







A Healthy People. A Wealthy Nation



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Acronyms

ANC Antenatal Care

CHWs Community Health Workers

EPDS Edinburgh Postnatal Depression Scale

GA Gestational Age

LMIC Low- and Middle-Income Country

PNC Postnatal Care

PTBi Preterm Birth Initiative
UPT Urine Pregnancy Testing

US Ultrasound

WHO World Health Organization



Executive Summary

Group antenatal care is an innovative model for antenatal care (ANC) delivery, that has shown evidence of health improvements across diverse settings and contributed to a reduction in preterm birth rates among high-risk women in the United States.1 Inspired by these results and motivated by the aim of reducing the global mortality and morbidity burden associated with prematurity, the Preterm Birth Initiative - Rwanda (PTBi Rwanda) sought to assess the health outcomes of a group ANC and postnatal care (PNC) model implemented as the standard for all pregnant women at select primary health centres in Rwanda. We hypothesized that women receiving group ANC would experience a greater gestational age (GA) at birth and a lower rate of prematurity than women who received ANC in the standard, individual model.

To test this hypothesis, we implemented a clusterrandomized trial in 36 primary health centres across Rwanda between May 2017 and May 2019, examining outcomes of 8,843 women in the largest cluster-randomized controlled trial of group ANC as of April 2021 (when this report was published).² This group ANC model was developed based on Rwanda's four Focused ANC model, and included an initial individual visit, followed by three group ANC visits and one group postnatal visit. Throughout the trial, we collected data from patients, providers and community health workers (CHWs), to ensure fidelity, track study outcomes, and understand patient experiences of care and barriers to accessibility. These data, described in this report, provide extensive learnings on the implementation and feasibility of group ANC in Rwanda.

This rigorous evaluation of group ANC showed no impact on preterm birth, as measured by GA at the time of birth, with an average GA of 39.3 weeks for both the standard and group ANC groups. Similarly, we saw no significant differences in secondary outcomes such as attendance at 4 ANC visits. However, the trial data, program monitoring data, and qualitative findings reveal important insights into this increasingly popular intervention with the potential to transform ANC delivery.

As reported by others in the field, our results show that group ANC was the preferred form of ANC delivery for both providers and patients in Rwanda.

Our analysis indicates this is, in part, the result of interconnectedness and improved relationships. We found:

- health centre providers reported increased satisfaction with their work, and strengthened relationships with their patients
- CHWs described an increased interest in providing health services and improved relationships with providers, and
- women expressed positive reactions to sharing with a group of peers, a newfound comfort in communicating with their providers and increases in health-related knowledge.

These strengthened support systems are critical to improving the experience of care and have potential to affect alternative health outcomes, such as maternal mental health and future family planning. Nonetheless, for group care to become a widely used model for ANC delivery, it is not enough to replicate this program without careful consideration to three important factors:

Structural barriers

Group ANC faces many of the same structural barriers common to ANC delivery everywhere, and in some cases these barriers may be accentuated by the group model. It is important to understand and mitigate these barriers for optimal success of ANC, and specifically group ANC.

Dose

We implemented a four-visit model, in accordance with national guidelines, but women on average attended only three visits. Evidence from the literature suggests a higher dose of group ANC is needed to achieve an impact on health outcomes.

Measurement

We struggled with the limitations of measurement, particularly with regard to accurate GA assessment and reporting, in this low-resource setting among low-risk women. To understand all benefits of group ANC, we need to invest in more accurate/inclusive tools of measurement for prematurity, as well as alternative benefits of group ANC including

women's satisfaction, maternal mental health, impact on future pregnancies etc.

Through lessons learned from the PTBi-Rwanda trial, this report provides insight for **programmatic considerations** to optimally implement group ANC and PNC at scale in low-resource settings, as well as **recommendations** for further research.

Programmatic considerations:

- Align national ANC and PNC program objectives and provider incentives with group ANC implementation.
- Address health facility staffing shortages and other structural barriers to group ANC, as consistent attendance and undivided provider attention are key to the model.
- Prepare for different service provision logistics required by group ANC and PNC, such as group organization and scheduling, and space preparation, which take additional time but can be done by non-clinical staff.
- Community sensitization, scheduling flexibility, and/or patient reminder systems may serve to bolster attendance.

Recommendations for further research:

Dose

The benefits of group care may increase with an increasing number of ANC contacts.

High-risk women

Women at the highest risk of preterm birth in any population may benefit most from group care.

Hybrid models

A flexible model or mixture of individual and group ANC and PNC visits during the childbearing year may be beneficial to both women and the health system.

Alternative benefits

There is a need for continued exploration of alternative benefits of group ANC already documented by others such as mental health, long-term family health outcomes, and cost-effectiveness.

Ultimately, we continue to believe that the group ANC model holds great potential for improvements in quality and experience of care that will ultimately improve a variety of health/birth outcomes. This report aims to summarize PTBi-Rwanda's lessons learned in order to inform other group ANC and PNC efforts and to identify additional opportunities for future research.

Published articles related to this study are listed in Appendix C, and the <u>East Africa Preterm Birth</u> Initiative website.



Introduction

There is a gap in antenatal care

In 2017 when our study began, approximately 810 women were dying around the globe each day from preventable causes associated with pregnancy and childbirth, with 94% of all maternal deaths occurring in low and lower middle-income countries.³ It is estimated that almost two-thirds of the maternal and neonatal disease burden could be eliminated through proper implementation of existing evidence-based practices and interventions.⁴

Antenatal care (ANC) provided by a skilled health professional is a key opportunity to address maternal and perinatal mortality/morbidity through the delivery of crucial health services during pregnancy. Core components of ANC include health promotion education, management and prevention of disease, and screening for maternal and fetal risk factors. As much as these technical components are known, quality of care is also important. As outlined by the World Health Organization (WHO), quality includes both the technical provision of care as well as the individual woman's experience of care.⁴

Globally, studies document that women often have poor satisfaction with their ANC, particularly those with complex or high-risk pregnancies.⁵ In fact, only 64% of pregnant women between 2007–2014 globally attended the four ANC visits recommended by the WHO.³ In Rwanda, as with many other settings, standard ANC involves one-on-one provider to client interactions, often with extremely long wait times and short visits with providers. Despite lack of satisfaction and calls for reform to this widely used method of health delivery, traditional one-on-one ANC remains the standard model worldwide.

Group ANC could be the solution

When we partnered with the Rwanda Ministry of Health and Rwanda Biomedical Centre, they saw group ANC as an opportunity to improve quality and uptake of ANC for women. In 2016, WHO recommended further research on the effect of group ANC at both the individual and systems levels. 4 Group care is regarded as a way to prioritize the experience and quality of ANC, in efforts to incentivize ANC attendance and promote the overall wellbeing of women and babies. This innovative model of ANC delivery has also demonstrated potential to

transform the provision of care from the provider and systems perspectives.

Generally, in a group care model, 8-12 women of similar gestational stage in pregnancy attend their ANC visits as a group, with the goal of creating a supportive peer group throughout their pregnancy and the postpartum period. Group ANC is facilitated by a maternity care provider who supports self and peer health assessments and provides education during 1- to 2-hour sessions at regularly scheduled appointments throughout pregnancy. The majority of the group ANC visits are geared toward a guided discussion among peers. 6 The practice of group ANC was first implemented in the United States in the 1990s, using the now popular CenteringPregnancy model.⁷ The core components of Centering-Pregnancy are to incorporate mutual support, risk assessment and education into each group session. Early studies reported decreased emergency room visits, increased knowledge, and greater satisfaction among women who experienced the group model.1

Three studies of group ANC completed in the United States (specifically, the CenteringPregnancy model) showed evidence of improved birth outcomes, such as lower odds of low birthweight, small for gestational age (GA), and preterm infants born to women who participated in group care - particularly among women who were at increased risk of adverse perinatal outcomes.^{8,9,10} A meta-analysis of multiple studies reported no overall effect of group ANC on preterm birth prevention, but the same review demonstrated a significant reduction in preterm birth among a subgroup of African-American women at elevated psychosocial risk.1 This report also found that group ANC resulted in alternative benefits of increased patient satisfaction, improved knowledge of family planning, and healthier weight gain during pregnancy. It is theorized that group ANC may also impact depression, breastfeeding, stress and positive health outcomes more generally, though studies are so far inconclusive.

Why group ANC in Rwanda?

Group ANC has demonstrated success in low- and middle-income countries. Participation in group ANC resulted in a significant increase in health literacy among a cohort of Ghanaian women.¹¹ In Malawi

and Tanzania, women who participated in group ANC reported increased satisfaction with care and demonstrated greater ANC attendance. ¹² Similar improvements in ANC attendance were also observed in group ANC trials in Nigeria and Kenya, and an increase in facility-based births in Nigeria. ¹³

The preterm birth rate in Rwanda is unknown, with regional estimates as high as 12%, but some country-level data report rates as low as 2.6%, which many in the field would interpret as under-reporting. 14,15,16 In 2015, Rwanda experienced a rate of maternal mortality of 210/100,000 and 20/1,000 for neonatal mortality. 17 Our Rwandan partners saw this program as an opportunity to improve the quality of

ANC care, thus bolstering attendance and preventing preterm birth, neonatal mortality and maternal mortality.

