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Effect of complete adherence to antenatal care guideline during first visit on maternal and neonatal complications during the intrapartum and postpartum periods: a prospective cohort study in Northwest Ethiopia

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Abstract

Objectives: To examine the relationship between complete of providers' adherence to antenatal care guideline during first visit and maternal and neonatal complications during intrapartum and postpartum periods.

Design: Prospective cohort study

Setting: Gondar town public health facilities in Northwest, Ethiopia.

Participants: A total of 832 pregnant women with gestational age < 28 weeks who came for first ANC visit were enrolled and followed up to the first six hours of the postpartum periods.

Exposure: Providers' adherence to antenatal care guideline during first visit was the exposure variable. An 18-point checklist was used to record the level of providers' adherence. Clients who received care from providers who adhered completely to the guideline constituted the "exposed group", and those who did not receive such care constituted the "unexposed group".

Main outcomes: Maternal and neonatal complications occurred during the intrapartum and postpartum periods.

Data analysis: Negative binomial regression model was used to analyze the data. The adjusted Incidence Risk Ratio (AIRR) with 95% confidence interval (CI) was reported in the final model.

Results: A total of 782 pregnant women were followed up and included in the final analysis (254 in the exposed group and 528 non-exposed). Complete adherence to the guidelines during first visit reduced the risk of neonatal complications (**AIRR=0.56; 95% CI: 0.39, 0.79**). However, complete adherence to the guidelines was not found to have a statistically significant effect on maternal complications (**AIRR=0.84; 95% CI: 0.67, 1.05**) during the intrapartum and the postpartum periods.

Conclusions: The group that received care from providers who completely adhered to the antenatal care guidelines during the first antenatal visit showed significantly improved neonatal outcomes but did not show significant improvement in maternal outcomes. Hence, focusing on safe motherhood programs like training that gears provider's conformity to antenatal care guideline is quite crucial to improve neonatal outcomes.

Keywords: Complete provider adherence, first ANC visit, maternal complications, neonatal complications, Ethiopia

Strengths and limitations of this study

➤ The prospective nature of the study is the main strength.

➤ The proportion of drop-out rate or loss to follow-up is under the acceptable range.

➤ The outcomes of women who gave birth at home were collected through the home visit.

➤ Hawthorne effect

➤ The majority of the participants had booked their first visit during the second trimester.

Introduction

Antenatal care (ANC) is an umbrella term used to describe the care that pregnant women receive from accredited health care providers. ANC aims to ensure the safety of pregnant women and fetuses through a range of medical, educational, nutritional, and health system interventions.[1] Thus, ANC is a well-proven internationally accepted strategy used in a number of countries to improve maternal and neonate outcomes.[2]

Effective and timely implementation of ANC alone has been projected to minimize maternal and neonatal mortality by 10-20%, given satisfactory quality of the care provided and given regular attendance.[3-5] One study found that utilization of ANC at least once during pregnancy reduced the risk of neonatal mortality by 39% in Sub-Saharan African (SSA) countries.[6] Although the proportion of women who attend focused ANC for at least four visits generally tend to be satisfactory globally including SSA[7], maternal and neonatal mortality in the region remains high.[8]

Not all studies of the effectiveness of ANC come to the same conclusions. One might assume that the better the ANC, the lower the risk of pregnancy outcomes. However, there are studies reporting paradoxical findings on perinatal outcomes the effectiveness of ANC in relation to the number of visits. In 2010, one Cochrane review and Zimbabwe's largest trial reported that there were an inverse association between the number of ANC visits and the risk of stillbirth[9] and preterm birth[10], respectively. Conversely, other Cochrane reviews have reported that reduced ANC contact numbers did not have a substantial effect on the risk reduction of maternal and neonatal complications.[11][12] The heterogeneity of these results suggested that it is not only the number of ANC visits that matters but also the quality and content of care given during each visit and especially in the first visit if made in the first trimester. Moreover, none of these studies recognize the gross effect of ANC interventions on the likelihood of maternal complications arising separately during the antenatal, intrapartum and postpartum periods.

The World Health Organization (WHO) has recently recommended that, to improve maternal and neonatal outcomes, women should have at least eight ANC contacts.[1] However, in many countries worldwide, including Ethiopia, the four visits focused ANC continues to be followed as the standard practice.[13] In comparison to other ANC visits, the first ANC contact is unique for its intent and requires special attention. The first ANC visit is an important point of entry for client-provider interaction. It also provides an opportunity to screen and identify pregnant

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women who require specialized care. In addition, it is the moment when preventive and promotive interventions should be initiated.[14] In spite of these benefits, the contribution of first ANC contact in improving perinatal outcomes is blurred and requires further evaluation.

In Ethiopia, only 43 % of pregnant women had received ANC visits at least four times, and even those who receive these four did not always get the quality of care services they deserved due to providers' failure to comply with the ANC guideline.[15] [16] As an example, findings from the baseline cross-sectional study of the this study indicated that only 32% of women received complete providers' adherence to national ANC guideline during the first visit.[17] On top of this, a qualitative study done in the same area indicated that lack of adequate training was a main reason for providers not following the ANC guideline.[18]

Previous longitudinal studies conducted in Ethiopia found that compliance with ANC guideline by the providers' increased the frequency of institutional delivery, improved care of the newborn, and reduced the incidence of adverse maternal and neonatal outcomes.[16] [19-21] The contribution of provider adherence to the first-visit ANC guideline in improving perinatal outcomes, however, has not been well studied. Therefore, the aim of the present study was to examine the connection between complete provider adherence to ANC guidelines during the first visit and the risk of maternal and neonatal complications during the intrapartum and postpartum periods in Gondar town public health facilities.

Methods and materials

Study design, setting, and period

A prospective cohort study was conducted in Gondar town public health facilities from May 12, 2019 to January 30, 2020. Gondar town is located in Northwest Ethiopia. The total population size of the town is estimated to be 306,246. Of these, 156,276 were females in reproductive age.[22] In Gondar town, there is one comprehensive specialized hospital, eight public health centers, and 15 private clinics.

Population and recruitment of study participants

All pregnant women who came for ANC service during the first visit to one of the selected public health facilities during the data collection period were eligible for inclusion in the study and were then followed from the first ANC visit through the first six hours of the postpartum period. According to the Ethiopian delivery protocol, women have to be discharged six hours following birth unless there is a serious complication.[23] Pregnant women recruited and followed were to be 18 years or older, have reached gestational age of 28 weeks and below, were permanent residents in the study area, and were willing to take the routine ANC service throughout pregnancy. Clients who received complete providers' adherence to ANC guideline during the first visit were designated as belonging to the **exposed group** and incomplete providers' adherence to ANC guideline during the first visit were designated as belonging to the **un-exposed group.**

Sample size and sampling procedure

The sample size was calculated using Epi Info 7 software [24] taking into account the following statistical assumptions:: confidence level of 95% (2-sided), power of 80 %, exposed to the non-exposed ratio of 1:2, the overall incidence (non-exposed group) for any pregnancy, delivery or postpartum complication was 68.6% taken from the study conducted in Ghana.[25] We believed that the status of health coverage and setting in Ghana and Ethiopia are almost the same. Quality of ANC alone has been reported to reduce maternal and neonatal mortality by 10-20%.[4] [5] Therefore, we assumed that the incidence of maternal and neonatal complications would be decreased by 15.4% if Ethiopian providers completely adhere to the ANC guidelines during the first visit, and would result in the overall incidence of complications to be 53.2% amongst the exposed group (complete adherence). This study also considered the design effect of 2 and lost

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follow-up and non-response rate of 10%. By considering all those assumptions, the minimum sample size required for the study was found to be 832 participants, of which 277 were exposed(complete adherence) and 555 un-exposed women (incomplete adherence).

To conduct this study, a multistage sampling technique was employed. In the first step, four health facilities (one university hospital and three health centers) were selected out of nine public health facilities by a simple random sampling technique. The details of the sampling procedure have been described elsewhere.[17]

Data collection processes and tools

Pregnant women who met the inclusion requirements and who gave informed consent for participation were enrolled in the study. After enrollment, an 18-item structured observation checklist developed on the basis of the ANC protocol was used to record how the ANC services were given and what information was provided during the first ANC visit.[23] [26] A pre-tested structured questionnaire was used to guide the collection of the baseline socio-demographic and obstetric characteristics of study participants by face-to-face interview.

Once the women had finished their first ANC visit, they were categorized as belonging to either the exposed group or the un-exposed group and then followed prospectively through the first six hours of the postpartum period. On the subsequent ANC visits, another structured 9-point checklist extracted from the ANC guideline was used to record how the care provided particularly counseling on iron and folic acid supplementation, tetanus immunization, how to recognize danger signs, what to do, and where to get help, HIV testing and counseling, the benefit of skilled attendance at birth, nutrition, de-worming, birth preparedness' and complication readiness plan, and risks of using tobacco and alcohol during pregnancy. At the same time, medical records and antenatal care charts of subsequent antenatal clinic visits were also reviewed and documented by following the checklist to be sure that any antenatal complications (antepartum hemorrhage, pregnancy induced hypertension, anemia, infection, gestational diabetes, abortion, premature rupture of membrane, and other medical complications) had been checked for and identified. Finally, maternal outcomes (antepartum hemorrhage, pregnancy induced hypertension, postpartum hemorrhage, obstructed labor, cesarean section, and tear) and neonatal outcomes (stillbirth, preterm birth, APGAR score, and low birth weight) during intrapartum and postpartum period were collected from both the maternal health record book and delivery register and documented in the checklist prepared for this purpose.

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The participants' addresses and telephone numbers were linked to their study identification numbers. Those clients who didn't avail themselves of the scheduled ANC visit were contacted through a telephone call. All participants received a phone call at the time of their expected delivery to determine if they had given birth or not. Once they assured us that they had experienced delivery, the data collectors went to the facility where the women had given birth and extracted delivery data from both the maternal health record or chart and the delivery register. Women who delivered at home and were reachable were called and a home visit was done to collect information about delivery outcomes. Those who could not be reached by any of these means were treated as lost to follow-up.

Seven female midwife data collectors and three supervisors with a Masters degree in clinical midwifery were recruited, and they were given three days of training on how to use the data collection instrument and how to approach the pregnant women and record the nature of the service they had received. On-site supervision was conducted during data collection.

Study variables

Outcome variable

The outcome variables were maternal and neonatal complications during the intrapartum and postpartum periods. A combined maternal complication was defined as occurrence complications such as Pregnancy-Induced Hypertension(PIH) (defined as systolic blood pressure $\geq$ 140 mmHg and/or diastolic blood pressure $\geq$ 90 mmHg after 20 weeks of pregnancy with or without proteinuria or with tonic-clonic convulsion), cesarean delivery, Antepartum Hemorrhage(APH) (defined as bleeding from or in to the genital tract, occurring during third trimesters of pregnancy and prior to the birth of the baby), Postpartum Hemorrhage (PPH) (was defined as any amount of bleeding from or into the genital tract following birth of the baby up to six hours in the postpartum period, which adversely affected the general condition of the patient as evidenced by rise in pulse rate and/or falling blood pressure), genital tear (defined as injuries following childbirth process involving vulva, perineum, vagina, and/or cervix), and /or obstructed labor (defined as arrest of descent in spite of good uterine contractions due to mechanical obstruction).[27]

Combined neonatal complications were also defined as the occurrence of adverse neonatal outcomes such as stillbirth, preterm birth (<37 weeks)[28], poor Apgar score (5th minute Apgar

score <7)[29], and/or low birth weight (<2500 gm)[30]. Both the women and the newborns could have more than one complication.

Primary exposure variable

The primary exposure variable for this study was the level of the **providers' adherence** to the ANC guideline during the first visit. Adherence was defined as the providers' degree of conformity to following the standard ANC guidelines as per the national protocols [31] by an observer using the 18-point checklist. The observed variables to be attended to as indicated by the checklist include age asked, gestational age calculated, parity asked, past obstetric history asked, previous abdominal-pelvic surgery asked or checked, medical general history asked, current pregnancy history asked, weight measured, blood pressure checked, the abdominal examination done, hemoglobin test done, urine test done, VDRL done, blood group and Rh, HIV test done, tetanus injection given, iron and folic tablets prescribed and counseling done. Each variable adhered to, scored a point of 1 while non-adherence scored 0. **Complete provider adherence** was defined as clients who received all the 18 items adhered to by the provider as listed in care guidelines for the first ANC visit (total score = 18). The observation checklist, scoring criteria, and the entire method for the baseline of the cohort study have been described elsewhere.[17]

Covariates

Several explanatory variables were included as covariates. These include a range of maternal socio-demographic variables such as maternal age, residence, religion, marital status, educational level, and employment status. Obstetric characteristics such as time of booking (early booking was defined as the initiation of first ANC <16 weeks of gestation)[26], gravidity, parity, previous history of obstetric complications, birth-to-pregnancy interval, the intention of the current pregnancy, history of female genital mutilation, current ANC complications, number of ANC visit attended, place of current delivery, mode of delivery of the current pregnancy, and counseling received during pregnancy.

Counseling service during pregnancy was measured by nine composite variables. Each counseling service occurrence was recorded starting from the second visit up to the last visit. To say the woman was counseled for one variable, the counseling had to be given in all visits. When one component of counseling service was given at all visits, it was coded as 1 otherwise 0.

Finally, composite counseling service was defined as pregnant women who got at least one or more variable out of the nine counseling variables.[16]

Data analysis

Data were entered using Epi Info version 7 and analyzed using Stata 14 software. Descriptive analysis of participants' socio-demographic and obstetric information was conducted by the use of frequencies and chi-square analysis. Incidences of maternal and neonatal complications during intrapartum and postpartum period were estimated in percentages. Possible associations of adherence with each adverse outcome were assessed using Pearson's chi-square test. Since the maternal and neonatal complications are outcome variables of the study and the numbers of complications are considered as count data, Poisson regression was used as a standard model for analysis. However, the observation should be independent over time and the mean and the variance should be equal. In this study, the variance was greater than the mean; this indicates the presence of overdispersion. Hence, the negative binomial model was used to estimate the effect of complete adherence on the risk of maternal, and neonatal complications were estimated and expressed as Incidence Risk Ratio (IRR) with their 95% confidence intervals (CI). Separate models were done for maternal and neonatal outcomes. To control confounders, the models were adjusted with selected maternal socio-demographic and obstetric variables (P-value ≤ 0.25 in bi-variable analysis) with outcome variables. The Adjusted Incidence Risk Ratio (AIRR) for the associations between complete provider adherence and adverse maternal and neonatal outcomes were determined after controlling for maternal socio-demographic and obstetric variables characteristics. A P-value of <0.05 was used to declare the statistical significance of independent variables. The likelihood ratio test of the parameter Alpha (α) was found to be P-value <0.001 for both models

Patient and public involvement

Patients and the public were not invited to comment on the study design or conduct of the study. However, they will be informed of the study results through publications.

Result

A total of 832 women were recruited at baseline with the number of exposed and unexposed women who were 277 and 555 respectively, prospectively followed from the first ANC visit to the first six hours of the postpartum period. Seven hundred eighty-two (93.99 %.) women were completed the follow-up and considered in the final analysis. Twenty-three (8.3%) study participants from the exposed group and 25 (4.5%) participants from the un-exposed group were lost in the follow-up. Self-referral to other health facilities and permanent change in workplace were the reasons. There was no statistically significant difference at baseline among women who completed and were then lost to follow up (Figure 1).

Adherence to first antenatal care guideline

The proportion of women who received complete providers' adherence was 32.48% [95% CI (29.3, 35.9%)].

Participants' baseline characteristics

The mean age of study participants was 25.9 years. About 651 (83.3%) were in the age group of 20-35 years. Six (2.1%) clients came from the rural area. A higher proportion of women (38.5%) who received complete adherence had no formal education (Table1). Regarding their obstetric characteristics, 551 (70.5%) booked their first ANC at 16 and above weeks of gestation. Three hundred and eight (39.4%) were primigravidea. Three-fourths of the women (73.4%) attended an antenatal clinic more than four times during the pregnancy. Forty-seven (6%) of the participants gave birth at home. Among 213 (27.2%) women who had current antenatal complications, 145 (27.5%) of them didn't receive complete providers' adherence to the first ANC guideline (Table2).

