INFORMED CONSENT FORM

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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IMPORTANT INFORMATION SHEET FOR PROSPECTIVE RESPONDENTS

A. Research Title :

Impact Analysis of the Implementation of the Digitally Enabled District (DED 2.0) on Maternal and Neonatal Services in Primary Healthcare

B. Researchers :

Principal Investigator	:	Yuni Dwi Setiyawati
Institution	:	*Summit Institute for Development*
Research Team Member	:	Muhammad Rizky Widodo, Dea Nurizza Allafia, Shabrina Arifia Qatrannada, Fika Rizkyanti, Hukma Shabiyya, Santi Deliani Rahmawati, Muhammad Angga, Azka Aghnianuri, Yobi Aditias, Ridwan Muhammad Syahrul, Lia Rosida
Research Location	:	Garut Regency

C. Research Background :

Monitoring the health of pregnant women through timely, high-quality antenatal care is an important component of efforts to reduce the risk of pregnancy complications and thereby contributes to reducing maternal mortality and morbidity. Quality antenatal care enables health workers to detect risk factors early and provide appropriate interventions throughout pregnancy until delivery. Garut Regency is one of the areas that still faces challenges in improving maternal and child health. According to health data for Garut Regency, maternal and neonatal deaths remain above the SDG targets. This underscores the need to strengthen the system for monitoring pregnant women's health and for early detection of pregnancy risk factors in order to prevent complications.

In recent years, the use of digital technology in health services has grown. Various forms of digital technology have begun to be used to improve the quality of antenatal care. In practice, however, health workers face obstacles because health information systems remain fragmented. Many applications are used separately, resulting in duplicate recording, inconsistent data, and delays in decision-making. In addition, most systems function only as reporting tools, without providing feedback that can be used immediately to improve services. As a result, health workers are burdened by repeated recording and are less able to provide direct care to pregnant women.

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The Digitally Enabled District (DED) program is a strategic solution to these problems. DED is an effort to support the use of digital systems in health services at the district level, including in the recording and monitoring of maternal health services at primary health facilities. DED integrates digital systems at the district level so that health data are recorded more completely, on time, and in a way that is visible as a whole. With this integration, health workers are no longer burdened by repeated recording and can focus on providing direct care to pregnant women. DED not only improves the recording system, but also helps address obstacles in the field, strengthens maternal and neonatal monitoring, and contributes to reducing maternal and infant mortality in areas such as Garut Regency. Thus, Summit Institute for Development is conducting this research to assess the impact of implementing the Digitally Enabled District (DED 2.0) on maternal and neonatal services in primary healthcare.

D. Research Objective :

This research aims to evaluate the impact of the phased implementation of the DED ecosystem in Puskesmas (community health centers) on the use of maternal and neonatal health services and on pregnancy outcomes in Garut Regency. Therefore, to achieve this, the study uses a Randomised Controlled Trial (RCT) design with a stepped wedge cluster model, in which the Puskesmas is the unit of the intervention. In this case, puskesmas are randomly assigned to control and intervention groups. Every three months, 15 Puskesmas move in stages from the control groupsperiod to intervention groups. Every three months, 15 Puskesmas move in stages from the control phase to the intervention phase, until all Puskesmas have received the DED ecosystem over a 12-month period from November 2026 to May 2027. Determining the order through randomization and in stages is the fairest and most optimal way to distribute access to the DED ecosystem intervention.

The evaluation assesses improvements in several aspects of service. First, the use of maternal health services, including the completeness and timeliness of antenatal care (ANC) and postnatal care (PNC) examinations. Second, the use of infant health services, through the completeness of neonatal visits and adherence to infant examination standards. Third, pregnancy and delivery outcomes, both in terms of services (place of delivery, birth attendant) and clinical outcomes (pregnancy outcome, low birth weight, and management of complications). The study also takes into account other factors that may influence outcomes, such as Puskesmas conditions (number of health workers, area accessibility) and maternal conditions (age, education, pregnancy history). This design shows how implementing the DED ecosystem helps improve the quality of maternal and neonatal health services, and supports better pregnancy and delivery outcomes in Garut Regency.

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E. Research Method :

This study uses a stepped-wedge cluster randomized trial design. Randomization is used to determine the order in which Puskesmas receive the DED program intervention. In this way, each cluster (Puskesmas) moves gradually from the control group to the intervention group. The study is unblinded because the intervention is a digital system operated directly by health workers, so it cannot be concealed. Because the study is open-label, you have the right to know your Puskesmas's status at the time you give consent, namely whether your Puskesmas is currently in the control period (standard care) or already in the intervention period (the DED ecosystem). The order of the waves for all Puskesmas is determined once through randomization before the study begins, and you may ask the researchers at any time about the estimated transition schedule for your Puskesmas. What will not be disclosed until the analysis is complete is the result of comparisons between groups, not your group status.

