STUDY PROTOCOL

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

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TABLE OF CONTENT

EXECUTIVE SUMMARY **4**

CHAPTER 1
INTRODUCTION AND LITERATURE REVIEW **6**

1.1 Background **6**

1.1.1 SUMMIT's Background 6

1.1.2 Summary of Literature Review 6

1.3 Research Objectives 7

1.4 Significance of the Research 10

1.4.1 Theoretical Benefits 10

1.4.2 Practical Benefits for Institution 10

1.4.3 Practical Benefits for Researchers 10

CHAPTER 2
RESEARCH METHODOLOGY **12**

2.1 Conceptual Framework 12

2.2 Research Design 13

2.2.1 Participant Flow 13

2.3 Study Location and Duration 14

2.3.1 Study Location 14

2.3.2 Study Duration 14

2.4 Intervention Arms and Sample Size 14

2.4.1 Intervention Group (DED Period) 14

2.4.2 Control Group (Pre-Crossover Period) 17

2.4.3 Randomization and Allocation (CCR) 17

2.4.4 Inclusion and Exclusion Criteria 18

2.4.5 Sample Size 18

2.5. Study Procedures 20

2.5.1 Field Team and Procedures 20

2.5.2 Subject Screening and Enrollment 21

2.5.3 Data Management 21

2.5.3.1 Data Collection 21

2.5.3.2 Data Processing 22

2.6 Data Analysis 22

2.6.1 Descriptive Analysis 22

2.6.2 Inferential Analysis 22

2.7 Ethics Considerations 24

2.7.1 Informed Consent 24

2.7.2 Confidentiality and Privacy 24

2.7.3 Participant Safety 25

2.7.4 Voluntary Participation 25

2.7.5 Transparency and Accountability 25

CHAPTER 3
IMPLEMENTATION PROGRAM **26**
3.1 Research Committee Structure 26
References **29**

EXECUTIVE SUMMARY

Background

Digital technology is increasingly used in health services to help providers record, monitor, and manage health information more systematically. However, rigorous evidence on how such systems actually support the monitoring of maternal health in routine district-level care remains limited.

The Digitally Enabled District (DED) programme is one effort to strengthen the use of digital systems in district health services, including the recording and monitoring of maternal care at primary health facilities. This study evaluates the effect of the phased rollout of the DED ecosystem across Puskesmas on the utilisation of maternal and neonatal health services and on pregnancy outcomes, compared with the control period

The study uses a stepped-wedge cluster randomised trial design. Following a randomly assigned order, each cluster crosses over from control to intervention in stages: 15 Puskesmas receive the intervention in the first wave, followed by subsequent clusters, until all clusters have been enrolled by the end of the study.

Data are drawn from routine service records held at the facilities (KuApps, ePuskesmas, SIGIZI, and Legacy Apps), supplemented by sociodemographic information collected once at enrolment. The findings are expected to inform efforts to improve the quality of maternal and child health care.

Rationale

Improving maternal and child health remains a national health priority in Indonesia and is central to the country's commitment under the United Nations Sustainable Development Goals (SDG), which set a target of reducing maternal mortality to fewer than 70 deaths per 100,000 live births. However, the progress has been uneven, and several districts continue to report maternal mortality well above that target.

Garut District is one such area. District health records for 2024 documented 50 maternal deaths and 330 neonatal deaths—figures that remain far above the SDG benchmark. This gap points to a continuing need to strengthen the monitoring of pregnant women and the early detection of risk factors, both of which are essential to preventing complications during pregnancy and childbirth.

Routine, good-quality antenatal monitoring matters because it allows risks to be identified early and ensures that women receive care consistent with prevailing standards. In recent years, digital health information systems have begun to be developed to support recording and monitoring at the facility level. Even so, access to optimal antenatal care remains a challenge in Indonesia, constrained by limited health resources, recording and reporting systems that are not yet fully integrated, and the absence of continuous mechanisms for tracking maternal and child health.

The DED programme responds to these gaps by promoting the use of digital systems in district health services, including support for the recording and monitoring of maternal care at the primary level. Importantly, the DED components, including KuApps, the PWS Dashboard, AI-OCR, and health communication tools, operate at the level of recording and monitoring. They do not alter the clinical standard of care a pregnant woman receives and therefore introduce no medical risk beyond routine practice. The system also integrates data from government applications built on FHIR and SATUSEHAT standards, which keeps patient records consistent across platforms.

Despite the rapid growth of digital health tools, robust evidence on how these systems support maternal monitoring in routine district practice remains scarce, particularly evidence capable of supporting causal conclusions. This study is therefore needed to generate such evidence in Garut District, covering the continuum from pregnancy through delivery. Its findings are intended to inform both policy and practice in maternal and child health, and ultimately to support efforts to reduce maternal mortality at the district level.

Potential Ethical Issues

This study involves pregnant women, who are considered a vulnerable population. For that reason, particular care has been taken over recruitment, the protection of privacy and confidentiality, and the process of obtaining consent. Recruitment takes place through the primary health facilities that serve as study sites. Women who meet the inclusion criteria receive an explanation of the study's purpose, its procedures, and their rights as participants before being asked to provide written consent. Participation is entirely voluntary and has no bearing on the care a woman receives.

The burden placed on participants is very low. Only one procedure involves participants directly: a brief sociodemographic questionnaire, completed once at an already scheduled visit and taking roughly five minutes. Any discomfort is minimal, and participants may decline to answer any item without consequence. The main risks are non physical: the possibility of a breach of confidentiality involving health data held in digital systems, and the possibility of a temporary disruption to service recording should the digital system experience a technical fault.

To keep these risks low, all participant data are stored in de-identified form, with access restricted to the research team. Electronic data are held securely and used solely for research purposes. No member of the research team has a conflict of interest that could influence the conduct of the study.

In the stepped-wedge design, there is potential for contamination between clusters that have crossed over and those that have not, as all are located within the same district (Garut Regency) and information can spread among the Puskesmas. This issue is handled operationally; subjects are not excluded from the analysis.

Puskesmas in the control period are not given access to, and do not implement, any components of the DED ecosystem during their control period. This includes the Puskesmas that previously received KuApps training (18 of the 58 eligible Puskesmas). Compliance with this protocol is monitored as a measure of fidelity and reported per cluster per period.

Furthermore, there is a consequence of this design, which is that clusters in the final wave will receive the DED intervention later than those in the initial waves. To manage this risk, transparent communication with all stakeholders is necessary to clarify that the phased rollout is not an intentional withholding of the intervention, but rather a consequence of human-resource and infrastructure constraints that make simultaneous implementation across all Puskesmas unfeasible. Determining the sequence through randomisation is the fairest method for distributing access to the intervention.

CHAPTER 1
INTRODUCTION AND LITERATURE REVIEW

1.1 Background

1.1.1 SUMMIT's Background

For over 25 years, the Summit Institute for Development (SUMMIT) has engaged communities to enhance public health. SUMMIT is also a founding partner of the Open Smart Register Platform (OpenSRP), which is currently used in 17 countries and has been recognised by the WHO as one of the top ten innovations in global healthcare. More recently, using Fast Healthcare Interoperability Resources (FHIR), SUMMIT developed a team-based care model in four districts in Indonesia (with plans to expand to ten districts by 2027), covering 10 million people.

