Effectiveness of Quality Maternal and Newborn Health Care for Improving Continuum of Care and Maternal Satisfaction in Timor-Leste: A Type 2 Implementation-effectiveness Hybrid Quasi-experimental Trial

RESEARCH PROPOSAL VER 7

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1. Introduction

Most maternal and newborn deaths occurred in low- and middle-income countries (LMICs), and most of these were preventable with appropriate antenatal care (ANC), deliveries with skilled birth attendants (SBA) and postnatal care (PNC). (1) These three components are usually referred to as Continuum of Care (CoC), which address access to the continuity of care throughout the lifecycle, including pre-pregnancy, pregnancy, childbirth, postpartum and childhood care, from households to hospitals. (2,3) World Health Organization (WHO) (2005) emphasised the importance of accelerating the CoC approach for the integration of programmes for maternal, newborn and child health (MNCH) to ensure access to needed services within the functional linkages among levels of care. (4) The effective CoC would reduce preventable child and maternal deaths; however, scaling up effective CoC is challenging because each transition of CoC requires connections between programmes, health providers, and levels of care. (2,3)

MNCH services in LMICs are often fragmented due to the different donors and management schemes. (4) This fragmentation causes inadequate standards of care and a lack of accountability and motivation of health workers, which cause dissatisfaction for both care providers and patients. (2) This dissatisfaction can lead to low demand for care and hinder the completion of CoC. For example, Bishanga et al. indicated that the poor completion of CoC resulted from dropouts at a postnatal level due to the negative experience of care. (5) This care experience is one of the dimensions of quality of care (QoC). (6)

Therefore, CoC should be highlighted in the framework of QoC in MNCH. WHO (2016) developed standards and measures of maternal and newborn health care quality to ensure mothers and newborns receive high QoC. (6) This framework consists of two dimensions of provision and experience of care for the process improvement of QoC. (6) While the outcome of QoC, it includes coverage of key practices, people-centred outcomes, and health outcomes. (6) According to this framework, high QoC consisting of provision and experience of care will increase CoC and maternal satisfaction (coverage of key practices and people-centred outcomes). The approach to improve the provision and experience of care are necessary for improving maternal satisfaction and CoC and the integration of programmes for MNCH. A qualitative study in Uganda used this WHO framework to identify themes of quality of maternity care from a health worker's view. (7) A quantitative study in Italy developed a survey based on these WHO standards and measures to assess QoC among service users and providers after one-day training on the WHO standards for health workers. (8) Therefore, these two linked dimensions of provision and experience of care are the basic structure for quality improvement in the health system.

To improve the provision of care, skilled health workers, who have sufficient knowledge and skills to perform evidence-based practices equipped with available supplies and equipment, are necessary. (6,9) In contrast to this necessity, the evidence-based practices are limited in many LMICs due to less competent health workers and lack of supplies. (10,11) For example, some health workers in LMICs do not have enough skills to identify obstetric complications like non-cephalic presentation, multiple pregnancies, and placenta previa. (10,11) Additionally, poor gestational age accuracy is due to the limitation of clinical estimators of gestational age or inaccurate maternal memory of the last menstrual period (12,13) These misdiagnoses related to poor evidence-based practices can be improved by training health workers with equipment such as ultrasound. (14)

Many LMICs do not commonly use ultrasound, but it is an essential component of quality ANC to estimate gestational age, detect complications, and improve a women's pregnancy experience, according to 2016 WHO recommendations on ANC. (15) Ultrasound training for local health workers in rural Indonesia, Mozambique, and Guatemala showed effective results in identifying high-risk pregnancies and estimating gestational age. (10,11,16) Although ultrasound is an effective technology for evidence-based practices, it is essential to ensure that all women receive essential ANC care. In Vietnam, many women visit ANC only for the ultrasound, and they are reluctant to receive other examinations because they believe ultrasound is a complete method to manage pregnancy. (17,18) This misconception can lead health workers to overlook potential complications.