What does this stepped-wedge design mean to you?

The DED program cannot be implemented in 45 Puskesmas on the same day because of limits on staff and infrastructure. Therefore, the Puskesmas are divided into 3 waves of 15 Puskesmas each. The order of the waves is determined by lottery (randomization), not chosen on the basis of who is judged to need it more or who is easier to reach. This lottery method was chosen precisely because it is fair.

Estimated transition schedule (may shift by up to 1 month):

1. Wave 1 (15 Puskesmas): begin using DED on November 2026
2. Wave 2 (15 Puskesmas): begin using DED on February 2027
3. Wave 3 (15 Puskesmas): begin using DED on May 2027
4. All 45 Puskesmas will be using DED fully from May 2027

Before your Puskesmas transitions, you will continue to receive pregnancy care in accordance with the current national standards. No service is reduced, delayed, or withheld. The only difference is how health workers record and monitor service data. Because you are served by a specific Puskesmas, you cannot choose which wave you are in. The researchers also cannot change the order that has already been drawn.

F. Research Procedures :

The research procedure begins with recruiting participants through primary health care facilities (Puskesmas). Participants who meet the inclusion criteria will be given an explanation of the purpose, procedures, and their rights before being asked to sign written informed consent. After signing informed consent, participants will be briefly interviewed by a field facilitator (enumerator) about sociodemographics. Medical records and the Puskesmas's existing routine registers, such as the KIA book (Maternal and Child Health

Handbook), the maternal cohort register, and so on, will also be accessed for ANC visit history before the study begins (August–September 2026). The intervention is then delivered using the stepped-wedge cluster randomized trial design, in which Puskesmas move in stages from the control group to the intervention group through implementation of the DED ecosystem.

Transitions occur every three months, with about 15 Puskesmas in Garut Regency moving from the control phase to the intervention phase in each period. This process takes 12 months, so that all Puskesmas will receive the DED intervention in full. The program starts in November 2026 and will reach full coverage in May 2027. With the implementation order determined randomly, this design ensures that the study remains fair and consistent with ethical principles and clinical trial standards, so that all Puskesmas ultimately benefit from the intervention.

Throughout the study period, maternal and neonatal health service data will be monitored systematically. Outcome monitoring is carried out by collecting data on health services for pregnant women from early pregnancy through delivery at health facilities in the study locations in Garut Regency. Data are obtained from the health service recording systems and medical records used by health workers. Data analysis is carried out to assess the completeness and timeliness of services, as well as pregnancy and delivery outcomes.

Therefore, if you are willing to participate in this study, the researchers will carry out the following activities:

Therefore, if you are willing to participate in this study, the researchers will carry out the following activities:

a. The researchers will collect information about your pregnancy condition and the health services you receive. Monitoring is carried out from pregnancy, after delivery, until the newborn period. This information is taken from health service records at health facilities, such as records of pregnancy examinations, your postpartum health examinations, and records of the baby's visits and examinations.
b. The researchers may ask you to answer several questions through a brief interview or questionnaire about your experience of receiving health services during pregnancy, after delivery, and through the newborn period.
c. The researchers will monitor information about the health services you receive during pregnancy, after delivery, and through the newborn period through the health recording systems used by health workers at health facilities.

Mothers who agree to participate in this study will receive the DED ecosystem as follows:

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1. Health Communication

Health Communication (HealthComm) is a communication and follow-up service that connects pregnant women, postpartum mothers, and mothers of infants and toddlers with health workers through WhatsApp and a call center. HealthComm does not replace clinical examination, diagnosis, medical management, or direct emergency services. When you are in the intervention phase, you will receive the following services:

1. **Contact validation and service introduction**

   Your phone (WhatsApp) number will be validated to make sure it is active and used by you. After validation, you will receive information about the purpose, scope, and use of the HealthComm service, including how to ask questions, use the consultation service, contact the call center, and seek help if you experience complaints or danger signs.

2. **Scheduled health education via WhatsApp Channel**

   You will receive health education messages through a WhatsApp Channel twice a week (Tuesdays and Thursdays) covering health during pregnancy, birth preparation, the postpartum period, infant and toddler health, breastfeeding, immunization, nutrition, and child growth and development.

