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Cost-effectiveness analysis of proactive home visits compared with site-based community health worker care on antenatal care outcomes in Mali: a cluster-randomised trial

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ABSTRACT

Introduction Despite recommendations from the WHO, antenatal care (ANC) coverage remains low in many low-income and middle-income countries (LMICs). Community health workers (CHWs) can play an important role in expanding ANC coverage through pregnancy identification, provision of health education, screening for complications, delivery of therapeutic care and referral to higher levels of care. However, despite the success of CHW programmes in various countries, WHO has called for additional research to develop evidence-based models that optimise CHW service delivery and that can be replicated across geographies.

Methods The ProCCM Trial was a cluster-randomised controlled trial to compare proactive home visits by CHWs (intervention, 69 village clusters) to the provision of CHW care at community fixed sites only (control, 68 village clusters) in the Bankass health district in Central Mali. In this study, we conducted a cost-effectiveness analysis of proactive CHW home visits in improving ANC utilisation, a secondary outcome of the ProCCM trial. We analysed five ANC outcomes: (1) number of ANC contacts, (2) at least one ANC contact, (3) at least four ANC contacts, (4) at least eight ANC contacts and (5) ANC initiated in the first trimester. We assumed two perspectives, a CHW programme's and the Full ANC programme's perspective, which included facility-based as well as community-based ANC. We estimated programme costs, incremental cost-effectiveness ratios (ICERs) and probabilities of the intervention being more cost-effective than the control at different willingness-to-pay (WTP) thresholds.

Results Proactive home visits were cost-saving from the CHW programme's perspective (ICERs: −\$21.39 to −\$79.20 per ANC utilisation outcome) and from the Full ANC programme perspective (ICERs: −\$1.70 to −\$6.30 per ANC utilisation outcome) compared with the fixed-site CHW care. The likelihood of the intervention being more cost-effective than the control was 100% at WTP thresholds \$0 per ANC utilisation outcome and between \$12.5 and \$50.00 per ANC utilisation outcome in the CHW- and Full ANC programme perspectives, respectively.

Conclusion Our results provide evidence that proactive home visits produce more value per dollar spent as a means of improving the uptake of ANC services compared with fixed-site CHW services.

Trial registration number NCT02694055.

INTRODUCTION

Despite recommendations from the WHO that antenatal care (ANC) is critical for maternal and newborn health, ANC coverage remains low in many low-income and middle-income countries (LMICs).[1 2] LMICs collectively account for 95% of all maternal deaths and 90% of all deaths among children under age 5 globally, and low ANC coverage contributes to the high maternal and perinatal morbidity and mortality burdens in these countries.[2] An analysis of household survey data from 58 LMICs showed that only 44% of pregnant women initiated ANC within their first trimester, and 61% received at least four ANC contacts. Only 11% received at least eight ANC contacts as per the WHO recommendation, and 11% received no ANC contacts.[3] In Mali, 80% of pregnancies in 2018 had at least one ANC contact, while only 43% of pregnancies had at least four ANC contacts.[4] Timely initiation

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WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Despite the WHO's recommendations for antenatal care (ANC), the use of ANC services in low-income settings like Mali has remained low.

⇒ Efforts to use community health worker (CHW) programmes to drive the uptake of ANC services have yielded mixed results.

⇒ This study is a cost-effectiveness analysis that compares the costs and ANC utilisation outcomes of two CHW workflows: care provided either proactively by door-to-door home visits or passively at a fixed site within a village.

WHAT THIS STUDY ADDS

⇒ We assessed the cost-effectiveness of proactive home visits versus passive site-based care for five ANC utilisation outcomes: (1) the number of ANC contacts in the current pregnancy, (2) at least one ANC contact, (3) at least four ANC contacts, (4) at least eight ANC contacts and (5) initiated ANC in the first trimester.

⇒ Our results show that, for all five outcomes, the proactive home visit workflow is more cost-effective than passive site-based care and is likely to lead to significant cost savings while simultaneously being more effective for these outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This is the first economic evaluation of proactive home visits by CHWs to increase ANC care within the context of a randomised controlled trial. It provides evidence to inform policy discussions around the adoption of proactive elements into national maternal health strategies and CHW programmes around the world.

of ANC and regular ANC contacts throughout the duration of pregnancy can reduce the risk of complication, facilitate institutional delivery and ultimately improve maternal and perinatal health outcomes.[1 5]

Community health workers (CHWs) can play an important role in expanding ANC coverage through early pregnancy identification, provision of health education, screening for complications, delivery of therapeutic care and referral to higher levels of care.[6] The delivery of these services by CHWs has been shown to improve facility-based care-seeking, institutional delivery, maternal health outcomes and neonatal health outcomes.[7–9] However, despite the success of CHW programmes in various countries, WHO has called for additional research to develop evidence-based models that optimise CHW service delivery and that can be replicated across geographies.[10 11] The development and implementation of such models benefit from an understanding of their larger population-level health and economic impact. More specifically, cost-effectiveness measures can help optimise CHW interventions within national health systems.

