);
b. KuApps;

Inclusion and exclusion criteria

Inclusion Criteria

Pregnant women

a. Women residing within the service area of participating Puskesmas in Garut Regency who participate during their pregnancy
b. Pregnancy registered in the maternal health records at participating Puskesmas within the study area in Garut Regency
c. Pregnant women provide informed consent to participate in the study

Puskesmas

a. Located within Garut Regency;
b. Had not yet implemented the DED ecosystem in daily service practices at the time of the baseline.

Exclusion Criteria

Pregnant Women

a. Participant permanently relocated outside the study area before the outcome observation window began.

Puskesmas

a. Puskesmas had fully implemented the DED ecosystem in routine practice before the study baseline period
b. Puskesmas does not have adequate routine service data for outcome measurement throughout the study period.

Recruitment

This study will be conducted in Garut District, West Java, Indonesia. Facility eligibility (Puskesmas) will be determined prior to randomization, based on the district's full roster of facilities meeting pre-specified inclusion criteria. Eligible Puskesmas will then be randomly allocated to one of three crossover waves using permutation-based covariate-constrained randomization (CCR), with 15 Puskesmas assigned to each wave following a shared baseline period. CCR restricts the randomization space to allocation schemes that achieve acceptable balance on pre-specified baseline covariates while preserving the validity of random assignment, reducing the risk of chance imbalance across waves that can occur with simple randomization when the number of clusters is limited. Because covariate balance is achieved through this allocation procedure, no additional facility-level matching was performed. No facility was permanently designated as intervention or control. Each Puskesmas' status as control or intervention is

time-varying, as all participating Puskesmas will eventually transition from control to DED implementation.

Eligible participants will be identified using routine maternal and child health data sources available at the participating health centers. During the baseline period, all facilities operate under the legacy systems, therefore the baseline participant records are drawn from LegacyApps. After crossing over, records for that facility's intervention periods are captured in KuApps. Records from LegacyApps (including SIGIZI, Electronic Medical Record/EMRand ASIK) as well as KuApps are linked at the individual level to construct the analytic dataset.

During the baseline period, sociodemographic characteristics and clinical and service-utilisation data, including obstetric and risk factor history as well as antenatal care recorded to date, will be collected/extracted from routine records. These records will be used to construct the sampling frame, identifying eligible beneficiaries, and verify prior service utilization history where available. Routine records will undergo quality checks, cleaning, deduplication, and validation using protocols and only eligible participants will complete data will be retained in the final analytic dataset.

Data Sources

KuApps will be used to obtain information on maternal registration, pregnancy monitoring, antenatal care utilization, maternal risk factors, referral processes, pregnancy outcomes, delivery information, and selected maternal and neonatal service indicators. Data will be extracted for both pre-intervention and post-intervention observation periods using standardized extraction procedures.

For the control period, Legacy Apps will be used, including EMR, SIGIZI, and ASIK. EMR will be used to obtain information on routine clinical encounters, antenatal care visits, postnatal care visits, delivery services, diagnoses, immunization records, and other maternal and child health services recorded at participating Puskesmas. SIGIZI will be used to obtain information on antenatal care services, postpartum (ibu nifas) data, detailed delivery records, maternal and child nutrition services, growth monitoring, nutritional assessments, and other relevant nutrition-related indicators available within the system. ASIK will be used for immunization-related data collection.

Records from KuApps, EMR, and SIGIZI will be linked at the individual level to create a unified analytic dataset. Record linkage will follow a hierarchical deterministic matching procedure:

1. Exact matching using the National Identification Number (NIK) where available;
2. For records without a valid NIK, exact matching using participant name and date of birth; for records without a valid NIK, matching is performed on name and date of birth after standardisation of name. Names are also normalised prior to comparison through case-folding, trimming of leading/trailing whitespace, removal of repeated whitespace, punctuation, and diacritics, and stripping of titles and honorifics;
3. Records remaining unmatched or generating multiple potential matches will undergo manual review using available supporting information, including residential location, pregnancy dates, facility registration information, and other available identifiers.

Routine health information systems will serve as the primary source for outcome ascertainment and service utilization data. Data quality procedures will include duplicate detection, verification of linkage accuracy, consistency checks across linked records, assessment of missingness patterns, review of implausible values, and validation of chronological waves of maternal and neonatal care events. The proportion of records successfully linked across data sources will be summarized descriptively. Duplicate NIK values and other potential record conflicts will be investigated and resolved before analysis.

Measures and variables

For binary variables, coding will be standardized such that a value of 1 generally represents the favorable or desired condition and a value of 0 represents the unfavorable or undesired condition whenever applicable. Multicategory variables will be treated according to their specified measurement scale and will not be interpreted as ordinal unless explicitly stated.