Studies in Africa showed a significant increase in the number of ANC visits four or more times and deliveries at health facilities after introducing antenatal ultrasound. (19,20) There are several reasons for these effects to motivate women to access CoC. First of all, this simple technology received remarkable attention from the communities and this improvement in technology increased trust in health services. (19) Second, ultrasound services lead to positive interactions between patients and health workers. (21,22) These positive interactions might result from increased women's trust in health care and the confidence of health workers. (20-22) Another reason was that visual images of ultrasound scans were persuasive enough to convince women and their families for a referral to deliver at health facilities. (13,23) Nevertheless, the most important reason is the psychological effects on women and their families. (18,19,24)

The image of ultrasonography can increase the emotional connections between fetuses and parents. (18,25,26) When people see the view of fetuses, they consider fetuses as real people, which results in a strong connectedness between fetuses and their families. (18,19,25) These emotional connections also encouraged males to attend ANC to see ultrasound images. (18,19,25) These positive psychological effects satisfied women and helped reduce their anxieties during pregnancy (21,27). Therefore, ultrasound can enhance both provision and experience of care.

In addition to the emotional improvement for women and their families, respectful and improved communication is essential for improving the experience of care for women and their families. (6) A study in Vietnam showed that women who received ultrasound services showed lower satisfaction than those who did not receive ultrasound services. (17) This is because they did not receive a sufficient explanation of the ultrasonography results. (17) It is undeniable that obstetric ultrasound is a valuable technology to improve evidence-based practices and manage complications, while ultrasound alone had a limited impact on increasing QoC. Therefore, providing health information and counselling with simple and clear language is crucial for strengthening the provision of care. This improved communication enables women to understand clinical explanations, and the positive attitudes of health workers enable women to interact with health workers.

Interpersonal communication skills are barriers to improving the experience of care, and language itself can be a barrier among health workers and between health workers and women, especially in multilingual societies. (30,31) Although a minimum common language is required to provide health care in India and South Africa, multilingual countries, there is no professional education to prepare for effective communication in multilingual settings. (28,29) In the United States, language barriers have emerged due to increasing population diversity. (30) These countries have faced difficulties in improving patient comprehension of treatment due to poor communication. (28-30) Meanwhile, health professionals also have

faced insufficient communication due to language barriers. In the Lao PDR, the complicated history of medical education from international involvement has caused the lack of a common professional language. (31) In Germany, the increase of foreign physicians due to the shortage of health workers results in miscommunication between foreign physicians and their colleagues. (31) These language disparities among health professionals can lower both provision and experience of care. Therefore, the minimum standard of communication tools among health workers and between health workers and women is required to improve effective and efficient provision and experience of care. (30)

A study in Ghana developed an educational and recording tool named 'CoC card' written in a simple language with many illustrations, containing the schedule and actual dates for health services, records of essential services and health education provided, and the presence of danger signs. (32) This card was a supplementary tool attached to the Maternal and Child Health Handbook (MCHB). The CoC completion rate increased significantly from 8% in the baseline to 50% after a year of intervention with the CoC card. (33) It also helped mothers and families understand CoC's importance and encouraged having a better relationship between mothers and health workers. (33,34) This positive impact of the CoC card on provision and experience of care shows that the CoC card is the possible minimum standard of communication tools. It also can be a tool to connect households to hospitals in an integrated manner which is one of the functions of MCHB. (35)

The MCHB has shown its effects in many countries to ensure service utilisation, increase health knowledge for mothers, and promote healthy behaviour. (36-38) It also functions as a checklist of service contents to provide essential health services and health information. (39) Although its function as a health record for both mothers and health workers has positive effects of increasing CoC, the lower impact of MCHB was identified among women from lower socioeconomic and with low educational levels. (37,39,40) To minimise these limitations, the CoC card has the potential to provide equal benefits to those disadvantaged women. Furthermore, the CoC card is possible to strengthen the functions of MCHB as a service checklist, which often provides fragmented service delivery in LMICs. The CoC card is a simple method to combine the fragmented programmes into a CoC approach, and it works as a reminder at a glance to mothers, which mobilises families to seek care. These improvements may encourage active communication between health workers and mothers through health education and guarantee essential service provision. (33,39) Therefore, the CoC card can be the communication tool and the integrated service delivery tool to enhance both provision and experience of care for the improvement of QoC and to ensure the CoC approach.