While many randomised controlled trials of CHW-based maternal and child health interventions have been conducted or are currently underway, only some have integrated a cost-effectiveness component.[12 13] There is a need to better understand the costs and benefits of particular CHW programme design decisions, including the organisation of CHW service delivery across service utilisation and health outcomes. The Trial of Proactive Community Case Management to Reduce Child Mortality (ProCCM), a cluster-randomised controlled trial conducted in Mali, was designed to evaluate the effect of proactive case detection home visits by CHWs on under-5 mortality.[14] A secondary aim of this trial included measuring the effect of proactive home visits by CHWs on a range of reproductive, maternal and child health service utilisation indicators, including timely initiation of ANC and number of ANC contacts because CHW home visits included pregnancy detection and follow-up. Although the trial found that the primary outcome, under-5 mortality, did not differ between proactive and passive arms, nor did facility-based delivery, ANC outcomes were significantly improved by the intervention. Patients in the proactive home visit arm were more likely to receive ANC in the first trimester, four or more ANC contacts and eight or more ANC contacts over the course of their pregnancy.[15] In this study, we estimated the cost-effectiveness of the proactive CHW home visit intervention in terms of the ANC outcomes that were measured and found to be effective in the trial.

METHODS

Health economic analysis plan

Details of the ProCCM trial methods have been published elsewhere.[14 15] The trial protocol included a health economics analysis plan for the primary and secondary outcomes. The protocol proposed to conduct a cost-effectiveness analysis (CEA) from a programmatic and household perspective to estimate the incremental cost-effectiveness ratios (ICERs) for ProCCM compared with fixed-site CHW care for the different trial outcomes.[14] In this paper, we focused on conducting a CEA of the ANC utilisation outcomes from the programmatic perspective, in line with the approach described in the trial protocol, and report our findings using the updated guidelines in the Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022).[16]

Population and setting

At the time of the trial's baseline evaluation, Mali's public healthcare system included more than 1000 community health centres nationally, at which patients paid for consultations, care services, diagnostics and therapeutics with out-of-pocket fees charged at the point of care. The trial was conducted in the Bankass health district in central Mali, which had a population of approximately 300 000 in 2016. The government and the private sector (including non-profit, informal health sector and private pharmacies) provided health services in the district. The district is divided into 22 health catchment areas, each served by a government-funded primary healthcare centre (PHC), while a government-funded secondary healthcare facility serves the entire district. Healthcare was provided at the community level by CHWs in line with the national CHW programme launched in 2016, but at baseline, CHWs covered less than 15% of the population.[17]

The ProCCM trial was conducted in seven of the 22 health catchment areas (Dimbal, Dounde, Ende, Kanibozon, Koulogon, Lessagou and Soubala). These seven catchment areas were selected in partnership with the Malian Ministry of Health's District Medical Director based on the lack of concurrent interventions in this area, willingness to participate, operational feasibility and poor maternal and child health indicators relative to the rest of the country. In 2016, at study baseline, the study area covered a population of approximately 100 000 people. All 160 villages and hamlets in the study area were mapped using a global positioning system. The great-circle distance between the centres of neighbouring villages was estimated, and villages or hamlets that were less than 1 km apart were grouped into clusters. In total, 137 clusters were formed after grouping villages and hamlets, and these were randomised to the ProCCM intervention (69 village clusters) and control (68 village clusters) arms. The trial estimated an average of 167 women of reproductive age (15–49 years) per cluster would be required to estimate the primary endpoint (under-5 mortality) using sample size estimation methods for cluster randomised trials. Trial design and sample size calculations are further detailed in the published study protocol.[14]

Trial and intervention design

The ProCCM trial was an implementation-effectiveness cluster randomised controlled trial with 137 village clusters. Sixty-nine clusters were randomised to receive proactive, systematic home visits by their CHWs (intervention), while 68 clusters were randomised to receive passive, village site-based services by their CHWs (control). In both intervention and control arms, user fees for CHW, primary care and referral care were removed, professional CHWs were deployed in each community targeting a 1 : 700 CHW to population ratio and government primary care clinics had their infrastructure, equipment and teams upgraded. Each arm was expected to provide a menu of CHW services aligned with Mali's national guidelines and globally acceptable standards. While ANC consultations were provided at the PHC level, CHWs provided ANC-related services in the community setting, such as pregnancy testing and referral, assessment of danger signs during pregnancy and referral and follow-up care (see online supplemental appendix A1 for details). Only the CHW workflow differed between study arms. In the control arm, CHWs provided care only at community fixed sites, and patients seeking care were expected to access care at these fixed sites. By contrast, in the intervention arm, CHWs conducted proactive home visits for active case finding, referral and follow-up, while also providing health services to care-seeking patients out of their home or community fixed site. Each CHW in the intervention arm was expected to visit each household in their catchment area at least two times per month. Facility-based ANC services did not differ by trial arm during the study (the seven participating PHCs serviced patients from both arms), so patients seeking ANC care at any PHC would receive the same service regardless of trial assignment.