Rwanda's national health system provided an excellent opportunity to test this service delivery model due to its community capacity, cultural foundations in community-based decision-making and cooperation, and extant, longitudinal ANC registers. Rwanda has achieved high proportions of women attending at least one ANC visit and delivering in a health facility but had a goal of higher proportions of four Focused ANC visit completion. The national ANC and PNC package offered across Rwanda during the study period is described in Box 1.

Box 1. Status of antenatal and postnatal care in Rwanda during this study period

ANC and PNC coverage prior to trial implementation (2015):^{17,21}

- 99% of pregnant women attended at least one ANC visit
- 44% attended the recommended four Focused ANC visits
- 91% of births occurred in a health facility
- 19% of newborns and 43% of women received postnatal care
- 56% of women reported they entered ANC before 16 completed weeks of pregnancy

Health centre staff participate in a performancebased incentive program that rewards them by the proportion of pregnant women who enroll in ANC before 16 weeks and the proportion who attend four ANC visits following the Focused ANC schedule. During the study period (May 2017– May 2019), Rwanda's national guidelines prescribed that each childbearing woman be offered

- Four Focused ANC visits
 - » Aligned with WHO recommendations prior to 2016
 - » Initiated by 16 weeks gestation
 - » Timed at approximately 8-week intervals
- Four PNC visits
 - » Newly implemented in 2017
 - » Timed at 4 timepoints: within 24 hours and at 2–3 days,7–14 days, and 42 days of infant life.

Routine ANC is provided in government health centres staffed by nurses and midwives. Ultrasound is not typically available at the health-centre level. A community-based insurance scheme is available to all Rwandan families, but most families must contribute to the annual premiums and there are co-payments for many services.



The PTBi-Rwanda Trial

We set out to test the effects of group ANC in Rwanda, motivated by the desire to improve the quality of ANC and the burden of preterm birth identified by our partners, as well as the documented successes of group ANC (including lower rates of preterm birth among high-risk women in the United States and alternative benefits in Sub-Saharan African settings). Our primary aim was to understand the effects of group ANC, compared to the standard individual ANC model, on prematurity, measured in our study by GA at birth.¹⁸ We predicted that Rwandan women receiving ANC at health centres randomized to group ANC would experience increased social support, health knowledge and early detection of complications, which would lead to a prevention of complications and mitigation of risks. We hypothesized this would lead to at least a 0.5-week increase in GA at birth compared to women at health centres randomized to standard individual care. This theory of change is outlined in Figure 1. Thirty-six health centres in five districts were chosen to participate in this trial, and half of these health centres were randomized to provide group ANC as their standard of care. More detailed information on our trial design and methods can be found in Appendix A.

PTBi-Rwanda partners also studied how community-based urine pregnancy testing by community health workers (CHWs) and basic obstetric ultrasound by nurses and midwives impacted timing of presentation for ANC and the number of ANC visits attended by each woman. These interventions were included as an opportunity to improve pregnancy surveillance and GA assessment, with the hope that mothers would be motivated to attend ANC earlier and more frequently.

A number of activities related to the design, implementation and monitoring of the intervention were conducted, such as training of facilitators and providers, and qualitative work to capture women and providers' perspectives regarding group care. The project timeline with key study milestones is shown in Figure 2.

Figure 1. PTBi-Rwanda's Theory of Change

Early entry and coverage of group ANC

- Increase coverage of screening, treatment and referral
- Increase health knowledge and empowerment
- Improve connection and support



Identification of risk factors and prevention of complications



Longer gestational length at delivery (prevention of PTB)

Provider training: Mar 2017–Jan 2019 Fidelity monitoring: Aug 2017-Jan 2019 **Facility Assessments** July 2016 Data collection: May 2017-Mar 2019 2016 2017 2018 2019 **Baseline Midline** qualitative qualitative work work Aug 2016 Apr 2018 Trial launch **Enrollment** complete

May 2017

Figure 2. A timeline of PTBi-Rwanda's study activities

The PTBi-Rwanda group ANC model

To develop what became our group ANC model specifically tailored to the local needs and context of the Rwandan system, we relied on the core values and structure of the group care intervention we planned to implement. We believe this facilitative model was effective throughout the trial in its promotion of local ownership and reliance on diverse perspectives. A visual representation of our model development and implementation can be seen in Figure 3, which is also detailed in our Model Development publication.¹⁹ The Rwandan women who participated in the first pilot groups named the model Ibaruke Neza Mubeyi, which means may every woman have a healthy birth.

What does group ANC look like?

The Technical Working Group adapted the group ANC model to the Rwanda context in several key ways:

- 1. Using a four-visit group ANC model to match the capacity and current standards of the Rwandan health system and the pre-2016 WHO recommendations
- 2. Creating a predictable 8-week interval between appointments
- 3. Limiting facilitated group discussion to 60 minutes, knowing there would be constraints on health provider time

4. Creating a group care curriculum that integrated discussion topics prioritized in the existing Rwanda ANC package¹⁹

Oct 2018

Box 2. The role of postnatal care in our trial

As we began our trial, the Rwanda Biomedical Centre was poised to roll out a new PNC schedule. It was important to local stakeholders to elevate and formalize these services. The previous schedule included only an in-facility visit within 24 hours of delivery. Our baseline qualitative work substantiated the importance of raising awareness of PNC, as many community members were not aware of there being any PNC program other than routine infant immunizations at 6 weeks.

Our group ANC model included a postnatal group visit. Our hope was that mothers attending group care would benefit from social support extending into the postnatal period. As the model was designed, a postnatal visit date was set at the first ANC visit, and was expected to be at approximately 6 weeks postpartum for most group members.

Developing the Rwanda-specific group ANC model¹³

Before beginning the trial, key stakeholders formed a Technical Working Group to develop a Rwanda-specific group ANC model, using the same processes applied in group care. Specifically, we met as a circle of peers and employed group-facilitated discussion in our meetings, so that (1) hierarchies were flattened, (2) decisions were made by consensus, and (3) the group facilitation model was a familiar and valued practice among stakeholders by the time the group care intervention was implemented.

Recruiting and training of Master Trainers

A team of six Rwandan providers (five nurse-midwives and one doctor) were recruited to be Master Trainers for the group ANC intervention, training ANC providers and CHWs at each health centre that was randomized to group ANC. The team's preparation included participation in several group ANC visits in varied and well-established group care programs in California. Subsequently, Master Trainers attended six follow-up meetings facilitated by a midwife experienced in group ANC, where they practiced skills and co-created a Rwanda group ANC training strategy for the trial. They also provided targeted training, mentoring and supervision throughout the study.

Training the new group ANC facilitators

Three ANC providers (nurses and midwives) at each health centre randomized to group ANC were invited to a 3-day training workshop. Additionally, 12 CHWs specializing in maternity care in each health centre's catchment area were invited to train as group care co-facilitators to improve linkages between their communities and health centres. Importantly, we chose to train ANC providers and CHWs together (which was not usual practice) to foster collaboration and teamwork.

Selecting group care participants

At sites randomized to group ANC, women attending their first ANC visit were invited to participate in group ANC by study staff and facility providers. To be enrolled in the study, women were required to be at least 15 years old, attend their first appointment before 24 completed weeks of pregnancy, and provide consent to participate.² Women who chose not to participate in group ANC or in the study were offered routine, individual care at study sites according to the Focused ANC model.



2

3

4

The final Rwanda group care model consisted of four total ANC appointments in alignment with the 4-visit Focused ANC model. During the first ANC visit at which they registered for care, women received standard, individual ANC and were invited to participate in group care for their future visits. If they agreed, they were placed into a group with 8-12 women with similar expected delivery dates.2 Women met with their assigned group for three subsequent group ANC appointments, which occurred approximately eight weeks apart. A group PNC appointment with the same group at approximately six weeks after birth was included in the model to promote the continuation of group support, with hopes of strengthening the PNC program and supporting a newly implemented national PNC program (See Box 2, p8). It was not expected that the PNC appointment would impact GA at birth given its timing post-pregnancy.