No	Variable	Operational Definition	Platform	Methods	Result	Scale
Outcome Primer						
1	Completeness of Antenatal Care (ANC) Services within the Gestational-Age Window	Completeness of ANC services within the gestational-age window, in accordance with the recommended schedule and standard: 1. Trimester 1 (1 visit, 1 ultrasound, 1 physician examination); 2. Trimester 2 (2 visits); 3. Trimester 3 (3 visits, 1 ultrasound, 1 physician examination). ANC service is classified as complete if every antenatal contact matches the schedule for its respective gestational-age window and all 12T components that should have been delivered by the end of that window are documented.	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Incomplete; 1 = Complete	Nominal
Secondary Outcome						
2	Proportion of Participants with Timely ANC Contacts	Proportion of pregnant women for whom mandated ANC visits are documented within the correct gestational-age window (per trimester schedule) in routine facility records (KuApps and Legacy Apps	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Missing or late; 1 = Timely	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
3	Proportion of Participants with Complete Postnatal Care (PNC)	Proportion of postpartum women for whom all four scheduled PNC contacts are documented by a health worker in routine facility records (KuApps and Legacy Apps): 1. PNC1 (6 hours–2 days), 2. PNC2 (3–7 days), 3. PNC3 (8–28 days), 4. PNC4 (29–42 days)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Incomplete; 1 = Complete	Nominal
4	Proportion of Participants with a Complete Standard PNC Assessment	Proportion of postpartum women with all 14 mandated components of the Book of KIA standard PNC assessment, documented in routine facility records (KuApps and Legacy Apps). Components include breast examination (assessment of lactation/breastfeeding), bleeding assessment, examination of the birth canal/perineum, Vitamin A administration, postpartum family planning, mental health screening, counselling, and case management. Documented in routine facility records (KuApps and Legacy Apps)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Incomplete; 1 = Complete	Nominal
5	Proportion of Neonates with Complete Neonatal Visits	Proportion of neonates for whom all three neonatal visits (KN1, KN2, and KN3) fully documented in routine facility records (KuApps and Legacy Apps). Classified as incomplete if one or more visits are not documented.	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Incomplete; 1 = Complete	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
6	Proportion of Neonates Receiving Complete Essential Neonatal Care	Proportion of neonates for whom all required essential neonatal care components are documented in routine facility records (KuApps and Legacy Apps). Assessing the completeness of all required essential neonatal care components documented, comprising eye antibiotic ointment, Vitamin K administration, umbilical cord care, early initiation of breastfeeding, and exclusive breastfeeding.	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Incomplete; 1 = Complete	Nominal
7	Proportion of Neonates Receiving Complete Standard Neonatal Examination	Completeness of the standard neonatal examination, comprising: KN1: weight measurement, length measurement, head circumference measurement, breastfeeding assessment, umbilical cord care, Vitamin K1 administration*, eye ointment/drops*, Hepatitis B immunisation, congenital hypothyroidism screening (after 24 hours), congenital heart disease screening, triple elimination screening. KN2: breastfeeding assessment, umbilical cord examination/care, danger-sign assessment, jaundice identification, Hepatitis B immunisation*, congenital hypothyroidism screening (if not yet given), triple elimination screening. KN3: breastfeeding assessment, umbilical cord examination/care, danger-sign assessment, jaundice identification, congenital	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Incomplete; 1 = Complete	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		hypothyroidism screening (if not yet given), triple elimination screening.				
8	Proportion of neonates with timely neonatal visits	Proportion of neonates for whom each neonatal visit is documented within the appropriate age window in routine facility records (KuApps and Legacy Apps): KN1 (6–48 hours), KN2 (3–7 days), KN3 (8–28 days)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Missing or late; 1 = Timely	Nominal
9	Proportion of Pregnancy Outcomes	Proportion of recorded pregnancies resulting in a live birth and non-live birth (such as stillbirth or miscarriage/abortion), ascertained at delivery from routine facility records (KuApps and Legacy Apps)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Death/stillbirth; 1 = Miscarriage/abortion; 2 = Live birth	Nominal
10	Proportion of Neonates with Birth Weight ≥ 2,500 g	Proportion of live-born neonates with birth weight ≥ 2,500 g, measured in grams using a calibrated infant scale and recorded in routine facility records (KuApps and Legacy Apps)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = <2500 g 1 = No (≥2500 g)	Nominal
11	Proportion of Facility-Based Deliveries	Proportion of deliveries occurring at a health facility, ascertained from routine facility records (KuApps and Legacy Apps)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Delivery outside a health facility; 1 = Delivery at a health facility	
12	Proportion of Deliveries Attended by a	Personnel who assisted the delivery process, ascertained from routine facility records	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Non-health-worker; 1 = Health worker	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
	Skilled Birth Attendant					
13	Proportion of Documented Complications with Documented Management	Proportion of participants with a documented obstetric complication for whom a documented set of clinical actions and care is recorded in routine facility records (KuApps and Legacy Apps)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Not managed 1 = Managed	Nominal
14	Mean Arterial Pressure (MAP)	A person's average blood pressure in the arteries during one complete cardiac cycle recorded as a continuous variable in mmHg. An additional ordinal variable derived from MAP, categorising the continuous value into clinical groups: 0 = Normal (<90 mmHg) 1 = Elevated (≥90–<92) 2 = Stage 1 hypertension (≥92–<96) 3 = Stage 2 hypertension (≥96)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Normal = <90 mmHg 1 = Elevated = 90-<92 2 = Stage 1 hypertension (92-≤96) 3 = Stage 2 hypertension (≥96)	Ordinal
15	Blood Pressure (Systolic)	The pressure inside the artery when the heart contracts and pumps blood through the body. the "top number" of a blood pressure reading. Recorded as a continuous variable in mmHg in routine facility records (KuApps and LegacyApps). An additional ordinal variable derived from systolic blood pressure for systolic status: 0 = Normal (<130 mmHg)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	Systolic = 0 = Normal < 129 mmHg 1 = Stage 1 hypertension (130–139 mmHg) 2 = Stage 2 hypertension (>140 mmHg)	Ordinal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		1 = Stage 1 hypertension (≥130–<140 mmHg) 2 = Stage 2 hypertension (≥140 mmHg)			Diastolic 0 = Normal < 80 mmHg 1 = Stage 1 hypertension (80–89 mmHg) 2 = Stage 2 hypertension (>90 mmHg)	
16	Blood Pressure (Diastolic)	The pressure inside the artery when the heart is at rest. Recorded as a continuous variable in mmHg. the "bottom number" of a blood pressure reading, recorded in routine facility records (KuApps and Legacy Apps). Reported as a continuous variable. An additional ordinal variable derived from diastolic blood pressure for diastolic status: 0 = Normal < 80 mmHg 1 = Stage 1 hypertension (80–89 mmHg) 2 = Stage 2 hypertension (>90 mmHg)	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = Normal < 80 mmHg 1 = Stage 1 hypertension (80–89 mmHg) 2 = Stage 2 hypertension (>90 mmHg)	
17	Maternal Body Height	Vertical distance from the soles of the feet to the top of the head of a person standing upright	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	Distance from the soles of the feet to the top of the head (cm)	Ratio
18	Maternal Body weight	The total amount of fluid, fat, muscle, and bone mineral in the human body, as	LegacyApps and KuApps	Data recorded in	Body weight (kg)	Ratio