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Table 1: Socio-demographic characteristics of study participants among exposed and un-exposed groups in Gondar town public health facilities, 2020

Socio-demographic variables		Frequency (%) of total participants N=782	Frequency (%) of the exposed group N=254	Frequency (%) of the un-exposed group N= 528	P-value
Type of health facility	Hospital	415(53.1)	131 (31.6)	284 (68.4)	0.56
	Health centers	367 (46.9)	123 (33.5)	244 (66.5)	
Age (in years)	<20	105(13.1)	27 (25.7)	78 (74.3)	0.28
	20-35	651(83.3)	218 (33.5)	433 (66.5)	
	>35	26 (3.3)	9 (34.6)	17 (65.4)	
Residence	Urban	766 (97.9)	248 (32.4)	518 (67.6)	0.66
	Rural	16 (2.1)	6 (37.5)	10 (62.5)	
Religion	Orthodox	715 (91.4)	227(31.8)	488 (68.2)	0.36
	Muslim	57 (7.3)	23(40.3)	34(59.7)	
	Others	10 (1.3)	4 (0.4)	6 (0.6)	
Marital status	Married	761 (97.3)	250(32.8)	511 (61.2)	0.18
	Unmarried	21(2.7)	4(19.1)	17 (80.9)	
Educational level	None	130 (16.6)	50 (38.5)	80 (61.5)	0.24
	Primary	191 (24.4)	56(29.3)	135 (70.7)	
	Secondary	241 (30.8)	72(29.9)	169 (70.1)	
	Tertiary	220 (28.1)	76 (34.5)	144 (65.5)	

Employment	Yes	183(23.4)	67(36.6)	116 (63.4)	0.17
	No	599 (76.6)	187(31.2)	412 (68.8)	

Table 2: Obstetric characteristics of study participants among exposed and un-exposed groups in Gondar town public health facilities, 2020

Obstetric variables		Frequency (%) of total participants N=782	Frequency (%) of Exposed group N=254	Frequency (%) of un-exposed group N= 528	P-value
Time booking	Early booking (<16 weeks)	231 (29.5)	61 (26.4)	170 (73.6)	0.02
	Late booking (≥ 16 weeks)	551 (70.5)	193 (35.0)	358 (65.0)	
Gravidity	Primigravidea	306 (39.4)	96 (31.2)	212 (68.8)	0.53
	Multigravidea	474 (60.6)	158 (33.3)	316 (66.7)	
Parity (number)	0	353 (45.1)	111 (31.4)	242 (68.6)	0.95
	1-2	355 (45.4)	119 (33.5)	236(66.5)	
	3-4	61 (7.8)	20 (32.8)	41 (67.2)	
	>4	13 (1.7)	4 (30.8)	9 (69.2)	
Previous history of pregnancy complications	Yes	105 (13.4)	42 (40.0)	63 (60.0)	0.07
	No	369(47.2)	115 (31.2)	254 (68.8)	
Birth to pregnancy interval	Short(≤24)	101(23.3)	36(35.6)	65(64.4)	0.39

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(in month)	Recommended (24-48)	172 (39.6)	55(32.0)	117(68.0)	
	Long(>48)	161(37.1)	53(32.9)	108(67.1)	
Intention of pregnancy	Planned	717 (91.7)	230(32.1)	487(67.9)	0.60
	Unplanned	65 (8.3)	24(36.9)	41(63.1)	
History of female genital mutilation	Yes	22 (2.8)	10 (45.5)	12 (54.5)	0.61
	No	760 (97.2)	244 (32.1)	516 (67.9)	
Received counseling during pregnancy	yes	702 (89.8)	231 (32.9)	471 (67.1)	0.95
	No	80 (10.2)	23 (28.8)	57 (72.2)	
Current antenatal complications	Yes	219 (28.6)	68 (31.1)	151 (68.9)	0.59
	No	569 (71.4)	186 (33.0)	377(67.0)	
Number of ANC visit attended	≤ 4 visits	208 (26.6)	66 (31.7)	142 (68.3)	0.78
	> 4visits	574 (73.4)	188(32.8)	386 (67.2)	
Place of current delivery	Health facility	735 (94.0)	242(32.9)	493(67.1)	0.30
	Home	47(6.0)	12(25.5)	35(74.5)	
Gestational age at delivery	< 37 weeks	60 (7.7)	19 (31.7)	41 (68.3)	0.82
	37-42	717 (91.7)	234 (48.4)	483 (67.4)	
	>42	5 (0.60)	1(20.0)	4 (80.0)	
Mode of delivery of the current pregnancy	Spontaneous vaginal delivery	620(79.3)	201(32.4)	419(67.6)	0.91
	Cesarean section	141(18)	47 (33.3)	94 (66.7)	
	Instrumental delivery	21(2.7)	6 (28.57)	15 (71.4)	

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The incidence of maternal and neonatal complications

Of the total of 782 women, 298 (38.1) (95% CI: 34.7, 41.6) had at least one type of maternal complications during the intrapartum and/or postpartum periods. The different incidence of maternal complications among women who received complete and incomplete providers' adherence was statistical significant; 32.7% and 40.7% respectively. Eighty-four (10.7%) participants developed PIH during intr-partum period though there was no statistical difference between the two groups (table 3).

The incidence of stillbirth, low birth weight, poor Apgar score were statistical significant higher in the un-exposed group (table 3). There was no maternal and neonatal death during the intrapartum and postpartum periods.

Table 3: Risk of maternal and neonatal complications during intra-partum and postpartum periods amongst exposed and controlled groups in Gondar town public health facilities, 2020

Complications	Incidence N=832	Exposed group n= 254	Unexposed group n= 528	P-value
Maternal				
PIH	84 (10.7)	23(9.1)	61 (11.6)	0.51
APH	43 (5.5)	14(4.7)	29 (5.9)	0.29
Obstructed labor	6 (0.8)	3 (1.2)	3 (0.6)	0.36
Tear	56 (7.2)	14 (5.5)	42 (8.0)	0.21
Cesarean section	141 (18.00)	47 (18.5)	94 (17.8)	0.81
PPH	23 (2.9)	6 (2.4)	17 (3.2)	0.5
Any intra-partum and/or postpartum complications (at least one)	298(38.1)	83 (32.7)	215(40.7)	0.03
Neonatal				
Preterm birth	60 (7.7)	19 (7.5)	41 (7.8)	0.08
Stillbirth	25 (3.2)	3 (1.2)	22 (4.2)	0.026
Low birth weight	62 (7.9)	9 (3.5)	53 (10.0)	0.02
Poor APGAR score	101 (12.9)	19 (7.5)	82 (15.5)	0.02

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Any neonatal complications(at least one)	179 (22.9)	40 (15.7)	139 (26.3)	0.001

The place of delivery was found to be one of the confounder variables for the risk of maternal and neonatal complications identified during intrapartum and within the first six hours of the postpartum period. The incidence of at least one neonatal complication among newborns who were delivered at home and at the health facilities were 44.7% and 21.5% respectively. The incidence of stillbirth and low Apgar score was much higher amongst newborns who were delivered at home than among those delivered at the health facility. The incidence of at least one maternal complication among women delivered at the facility and home was 38.4% and 34 % respectively. All women who had obstructed labor gave birth at the health facility (Figure 2).

Effect of received complete provider adherence to guidelines during the first ANC on the risk of maternal and neonatal complications

In the unadjusted negative binomial regression, complete provider adherence, maternal age, maternal education, parity, place of ANC attendance, number of ANC visits, counseling during pregnancy, current ANC complications, and place of delivery were associated with maternal and neonatal complications during intrapartum and postpartum periods. After controlling for confounding variables, only the presence of antenatal complications **(AIRR=1.83; 95% CI: 1.48, 2.26)** remained as being significantly associated with maternal complications identified during the intra-partum and postpartum periods. Similarly complete provider adherence **(AIRR=0.56; 95% CI: 0.39,0.79)**, presence of antenatal complications **(AIRR=1.9; 95% CI: 1.40, 2.58)**, attended ANC at the hospital **(AIRR=1.88; 95% CI: 1.31,2.69)**, had ANC visit more than four times **(AIRR=0.41;95% CI: 0.30,0.57),** gave birth at the health facility **(AIRR=0.49 ; 95% CI: 0.30,0.81)**, and maternal complications during intrapartum and/or the first six hour of postpartum period **(AIRR=1.48; 95% CI: 1.10,2.00)**   were significantly associated with the risk of neonatal complications (Table 4).

Table 4: Negative binomial Poisson regression analysis showing the effect of received complete provider adherence to guidelines during the first ANC on the risk of maternal and neonatal complications during intrapartum and postpartum periods

Explanatory Variables	Maternal complications			Neonatal complications		
	Unadjusted IRR (95%CI)	Adjusted IRR (95%CI)	Adjusted P-value	Unadjusted IRR (95%CI)	Adjusted IRR(95%CI)	Adjusted P-value
Received complete adherence	0.85 (0.67,1.07)	0.84(0.67,1.05)	0.14	0.51(0.36, 0.74)	**0.56 (0.39,0.79)**	**0.001**
Age (in years)						
<20	1	1		1	1	
20-35	1.24(0.89,1.72	1.2(0.85,1.71)	0.28	0.95 (0.61,1.47)	1.01 (0.65,1.59)	0.93
>35	1.31(0.70,2.45)	1.46(0.74,2.88)	0.27	1.30 (0.55,3.05)	1.28 (0.51,3.18)	0.59
Educational level						
None	1	1		1	1	1
Primary	1.1(0.78,1.56)	1.03(0.72,1.46)	0.87	1.09 (0.69,1.73)	1.08 (0.68,1.71)	0.73
Secondary	1.12(0.81,1.55)	1.11 (0.78,1.59)	0.53	0.94 (0.60,1.47)	0.97 (0.60,1.56)	0.90
Tertiary	1.24(0.90,1.73)	1.21(0.84,1.74)	0.29	0.72 (0.45,1.16	0.74 (0.44,1.24)	0.25
Parity (number)						
0	1	1		1	1	1
1-2	1.02(0.82,1.27)	1.01 (0.8,1.27)	0.91	1.04 (0.75,1.43)	0.99 (0.72,1.38)	0.99
3-4	1.11 (0.75,1.63)	1.18 (0.77,1.81	0.43	1.32 (0.76,2.28)	0.97 (0.54,1.74)	0.92
>4	0.5 (0.16,1.58)	0.46(0.14,1.55)	0.21	1.81 (0.66,4.95)	1.71 (0.59,4.94)	0.31
Place of ANC attendance						

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Hospital	0.95 (0.77,1.16)	0.88(0.68,1.12)	0.32	1.04 (0.77,1.04)	**1.88 (1.31,2.69)**	**0.001**
Health centers	1	1		1	1	
Number of ANC visit attended						
≤ 4 visits	1	1		1	1	
>4 visits	1.14 (0.89,1.45)	1.12 (0.87,1.46	0.30	0.51 (0.37,0.69)	**0.41 (0.30,0.57)**	**0.00**
Received counseling during pregnancy						
Yes	1.02 (0.79,1.33)	1.05(0.78,1.41)	0.70	0.70 (0.49,1.01)	0.69 (0.47,1.03)	0.07
No	1	1		1	1	
Current antenatal complications						
Yes	1.85 (1.50,2.28)	**1.83(1.48,2.26)**	**0.00**	1.82 (1.34,2.49)	**1.9 (1.40,2.58)**	**0.00**
No	1	1		1	1	
Place of current delivery						
Facility	1.29 (0.79,2.10)	1.21 (0.72,2.01	0.45	0.42 (0.25,0.70)	**0.49 (0.30,0.81)**	**0.005**
Home	1	1		1	1	
Maternal complications during intrapartum and/or postpartum periods	NA					
Yes	-	-	-	1.57 (1.16,2.12)	**1.48 (1.10,2.00)**	**0.009**
No	-	-	-	1	1	

NA= Not Applicable

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Discussion

The current study demonstrates the role of a provider's adherence to the ANC guidelines during the first visit in leading to improvement of maternal and neonatal outcomes. The key findings of this study are that complete adherence by the providers to the ANC guidelines during the first visit reduced the risk of neonatal complications but did not have any statistically significant effect on the risk of maternal complications occurring during the intrapartum and/or postpartum periods.

In general, improving the quality of obstetric care, if supported by guidelines, can directly reduce the incidence of maternal and neonatal deaths.[1] Guidelines can, however only lead to improved quality care if they are translated into daily provider practice.[32]

In contrast to the findings from the Ghana study [25] and contrary to our original alternative hypothesis, we found that complete provider adherence to the ANC guideline during the first visit did not have a significant effect on the risk of maternal complications during the intrapartum and/or postpartum periods. The plausible explanation for the observed difference between the findings of our present study and the study conducted in Ghana could be due to the disparity in inclusion criteria. The Ghana study included women who had their first ANC visit at gestational age below or equal to 20 weeks. But in our current study, we included women whose gestational age was below 28 weeks. This could miss opportunities for early detection of complications and initiation of certain preventive measures such as prescribing iron tablet in a timely manner.[33] There may be other factors in addition to providers' adherence to the ANC guidelines during the first visit. It is recognized that the regular subsequent antenatal attendance would encourage providers to review and provide care for what they might have missed out during the first antenatal visit. In addition, the quality of intra-partum care could affect the risk of maternal complications as well.[34] Therefore, interventions should be promoted at all levels of care that enhance providers' adherence to both the ANC and the delivery guidelines.

Other confounding determinant factors may contribute to raising the incidence of risks of maternal complications during the intrapartum and/or postpartum periods. The finding of our study revealed that the risk of clients who had any antenatal complications was 1.83 times more likely to develop maternal complications which occurred during intrapartum and/or postpartum periods compared to women to clients who had no antenatal complications. This might be due to the recurring nature of complications during labor and childbirth once they have been detected

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and treated during the antenatal period.[35] Therefore, full quality of care throughout pregnancy is very crucial.

Although there was no significant effect of level of adherence on the incidence of maternal complications identified during the intrapartum and postpartum periods on the final model, there was a difference in the incidence of particular complications among the two groups. We found that the incidence of intrapartum PIH was lower among the women who received care by providers adhering completely to the ANC guidelines during the first visit. This finding is consistent with results from the other study conducted in Northwest Ethiopia[21] and the Ghana study[25]. The similarities found between the findings of our present study and the findings from other studies might be explained by the fact that these women may receive individual risk screening elements for gestational hypertension, pre-eclampsia, and eclampsia like taking the client's blood pressure, urine analysis for protein and for multigravida women and they might be asked about a history of PIH during the first visit.[26] Any substandard practice as concerns these measures has serious clinical implications because most pregnancy complications occurring in the first pregnancy tend to recur in subsequent pregnancies and/or predispose women to other pregnancy complications.[36] Thus, a major opportunity for prevention, detection, and/or early management would be missed. A past history of PIH should prompt providers to look actively for PIH in the current pregnancy to be able to detect it before serious complications occur and/or institute timely management.

The incidence of PPH was low (2.9 %) amongst our study participants as has been reported in other studies.[21] [25] There was a slight difference in the risk of PPH amongst the two groups. These might be due to the fact that the first ANC visit offers opportunities to reduce the risk of PPH by if the woman is asked about bleeding in previous pregnancies as well as in the current pregnancy, and then by prescribing iron/folate as appropriate and advising clients on how to use these medications.[37]

Eighteen percent of the women in our study gave birth through cesarean section. The rate of cesarean section was slightly higher among women who received complete provider adherence to ANC guideline (18.5%) than their counterparts (17.8%). Identification of clients who had previous abdominal-pelvic surgery during the first ANC visit might aid in deciding on the mode of delivery as early as possible. The probability of having another cesarean section is high if the

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women had one or more previous cesarean section scars[38]. However, this was within the range of globally accepted rate.[39]

The finding of our study revealed that those women who received complete providers' adherence to ANC guideline during the first visit had a 44% reduction in the risk of combined neonatal complications. We speculate that this is in part determined by the completeness of the guidelines for the first ANC visit that are far more detailed than guidelines, if any, for subsequent visits. These elements are all named in the WHO recommendations.[1] It is not enough simply to name these elements; the provider must follow them.[25] The finding of our current study are consistent with findings from the study conducted in Ghana[25] and in northwest Ethiopia.[21] These similarities might be due to the similarity of the ANC guideline checklists in the two countries. This is supported with other prior small scale studies that ANC interventions in the first visit have reduced the risk of low birth weight, pre-term birth, and stillbirth.[40-42] Refresher training programs and mentorship guidance should given regularly for providers can be expected to raise the level of adherence to the ANC guidelines for the first visit.

The number of ANC visits attended by mothers to be is inversely related to the incidence of adverse neonatal outcomes. The greater the number of visits, the lower the incidence of neonatal complications as shown by the 59.0% reduction amongst women who had more than four ANC visits. This finding was supported by another study done in Ethiopia[21]. The possible explanation is that frequent antenatal visits might create a better quality of contact between the provider and the pregnant woman and this might lead both the provider and the pregnant woman to identify and address any challenges of the pregnancy. This creates an opportunity to screen and provide interventions for anything missed during the first ANC visit.[43] A Cochrane review found that there was an inverse relationship between the number of ANC visits and risk of stillbirth, the smaller the number of visits, the greater the risk.[44] This was one of the best reasons for the development of the 2016 eight-contact ANC guideline.