An overview of the educational curriculum is presented in Table 1 and is further detailed in our Study Protocol publication. Group ANC and PNC visits were co-facilitated by one provider and at least one CHW, all of whom had completed group care training. At the request of local stakeholders, group ANC and PNC were integrated into the existing structure of health services delivery, without the addition of any clinical staff. During the first half of the 2-hour group visits, providers met with each of the women in turn for brief individual assessments within a semi-private area, while other women socialized and engaged in health assessment activities. These activities included taking blood pressure (using an electronic blood pressure cuff) and weight measurements for one another, with guidance from the CHW. During the second half of the visit, the group engaged in a discussion on various health

Table 1. Rwanda group ANC and PNC visitation timing and curriculum

Visit Type	Visit Number	Timing (Weeks)	Structure	Education
	Visit 1	Ideally before 16 wks	Standard individual care	HIV Counseling and TestingExtend invitation to group ANC
	Visit 2	20-24 wks	Group ANC care 1 hour: Self-health assessments (weight & blood pressure) and nurse check behind privacy screen 1 hour: Facilitated group discussion and education	 Nutrient supplements, and harmful substances Pregnancy danger signs Infection prevention and treatment
	Visit 3	28-32 wks		 Birth plan (including signs of labor) Health birth spacing and family planning Maternal mental health Review pregnancy danger signs
	Visit 4	36-40 wks		 Respectful maternity care Breastfeeding and newborn care Postnatal and newborn danger signs Review family planning Review pregnancy danger signs
	Visit 5	~6 wks after birth		 Review breastfeeding and infant feeding Review newborn danger signs Preventing health problems Newborn and infant cognitive development

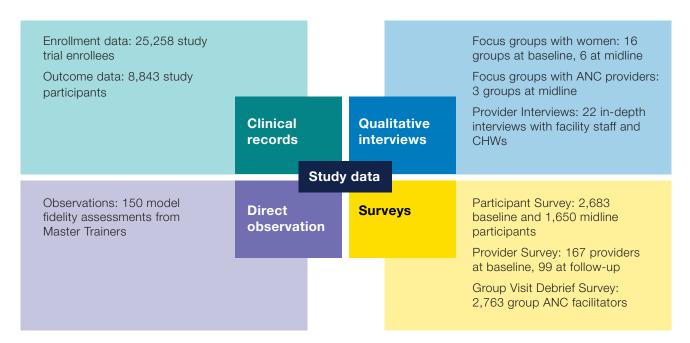
Adapted from Musange et al. 2019.

topics related to pregnancy and parenting. While the discussions were co-facilitated by the ANC provider and CHW, the primary goal was for women to ask questions, share knowledge, and offer support to one another.

Implementation and monitoring

From 2017 to 2019 local providers were able to facilitate at least 2,788 group ANC visits for over 4,752 women across 18 health facilities. Because this study largely relied on existing data sources and providers, our findings led to a unique set of learnings that are applicable to real-world settings. Throughout implementation, we collected data from women, providers and group sessions to understand the patient and provider experience, and to ensure model fidelity. Study participants provided additional insight into women's experience on mental health, empowerment, and structural barriers to accessibility of care. We also extracted individual-level health data from clinical records and facility maternity registers to track care provision and health outcomes from enrollment to the 6-week postnatal visit. These study data, summarized in Figure 4, were used to develop the extensive real-world learnings produced in this report.

Figure 4. Study data collected during the trial



Clinical data and direct observations were recorded continuously throughout the trial period, while qualitative interviews and survey data were collected at various periods before during and after the trial.

A detailed assessment of group visit data based on provider self-assessments from 2,763 group visits (further outlined in our publication on Model Fidelity) found that approximately 80% of the group visits were conducted as they were intended, in relation to both process fidelity and objective measures. 19 Direct observational data revealed that the intervention was implemented as intended, while also adhering to the Rwandan service package, as reported by Master Trainers. The "soft skills" critical to the successful implementation of group ANC, reminiscent of leadership skills, were difficult to train and implement, as expected. Nonetheless, Master Trainers observed providers demonstrating the skills of encouraging participant engagement, asking open-ended questions, and speaking less than participants approximately 80% of the ideal, on average.²⁰ Table 2 compares actual visit characteristics to the intended ideal, demonstrating the success of group ANC implementation.

Table 2. Group ANC model fidelity measures

Assessment Measure	Intended	Average
Number of pregnant or postnatal women who participated in the group visit	8–12	9
Number of minutes spent in health assessments	60	51
Number of minutes spent in group discussion	60	63
Total number of minutes spent, group visit including health assessment and group discussion	120	114
Number of minutes spent during group visit, divided by the number of women in attendance	10–15	12
Group visit was co-facilitated by at least one provider and one CHW	100%	89%
Clean water was provided to the participants to drink	100%	83%

Primary trial results

Did group care reduce rates of preterm birth among study participants?

Our primary aim was to report the effect of group ANC on GA at birth, testing the hypothesis that women who attended health centres randomized to group ANC would experience a 0.5 week increase in GA at birth compared to those receiving the standard individual care model. Birth outcomes data for 8,843 mother-baby dyads (4,752 intervention; 4,091 control) revealed that the average GA at birth was 39.3 weeks among women in both the intervention and control groups.

We observed no significant difference in GA age at birth between women who received group ANC compared to women who received standard individual ANC.

Primary and secondary outcomes are shown in Figure 5 below (further outlined in our Trial Results publication). The secondary results show that group care did not lead to statistically significant improvements in other outcomes, such as preterm birth rate. completion of the four Focused ANC schedule, or ANC initiation before 14 weeks. However, we found that attendance at 3 and 4 total ANC visits was higher at group ANC sites. This attendance increase was statistically significant for 3 total visits but not for 4 total visits. We also found a statistically significant lower rate of postnatal visit attendance at approximately 6 weeks after birth among participants randomized to group ANC. This lower rate of PNC among group attendees might in part be attributed to the newness of the PNC program described in Box 2 (p8) or may reflect the challenge of the rigidity of pre-scheduled visits, especially for women whose delivery date was difficult to predict and occurred earlier or later than expected. It is possible that group PNC visits are not the preferred model among Rwandan women.

What was the impact of community-based urine pregnancy testing and basic obstetric ultrasound at the health centre level?

A secondary goal of PTBi-Rwanda partners was to encourage women to initiate ANC earlier, so that they would have sufficient time in their pregnancy to attend all the recommended ANC visits. To support this goal, we implemented community-based urine pregnancy testing and basic obstetric ultrasound at half of the intervention and half of the control sites (balancing them across study arms). Our partners hoped that confirming pregnancy with communitybased testing would lead mothers to attend ANC

50 40 30 20 10 0 Primary Preterm Cesarean Attendance of 4 ANC Attendance Outcome: birth (%) birth (%) ANC1 before attendee women of PNC visit Gestational 14 weeks, who attended at 6 weeks* ANC 1 before length among women (%) who attended 14 weeks (in weeks) 4 ANCs gestation (%)

Figure 5. Secondary outcomes from the PTBi-Rwanda group ANC trial

*Statistically significant result



Data from Sayinzoga et al. 2021.

appointments earlier and thus complete the recommended four ANC visits. We hypothesized that availability of an ultrasound at the health centre might serve to draw mothers in for early ANC registration.

There was no difference in GA at first ANC visit or attendance of 4 ANC visits among women who were exposed to community-based urine pregnancy testing and basic obstetric ultrasound, compared to facilities without these secondary interventions. However, we found that these two interventions were well-received by women and providers. Providers who were trained in ultrasound reported higher diagnostic confidence and higher job satisfaction, although they also noted an increase in workload and time constraints.

How do we understand these results?

There are several important factors to consider in interpreting our primary and secondary outcome data, including the dose of ANC visits attended, measurement of variables such as GA, and the

impact of structural barriers. We will discuss these aspects further in the section on our learnings, where we integrate additional qualitative and quantitative data. It is also important to note that the drivers of preterm birth among the population of low-risk women who participated in this study are not yet understood and may be different from those in other contexts.

We believe that the lack of impact of group ANC on prematurity in our study does not mean that the group ANC model is ineffective. Rather, we believe further research on the effects of group ANC is indicated, especially with respect to maternal mental health, impact on future pregnancies, and cost-effectiveness. It is also important to remove structural barriers that impact ANC uptake and delivery, including workforce shortages, transportation difficulties and out-of-pocket costs to access services. These barriers were all documented in our study, at both control and intervention sites, and likely resulted in difficulty implementing an alternative model of ANC care.



What We I earned

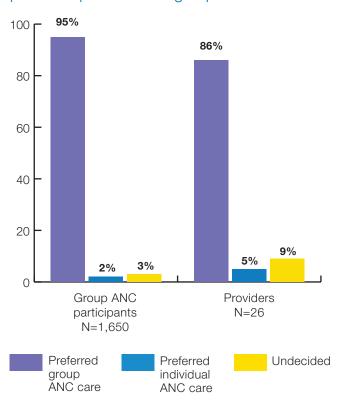
While our study showed that group ANC at an average dose of 3 group visits does not prevent preterm birth in this context, we learned a great deal about the group care model that should be taken in to account when planning future group care interventions. These insights are informed by the perspectives of patients and providers in the rich data set described in Figure 4 above. Most promisingly, qualitative work revealed a strong preference towards group ANC as the primary form of ANC delivery among both providers and patients. In this section, we outline four important lessons from our trial, each with their own set of considerations, crucial for those who plan to study and implement group ANC in the future, particularly in low-resource settings.