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		measured using a scale, expressed in kilograms (kg).		KuApps/Legacy Apps		
19	Body Mass Index (BMI)	Maternal BMI which considered as an index used to determine ideal body weight based on the ratio of weight to height. Reported as a continuous variable. Descriptive categorisation: underweight <18.5 normal 18,5-22,9 overweight 23-24.9 obesity type 1: 25-29.9 obesity type 2: >30	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = < 18.5 Underweight 1 = 18.5–24.9 (Normal weight) 2 = 25–27 (Overweight) 3 = ≥ 27 (Obesity)	Ordinal
20	Maternal Mid-Upper Arm Circumference (MUAC)	Maternal upper arm circumference measured in centimetres using a standard non-elastic MUAC measuring tape at the first ANC contact, recorded in routine facility records (KuApps and Legacy Apps). Reported as a continuous variable.	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	0 = <23.5 cm (insufficient) 1 = ≥23.5 cm (sufficient)	Ordinal
21	Proportion of participants with Chronic Energy Deficiency (CED)	Proportion of pregnant women are classified as having Chronic Energy Deficiency (CED) if their Mid-Upper Arm Circumference (MUAC) is < 23.5 cm, measured at the first Antenatal Care (ANC) visit	LegacyApps and KuApps	Data recorded in KuApps/Legacy Apps	Proportion of CED	Ratio
22	Occurrence of Stock Out of Essential ANC	Occurrence of at least one day of unavailability (recorded stock = 0) during the observation month for essential ANC	PWS Dashboard	Data recorded from the PWS Dashboard and	0 = Stock-out occurred;	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
	Medications and Supplements per Month	medications and supplements, such as Iron-Folic Acid (IFA) tablets, calcium, and folic acid, ascertained from monthly Puskesmas pharmacy and logistics records.	and structured questionnaire	structured questionnaire	1 = No stock-out occurred	
23	Community Health Center Performance Assessment [Puskesmas Performance Score (PKP)]	Aggregate score of Puskesmas (Community Health Centre) service performance, ascertained from the Ministry of Health's Puskesmas Performance Assessment (Penilaian Kinerja Puskesmas, called PKP) monthly tabulations. Reported as a continuous score per Puskesmas per observation month	LegacyApps and KuApps	Secondary data analysis, each indicator is calculated using the numerator/denominator x 100% and then compared against the target	0 = Not achieved 1 = Achieved	Nominal
24	Workload Distribution per Health Worker	Number of pregnant women served per health worker (midwife or cadre) per Puskesmas per observation month, computed from routine service records (KuApps and Legacy Apps) divided by the roster of active ANC providers per Puskesmas.	LegacyApps and KuApps	Data recorded from KuApps/Legacy Apps	Percentage	Ratio
25	Proportion of ANC contacts recorded by cadres (Task Shifting)	Proportion of documented ANC contacts recorded by cadres compared with the total number of ANC contacts documented during the period, ascertained from KuApps and Legacy Apps entry logs.	LegacyApps and KuApps	Logistics document review	Percentage	Ratio

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		Reported as a continuous proportion (0–100%)				
26	Proportion of Health Workers Actively Using the KuApps per Observation Month	Proportion of registered health workers and cadres per Puskesmas who actively used the KuApps application at least once during the observation month, ascertained from KuApps user activity logs (log-in timestamps and data entry events). Reported as a continuous proportion (0–100%) per Puskesmas per month	LegacyApps and KuApps	Logistics document review	Percentage	Ratio
27	Availability of digital infrastructure	Availability of supporting devices and connectivity (computers/tablets, internet connection) at health facilities. This is ascertained by facility inventory checklist adapted from the Digital Readiness Assessment (DRA).	DESI/DRA 2023 readiness instruments; targeted update	Secondary data review and brief update	0 = Not available; 1 = Partially available; 2 = Fully available	Ordinal
28	Electronic medical record integration	Connectivity status of the Puskesmas recording system with the national Electronic Medical Record system (SATUSEHAT), ascertained by facility inventory checklist and confirmed via SATUSEHAT integration logs	DESI/DRA 2023 readiness instrument; focused update	Secondary data review and brief update	0 = Not yet integrated; 1 = Partially integrated; 2 = Fully integrated	Ordinal
29	Proportion of routine reports submitted on time	Proportion of routine Puskesmas reports (monthly ANC, PNC, and neonatal reports) submitted by the established Dinas Kesehatan deadline during the observation	Puskesmas reporting records	Document Review	Percentage	Ratio

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		month, ascertained from Dinas Kesehatan report intake logs				
30	Training Costs	Hardware and network costs (such as tablets/mobile phones, servers/cloud, internet) measured based on economic lifespan, attributable to the DED ecosystem, annualised over economic lifespan, ascertained from a prospective cost inventory.	Training cost recording sheet	Summation of all training cost components from program financial records	Training cost in Rupiah per Puskesmas (Rp)	Ratio
31	Infrastructure costs	Hardware and network costs (e.g., tablets/mobile phones, servers/cloud, internet) measured based on economic lifespan	Procurement/ asset records + annualization worksheet	Micro-costing; investment costs annualized (divided by economic lifespan, discount rate applied)	Annualized infrastructure cost value per community health center/period (IDR)	Ratio
32	Dashboard & Software Costs	Annualised development and licensing costs of the KuApps application and PWS dashboard attributable to the DED ecosystem, ascertained from a prospective cost inventory.	Developer notes/license contract + annualization sheet	Micro-costing: development/license costs allocated to units and annualized	Anualized software cost in Rupiah (IDR)	Ratio
33	Digital interoperability/ integration costs	Costs of RME and AI-OCR integration attributable to the DED ecosystem, ascertained from a prospective cost inventory.	Technical notes/integration contracts	Micro-costing; sum of integration costs,	Monetary value of digital integration costs (IDR)	Ratio

No	Variable	Operational Definition	Platform	Methods	Result	Scale
				annualized if treated as an investment		
33	Technical support & maintenance costs	Ongoing operational costs of HealthComm, Tableau, PWS, and KuApps dashboard servers per period, ascertained from a prospective cost inventory.	Program operational financial records	Micro-costing; summing ongoing costs per observation period	Maintenance cost per period (Rp)	Ratio
34	Healthcare service costs per unit	Cost of providing ANC, PNC, delivery, and referral services per service unit, ascertained from a prospective service costing exercise (facility-based micro-costing).	KuApps usage logs	Time-driven micro-costing: number of hours × hourly wage cost	Monetary value of health worker time costs per Community Health Center (Puskesmas)/period (IDR)	Ratio
35	Cost time horizon & period	The timeframe over which costs are calculated covering the identification of incurred costs and the duration (time horizon) of the study, as well as costs categorized by source and expenditure period. Reported as a structured cost inventory in Indonesian Rupiah (IDR), stratified by source and expenditure period	Puskesmas cost records	Unit cost assessment per service type	Monetary value of cost per service unit (IDR)	Ratio
36	Number of additional services	Difference in the number of documented services and visits delivered between the intervention and control periods,	LegacyApps and KuApps	Extraction of service counts from routine registers	Number of additional services (service units)	Ratio