3. **Reminder and service confirmation messages**

   You will receive direct messages tailored to your stage of pregnancy and your service schedule, including: reminders for pregnancy check-up visits (ANC), follow-up after ANC visits, identification of service gaps (care gaps), birth confirmation, reminders for postpartum and neonatal visits (PNC/KNKF), follow-up after PNC visits, immunization reminders, Posyandu visit reminders, and periodic condition monitoring (wellness tracking). Some of these messages include response options or interactive buttons so that it is easy for you to confirm.

4. **Birth confirmation**

   At 36–40 weeks of gestation, you will receive a message to confirm whether you are still pregnant, have given birth, or have had a miscarriage. This information is used to update your status and activate the next series of communications (postpartum messages, neonatal visits, immunization). If your status cannot be confirmed by the end of week 40, you will be followed up through a home visit and/or coordination with health workers.

5. **Consultation and two-way communication**

   You can respond to messages you receive, ask questions, or raise complaints through the service's WhatsApp number. The HealthComm team will provide initial information in accordance with guidelines and the scope of its authority. Questions or complaints that require clinical assessment will be forwarded to a midwife or an authorized health worker. The HealthComm team does not provide diagnoses or make clinical decisions.

6. **Follow-up through the call center**

   If a WhatsApp message is not delivered, the number is inactive, or you have not responded, the HealthComm team may contact you by phone. The call center operates from 08.00 to 21.00 WIB. HealthComm is not a 24-hour emergency service. If you experience danger signs or an emergency outside operating hours, you are directed to immediately contact a health worker or go to the nearest health facility.

7. **Initial assessment, triage, and escalation**

   Questions and complaints received will be classified by level of urgency. The HealthComm team's assessment is an initial assessment based on communication information and does not replace clinical assessment or diagnosis by health workers. Cases that require clinical assessment will be forwarded to a midwife, Puskesmas, or relevant health facility. If the information received indicates possible danger signs, you will be directed to immediately access an appropriate health facility, and the relevant health workers will be notified according to the applicable escalation mechanism.

2. AI-OCR

AI OCR (Artificial Intelligence Optical Character Recognition) is a web-based application that reads handwriting from photos or PDF files of the KIA Book and converts it into structured digital data that can be stored. The photos are not stored on the health worker's phone, but are sent directly to a server located in Jakarta. The system's readings are always re-checked by health workers before being saved, to ensure that your data are recorded correctly.

3. KuApps

Health workers such as cadres (kader) and midwives will use a mobile app to record maternal health service data during activities outside the Puskesmas, such as home visits and Posyandu. This application replaces manual recording so that your data are recorded more

completely and do not need to be written repeatedly. The recorded data include your identity as well as relevant health service history and plans.

4. DWS

This system helps health workers schedule field activities, such as Posyandu activities and home visits, so that services can be delivered on time and according to need. You do not interact directly with this system, as it is used by health workers to ensure you receive services according to schedule.

5. Dashboard PWS

Maternal health service data recorded at the Puskesmas will be displayed as a summary on a computer screen (dashboard) used by health workers and program managers. This dashboard helps health workers monitor whether you have received the services you should receive, and identify any services you have not yet received. Health workers at a Puskesmas can only view data from their own working area, so your data cannot be seen by other Puskesmas.

G. Participants Criteria:

Prospective research participants are pregnant women who meet the inclusion criteria in the working areas of the selected Puskesmas. Participants are invited to take part because this study aims to assess the completeness and timeliness of maternal health services from pregnancy through delivery. The involvement of pregnant women is therefore essential so that the data obtained match the study's objectives, and participation in this study is voluntary.

Inclusion criteria:

1. Mothers who reside within the service area of a participating Puskesmas in Garut Regency during pregnancy;
2. The pregnancy is registered in the maternal health records at a participating Puskesmas in the study service area in Garut Regency;
3. The pregnant woman gives informed consent to participate in the study;
4. Has data on gestational age, estimated date of delivery, and key maternal service dates, including pregnancy registration and ANC visits.

Exclusion criteria:

1. Participants who are permanently relocated outside the study area before the outcome observation window begins.
2. Pregnant women under 18 years of age.

3. Pregnant women under 18 years of age may be included in this study because this group in fact has a higher pregnancy risk and should not be left out of the study evidence. The following additional protections apply to this group:

- Permission is given by a parent or legal guardian, unless the prospective participant is already legally married, in which case she is considered legally competent and gives consent herself in accordance with applicable provisions;
- In addition to parental/guardian permission, the prospective participant herself must give personal assent using the adolescent version of the information sheet, in simpler language;
- The adolescent prospective participant's refusal is still respected even if the parent/guardian has given permission;
- Interviews are conducted privately, and pregnancy status is not disclosed to others without the participant's permission.