1. Relationships matter: Experience of care is improved through interconnectedness

Group ANC improves the experience of care

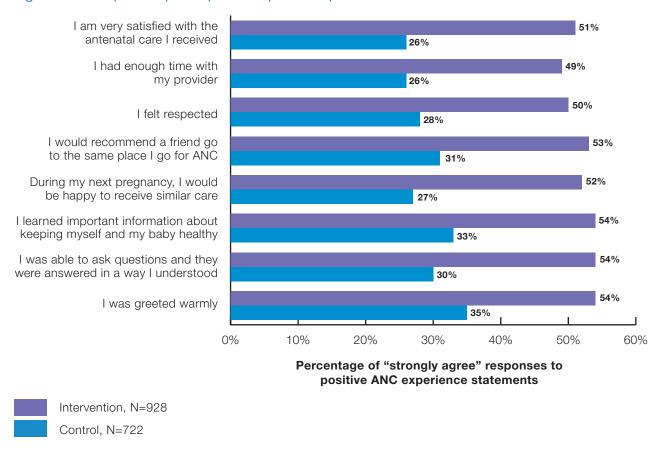
We asked women at group ANC sites which model of ANC care they would prefer for their next pregnancy, as well as nurses and midwives which model of ANC they preferred as the service provider. As shown in Figure 6, both providers and participants reported a strong preference for the group ANC model. This finding is consistent with many other studies and is supported by qualitative work conducted with both providers and participants. Among women responding to our post-pregnancy Participant Survey, group care participants were much more likely to strongly endorse all positive statements about their care experience compared to women who received standard ANC (Figure 7).

Figure 6. Both group ANC participants and providers preferred the group ANC model



Data from Participant Survey (unpublished) and Provider Survey (Lundeen et al. 2019) further described in Appendix B.

Figure 7. Group ANC participants expressed positive sentiments about their care



Data from Participant Survey (unpublished) further described in Appendix B.

How does group ANC improve the experience of care? Our analysis of qualitative data revealed that the primary driver of satisfaction was improved relationships and social support. Group ANC's model of guided discussion and peer-to-peer interaction allowed the opportunity for providers, CHWs and women to deepen their relationships with one another. Women were given the opportunity to share and learn from each other's experiences through this discussion-based format and engage in more face time with providers. This increased interconnectedness was a significant part of the group ANC experience and played an important role in why group ANC was the preferred ANC delivery method. It is this increased social support in group ANC that has potential to improve maternal health outcomes including mental health.

Interconnectedness among women

Women who participated in focus group discussions (further detailed in the publication on Womens' Experiences) reported that participating in group ANC generated benefits of improved relationships and increased discussion with their peers, leading to increased health and self-care knowledge.²¹ While some expressed fears around lack of privacy or confidentiality prior to the study, women in group ANC later expressed the benefits of social cohesion and shared accountability. Many women shared that learning about pregnancy experiences from other women in the group was useful as they re-examined myths about pregnancy, facility delivery, use of traditional medicines, and family planning. For example, women shared that they stopped using some traditional medicines after learning from peers they are not necessary for good pregnancy outcomes.

"Before I joined this group, I was told that if a pregnant woman does not take traditional medications, her child may suffer from skin diseases and other diseases. But now I know that it was a lie."

-Group ANC participant/client

Peer-to-peer learning has been shown to be an effective behavior-change strategy, and the safety to discuss freely with peers, with expert guidance from a health professional, likely makes group ANC a better learning environment than individual ANC. Considering their peers' experiences seemed to increase women's confidence to ask questions and adopt new practices.

Interconnectedness between women and providers

Women who participated in focus group discussions reported that participating in group ANC increased their health and self-care knowledge and improved their relationships with their providers. The relationships built during group ANC sessions led women to feel that their provider had a greater connection and interest in their health. Both women and providers brought up this increased sense of connection during qualitative interviews. This improved relationship reduced the barrier for women to seek help with their problems, as well as added to their satisfaction with the group ANC appointments.

"Some mothers who were not yet in the group care...were surprised at seeing the nurse come and sit near me, and then ask me about my health and my child's health. They eagerly inquired why she was much interested in me only to learn that we got to know each other when she was training us in the group care. Therefore, I found that there is a difference, and this led me to like the program much more and attend it."

-Group ANC participant/client

Providers positively expressed that they witnessed increased health-seeking behaviors as a result of women's increased knowledge gained in group ANC. These providers also observed increased satisfaction with care among women, consistent with the ANC experience results from the Participant Survey (shown in Figure 7).

"As for me, this group care program has pleased us very much; you can even learn of this fact through much excitement of the group members. For us who lead group care, we can see it. You can see that mothers are thirsty for knowing all those new things. When you discuss with them and when you are making conclusions together with them, you find the members happy, and most of them wish never to miss out. A woman says that she is happy to learn something new."

-Group ANC provider

Providers noted that women's engagement in group ANC was increased compared to individual ANC. They reported that women were more interested in ANC-related health information and were more willing to share it with their community. Both providers and patients expressed that they experienced warm and positive relationships, leading to an increase in trust and more vulnerable and fruitful discussions. One provider compared this new relationship to a sisterhood:

"The group care program has brought the nurses closer to their clients. Before one could see a nurse as someone who is in a very high level, but today we can talk and laugh together in groups. We find that we have freedom; even when a woman has a problem she comes again and asks you. In fact, it is like a friendly relationship between the woman and the nurse. She considers you as a sister rather than a health centre employee."

-Group ANC provider

Interconnectedness among providers

Providers described an increased emotional connection to women, as well as an increased connection to other providers. ²² Because they were able to share more knowledge and provide more support for women, they experienced a deeper sense of pride in their work. However, this preference among providers did not lead to an overall increase in job satisfaction ratings within provider follow-up surveys. ²² While providers appreciated the benefits of group ANC provision, they likely felt the burden of an increased workload related to workforce shortages and administrative requirements of group ANC. This insight (further detailed in the Providers' Experiences

publication) echoes the importance of providing adequate support and addressing structural barriers to create effective and sustainable group ANC delivery.

In a focus group conducted among CHWs who co-facilitated group care, they echoed these positive experiences in group ANC. CHWs reported satisfaction with their training, increased collaboration with nurses, and a perceived complementarity between their existing responsibilities and group ANC.²³

"To me, there has been a strong relationship and effective collaboration between us and nurses in the sense that we thought we had the same workload. They really appreciated our assistance to the extent that they worry about losing our support. Truly speaking, if means should be devised to train us more and equip us with advanced skills so that we can keep on assisting them, it would be better."

-Group ANC CHW

Group ANC has potential to improve maternal mental health

Women in low- and middle-income countries (LMICs) experience a disproportionately high rate of maternal mental health disorders (16% of pregnant women in LMICs compared to 10% of pregnant women in high-income countries).²⁴ Maternal mental health disorders are associated with substance use, poor nutrition, pre-eclampsia, postpartum depression, suicide, work disability, lower income and insufficient ANC for the mother, as well as prematurity and low birthweight among newborns.²⁴ Since prior studies have shown that group ANC led to significant reductions in preterm birth among a subgroup of women at elevated psychosocial risk, we sought to examine the effect of group ANC on maternal mental health.

We measured depressive symptoms during and after pregnancy in a sub-sample of Rwandan women using the Edinburgh Postnatal Depression Scale (EPDS). We administered the EPDS to a convenience sample of the first five women to present for their first ANC visit each new calendar month, and these women were surveyed again at approximately 6 weeks after birth. This was accomplished at both control and intervention sites throughout the study period.

Using an EPDS score of ≥13 as the cut-off, 18.8% of these pregnant Rwandan women screened positive for antenatal depression. This is a depression prevalence rate twice as high as women in high-income countries and 32% higher than the average

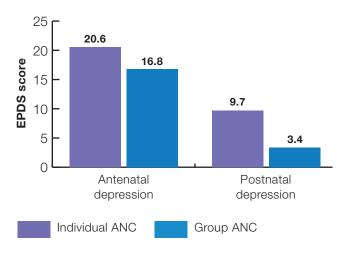
prevalence of all common mental health disorders among women in LMICs.²⁵

Statistically significant results showed that women in our study with high social support from friends had 66.2% lower odds of antenatal depression than those who reported low social support from friends. Other factors demonstrating protection against antenatal depression were perceived family support, low perceived stress, increased maternal age, and being able to discuss pregnancy with a partner.

Comparing women at control sites to women at intervention sites, we found that women randomized to group ANC had a lower baseline rate of depression and experienced a larger decrease in EPDS scores compared to women randomized to individual ANC (Figure 8). Women in group ANC had almost four times lower odds of postpartum depression. with a p-value of 0.051. Our sample size was likely too small to show a statistically significant difference, but the trend is compelling.

Our results suggest that group ANC could improve maternal mental health outcomes in a low-resource context. Given the importance of alleviating suffering that results from maternal mental health disorders and the promising results from this study that suggest group-ANC-related social support systems serve as protectors against antenatal depression, it is important to further investigate the role that group ANC plays as primary prevention and treatment of maternal depression.

Figure 8. Group ANC participants had lower rates of depression



Data from Participant Survey (unpublished) further described in Appendix B.