As a key partner of the Ministry of Health in accelerating integrated primary health services (ILP), SUMMIT collaborates with the Center of Data and Information (Pusdatin)–Digital Health Transformation Team (TTDK), formerly known as the Digital Transformation Office (DTO). SUMMIT digitises frontline health workers' workflows and connects communities with facilities through the FHIR data ecosystem, including SATUSEHAT (the national platform). This system supports a dashboard for local monitoring and decision-making, used by primary healthcare managers and district health offices.

1.1.2 Summary of Literature Review

Timely, good-quality antenatal care is a cornerstone of efforts to reduce the risk of pregnancy complications and, in turn, maternal mortality and morbidity (Mohamud et al., 2026). Quality antenatal care enables providers to detect risk factors early and to intervene appropriately across the course of pregnancy and delivery (Hadriani et al., 2025). In Indonesia, however, access to optimal antenatal care remains constrained by limited health resources, recording and reporting systems that are not yet fully integrated, and the lack of continuous monitoring of maternal and child health (Ministry of Health, 2026).

The use of digital technology in maternal and child health has expanded rapidly in recent years. Tools such as mobile health (mHealth) applications, electronic health information systems, teleconsultation platforms, and pregnancy-monitoring apps have been introduced to improve the quality of antenatal care (Khan et al., 2026; Endehabtu et al., 2024). Studies report that these technologies can widen access to care, improve women's knowledge of pregnancy, and support more effective monitoring of maternal health (Mohamed et al., 2025).

Several studies also indicate that mHealth interventions can improve pregnant women's adherence to antenatal care visits (Nuhu et al., 2023; Coleman et al., 2020). A meta-analysis involving several low- and middle-income countries found that pregnant women using mHealth interventions have a higher likelihood of attending antenatal care visits than those not using digital interventions (Mishra et al., 2023). In addition to increasing service access, digital technology also has the potential to improve maternal health monitoring systems in a more integrated manner (Mohamed et al., 2025). Implementation studies of digital health information systems in health facilities show that integrating digital systems between community services and health facilities can improve maternal health indicators, including increased antenatal visits, deliveries by skilled health personnel, and postnatal monitoring (Ombech et al., 2025).

Nevertheless, the effectiveness of digital tools depends not only on their functionality but also on their acceptance by health workers and the readiness of the system in which they are deployed. A qualitative study in Lombok, Indonesia, involving 68 health workers across levels (cadres, village midwives, facility midwives, medical specialists, and health system managers), examining self-monitoring of blood pressure by pregnant women, found that the acceptance of digital interventions depends on the availability of clear clinical and data-management protocols, referral mechanisms, and trust in measurement accuracy (Tamrat et al., 2025). The health workers in that study cited digital communication channels such as WhatsApp as a means to facilitate the exchange of

examination results and to reinforce education. These findings confirm that integrating digital technology into routine antenatal care workflows requires more than just an application; it demands clear data protocols, follow-up mechanisms, and trust built among pregnant women, frontline health workers, and the referral system (Tamrat et al., 2025).

Although various studies demonstrate the potential benefits of digital technology in maternal health services, most research still focuses on trials of digital interventions or evaluations of specific health applications (Coleman et al., 2020; Coulibaly & Kouanda, 2023; Paduano et al., 2022). Even the developers of the WHO digital ANC module themselves emphasise that evidence on the tool's impact on implementing recommendations in routine practice is still needed (Haddad et al., 2020), while qualitative readiness studies such as the one conducted by Tamrat et al. (2025) call for evaluation after the interventions have actually been implemented in the field.

Furthermore, the digital systems evaluated to date are generally not yet integrated to a level that allows policymakers to monitor maternal health care data in real time as a basis for decision-making (Coleman et al., 2020; Coulibaly & Kouanda, 2023). At the same time, scientific evidence evaluating the use of digital health systems in routine district-level health care practice, particularly in the continuous monitoring of maternal health from pregnancy to delivery remains limited, especially evidence capable of supporting causal inference (Priambodo et al., 2026).

This study is therefore conducted to evaluate the use of the Digitally Enabled District (DED) ecosystem in supporting the monitoring of pregnant women's health within routine health care practice at the primary care level, using a stepped-wedge cluster randomised trial design to provide a stronger basis for causal inference.

1.2 Research Objectives

Research Questions

1. Does the phased implementation of the DED ecosystem in Community Health Centers (Puskesmas) influence the completeness and timeliness of maternal health services, including antenatal care (ANC), "12T" ANC services, postnatal care (PNC), and adherence to PNC standards, compared to the control period?
2. Does the phased implementation of the DED ecosystem in Community Health Centers (Puskesmas) influence the completeness and timeliness of neonatal health services, including neonatal visits and examinations, compared to the control period?
3. Does the phased implementation of the DED ecosystem in Community Health Centers (Puskesmas) influence pregnancy and childbirth outcomes, including birth outcomes, place of delivery, and the healthcare personnel attending the delivery, compared to the control period?

Research Objectives

General Objectives

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.

Specific 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.

Research 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.

Independent variable

DED ecosystem implementation status at each Community Health Center (Puskesmas) during each period.

Secondary Outcomes

Maternal Services

1. Timeliness of Antenatal Care (ANC) services
2. Completeness of Postnatal Care (PNC)
3. Timeliness of PNC
4. Completeness of standard PNC assessments
5. Time to completion of full standard antenatal care
6. Mean Arterial Pressure (MAP)
7. Blood pressure
8. Height
9. Weight
10. Body Mass Index (BMI)
11. Mid-Upper Arm Circumference (MUAC)

Neonatal Services

1. Completeness of neonatal visits (KN)
2. Standard/completeness of neonatal examination
3. Timeliness of neonatal visits

Pregnancy & Delivery Outcomes

1. Pregnancy outcomes
2. Low birth weight (LBW)
3. Place of delivery
4. Birth attendant
5. Management of complications

Operational Variables

1. Drug stockouts
2. Puskesmas Performance Assessment (PKP)
3. Workload distribution
4. Task-shifting
5. Adoption of digital tools
6. Availability of digital infrastructure
7. Electronic medical record integration
8. Timeliness of reporting
9. Training costs
10. Infrastructure costs
11. Dashboard & software costs
12. Interoperability/digital integration costs
13. Technical support & maintenance costs
14. Healthcare service costs
15. Cost time & period
16. Number of additional services
17. Complete continuum of maternal care
18. DALYs averted (Rupiah per DALY averted)

Confounding Variables (Covariates) Primary Health Center (Puskesmas) Level:

1. Baseline K6 coverage
2. Geographical access
3. Ratio of health workers per pregnant woman
4. Target population
5. Status of Puskesmas trained in KuApps (from DED 1.0)
6. Accreditation status

7. Drug stockouts
8. Puskesmas Performance Assessment (PKP)
9. Workload distribution
10. Task-shifting
11. Adoption of digital tools
12. Availability of digital infrastructure
13. Electronic medical record integration
14. Timeliness of reporting

Confounding Variables (Covariates) Individual Level:

1. Maternal age
2. Maternal education
3. Socioeconomic status
4. Parity
5. Gravida
6. History of miscarriage/abortion
7. Pregnancy complications
8. Delivery complications
9. JKN (National Health Insurance) ownership status
10. Mobile phone ownership status
11. Marital status
12. Cultural practices
13. Maternal decision-making autonomy in the household
14. History of chronic disease
15. Distance to the nearest health facility

1.3 Significance of the Research

1.3.1 Theoretical Benefits

This study is expected to make a scientific contribution to the public health literature, particularly concerning the use of digital technology within primary health care systems. It further offers empirical evidence on the effectiveness of digital health approaches in improving the utilisation of maternal and neonatal health services through a rigorous comparison between intervention and control periods.