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		ascertained from routine facility records (KuApps and Legacy Apps)				
37	Number of Participants completing the complete continuum of maternal care	Number of mothers documented as completing the full continuum: ANC (per standard), delivery, and PNC (all four contacts), ascertained from routine facility records (KuApps and Legacy Apps).	LegacyApps and KuApps	Calculation of mothers with "complete" continuum status based on linked data	Number of mothers completing the continuum (persons)	Ratio
38	Incremental Cost per Disability-Adjusted Life Year (DALY) Averted	Incremental cost of the DED ecosystem per DALY averted, computed by linking observed improvements in maternal and neonatal care coverage to modelled reductions in mortality and morbidity risk using published transition-model parameters	LegacyApps and KuApps	DALY calculation using Years of Life Lost (YLL) plus Years Lived with Disability (YLD)	Number of DALYs Averted (DALYs)	Ratio
Covariates						
39	Maternal Age	Mother's age during pregnancy, calculated in years based on the most recent birthday.	LegacyApps and EMR/ KuApps	Data recorded in KuApps/Legacy Apps	0 = <20 years old 1 = >35 years old 2 = 20–35 years old	Ordinal
40	Maternal Education	Highest level of formal education completed by the mother as of her most recent delivery.	LegacyApps and EMR/KuApps	Data recorded in KuApps/Legacy Apps	0 = Low (≤Sekolah Dasar) 1 = Middle (SMP–SMA)	Ordinal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
					2 = High (Perguruan Tinggi/Universitas)	
41	Socioeconomic Status	Household economic condition based on income or welfare indicators.	LegacyApps and EMR/ KuApps	Data recorded in KuApps/Legacy Apps	0 = Rendah; 1 = Menengah; 2 = Tinggi	Ordinal
42	Parity	Number of previous births experienced by the mother.	LegacyApps and EMR/ KuApps	Data recorded in KuApps/Legacy Apps	0 = ≥5 (Grande multipara) 1 = 2–4 (Multipara) 2 = 1 (Primipara)	Ordinal
43	Gravidity	Total number of pregnancies experienced by the mother, including the current pregnancy.	LegacyApps and EMR/KuApps	Data recorded in KuApps/Legacy Apps	0 = Gravida ≥4 1 = Gravida 2–3 2 = Gravida 1	Ordinal
44	History of Miscarriage	History of miscarriage in a previous pregnancy.	LegacyApps and EMR/ KuApps	Data recorded in KuApps/Legacy Apps	0 = Pernah 1 = Tidak pernah	Nominal
45	Pregnancy Complications	Complications experienced by the woman during pregnancy, indicated by pre-term contractions (before nine months of	LegacyApps dan KuApps	Data recorded in	0 = Ya 1 = Tidak	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		pregnancy), bleeding, high fever, seizures and loss of consciousness, persistent vomiting with loss of appetite, swelling of the feet, hands, and face or headache accompanied by seizures, premature rupture of membranes, and others		KuApps/Legacy Apps		
46	Delivery Complications	Complications occurring during delivery, which may include prolonged labour, excessive bleeding, fever with foul-smelling discharge, seizures, rupture of membranes more than 6 hours before delivery, ineffective pushing, and others.	LegacyApps and EMR/KuApps	Data recorded in KuApps/Legacy Apps	0 = Ya 1 = Tidak	Nominal
47	JKN Coverage Status	Active membership status of pregnant women in the National Health Insurance (JKN) program managed by BPJS Kesehatan	Structured questionnaire	Face-to-face interview	0 = Does not have active JKN coverage 1 = Has active JKN coverage	Nominal
48	Mobile Phone Ownership Status	Personal mobile phone ownership by pregnant women, including the capacity to access health information or digital applications	Structured questionnaire	Face-to-face interview	0 = Does not own a personal mobile phone 1 = Owns a personal mobile phone	Nominal
49	Marital Status	The legal/social status of the pregnant woman's marital relationship at the time of data collection, which potentially	Structured questionnaire	Face-to-face interview	0 = Never married 1 = Divorced/Separated 2 = Widowed	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
		influences social support and pregnancy-related decision-making			3 = Married	
50	Cultural Practice (Early Marriage/Young Marriage)	The practice of entering into a first marriage at an age below the prevailing statutory minimum marriage age; this represents cultural or social norms regarding early marriage that may influence access to and utilization of antenatal services (e.g., through education level, decision-making autonomy, and psychosocial readiness for pregnancy). Categorized as Early Marriage (age at first marriage < 19 years, based on the minimum marriage age in Law No. 16 of 2019) vs. Not Early Marriage (≥ 19 years)	Structured questionnaire	Face-to-face interview	0 = Early Marriage 1 = Not Early Marriage	Nominal
51	Mothers' Household Decision-Making Autonomy	The degree of authority pregnant women have to participate in or independently make decisions regarding their own healthcare, household expenditures, and personal mobility	Validated instrument adapted from the Women's Empowerment/ Decision-Making Autonomy domain of the SDKI (Indonesian Demographic and Health	Face-to-face interview	0 = Low 1 = Moderate 2 = High	Ordinal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
			Survey) or DHS			
52	History of Chronic Disease	Presence or absence of a chronic disease diagnosis in the mother established prior to or during the pregnancy (e.g., chronic hypertension, diabetes mellitus, heart disease, kidney disease, asthma, tuberculosis)	Structured questionnaire; LegacyApps and KuApps used for confirmation	Face-to-face interview (self-reported history of diagnosis), confirmed via medical records	0 = History of chronic disease present 1 = No history of chronic disease	Nominal
53	Distance to the nearest health facility	Distance traveled from the place of residence to the nearest health facility	LegacyApps/ KuApps	Data recorded in KuApps/Legacy Apps	Distance in kilometers (km)	Ratio
54	K6 Baseline Coverage	Percentage of pregnant women in the Community Health Center (Puskesmas) service area who have completed at least 6 Antenatal Care (ANC) visits (K6) according to standards, calculated during the baseline period prior to the start of the intervention	LegacyApps	Data recorded in KuApps/Legacy Apps	Percentage	Ratio
55	Geographic Access	The level of ease with which the population in the service area can reach the Community Health Center (Puskesmas), represented by the distance of the facility from the regency town center and/or the area's topographical classification	BPS data/regency health profile (urban/rural classification)	Document Review	0 = Rural 1 = Urban	Nominal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
56	Ratio of Health Workers per Pregnant Woman	Ratio of ANC-providing health workers (active midwives/nurses) at the Community Health Center (Puskesmas) to the target number of pregnant women in its service area during the same period	Puskesmas staffing data (SISDMK); estimated target data for pregnant women	Calculation: (number of active ANC midwives/health workers) / (estimated target of pregnant women) × 100, taken at baseline	Number of midwives per 100 pregnant women (continuous)	Ratio
57	Target Population	Estimated number of pregnant women targeted for ANC services in the Community Health Center (Puskesmas) service area during the baseline period; serves as a workload indicator/cluster size measure	Data on estimated target population of pregnant women	Garut Regency Minimum Service Standards (SPM)	Number of pregnant women	Ratio
58	KuApps Training Status (DED 1.0)	Status of Puskesmas exposure to KuApps training provided during the DED 1.0 pilot phase prior to the start of this study DED 1.0	program administrative data	Document Review	0 = Previously trained in KuApps 1 = Not previously trained in KuApps	Nominal
59	Accreditation Status	Accreditation status (Primary Health Care Accreditation Commission) reflecting the institutional capacity of the Puskesmas	Official data from the Garut Regency Health Office	Document review	0 = Basic (Dasar) 1 = Intermediate (Madya) 2 = Advanced (Utama)	Ordinal

No	Variable	Operational Definition	Platform	Methods	Result	Scale
					3 = Comprehensive (Paripurna)	

Statistical analysis

Selection of sample size

The number of research participants in this study was determined using a cluster sampling method, with all pregnant women who meet the inclusion criteria and do not meet the exclusion criteria at the health care facilities serving as study sites during the study period. The population is divided into several clusters based on geographic location. Clusters are then randomly selected, and all members within the selected clusters are enrolled as a sample considered representative of the overall population.