Considerations for relationship strengthening

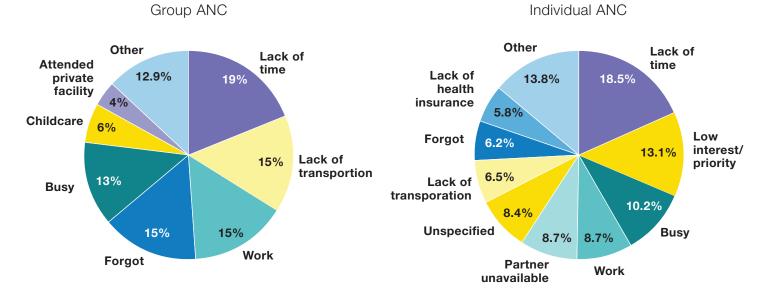
- Consistency in group membership and facilitators will further strengthen relationships and research is needed to better understand the importance of group membership consistency.
- Integration of CHWs as facilitators can help strengthen relationships between facility- and community-based health care workers.
- Facilitative leadership by group ANC providers is key to achieving social support of group members by group members.

2. Group ANC magnified pre-existing structural barriers to ANC delivery

We hoped that the accountability and relational aspects of group ANC would incentivize women to seek preventative health care during pregnancy and, in turn, demonstrate improved health outcomes. However, we did not see significant improvements in any ANC coverage outcomes. Interestingly, when we asked women in focus groups how we might improve the program, they did not mention changes to the fundamental model of group care with facilitated group discussion.

Rather, qualitative and survey data (reported in published work on Womens' Experiences and Providers' Experiences) and from a subset of women at intervention sites revealed that structural barriers inhibit ANC attendance. Among women who enrolled in the study during pregnancy and then participated in a questionnaire at approximately 6 weeks after birth, 18% of women at standard ANC sites and 17% of women at group ANC sites reported that they experienced difficulties that prevented them from attending ANC visits at the health facility. Figure 9 shows the differing barriers that group ANC and individual ANC participants faced when accessing care. These barriers were also mentioned by women in focus group discussions. Approximately 47% of group ANC and 38% of individual ANC participants reported lack of available time, some due to work and competing priorities, as the main barrier to ANC attendance. More individuals who received individual ANC reported a lack in their interest or prioritization of ANC visits as a barrier to attendance, while forgetting the appointment time was a more common barrier for those who received group ANC.

Figure 9. Barriers that impacted ANC attendance among women who received group ANC and individual ANC



^{*}Other Includes late pregnancy recognition (2.5%), unspecified (2.5%), husband prevented (1.8%), sick (1.8%), insufficient funds (1.2%), moved (1.2%), and categories with under 1% of responses

Data from Participant Survey (unpublished) further described in Appendix B.

^{*}Other includes sick (2.9%), childcare (2.9%), late pregnancy recognition (2.2%), attended private facility (1.8%) and categories with under 1% responses

Barriers faced by the group ANC participants may have been exacerbated by the newness of the scheduling and communal nature of group ANC. For example, it may have been harder for women to adjust to having an exact date and time of their group visit versus the standard ANC model in which women are served on a first-come, first-served basis. When women arrived late to group ANC or providers were called to attend a delivery during a group session, group ANC participants may have experienced a more obvious disruption and therefore increased frustration.

Programs that hope to increase ANC coverage and implement group ANC should consider these barriers. Some solutions may be straightforward, such as an innovative method to help women remember group visit dates and times. Other solutions will require structural changes at the facility level, such as transportation, childcare, and removing co-payments at the time of service. The most significant barriers uncovered in our study are discussed below.

Affordability

In Rwanda, a public, community-based insurance program exists with variable annual premiums and co-payments based on family resources. All individuals in a household must enroll together annually and present proof of income. Once enrolled in the community-based insurance program, the total estimated cost per woman for ANC services is approximately 3,000 Rwandan Francs (3.05 USD, 2020). 15,20 Participants in our study said that timely enrollment in the insurance program and the co-payments required for ANC visits can be a barrier to attendance.¹⁷ Focus group discussions revealed unexpected ways in which the insurance system interacted with the group ANC intervention. First, several women could not afford the co-payment required at the time of an ANC visit and reported that this barrier decreased the number of ANC visits they attended. Some women found themselves in the annual enrolment process during pregnancy, which interrupted their insurance "coverage." A few women reported that when they attempted to make the co-payment in order to attend an ANC visit, they were rebuffed by the facility's insurance clerk, who was trained to only accept ANC co-payments according to a strict Focused-ANC model schedule.

Transportation

Women in our study faced difficulties in traveling to the health facility because walking was the primary form of transportation, alternative forms of transportation are relatively expensive, and many study sites were in rural areas. Both survey and focus group data revealed that transportation was a significant barrier to ANC attendance.

"All of us [in the same group] didn't arrive here at the same time because of different distances we have to walk. A long distance can also discourage a person from coming here for consultation or tests."

-Group ANC participant

This barrier, while not unique to group ANC, may have resulted in women missing group appointments if walking the required distance took longer than expected.

Support from family and community

The presence or absence of support from a woman's community, especially from her partner, can impact her care-seeking behaviors. Qualitative data revealed that family expectations and cultural norms may have also negatively impacted women's ANC attendance. In focus group discussions among a sub-sample of participants, several women stated that their husbands did not view ANC attendance as important enough that they should be excused from work duties (both inside and outside their homes). Several women mentioned that members of their community, including their husbands, discouraged them from attending ANC.

"Your husband may feel annoyed by the number of times you go to the health centre; and when he has compared them to what he may see other women do – like weeding their crops – he may order you not to go there once again."

-Group ANC participant

Results from the Participant Survey revealed that being able to discuss pregnancy with their partners was an important factor for women, impacting their experience of person-centered antenatal care and the attendance of their second visit.²⁶ This demonstrates the importance of addressing gender-based norms and structures to impact and promote access to care.

Scheduling/rigidity

Women at all study sites were given a written reminder about their next ANC or PNC visit, and ideally, they were reminded of these visits by a CHW working in their respective villages. This is the standard method in Rwanda and was not changed for the study. However, forgetting about appointments was a commonly reported reason among women

who missed their visits. Women suggested that a better reminder system should be used, particularly among those who cannot read or do not have telephones. Approximately 9% of women named "I forgot" as the main barrier they faced to ANC attendance (15% at group ANC sites and 6% at individual ANC sites).

In this study, we encouraged women to attend with their assigned group as scheduled, but they were welcome to attend on a drop-in basis if they forgot their appointment details. Despite this, appointment rigidity was also described as a reason that women did not attend the planned four visits. Women, providers, and health centre staff were influenced by the national Focused ANC guideline that promoted four ANC visits at specific GA windows during pregnancy. The nature of group ANC, with a consistent group of women and providers meeting throughout pregnancy and after, requires both more flexibility with respect to GA at the time of the group visit and more rigidity with respect to attendance on a certain date at a certain time.

Fewer women at group care sites attended PNC visits. This may have been related to inaccurate GA estimates resulting in their scheduled PNC visits being poorly aligned with 6 weeks postpartum. It is possible that group visits are not the preferred PNC model among Rwandan women.

Workforce shortage / organizational structures

Providers most commonly cited health facility staff shortages as a significant structural barrier to group ANC. Group care was integrated into the existing ANC infrastructure, without the addition of any clinical staff. While group visits generally convened as planned, the responsible nurse or midwife was frequently called to other service areas during the group visit to assist with emergency care, including labor and delivery. Across facilities, group ANC providers were not able to protect time that could be exclusively dedicated to group ANC visits; calls for help from other services made it impossible to start some group sessions at the scheduled time.

"It happens sometimes for a service provider to feel stressed due to the fact that we work in more than one service; we get a challenge of failing to render an adequate service because the group care activities require you sit in one place – to stay there. It happens that you may be urgently needed in a different service; you are thus obliged to excuse yourself for an absence of a little while to provide the services

called for, and this becomes a disturbance. You may be working from maternity and find yourself at the same time in post-natal group care of those very mothers; so, you feel puzzled. It is due to the low number of workers whereby we are bound to combine services because they are more than the number of workers available."

-Group ANC provider

The group ANC model required that providers plan group visit schedules and do some basic preparation before each visit, without any increase in available human resources. Providers reported that health centre managers supported group ANC in varying degrees, with some offering to protect provider time for group ANC planning and others unable to offer any support at all. Expanding the role of CHWs in planning and preparation or distributing this work to an alternative non-clinical staff member, health provider, or facility administrator might help address these challenges.

Considerations for structural barriers

- Financial barriers to ANC attendance should be removed.
- Allowing drop-in scheduling or flexible group configuration, especially for postnatal visits, may alleviate scheduling conflicts.
- Raising community awareness regarding the importance of attending several ANC visits is warranted.
- Patients may benefit from appointment reminder systems.
- Health centre leadership needs to be engaged to support the protection of provider time during group visits.
- CHWs or other group care co-facilitators may help reduce provider workload related to group ANC.