Our present study finding revealed that facility delivery was one of the contributory factors to reduce the risk of neonatal complications. Almost 94% of the study participants gave birth at the health facilities'. The majority of the incidences of maternal and neonatal mortality occur during delivery or within 24 hours afterward.[45] Institutional delivery makes it easier to get intrapartum quality of care without delay.

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There are many indications that neonatal outcomes are the direct reflection of maternal health conditions.[46] In the current study, newborns who were delivered from mothers with antenatal and intrapartum complications were at a higher risk of neonatal complications. Early detection and treatment of maternal complications is an effective strategy to achieve the goal of sustainable neonatal mortality rate reduction.[1]

The strengths of our study included its prospective nature, which ensured the availability of sufficiently detailed information on maternal and neonatal characteristics. The proportion of drop-out rate or loss to follow-up is under the acceptable range. Furthermore; the outcomes of women who gave birth at home were collected through the home visit. To increase the generalizability of our study findings, adequate sample size was calculated. However, the study also has limitations. Firstly, health care providers might make maximum effort to carry out the first ANC visit if the data collectors were directly observing that visit (Hawthorne effect). However, the effect of an observer lasts only for a short time and it slowly decreases when the providers adapt to the presence of the observer.[47] Secondly, the majority of enrolled participants book their first visit during the second trimester. This might be underestimating the contribution adherence to the ANC visit guideline on the reduction of maternal and neonatal outcomes. At last, we didn't estimate the effect of complete provider adherence on specific maternal and neonatal complications.

Conclusions

In this study, received complete provider adherence to ANC guideline during the first contact significantly reduced the risk of neonatal complications but no statistically significant reduction in maternal adverse outcomes during the intrapartum and/or postpartum periods. There was a strong association between maternal and neonatal adverse outcomes. Therefore, our findings point to the important implications of developing safe motherhood programs that build on institutional practice of providing a tested set of ANC guidelines that are followed completely by health care providers. We also believe that early detection and management of antenatal complications is very crucial if maternal and neonatal outcomes are to be improved during the intrapartum and/or postpartum periods.

Abbreviations

AIRR	Adjusted Incidence Risk Ratio
ANC	Antenatal Care
APH	Antepartum Hemorrhage
CI	Confidence Interval
PIH	Pregnancy Induced Hypertension
PPH	Postpartum Hemorrhage
SSA	Sub-Saharan Africa
VDRL	Venereal Disease Reference Laboratory
WHO	World Health Organization

Acknowledgments

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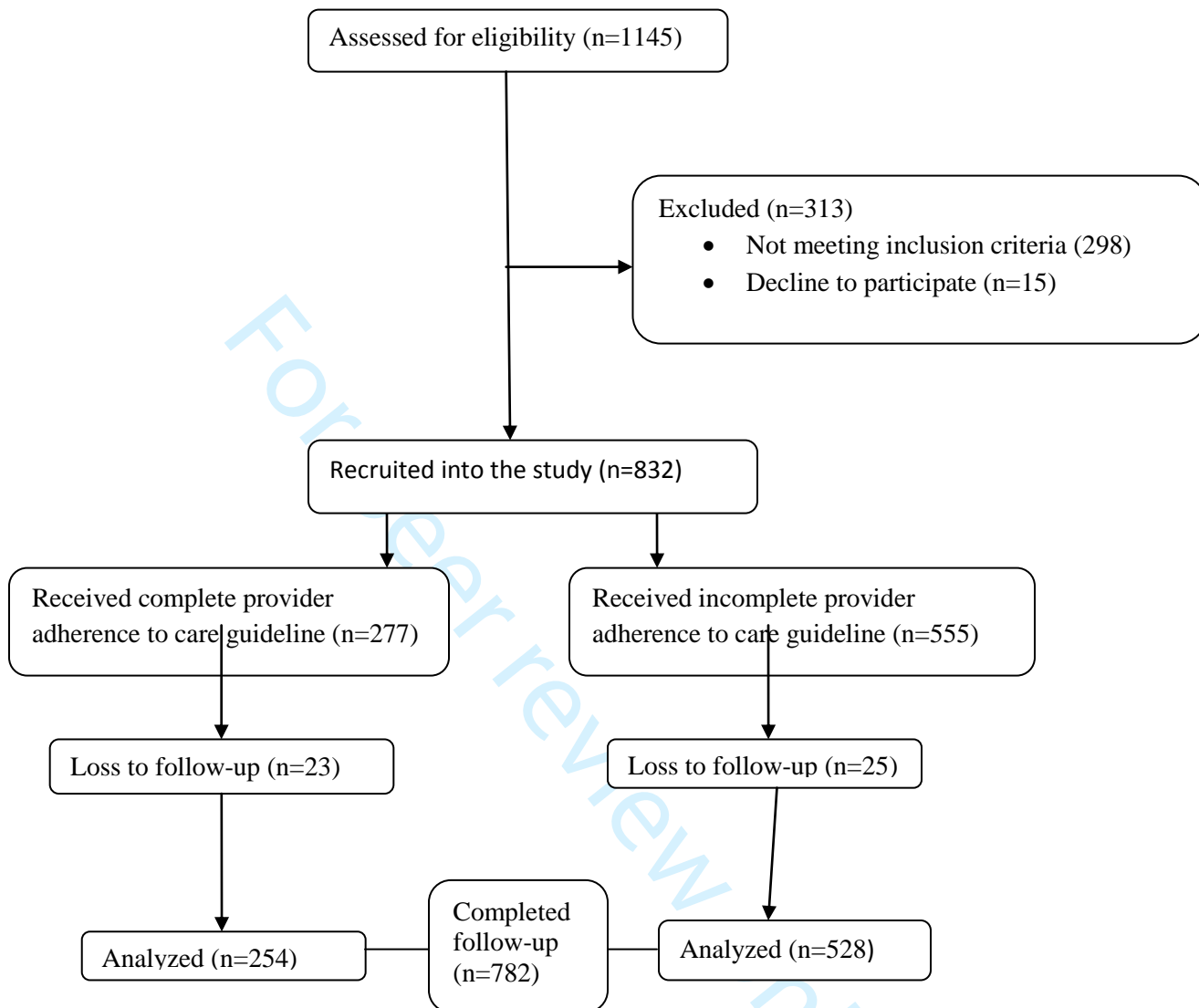
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Fig. 1: Flow diagram for participants' in the study. A description of participants' recruitment, follow-up, and analysis in the study in Gondar town public health facilities, 2020
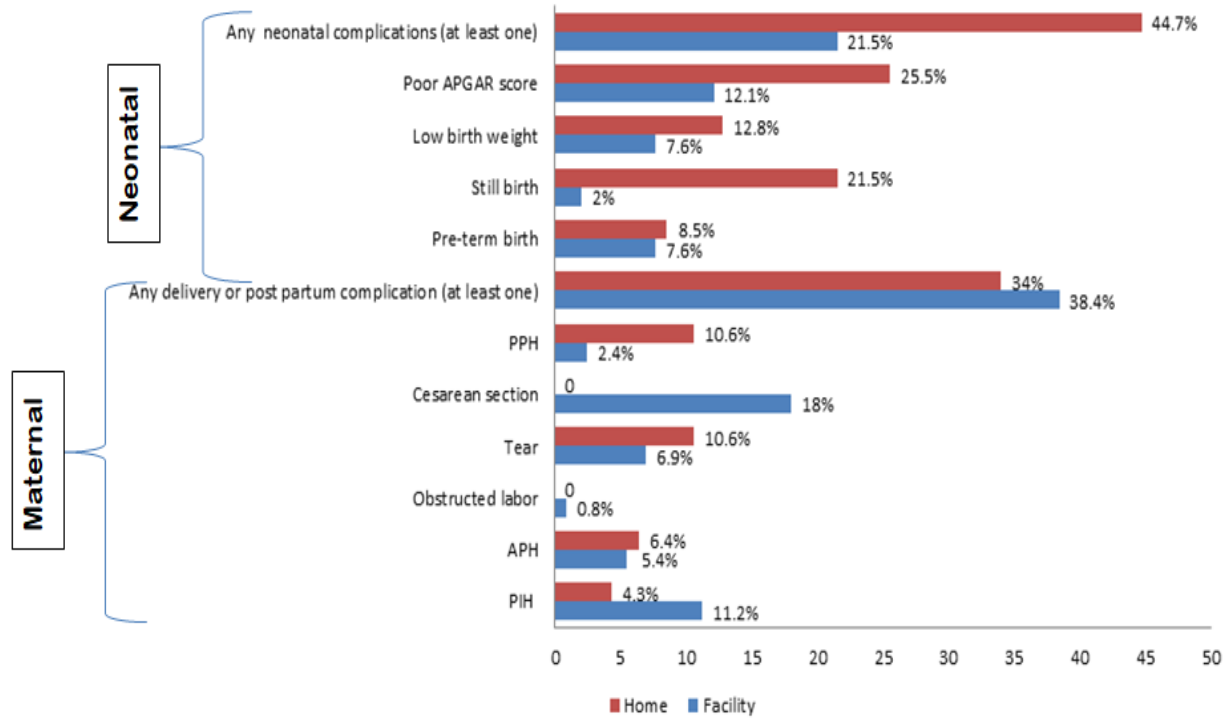
Fig. 2: Risk of maternal and neonatal complications during intrapartum and postpartum periods based on place of delivery among women completed the follow in Gondar town public health facilities, 2020

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8-9*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	-
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, explain how loss to follow-up was addressed	8
		(*e*) Describe any sensitivity analyses	8
Results			-

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	11
		(c) Summarise follow-up time (eg, average and total amount)	11
Outcome data	15*	Report numbers of outcome events or summary measures over time	15
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16
		(*b*) Report category boundaries when continuous variables were categorized	16
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations			22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-22
Generalisability	21	Discuss the generalisability (external validity) of the study results	22
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of complete adherence to antenatal care guideline during first visit on maternal and neonatal complications during the intrapartum and postpartum periods: a prospective cohort study in Northwest Ethiopia

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Effect of complete adherence to antenatal care guideline during first visit on maternal and neonatal complications during the intrapartum and postpartum periods: a prospective cohort study in Northwest Ethiopia

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1

Abstract

Objectives: To examine the relationship between complete of providers' adherence to antenatal care guideline during first visit and maternal and neonatal complications during intrapartum and postpartum periods.

Design: Prospective cohort study

Setting: Gondar town public health facilities in Northwest, Ethiopia.

Participants: A total of 832 pregnant women with gestational age < 28 weeks who came for first ANC visit were enrolled and followed up to the first six hours of the postpartum periods.

Exposure: Providers' adherence to antenatal care guideline during first visit was the exposure variable. An 18-point checklist was used to record the level of providers' adherence. Clients who received care from providers who adhered completely to the guideline constituted the "exposed group", and those who did not receive such care constituted the "unexposed group".

Main outcomes: Maternal and neonatal complications occurred during the intrapartum and postpartum periods.

Data analysis: Negative binomial regression model was used to analyze the data. The adjusted Incidence Risk Ratio (AIRR) with 95% confidence interval (CI) was reported in the final model.

Results: A total of 782 pregnant women were followed up and included in the final analysis (254 in the exposed group and 528 non-exposed). Complete adherence to the guidelines during first visit reduced the risk of neonatal complications (**AIRR=0.56; 95% CI: 0.39, 0.79)**. However, complete adherence to the guidelines was not found to have a statistically significant effect on maternal complications (**AIRR=0.84; 95% CI: 0.67, 1.05)** during the intrapartum and the postpartum periods.

Conclusions: The group that received care from providers who completely adhered to the antenatal care guidelines during the first antenatal visit showed significantly improved neonatal outcomes but did not show significant improvement in maternal outcomes. Hence, focusing on safe motherhood programs like training that gears provider's conformity to antenatal care guideline is quite crucial to improve neonatal outcomes.

Keywords: Complete provider adherence, first ANC visit, maternal complications, neonatal complications, Ethiopia

Strengths and limitations of this study

➢ The prospective nature of the study is the main strength.

➢ The proportion of drop-out rate or loss to follow-up is under the acceptable range.

➢ The outcomes of women who gave birth at home were collected through the home visit.

➢ Hawthorne effect

➢ The majority of the participants had booked their first visit during the second trimester.

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Introduction

Antenatal care (ANC) is an umbrella term used to describe the care that pregnant women receive from accredited health care providers. ANC aims to ensure the safety of pregnant women and fetuses through a range of medical, educational, nutritional, and health system interventions.[1] Thus, ANC is a well-proven internationally accepted strategy used in a number of countries to improve maternal and neonate outcomes.[2]

Effective and timely implementation of ANC alone has been projected to minimize maternal and neonatal mortality by 10-20%, given satisfactory quality of the care provided and given regular attendance.[3-5] One study found that utilization of ANC at least once during pregnancy reduced the risk of neonatal mortality by 39% in Sub-Saharan African (SSA) countries.[6] Although the proportion of women who attend focused ANC for at least four visits generally tend to be satisfactory globally including SSA[7], maternal and neonatal mortality in the region remains high.[8]

Not all studies of the effectiveness of ANC come to the same conclusions. One might assume that the better the ANC, the lower the risk of pregnancy outcomes. However, there are studies reporting paradoxical findings on perinatal outcomes the effectiveness of ANC in relation to the number of visits. In 2010, one Cochrane review and Zimbabwe's largest trial reported that there were an inverse association between the number of ANC visits and the risk of stillbirth[9] and preterm birth[10], respectively. Conversely, other Cochrane reviews have reported that reduced ANC contact numbers did not have a substantial effect on the risk reduction of maternal and neonatal complications.[11] [12] The heterogeneity of these results suggested that it is not only the number of ANC visits that matters but also the quality and content of care given during each visit and especially in the first visit if made in the first trimester. Moreover, none of these studies recognize the gross effect of ANC interventions on the likelihood of maternal complications arising separately during the antenatal, intrapartum and postpartum periods.

The World Health Organization (WHO) has recently recommended that, to improve maternal and neonatal outcomes, women should have at least eight ANC contacts.[1] However, in many countries worldwide, including Ethiopia, the four visits focused ANC continues to be followed as the standard practice.[13] In comparison to other ANC visits, the first ANC contact is unique for its intent and requires special attention. The first ANC visit is an important point of entry for client-provider interaction. It also provides an opportunity to screen and identify pregnant

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women who require specialized care. In addition, it is the moment when preventive and promotive interventions should be initiated.[14] In spite of these benefits, the contribution of first ANC contact in improving perinatal outcomes is blurred and requires further evaluation.

On mini Ethiopian Demographic health survey 2019 report, 74% of pregnant women had attended at least one ANC visit. However, only 43% of women had at least four ANC visits during their last pregnancy.[15] This discontinuity of care has created a doubt on the quality of ANC provided this doubt leads to the question: Can health care providers delivered appropriate quality care, or is it because women were unable to attend the facilities? Therefore, research on how ANC is ANC is provided as per local guideline and how much it is effective to reduce maternal and neonatal outcomes is needed.

The Federal Ministry of Health of Ethiopia has implemented focused ANC guideline for the last two decades.[16] However, the level of provider's adherence to national ANC guidelines is low[17] [18]. Lack of in-service training and unavailability of ANC guidelines were the main reasons for providers not following the ANC guideline.[19]

Studies in Ethiopia have assessed on the effectiveness of ANC in reducing maternal and neonatal complications.[20-22] However, these measures often focus on service contacts as opposed to the interventions delivered during those contacts. In addition, Ethiopia has taken the coverage of ANC visit at least once as an indicator of maternal health.[23] In order to attain effectiveness of ANC interventions, insuring quality of ANC during the first visit is very crucial. However, there is a scarcity of evidence in Ethiopia on the extent to which providers' adherence to ANC guideline during the first visit guideline with direct observations, and its relationship with maternal and neonatal complications.

Therefore, the aim of the present study was to examine the connection between complete provider adherence to ANC guidelines during the first visit and the risk of maternal and neonatal complications during the intrapartum and postpartum periods in Gondar town public health facilities.

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Methods and materials

Study design, setting, and period

A prospective cohort study was conducted in Gondar town public health facilities from May 12, 2019 to January 30, 2020. Gondar town is located in Northwest Ethiopia. The total population size of the town is estimated to be 306,246. Of these, 156,276 were females in reproductive age.[24] In Gondar town, there is one comprehensive specialized hospital, eight public health centers, and 15 private clinics. An average of 100-150 clients visit the University of Gondar specialty hospital everyday for ANC service, and 20- 30 ANC users visit each health center every day. Such health facilities are staffed by midwives, obstetricians, nurses and general physician. In each health facility, at least five midwives have been permanently appointed. However, these midwives are expected to cover all maternal services.