1.3.2 Practical Benefits for Institution

The findings of this study are expected to serve as a critical resource for the Garut Regency Government, the Garut Regency Health Office, and primary health care facilities in developing and optimising digital health systems to enhance the quality of maternal and neonatal care. The research also aims to support evidence-based health policy planning in efforts to accelerate the reduction of maternal and neonatal mortality rates at the district level.

1.3.3 Practical Benefits for Researchers

This study is expected to enhance the researcher's insight and practical experience in conducting digital-systems-based public health research, specifically in evaluating complex health interventions within routine primary care settings

CHAPTER 2
RESEARCH METHODOLOGY

2.1 Conceptual Framework

This study is grounded in the premise that implementation of an integrated digital ecosystem at the district level can strengthen the monitoring of pregnant women's health by improving recording, communication, and data-driven decision-making processes within primary health care services. The conceptual framework draws on three main theories:

a. Three Delays Model (Thaddeus & Maine, 1994):

This model identifies three critical points of failure in maternal health care, delay in deciding to seek care, delay in reaching a health facility, and delay in receiving adequate care. The DED reminder system directly addresses the first delay, and interoperable data integration targets the third delay.

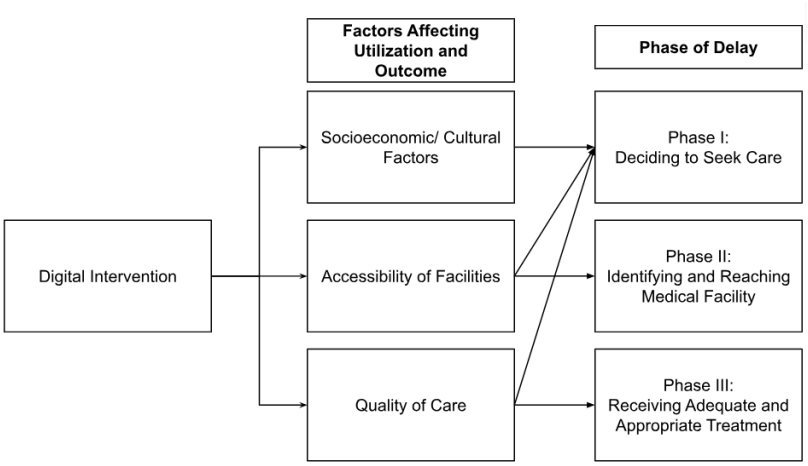


Figure 2.1.1 Three Delays Model

b. Health Belief Model (HBM):

This model explains that health behaviour is shaped by perceptions of susceptibility, severity, benefits, barriers, and self-efficacy. HealthComm acts as a cue to action that encourages regular ANC behaviour.

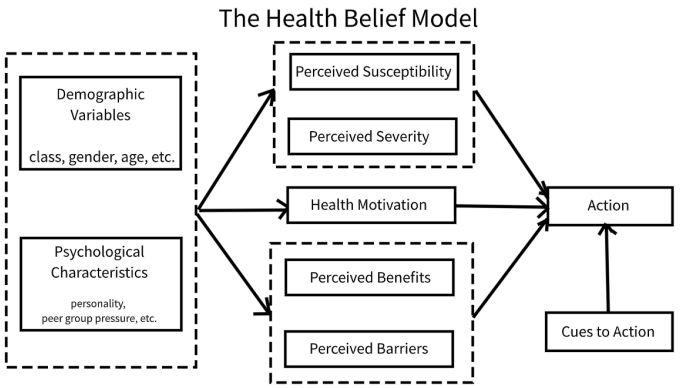


Figure 2.1.2 Health Belief Model

The conceptual relationship underlying this study can be defined as from DED Ecosystem Implementation, continues to Recording, Monitoring, and Communication Processes. Then, it continues to Maternal-Neonatal Service Outcomes, resulting in pregnancy and delivery outcomes.

2.2 Research Design

This study uses a stepped-wedge cluster randomised trial design, with the Puskesmas as the unit of intervention. A total of 45 Puskesmas are randomly allocated to three waves of 15 Puskesmas each through a single covariate-constrained randomisation draw that determines all three waves simultaneously. The baseline period (August-October 2026) is measured retrospectively from routine service registers, because during this period all 45 Puskesmas are still under control conditions and none have received the DED 2.0 ecosystem. After the baseline, one wave crosses over to the intervention condition at the beginning of each subsequent three-month phase: November 2026, February 2027, and May 2027. All Puskesmas will have received the DED ecosystem by May 2027.

Although baseline data are drawn from routine service records that existed prior to recruitment, retrospective data collection still requires informed consent from participants. Retrospective baseline data are accessed for research purposes only after informed consent has been obtained from each participant individually. No individual data are accessed, extracted, or used for research before the participant signs the consent, even where the data were previously recorded in the routine service recording systems. The informed consent provided by the mother covers three components: (1) her participation in the study, (2) her acceptance of Health Communication services, and (3) her permission for researchers to access previously recorded service data, including medical records and KIA (Kesehatan Ibu dan Anak / Maternal and Child Health) book data. If a mother does not provide consent, her retrospective data will neither be accessed nor used in the analysis.

In this design, no Puskesmas permanently serves as a "control" or "intervention" cluster. The status of each Puskesmas changes over time, depending on the observation period. Each Puskesmas contributes to two phases: the pre-crossover phase (while still under control status) and the post-crossover phase (after receiving the DED intervention). In this way, the study remains fair and complies with research ethics principles, because ultimately all Puskesmas benefit from the intervention. The intention-to-treat principle is applied: each cluster–period is analysed according to the condition specified by the randomisation schedule, regardless of the actual level of implementation, and no cluster or individual is excluded on the basis of post-randomisation behaviour.

2.2.1 Participant Flow

The participant flow follows a structured SW-CRT framework:

a. Pre-population: 45 eligible Puskesmas are identified from 67 Puskesmas in Garut District based on inclusion/exclusion criteria.
b. CCR Stage 1 Randomization: 15 of 45 Puskesmas are selected for Wave 1 (before 1 October 2026).
c. Retrospective baseline: Service data from all 45 Puskesmas (August–October 2026) are accessed after individual informed consent.
d. Wave 1 crossover (November 2026): 15 Wave 1 Puskesmas transition to DED intervention.
e. CCR Stage 2 Randomization (January 2027): The remaining 30 Puskesmas are divided into Wave 2 and Wave 3.
f. Wave 2 crossover (February 2027): 15 Wave 2 Puskesmas transition to DED intervention.
g. Wave 3 crossover (May 2027): 15 Wave 3 Puskesmas transition to DED intervention.
h. End of observation: 31 July 2027.