2. Problem Statement (study rationale)

Timor-Leste is mountainous, the eastern half of the island of Timor having 1.2 million people, with Tetun and Portuguese as official languages, English and Indonesian as working languages, and 30 other local languages. (41-43). It became a multilingual society because the Portuguese colonised Timor-Leste for 400 years, followed by 24 years of Indonesian occupation. (42,44) More than 70% of the health facilities were destroyed during the civil war, and only 31 doctors remained when it became independent. (44,45)

MNCH is a major public health issue in Timor-Leste, but its progress is slow. The maternal mortality ratio was 215 per 100,000 live births, and the neonatal mortality rate was 21.6 per 1,000 live births in 2015-2016, which was higher than those of other South-East Asian countries. (1,41) For the reduction of these mortalities, the Ministry of Health (MoH) has rebuilt its health systems, and there are one national tertiary hospital, five referral hospitals,

66 Community Health Centres (CHCs), and 192 Health Posts (HPs) so far. With the support of the Cuban Government, approximately 1,000 medical students studied in Cuba and MoH simultaneously established medical school. (44,45)

Although the development of health facilities and health workforce, CoC remains challenging. In 2016, 56.7% of the pregnant women delivered with SBA, and 48.5% of deliveries happened at health facilities. (46) While most mothers (76.7%) received ANC, only a few mothers and newborns (34.5%) received the recommended PNC, despite the increase in deliveries with SBA. (46) These are far below the national target of the National Health Sector Strategic Plan 2011-2030. (44) The increase in the number of health facilities and health workforce has not matched the increase of CoC as expected. Poor QoC is probably the most critical factor in explaining this discrepancy between the development of the health system and inadequate coverage of CoC, as mentioned above.

Determinants of poor health-seeking behaviours in Timor-Leste were geographic inaccessibility, socioeconomic status, the shortage of medical supplies and equipment, and the negative attitudes of health workers towards patients. (47-49) Additionally, the complex multilingual situation in Timor-Leste might have hindered effective communication between health workers and patients. These factors can lower the satisfaction of care. Alternatively, women tend to utilise traditional birth attendants because Timorese culturally received traditional medicine due to the suspicion of Indonesian health services during the occupation. (47,50) Other issues are the absenteeism of Cuban trained doctors and their poor performance. (45,51) To reduce mortality toward SDGs goals, increasing health facilities and health workers are not enough, and there are concerns about QoC to meet the people's preferences of care. Especially the coverage of key MCH services in this study area is poor compared to the other municipalities, and ANC is the key to increasing CoC. To increase the continuity of care, improving the QoC of ANC is important.

Few studies have been conducted in Timor-Leste to accelerate the coverage of MNCH services such as mHealth, but little evidence is available to improve QoC. (52) This study will use QoC as two components of provision and experience of care and CoC, maternal satisfaction, and health outcomes will improve when QoC increase, based on the concept of WHO framework of QoC. Additionally, the improvement of CoC requires integrated service delivery throughout the lifecycle. Iqbal et al. emphasised that the quality of ANC is related to women's use of deliveries with SBA and PNC. (53) Therefore, this study will plan an intervention, especially during the ANC period, to improve the provision and experience of care through ultrasound and CoC card.

The results of this study will have potentialities to expand to other municipalities in Timor-Leste. Also, effective interventions are necessary to increase access to high QoC throughout the CoC to all populations to achieve the Sustainable Development Goals (SDGs) for health by 2030 (1,54,55). This intervention can be a potential model of integrated QoC for MNCH throughout CoC, especially in the lower literacy level and low-resource context.

3. Conceptual framework and Study hypothesis

The Conceptual framework for this intervention study is the WHO QoC framework (6). In this framework, the health system provides the structure where mothers can access good quality care, and the provision and experience of care is part of the process that determines the QoC. As a result of the improvement of QoC, the expected outcomes are coverage of key practices, people-centred outcomes, and health outcomes. Based on this conceptual framework, this study has the following hypothesis:

(1) The quality of ANC in Ermera municipality is likely to influence the uptake of three key maternal and newborn health services.
(2) The planned intervention (ultrasound and CoC card) increases the QoC of ANC.
(3) The improved QoC through the intervention affects the uptake of continuity of maternal and newborn health services and maternal satisfaction.