Population and recruitment of study participants

All pregnant women who came for ANC service during the first visit to one of the selected public health facilities during the data collection period were eligible for inclusion in the study and were then followed from the first ANC visit through the first six hours of the postpartum period. According to the Ethiopian delivery protocol, women have to be discharged six hours following birth unless there is a serious complication.[16] Pregnant women recruited and followed were to be 18 years or older, have reached gestational age of 28 weeks and below, were permanent residents in the study area, and were willing to take the routine ANC service throughout pregnancy. Clients who received complete providers' adherence to ANC guideline during the first visit were designated as belonging to the **exposed group** and incomplete providers' adherence to ANC guideline during the first visit were designated as belonging to the **un-exposed group.**

Sample size and sampling procedure

The sample size was calculated using Epi Info 7 software [25] taking into account the following statistical assumptions:: confidence level of 95% (2-sided), power of 80 %, exposed to the non-exposed ratio of 1:2, the overall incidence (non-exposed group) for any pregnancy, delivery or postpartum complication was 68.6% taken from the study conducted in Ghana.[26] We believed that the status of health coverage and setting in Ghana and Ethiopia are almost the same. Quality of ANC alone has been reported to reduce maternal and neonatal mortality by 10-20%.[4] [5]

Therefore, we assumed that the incidence of maternal and neonatal complications would be decreased by 15.4% if Ethiopian providers completely adhere to the ANC guidelines during the first visit, and would result in the overall incidence of complications to be 53.2% amongst the exposed group (complete adherence). This study also considered the design effect of 2 and lost follow-up and non-response rate of 10%. By considering all those assumptions, the minimum sample size required for the study was found to be 832 participants, of which 277 were exposed(complete adherence) and 555 un-exposed women (incomplete adherence).

To conduct this study, a multistage sampling technique was employed. In the first step, four health facilities (one university hospital and three health centers) were selected out of nine public health facilities by a simple random sampling technique. The details of the sampling procedure have been described elsewhere.[18]

Data collection processes and tools

Pregnant women who met the inclusion requirements and who gave informed consent for participation were enrolled in the study. After enrollment, an 18-item structured observation checklist developed on the basis of the ANC protocol was used to record how the ANC services were given and what information was provided during the first ANC visit.[16] A pre-tested structured questionnaire was used to guide the collection of the baseline socio-demographic and obstetric characteristics of study participants by face-to-face interview.

The data collectors were midwives who were trained about the data collection tool and how to collect data with direct observation. Both the data collectors and supervisors were not employed in the health facilities under the study. Pregnant women who met the inclusion requirements and who gave informed consent for participation were enrolled in the study. After enrollment, a direct observation and recording was done by data collectors(midwives) to assess how the ANC services/contents were given as well as the information provided using the observation protocol. So, direct observation and filling the checklist was done while the providers were doing the first ANC service as per national guideline.

Once the women had finished their first ANC visit, they were categorized as belonging to either the exposed group or the un-exposed group and then followed prospectively through the first six hours of the postpartum period. On the subsequent ANC visits, another structured 9-point checklist extracted from the ANC guideline was used to record how the care provided particularly counseling on iron and folic acid supplementation, tetanus immunization, how to

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recognize danger signs, what to do, and where to get help, HIV testing and counseling, the benefit of skilled attendance at birth, nutrition, de-worming, birth preparedness' and complication readiness plan, and risks of using tobacco and alcohol during pregnancy. At the same time, medical records and antenatal care charts of subsequent antenatal clinic visits were also reviewed and documented by following the checklist to be sure that any antenatal complications had been checked for and identified. Finally, maternal outcomes (antepartum hemorrhage, pregnancy induced hypertension, postpartum hemorrhage, obstructed labor, cesarean section, and tear) and neonatal outcomes (stillbirth, preterm birth, APGAR score, and low birth weight) during intrapartum and postpartum period were collected from both the maternal health record book and delivery register and documented in the checklist prepared for this purpose.

The participants' addresses and telephone numbers were linked to their study identification numbers. Those clients who didn't avail themselves of the scheduled ANC visit were contacted through a telephone call. All participants received a phone call at the time of their expected delivery to determine if they had given birth or not. Once they assured us that they had experienced delivery, the data collectors went to the facility where the women had given birth and extracted delivery data from both the maternal health record or chart and the delivery register. Women who delivered at home and were reachable were called and a home visit was done to collect information about delivery outcomes. Those who could not be reached by any of these means were treated as lost to follow-up.

Training was given for data collectors and supervisors for three days on how to use the data collection instrument and how to approach the pregnant women and record the nature of the service they had received. On-site supervision was conducted during data collection.

Study variables

Outcome variable

The outcome variables were maternal and neonatal complications during the intrapartum and postpartum periods. A combined maternal complication was defined as occurrence complications such as Pregnancy-Induced Hypertension(PIH) (defined as systolic blood pressure $\geq$ 140 mmHg and/or diastolic blood pressure $\geq$ 90 mmHg after 20 weeks of pregnancy with or without proteinuria or with tonic-clonic convulsion), cesarean delivery, Antepartum Hemorrhage(APH)

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(defined as bleeding from or in to the genital tract, occurring during third trimesters of pregnancy and prior to the birth of the baby), Postpartum Hemorrhage (PPH) (was defined as any amount of bleeding from or into the genital tract following birth of the baby up to six hours in the postpartum period, which adversely affected the general condition of the patient as evidenced by rise in pulse rate and/or falling blood pressure), genital tear (defined as injuries following childbirth process involving vulva, perineum, vagina, and/or cervix), and /or obstructed labor (defined as arrest of descent in spite of good uterine contractions due to mechanical obstruction).[27]

Combined neonatal complications were also defined as the occurrence of adverse neonatal outcomes such as stillbirth, preterm birth (<37 weeks)[28], poor Apgar score (5th minute Apgar score <7)[29], and/or low birth weight (<2500 gm)[30]. Both the women and the newborns could have more than one complication.

Primary exposure variable

The primary exposure variable for this study was the level of the **providers' adherence** to the ANC guideline during the first visit. Adherence was defined as the providers' degree of conformity to following the standard ANC guidelines as per the national protocols [31] by an observer using the 18-point checklist. The observed variables to be attended to as indicated by the checklist include age asked, gestational age calculated, parity asked, past obstetric history asked, previous abdominal-pelvic surgery asked or checked, medical general history asked, current pregnancy history asked, weight measured, blood pressure checked, the abdominal examination done, hemoglobin test done, urine test done, VDRL done, blood group and Rh, HIV test done, tetanus injection given, iron and folic tablets prescribed and counseling done. Each variable adhered to, scored a point of 1 while non-adherence scored 0. **Complete provider adherence** was defined as clients who received all the 18 items adhered to by the provider as listed in care guidelines for the first ANC visit (total score = 18). The observation checklist, scoring criteria, and the entire method for the baseline of the cohort study have been described elsewhere.[18]

Covariates

Several explanatory variables were included as covariates. These include a range of maternal socio-demographic variables such as maternal age, residence, religion, marital status, educational level, and employment status. Obstetric characteristics such as time of booking (early booking

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was defined as the initiation of first ANC <16 weeks of gestation)[16], gravidity, parity, previous history of obstetric complications, birth-to-pregnancy interval, the intention of the current pregnancy, history of female genital mutilation, current ANC complications, number of ANC visit attended, place of current delivery, mode of delivery of the current pregnancy, and counseling received during pregnancy.

Current antepartum complication: was defined as the presence of at least one of the complications occurs during antepartum period (anemia, PIH, APH, urinary tract infection, gestational Diabetic Mellitus and premature rupture of membrane).

Counseling service during pregnancy was measured by nine composite variables. Each counseling service occurrence was recorded starting from the second visit up to the last visit. To say the woman was counseled for one variable, the counseling had to be given in all visits. When one component of counseling service was given at all visits, it was coded as 1 otherwise 0. Finally, composite counseling service was defined as pregnant women who got at least one or more variable out of the nine counseling variables.[17]

Data analysis

Data were entered using Epi Info version 7 and analyzed using Stata 14 software. Descriptive analysis of participants' socio-demographic and obstetric information was conducted by the use of frequencies and chi-square analysis. Incidences of maternal and neonatal complications during intrapartum and postpartum period were estimated in percentages. Possible associations of adherence with each adverse outcome were assessed using Pearson's chi-square test. Since the maternal and neonatal complications are outcome variables of the study and the numbers of complications are considered as count data, Poisson regression was used as a standard model for analysis. However, the observation should be independent over time and the mean and the variance should be equal. In this study, the variance was greater than the mean; this indicates the presence of overdispersion. Hence, the negative binomial model was used to estimate the effect of complete adherence on the risk of maternal, and neonatal complications were estimated and expressed as Incidence Risk Ratio (IRR) with their 95% confidence intervals (CI). Separate models were done for maternal and neonatal outcomes. To control confounders, the models were adjusted with selected maternal socio-demographic and obstetric variables (P-value ≤ 0.25 in bi-variable analysis) with outcome variables. The Adjusted Incidence Risk Ratio (AIRR) for the associations between complete provider adherence and adverse maternal and neonatal outcomes

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were determined after controlling for maternal socio-demographic and obstetric variables characteristics. A P-value of <0.05 was used to declare the statistical significance of independent variables. The likelihood ratio test of the parameter Alpha (α) was found to be P-value <0.001 for both models

Patient and public involvement

Patients and the public were not invited to comment on the study design or conduct of the study. However, they will be informed of the study results through publications.

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Result

A total of 832 women were recruited at baseline with the number of exposed and unexposed women who were 277 and 555 respectively, prospectively followed from the first ANC visit to the first six hours of the postpartum period. Seven hundred eighty-two (93.99 %.) women were completed the follow-up and considered in the final analysis. Twenty-three (8.3%) study participants from the exposed group and 25 (4.5%) participants from the un-exposed group were lost in the follow-up. Self-referral to other health facilities and permanent change in workplace were the reasons (Figure 1).

Participants' baseline characteristics

The mean age of study participants was 25.9 years. About 651 (83.3%) were in the age group of 20-35 years. Six (2.1%) clients came from the rural area. A higher proportion of women (38.5%) who received complete adherence had no formal education (Table1). Regarding their obstetric characteristics, 551 (70.5%) booked their first ANC at 16 and above weeks of gestation. Three hundred and eight (39.4%) were primigravidea. Three-fourths of the women (73.4%) attended an antenatal clinic more than four times during the pregnancy. Forty-seven (6%) of the participants gave birth at home. Among 219 (28.6%) women who had current antenatal complications, 68 (31.1%) of them received complete providers' adherence to the first ANC guideline (Table2).

Table 1: Socio-demographic characteristics of study participants among exposed and un-exposed groups in Gondar town public health facilities, 2020

Socio-demographic variables		Frequency (%) of total participants N=782	Frequency (%) of the exposed group N=254	Frequency (%) of the un-exposed group N= 528	P-value
Type of health facility	Hospital	415(53.1)	131 (31.6)	284 (68.4)	0.56
	Health centers	367 (46.9)	123 (33.5)	244 (66.5)	
Age (in years)	<20	105(13.1)	27 (25.7)	78 (74.3)	0.28
	20-35	651(83.3)	218 (33.5)	433 (66.5)	
	>35	26 (3.3)	9 (34.6)	17 (65.4)	
Residence	Urban	766 (97.9)	248 (32.4)	518 (67.6)	0.66
	Rural	16 (2.1)	6 (37.5)	10 (62.5)	
Religion	Orthodox	715 (91.4)	227(31.8)	488 (68.2)	0.36
	Muslim	57 (7.3)	23(40.3)	34(59.7)	
	Others	10 (1.3)	4 (0.4)	6 (0.6)	
Marital status	Married	761 (97.3)	250(32.8)	511 (61.2)	0.18
	Unmarried	21(2.7)	4(19.1)	17 (80.9)	
Educational level	None	130 (16.6)	50 (38.5)	80 (61.5)	0.24
	Primary	191 (24.4)	56(29.3)	135 (70.7)	
	Secondary	241 (30.8)	72(29.9)	169 (70.1)	
	Tertiary	220 (28.1)	76 (34.5)	144 (65.5)	

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| Employment | Yes | 183(23.4) | 67(36.6) | 116 (63.4) | 0.17 |
| | No | 599 (76.6) | 187(31.2) | 412 (68.8) | |

Table 2: Obstetric characteristics of study participants among exposed and un-exposed groups in Gondar town public health facilities, 2020

Obstetric variables		Frequency (%) of total participants N=782	Frequency (%) of Exposed group N=254	Frequency (%) of un-exposed group N= 528	P-value
Time booking	Early booking (<16 weeks)	231 (29.5)	61 (26.4)	170 (73.6)	0.02
	Late booking (≥ 16 weeks)	551 (70.5)	193 (35.0)	358 (65.0)	
Gravidity	Primigravidea	306 (39.4)	96 (31.2)	212 (68.8)	0.53
	Multigravidea	474 (60.6)	158 (33.3)	316 (66.7)	
Parity (number)	0	353 (45.1)	111 (31.4)	242 (68.6)	0.95
	1-2	355 (45.4)	119 (33.5)	236(66.5)	
	3-4	61 (7.8)	20 (32.8)	41 (67.2)	
	>4	13 (1.7)	4 (30.8)	9 (69.2)	
Previous history of pregnancy complications	Yes	105 (13.4)	42 (40.0)	63 (60.0)	0.07
	No	369(47.2)	115 (31.2)	254 (68.8)	
Birth to pregnancy interval	Short(≤24)	101(23.3)	36(35.6)	65(64.4)	0.39

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(in month)	Recommended (24-48)	172 (39.6)	55(32.0)	117(68.0)	
	Long(>48)	161(37.1)	53(32.9)	108(67.1)	
Intention of pregnancy	Planned	717 (91.7)	230(32.1)	487(67.9)	0.60
	Unplanned	65 (8.3)	24(36.9)	41(63.1)	
History of female genital mutilation	Yes	22 (2.8)	10 (45.5)	12 (54.5)	0.61
	No	760 (97.2)	244 (32.1)	516 (67.9)	
Received counseling during pregnancy	yes	702 (89.8)	231 (32.9)	471 (67.1)	0.95
	No	80 (10.2)	23 (28.8)	57 (72.2)	
Current antenatal complications	Yes	219 (28.6)	68 (31.1)	151 (68.9)	0.59
	No	569 (71.4)	186 (33.0)	377(67.0)	
Number of ANC visit attended	≤ 4 visits	208 (26.6)	66 (31.7)	142 (68.3)	0.78
	> 4visits	574 (73.4)	188(32.8)	386 (67.2)	
Place of current delivery	Health facility	735 (94.0)	242(32.9)	493(67.1)	0.30
	Home	47(6.0)	12(25.5)	35(74.5)	
Gestational age at delivery	< 37 weeks	60 (7.7)	19 (31.7)	41 (68.3)	0.82
	37-42	717 (91.7)	234 (48.4)	483 (67.4)	
	>42	5 (0.60)	1(20.0)	4 (80.0)	
Mode of delivery of the current pregnancy	Spontaneous vaginal delivery	620(79.3)	201(32.4)	419(67.6)	0.91
	Cesarean section	141(18)	47 (33.3)	94 (66.7)	
	Instrumental delivery	21(2.7)	6 (28.57)	15 (71.4)	

The incidence of maternal and neonatal complications

Of the total of 782 women, 298 (38.1%) (95% CI: 34.7, 41.6) had at least one type of maternal complications during the intrapartum and/or postpartum periods. The different incidence of maternal complications among women who received complete and incomplete providers' adherence was statistical significant; 32.7% and 40.7% respectively. Eighty-four (10.7%) participants developed PIH during intr-partum period though there was no statistical difference between the two groups (table 3).

The incidence of stillbirth, low birth weight, poor Apgar score were statistical significant higher in the un-exposed group (table 3). There was no maternal and neonatal death during the intrapartum and postpartum periods.