2.3 Study Location and Duration

2.3.1 Study Location

This study is conducted in 45 Puskesmas in Garut District, West Java Province, Indonesia. Garut is one of the largest regencies in West Java geographically, covering approximately 3,065 square kilometres across 42 districts (Statistics Garut Regency, 2026). The regency comprises both urban and rural areas, is surrounded by mountain ranges, and includes a number of coastal areas. Its total population is 2.78 million. In terms of maternal and child health epidemiology, Garut District recorded 34,357 pregnant women receiving health care services in 2024, with 50 maternal deaths and 330 neonatal deaths (an increase from 291 neonatal deaths in 2023). These figures underscore the urgency of strengthening maternal and child health services in Garut District to reduce maternal and child mortality.

The Puskesmas serving as study sites have recording systems for maternal health care services, in the form of both medical records and digital health information systems used by health workers to record antenatal care. These facilities also have trained personnel for maternal and child health care.

2.3.2 Study Duration

The shared baseline period runs from August to October 2026 and is drawn retrospectively from routine service data with all 45 Puskesmas in the control condition. Three crossover stages begin in November 2026, February 2027, and May 2027, with wave-specific training conducted in the month before each crossover (November 2026, February 2027, May 2027). Exposure and utilization observation ends on 31 July 2027

2.4 Intervention Arms and Sample Size

This study is designed to ensure strong internal validity by keeping key components consistent between the intervention and control conditions:

a. Clinical standards of care are not changed in either period.
b. Measurement instruments (sociodemographic questionnaire, outcome indicator definitions, data extraction algorithms) are identical across both periods.
c. Duration and exposure window are set through the predetermined crossover schedule.
d. Subject eligibility criteria are the same in both periods.
e. The only difference between the two conditions is therefore access to and use of the DED 2.0 ecosystem.

2.4.1 Intervention Group (DED Period)

During the intervention period, Puskesmas will implement all five components of the DED 2.0 ecosystem (KuApps, PWS Dashboard, AI-OCR, Health Communication, and DWS) in accordance with the programme's operational guidelines. This is a stepped-wedge cluster randomised trial in which study subjects may be exposed to the following interventions:

KuApps:

A suite of open-source software tools designed to support health digitalization in the process of health service data collection by frontline health workers, assisting in patient management and service delivery. KuApps consists of BidanKu and KaderKu, applications for recording community-based (outreach) services, built on the Open Smart Register Platform and using the FHIR standard, enabling integration with the SATUSEHAT ecosystem. The functions of KuApps are: 1) registering community members as electronic patients; 2) storing patient identity data centrally; and 3) linking patient data to the relevant care plan, so that data are stored in a structured manner consistent with applicable health data standards. The key features of KuApps are as follows:

a. Data integration with government applications (based on FHIR and SATU SEHAT), ensuring patient data consistency across systems, preventing data duplication between

applications, and ensuring that field applications always display the most current, validated data.

b. All forms within the KuApps application are integrated with the ILP Posyandu Service Assistance Card, the ILP Service Recapitulation, and the Posyandu Information System Register.
c. Offline input mode (supporting field work without an internet connection.
d. Support for data synchronization across midwife and kader (community health worker) accounts within the same organization and assignment area.
e. Display a complete patient data history, encompassing both application-generated data and government-sourced data, allowing midwives and kader to view a patient's full service history, avoid duplicating the same actions, and continue care based on prior data.
f. Use of centralized patient record concept, eliminating the need for repeated entry of basic patient data.

Dashboard:

The PWS (Pemantauan Wilayah Setempat/Local Area Monitoring) Dashboard is used to monitor all activities occurring within primary health care services at the regional level, ranging from community health services to Puskesmas operational activities, such as workforce monitoring and the procurement of medicines and vaccines. This monitoring is based on data collected by the Puskesmas team, encompassing both facility-based and outreach (community) service data.

The PWS Dashboard covers monitoring across all clusters, from Cluster 1 through cross-cluster indicators, together with a morbidity dashboard and a main landing-page dashboard. These clusters follow the Integrated Primary Health Care Services (ILP) standard established by the Indonesian Ministry of Health. Cluster 1 covers Puskesmas management data; Cluster 2, maternal and child health data; Cluster 3, adult and elderly health data; Cluster 4, communicable diseases; and Cluster 5 (cross-cluster), pharmaceutical supplies, vaccines, laboratory services, and inpatient care. The dashboard operates at three levels: District/District Health Office (Dinas Kesehatan Kabupaten), Puskesmas, and Village/Posyandu.

AI OCR (Artificial Intelligence Optical Character Recognition):

AI-OCR is a technology designed to read handwritten entries from photographs or PDF files of the Maternal and Child Health Handbook (Buku KIA) and convert them into digital data that can be stored, searched, and exported for reporting purposes. Its functions include reading handwritten entries from the Buku KIA, automatically populating digital forms, storing data in a database, and supporting data verification. The application improves efficiency by reducing digitisation time to 5–10 minutes per Buku KIA; improves accuracy through automated reading and data validation; improves accessibility, as data are stored in an organised manner that can be searched and exported at any time; and improves security, as data are stored in the cloud (Google Drive) and in a database, reducing the risk of data loss. Photographs of the KIA book are not stored on the mobile phone or the device taking the photo; instead, they are saved directly to the Google Cloud Platform server located in Jakarta and re-verified by health workers.

Health Communication:

HealthComm is a telehealth-based, end-to-end communication and follow-up service that connects pregnant women, postpartum women, and mothers with infants/toddlers to frontline health workers (midwives and other health personnel). The service facilitates education, reminders, two-way communication, monitoring, communication-based initial assessments, and case escalation to authorised health workers. HealthComm does not replace clinical examinations, diagnoses, medical treatments, or emergency services.

HealthComm uses several channels. WhatsApp (channel broadcasts and segmented direct messages) is the primary channel, with a call centre as an alternative channel for targets

who are unreachable or have not responded via WhatsApp. As the primary channel, HealthComm provides a WhatsApp Channel for general education, segmented WhatsApp messages (blasts) for reminders and service confirmations based on individual data, and two-way WhatsApp consultations through the service number. Call centre follow-up is used for clarification, follow-up, and monitoring.

WhatsApp Channel education is conducted twice a week (Tuesdays and Thursdays). The messages sent are segmented, which is triggered per event according to individual data and service stages and include ANC reminders, ANC follow-ups, care gaps, birth confirmation, PNC/KNKF (neonatal visit) reminders, PNC follow-ups, immunisation reminders, Posyandu reminders, and periodic wellness tracking. Birth confirmation is sent between 36 and 40 weeks of gestation. Call centre follow-up for non-emergency messages occurs if the target has not responded within 24 hours. Responses to urgent conditions during operational hours are completed within one hour of the message being received.