A total of 45 Puskesmas in the Garut Regency was designated as clusters and randomly allocated into three waves, each consisting of 15 Puskesmas. In this study design, all clusters ultimately receive the intervention: what is randomized is the timing (wave) of each cluster's crossover from the control period to the intervention period, Garut Regency was designated as a cluster and randomly allocated into three stages, each consisting of 15 Puskesmas. In this study design, all clusters ultimately received the intervention; what was randomized was the timing (wave) of each cluster's crossover from the control to the intervention condition. Thus, each Puskesmas contributed to both the control and intervention phases and served as its own control (within-cluster comparison), while also being compared to clusters that had not yet crossed over during the same measurement period. The determination of Puskesmas as clusters was carried out comprehensively across the facilities where the DED program was implemented, not through random sampling from the Puskesmas population.

Primary Outcome for Sample Size Determination

The sample size is calculated using the approach of Hussey & Hughes (2007) for the design and analysis of stepped-wedge cluster randomized trials, extended by Hooper et al. (2016) and Girling & Hemming (2016), with the following assumptions.

Parameter	**Nilai**	**Justifikasi**
I :	45	Number of clusters
T:	4	Number of Periode (T1/Baseline: Aug-Sep 2026; T2: Oct-Des 2026; T3: Jan-Mar 2027; T4: Apr-May 2027
U:	90	Total intervention cluster-periods = 15x(3+2+1) = 90, from 180 cluster-periode
W:	3150	Σ column^2 = $0 + 15^2 + 30^2 + 45^2$
V:	210	Σ row^2 = $15x3^2 + 15x2^2 + 15x1^2$
p_0:	47%	Baseline ANC visit coverage, based on the findings of Indriyani, D. et al. (2024).
p_1:	55%	Post-intervention target coverage, based on a relative risk (RR) of 1.17 obtained from the study by Rahman, M. O. et al. (2022) = 0.47 × 1.17 =

		0.5499
ρ (ICC):	0,1	*Intracluster correlation coefficient* (ICC) based on the previous study from Venkateswaran, M et al., (2024)
π (CAC):	0.8	Conservative estimate to accommodate the decay-of-correlation phenomenon in stepped-wedge designs
α:	0,05	Two-sided hypothesis
power:	80%	

Effect Size :

$$\theta = p_1 - p_0 = 0.55 - 0.47 = 0.08$$

Variance:

$$\bar{p} = \frac{(0.47 + 0.55)}{2} = 0,51$$

$$\sigma^2 \; Total = \bar{p} \; x \; (1 - \bar{p}) = 0,51 \; x \; 0,49 = 0,2499$$

τ^2 (*between-cluster*) = 0.10 × 0.2499 = 0,024990

σ^2_e (*within-cluster*) = 0.90 × 0.2499 = 0,224910

$$\gamma^2 = \tau^2 \times \frac{(1 - CAC)}{CAC} = 0,024990 \times \frac{(1 - 0,8)}{0,8} = 0,024990 \times 0,25 = 0,006247$$

Target variance :

$$\text{Var}(\theta) = \frac{\theta_A^2}{(Z_{1-\beta} + Z_{1-\alpha/2})^2} = \frac{0,08^2}{(0,84+1,96)^2} = 0,0008154$$

Calculating σ^2

$$\text{Var}(\hat{\theta}) = \frac{I\sigma^2(\sigma^2 + T\tau^2)}{(IU - W)\sigma^2 + (U^2 + ITU - TW - IV)\tau^2}$$

$$\text{Var}(\theta) = \frac{45\sigma^2 (\sigma^2 + 4r^2)}{(900\sigma^2) + 2250\, r^2}$$

$$0,0008154 = \frac{45\sigma^2 (\sigma^2 + 0.09996)}{(900\sigma^2) + 26.2275}$$

$$\sigma^2 = 0.01079$$

Calculating m

$$\sigma^2 = \gamma^2 + \frac{\sigma_e^2}{m}$$

$$0,01079 = 0,006247 + \frac{0,224910}{m}$$

$$0,004543 = \frac{0,224910}{m}$$

$$m = 49.5$$

Rounding up, so that m = 50

Power calculation for m = 50

$$\sigma^2 = \gamma^2 + \frac{\sigma_e^2}{m} = 0,006247 + \frac{0,224910}{50} = 0,010745$$

$$\text{Var}(\theta) = 0,00081231$$

$$power = \Phi(0.8469)$$

$$power = 0,8015$$

Thus, the power to detect the effect of the specified intervention is 80.15%

Based on those calculation results, the overall total sample size can be calculated by multiplying the number of individuals per cluster per period (m), the number of clusters (I), and the number of periods (T) using the following formula:

Total sample size = m x I x T
= 50 x 45 x 4
= 9000

Furthermore, to anticipate a potential 20% loss to follow-up, the sample size is adjusted as follows:

Final total sample size = 9000 + (20% 9000) = 10800 subjects.

Based on the simulation results, the design achieved a statistical power of 80.15%, exceeding the commonly accepted minimum threshold of 80%. This indicates that the proposed sample size (m = 50 pregnant women per cluster-period across 45 clusters and 4 periods) provides sufficient statistical power to detect the hypothesized difference in antenatal care visit coverage between the pre- and post-intervention periods.

Primary analyses

Statistical analysis will be conducted to assess the impact of implementing the Digitally Enabled District (DED) ecosystem towards maternal and child health and pregnancy outcomes. Descriptive analysis will be used to characterize demographic profiles, such as educational level, maternal age, etc. map health service coverage (ANC, PNC, and neonatal care) and identify the distribution of pregnancy outcomes. categorical variables will be presented as frequencies and percentages, while numerical variables will be presented as means and standard deviations or medians and interquartile ranges.