Table 3: Risk of maternal and neonatal complications during intra-partum and postpartum periods amongst exposed and controlled groups in Gondar town public health facilities, 2020

Complications	Incidence N=832	Exposed group n= 254	Unexposed group n= 528	P-value
Maternal				
PIH	84 (10.7)	23(9.1)	61 (11.6)	0.51
APH	43 (5.5)	14(4.7)	29 (5.9)	0.29
Obstructed labor	6 (0.8)	3 (1.2)	3 (0.6)	0.36
Tear	56 (7.2)	14 (5.5)	42 (8.0)	0.21
Cesarean section	141 (18.00)	47 (18.5)	94 (17.8)	0.81
PPH	23 (2.9)	6 (2.4)	17 (3.2)	0.5
Any intra-partum and/or postpartum complications (at least one)	298(38.1)	83 (32.7)	215(40.7)	0.03
Neonatal				
Preterm birth	60 (7.7)	19 (7.5)	41 (7.8)	0.08
Stillbirth	25 (3.2)	3 (1.2)	22 (4.2)	0.026
Low birth weight	62 (7.9)	9 (3.5)	53 (10.0)	0.02
Poor APGAR score	101 (12.9)	19 (7.5)	82 (15.5)	0.02

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Any neonatal complications(at least one)	179 (22.9)	40 (15.7)	139 (26.3)	0.001

The incidence of at least one neonatal complication among newborns who were delivered at home and at the health facilities were 44.7% and 21.5% respectively. The incidence of stillbirth and low Apgar score was much higher amongst newborns who were delivered at home than among those delivered at the health facility. The incidence of at least one maternal complication among women delivered at the facility and home was 38.4% and 34 % respectively. All women who had obstructed labor gave birth at the health facility (Figure 2).

Effect of received complete provider adherence to guidelines during the first ANC on the risk of maternal and neonatal complications

In the unadjusted negative binomial regression, complete provider adherence, maternal age, maternal education, parity, place of ANC attendance, number of ANC visits, counseling during pregnancy, current ANC complications, and place of delivery were associated with maternal and neonatal complications during intrapartum and postpartum periods. After controlling for confounding variables, complete providers' adherence **(AIRR=0.56; 95% CI: 0.39, 0.79)** was significantly associated with neonatal complications. However, complete providers' adherence was not significantly associated with maternal complications during the intra-partum and/or postpartum periods (Table 4).

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Table 4: Negative binomial Poisson regression analysis showing the effect of received complete provider adherence to guidelines during the first ANC on maternal and neonatal complications during intrapartum and/or postpartum periods

Explanatory Variables	Maternal complications			Neonatal complications		
	Unadjusted IRR (95%CI)	Adjusted IRR (95%CI)	Adjusted P-value	Unadjusted IRR (95%CI)	Adjusted IRR(95%CI)	Adjusted P-value
Received complete adherence	0.85 (0.67,1.07)	0.84(0.67,1.05)	0.14	0.51(0.36, 0.74)	**0.56 (0.39,0.79)**	**0.001**
Age (in years)						
<20	1	1		1	1	
20-35	1.24(0.89,1.72	1.2(0.85,1.71)	0.28	0.95 (0.61,1.47)	1.01 (0.65,1.59)	0.93
>35	1.31(0.70,2.45)	1.46(0.74,2.88)	0.27	1.30 (0.55,3.05)	1.28 (0.51,3.18)	0.59
Educational level						
None	1	1		1	1	1
Primary	1.1(0.78,1.56)	1.03(0.72,1.46)	0.87	1.09 (0.69,1.73)	1.08 (0.68,1.71)	0.73
Secondary	1.12(0.81,1.55)	1.11 (0.78,1.59)	0.53	0.94 (0.60,1.47)	0.97 (0.60,1.56)	0.90
Tertiary	1.24(0.90,1.73)	1.21(0.84,1.74)	0.29	0.72 (0.45,1.16	0.74 (0.44,1.24)	0.25
Parity (number)						
0	1	1		1	1	1
1-2	1.02(0.82,1.27)	1.01 (0.8,1.27)	0.91	1.04 (0.75,1.43)	0.99 (0.72,1.38)	0.99
3-4	1.11 (0.75,1.63)	1.18 (0.77,1.81	0.43	1.32 (0.76,2.28)	0.97 (0.54,1.74)	0.92
>4	0.5 (0.16,1.58)	0.46(0.14,1.55)	0.21	1.81 (0.66,4.95)	1.71 (0.59,4.94)	0.31
Place of ANC attendance						

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Hospital	0.95 (0.77,1.16)	0.88(0.68,1.12)	0.32	1.04 (0.77,1.04)	**1.88 (1.31,2.69)**	**0.001**
Health centers	1	1		1	1	
Number of ANC visit attended						
≤ 4 visits	1	1		1	1	
>4 visits	1.14 (0.89,1.45)	1.12 (0.87,1.46	0.30	0.51 (0.37,0.69)	**0.41 (0.30,0.57)**	**0.00**
Received counseling during pregnancy						
Yes	1.02 (0.79,1.33)	1.05(0.78,1.41)	0.70	0.70 (0.49,1.01)	0.69 (0.47,1.03)	0.07
No	1	1		1	1	
Current antenatal complications						
Yes	1.85 (1.50,2.28)	**1.83(1.48,2.26)**	**0.00**	1.82 (1.34,2.49)	**1.9 (1.40,2.58)**	**0.00**
No	1	1		1	1	
Place of current delivery						
Facility	1.29 (0.79,2.10)	1.21 (0.72,2.01	0.45	0.42 (0.25,0.70)	**0.49 (0.30,0.81)**	**0.005**
Home	1	1		1	1	
Maternal complications during intrapartum and/or postpartum periods	NA					
Yes	-	-	-	1.57 (1.16,2.12)	**1.48 (1.10,2.00)**	**0.009**
No	-	-	-	1	1	

NA= Not Applicable

Discussion

The current study demonstrates the role of a provider's adherence to the ANC guideline during the first visit in leading to improvement of maternal and neonatal outcomes. The key findings of this study are that complete adherence by the providers to the ANC guidelines during the first visit reduced the risk of neonatal complications but did not have any statistically significant effect on the risk of maternal complications occurring during the intrapartum and/or postpartum periods.

In general, improving the quality of obstetric care, if supported by guidelines, can directly reduce the incidence of maternal and neonatal deaths.[1] Guidelines can, however only lead to improved quality care if they are translated into daily provider practice.[32]

The finding of our study revealed that those women who received complete providers' adherence to ANC guideline during the first visit had a 44% reduction in the risk of combined neonatal complications. . It is possible to explain the preventive association between providers adherence to the contents of ANC guideline with risk of neonatal complications can be explained in different ways. Complete providers adherence to ANC guideline during the first creates an opportunity for a woman to connect with formal health services like screening of pregnant women who have and at risk of developing complications.[23] Because neonatal outcomes are the direct reflection of maternal health conditions.[33]. The first visit is the exact moment to deliver cost effective preventive interventions like Iron–folic acid supplementation, nutritional advice, tetanus toxoid vaccination.[34-36] These interventions have been shown to be cost-effective in a Sub-Saharan African context.[37] The first ANC visit also provides an important opportunity for midwives to teach mothers how to recognize warning signs of complications during pregnancy, labor, and delivery and encourage them to plan clean and safe deliveries[17].

The finding of our current study are consistent with findings from the study conducted in Ghana[26] and in Ethiopia.[20 21] The observed difference between the findings of our present study and the findings from Ghana and other studies in Ethiopia might be due to the similarity of the ANC guideline in the two countries. In both countries the format and contents of the first ANC guideline is quite similar.[16 38]

The number of ANC visits attended by mothers to be is inversely related to the incidence of adverse neonatal outcomes. The greater the number of visits, the lower the incidence of neonatal complications as shown by the 59.0% reduction amongst women who had more than four ANC

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visits. This finding was supported by another study done in Ethiopia[20]. The possible explanation is that frequent antenatal visits might create a better quality of contact between the provider and the pregnant woman and this might lead both the provider and the pregnant woman to identify and address any challenges of the pregnancy. This creates an opportunity to screen and provide interventions for anything missed during the first ANC visit.[39] A Cochrane review found that there was an inverse relationship between the number of ANC visits and risk of stillbirth, the smaller the number of visits, the greater the risk.[40] This was one of the best reasons for the development of the 2016 eight-contact ANC guideline.

The result of this study indicated that those women who attended ANC at the hospital were more likely to develop neonatal complications compared to health center. Studies have shown that women who attended their ANC at higher level facilities were more likely to receive incomplete adherence to ANC guideline during the first visit.[41] On the other hand, majority of study participants who received their at ANC hospital were referral cases with obstetric complications. They might opt in to attend birth in the hospital than health centers. It is supported by the other finding of our study that newborns who were delivered from mothers with antepartum complications were at a higher risk developing neonatal complications. This implies that women who attend their ANC at the hospital special attention.

In contrast to the findings from the Ghana study[26] and contrary to our original alternative hypothesis, we found that complete provider adherence to the ANC guideline during the first visit did not have a significant effect on the risk of maternal complications during the intrapartum and/or postpartum periods. The plausible explanation for the observed difference between the findings of our present study and the study conducted in Ghana could be due to the disparity in inclusion criteria. The Ghana study included women who had their first ANC visit at gestational age below or equal to 20 weeks. But in our current study, we included women whose gestational age was below 28 weeks. This could miss opportunities for early detection of complications and initiation of certain preventive measures such as prescribing iron tablet in a timely manner.[42] There may be other factors in addition to providers' adherence to the ANC guidelines during the first visit. It is recognized that the regular subsequent antenatal attendance would encourage providers to review and provide care for what they might have missed out during the first antenatal visit. In addition, the quality of intrapartum care could affect the risk of

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maternal complications as well.[43] Therefore, interventions should be promoted at all levels of care that enhance providers' adherence to both the ANC and the delivery guidelines.

Other confounding determinant factors may contribute to raising the incidence of risks of maternal complications during the intrapartum and/or postpartum periods. The finding of our study revealed that the risk of clients who had any antepartuml complications was 1.83 times more likely to develop maternal complications which occurred during intrapartum and/or postpartum periods compared to women to clients who had no antenatal complications. This might be due to the recurring nature of complications during labor and childbirth once they have been detected and treated during the antenatal period.[44] Therefore, full quality of care throughout pregnancy is very crucial.

Although there was no significant effect of level of adherence on the incidence of maternal complications identified during the intrapartum and postpartum periods on the final model, there was a difference in the incidence of particular complications among the two groups. We found that the incidence of intrapartum PIH was lower among the women who received care by providers adhering completely to the ANC guidelines during the first visit. This finding is consistent with results from the other study conducted in Northwest Ethiopia[20] and the Ghana study[26]. The similarities found between the findings of our present study and the findings from other studies might be explained by the fact that these women may receive individual risk screening elements for gestational hypertension, pre-eclampsia, and eclampsia like taking the client's blood pressure, urine analysis for protein and for multigravida women and they might be asked about a history of PIH during the first visit.[16] Any substandard practice as concerns these measures has serious clinical implications because most pregnancy complications occurring in the first pregnancy tend to recur in subsequent pregnancies and/or predispose women to other pregnancy complications.[45] Thus, a major opportunity for prevention, detection, and/or early management would be missed. A past history of PIH should prompt providers to look actively for PIH in the current pregnancy to be able to detect it before serious complications occur and/or institute timely management.

The incidence of PPH was low (2.9 %) amongst our study participants as has been reported in other studies.[20] [26] There was a slight difference in the risk of PPH amongst the two groups. These might be due to the fact that the first ANC visit offers opportunities to reduce the risk of PPH by if the woman is asked about bleeding in previous pregnancies as well as in the current

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pregnancy, and then by prescribing iron/folate as appropriate and advising clients on how to use these medications.[46]

Eighteen percent of the women in our study gave birth through cesarean section. The rate of cesarean section was slightly higher among women who received complete provider adherence to ANC guideline (18.5%) than their counterparts (17.8%). Identification of clients who had previous abdominal-pelvic surgery during the first ANC visit might aid in deciding on the mode of delivery as early as possible. The probability of having another cesarean section is high if the women had one or more previous cesarean section scars[47]. However, this was within the range of globally accepted rate.[48]

In the last few years, it is easy to become optimistic increasing the coverage focused ANC is a top priority of the Ethiopian government. However, the quality of care lags behind. In general, the finding of our present study will give an overall insight for maternal health care programmers and implementers in Ethiopia and similar countries to focus on improving the quality ANC based on the up-to-date guideline in order to improve neonatal outcomes..

The strengths of our study included its prospective nature, which ensured the availability of sufficiently detailed information on maternal and neonatal characteristics. The proportion of drop-out rate or loss to follow-up is under the acceptable range. The proportion of drop-out rate or loss to follow-up is under the acceptable range. To increase the generalizability of our study findings, adequate sample size was calculated. However, the study also has limitations. The outcomes of women who gave birth at home were collected through the home visit. However, measurement bias was one of biggest trait at there. Some of the neonatal outcomes were measured with instruments like bin balance to measure the baby wait at home. Other variables like APGARE score were measured subjectively by asking clients what was happening during and after child birth. The other trait of our study was Hawthorne effect. Health care providers might make maximum effort to carry out the first ANC visit if the data collectors were directly observing that visit. However, the effect of an observer lasts only for a short time and it slowly decreases when the providers adapt to the presence of the observer.[49] To decrease the bias, we were discarding the first few observations during the start of data collection. On the top of that, prospective (longitudinal) nature of the study would also significantly reduce its effect. The majority of enrolled participants book their first visit during the second trimester. This might be

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underestimating the contribution adherence to the ANC visit guideline on the reduction of maternal and neonatal outcomes. At last, we didn't estimate the effect of complete provider adherence on specific maternal and neonatal complications.

Conclusions

In this study, received complete provider adherence to ANC guideline during the first contact significantly reduced the risk of neonatal complications but no statistically significant reduction in maternal adverse outcomes during the intrapartum and/or postpartum periods. Therefore, our findings point to the important implications of developing interventions that build on institutional practice of providing a tested set of ANC guidelines that are followed completely by health care providers. We also believe that early detection and management of antenatal complications is very crucial if maternal and neonatal outcomes are to be improved during the intrapartum and/or postpartum periods.

Abbreviations

AIRR	Adjusted Incidence Risk Ratio
ANC	Antenatal Care
APH	Antepartum Hemorrhage
CI	Confidence Interval
PIH	Pregnancy Induced Hypertension
PPH	Postpartum Hemorrhage
SSA	Sub-Saharan Africa
VDRL	Venereal Disease Reference Laboratory
WHO	World Health Organization

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Patient consent for publication: Not required.

Ethics approval: The protocol has been reviewed by the Institutional ethical review board of University of the Gondar for its ethical soundness, ID: O/V/P/RCS/05/498/2018. Confidentiality was maintained.