The HealthComm schedule includes call centre operational hours from 08:00 to 21:00 WIB, with a systematically arranged content calendar to ensure consistency of exposure during the intervention period. Materials are tailored to the respective stages: pregnancy, delivery, postpartum, neonatal, and child growth and development.

The intervention duration for HealthComm spans from the pregnancy period through the toddler years, following the stages of KIA services. The communication sequence is activated or updated based on status. For example, transitioning from pregnancy status to postpartum status.

The eight components of HealthComm are: (1) service introduction and contact validation; (2) scheduled education via WhatsApp Channel; (3) segmented automated messages for reminders and confirmations; (4) birth confirmation; (5) two-way consultation and communication via WhatsApp; (6) call centre follow-up; (7) initial assessment, communication triage, and escalation to midwives/Puskesmas/health facilities; and (8) service recording, monitoring, and feedback.

Dynamic Worker Support:

In general, Dynamic Worker Support (DWS) aims to facilitate activities, enhance productivity, and ensure that desired outcomes can be achieved consistently. This system is developed to improve the quality and effectiveness of field activities through automated scheduling, as well as the monitoring and mentoring of field operations. This automation is designed to distribute daily schedules based on priorities and needs, enable real-time updates, and ensure that field activities run smoothly.

The system aims to automate repetitive tasks during the implementation of activities to address the delays and errors that frequently occur in manual processes. The DWS system ensures that all resources are utilized optimally and tasks are distributed seamlessly, utilizing reports to verify that tasks are executed according to targets, while also providing benefits to the communities served. Automated scheduling is generated using complex script logic. Data will be extracted and processed to produce a new set of tasks that are subsequently distributed to field workers.

2.4.2 Control Group (Pre-Crossover Period)

During the control period, Puskesmas continued standard recording and service practices using LegacyApps (SIGIZI, EMR, and ASIK) without access to DED 2.0 components. Clinical standards of ANC, PNC, and neonatal services continue to follow applicable Ministry of Health protocols.

This provision also applies to the 18 Puskesmas that previously received KuApps training during DED 1.0. Fidelity monitoring is carried out to ensure there is no leakage of DED implementation during the control period. The monitoring results are reported per cluster per period in the Statistical Analysis Plan.

2.4.3 Randomization and Allocation (CCR)

Randomization uses the Covariate-Constrained Randomization (CCR) method to control for imbalances in important baseline covariates in cluster-randomized trials (Ivers et al., 2012). The allocation of Puskesmas to intervention periods or waves is determined through a two-stage permutation draw:

First Stage (before November 2026)

Carried out by selecting 15 out of 45 Puskesmas for Wave 1 (yielding 344,867,425,584 combinations). The selection of these 15 Puskesmas is ensured to have balanced characteristics compared to the 30 unassigned Puskesmas, based on baseline covariates (K6 coverage, geographical access, ratio of health workers per pregnant woman, target population, KuApps DED 1.0 training status, accreditation status, and Puskesmas performance).

Second Stage (before Wave 2 begins, specifically before February 2027)

Carried out by dividing the remaining 30 Puskesmas into Wave 2 and Wave 3 (with a total of 155,117,520 combinations). This step takes into account the characteristics of Wave 1 to ensure that balance is maintained across all three waves.

To guarantee transparency and prevent any modifications after the draw begins, all technical provisions are predetermined: the variables used as the basis for assessing balance, the acceptable imbalance tolerance limits, the sequence for examining combinations, and the acceptance criteria for the draw results. All these technical provisions are documented in writing and assigned a digital verification code (hash) as proof that the document has not been altered after being established. The randomization result is final and cannot be revoked once the outcome is revealed.

Blinding

The DED study is unblinded (open-label). The intervention involves implementation of DED by health care workers directly; consequently, blinding of clusters (Puskesmas) or researchers is not practically feasible in this type of cluster randomised trial. This is an inherent limitation of the design. To mitigate the risk of bias, the following measures are implemented: centralised allocation via CCR in a single draw conducted before implementation; objective measurement, with outcome data derived from routine records using a pre-established, pre-locked algorithm; a Statistical Analysis Plan that is locked and signed off before allocation is revealed; and a primary analyst who works on a dataset in which intervention indicators are neutrally labelled until the primary model has been fitted and the analysis code locked.

2.4.4 Inclusion and Exclusion Criteria

Inclusion criteria

a. Pregnant women

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

b. Puskesmas

1. Located within Garut Regency;
2. Had not implemented the DED ecosystem in daily service practice at the time of baseline.

Exclusion criteria

a. Pregnant Women

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

b. Puskesmas

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

2.4.5 Sample Size

This study uses cluster-based sampling, with the Puskesmas as both the randomisation and sampling unit. This approach was chosen because the intervention (digital ecosystem/KuApps) is implemented at the facility level and cannot be allocated individually; randomisation at the Puskesmas level also minimises inter-group contamination and is more feasible logistically and ethically. The statistical consequence is that individual responses within a single Puskesmas are correlated. This correlation is quantified by the intraclass correlation (ICC) and must be accounted for when calculating sample size. Ignoring the ICC would result in an under-powered sample.

Sample size for this study is determined in two stages: the number of clusters, and the number of individuals per cluster per period. A total of 45 Puskesmas in Garut Regency are designated as clusters and randomly allocated into three waves of 15 Puskesmas each. The sample size that needs to be determined statistically is therefore the number of individuals surveyed at each Puskesmas in each period (m), which determines the power to detect effects deemed programmatically significant.

In this design, all clusters ultimately receive the intervention; the time sequence (wave) in which each cluster transitions from control to intervention is randomised. This allows each Puskesmas to contribute to both the control and intervention phases and to serve as its own control (within-cluster comparison), while also being compared with clusters that have not yet crossed over during the same measurement period. The designation of Puskesmas as clusters is made comprehensively across the facilities where the DED programme is implemented, not through random sampling from a Puskesmas population.

Sample size calculation uses the Hussey & Hughes (2007) approach for the design and analysis of stepped-wedge cluster randomised trials, as extended by Hooper et al. (2016) and Girling & Hemming (2016), with the following assumptions.

Parameter	**Value**	**Justification**
I :	45	Number of clusters (Puskesmas)
T:	4	Number of periods: (T1/Baseline: Aug-Oct 2026; T2: Nov-Jan 2026; T3: Feb-Apr 2027; T4: May-Jul 2027
U:	90	Total intervention cluster-periods = 15x(3+2+1) = 90, from 180 periode-klaster
W:	3150	Σ columns^2 = $0 + 15^2 + 30^2 + 45^2$
V:	210	Σ rows^2 = $15x3^2 + 15x2^2 + 15x1^2$
p_0:	47%	Baseline ANC visit coverage derived from previous regional findings by Indriyani, D. et al. (2024).
p_1:	55%	Target post-intervention coverage, assuming a Relative Risk (RR) of 1.17 from Rahman, M. O. et al. (2022) : 0,77 × 1,17 = 0.9009
ρ (ICC):	0,1	Intracluster Correlation Coefficient (ICC) based on a similar digital health trial implementation by Venkateswaran, M. et al. (2024)

π (CAC):	0.8	Cluster Autocorrelation Coefficient (CAC). A conservative estimate chosen to account for potential decay of correlation over time in the stepped-wedge design
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

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

$$\text{Var}(\hat{\theta}) = 0{,}00081231$$
$$power = \Phi(0.8469)$$
$$power = 0{,}8015$$

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:

$$\text{Total sample size} = m \times I \times T$$
$$= 50 \times 45 \times 4$$
$$= 9000$$

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.