The primary analysis employs the Generalized Linear Mixed Models (GLMM) approach. This analytical approach follows the stepped-wedge cluster randomized trial design and analysis framework established by Hussey and Hughes (2007). The exposure of the interest is the DED implementation status of each Puskesmas in each period (1= Intervention phase, 0= control). The model incorporates DED implementation status for each Puskesmas and the time period as primary independent variables; a time (period) effect as a fixed variable to control for secular trends; and random effects at the Puskesmas level to account for correlations between individuals within the same cluster and across periods (cluster autocorrelation). For binary outcomes, a logit link with a binomial distribution is used, and effects are reported as odds ratios with 95% confidence

interval (CIs). GLMM estimates are cluster-specific (conditional), meaning they describe the effect of the DED within a specific Puskesmas, the GLMM comprises three components, including:

a. An intervention exposure indicator: a value of 1 if the Puskesmas is in the intervention phase during period "j", and 0 if it remains in the control condition.
b. The measurement period as a categorical fixed effect, to control for secular trends (changes in outcomes over time unrelated to the intervention).
c. A random effect at the Puskesmas level, to account for correlations between individuals within the same cluster.

Sensitivity Analyses

Generalized Estimating Equations (GEE) will also be used as a complementary method and for sensitivity analysis. GEE will be employed to estimate the population-averaged effect of the DED ecosystem intervention. Consequently, the average effect of the DED across all Community Health Centers (Puskesmas) is calculated using a nested block-exchangeable correlation structure and robust variance estimation. With 45 Community Health Centers serving as clusters, a small-sample variance correction is applied to prevent Type I error inflation. The consistency of the effect direction and magnitude between GLMM and GEE models will be assessed to ensure the robustness of the conclusions. The GEE has been known to be prone to bias with a small number of clusters, both in terms of estimation of correlation parameters and variances, therefore, finite-sample corrections have been carefully studied and recommended (Li et al., 2021).

A delayed treatment effect will be considered, given that the implementation of the digital system requires an adaptation period; this will be addressed through exposure-time-based modeling. All hypothesis tests will utilize a two-sided significance level of 0.05. An intention-to-treat analysis will be conducted based on the staggered rollout allocation. Analyses will be performed using R software.

Supporting Analysis (Survival Analysis)

This analysis is secondary and does not replace the study's primary analysis. All mothers whose pregnancies were registered at a gestational age of less than 14 weeks across all 45 Community Health Centers (Puskesmas) were followed longitudinally to answer whether the intervention increased the likelihood of pregnant women achieving complete and timely prenatal care (ANC) prior to delivery, and whether they achieved this earlier. The cohort encompasses all 45 Puskesmas, rather than just the 15 in the first wave, because a cohort restricted to the first wave would lack a concurrent randomized comparator, and its within-cluster contrasts would be confounded by calendar time.

The analysis adheres to the following specifications: 1) The analysis time axis is gestational age, with delayed entry at the gestational age of registration (left-truncated data). 2) Delivery prior to completion is treated as a competing event rather than censoring; since the standard completion criteria require three third-trimester contacts, mothers who deliver prematurely are structurally unable to meet the completion requirement. True censoring applies only to three situations: study conclusion (May 31, 2027), the mother permanently moving out of the study area, or the mother withdrawing

consent. 3) Exposure is time-varying, reflecting the cluster's crossover. 4) The calendar period is included as a distinct time-varying covariate.

The primary model is the cause-specific Cox hazard model (a standard model for calculating the "rate" of event occurrence) specifically adjusted for competing risks, incorporating a gamma frailty term at the Community Health Center (Puskesmas) level to account for the fact that mothers attending the same center tend to exhibit similar outcome patterns (i.e., their outcomes are not fully independent). The Fine-Gray model, a statistical method used to analyze competing risks (in this case, delivery occurring before the completion of the standard ANC regimen, which renders it structurally impossible for the mother to complete the standard), is reported alongside the difference in the percentage of mothers completing the standard ANC regimen by 40 weeks of gestation, as calculated using the Aalen-Johansen method. The difference in cumulative incidence at 40 weeks is the primary metric reported, as it operates on the same absolute scale as the study's main estimand.

Service Delivery Indicator

Service Delivery Indicators were analyzed using GLMM. There are four service delivery indicators: 1) ANC/PNC visit coverage, measured at the maternal level, accounting for the gestational age window for ANC (primary outcome) and the maternal level for PNC; data sources include routine registers (LegacyApps for the control period and KuApps for the intervention period); 2) Continuity of care completion rates, defined as the completion of the full sequence from ANC through delivery to PNC; 3) Referral completion and timeliness, covering whether indicated referrals were completed and the associated time intervals; and 4) Patient satisfaction/experience scores, collected via WhatsApp within the HealthComm component of the DED ecosystem. Meanwhile, the Community Satisfaction Index serves as a secondary source to gain insights from beneficiaries, rather than acting as a primary metric.

Operational indicators

In these operational indicators, human resources aspects, including workload distribution, task-shifting, and the adoption of digital tools by health cadres or midwives, are measured using usage logs from KuApps (intervention period) and LegacyApps (control period) or through Community Health Center (Puskesmas) staffing records. Furthermore, data collection efficiency is achieved by utilizing 2023 DESI and DRA readiness survey data, which covers approximately 80% of facilities, and employing data linkage based on Puskesmas typology. For facilities not surveyed in 2023 (specifically Pustu), targeted readiness data updates are conducted rather than repeating the comprehensive survey. All operational indicators are summarized descriptively by period-cluster and status; baseline readiness is included as a cluster-level covariate and a pre-specified effect modifier (readiness tertile) and serves as an input for the cost model.

Cost-effectiveness analysis

The cost-effectiveness analysis will be conducted based on the CHEERS 2022 guidelines (Husereau et al., 2022) and standard methods (Drummond et al., 2016; Glick et al., 2015). The analysis will involve the following steps: a) establishing incurred costs and the duration (time horizon) of the study; b) identifying and measuring resource

utilization within the DED ecosystem (such as training, infrastructure, dashboards, technical support, digital interoperability, and service costs) using detailed operational indicators as inputs; c) valuing costs according to their source and the period in which they were incurred; d) establishing measures of effectiveness, namely incremental cost per additional service delivered and cost per DALY averted or per completed continuum of maternal care; e) calculating the ICER (ΔCost/ΔEffect) comparing the intervention group (person-periods) against the control group; f) conducting alternative tests via statistical simulations (bootstrapping, CEAC [Cost-Effectiveness Acceptability Curve], sensitivity analysis); and g) reporting the comparative efficiency results across intervention and control clusters.