3. Women need a higher dose of group ANC

Adherence to the four-visit, Focused ANC model was comparable between our study groups (as shown in Figure 4 of the Primary Trial Results section). About 80.7% of women at group ANC facilities and 71.7% of women at standard care facilities attended at least three total ANC visits. The percentage of women who attended at least 4 ANC visits, which was ultimately Rwanda's ANC coverage goal, was 35.0% among those in the control group and 42.1% among those in the intervention group

(p-value = 0.29).²⁷ While the mean number of visits was slightly higher at intervention facilities, the total dose of group ANC visits in this study was low. Each participant in the intervention arm attended an average of two group ANC visits, in addition to the initial one-on-one ANC visit. While the minimum "therapeutic" dose of group visits is likely to vary by context, evidence from a study in the United States that offered ten group ANC visits reported that improved health outcomes occurred among those who attended five or more group visits.⁷ It is possible that in this trial women in the intervention group did not achieve a minimum therapeutic dose of group ANC visits, and that this contributed to no observed difference in GA at birth between groups.

Increasing ANC visit dose is not as simple as designing a model in which women are invited to attend more ANC visits than they attended in the past. The existing ANC delivery system in Rwanda at the time of our study may not have permitted a higher dose of group ANC. The national ANC program, including both staffing models and tools, are designed to accommodate only four ANC visits at prescribed intervals during pregnancy. This likely resulted in a service delivery ceiling that did not allow women to exceed the four total visits that facility staff models were calibrated for. Women may have had difficulties in accessing additional care even if they were interested in receiving it due to system limitations.

In 2016, the WHO recommended shifting to an 8-contact ANC model.4 Since then, efforts have been made in Rwanda and other LMICs to double the number of ANC contacts the health system can offer. The WHO recommendations allow for different types of contacts, such as ultrasound exams or CHW visits, and emphasize that an increased number of contacts gives the health system better opportunity to assess risks and improves women's experience. We believe that this increased contact model could increase the effect of group ANC on health outcomes. However, shifting to this model will require significant systems-level changes to tools, registries, and staffing models. Further research should assess the cost-effectiveness of shifting to an increased ANC contact model compared to other maternal and child health interventions.

Considerations for group ANC dose

 Research on the minimum effective dose of group ANC visits for specific outcomes, such as decreased incidence of maternal depression or uptake of postpartum contraceptive methods, is needed.

- Hybrid ANC delivery models that combine individual and group visits should be explored.
- Systems-level changes needed to implement 8 ANC contacts must be considered, including community sensitization about the advantages of 8 ANC contacts.

4. Improved measurement is needed to assess impact of group ANC

The preterm birth rate in Rwanda is unknown. Globally, the average rate is around 10% with few countries having rates lower than 5%.24 A 2016 estimate from Rwanda's Integrated Health Management Information System suggested a prematurity rate of 2.6%, which is significantly lower than sub-Saharan Africa regional estimates of 12%. A small prospective study conducted in Rwanda and published in 2020 used first trimester ultrasound for all participants to assign GA at birth and reported a preterm birth rate of 10%. ^{21,22,23} We report a preterm birth rate of 4% in this study, much lower than other estimates. We believe this variation is a result of biases inherent to misclassification of GA, as well as selection bias given that our data is limited to women giving birth in primary health centres. Women in our trial were more likely to be considered low-risk, since pregnant women with an identified complication are referred for follow up care at a higher-level facility.

To better understand GA accuracy in this context, we compared GA data from multiple primary sources and found that GA recorded by the birth provider at the time of delivery resulted in the fewest instances of implausible GA compared to birthweight.²⁷ Box 3 summarizes various methods for assigned GA at birth. We found that using GA at entry to ANC resulted in an abnormally large proportion of infants born very preterm, suggesting some systematic error. Therefore, as a quality check to our GA at delivery data, we compared these data to the Intergrowth 21st Project's standard for birth weight by sex, and excluded 26% of preterm-classified infants because their birth weights were not within the 3rd-97th percentiles for their GA.25 This exclusion led to a smaller percentage of low birthweight (<2500g) infants, which is inconsistent with alternative Rwandan reports.²⁶ These analyses suggest that some preterm infants were misclassified as term, and this degree of inaccuracy may have resulted in similar prematurity rates across our intervention and control groups.²⁷

These measurement challenges are particularly problematic given our desired endpoint but are common anywhere menstrual dating is used for GA

assessment. Until pregnancy dating by first trimester ultrasound can be done accurately and inexpensively at scale, measurement of accurate GA will continue to be a problem.

Box 3. Methods for gestational age measurement

Gestational age (GA) is a measurement of pregnancy length in weeks. The average length of pregnancy is 40 completed weeks from the first day of the last normal menstrual period, and births that occur before 37 completed weeks of gestation are defined as preterm births.

GA is measured in a variety of ways, depending on resources available in the health delivery system. In settings where ultrasound is available and women seek ANC early, first-trimester obstetric ultrasonography (US) is considered the most accurate method when the GA assessment by US is different from than the GA assessment calculated by last menstrual period (LMP). When first-trimester US is not available. GA is estimated using a woman's LMP. This measurement can be inaccurate for several reasons, including variations in menstrual cycle length, recall bias, and even social desirability bias when women understand that providers prefer they register for ANC early. Women may purposefully misreport LMP when they are incentivized to do so. GA is often compared to symphysis-fundus height at the time of antenatal assessments. GA is often re-assessed at the time of delivery with a standardized postnatal infant assessment, such as the Ballard scale. Generally, assessment methods applied at the time of delivery have wide margins of error.

The challenges around GA measurement are just one example of the difficulties in assessing impacts of group ANC and alternative innovations to ANC delivery in LMICs. In Rwanda, ANC registers and patient files capture the four standard visits but not any additional visits for illness outside the usual schedule. Maternal mental health, which may be improved in group care, is not routinely measured. Further benefits may be conferred in the post-pregnancy interval or subsequent pregnancies, none of which are currently measured. Therefore, strengthening systems for routine monitoring of an increased set of outcomes is imperative to the improvement of ANC delivery.

In spite of measurement challenges in our study, it is also important to note that group care may not have had an impact on preterm birth because the study population comprised low-risk women. As per local standards of care, women with identified risks in pregnancy were referred up to the nearest district hospital for assessment and may have continued their ANC there. Our analysis of risk factors in the study population showed very low numbers of women with identified risks for preterm birth, such as preterm birth, multiple gestation, malnutrition, smoking, and high blood pressure. Future studies of the impact of group care should focus on populations with documented elevated risk for poor outcomes such as preterm birth.

Considerations for gestational age measurement

- Universal, high-quality first-trimester ultrasound to assess GA is recommended for future studies of the impact of group ANC on preterm birth.
- Strengthening systems to routinely assess a wide range of ANC-related outcomes is needed to detect all benefits of group ANC.
- Future studies of the impact of group ANC on preterm birth should focus on populations of women in which a higher-than-average rate of preterm birth is documented.



Conclusion

Group ANC can improve the quality of care, but further work is needed

Our trial demonstrated the feasibility of group ANC implementation in a real-world setting among 15,838 women over a period of 24 months, demonstrating promise for the future of group ANC in LMICs. Following our trial, health centres randomized to group ANC continue to provide it. However, health centres report difficulties in group ANC provision without continued support for on-going trainings for new staff, and without co-facilitation by CHWs whose participation was specifically supported for this study.

Box 4. Global Group Antenatal Care Collaborative

Started in 2015, the Global Group Antenatal Care Collaborative is an open forum for researchers, with the goal of sharing learning and building partnerships within the field of group ANC provision in low- and middle-income countries. The collaborative's tasks include:

- Defining group care components, principles, and best practices
- Developing core indicators to track research and implementation
- Sharing and disseminating relevant information
- Advocating for the use of group antenatal care
- Identifying research opportunities and gaps
- Providing resources to support a growing community of researchers

UCSF served as the secretariat from 2018–2020. During this appointment, the collaborative has made several significant achievements including the development of a website and engagement on webinars and discussions to promote the use of group ANC globally. More information on the Global Group Antenatal Care Collaborative and its achievements can be found at ganccollaborative.com.

Despite the successful implementation of group ANC for this trial in Rwanda, two years is a short time frame to document all the possible effects of group ANC on family health. Many women may be more motivated to use family planning later in the year after an infant's birth or increase their ANC attendance for subsequent pregnancies. Behavioral change and community acceptance of this new ANC model will take time to develop. We assert that group ANC should be studied across longer evaluation timelines and with a wider set of study outcomes.

We are confident in the power of group ANC and the importance of prioritizing the experience of care to develop healthy outcomes for mothers and babies around the world. In our trial, we observed the impact that support systems and deepened relationships among facility providers, CHWs and women could have on women's pursuit of health knowledge and comfort with taking steps to best support their health and their baby's health. Nevertheless, we were confronted with the barriers that affect ANC delivery everywhere, including workforce shortages, staffing models, scheduling inflexibility, and lack of community support.