Data availability statement: Data are available upon reasonable request. The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Fig. 1: Flow diagram for participants' in the study. A description of participants' recruitment, follow-up, and analysis in the study in Gondar town public health facilities, 2020

Fig. 2: Risk of maternal and neonatal complications during intrapartum and postpartum periods based on place of delivery among women completed the follow in Gondar town public health facilities, 2020
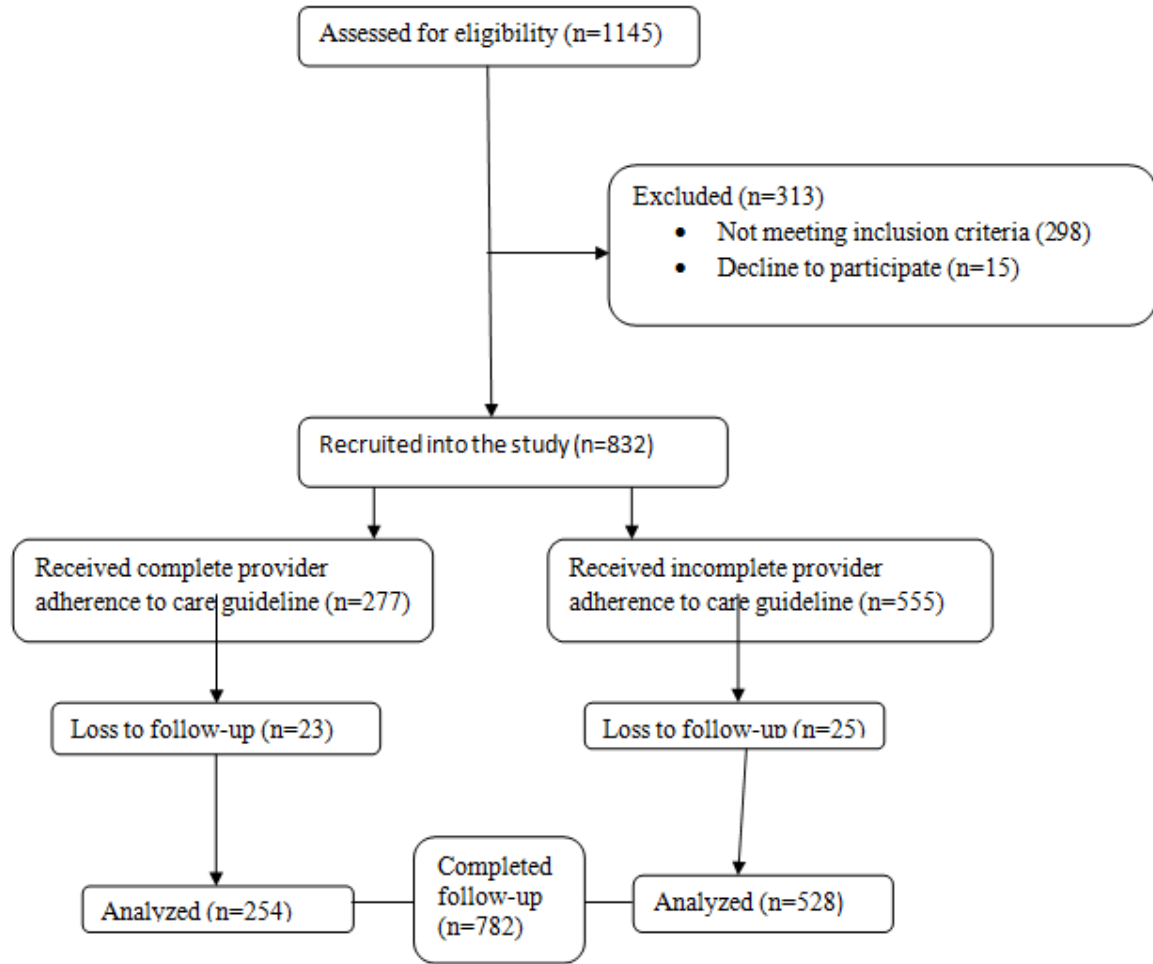
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Fig. 1: Flow diagram for participants' in the study. A description of participants' recruitment, follow-up, and analysis in the study in Gondar town public health facilities, 2020
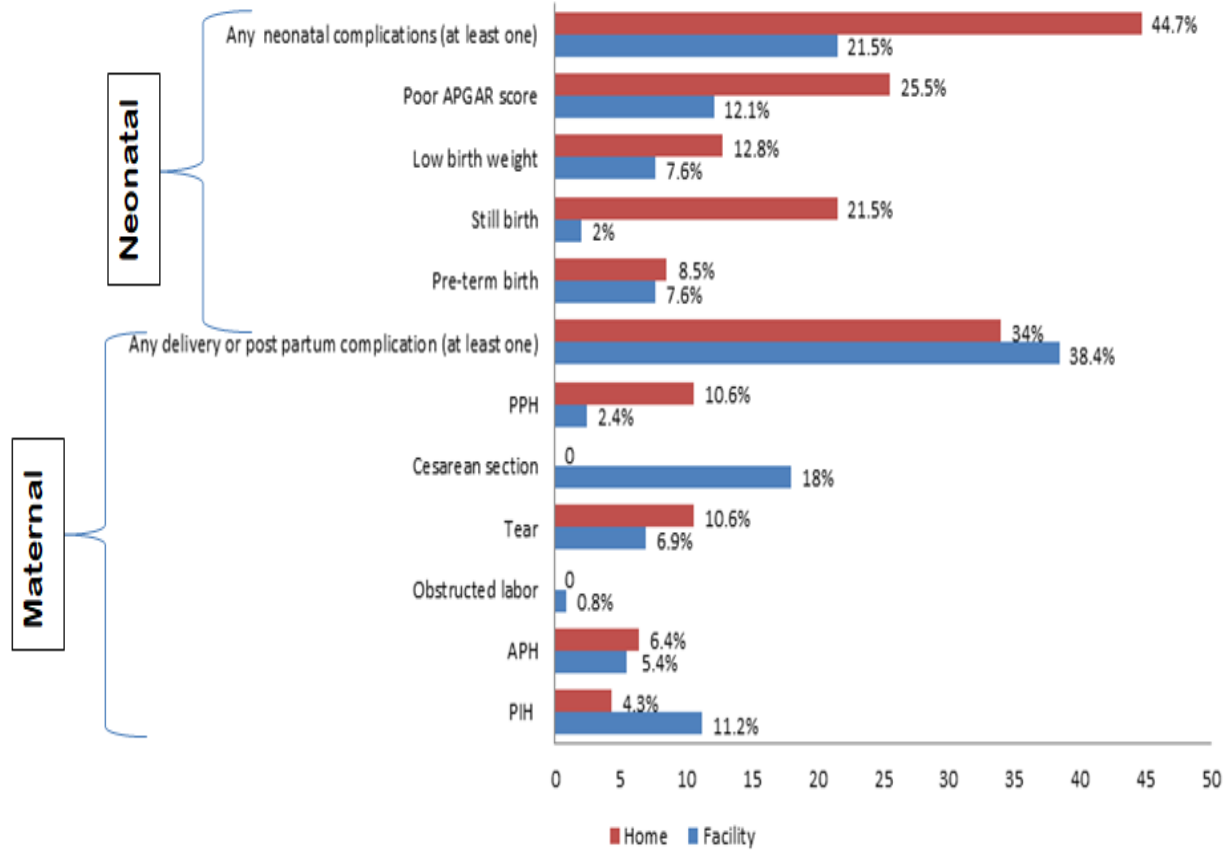
Fig. 2: Risk of maternal and neonatal complications during intrapartum and postpartum periods based on place of delivery among women completed the follow in Gondar town public health facilities, 2020

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8-9*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	-
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, explain how loss to follow-up was addressed	8
		(*e*) Describe any sensitivity analyses	8
Results			-

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	11
		(c) Summarise follow-up time (eg, average and total amount)	11
Outcome data	15*	Report numbers of outcome events or summary measures over time	15
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16
		(*b*) Report category boundaries when continuous variables were categorized	16
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations			22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-22
Generalisability	21	Discuss the generalisability (external validity) of the study results	22
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of complete adherence to antenatal care guideline during first visit on maternal and neonatal complications during the intrapartum and postpartum periods: a prospective cohort study in Northwest Ethiopia

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Abstract

Objectives: To examine the relationship between complete of providers' adherence to antenatal care guideline during first visit and maternal and neonatal complications during intrapartum and postpartum periods.

Design: Prospective cohort study

Setting: Gondar town public health facilities in Northwest, Ethiopia.

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Participants: A total of 832 pregnant women with gestational age < 28 weeks who came for first ANC visit were enrolled and followed up to the first six hours of the postpartum periods.

Exposure: Providers' adherence to antenatal care guideline during first visit was the exposure variable. An 18-point checklist was used to record the level of providers' adherence. Clients who received care from providers who adhered completely to the guideline constituted the "exposed group", and those who did not receive such care constituted the "unexposed group".

Main outcomes: Maternal and neonatal complications occurred during the intrapartum and postpartum periods.

Data analysis: Negative binomial regression model was used to analyze the data. The adjusted Incidence Risk Ratio (AIRR) with 95% confidence interval (CI) was reported in the final model.

Results: A total of 782 pregnant women were followed up and included in the final analysis (254 in the exposed group and 528 non-exposed). Complete adherence to the guidelines during first visit reduced the risk of neonatal complications (**AIRR=0.56; 95% CI: 0.39, 0.79)**. However, complete adherence to the guidelines was not found to have a statistically significant effect on maternal complications (**AIRR=0.84; 95% CI: 0.67, 1.05)** during the intrapartum and the postpartum periods.

Conclusions: The group that received care from providers who completely adhered to the antenatal care guidelines during the first antenatal visit showed significantly improved neonatal outcomes. However, itdid not show a significant improvement in maternal outcomes. Hence, focusing on safe motherhood programs like training that gears provider's conformity to antenatal care guideline is quite crucial to improve neonatal outcomes.

Keywords: Complete provider adherence, first ANC visit, maternal complications, neonatal complications, Ethiopia

Strengths and limitations of this study

➢ The prospective nature of the study is the main strength.

➢ The proportion of drop-out rate or loss to follow-up is under the acceptable range.

➢ The outcomes of women who gave birth at home were collected through the home visit.

➢ Hawthorne effect

➢ The majority of the participants had booked their first visit during the second trimester.

Introduction

Antenatal care (ANC) is an umbrella term used to describe the care that pregnant women receive from accredited health care providers. ANC aims to ensure the safety of pregnant women and fetuses through a range of medical, educational, nutritional, and health system interventions.[1] Thus, ANC is a well-proven internationally accepted strategy used in a number of countries to improve maternal and neonate outcomes.[2]

Effective and timely implementation of ANC alone has been projected to minimize maternal and neonatal mortality by 10-20%, given satisfactory quality of the care provided and given regular attendance.[3-5] One study found that utilization of ANC at least once during pregnancy reduced the risk of neonatal mortality by 39% in Sub-Saharan African (SSA) countries.[6] Although the proportion of women who attend focused ANC for at least four visits generally tend to be satisfactory globally including SSA[7], maternal and neonatal mortality in the region remains high.[8]

Not all studies of the effectiveness of ANC come to the same conclusions. One might assume that the better the ANC, the lower the risk of pregnancy outcomes. However, there are studies reporting paradoxical findings on perinatal outcomes the effectiveness of ANC in relation to the number of visits. In 2010, one Cochrane review and Zimbabwe's largest trial reported that there were an inverse association between the number of ANC visits and the risk of stillbirth[9] and preterm birth[10], respectively. Conversely, other Cochrane reviews have reported that reduced ANC contact numbers did not have a substantial effect on the risk reduction of maternal and neonatal complications.[11] [12] The heterogeneity of these results suggested that it is not only the number of ANC visits that matters but also the quality and content of care given during each visit and especially in the first visit if made in the first trimester. Moreover, none of these studies recognize the gross effect of ANC interventions on the likelihood of maternal complications arising separately during the antenatal, intrapartum and postpartum periods.

The World Health Organization (WHO) has recently recommended that, to improve maternal and neonatal outcomes, women should have at least eight ANC contacts.[1] However, in many countries worldwide, including Ethiopia, the four visits focused ANC continues to be followed as the standard practice.[13]

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All contents in each ANC visit might contribute in reducing maternal and neonatal complications. However, unlike other visits, the first ANC visit is unique in its intent and requires special attention because of the following reasons:

. Unlike other visits, the first ANC visit is unique in its intent. A timely first ANC visit creates an opportunity for a woman to connect with formal health services and provides the possibility that early screening of pregnant women can identify those who will require specialized care [14].. In addition, The first visit also helps the provider identify those pregnant women who are very likely to experience unfavorable obstetrical outcomes like hemorrhage[15]. The first visit is the proper time to provide preventive interventions, for example providing iron tablets and explaining why and also providing counseling if there are any danger signs [16]. In spite of these benefits, the contribution of first ANC contact in improving perinatal outcomes is blurred and requires further evaluation.

On mini Ethiopian Demographic health survey 2019 report, 74% of pregnant women had attended at least one ANC visit. However, only 43% of women had at least four ANC visits during their last pregnancy.[17] This discontinuity of care has created a doubt on the quality of ANC provided. This doubt leads to the question: Can health care providers delivered appropriate quality care, or is it because women were unable to attend the facilities? Therefore, research on how ANC is ANC is provided as per local guideline and how much it is effective to reduce maternal and neonatal outcomes is needed.

The Federal Ministry of Health of Ethiopia has implemented focused ANC guideline for the last two decades.[18] However, the level of provider's adherence to national ANC guidelines is low[19] [20].Poor providers competency, Lack of in-service training and unavailability of ANC guidelines were the main reasons for providers not following the ANC guideline.[21]

Studies in Ethiopia have assessed on the effectiveness of ANC in reducing maternal and neonatal complications.[22-24] However, these measures often focus on service contacts as opposed to the interventions delivered during those contacts. In addition, Ethiopia has taken the coverage of ANC visit at least once as an indicator of maternal health.[14] In order to attain effectiveness of ANC interventions, insuring quality of ANC during the first visit is very crucial. However, there is a scarcity of evidence in Ethiopia on the extent to which providers' adherence to ANC

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guideline during the first visit guideline with direct observations, and its relationship with maternal and neonatal complications.

Therefore, the aim of the present study was to examine the effect of complete provider adherence to ANC guidelines during the first visit on the risk of maternal and neonatal complications during the intrapartum and postpartum periods in Gondar town public health facilities.

Methods and materials

Study design, setting, and period

A prospective cohort study was conducted in Gondar town public health facilities from May 12, 2019 to January 30, 2020. Gondar town is located in Northwest Ethiopia. The total population size of the town is estimated to be 306,246. Of these, 156,276 were females in reproductive age.[25] In Gondar town, there is one comprehensive specialized hospital, eight public health centers, and 15 private clinics. An average of 100-150 clients visit the University of Gondar specialty hospital everyday for ANC service, and 20- 30 ANC users visit each health center every day. Such health facilities are staffed by midwives, obstetricians, nurses and general physician. In each health facility, at least five midwives have been permanently employed. However, these midwives are expected to cover all maternal services.

Population and recruitment of study participants

All pregnant women who came for ANC service during the first visit to one of the selected public health facilities during the data collection period were eligible for inclusion in the study and were then followed from the first ANC visit through the first six hours of the postpartum period. According to the Ethiopian delivery protocol, women have to be discharged six hours following birth unless there is a serious complication.[18] Pregnant women recruited and followed were to be 18 years or older, have reached gestational age of 28 weeks and below, were permanent residents in the study area, and were willing to take the routine ANC service throughout pregnancy. Clients who received complete providers' adherence to ANC guideline during the first visit were designated as belonging to the **exposed group** and incomplete providers' adherence to ANC guideline during the first visit were designated as belonging to the **un-exposed group.**

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Sample size and sampling procedure

The sample size was calculated using Epi Info 7 software [26] taking into account the following statistical assumptions:: confidence level of 95% (2-sided), power of 80 %, exposed to the non-exposed ratio of 1:2, the overall incidence (non-exposed group) for any pregnancy, delivery or postpartum complication was 68.6% taken from the study conducted in Ghana.[27] We believed that the status of health coverage and setting in Ghana and Ethiopia are almost the same. Quality of ANC alone has been reported to reduce maternal and neonatal mortality by 10-20%.[4] [5] Therefore, we assumed that the incidence of maternal and neonatal complications would be decreased by 15.4% if Ethiopian providers completely adhere to the ANC guidelines during the first visit, and would result in the overall incidence of complications to be 53.2% amongst the exposed group (complete adherence). This study also considered the design effect of 2 and lost follow-up and non-response rate of 10%. By considering all those assumptions, the minimum sample size required for the study was found to be 832 participants, of which 277 were exposed(complete adherence) and 555 un-exposed women (incomplete adherence).

To conduct this study, a multistage sampling technique was employed. In the first step, four health facilities (one university hospital and three health centers) were selected out of nine public health facilities by a simple random sampling technique. The details of the sampling procedure have been described elsewhere.[20]

Data collection processes and tools

Pregnant women who met the inclusion requirements and who gave informed consent for participation were enrolled in the study. After enrollment, an 18-item structured observation checklist developed on the basis of the ANC protocol was used to record how the ANC services were given and what information was provided during the first ANC visit.[18] A pre-tested structured questionnaire was used to guide the collection of the baseline socio-demographic and obstetric characteristics of study participants by face-to-face interview.

The data collectors were midwives who were trained about the data collection tool and how to collect data with direct observation. Both the data collectors and supervisors were not employed in the health facilities under the study. Pregnant women who met the inclusion requirements and who gave informed consent for participation were enrolled in the study. After enrollment, a direct observation and recording was done by data collectors(midwives) to assess how the ANC

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services/contents were given as well as the information provided using the observation protocol. So, direct observation and filling the checklist was done while the providers were doing the first ANC service as per national guideline.

Once the women had finished their first ANC visit, they were categorized as belonging to either the exposed group or the un-exposed group and then followed prospectively through the first six hours of the postpartum period. On the subsequent ANC visits, another structured 9-point checklist extracted from the ANC guideline was used to record how the care provided particularly counseling on iron and folic acid supplementation, tetanus immunization, how to recognize danger signs, what to do, and where to get help, HIV testing and counseling, the benefit of skilled attendance at birth, nutrition, de-worming, birth preparedness' and complication readiness plan, and risks of using tobacco and alcohol during pregnancy. At the same time, medical records and antenatal care charts of subsequent antenatal clinic visits were also reviewed and documented by following the checklist to be sure that any antenatal complications had been checked for and identified. Finally, maternal outcomes (antepartum hemorrhage, pregnancy induced hypertension, postpartum hemorrhage, obstructed labor, cesarean section, and tear) and neonatal outcomes (stillbirth, preterm birth, APGAR score, and low birth weight) during intrapartum and postpartum period were collected from both the maternal health record book and delivery register and documented in the checklist prepared for this purpose.