4. Objectives

This study aims to assess the effectiveness of the intervention on QoC of ANC to increase CoC in Ermera municipality in Timor-Leste.

This study has the following objectives:

(1) Examine the association between experienced QoC during ANC and the CoC.
(2) Evaluate the effect of USG and CoC card intervention on the process (provision and experience of care) and outcomes (CoC, maternal satisfaction, health outcomes) of QoC.
(3) Evaluate the acceptability and feasibility of the intervention (the potential obstacles associated with its implementation).
(4) Identify the effective strategies to improve the utilisation of maternal and newborn health services in rural areas.

5. Supportive research objectives

Baseline research aims to identify factors associated with the mother's continuation of maternal and newborn health services in Ermera municipality in Timor-Leste.

This research has the following objectives:

(1) Identify the current level of CoC.
(2) Identify the current factors and barriers associated with the mother's continuation in receiving health services in the rural area.

Another aim of baseline research is to explore the perception of QoC of both mothers and health workers in Ermera municipality in Timor-Leste.

This research has the following objectives:

(1) Evaluate both mothers' and health workers' perceived QoC and satisfaction with ANC.
(2) Identify the facilitators and barriers to ANC quality in rural areas.

This study includes ultrasound training for health workers. This implementation aims to develop an effective short ultrasound training course on OBGYN for health workers at the Primary Health Care level.

This research has the following objectives:

(1) Evaluate the effect of the short ultrasound training course on OBGYN for health workers at the Primary Health Care level.
(2) Examine the changes in the patient management by ultrasound.
(3) Examine the changes in diagnosis by ultrasound.

6. Methods

6.1. Study design

This study will conduct type 2 hybrid effectiveness-implementation research, which simultaneously evaluates the effect of the intervention and assesses the implementation strategies using a quasi-experimental trial. (56) The reason for adopting a quasi-experimental trial is that the random allocation of the intervention might not be possible due to the logistical constraints and the acceptability of stakeholders. This study will use a convergent parallel mixed-methods approach to collect, analyse, and interpret quantitative and qualitative measures. A mixed-methods analysis will allow for a complete understanding of the effects on the process and outcomes of QoC. In addition, the evaluation of the implementation process will use qualitative measures. This intervention will be conducted as part of the project of the Non-profit Organization' Chikyu-no-Stage (English: Frontline)' funded by Grant Assistance for Japanese NGO Projects.

6.2. Intervention

This study has two interventions. One is the ultrasound implementation during ANC, and the other is a health promotion card called the CoC card. This study developed ultrasound training for health workers and implemented ultrasound scans at least once during the pregnancy for all pregnant women in the intervention area. We also developed a CoC card with the expert who implemented the CoC card in Ghana and will be used to use from pregnancy to postpartum care along with the ultrasound in the one CHC covered area.

6.3. Phases of implementation

This intervention study has three phases, as detailed below.

Phase1: Formative research and developing implementation materials (4 months: April 2021-October 2022)

The formative research will include a baseline survey of mothers and health workers to assess the level of CoC and QoC and focus group discussion (FGD) with community members and health workers for the situation analysis. Also, the researcher and related Chikyu-no-Stage project members will develop the CoC care card adjusted to Timor-Leste based on the CoC card in Ghana, training manual of CoC card, ultrasound training including ultrasound guidelines, training materials and ultrasound report format.

Phase2: Utilisation of CoC card and Ultrasound (6 months: From 9 May 2022 to 8 November 2022)

This study will conduct the following preparations and management for the implementation:

① Stakeholder meeting with local government officials, community leaders and community health volunteers (July 2022);

② training on the survey to selected interviewers (July 2022);

③ Ultrasound training to 12 health workers in the intervention area who are selected based on the analysis of baseline research and recommendations from key informants from local authorities (November 2022);

④ Pilot implementation of ultrasound at five health facilities in the intervention area (Four months from December 2022 to April 2023);

⑤ training on the CoC card to all health workers in the intervention area who provide MNCH services (April 2023);

⑥ On-the-Job training on ultrasound at selected health facilities; and
⑦ Monitoring.