2.5. Study Procedures

2.5.1 Field Team and Procedures

Prior to study implementation, all field team members (Field Facilitator/FF, Enumerator, and Research Assistant/RA) will attend a briefing session to discuss materials, align perspectives, and standardize delivery methods for both the control and intervention periods. This is intended to ensure that materials are delivered fairly across periods, with consistent levels of engagement, thereby minimizing potential bias.

DED 2.0 field team structure:

a. Field Facilitator (FF): responsible for pregnant women recruitment, informed consent, Phone Number Verification (PNV), and sociodemographic data collection.
b. Enumerator: responsible for collecting routine service data through integration with the EMR system and digitalization of the Buku KIA via AI-OCR.
c. Research Assistant (RA) and Monitoring, Evaluation, and Learning Officer (MEL Officer): responsible for field supervision, data quality control, and coordination with Puskesmas and the District Health Office.
d. The allocation of field teams to the 45 Puskesmas is adjusted to the Puskesmas typology (large, medium, small) based on the burden of the pregnant women population. Rotation of teams between Puskesmas is performed to minimize individual enumerator effects.

2.5.2 Subject Screening and Enrollment

Subject screening and enrollment is conducted through a structured multi-stage evaluation:

Stage 1: Pre-population from LegacyApps

Prospective subjects are identified through a pre-population process using routine data available at the health facility (LegacyApps), to build a sampling frame according to the study's inclusion criteria. Initial data covers minimal identity needed for follow-up contact.

Stage 2: Initial Contact and Informed Consent

Once prospective subjects are identified, an authorized FF will make limited initial contact to invite participation. The approach is conducted individually at the health facility during a scheduled service visit or through direct contact following proper procedure. The FF explains the study's purpose, procedures, types of data collected, interview duration, benefits and risks, guarantees of confidentiality of identity and personal data, the voluntary nature of participation,

the right to refuse or withdraw at any time without consequence, and researcher contact information.

Stage 3: Phone Number Verification (PNV) and Sociodemographic Questionnaire

After the informed consent is signed, the FF performs Phone Number Verification (PNV) to ensure the number is active and can be used for Health Communication. Participants then complete a short sociodemographic questionnaire (approximately 10 minutes) that covers maternal age, education, socioeconomic status, parity, gravida, pregnancy history, JKN ownership, mobile phone ownership, marital status, and decision-making autonomy.

2.5.3 Data Management

In this study, the data custodian for all health data is the Garut District Health Office. Summit Institute for Development (SID) acts as the technical data manager based on a cooperation agreement that includes a Non-Disclosure Agreement (NDA) regarding the management of Electronic Medical Records (EMR).

2.5.3.1 Data Collection

Data collection is conducted at several time points throughout the study:

a. Baseline Data (Pre-Intervention)

Baseline data are collected retrospectively from routine service registers (LegacyApps, SIGIZI, EMR, ASIK) after individual informed consent is obtained. Data include demographic characteristics of pregnant women, ANC visits, pregnant women's health status records, and monitoring of pregnancy risk factors. Periodic data collection follows the antenatal visit schedule recorded in the health service system.

b. Intervention Monitoring Data: November 2026 – May 2027

During the intervention period in each wave, data are collected from multiple sources: KuApps (outreach service data), EMR and Ministry of Health applications (in-facility data), AI-OCR (Buku KIA digitalization), and Health Communication (communication and follow-up data). The PWS Dashboard functions as a real-time data quality monitoring mechanism.

c. Puskesmas Operational Data (Phase 2.2: KuApps Utilization)

Carried out when Puskesmas enter the intervention phase after baseline, covering seven operational indicators:

1. Drug Stock Outs
2. Puskesmas Performance Assessment (PKP)
3. Workload per Health Worker
4. ANC Contact by Cadres
5. Active Health Workers Using KuApps
6. Availability of Digital Infrastructure
7. Timeliness of Reporting

2.5.3.2 Data Processing

All collected data will undergo data cleaning, coding, and anonymization procedures. Data cleaning will include checks for completeness, consistency, missing values, and duplication. Incomplete or invalid responses are handled according to predefined criteria.

Data from multiple sources (KuApps, LegacyApps, PWS Dashboard, AI-OCR, HealthComm, and operational logs) are integrated into a unified database for analysis. Variables are coded and transformed as needed; for example, categorical responses will be assigned numerical scores, rubric-based assessments will be standardized, and composite indices will be computed.

Each participant will be assigned a unique identifier to ensure data confidentiality. All personally identifiable information will be removed or replaced with these identifiers,

so that only anonymized data are used in the analysis process. Statistical analyses will be conducted using SAS version 9.4 and R.

2.6 Data Analysis

Statistical analysis follows the design and analysis framework for stepped-wedge cluster randomized trials by Hussey and Hughes (2007). The analysis is conducted by the study's analysis team under the supervision of the Principal Investigator, according to the Statistical Analysis Plan (SAP), which is locked before allocation is revealed.

2.6.1 Descriptive Analysis

Descriptive analysis is used to describe participants' demographic characteristics (such as education level, maternal age, etc.), map health service coverage (ANC, PNC, and neonatal), and identify the distribution of pregnancy outcomes. At the baseline starting point, no clusters will have crossed over to the intervention, as all clusters will be in the control period. There is no significance test for baseline balance.

Continuous variables are presented as means and standard deviations (or median and ranges, as appropriate), while categorical variables are summarized using frequencies and percentages.

2.6.2 Inferential Analysis

Primary Analysis: Generalized Linear Mixed Models (GLMM)

The primary analysis uses a GLMM approach with a logit link and binomial error, fitted to binary data at the mother × gestational-age window level. To control for secular trends, calendar period is modeled as a categorical fixed effect in the primary analysis model. This model includes a non-categorical fixed effect intercept for the gestational-age window (three levels), an intervention exposure indicator, and three random effects:

a. Cluster random intercept to account for different baselines across Puskesmas and the correlation of individuals within the same Puskesmas.
b. Cluster × period random effect to account for cluster autocorrelation.
c. Random intercept for mothers nested within clusters, indicating that each mother contributes up to 3 correlated observations.

Although the analysis is conducted at the pregnant woman level, the independent unit in this study is the Puskesmas because randomization is performed at the Puskesmas level.

Sensitivity Analysis: Generalized Estimating Equations (GEE)

GEE is used as a complement and sensitivity test to estimate the population-averaged effect of the DED ecosystem intervention. The average effect of DED across all Puskesmas is calculated using a nested block-exchangeable working correlation structure and robust variance estimation. With a total of 45 clusters, small-sample variance correction is applied to avoid Type I error inflation. The consistency of the direction and magnitude of the effect between GLMM and GEE will be assessed to ensure the robustness of the conclusions.