The participants' addresses and telephone numbers were linked to their study identification numbers. Those clients who didn't avail themselves of the scheduled ANC visit were contacted through a telephone call. All participants received a phone call at the time of their expected delivery to determine if they had given birth or not. Once they assured us that they had experienced delivery, the data collectors went to the facility where the women had given birth and extracted delivery data from both the maternal health record or chart and the delivery register. Women who delivered at home and were reachable were called and a home visit was done to collect information about delivery outcomes. Those who could not be reached by any of these means were treated as lost to follow-up.

Training was given for data collectors and supervisors for three days on how to use the data collection instrument and how to approach the pregnant women and record the nature of the service they had received. On-site supervision was conducted during data collection.

Study variables

Outcome variable

The outcome variables were maternal and neonatal complications during the intrapartum and postpartum periods. A combined maternal complication was defined as occurrence complications such as Pregnancy-Induced Hypertension(PIH) (defined as systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg after 20 weeks of pregnancy with or without proteinuria or with tonic-clonic convulsion), cesarean delivery, Antepartum Hemorrhage(APH) (defined as bleeding from or in to the genital tract, occurring during third trimesters of pregnancy and prior to the birth of the baby), Postpartum Hemorrhage (PPH) (was defined as any amount of bleeding from or into the genital tract following birth of the baby up to six hours in the postpartum period, which adversely affected the general condition of the patient as evidenced by rise in pulse rate and/or falling blood pressure), genital tear (defined as injuries following childbirth process involving vulva, perineum, vagina, and/or cervix), and /or obstructed labor (defined as arrest of descent in spite of good uterine contractions due to mechanical obstruction).[28]

Combined neonatal complications were also defined as the occurrence of adverse neonatal outcomes such as stillbirth, preterm birth (<37 weeks)[29], poor APGAR score (5th minute APGAR score <7)[30], and/or low birth weight (<2500 gm)[31]. Both the women and the newborns could have more than one complication.

Primary exposure variable

The primary exposure variable for this study was the level of the **providers' adherence** to the ANC guideline during the first visit. Adherence was defined as the providers' degree of conformity to following the standard ANC guidelines as per the national protocols [32] by an observer using the 18-point checklist. The observed variables to be attended to as indicated by the checklist include age asked, gestational age calculated, parity asked, past obstetric history asked, previous abdominal-pelvic surgery asked or checked, medical general history asked, current pregnancy history asked, weight measured, blood pressure checked, the abdominal examination done, hemoglobin test done, urine test done, VDRL done, blood group and Rh, HIV test done, tetanus injection given, iron and folic tablets prescribed and counseling done. Each variable adhered to, scored a point of 1 while non-adherence scored 0. **Complete provider**

adherence was defined as clients who received all the 18 items adhered to by the provider as listed in care guidelines for the first ANC visit (total score = 18). The observation checklist, scoring criteria, and the entire method for the baseline of the cohort study have been described elsewhere.[20]

Covariates

Several explanatory variables were included as covariates. These include a range of maternal socio-demographic variables such as maternal age, residence, religion, marital status, educational level, and employment status. Obstetric characteristics such as time of booking (early booking was defined as the initiation of first ANC <16 weeks of gestation)[18], gravidity, parity, previous history of obstetric complications, birth-to-pregnancy interval, the intention of the current pregnancy, history of female genital mutilation, current ANC complications, number of ANC visit attended, place of current delivery, mode of delivery of the current pregnancy, and counseling received during pregnancy.

Current antepartum complication: was defined as the presence of at least one of the complications occurs during antepartum period (anemia, PIH, APH, urinary tract infection, gestational Diabetic Mellitus and premature rupture of membrane).

Counseling service during pregnancy was measured by nine composite variables. Each counseling service occurrence was recorded starting from the second visit up to the last visit. To say the woman was counseled for one variable, the counseling had to be given in all visits. When one component of counseling service was given at all visits, it was coded as 1 otherwise 0. Finally, composite counseling service was defined as pregnant women who got at least one or more variable out of the nine counseling variables.[19]

Data analysis

Data were entered using Epi Info version 7 and analyzed using Stata 14 software. Descriptive analysis of participants' socio-demographic and obstetric information was conducted by the use of frequencies and chi-square analysis. Incidences of maternal and neonatal complications during intrapartum and postpartum period were estimated in percentages. Possible associations of adherence with each adverse outcome were assessed using Pearson's chi-square test. Since the maternal and neonatal complications are outcome variables of the study and the numbers of complications are considered as count data, Poisson regression was used as a standard model for analysis. However, the observation should be independent over time and the mean and the

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variance should be equal. In this study, the variance was greater than the mean; this indicates the presence of overdispersion. Hence, the negative binomial model was used to estimate the effect of complete adherence on the risk of maternal, and neonatal complications were estimated and expressed as Incidence Risk Ratio (IRR) with their 95% confidence intervals (CI). Separate models were done for maternal and neonatal outcomes. To control confounders, the models were adjusted with selected maternal socio-demographic and obstetric variables (P-value ≤ 0.25 in bi-variable analysis) with outcome variables. The Adjusted Incidence Risk Ratio (AIRR) for the associations between complete provider adherence and adverse maternal and neonatal outcomes were determined after controlling for maternal socio-demographic and obstetric variables characteristics. A P-value of <0.05 was used to declare the statistical significance of independent variables. The likelihood ratio test of the parameter Alpha (α) was found to be P-value <0.001 for both models

Patient and public involvement

Patients and the public were not invited to comment on the study design or conduct of the study. However, they will be informed of the study results through publications.

Result

A total of 832 women were recruited at baseline with the number of exposed and unexposed women who were 277 and 555 respectively, prospectively followed from the first ANC visit to the first six hours of the postpartum period. Seven hundred eighty-two (93.99 %.) women were completed the follow-up and considered in the final analysis. Twenty-three (8.3%) study participants from the exposed group and 25 (4.5%) participants from the un-exposed group were lost in the follow-up. Self-referral to other health facilities and permanent change in workplace were the reasons (Figure 1).

Participants' baseline characteristics

The mean age of study participants was 25.9 years. About 651 (83.3%) were in the age group of 20-35 years. Six (2.1%) clients came from the rural area. A higher proportion of women (38.5%) who received complete adherence had no formal education (Table1). Regarding their obstetric characteristics, 551 (70.5%) booked their first ANC at 16 and above weeks of gestation. Three hundred and eight (39.4%) were primigravidea. Three-fourths of the women (73.4%) attended an antenatal clinic more than four times during the pregnancy. Forty-seven (6%) of the participants gave birth at home. Among 219 (28.6%) women who had current antenatal complications, 68 (31.1%) of them received complete providers' adherence to the first ANC guideline (Table2).

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Table 1: Socio-demographic characteristics of study participants among exposed and un-exposed groups in Gondar town public health facilities, 2020

Socio-demographic variables		Frequency (%) of total participants N=782	Frequency (%) of the exposed group N=254	Frequency (%) of the un-exposed group N= 528	P-value
Type of health facility	Hospital	415(53.1)	131 (31.6)	284 (68.4)	0.56
	Health centers	367 (46.9)	123 (33.5)	244 (66.5)	
Age (in years)	<20	105(13.1)	27 (25.7)	78 (74.3)	0.28
	20-35	651(83.3)	218 (33.5)	433 (66.5)	
	>35	26 (3.3)	9 (34.6)	17 (65.4)	
Residence	Urban	766 (97.9)	248 (32.4)	518 (67.6)	0.66
	Rural	16 (2.1)	6 (37.5)	10 (62.5)	
Religion	Orthodox	715 (91.4)	227(31.8)	488 (68.2)	0.36
	Muslim	57 (7.3)	23(40.3)	34(59.7)	
	Others	10 (1.3)	4 (0.4)	6 (0.6)	
Marital status	Married	761 (97.3)	250(32.8)	511 (61.2)	0.18
	Unmarried	21(2.7)	4(19.1)	17 (80.9)	
Educational level	None	130 (16.6)	50 (38.5)	80 (61.5)	0.24
	Primary	191 (24.4)	56(29.3)	135 (70.7)	
	Secondary	241 (30.8)	72(29.9)	169 (70.1)	
	Tertiary	220 (28.1)	76 (34.5)	144 (65.5)	

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| Employment | Yes | 183(23.4) | 67(36.6) | 116 (63.4) | 0.17 |
| | No | 599 (76.6) | 187(31.2) | 412 (68.8) | |

Table 2: Obstetric characteristics of study participants among exposed and un-exposed groups in Gondar town public health facilities, 2020

Obstetric variables		Frequency (%) of total participants N=782	Frequency (%) of Exposed group N=254	Frequency (%) of un-exposed group N= 528	P-value
Time booking	Early booking (<16 weeks)	231 (29.5)	61 (26.4)	170 (73.6)	0.02
	Late booking (≥ 16 weeks)	551 (70.5)	193 (35.0)	358 (65.0)	
Gravidity	Primigravidea	306 (39.4)	96 (31.2)	212 (68.8)	0.53
	Multigravidea	474 (60.6)	158 (33.3)	316 (66.7)	
Parity (number)	0	353 (45.1)	111 (31.4)	242 (68.6)	0.95
	1-2	355 (45.4)	119 (33.5)	236(66.5)	
	3-4	61 (7.8)	20 (32.8)	41 (67.2)	
	>4	13 (1.7)	4 (30.8)	9 (69.2)	
Previous history of pregnancy complications	Yes	105 (13.4)	42 (40.0)	63 (60.0)	0.07
	No	369(47.2)	115 (31.2)	254 (68.8)	
Birth to pregnancy interval	Short(≤24)	101(23.3)	36(35.6)	65(64.4)	0.39

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(in month)	Recommended (24-48)	172 (39.6)	55(32.0)	117(68.0)	
	Long(>48)	161(37.1)	53(32.9)	108(67.1)	
Intention of pregnancy	Planned	717 (91.7)	230(32.1)	487(67.9)	0.60
	Unplanned	65 (8.3)	24(36.9)	41(63.1)	
History of female genital mutilation	Yes	22 (2.8)	10 (45.5)	12 (54.5)	0.61
	No	760 (97.2)	244 (32.1)	516 (67.9)	
Received counseling during pregnancy	yes	702 (89.8)	231 (32.9)	471 (67.1)	0.95
	No	80 (10.2)	23 (28.8)	57 (72.2)	
Current antenatal complications	Yes	219 (28.6)	68 (31.1)	151 (68.9)	0.59
	No	569 (71.4)	186 (33.0)	377(67.0)	
Number of ANC visit attended	≤ 4 visits	208 (26.6)	66 (31.7)	142 (68.3)	0.78
	> 4visits	574 (73.4)	188(32.8)	386 (67.2)	
Place of current delivery	Health facility	735 (94.0)	242(32.9)	493(67.1)	0.30
	Home	47(6.0)	12(25.5)	35(74.5)	
Gestational age at delivery	< 37 weeks	60 (7.7)	19 (31.7)	41 (68.3)	0.82
	37-42	717 (91.7)	234 (48.4)	483 (67.4)	
	>42	5 (0.60)	1(20.0)	4 (80.0)	
Mode of delivery of the current pregnancy	Spontaneous vaginal delivery	620(79.3)	201(32.4)	419(67.6)	0.91
	Cesarean section	141(18)	47 (33.3)	94 (66.7)	
	Instrumental delivery	21(2.7)	6 (28.57)	15 (71.4)	

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The incidence of maternal and neonatal complications

Of the total of 782 women, 298 (38.1%) (95% CI: 34.7, 41.6) had at least one type of maternal complications during the intrapartum and/or postpartum periods. The different incidence of maternal complications among women who received complete and incomplete providers' adherence was statistical significant; 32.7% and 40.7% respectively. Eighty-four (10.7%) participants developed PIH during intr-partum period though there was no statistical difference between the two groups (table 3).

The incidence of stillbirth, low birth weight, poor Apgar score were statistical significant higher in the un-exposed group (table 3). There was no maternal and neonatal death during the intrapartum and postpartum periods.

Table 3: Risk of maternal and neonatal complications during intra-partum and postpartum periods amongst exposed and controlled groups in Gondar town public health facilities, 2020

Complications	Incidence N=832	Exposed group n= 254	Unexposed group n= 528	P-value
Maternal				
PIH	84 (10.7)	23(9.1)	61 (11.6)	0.51
APH	43 (5.5)	14(4.7)	29 (5.9)	0.29
Obstructed labor	6 (0.8)	3 (1.2)	3 (0.6)	0.36
Tear	56 (7.2)	14 (5.5)	42 (8.0)	0.21
Cesarean section	141 (18.00)	47 (18.5)	94 (17.8)	0.81
PPH	23 (2.9)	6 (2.4)	17 (3.2)	0.5
Any intra-partum and/or postpartum complications (at least one)	298(38.1)	83 (32.7)	215(40.7)	0.03
Neonatal				
Preterm birth	60 (7.7)	19 (7.5)	41 (7.8)	0.08
Stillbirth	25 (3.2)	3 (1.2)	22 (4.2)	0.026
Low birth weight	62 (7.9)	9 (3.5)	53 (10.0)	0.02
Poor APGAR score	101 (12.9)	19 (7.5)	82 (15.5)	0.02

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Any neonatal complications(at least one)	179 (22.9)	40 (15.7)	139 (26.3)	0.001

The incidence of at least one neonatal complication among newborns who were delivered at home and at the health facilities were 44.7% and 21.5% respectively. The incidence of stillbirth and low APGAR score was much higher amongst newborns who were delivered at home than among those delivered at the health facility. The incidence of at least one maternal complication among women delivered at the facility and home was 38.4% and 34 % respectively. All women who had obstructed labor gave birth at the health facility (Figure 2).

Effect of received complete provider adherence to guidelines during the first ANC on the risk of maternal and neonatal complications

In the unadjusted negative binomial regression, complete provider adherence, maternal age, maternal education, parity, place of ANC attendance, number of ANC visits, counseling during pregnancy, current ANC complications, and place of delivery were associated with maternal and neonatal complications during intrapartum and postpartum periods. After controlling for confounding variables, complete providers' adherence **(AIRR=0.56; 95% CI: 0.39, 0.79)** was significantly associated with neonatal complications. However, complete providers' adherence was not significantly associated with maternal complications during the intra-partum and/or postpartum periods (Table 4).

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Table 4: Negative binomial Poisson regression analysis showing the effect of received complete provider adherence to guidelines during the first ANC on maternal and neonatal complications during intrapartum and/or postpartum periods

Explanatory Variables	Maternal complications			Neonatal complications		
	Unadjusted IRR (95%CI)	Adjusted IRR (95%CI)	Adjusted P-value	Unadjusted IRR (95%CI)	Adjusted IRR(95%CI)	Adjusted P-value
Received complete adherence	0.85 (0.67,1.07)	0.84(0.67,1.05)	0.14	0.51(0.36, 0.74)	**0.56 (0.39,0.79)**	**0.001**
Age (in years)						
<20	1	1		1	1	
20-35	1.24(0.89,1.72	1.2(0.85,1.71)	0.28	0.95 (0.61,1.47)	1.01 (0.65,1.59)	0.93
>35	1.31(0.70,2.45)	1.46(0.74,2.88)	0.27	1.30 (0.55,3.05)	1.28 (0.51,3.18)	0.59
Educational level						
None	1	1		1	1	1
Primary	1.1(0.78,1.56)	1.03(0.72,1.46)	0.87	1.09 (0.69,1.73)	1.08 (0.68,1.71)	0.73
Secondary	1.12(0.81,1.55)	1.11 (0.78,1.59)	0.53	0.94 (0.60,1.47)	0.97 (0.60,1.56)	0.90
Tertiary	1.24(0.90,1.73)	1.21(0.84,1.74)	0.29	0.72 (0.45,1.16	0.74 (0.44,1.24)	0.25
Parity (number)						
0	1	1		1	1	1
1-2	1.02(0.82,1.27)	1.01 (0.8,1.27)	0.91	1.04 (0.75,1.43)	0.99 (0.72,1.38)	0.99
3-4	1.11 (0.75,1.63)	1.18 (0.77,1.81	0.43	1.32 (0.76,2.28)	0.97 (0.54,1.74)	0.92
>4	0.5 (0.16,1.58)	0.46(0.14,1.55)	0.21	1.81 (0.66,4.95)	1.71 (0.59,4.94)	0.31
Place of ANC attendance						

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Hospital	0.95 (0.77,1.16)	0.88(0.68,1.12)	0.32	1.04 (0.77,1.04)	**1.88 (1.31,2.69)**	**0.001**
Health centers	1	1		1	1	
Number of ANC visit attended						
≤ 4 visits	1	1		1	1	
>4 visits	1.14 (0.89,1.45)	1.12 (0.87,1.46	0.30	0.51 (0.37,0.69)	**0.41 (0.30,0.57)**	**0.00**
Received counseling during pregnancy						
Yes	1.02 (0.79,1.33)	1.05(0.78,1.41)	0.70	0.70 (0.49,1.01)	0.69 (0.47,1.03)	0.07
No	1	1		1	1	
Current antenatal complications						
Yes	1.85 (1.50,2.28)	**1.83(1.48,2.26)**	**0.00**	1.82 (1.34,2.49)	**1.9 (1.40,2.58)**	**0.00**
No	1	1		1	1	
Place of current delivery						
Facility	1.29 (0.79,2.10)	1.21 (0.72,2.01	0.45	0.42 (0.25,0.70)	**0.49 (0.30,0.81)**	**0.005**
Home	1	1		1	1	
Maternal complications during intrapartum and/or postpartum periods	NA					
Yes	-	-	-	1.57 (1.16,2.12)	**1.48 (1.10,2.00)**	**0.009**
No	-	-	-	1	1	

NA= Not Applicable

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Discussion

The current study demonstrates the role of a provider's adherence to the ANC guideline during the first visit in leading to improvement of maternal and neonatal outcomes. The key findings of this study are that complete adherence by the providers to the ANC guidelines during the first visit reduced the risk of neonatal complications but did not have any statistically significant effect on the risk of maternal complications occurring during the intrapartum and/or postpartum periods.