Phase3: Evaluation of implementation and effect (1 month: October 2022- 8 November)

This phase will conduct the follow-up survey and FGD to mothers and health workers to assess the effect of the intervention.

6.4. Study area

This study selected Ermera as the research field due to the poorer coverage of maternal and newborn health services and the higher maternal, fetal and neonatal deaths cases than the other municipalities.

Ermera municipality comprises five sub-municipalities, including 52 villages with six CHCs, four maternity wards and 28HPs. (57) Ermera municipality has a population of slightly over 110,000 people, located about 30 km to the southwest of Dili, which is the national capital, and 93 % of the population live in the rural area. (46,57) According to Health Service in Ermera municipal in 2018, the coverage of ANC (4 times) was 47%, the coverage of PNC (within one week) was 35%, PNC (within 7-42 days) was 33%, the coverage of deliveries with SBA and deliveries at health facilities were 48% and 29%, respectively. (57)

This study selected an intervention group from three municipalities sorted by health units; Hatolia, Guisarudu and Gleno. This study includes Guisarudu because it is the subject of the pilot area of Frontline's project. Additionally, these two sub-municipalities are selected for geographical consideration to avoid contamination and the prioritised area by the Government. The rest of the area (Letefoho, Atsabe, Railaco and Ermera) is controlled. Most villages are scattered in the mountainous area of unpaved roads without regular transportation, and each sub-municipality has irregular public transportation between the centre of the sub-municipality and Gleno.

Hatolia includes seven villages, and the population was 19,644, with 587 pregnant women in 2020. There are CHC with a maternity ward and 5 HPs. (58)

Guisarudu includes five villages, and the population was 15,904, with 537 pregnant women in 2020. There are CHC with a maternity ward and 5 HPs. (58)

Gleno includes five villages, and the population was 19,259, with 565 pregnant women in 2020. There are CHC with a maternity ward and 2 HPs. (58)

Railaco includes nine villages, and the population was 13,387, with 421 pregnant women in 2020. There are CHC and 4 HPs. (58)

Ermera includes five villages, and the population was 24,442, with 722 pregnant women in 2020. There are CHC and 2 HPs. (58)

Letefoho includes nine villages, and the population was 24,916, with 689 pregnant women in 2020. There are CHC with a maternity ward and 7 HPs. (58)

Atsabe includes seven villages, and the population was 20,317, with 421 pregnant women in 2020. There are CHC with a maternity ward and 7 HPs. (58)

6.5. Study participants and inclusion criteria

The study population is women of reproductive age between 15 and 49 years old who live in Ermera municipality. The eligible participants will be women who have delivered between 1 January 2020 and 31 December 2020 for the baseline period and between 1 May 2022 and 26 October 2022 for the follow-up period. Inclusion criteria for the trial are pregnant women

aged between 15 and 49 years old who have the name list at the health facility and between 12 and 28 weeks of gestation in April 2022.

6.6. Sampling method and sample size

This study used multistage purposive sampling methods. First, the project team will select all villages that meet all the following criteria:

① a village with a health facility or monthly mobile clinic;
② a minimum of one doctor or one midwife to provide RMNCH services at a health facility or mobile clinic; and
③ a village with electricity or solar electric system to charge portable an ultrasound machine.

Then, the researcher purposely selected nine villages (Hatolia, Manusae, Asulau-sare, Coliate, Urahou, fatobessi, Fatobolo, riheu, Estado) for the intervention group and ten villages (Poetete, Haupu, Eraulo, Ducurai, Laclo, boboileten, Malabe, Liho, Fatuquero, Matata) for the control group considering the geographical allocation, availability of health workers to participate at the ultrasound training and availability of health volunteers to conduct the baseline survey.

Quantitative data

Trained community health volunteers will approach households having an eligible woman and invite them to participate in the survey. Those willing will participate in the survey at their home or assigned venues in their villages by the trained interviewers.