Transforming ANC into a positive experience for women, as well as reducing prematurity and preventable maternal and neonatal mortality will require a comprehensive and multifaceted approach. The Global Group ANC Collaborative, summarized in Box 4, exists to advance group ANC's role in this transformation.

In conclusion, we hope our lessons learned and recommendations (Figure 10) can help others to further refine their implementation and research plans so that all women will have a positive pregnancy experience that meets their needs and ensures a healthy outcome for mother and baby.

Figure 10. Lessons and recommendations for group ANC implementation

Strengthening relationships

Experience of care is transformed by social support

Key to success is facilitative leadership, group consistency, and the integration of CHWs in group ANC facilitation

Structural barriers

Group ANC magnified existing and urgent ANC delivery barriers

We must understand and mitigate these barriers for the optimal success of ANC, specifically group ANC

Increased dose

Group ANC benefits may increase with more contacts

A flexible model or mixture of individual and group ANC and PNC visits during the childbearing year may increase attendance and be beneficial to both women and the health system.

Improved measurements

A high-quality first-trimester GA assessment is needed to optimally assess outcomes on preterm birth rates

Strengthening routine measurement for a wide range of ANC-related outcomes will allow for the detection of all benefits of group ANC

Alternative benefits

Group ANC may be most beneficial for alternative outcomes or targeted populations, specifically for women at the highest risk of preterm birth.

There is a need for continued exploration of alternative benefits of group ANC already documented by others such as mental health, long-term family health outcomes, and cost-effectiveness.



Appendix A: Study Methods & Implementation

Study design

To test our hypothesis, we developed a cluster randomized control trial, in which randomization was conducted at the health centre level so that all women at each health centre were offered the same model of care. Facilities were matched based on similarity, using the characteristics shown in Figure 11. Once separated into matched pairs, one facility in each pair was randomized to continue individual ANC/PNC (control) while the other was assigned to group ANC /PNC (intervention). These health centre pairs were then matched to similar pairs and further randomized so that half of all health centre pairs offered basic ultrasound and urine pregnancy testing (UPT) at the community level, as a secondary intervention. This ultimately created an intervention group of 18 health centres providing group ANC, half of which included ultrasound and UPT, and a control group of 18 health centres providing standard individual ANC, half of which included ultrasound and UPT, as shown in Figure 12. A more in-depth description of our study model can be found in our published paper on the Study Protocol.²

Figure 11. Characteristics used for pair-matching of health centres

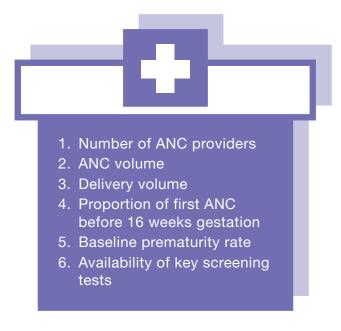
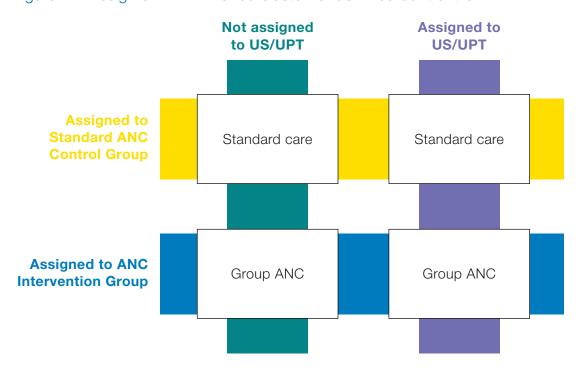


Figure 12. Design of PTBi-Rwanda cluster-randomized control trial



UPT within the community were administered by community health workers (CHWs) following training from the Rwanda Biomedical Centre and the provision of testing kits. CHWs who administered these tests were supervised by the health facilities. Ultrasound examinations were conducted by nurses and midwives who were newly trained by the Rwanda Society of Radiologists and subsequently received mentorship from the nearest district hospital. Ultrasound scans were conducted on the day of a woman's first ANC visit or soon following.

Implementation setting

The study took place at 36 health centres across five districts in Rwanda. The 36 health centres were selected, before matching and randomization, from 55 possible centres because they met our volume estimates for patients and providers needed to implement this group ANC and PNC model. We included centres that 1) reported more than 48 first ANC appointments per month and 2) on any day ANC was provided, 2 or more providers were assigned to ANC service. This selection criteria ensured group care sizes could be met and that each site had the infrastructure to deliver group ANC.

All of the 36 facilities within our study were government-run health centres that provided many primary services, including intrapartum care for uncomplicated vaginal deliveries. Each facility had approximately 11 nurses and no physicians. At baseline, these 36 health centres averaged 50 deliveries and 98 new ANC registrants per month. Half of these pregnant women enrolled in ANC before 16 weeks' gestation. Seventy-eight percent of facilities were in rural settings, and the average distance to the nearest referral hospital was 30 kilometers. Additional baseline characteristics of the health facilities by study arm (i.e. control = standard ANC; intervention = group ANC) are in Table 3.

Table 3. Baseline facility characteristics of PTBi-Rwanda trial by study group

	Control	Intervention
Average facility births (per month)	57	50
Average facility enrollment in ANC (per month)	98	97
Proportion of women attending their 1st ANC before 16 weeks	45%	53%
Number of basic ANC screening tests available (out of 5)	4.7	4.5
Proportion of facilities considered rural	83%	72%
Average distance to referral hospital (kilometers)	31	32

Adapted from Sayinzoga et al. 2021

Participants

During the first ANC visit, we collected baseline characteristics from women who agreed to participate in the study, some of which are represented in Table 4.28 A complete list of baseline characteristics and risk factors among women within our study were used to determine whether the two study groups were equivalent. As is common with such large sample sizes, there were various differences in the populations, however it seemed unlikely that these differences greatly impacted our outcomes because they did not combine to an overall pattern of higher risk in one group or another. The two groups were similar for most characteristics, though some interesting differences included fewer women in the intervention group with health insurance, but more women in the control group engaged in agricultural work. Women in the intervention group had higher levels of education (protective) but also higher levels of maternal stunting and wasting (risk factors). Overall, we concluded that the groups were successfully balanced. We adjusted for these differences in the analysis of both the primary and secondary outcomes.

Table 4: Characteristics of women within PTBi-Rwanda trial

Control	Intervention	
82%	86%	Between ages 18-35
18%	19%	Within the lowest socioeconomic status "Ubudehe" category
91%	89%	Access to health insurance
76%	71%	Primary education or less
78%	69%	Work in agriculture outside the home
.3%	.7%	History of preterm birth
1.6%	2.4%	History of stillbirth
26%	30%	Nulliparous
2%	2%	History of infant with low birthweight

Adapted from Sayinzoga et al. 2021.

Appendix B: Data Sources

	Population & size	Time frame	Purpose
Trial Enrollment Survey	Cohort	At the time of enrollment	To collect data on demographics, risk factors, health history, care recieved and health status.
Trial Follow-up Survey	Cohort	At each subsequent ANC visit	To collect data on services received and health status at each visit
Participant Survey	2682 baseline, 1650 end line responses (surveyed first 5 women each month, at each facility)	At enrollment and repeated at 6 weeks postnatal	To understand participants' experience of group care, pregnancy knowledge, presence or absence of social support (MSPSS survey), mental health status (EPDS depression screening), barriers to care and family planning.
Provider Survey	167 health providers at baseline, 99 providers at follow up	At provider training and 9 months after implementation	To understand provider attitudes and stressors involving group ANC
Group Visit Debrief Questionnaire	2763 questionnaires from group ANC facilitators	Continuously throughout study	To collect descriptive details completed by providers after each group session, as well as successes and challenges of the visit and process indicators through pre-determined checkboxes
Model Fidelity Assessment	150-questionnaires completed by Master Trainers (84 matched with provider debriefs)	Continuous throughout study	To assess fidelity and performance indicators of group ANC sessions using 5-point Likert scale
Preliminary qualitative study with women	16 focus group discussions (FGDs) with 180 participants	August 2016	To capture the context of experiences with ANC service delivery, perceptions of benefits and limitations with current ANC and PNC services, and perceptions of the feasibility and acceptability of group care
Post group ANC qualitative study with women	6 focus groups (3 health centres with the highest and 3 with the lowest group visit attendance rates)	April 2018 (~9 months after group ANC model implemented)	To capture reasons women chose to attend or not attend group ANC and PNC visits, as well as soliciting suggestions to strengthen the program
Preliminary provider experiences	22 in-depth interviews with providers and health officials	August 2016	To capture perceptions of ANC and PNC generally as well as interests and/or concerns about group care

Appendix C: Published Work

Assessing the impact of group antenatal care on gestational length in Rwanda: A cluster-randomized trial.

Sayinzoga F, Lundeen T, Musange SF, Butrick E, Nzeyimana D, Murindahabi N, Azman-Firdaus H, Sloan NL, Benitez A, Phillips B, Ghosh R, Walker D. Assessing the impact of group antenatal care on gestational length in Rwanda: A cluster-randomized trial. PLoS One. 2021 Feb 2;16(2):e0246442. doi: PMID: 33529256; PMCID: PMC7853466.