Perspectives, time horizon and discount rates

We adopted two perspectives, the CHW budget holder's perspective and the Full ANC programme budget holder's perspective (see impact inventory in online supplemental appendix A2). From the CHW programme perspective, we assumed that the budget holder is responsible for community-level ANC activities implemented by CHWs, but is not accountable for facility-based ANC services. From the perspective of the entire ANC programme (facility-based and community-based ANC), we assumed that the budget holder is responsible for facility-based ANC services at the primary health centre level and community-based CHW services. The time horizon for the study was the ProCCM trial period of 3 years (February 2017 through January 2020), and ANC-related data were collected for each pregnant woman for the duration of the index pregnancy. Women who were pregnant towards the end of the study and delivered their babies after the study duration were not included. We did not discount future costs and health benefits as the time horizon for our analysis was short. We performed both an intent-to-treat (ITT) analysis, reported in the main paper and a per-protocol (PP) analysis, reported in the appendix.

Data, study sample and outcome measures

The ProCCM trial conducted annual household surveys at baseline, year 1, year 2 and year 3, and we used this as the primary source of service use and ANC outcomes data. All women of reproductive age (15–49 years) residing in the trial area for at least 6 months and with no plans to move in the next 3 years were eligible and asked to be surveyed. Women were asked about their pregnancy history, health-seeking behaviours during pregnancy, whether they received ANC or ANC-related services, where they received the services and which cadre of health worker(s) provided them. A total of 23 794 individuals were interviewed, with 8596 reporting at least one pregnancy during the study period. Cost data were obtained primarily from programme financial records and secondary data sources (see online supplemental appendix A3).

We focused on five ANC utilisation measures (box 1), including (1) ANC count, that is, the number of ANC contacts in the current pregnancy, (2) at least one ANC contact, (3) at least four ANC contacts, (4) at least eight ANC contacts and (5) initiated ANC in the first trimester.

Estimation of resources used by trial arm

We adopted the hybrid approach to cost estimation[18] with a combination of top-down allocation of costs for community-based CHW services and bottom-up (ingredient-based) micro-costing of services for facility-based ANC services. We adopted the hybrid approach

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Box 1 Definition of variables and parameters used in the study

Antenatal care outcomes

ANC count

The number of facility-based antenatal care (ANC) contacts at a primary health centre (PHC) for each pregnancy episode.

At least one (1) ANC contact

The proportion of pregnant women who received ANC at a PHC at least once during the current pregnancy.

At least four (4) ANC contacts

The proportion of pregnant women who received ANC at a PHC at least four times during the current pregnancy.

At least eight (8) ANC contacts

The proportion of pregnant women who received ANC at a PHC or ANC-related services from a CHW in the community at least eight times during the current pregnancy.

Initiated ANC in first trimester

The proportion of pregnant women who started ANC at a PHC in the first trimester for the current pregnancy.

CHW service uptake

Community-based CHW ANC contacts (community and home)

Mean number of community-based ANC contacts at any location in the community setting (outside PHCs). Estimates derived from household surveys.

Community-based CHW ANC contacts (at community fixed sites only)

Average number of ANC contacts at CHWs' community fixed sites. Estimates derived from household surveys.

Home-based CHW contacts

Average number of home-based ANC contacts (at the patient's home). Estimates derived from household surveys.

Resource use indicators

Community-based CHW costs

Average cost of a community-based ANC contact. Costs estimated per contact and per person. Estimates derived from ProCCM programme financial records.

Facility-based ANC costs

Average cost of providing facility-based ANC at the primary health centre. Costs estimated per contact and per person. Estimates derived from Programme ANC guidelines (online supplemental appendix A3) and ProCCM programme financial records.

CHW, community health worker; ProCCM, Proactive Community Case Management.

because programme financial records captured data that were sufficient for a top-down estimation of CHW services, but not sufficient for facility-based ANC services at the PHC level. Although data were available for ProCCM's support to PHC service-provision during the trial, data on contributions from others, including the government were not available.

For facility-based ANC services, we relied on the detailed specification of services included in the Programme guidelines for ANC service provision. The guidelines include services to be performed, diagnostic tests, medications and frequency of ANC care. The guidelines also include specific recommendations from the first ANC contact that differs from subsequent ANC contacts. Using unit cost data obtained from ProCCM invoices and secondary data sources (eg, Management Sciences for Health Drug Price Index),[19 20] we estimated costs for the first ANC contact and an average cost for subsequent ANC contacts. We then used a weighted average of ANC contacts (first ANC contacts and three follow-up ANC contacts) for our analysis (see online supplemental appendix A3.1 for details of facility-based ANC cost estimation).

We estimated the costs of community-level CHW contact by allocating costs in several steps. First, using programme financial records, we estimated costs directly allocated to the CHW components of the ProCCM programme, including CHW salaries, CHW training, CHW kits and CHW supervision. Next, as CHWs were expected to provide other services that were not ANC-related, we used time and motion data to estimate the proportion of total CHW time that was devoted to ANC-related services and applied this to the total CHW costs. Then, we added a portion of the ProCCM trial's total fixed costs to the CHW costs and divided that by the total number of CHW-years to arrive at the average cost per CHW-year for the entire programme. The total cost for each trial arm was then estimated by multiplying the average cost per CHW-year by the total number of CHW-years for that arm, and the cost-per-CHW contact was estimated by dividing the total CHW cost for each arm by the total number of CHW contacts in that arm. Details are provided in online supplemental appendix A3.