Delayed Treatment Effect

The delayed treatment effect will be considered given that the implementation of a digital system requires an adaptation period. This will be handled by modeling based on exposure time.

Single Primary Outcome and Multiplicity Control

This study establishes a single primary outcome, namely gestational-window ANC completeness, which is tested at a two-sided significance level of $\alpha = 0.05$ without requiring multiplicity adjustment, as there is only one pre-specified comparison tested inferentially. Other secondary outcomes are grouped into three families (Family A: maternal services; Family B:

neonatal services; Family C: pregnancy and delivery outcomes), each controlled using the Benjamini–Hochberg False Discovery Rate (FDR) procedure at a 5% level within each family.

Survival and Trajectory Analysis

Survival analysis is used as a secondary analysis to follow all pregnant women longitudinally across all 45 Puskesmas, starting from gestational age < 14 weeks (K1), to determine whether the intervention increases pregnant women's chances regarding the completeness and timeliness of ANC prior to delivery, and whether such completeness can be achieved earlier. Two models are used:

1. Cause-specific Cox hazard model for completion, containing a time-varying DED indicator, a time-varying calendar period, a gestational age time axis with delayed entry, and a shared frailty component at the Puskesmas level.
2. Cumulative incidence function (CIF) of completion at 40 weeks of gestation, estimated using the Aalen-Johansen estimator, calculated per randomized sequence, and reported as the inter-sequence difference with cluster bootstrap confidence intervals.

Multistate Trajectory Analysis

Trajectory analysis is used as an extension of the time-to-event framework. The pathway includes ANC1 visits, ANC6 visits, delivery, through to PNC, modeled as a multistate process to capture delays and accelerations not visible in aggregate models. The results of this trajectory analysis are reported as secondary and descriptive.

Cost-Effectiveness Analysis

The cost-effectiveness analysis is conducted based on the CHEERS 2022 guidelines (Husereau et al., 2022) and standard methods (Drummond et al., 2016; Glick et al., 2015). The following steps are performed: (a) determining the incurred costs and time horizon during the study; (b) identifying and measuring the utilization of DED ecosystem resources (training, infrastructure, dashboards, technical support, digital interoperability, and service costs); (c) valuing costs according to their source and expenditure period; (d) establishing the measure of effectiveness, namely the incremental cost per additional service delivered and the cost per DALY averted or per completed continuum of maternal care; (e) calculating the ICER (ΔCost / ΔEffect); (f) conducting alternative testing through statistical simulations (bootstrap, CEAC, sensitivity analysis); (g) reporting the comparative efficiency across intervention versus control clusters.

Safeguards and Negative Controls

Safeguards that must be reported alongside the primary results include: (1) negative control outcomes such as the proportion of male infants and the distribution of maternal blood types, which are impossible to be influenced by DED; (2) documentation process controls, namely the completeness of administrative fields that do not contain services, such as maternal height, education, and blood type; (3) bounding analysis, which brackets the primary estimate between two opposing assumptions; (4) differential exclusion diagnosis, to ensure the intervention does not subtly alter the composition of observed subjects. If negative controls or documentation process controls indicate a general shift in recording behavior, the primary estimate must be reported as uninterpretable as a service delivery effect.

2.7 Ethics Considerations

This study has been designed to adhere to the ethical principles of research involving human subjects, including respecting the rights, dignity, and welfare of participants. Prior to implementation, the study will obtain approval from the relevant Ethics Committee (KEPK) to ensure that all aspects of the research comply with applicable ethical standards.

2.7.1 Informed Consent

Each selected participant will be provided with comprehensive information about the study's objectives, benefits, potential risks, and procedures. This information will be delivered in both written and verbal forms in plain Bahasa Indonesia that is easy to understand, supplemented with the local regional language if needed.

The informed consent provided by the mother focuses on three components of agreement:

1. The mother's participation in the study;
2. The acceptance of Health Communication services;
3. Permission for researchers to access previously recorded service data, including medical records and KIA book data.

If the mother does not provide consent, her retrospective data will neither be accessed nor used in the analysis. For subjects unable to provide consent themselves due to limited legal capacity or medical condition, consent will be sought from the legal guardian/closest responsible family member, in accordance with applicable regulations.

Special Protection for Participants Under 18

This study includes pregnant women aged 18 years or younger as research subjects. This group is not excluded because it carries a higher pregnancy risk and should not be excluded from the research evidence base. For pregnant women under 18, the following provisions apply: (1) Permission is given by parents or a legal guardian, unless the prospective participant is legally married; (2) In addition to parental/guardian permission, the prospective subject must provide assent to the researcher; (3) If the prospective subject refuses to participate even though the parent/guardian has given permission, the subject will not be enrolled; (4) Pregnancy status will not be disclosed to other parties without the individual's permission.

2.7.2 Confidentiality and Privacy

Participants' personal data will be kept confidential using a coding system to protect their identities. Only the principal investigator and authorized team members will have access to the data, which will be stored in a secure system. Research findings will be presented in aggregate form without disclosing individual information. Data protection mechanisms include:

a. Access control: data center with controlled access.
b. Encryption: all digital data encrypted.
c. Role-based permissions: user access restricted through role-based permissions, authentication, and detailed access logs.
d. De-identification: participant information anonymized using unique study codes.
e. Role-based access control in KuApps: BidanKu, KaderKu, and Field Facilitator accounts have different levels of access according to their respective authorities.
f. Role-based access control on the PWS Dashboard: Puskesmas can view by-name-by-address data only for their working area, while the District Health Office receives only aggregate data.

All data within the DED ecosystem are consolidated at the district level and stored on Google Cloud Platform (GCP) servers located in Jakarta, Indonesia. No participant health data is transferred or stored outside the territory of Indonesia, in accordance with the provisions of Law No. 27 of 2022 concerning Personal Data Protection.

2.7.3 Participant Safety

This study does not involve the administration of medications, vaccines, or additional clinical procedures, so there are no clinical adverse events resulting from the research intervention. However, there is a possibility that cases or adverse events may occur related to data entry and digital systems, which will be recorded and followed up. Types of adverse events relevant to the nature of the intervention include:

a. Events related to data security and confidentiality (suspected leaks, unauthorized access, or loss of health data).
b. Events related to system functionality that impact service delivery (digitization or AI-OCR reading errors, system disruptions or failures).
c. Complaints, inconveniences, or adverse impacts reported by participants or healthcare professionals.

Reporting is carried out sequentially to the Principal Investigator, and data incidents are reported to participants and the Ethics Committee within 3 × 24 hours, as required by Law No. 27 of 2022.

2.7.4 Voluntary Participation

Participation in this study is voluntary. Participants have the right to refuse to participate or withdraw from the study at any time without any negative consequences to the health services they receive.

No incentives are given to pregnant women who participate and complete the full data collection series through the end of the study or through delivery, given that all pregnant women continue to receive health services according to applicable standards, whether in the control or intervention period. Transportation cost reimbursement is also not provided, because the study does not require participants to visit the Puskesmas outside their regular service schedule.