Trajectory analysis

This analysis extends the scope to a time-to-event framework. The pathway encompasses ANC1 and ANC6 visits, childbirth, and PNC, modeled as a multi-state process to capture delays and accelerations that are not apparent in aggregate models. The analysis involves the following steps: a) defining states and transitions, (starting from registration, ANC visits, and childbirth to PNC1 and completion) with the mother as the unit of analysis and Puskesmas as the cluster; b) setting the time axis based on gestational or postpartum age, accounting for delayed entry (left-truncation); c) calculating transition probabilities using the Aalen-Johansen estimator; d) modeling transition intensities using a cause-specific Cox model incorporating a Puskesmas-level frailty term and time-varying DED exposure covariates (treatment policy) to identify transitions accelerated by DED; and e) tracking mothers from one care stage to the next (using provider attribution to link each transition to the recorded provider type). The results regarding these trajectories are reported as secondary and descriptive findings. Survival analysis (time-to-event modeling) was also conducted to document delays or barriers, as well as drivers (accelerators), within the service pathway.

Facility readiness and Provider contribution

Facility readiness encompasses digital infrastructure availability, EMR integration, and reporting timeliness. Readiness data is derived from the 2023 DESI and DRA assessments, which covered approximately 80% of facilities. This data was linked to specific facilities using existing Community Health Center (Puskesmas) typologies. Data updates were limited to two groups: a) facilities not surveyed in 2023, specifically Auxiliary Community Health Centers (Pustu), and b) facilities with incomplete data. These updates involved collecting brief readiness data from the relevant facilities rather than re-surveying the entire set.

All operational indicators are summarized descriptively by period-cluster and status; baseline readiness is included as a cluster-level covariate and a pre-specified effect modifier (readiness tertiles) and serves as an input for the costing model (Proctor et al., 2011).

Meanwhile, the Provider Contribution component involves assessing and comparing the care providers associated with successful completion of care by pregnant women (from early pregnancy through to postnatal care) and analyzing logs of digital tool usage linked to provider actions throughout the mother's care trajectory. This analysis is descriptive-exploratory in nature, intended to visualize the care pathway. It is

not used to infer causality, as the selection of health workers occurs naturally in the field and is influenced by the pregnant woman's condition or clinical severity (case-mix).

Primary Outcome
Completeness of antenatal care services within the gestational age window.

Secondary Outcomes
Maternal Services:

a. Timeliness of Antenatal Care (ANC) services
b. Completeness of Postnatal Care (PNC)
c. Timeliness of PNC
d. Completeness of standard PNC assessments
e. Time to completion of full standard antenatal care services
f. Mean Arterial Pressure (MAP)
g. Blood pressure
h. Height
i. Weight
j. Body Mass Index (BMI)
k. Mid-Upper Arm Circumference (MUAC)

Neonatal Services:

a. Completeness of neonatal visits (KN)
b. Standard/completeness of neonatal examinations
c. Timeliness of neonatal visits

Pregnancy & Childbirth Outcomes:

a. Pregnancy outcomes
b. Low birth weight
c. Place of delivery
d. Birth attendant
e. Complication management

Operational Variables:

a. Medicine stock-outs
b. Community Health Center (Puskesmas) Performance Assessment (PKP)
c. Workload distribution
d. Task-shifting
e. Digital tool adoption
f. Availability of digital infrastructure
g. Electronic medical record integration
h. Reporting timeliness
i. Training costs
j. Infrastructure costs
k. Dashboard & software costs
l. Interoperability/digital integration costs
m. Technical support & maintenance costs
n. Healthcare service costs
o. Cost timing & periods
p. Number of additional services

q. Complete maternal continuum of care
r. DALYs averted

Confounding Variables (Covariates)

Primary Health Center (Puskesmas) Level:

a. Baseline K6 coverage
b. Geographic access
c. Health worker-to-pregnant woman ratio
d. Target population
e. KuApps training status (from DED 1.0)
f. Accreditation status
g. Medicine stock-outs
h. Puskesmas Performance Assessment (PKP)
i. Workload distribution
j. Task-shifting
k. Digital tool adoption
l. Availability of digital infrastructure
m. Electronic medical record integration
n. Reporting timeliness

Individual Level:

a. Maternal age
b. Maternal education
c. Socioeconomic status
d. Parity
e. Gravidity
f. History of abortion
g. Pregnancy complications
h. Childbirth complications
i. Ownership status JKN
j. Mobile phone ownership status
k. Marital status
l. Cultural practices
m. Maternal autonomy in household decision-making
n. History of chronic illness
o. Distance to the nearest health facility

Contamination and prior DED exposure

Both prior exposure to the intervention and the risk of contamination were addressed at the design stage rather than through analytical adjustment.

Puskesmas that had previously been exposed to DED 1.0 were excluded from the sampling frame before randomization, yielding 58 eligible Puskesmas, from which 45 were selected through a permutation-based covariate-constrained randomization (CCR) process. Therefore, this removes the contamination risk arising from the exposure.

Contamination during the trial, specifically in the intervention spreading between clusters within the same district, cannot be excluded by design. Therefore, to manage the contamination, Puskesmas in the control period are given no access to any DED ecosystems component, and adherence is monitored as a fidelity measure and reported for each cluster in each period, reported for each cluster in each period. As contamination would make control clusters resemble intervention clusters, its effect would bias the estimated intervention effect toward the null (such as toward underestimation).

Intention-To-Treat and Per-Protocol (implementation fidelity) analysis

The primary analysis will be conducted on an intention-to-treat (ITT) according to the randomised crossover wave. A separate per-protocol (PP) analysis will additionally be conducted, restricted to clusters meeting predefined implementation-fidelity criteria. Comparing the two indicates the robustness of the estimated effect to non-adherence and variation in implementation fidelity, rather than selection bias. The same multilevel logistic regression (GLMM) specification will be applied consistently for both analysis, with ITT retained as the primary analysis. (van Zwicht, B S et al, 2016; Kirwan, G et al, 2025)

Data linkage and eligibility uncertainty

As outcomes are constructed by linking routine records from KuApps and LegacyApps, linkage failure may lead to incomplete or misclassified records. The DED ecosystem strengthens identifier capture and record validation; therefore linkage success is expected to be higher during intervention periods than control periods. Any resulting misclassification or selective record loss is thus likely to be Any resulting misclassification or selective record loss is likely to be differential with respect to exposure, and its direction cannot be assumed to be toward the null; it may inflate the apparent DED effect. To assess this, linkage Therefore, to assess the impact of the uncertainty of linkage, the analysis will be repeated under alternative eligibility definitions and linkage assumptions. Provided any misclassification is non-differential between arms, its expected effect is toward the null.