Estimation of incremental cost-effectiveness ratios (ICERs) and sensitivity analysis

For each ANC outcome, we estimated ICERs using the formula in Equation 1.

$$\frac{Cost_{ProCCM} - Cost_{iCCM}}{Outcome_{ProCCM} - Outcome_{iCCM}},\ Equation\ (1)$$

To assess the uncertainty of our estimates, we conducted probabilistic sensitivity analyses (PSA) using the bootstrap approach. We performed 10 000 bootstraps ICER estimations for each ANC outcome by randomly sampling 5000 observations from the intervention arm and 5000 observations from the control arm. We then plotted all 10 000 bootstrap results on a cost-effectiveness plane to assess uncertainty. We also plotted cost-effectiveness acceptability curves for a range of willingness-to-pay (WTP) thresholds to determine the likelihood of proactive CHW home visits being more cost-effective than the fixed site-based workflow. WTP thresholds describe how much a budget holder is willing to pay for an outcome, and are therefore used in CEA, to ascertain the cost-effectiveness of an intervention. Since, there are no published WTP thresholds for ANC utilisation outcomes in Mali, plotting a cost-effectiveness acceptability curve allowed us to show the cost-effectiveness of each ANC utilisation outcome over a range of WTP thresholds.

Patient and public involvement statement

The ProCCM trial was designed and implemented in collaboration with several important stakeholders,

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Table 1 Descriptive analysis—costs and outcomes over the 3 years of the ProCCM trial

ANC outcome	Intervention	Control	Difference=T-C (ratio=T/C)
ANC counts (mean)	2.98 contacts	2.74 contacts	0.24 contacts
ANC in first trimester*	51%	45%	1.13
At least one (1) ANC contact†	79%	65%	1.21
At least four (4) ANC contacts‡	71%	53%	1.34
At least eight (8) ANC contacts‡	17.7%	5.1%	3.48
CHW and ANC service provision			
Total number of CHW ANC contacts (community fixed sites and home based)	9272	2133	7139
Total number of PHC ANC contacts	2040	791	1249
Mean community-based CHW ANC contacts (community fixed sites and home-based) per pregnancy	2.71 contacts	1.62 contacts	Difference: 1.09 contacts Ratio: 1.67
Mean community-based CHW ANC contacts (community only)	0.59 contacts	1.02 contacts	Difference: −0.43 contacts Ratio: 0.58
Mean home-based CHW ANC contacts	2.1 contacts	0.61§	Difference: 1.49 contacts Ratio: 3.45
Costs			
Cost per CHW-year	$110.94	$110.94	
Number of CHW-years¶	337	279	
CHW cost per single contact**	$4.03	$14.51	
CHW cost per person contacted††	Mean= $10.90 Median= $8.06 IQR = $12.10	Mean= $17.20 Median= $14.50 IQR = $29.00	
Facility-based ANC cost per contact††	First ANC contact = $32.27 Subsequent ANC contacts‡‡ = $15.49 Weighted average§§ = $19.69	First ANC contact = $32.27 Subsequent ANC contacts‡‡ = $15.49 Weighted average§§ = $19.69	
Facility-based ANC cost per person††	Mean= $58.80 Median= $59.10 IQR = $39.40	Mean= $53.90 Median= $59.10 IQR = $39.40	

*Numerator=number of pregnancies that had ANC in the first trimester; denominator=total number of pregnancies.
†Numerator=number of pregnancies with at least one facility-based ANC contact; denominator=total number of pregnancies.
‡Numerator=number of pregnancies with at least x facility-based ANC contacts, where x=4, or x=8; denominator=total number of pregnancies.
§Although the protocol did not include home-based contacts in the control group, some women reported receiving home-based CHW contacts in the control group.
¶Annual cost per CHW did not vary by intervention arm. All CHWs were paid equally and had the same benefits.
**Cost per CHW contact = ((cost per CHW-year) * (total number of CHW years))/total number of CHW contacts. See online supplemental appendix for details.
††ANC costs were estimated using Mali's national ANC guidelines and unit cost estimates from ProCCM supplier records. The package of ANC services was similar for intervention and control arms according to the study design.
‡‡Cost per person estimates were derived by multiplying the cost per contact by the number of contacts.
§§The weighted average was estimated assuming a first ANC contact and three subsequent ANC contacts.
ANC, antenatal care; CHW, community health worker; PHC, primary healthcare centre; ProCCM, Proactive Community Case Management .

including government policymakers, service providers and patients. Communities were consulted before community entry and all stakeholders were actively engaged throughout the duration of the trial.