Before and after implementation of group antenatal care in Rwanda: a qualitative study of women's experiences.

Musabyimana A, Lundeen T, Butrick E, Lundeen T, Butrick E, Sayinzoga F, Rwabufigiri BN, Walker D, Musange SF. Before and after implementation of group antenatal care in Rwanda: a qualitative study of women's experiences. Reprod Health. 2019 Jun 27;16(1):90. doi: 10.1186/s12978-019-0750-5.

Group antenatal care versus standard antenatal care and effect on mean gestational age at birth in Rwanda: protocol for a cluster randomized controlled trial.

Musange SF, Butrick E, Lundeen T, Phillips BS, Tengera O, Kambogo A, Uwera YDN, Musabyimana A, Sayinzoga F, Nzeyimana D, Murindahabi N, Musange S, Walker D. Model fidelity of group antenatal and postnatal care: a process analysis of the first implementation of this innovative service model by the Preterm Birth Initiative-Rwanda. Gates Open Res. 2020 Jan 7;4:7. doi: 10.12688/ gatesopenres.13090.1.

Model fidelity of group antenatal and postnatal care: a process analysis of the first implementation of this innovative service model by the Preterm Birth Initiative-Rwanda.

Butrick E, Lundeen T, Phillips BS, Tengera O, Kambogo A, Uwera YDN, Musabyimana A, Sayinzoga F, Nzeyimana D, Murindahabi N, Musange S, Walker D. Model fidelity of group antenatal and postnatal care: a process analysis of the first implementation of this innovative service model by the Preterm Birth Initiative-Rwanda. Gates Open Res. 2020 Jan 7;4:7. doi: 10.12688/ gatesopenres.13090.1

Nurses and midwives' experiences of providing group antenatal and postnatal care at 18 health centres in Rwanda: A mixed methods study.

Lundeen T, Musange S, Azman H, Nzeyimana D, Murindahabi N, Butrick E, Walker D. Nurses' and midwives' experiences of providing group antenatal and postnatal care at 18 health centers in Rwanda: A mixed methods study. PLoS One. 2019 Jul 11;14(7):e0219471. doi: 10.1371/journal. pone.0219471.

Postnatal care in Rwanda: facilitators and barriers to postnatal care attendance and recommendations to improve participation.

Williams P, Murindahabi NK, Butrick E, Nzeyimana D. Sayinzoga F. Ngabo B. Musabyimana A. Musange SF. Postnatal care in Rwanda: facilitators and barriers to postnatal care attendance and recommendations to improve participation. J Glob Health Rep. 2019;3(1). doi: 10.29392/joghr.3.e2019032.

Predictors of postpartum family planning in Rwanda: the influence of male involvement and healthcare experience.

Williams P, Santos N, Azman-Firdaus H, Musange S, Walker D, Sayinzoga F, Chen YH. Predictors of postpartum family planning in Rwanda: the influence of male involvement and healthcare experience. BMC Womens Health. 2021 Mar 19;21(1):112. doi: 10.1186/s12905-021-01253-0.

Use of a Facilitated Group Process to Design and Implement a Group Antenatal and Postnatal Care Program in Rwanda.

Sayinzoga F, Lundeen T, Gakwerere M, Manzi E, Nsaba YDU, Umuziga MP, Kalisa IR, Musange SF, Walker D. Use of a Facilitated Group Process to Design and Implement a Group Antenatal and Postnatal Care Program in Rwanda. J Midwifery

Endnotes

- Mazzoni, S. E. & Carter, E. B. Group prenatal care. American Journal of Obstetrics and Gynecology vol. 216 552-556 (2017).
- Musange, S. F. et al. Group antenatal care versus standard antenatal care and effect on mean gestational age at birth in Rwanda: protocol for a cluster randomized controlled trial. Gates Open Res. 3, 1548 (2019).
- 3 Maternal mortality. World Health Organization (2019). Available at: https://www.who.int/news-room/ fact-sheets/detail/maternal-mortality.
- WHO recommendations on antenatal care for a positive pregnancy experience.
- Hildingsson, I., Haines, H., Cross, M., Pallant, J. F. & Rubertsson, C. Women's satisfaction with antenatal care: Comparing women in Sweden and Australia. Women and Birth 26, e9-e14 (2013).
- Catling, C. J. et al. Group versus conventional antenatal care for women. Cochrane Database of Systematic Reviews vol. 2015 (2015).
- 7 Rising, S. S. Centering pregnancy: An interdisciplinary model of empowerment. J. Nurse. Midwifery. 43, 46-54 (1998).
- Ickovics, J. R. et al. Cluster randomized controlled trial of group prenatal care: Perinatal outcomes among adolescents in New York city health centers. Am. J. Public Health 106, 359-365 (2016).
- Picklesimer, A. H., Billings, D., Hale, N., Blackhurst, D. & Covington-Kolb, S. The effect of CenteringPregnancy group prenatal care on preterm birth in a low-income population. Am. J. Obstet. Gynecol. 206, 415.e1-415. e7 (2012).
- 10 Ickovics, J. R. et al. Group prenatal care and perinatal outcomes: A randomized controlled trial. Obstet. Gynecol. 110, 330-339 (2007).
- 11 Lori, J. R., Ofosu-Darkwah, H., Boyd, C. J., Banerjee, T. & Adanu, R. M. K. Improving health literacy through group antenatal care: a prospective cohort study. BMC Pregnancy Childbirth 17, 228 (2017).
- 12 Patil, C. L. et al. Implementation challenges and outcomes of a randomized controlled pilot study of a group prenatal care model in Malawi and Tanzania. Int. J. Gynecol. Obstet. 139, 290-296 (2017).
- 13 Grenier, L. et al. Impact of group antenatal care (G-ANC) versus individual antenatal care (ANC) on quality of care, ANC attendance and facility-based delivery: A pragmatic cluster-randomized controlled trial in Kenya and Nigeria. PLoS One 14, (2019).
- 14 Rwanda Ministry of Health. Personal Communication, HMIS Data.
- 15 Chawanpaiboon, S. et al. Global, regional, and national estimates of levels of preterm birth in 2014: a systematic review and modelling analysis. Lancet Glob. Heal. 7, e37-e46 (2019).

- 16 Nsereko, E. et al. Maternal genitourinary infections and poor nutritional status increase risk of preterm birth in Gasabo District, Rwanda: A prospective, longitudinal, cohort study. BMC Pregnancy Childbirth 20, 345 (2020).
- 17 Kigali, R. Republic of Rwanda Rwanda Demographic and Health Survey 2014-15 Final Report National Institute of Statistics of Rwanda Kigali, Rwanda Ministry of Finance and Economic Planning Kigali, Rwanda Ministry of Health. (2016).
- 18 Miller, L. et al. Working with what you have: How the East Africa Preterm Birth Initiative used gestational age data from facility maternity registers. PLoS One 15, e0237656 (2020).
- 19 Sayinzoga, F. et al. Use of a Facilitated Group Process to Design and Implement a Group Antenatal and Postnatal Care Program in Rwanda. J. Midwifery Women's Heal. 63, 593-601 (2018).
- 20 Butrick, E. et al. Model fidelity of group antenatal and postnatal care: a process analysis of the first implementation of this innovative service model by the Preterm Birth Initiative-Rwanda. Gates Open Res. 4, 7 (2020).
- 21 Musabyimana, A. et al. Before and after implementation of group antenatal care in Rwanda: A qualitative study of women's experiences. Reprod. Health 16, (2019).
- 22 Lundeen, T. et al. Nurses' and midwives' experiences of providing group antenatal and postnatal care at 18 health centers in Rwanda: A mixed methods study. PLoS One 14, e0219471 (2019).
- 23 Singh, Kalee. Innovating in Rwanda's Antenatal Care programs: CHW Experiences leading Group Antenatal Care Pilot Programs, Unpublished manuscript, University of California, Berkeley (2018).
- 24 Millar, K. Prevalence and Associated Factors of Antenatal Depression in Post-Conflict Rwanda: Implications for Nurse Midwifery Policy and Practice. Unpublished manuscript, University of California, San Francisco (2018).
- 25 Fisher, J. et al. Prevalence and determinants of common perinatal mental disorders in women in low-and lower-middle-income countries: A systematic review. Bulletin of the World Health Organization vol. 90 139-149 (2012).
- 26 Phoebe, M. The Measurement of Empowerment in Group Antenatal Care. Unpublished manuscript, University of California, Berkeley (2018).
- 27 Sayinzoga, F. et al. Assessing the impact of group antenatal care on gestational length in Rwanda: A cluster-randomized trial. PLoS One 16, e0246442 (2021).
- 28 Nizeyimana, P., Lee, K.W.; Sim S. A study on the classification of households in Rwanda based on factor scores. J Korean Data Inf Sci Soc. 2018;(29):947-955.



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