H. Participant Rights

If you participate in this study, you have several rights to:

1. Refuse to participate in the study
2. Withdraw from the study
3. Ask the researchers for information about this study
4. Request information about your health data used in the study
5. Receive an explanation if, during or after the study, important health information is found that is significant to the safety of life
6. Receive information about unexpected findings, should they occur
7. Access relevant medical data obtained during the study upon request. If there are temporary or permanent restrictions on data disclosure based on a decision of the ethics committee, you will be informed along with the reasons.
8. Competent adult women have the absolute right to give consent to participate independently, without requiring permission or consent from a husband or family. Guardianship applies only in conditions of medical condition/capacity that legally restrict decision-making, with an obligation on the researchers to document the reasons for guardianship.
9. With regard to HealthComm, you may decline to receive WhatsApp messages at any time without leaving the study and without affecting your health care.

All of these rights can be exercised without affecting your right to receive health services. If you decide to withdraw from the study: (1) collection of new data about you stops immediately; (2) you may request that data already collected but not yet analyzed be destroyed; (3) data that have entered a locked analysis cannot be withdrawn because they can no longer be linked to your identity; (4) your routine

health service records at the Puskesmas remain as medical records and are not destroyed, because this is an obligation of the health facility, not part of the study; and (5) your withdrawal has no effect whatsoever on your right to receive health services.

Consent at the Puskesmas (Cluster) Level

As what is randomized in this study is the Puskesmas (not you personally), the decision to participate as a study site is given by the Garut District Health Office and the Head of the Puskesmas. Your consent in this sheet is personal consent for: (a) your service data to be used as research data, (b) you to be interviewed, and (c) you to receive health reminder messages. If a Puskesmas or the District Health Office decides to withdraw from the study, your health services will continue as usual and you will be informed.

I. Duration of Participation in the Study

Your participation in this study will last from early pregnancy until after the delivery process (postnatal services or postpartum visits).

J. Incentives

No payment or reward is given to encourage you to take part in the study, so that your participation is truly voluntary and not coercive. However, if an interview requires you to come to the Puskesmas specifically for research purposes (not on your ANC visit schedule), you will be given reasonable transportation reimbursement so that participation does not burden you economically. This reimbursement is not compensation for participation. In addition, the unit of study is the cluster (Puskesmas), not the individual, so individual incentives are not relevant in this study.

K. Research Risks

This study does not provide any additional medical procedures to you. All health services you receive continue to follow the service procedures in force at the health facility. The risks of this study are considered minimal, namely:

1. mild discomfort when answering interview questions (the interview is expected to take 15–20 minutes; you may decline to answer any question, or ask for the interview to be stopped or rescheduled);
2. data confidentiality risk, because your health data are recorded in a digital system;
3. possible temporary disruption to service recording if the digital system experiences technical problems. In such cases health workers will continue to record manually so that your care is not interrupted; and
4. Puskesmas in the last wave receive the DED ecosystem about 6 months later than the first wave. Please be aware that this delay is NOT a withholding of services: during the control period, all pregnancy services continue to be provided according to the national standards currently in force, and to date there is no scientific evidence

confirming that the DED ecosystem is better than current recording practices. That is precisely why this study is being conducted.

L. Data Confidentiality

To minimize research risks, all information collected in this study will be kept confidential in accordance with Law No. 27 of 2022 on Personal Data Protection (UU PDP). This is the the detail information:

1. Your name is replaced with a unique code; the list linking codes to identities is stored separately in an encrypted file that can only be opened by the Principal Investigator and the Data Manager;
2. Electronic data is stored on servers with role-based access, and access trails are logged;
3. Data are stored for 5 (five) years after the study ends, then permanently destroyed;

Study results are reported only in aggregate form, not per person and not per Puskesmas in a way that could identify individuals;

4. Your data will NOT be sold, and will not be used for other future research without new consent from you and ethics committee approval;
5. In the event of a data breach, you and the Ethics Committee will be notified within a maximum of 3x24 hours in accordance with the PDP Law.

Please be aware that the health reminder service (health communication) is sent through the WhatsApp application, so your phone number and message content are also subject to the privacy policy of the WhatsApp provider. You may decline to receive WhatsApp messages at any time without leaving the study and without affecting your health care.