RESULTS

Study parameters

Table 1 summarises the variables and parameters included in this study. On average, the number of facility-based ANC contacts per pregnancy was 2.98 in the intervention arm and 2.74 in the control arm. Fifty-one per cent of women in the intervention arm started ANC in the first trimester, compared with 45% in the control arm. Seventy-nine per cent and 65% had at least one ANC contact during pregnancy in the intervention and control arms, respectively. Seventy-one per cent of pregnancies in the intervention arm had at least four ANC contacts, while 53% had at least four ANC contacts in the control arm. By contrast, a smaller proportion had at least eight ANC contacts in the intervention (17.7%) and control (5.1%) arms. On average, women in the intervention arm had 1.09 more CHW

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Table 2 Incremental cost-effectiveness ratios

ANC outcome	CHW perspective ICER	Full ANC programme perspective ICER
Incremental cost per additional ANC contact*	–$21.39	–$1.70
Incremental cost per additional person who initiated ANC in the first trimester*	–$79.20	–$6.30
Incremental cost per additional person with at least one (1) ANC contact*	–$38.71	–$3.08
Incremental cost per additional person with at least four (4) ANC contacts*	–$32.54	–$2.59
Incremental cost per additional person with at least eight (8) ANC contacts	–$47.65	–$3.79
Mali's GDP per capita (2021)†	$881.51	

*Negative values indicate lower costs (or effects) in the treatment arm compared with the control arm. In our analysis, all bootstrap scenarios that included negative effectiveness also included negative costs, therefore the negative ICERs reflect true cost savings.
†The WHO recommends a willingness to pay threshold for health outcomes of two to three times a country's GDP per capita. Although ANC uptake is a behavioural outcome, not a health outcome, we include Mali's GDP per capita as a reference for comparison.
ANC, antenatal care; CHW, community health worker; GDP, gross domestic product; ICER, incremental cost-effectiveness ratios.

contacts for ANC (2.71) than those in the control arm (1.62).

The mean cost to the ANC programme per CHW-year was $110.94, and this included CHW salaries, training, supervision and kits. These costs did not differ per study arm because CHWs received the same pay, supervision, training and equipment. The mean cost per CHW contact for ANC in the community (including home contacts) was $4.03 in the intervention arm and $14.51 in the control arm. The mean cost of the first facility-based ANC contact was $32.27, and subsequent facility-based ANC contacts were $15.49 per contact, for a weighted average of $19.69 per contact. Mean CHW ANC cost per person was $10.90 (median= $8.06; IQR= $12.10) in the intervention arm and $17.20 (median= $14.50; IQR = $29.00) in the control arm. The mean facility-based ANC cost per person was $58.80 (median= $59.10; IQR= $39.40) in the intervention arm and $53.90 (median= $59.10; IQR = $39.40) in the control arm.

Main outcomes

Table 2 provides estimates of ICERs for all four ANC utilisation outcomes and both analytic (CHW and Full ANC programme) perspectives. From the CHW programme's perspective, proactive CHW service delivery dominates fixed site-based CHW service delivery as an ANC uptake strategy, as it costs less per person but leads to better ANC outcomes. The intervention costs $21.39 less than the control for each additional ANC contact, $79.20 less for each additional pregnancy that initiates ANC in the first trimester, $38.71 less for each additional pregnancy with at least one ANC contact, $32.54 less for each additional pregnancy with at least four ANC contacts and $47.65 less for each additional pregnancy with at least eight ANC contacts.

From the Full ANC programme perspective, the intervention (proactive home visit) arm was cost-effective compared with the control (passive site-based) arm for all four ANC outcomes. On average, it would cost $1.70 less to get one additional ANC contact in the intervention arm, $6.30 less per additional pregnancy that initiates ANC in the first trimester, $3.08 less for each additional pregnancy with at least one ANC contact, $2.59 less for each additional pregnancy with at least four ANC contacts and $3.79 less for each additional pregnancy with at least eight ANC contacts. Results from the PP analysis are presented in online supplemental appendix A4.

Figure 1 shows the distribution of incremental costs and effectiveness from the CHW programme perspective, with each dot representing one of the 10 000 bootstrap estimates. For two ANC outcomes (at least one ANC contact and at least four ANC contacts), the intervention costs less and is more effective than the control for all bootstrap estimates. Some bootstrap estimates have negative incremental effectiveness for ANC counts and first-trimester ANC contact outcomes. However, the proactive intervention still dominates the control as the mass of bootstrap ICER estimates for the intervention arm cost less and are more effective than the control arm for these outcomes. The cost-effectiveness acceptability curves (see online supplemental appendix A5.1) show that for WTP thresholds spanning $0–$250, the proactive intervention was more cost-effective than the control 100% of the time.