Missing data

There is a distinction between empty data and missing data. An empty data in the routine records is treated as service not received, not as a missing value because blank fields are more frequent in control periods and this convention is the conservative choice. (Díaz-Ordaz et al., 2014). The main analysis performs no imputation, it uses likelihood-based estimates on all available observations, which yields valid inference under a missing-at-random (MAR) assumption without deleting incomplete observations (Little & Rubin, 2019). Missing covariate data will be handled via multiple imputation by chained equations called MICE, with ≥50 imputations, indicating that the number of imputations set at least equal to the percentage of incomplete cases. Additionally, with cluster and period included in the imputation model), following Rubin's rules (Rubin, 1987; White et al., 2011; Diaz-Ordaz et al., 2014). Complete-case analyses are reported alongside, accompanied by pattern-mixture sensitivity analyses (point-reversal/tipping point) (Díaz-Ordaz et al., 2014). For secondary open-cohort (visit-level) outcomes, missingness of repeated visit measurements will additionally be examined (Twisk, 2009).

Analysis populations

Pregnant women as participants are classified by the Puskesmas at which they received care and the period of record; treatment status is determined by whether that Puskesmas had crossed to DED by that period, per the randomised schedule, and therefore varies over time rather than defining fixed arms

a. The Primary Analysis will include all eligible pregnant women at participating Puskesmas in the defined periods with records in the study database, analysed by facility of registration and its randomised status in the corresponding period, regardless of actual DED exposure (intention-to-treat at the facility level).
b. Baseline Population will be all eligible participants recorded in the baseline period (before any crossover), used to assess baseline comparability across the randomised waves.
c. Control and Intervention Person-Time will be pre-crossover person-time, which constitutes control observations and post-crossover person-time, which constitutes intervention observations, meaning that every Puskesmas contributes to both and these time-varying states define the treatment contrast.
d. Per-Protocol Population, which means that participants at Puskesmas meeting a prespecified threshold of actual DED usage in the corresponding period, for a per-protocol sensitivity analysis

References

Ciolino JD, Diebold A, Jensen JK, Rouleau GW, Koloms KK, Tandon D. 2019. Choosing an imbalance metric for covariate-constrained randomization in multiple-arm cluster-randomized trials. Trials. 20(1):293. doi: 10.1186/s13063-019-3324-5. PMID: 31138319.

Díaz-Ordaz, K., Kenward, M. G., Cohen, A., Coleman, C. L., & Eldridge, S. (2014). Are missing data adequately handled in cluster randomised trials? A systematic review and guidelines. Clinical Trials, 11(5), 590–600. https://doi.org/10.1177/1740774514537136

Girling, A. J., & Hemming, K. (2016). Statistical efficiency and optimal design for stepped cluster studies under linear mixed effects models. Statistics in Medicine, 35(13), 2149–2166.

Hooper, R., Teerenstra, S., de Hoop, E., & Eldridge, S. (2016). Sample size calculation for stepped wedge and other longitudinal cluster randomised trials. Statistics in Medicine, 35(26), 4718–4728. https://doi.org/10.1002/sim.7028

Ivers NM, Halperin IJ, Barnsley J, et al. (2012). Allocation techniques for balance at baseline in cluster randomized trials: a methodological review. Trials. 13:120. doi: 10.1186/1745-6215-13-120. PMID: 22853820.

Kirwan, G., Allen, A., Deasy, E., Delaney, T., Hayde, J., McManamly, C., ... & Grimes, T. (2025). The impact of collaborative pharmaceutical care on hospital discharge medication error prevalence: A stepped-wedge cluster randomised trial. Exploratory Research in Clinical and Social Pharmacy, 100638.

Kristunas, C., Grayling, M., Gray, L. J., & Hemming, K. (2022). Mind the gap: covariate constrained randomisation can protect against substantial power loss in parallel cluster randomised trials. BMC medical research methodology, 22(1), 111. https://doi.org/10.1186/s12874-022-01588-8

Little, R. J. A., & Rubin, D. B. (2019). Statistical analysis with missing data (3rd ed.). Wiley.

Maryuni, M., & Kurniasih, D. (2017). Risk factors of premature rupture of membrane. Kesmas: Jurnal Kesehatan Masyarakat Nasional (National Public Health Journal), 11(3), 133–137. Available at: https://doi.org/10.21109/kesmas.v11i3.1153.

Nuryanti, N. (2025). Bupati Garut Dukung Penuh IBI Kabupaten Garut Dalam Upaya Menurunkan AKI/AKB. Pemerintah Kabupaten Garut. Available at: https://www.garutkab.go.id/berita/bupati-garut-dukung-penuh-ibi-kabupaten-garut-dalam-upaya-menurunkan-akiakb

Rahim, M. R., Sanyoto, D. D., Istiqamah, E., Adhani, R., & Husaini, H. (2024). Analisis Faktor yang Berhubungan dengan Angka Kematian Ibu: Analysis of Factors Associated with Maternal Mortality Rates. Jurnal Surya Medika, 10(3), 365–373. https://doi.org/10.33084/jsm.v10i3.9204

Rubin, D. B. (1987). Multiple imputation for nonresponse in surveys. John Wiley & Sons. https://doi.org/10.1002/9780470316696

Supriyanti, R. et al. (2016) "Blood Pressure Mobile Monitoring for Pregnant Woman Based Android System," IOP Conf. Ser. Mater. Sci. Eng. IOP Conference Series: Materials Science and Engineering, Institute of Physics Publishing. Available at: https://doi.org/10.1088/1757-899X/105/1/012048.

Syairaji M, Nurdiati DS, Wiratama BS, Prüst ZD, Bloemenkamp KWM, Verschueren KJC. Trends and causes of maternal mortality in Indonesia: a systematic review. BMC Pregnancy Childbirth. 2024;24(1):515. Published 2024 Jul 30. doi:10.1186/s12884-024-06687-6

Twisk, J. W. R. (2009). Applied longitudinal data analysis for epidemiology: A practical guide (1st publ., 4th print). Cambridge University Press.

van Zwicht, B. S., Crone, M. R., van Lith, J. M., & Rijnders, M. E. (2016). Group based prenatal care in a low-and high risk population in the Netherlands: a study protocol for a stepped wedge cluster randomized controlled trial. BMC pregnancy and childbirth, 16(1), 354.

Watson H. J. (2025). A Statistical Analysis Plan Template for Observational Studies: Promoting Quality and Rigor in Research. *Journal of statistical theory and practice*, 19(4), 10.1007/s42519-025-00504-9. https://doi.org/10.1007/s42519-025-00504-9

White, I. R., Royston, P., & Wood, A. M. (2011). Multiple imputation using chained equations: Issues and guidance for practice. Statistics in Medicine, 30(4), 377–399. https://doi.org/10.1002/sim.4067