In general, improving the quality of obstetric care, if supported by guidelines, can directly reduce the incidence of maternal and neonatal deaths.[1] Guidelines can, however only lead to improved quality care if they are translated into daily provider practice.[33]

The finding of our study revealed that those women who received complete providers' adherence to ANC guideline during the first visit had a 44% reduction in the risk of combined neonatal complications. . It is possible to explain the preventive association between providers adherence to the contents of ANC guideline with risk of neonatal complications can be explained in different ways. Complete providers adherence to ANC guideline during the first creates an opportunity for a woman to connect with formal health services like screening of pregnant women who have and at risk of developing complications.[14] Because neonatal outcomes are the direct reflection of maternal health conditions.[34]. The first visit is the exact moment to deliver cost effective preventive interventions like Iron–folic acid supplementation, nutritional advice, tetanus toxoid vaccination.[16 35 36] These interventions have been shown to be cost-effective in a Sub-Saharan African context.[37] The first ANC visit also provides an important opportunity for midwives to teach mothers how to recognize warning signs of complications during pregnancy, labor, and delivery and encourage them to plan clean and safe deliveries[19].

The finding of our current study are consistent with findings from the study conducted in Ghana[27] and in Ethiopia.[22 23] The observed similarity between the findings of our present study and the findings from Ghana might be due to the similarity of the ANC guideline in the two countries. In both countries the format and contents of the first ANC guideline is quite similar.[18] [38] Even though there is a similarity between our study findings and the findings of Abera H et al 2018 and Tafere TE et al 2018.; However, the types of exposures were somehow different among the three studies. In the case of our current study, the exposure variable was the provider's adherence to ANC guideline during the first visit. In the study done by Abera H et al,

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the exposure variable was the number of ANC visit. On the other hand, the quality of ANC throughout pregnancy was the primary exposure in the other study done in Bahirdar city. On top of that the way we measured the association between the outcome variables and the exposure variable was different in the three studies.

The number of ANC visits attended by mothers to be is inversely related to the incidence of adverse neonatal outcomes. The greater the number of visits, the lower the incidence of neonatal complications as shown by the 59.0% reduction amongst women who had more than four ANC visits. This finding was supported by another study done in Ethiopia[22]. The possible explanation is that frequent antenatal visits might create a better quality of contact between the provider and the pregnant woman and this might lead both the provider and the pregnant woman to identify and address any challenges of the pregnancy. This creates an opportunity to screen and provide interventions for anything missed during the first ANC visit.[39] A Cochrane review found that there was an inverse relationship between the number of ANC visits and risk of stillbirth, the smaller the number of visits, the greater the risk.[40] This was one of the best reasons for the development of the 2016 eight-contact ANC guideline.

The result of this study indicated that those women who attended ANC at the hospital were more likely to develop neonatal complications compared to health center. Studies have shown that women who attended their ANC at higher level facilities were more likely to receive incomplete adherence to ANC guideline during the first visit.[41] On the other hand, majority of study participants who received their at ANC hospital were referral cases with obstetric complications. They might opt in to attend birth in the hospital than health centers. It is supported by the other finding of our study that newborns who were delivered from mothers with antepartum complications were at a higher risk developing neonatal complications. This implies that women who attend their ANC at the hospital special attention.

In contrast to the findings from the Ghana study[27] and contrary to our original alternative hypothesis, we found that complete provider adherence to the ANC guideline during the first visit did not have a significant effect on the risk of maternal complications during the intrapartum and/or postpartum periods. The plausible explanation for the observed difference between the findings of our present study and the study conducted in Ghana could be due to the disparity in inclusion criteria. The Ghana study included women who had their first ANC visit at gestational age below or equal to 20 weeks. But in our current study, we included women whose

gestational age was below 28 weeks. This could miss opportunities for early detection of complications and initiation of certain preventive measures such as prescribing iron tablet in a timely manner.[42] There may be other factors in addition to providers' adherence to the ANC guidelines during the first visit. It is recognized that the regular subsequent antenatal attendance would encourage providers to review and provide care for what they might have missed out during the first antenatal visit.

Other confounding determinant factors may contribute to raising the incidence of risks of maternal complications during the intrapartum and/or postpartum periods. The finding of our study revealed that the risk of clients who had any antepartuml complications was 1.83 times more likely to develop maternal complications which occurred during intrapartum and/or postpartum periods compared to women to clients who had no antenatal complications. This might be due to the recurring nature of complications during labor and childbirth once they have been detected and treated during the antenatal period.[43] Therefore, full quality of care throughout pregnancy is very crucial.

In the last few years, it is easy to become optimistic increasing the coverage focused ANC is a top priority of the Ethiopian government. However, the quality of care lags behind. In general, the finding of our present study will give an overall insight for maternal health care programmers and implementers in Ethiopia and similar countries to focus on improving the quality ANC based on the up-to-date guideline in order to improve neonatal outcomes..

The strengths of our study included its prospective nature, which ensured the availability of sufficiently detailed information on maternal and neonatal characteristics. The proportion of drop-out rate or loss to follow-up is under the acceptable range. The proportion of drop-out rate or loss to follow-up is under the acceptable range. To increase the generalizability of our study findings, adequate sample size was calculated. However, the study also has limitations. The outcomes of women who gave birth at home were collected through the home visit. However, measurement bias was one of biggest trait at there. Some of the neonatal outcomes were measured with instruments like bin balance to measure the baby wait at home. Other variables like APGAR score were measured subjectively by asking clients what was happening during and after child birth. The other trait of our study was Hawthorne effect. Health care providers might make maximum effort to carry out the first ANC visit if the data collectors were directly

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observing that visit. However, the effect of an observer lasts only for a short time and it slowly decreases when the providers adapt to the presence of the observer.[44] To decrease the bias, we were discarding the first few observations during the start of data collection. On the top of that, prospective (longitudinal) nature of the study would also significantly reduce its effect. The majority of enrolled participants book their first visit during the second trimester. This might be underestimating the contribution adherence to the ANC visit guideline on the reduction of maternal and neonatal outcomes. At last, we didn't estimate the effect of complete provider adherence on specific maternal and neonatal complications.

Conclusions

In this study, received complete provider adherence to ANC guideline during the first contact significantly reduced the risk of neonatal complications but no statistically significant reduction in maternal adverse outcomes during the intrapartum and/or postpartum periods. Therefore, our findings point to the important implications of developing interventions that build on institutional practice of providing a tested set of ANC guidelines that are followed completely by health care providers. We also believe that early detection and management of antenatal complications is very crucial if maternal and neonatal outcomes are to be improved during the intrapartum and/or postpartum periods.

Abbreviations

AIRR	Adjusted Incidence Risk Ratio
ANC	Antenatal Care
APH	Antepartum Hemorrhage
CI	Confidence Interval

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PIH	Pregnancy Induced Hypertension
PPH	Postpartum Hemorrhage
SSA	Sub-Saharan Africa
VDRL	Venereal Disease Reference Laboratory
WHO	World Health Organization

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Author contributions: TS conceived and designed the study, analyzed the data and prepared the manuscript. MA, KC, and HL assisted in the development of the research idea, analysis, interpretation and preparation of the manuscript. All authors read and approved the final manuscript.

Competing interest: None declared.

Patient consent for publication: Not required.

Ethics approval: The protocol has been reviewed by the Institutional ethical review board of University of the Gondar for its ethical soundness, ID: O/V/P/RCS/05/498/2018. Confidentiality was maintained.

Data availability statement: Data are available upon reasonable request. The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Fig. 1: Flow diagram for participants' in the study. A description of participants' recruitment, follow-up, and analysis in the study in Gondar town public health facilities, 2020

Fig. 2: Risk of maternal and neonatal complications during intrapartum and postpartum periods based on place of delivery among women completed the follow in Gondar town public health facilities, 2020
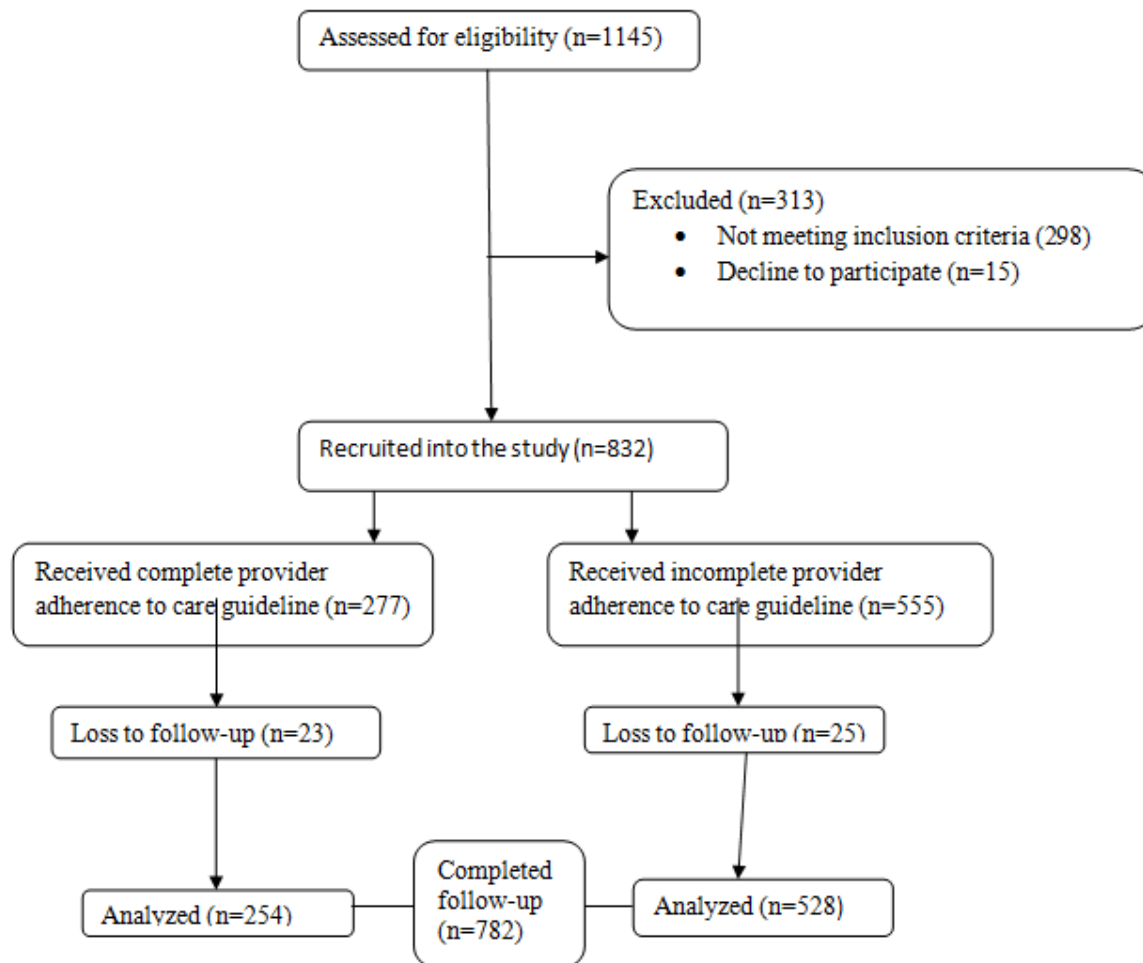
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Fig. 1: Flow diagram for participants' in the study. A description of participants' recruitment, follow-up, and analysis in the study in Gondar town public health facilities, 2020
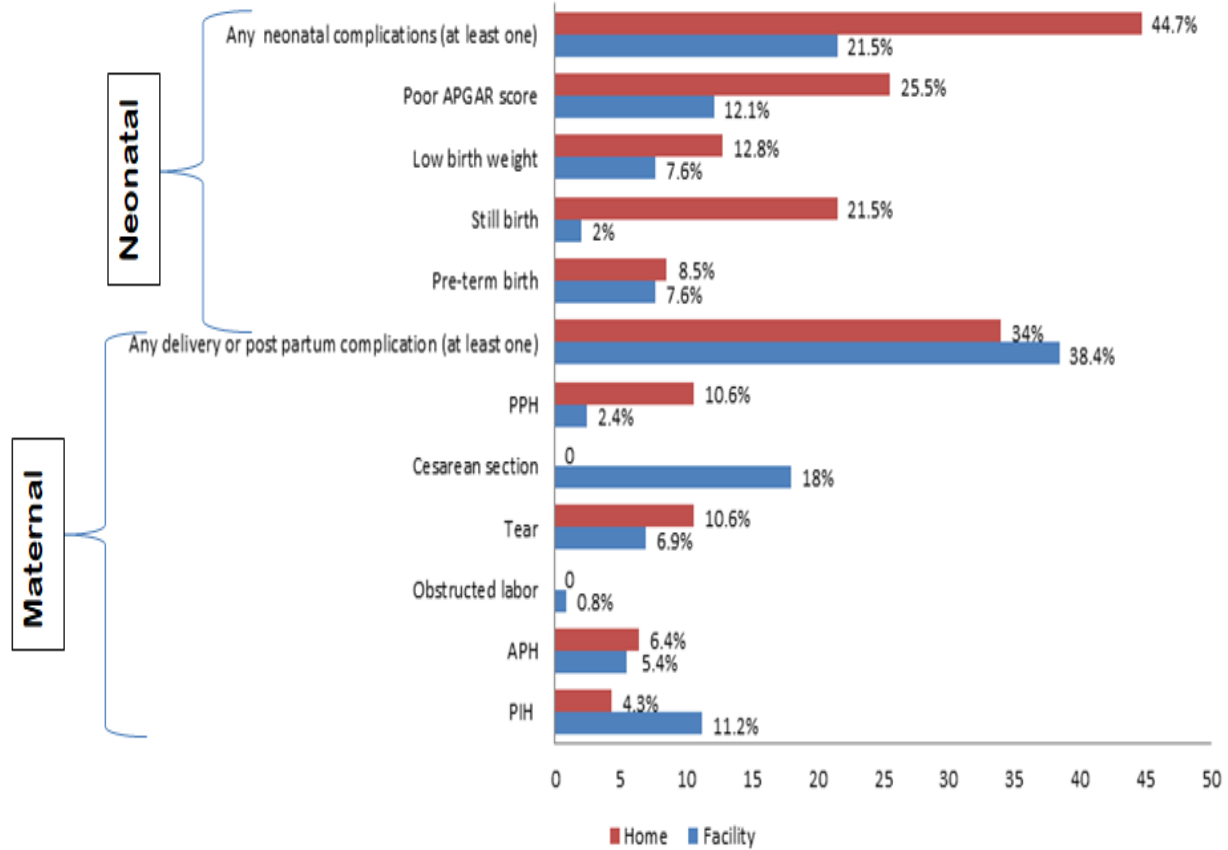
Fig. 2: Risk of maternal and neonatal complications during intrapartum and postpartum periods based on place of delivery among women completed the follow in Gondar town public health facilities, 2020

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8-9*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	-
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, explain how loss to follow-up was addressed	8
		(*e*) Describe any sensitivity analyses	8
Results			-

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	11
		(c) Summarise follow-up time (eg, average and total amount)	11
Outcome data	15*	Report numbers of outcome events or summary measures over time	15
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16
		(*b*) Report category boundaries when continuous variables were categorized	16
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations			22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-22
Generalisability	21	Discuss the generalisability (external validity) of the study results	22
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.