The results from PSA of the Full ANC programme perspective are more nuanced but still show that the intervention is more cost-effective than the control for all four ANC outcomes. For two outcomes (at least one ANC contact and at least four ANC contacts), all bootstrap estimates showed that the intervention arm was more effective than the control arm, while most estimates showed that the intervention costs less than the control (figure 2). Consequently, at a WTP of $0 to achieve at

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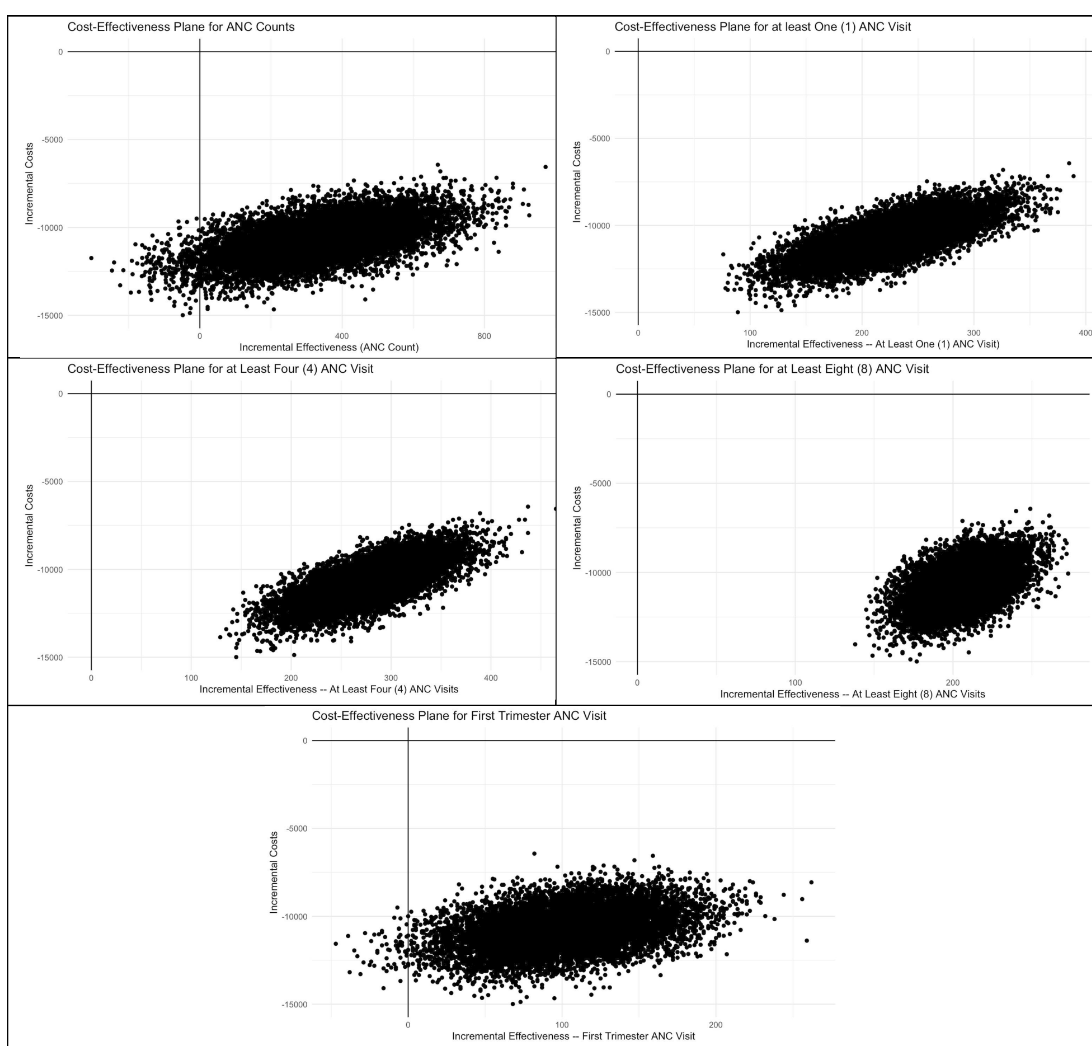

Figure 1 The results of the bootstrap analysis for each of the five ANC outcomes from the CHW programme's perspective. ANC, antenatal care; CHW, community health worker.

least one, four or eight ANC contacts, the intervention arm was more cost-effective than the control arm ~80% of the time, and this increased to 100% at a WTP of $25 for both outcomes (online supplemental appendix A5.2).

For ANC counts, the intervention arm was mostly more effective and less costly than the control, but many estimates were more effective and more expensive. As a result, at a WTP of $0 to increase ANC contacts by one, the intervention was more cost-effective than the control ~80% of the time but quickly increased to 100% at a WTP of $12.50 (online supplemental appendix A5.2). Similarly, first-trimester ANC contacts were cost-effective for most scenarios, as seen in the mass of bootstrap estimates in figure 2. At a WTP of $0 to achieve one first-trimester ANC contact, the intervention was more cost-effective than the control ~80% of the time, and this increased to 100% at a WTP of $50 (online supplemental appendix A5.2).

Results from the PP analysis showed that the proactive workflow intervention was more cost-effective than the control 100% of the time at WTP thresholds of $12.5—$50 for the CHW programme perspective (online supplemental appendix A4.3.1), and WTP thresholds of $25—$225 for the Full ANC programme's perspective (online supplemental appendix A4.3.2). Though these results are quantitatively different (higher ICERs) than ITT analysis, they nevertheless suggest that proactive intervention is more cost-effective than the control once the relevant WTP is reached. Details of PP analysis are reported in online supplemental appendix A4.