The sample size will be calculated based on the assumption that the coverage of CoC in Ermera municipality would be 11.5% in the control group based on the past study. The expected coverage of CoC throughout the intervention will be 19.5% in the intervention group, which was estimated from the study in Ghana that CoC coverage in the intervention group would increase by eight percentage points from those in the control group. (37,49,56) This study adds 10% of the calculated sample size, considering missing data. The total sample size will be 343 from the intervention group and 343 from the control group for each baseline and follow-up survey (significance level =0.05; power =0.8, enrolment ratio=1).

Qualitative data

This study will include all health facilities located in the selected intervention and control villages using the maximum variation sampling for the quality assessment of the health facility. The researcher will select twenty-five health workers who provide RMNCH services for the in-depth interviews from these health facilities. The health workers will be selected using the maximum variation sampling and considering their available time to conduct the interviews.

The participants of FGD in the formative research will be selected from the women and their families who agree to participate in FGD when CHVs approach households for the survey. The participants of FGD in the follow-up research will be selected from the women and their families who receive the intervention and agree to participate in FGD when CHVs approach households for the survey. From the list of agreed potential participants, the researcher will select villages based on the survey results using the maximum variation sampling. Each focus group size is five participants for a one-hour session, and women and

their families will be assigned to the different groups. Although this study plans ten FGD for women and ten FGD for their families, the researcher will conduct FGD until data saturation is achieved.

6.7. Data collection methods

Quantitative data

This study will collect quantitative data from women through Face-to-Face interviews using a semi-structured questionnaire using the electronic data collection tool (KoBoToolbox, the Harvard Humanitarian Initiative, MA, United States) to evaluate the effect of the intervention. The questionnaire items on the demographic information and reproductive history will be developed based on items in Demographic and Health Surveys questionnaires.(60) The questionnaire items on the QoC will be developed using the WHO quality statements and measures and the national guideline on MNCH in combination with existing evidence on the questionnaire to assess QoC. (6,8,61) To assess maternal satisfaction, the questionnaire items will be developed based on Clark's scale to assess women's perception of their entire maternity-care experience, adding questions for the intervention. (62) This scale will be used because of the unavailability of other appropriate tools that assess maternal satisfaction across the CoC, from pregnancy to postpartum. This study will design the questionnaires in English, and this study will test them after translation into the local Tetun language. The researcher will select interviewers and train them on the ethical issue, interviewing methods, the procedure of the electronic survey, and the contents of the questionnaire. The interviewers from the survey area will be selected because some women cannot speak the Tetun language fluently; instead, they speak local languages.

This study will also measure the health worker's perspective of QoC using the same questionnaire items of QoC developed for women. The trained interviewer will conduct the interviews using the electronic data collection tool.

Additionally, this study will assess the quality assessment of the health facility developed from the WHO quality statements, Demographic and Health Surveys questionnaires and the national guideline on MNCH. The trained interviewer will visit and observe the health facility using the electronic data collection tool.

Qualitative data

This study will use FGD for the situation analysis during the baseline research and the intervention assessment during the follow-up research. This study will use qualitative and quantitative data to assess maternal satisfaction during the follow-up survey. Adjei et al. found a discrepancy between quantitative and qualitative data on satisfaction with health facility delivery services in Ghana. (63) The FGD guides will be developed in English using the WHO quality statements and Demographic and Health Surveys questionnaires, and then these will be translated into the Tetun language. Then, the research member will review the content validity and reliability of the FGD guides before and after the pre-test.

For the in-depth interviews with health workers for the situation analysis during the baseline research and the intervention assessment during the follow-up research, the researcher will develop an in-depth interview guide in English. Then there will be translated into the Tetun language. Then, the research member will review the content validity and reliability of the guide before and after the pre-test.

The researcher will train the NGO Frontline local staff interviewers and facilitators on the ethical issue, interviewing methods, and FGD facilitation methods. After obtaining permission, the interviewers and facilitators will record all in-depth interviews and FGD.

This study will assess the evaluation of the implementation process through monthly Monitoring and supervision of the intervention. Additionally, this study will measure the implementation process, including the organisation's feasibility, the intervention acceptability, and the financial feasibility of implementing the intervention using the monitoring sheet and NGO Frontline's project records.