M. Research Benefit

1. For you as a pregnant woman
   As a research participant, you may not obtain a direct medical benefit from taking part in this study. After your Puskesmas moves to the intervention period, you can receive reminder messages through health communication regarding ANC visits, Posyandu visits, and consultation if you have any complaints as a pregnant woman. You will also receive monitoring of the health services you receive from pregnancy through delivery, through the recording and evaluation of service data.
2. For the community
   This study is expected to contribute to improving the quality of maternal and child health services in Garut Regency.
3. For science
   This study is expected to improve understanding of the use of digital systems in monitoring maternal health services.

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This study does not provide additional medical interventions or therapy to research participants. Nevertheless, the researchers are committed to ensuring that all 45 Puskesmas, including those in the last wave, will continue to have access to the DED ecosystem (KuApps, Dashboard PWS, AI-OCR, health communication, and DWS) after the study ends, through a cooperation agreement with the Garut District Health Office and the Ministry of Health. No Puskesmas will lose access when the study is completed. The health services received by participants continue to follow the service standards in force at health facilities. However, if the use of digital systems in health services proves beneficial for monitoring the health of pregnant women, the results of this study can serve as a consideration for policymakers in developing and strengthening the implementation of digital systems in health services at the regional level.

N. Funding Source

This study is supported by the Gates Foundation under Investment ID INV-083581 and does not charge you any costs.

O. Ethical Approval

This study has obtained approval from the Health Research Ethics Committee of the Faculty of Public Health, Universitas Indonesia (KEPK FKM UI) under number Ket-640/UN2.F10.ETK/PPM.00.02/2026, and is registered on ClinicalTrials.gov under number NCT07842224.

P. Researcher Contact

If you have questions about this study, you may contact the researcher at the contact below.

Name: Yuni Dwi Setiawati
Institution: Summit Institute for Development
Phone Number: 085337006810

If you have questions about your rights as a research participant, you may contact Muhammad Rizky Widodo (+6281357234931) or Fika Rizkyanti (+6289680703737).

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INFORMED CONSENT FORM

I have read or have been given an explanation of this study. I understand the purpose of the study, the procedures to be carried out, the benefits, and the possible risks of this study. I understand that my participation in this study is voluntary and that I am providing data to achieve the objectives of this study.

I, the undersigned:
Participant Name : .....
NIK : …….
Age : .....
Phone Number : .....
Address : .....
Mother code : ……..
Area code : ……..

hereby declare that I am willing to be a respondent in the study conducted by:
Researcher Name : Yuni Dwi Setiyawati
Institution : *Summit Institute for Development*
Judul Penelitian :

"Impact Analysis of the Implementation of the Digitally Enabled District (DED 2.0) on Maternal and Neonatal Services in Primary Healthcare

I sign this consent letter without coercion from any party. I understand that this study will not harm me as a respondent.

Respondent,	Witness,
Garut, ……..	Garut, ……..
SIGNATURE	SIGNATURE
(……)	(……)

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INFORMED CONSENT

For **adolescents** participating in the study: Impact Analysis of the Implementation of the Digitally Enabled District (DED 2.0) on Maternal and Neonatal Services in Primary Healthcare

I have read and understood the information in the information sheet and have been given the opportunity to discuss it and ask questions. I agree to allow my child to receive the DED 2.0 ecosystem for maternal and neonatal services in primary healthcare. I understand that I may refuse to take part in the study. I am aware that I may withdraw from this study at any time I wish.

If I do not take part in this study, my child will still receive primary health services like everyone else.

I, as the **PARENT/GUARDIAN** of .....
with contact number (mobile) ……
AGREE to participate in this study.

Date : ……

Parent/Guardian Signature : ……
Parent/Guardian Name : ……

Witness Signature : ……
Witness Name : ……

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ASSENT FORM

I understand that this study intends to trial the Digitally Enabled District (DED) ecosystem, which helps health workers monitor my pregnancy, and that I may benefit from more regular, faster, and more comprehensive pregnancy monitoring.

I understand that my health data during pregnancy, such as examination results, blood pressure, weight, gestational age, and visit records, will be recorded by health workers through a digital application, and that these data are displayed as a summary (dashboard) used by Puskesmas staff to monitor and improve services for pregnant women.

I have read this information (or this information has been read to me). I have received answers to my questions, and I understand that I can ask additional questions later.

I agree to take part in this study.

Date : ……

Child's Signature : ……

Child's Name : ……

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WITNESS FORM

(If the child participant is illiterate)

I have witnessed the accurate reading of the assent form to the child, and the child was given the opportunity to ask questions. I confirm that the child has given her consent freely.

Date : ……

: ……

Witness Signature

Witness Name (Not a Parent) : ……