DISCUSSION

Our results show that, even at low WTP thresholds of $0, proactive home visit CHW workflow is a more cost-effective approach than passive site-based CHW workflow in improving ANC use outcomes in central Mali. Notably, home visit workflow provides significant cost savings and is more effective than site-based workflow from the CHW programme budget holder's perspective. Furthermore, it is still cost-saving from the Full ANC programme budget holder's perspective, which suggests that the costs associated with the increased ANC use stimulated by proactive home visits will be offset by the cost savings associated with

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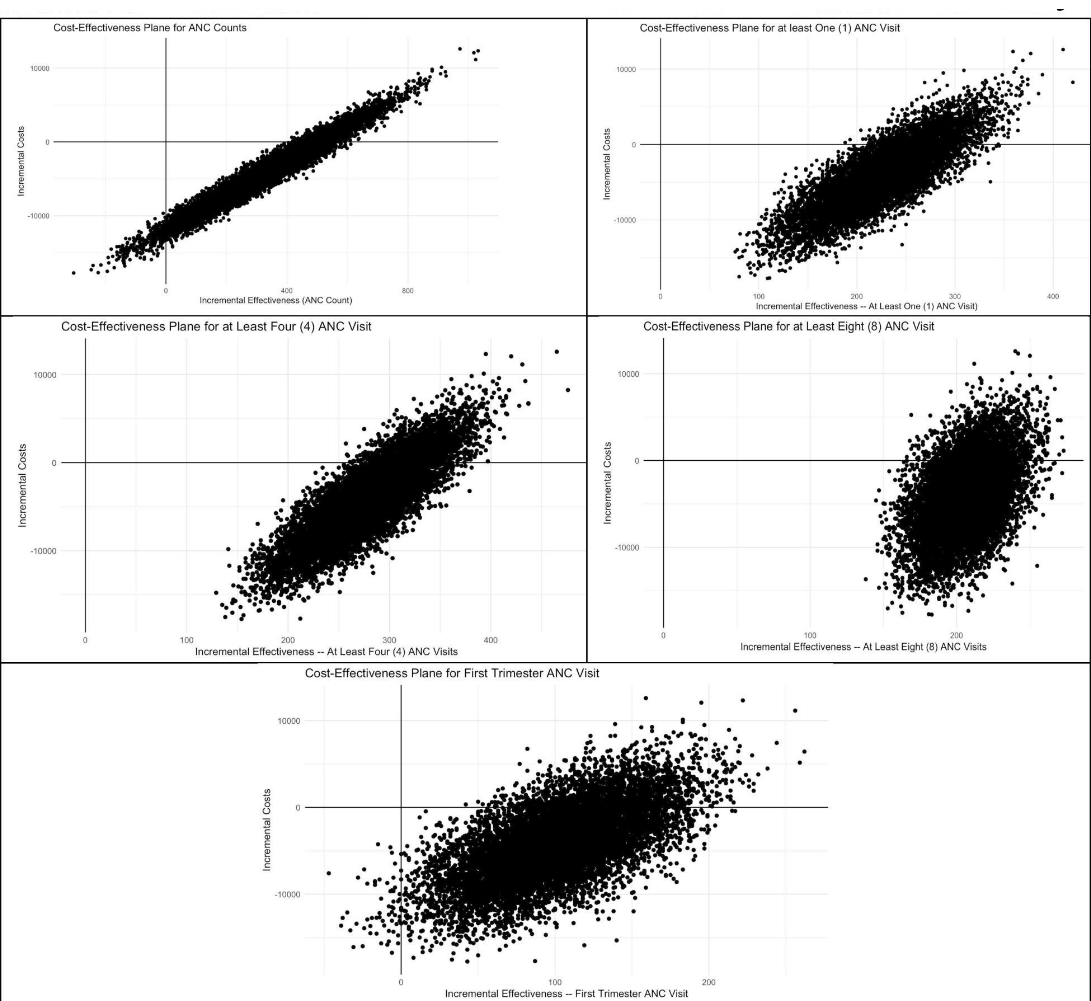

Figure 2 shows the results of the bootstrap analysis for each of the five ANC outcomes from the Full ANC programme's perspective. ANC, antenatal care; CHW, community health worker

switching from passive site-based workflow to a proactive home visit workflow for CHWs. Since average costs per CHW were similar in the intervention and control arms, the cost savings were driven mainly by the higher number of patient contacts per CHW in the intervention arm and the corresponding lower cost per contact. Similarly, as reported for other ProCCM trial services, the frequent patient contact in the intervention arm appears to drive the increased use of ANC services.[21]

These results have important implications for ANC service delivery and policy in Mali. The WHO advocates for starting ANC in the first trimester and having multiple ANC contacts during pregnancy, depending on a patient's risk profile.[1] This study provides valuable information about costs and potential impact for a policymaker considering using proactive home visits to promote ANC uptake. Mali currently has a National Strategic Plan for Community Health designed around the fixed-site model of community healthcare delivery.[17] Our results suggest that incorporating routine, proactive home visits into Mali's national community health strategy could accelerate the uptake of essential ANC services and yield cost savings that can be applied to improve service access in other areas.