2.7.5 Transparency and Accountability

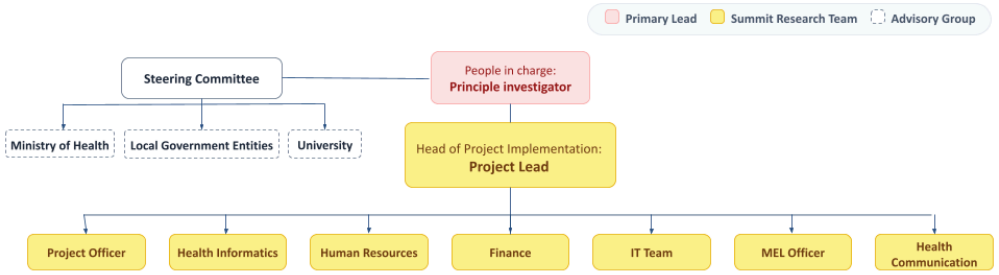
This study will be conducted with full transparency, and the results will be reported honestly and made accessible to relevant stakeholders. The procedures will comply with national and international research ethics guidelines, including the Declaration of Helsinki. This study also complies with the Personal Data Protection Act No. 27 of 2022 in the Health Sector to protect patients' personal data.

The research findings are planned for publication in the fields of public health, epidemiology, maternal and child health, digital health systems, and health policy. Publication standards will adhere to the recommendations of the International Committee of Medical Journal Editors (ICMJE). If the research results are negative or show no intervention effect, the findings will still be reported objectively through official reports, scientific publications, or communication to the relevant institutions.

CHAPTER 3
IMPLEMENTATION PROGRAM

3.1 Research Committee Structure

In this research, the SUMMIT team has established a close collaboration with the Steering Committee, which comprises the Garut District Health Office, the Garut District Government, and the Ministry of Health of the Republic of Indonesia (through TTDK/Pusdatin). This collaboration is crucial to ensure the sustainability of the implemented programs. Support from Gates Foundation (GF) as a donor, together with collaboration with other research institutions, strengthens implementation.



The SUMMIT Team

a. Principal Investigator (PI)
- Focuses on the scientific and academic aspects of the research, directing and designing the study.
- Responsible for research design, methodology, and scientific validity.
- Makes key research decisions.
- Leads a team of scientists and researchers.
- Oversees the use of research data.
- Responsible for reporting research findings to sponsors or scientific journals.

b. Project Lead
- Focuses on project management and operational execution.
- Supports research design, methodology, and scientific validity.
- Responsible for daily management, timelines, and project target achievements.
- Manages the budget within the project's scope.
- Coordinates the team to ensure the project runs as planned and on schedule.
- Reports project progress to partners and management.

c. Research Assistant (RA)
- Assists in technical and administrative research tasks.
- Person in charge for DED field activity implementation.
- Collects data, supports research administration.
- Works under the supervision of the Project Lead.
- Reports work results to the MEL Officer

d. Field Facilitator (FF)
- Responsible for participant recruitment in the field.
- Carries out the informed consent process and Phone Number Verification (PNV).
- Collects sociodemographic data from participants.
- Works under the supervision of the RA.

e. Enumerator
- Responsible for collecting routine service data from Puskesmas.
- Performs Buku KIA digitalization through AI-OCR.
- Performs verification and validation of field data.

- Works under the supervision of the RA.

f. MEL Officer (Monitoring, Evaluation, and Learning)
- Prepares required documents for ethical registration and clinical trial registration.
- Designs and supports data collection.
- Oversees data quality and ethical research practices.
- Identifies implementation challenges and recommends adjustments.
- Documents lessons learned and best practices.
- Works under the supervision of the Project Lead.

g. Health Communication
- Service Introduction and Contact Validation, including active number validation, explanation of purpose/scope/channels
- Make a schedule for education via WhatsApp Channel every Tuesdays and Thursdays, topics covering pregnancy → childbirth → postpartum → infants → toddlers → nutrition → immunization, systematic content calendar
- Segmented Automated Messages (Blasts), including 9 reminder types (ANC, ANC follow-up, care gap, birth confirmation, PNC/KNKF, PNC follow-up, immunization, Posyandu, wellness tracking), with interactive buttons and response verification logic
- Birth Confirmation while sending at 36–40 weeks, triggers status updates and activates postpartum sequence, protocol for unconfirmed cases by the end of week 40 (home visit)
- Create a two-Way Consultation via WhatsApp, including team authorization scope, limitations (no clinical diagnosis/decision-making), consultation logs (timestamp/topic/urgency level/action taken/escalation/status)
- Conduct call Center Follow-Up, 6 conditions triggering calls, 1×24-hour rule for non-urgent cases, operational hours 08:00–21:00 WIB, response time <1 hour for urgent cases, guidance for messages received outside operational hours
- Make an Initial Assessment, Triage & Escalation, strict distinction between initial assessment vs. clinical assessment, handover mechanism to midwives/Puskesmas (community health centers), confirmation of receipt
- Service Recording, Monitoring & Feedback, 9 tracked indicators (messages sent/read/responded to, call reach rate, response time, escalations, resolution status, care gap)

h. Finance
- Identifies and develops strategic partnerships.
- Manages partnership outreach, engagement, and relationship-building with key stakeholders.
- Leads partnership negotiations and formalization processes, including MoUs and collaboration agreements.
- Coordinates external partners and collaborators.

i. General Affairs
- Manage logistics and operations to ensure smooth research implementation
- Ensure facility, equipment, transportation, and administrative needs are well met

j. Project Officer
- Coordinate training programs for frontline health workers (midwives, vaccinators, nutritionists, and cadres) on DED 2.0 digital tools, including KuApps, PWS Dashboard, and AI-OCR.
- Oversee the preparation of field trainers and champion teams to deliver wave-specific orientation and ensure smooth rollouts across Puskesmas.
- Manage capacity-building activities for district IT/data staff regarding dashboard customization, FHIR mapping, EMR integration and registration in Plataran Sehat
- Stakeholder Engagement and Change Management: Engage with District Health Office (DHO) and Puskesmas leadership to drive managerial mindset shifts, performance assessments, and staff retention strategies

- Monitoring, Evaluation & Learning (MEL) Support: Collaborate with the MEL Officer to conduct pre-post assessments, track training effectiveness, refine toolkits, and document key lessons learned

k. IT Team
   - Develop and operate intervention ecosytems, including KuApps, PWS Dashboard, DWS, and AI OCR
   - Giving the research team the exports and log data they need, such as KuApps and LegacyApps usage logs for the digital adoption indicators
   - Keeping the data pipeline identical in control and intervention periods, so outcome measurement doesn't change when a cluster crosses over
   - Managing the Google Cloud Platform environment in Jakarta that consolidates all DED data

l. Health Informatics
   - Map and validate FHIR resources and terminology to ensure accurate data integration between the FHIR server and SATUSEHAT, Indonesia's national health data platform
   - Perform QA and validation of FHIR scripts, catching integration issues before deployment
   - Deliver FHIR Introduction training sessions for regional stakeholders and new team members, supporting onboarding and platform rollout across Indonesia
   - Coordinate with cross-functional stakeholders to keep interoperability projects aligned with goals and deadlines

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