6.8. Variables

- **Primary outcome measure**: CoC completion level from pregnancy to delivery.
- **Secondary outcome measures:** CoC completion level from pregnancy to postnatal period, completion of recommended four ANC, coverage of institutional delivery, the QoC level (total 16 points of the essential ANC care received, total 7 points of the health education received, total 18 points of the experience of care), the maternal satisfaction level (total 13 points), and the selected WHO QoC health outcome (perinatal mortality rate, stillbirth rate, maternal mortality rate).
- **Covariates**: socio-demographic information (age, women and their husbands' education status and employment status, language preference, exposure to mass media, wealth index, distance to the nearest health facility), place of health facility for the first ANC, the gestational age at the first ANC, the partner's involvement in pregnancy care, health facility's physical structure level (total 50 points).
- **Process outcomes**: the number of health workers successfully trained, the pre/post-test results at the ultrasound training, the coverage of the intervention, and the implementation cost.

The research member will review the content validity and reliability of the QoC measurement before and after the formative research.

This study includes the following as CoC components by indicators of Health Service in Ermera municipality:

① Received ANC at least four times by health workers at a health facility and in the community.
② delivery assisted by SBAs at a health facility or home.
③ Received PNC at a health facility and in the community or at home, within 48 hours and between days 3-28 days.

6.9. Data analysis

Quantitative analyses

This study will use descriptive statistics (number, frequency, and percentage) for summarising the characteristics of respondents to the survey and process outcomes.

The top 20 percentile of the total scores of the QoC level will be categorised as high-quality care based on the study in Myanmar and Malawi. (65,66)

The characteristics of respondents of the survey across intervention and control areas at both baseline and follow-up surveys will be compared using unpaired t-tests/Chi-square test.

For the formative survey, the Chi-square test will examine the association between the CoC level and each variable. Then multiple logistic regression analyses will be performed to assess

the factors associated with the CoC level or QoC level. Also, the subscale scores of QoC will be calculated as the mean of the item scores in each subscale. Differences between means of subscale scores will be examined with the t-test. A P-value of ≤0.05 will be considered statistically significant.

For the follow-up survey, the characteristics of respondents of the survey and the intervention outcomes will be compared at baseline and follow-up using survey-adjusted unpaired t-tests. Also, the difference in differences (DIDs) analyses will be used to assess the effect of the intervention on the intervention outcomes over intervention periods. Unadjusted DIDs will estimate each CoC component using logistic regression models. This study will also estimate DIDs in subgroup analysis based on health facilities where women received ANC.

This study will use Stata version 15.1 (Stata Corp, College Station, Texas, United States) for analyse.

Qualitative analyses

The researcher will transcribe and develop the coding framework of in-depth interviews, quality assessment of health facility, and FGD by thematic content analysis to assess the implementation outcomes using an Excel spreadsheet. The researcher will sort monitoring and supervision records and pre/post-test results by theme and develop a thematic matrix to assess logistical challenges and solutions related to the intervention using Microsoft Excel.

Mixed-methods analyses

The researcher will create a mixed-methods matrix, and both quantitative and qualitative data will be presented together in the matrix. Then, this study will compare the similarities and differences between qualitative and quantitative data to evaluate maternal satisfaction.

6.10. Potential risks

This study will use a purposive sampling method to select an intervention group which might cause selection bias. Therefore this study will carefully select target villages and analyse data in the DIDs approach, which is the feasible method to learn about the causal relationships in the quasi-experimental design for public health research to reduce the selection bias. Additionally, the set of CoC cards and ultrasound intervention has not established its effectiveness and might depend on the contextual factors. To minimise this issue, this study will conduct the effectiveness-implementation hybrid trial to evaluate the effect of the intervention in a real-world setting and assess the implementation process for the future expand the intervention to the control area.

6.11. Ethical issues

This study was reviewed by ethics committees at Tokyo University and approved by the National Institution of Health in Timor-Leste. Before the interviews, this study will obtain written informed consent from interviewees.

6.12. Dissemination plan

The researcher will present the results of this study to MoH, local government officials and community leaders at a meeting. Additionally, the researcher will submit the results to related organisations and academic journals.

7. Trial status

The trial will be registered in the International Standard Randomized Controlled Trial Number (ISRCTN) registry.

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