Our findings are also crucial for research. Importantly, although CHW services have been shown to improve the uptake of health services, outcomes have varied at national scale in the many countries that have adopted the fixed-site model, as programme design has also varied. The 2018 WHO guidelines for community health programmes highlighted the need for more research on optimising CHW workflow.[11] To the best of our knowledge, this is the first study that compares the costs and ANC outcomes of proactive home visit and passive site-based CHW workflows in a randomised controlled trial. We, therefore, contribute robust evidence to the existing body of knowledge and advance discussions on the CHW models that support better ANC outcomes. Future research should consider addressing implementation challenges, analysing the impact of armed conflict on costs and outcomes and assessing the impact on ANC health outcomes like mortality.

There are limitations to our study. First, we did not assess pregnancy health outcomes like pregnancy complications

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and mortality, which are better measures of the ultimate effect of ANC use. Instead, we assumed that increased use of ANC services would translate to better ANC outcomes. Although this is a reasonable assumption, other factors, like the quality of ANC services used, can affect maternal and child health outcomes. It is important to note that the trial found no significant difference in facility-based delivery and under-5 mortality between study arms. Therefore, we urge caution in extrapolating our results to imply a guaranteed positive impact on facility-based deliveries or health outcomes. However, the positive impact of ProCCM on ANC should not be discounted as it is important in its own right. ANC uptake is a valuable health system behavioural outcome and is strongly recommended by WHO because of the expected benefits to the mother and newborn. The WHO recommends eight or more antenatal contacts to reduce maternal morbidity and mortality and perinatal mortality, particularly stillbirths. Yet considerable coverage gaps remain in settings of poverty. Therefore, it is important to understand the cost-effectiveness of interventions that improve ANC uptake. Second, in terms of the trial overall, we were unable to conduct the CEA as outlined in the health economic analysis plan as the trial did not report effectiveness for the primary outcome, under-5 mortality. In this analysis, we limited costs to only ANC-related services (excluding any non-ANC-related costs), and our findings should not be generalised to other non-ANC services. Furthermore, our analysis did not include individual-level expenses or productivity losses for pregnant women and accompanying family members; this may be different across intervention and control arms and might influence results at a societal level. Third, we estimated facility-based ANC costs using an ingredients-based approach because of a lack of sufficient detail in facility-based financial records to disaggregate by study arm. This resulted in estimating a cost-per-contact that assumes a patient will receive all recommended services in the guideline. But this is only sometimes the case, in practice, and the actual costs might be lower. We reviewed cost estimates from other studies and found that they were comparable to our estimates.[22 23] Fourth, we used household survey data subject to recall bias to assess CHW and ANC service use. A comparison of the survey data with programmatic data suggests that this approach likely underestimated the number of CHW contacts in the intervention arm.[15] The survey data showed some home-based CHW contacts in the control arm, probably due to contamination or recall bias. So, we conducted a PP analysis, and the results support our general conclusion that the intervention is more cost-effective than the control but at higher WTP thresholds (online supplemental appendix A4). Finally, our results may not be generalisable to other countries as Mali is a conflict-affected state, armed conflict arose in the trial area during the trial and service delivery and service uptake experiences differ from regions/countries not experiencing conflict.

Nevertheless, our study is critical because it provides strong evidence to support scaling up the uptake of ANC services through proactive home visits in similar low-ANC utilisation settings common in LMICs. Given the disproportional burden of maternal and child death in conflict-affected countries, this study adds to a much-needed area of research concerning how to improve ANC in conflict zones. It was a pragmatic RCT, so it combined the evidentiary strength of RCTs with the reality of implementing such a programme in real life. Also, in analysing household survey data, we assessed people's experience separate from the service they received and, therefore, less likely to overinflate the importance of the findings. Yet, our results unambiguously show that proactive home visit workflow dominates site-based CHW workflow in improving ANC use outcomes per dollar spent.

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Competing interests OO, MS and AZ report other grants from the Bill and Melinda Gates Foundation. OO also reports grants and consulting fees from the Partnership for Maternal Newborn and Child Health. OO is a board member of the Health Economics and Financing Programme at the Africa Centers for Disease Control. CW was employed by Muso at the time of the trial. AJ is the CEO of Muso Health and also serves as a voluntary member of the WHO's external review group for the development of a curriculum guide for community health workers and as advisory board chair of the community health impact coalition.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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Patient consent for publication Not applicable.

Ethics approval The protocol of the ProCCM trial, which included an overview of the planned cost-effectiveness analysis, was approved by the University of Bamako, Faculty of Medicine, Ethics Committee. Secondary analysis of the trial data was exempted from ethical approval by the University of California, San Francisco (ref. # 154824). The cost-effectiveness analysis was approved by the Institutional Review Board at Duke University (#2023-0564).

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