Intervention fidelity and its determinants of focused antenatal care package implementation, in South Wollo, Northeast Ethiopia.

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Asressie Molla Tessema
WOLLO UNIVERSITY

asressie@gmail.com
Corresponding Author
ORCID: https://orcid.org/0000-0002-8286-5870

Abebaw Gebeyehu
University of Gomdar, Institution of public health

Solomon Mekonnen
Department of human nutrition, Institute of public health, University of Gondar, Gondar, Ethiopia

Kassahun Alemu
Department of Epidemiology and Biostatistics, Institution of Public health, University of Gondar, Gondar, Ethiopia

Zemene Tigabu
Department of pediatrics and child health, University of Gondar, Gondar, Ethiopia

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Abstract
Introduction Evidences show that intervention packages at home-community setting are found to reduce neonatal mortality significantly. But millions of neonates are still dying by preventable causes with the implementation of these effective interventions. This might be due to evidence-practice gap. Therefore, this study aimed at assessing the intervention fidelity and factors influencing focused antenatal care package.

Methods Cross-sectional study design was employed in this study. In the selected kebeles’, a total of 898 mothers who gave birth within six months before data collection, ten health posts with their health extension workers were employed. Interview-administered, self-administered and facility audit checklist were used for collecting data from all mothers, health extension workers and health posts respectively. Mothers were asked whether or not the required level of care were provided to them. Health extension workers & health posts were assessed for the competency and organizational drivers. Multilevel linear regression model were used to identify the possible moderating factors at individual and organizational level for intervention fidelity.

Result The overall weighted average focused antenatal care package intervention fidelity was 49.78% (95% CI: 47.73 – 51.83). The weighted average focused antenatal care package intervention fidelity by health extension workers was 62.02% (95% CI: 59.71 – 64.32) and skilled providers were 56.57% (95% CI: 53.94 – 59.19). The overall antenatal care coverage were 83.7% (95% CI: 81.28 – 86.12) with 34.97% (95% CI: of 31.56 – 38.39) of mothers received at least four antenatal visit and 6.12% (95% CI: 4.40-7.83) of them received all the recommended components of focused antenatal care. Previous maternal problem, paternal education and implementation of supportive/facilitation strategy were significant facilitators for focused antenatal care package intervention fidelity.

Conclusion In this study, focused antenatal care package intervention fidelity was low. This implies that the stagnation of neonatal mortality reduction might be partly due to the low focused antenatal care packages intervention fidelity. Paternal education and implementation of supportive/facilitation strategies were statistically significant facilitators of focused antenatal care intervention package fidelity. Therefore, improvement of implementation of facilitation strategy is recommended.
Contribution To The Literature

This study tries to compute complex public health intervention fidelity as a composite variable (composite indexing) using the concepts of weighting and conditional probability. The hierarchical or nested nature of intervention customers from the health institutions or health care providers were treated properly using multilevel statistical technique. The effect of facilitation/supporting strategy to the complex public health intervention fidelity was statistically quantified or measured.

Introduction

Neonatal mortality is the death of new born within 28 days of life after birth(1). In the year 2017 alone, 2.5 million neonates died(2–4). It is also estimated that between 2018 and 2030, 28.7 million neonates will die if the current rate of reduction continuous(3). Majority of these newborn deaths occur in low and middle income countries especially in sub-Saharan Africa. Projections indicate that achievement of child related sustainable development goal will be difficult especially in sub-Saharan Africa if the current mortality trend continues(5–7). According to world data atlas, Ethiopia is among the top countries with highest neonatal mortality rate (29deaths/1000 live births) with a slower rate of decline (41%) since 2000(8–10).

Evidences show that public health interventions during antenatal period are effective to significantly reduce neonatal mortality(10). In all the studies reviewed here, interventions during pregnancy significantly reduces neonatal mortality. Increasing antenatal care frequency improves the neonatal mortality reduction(11–15). Similarly, several studies demonstrated that maternal iron and folic acid supplementation(16–22), tetanus toxoid vaccination of mothers(16,23–26) sleeping under insecticide impregnated bed net during pregnancy (10) and syphilis screening(22) significantly reduces neonatal mortalities.

The implementation of these interventions in the form of package at home-community setting results in a significant reduction of neonatal mortality and increase maternal and child care services uptake(10,27). Different meta-analysis, randomized control trials and other observational studies shows that home-community based focused antenatal care intervention packages are found to reduce neonatal mortality significantly(28–37). From these evidences, it is indicated that the bare number of
antenatal visit could not have a significant effect on neonatal mortality reduction (29).

Ethiopia is implementing focused antenatal care package at home-community setting since 2013 to reduce neonatal mortality (36). This package links one to five network, health development army, health extension workers (HEWs) and skilled professionals working at health centers. The aim of this intervention package is early identification and provision of focused antenatal care (FANC) for pregnant women by linking home-community level of care to primary health care unit. But neonatal mortality rate in Ethiopia is still among one of the highest in the world. The question here is that why millions of neonates are still dying while these effective intervention packages are implemented? The possible hypothesis will be “there might be a problem of evidence-practice gap” meaning that effective interventions might not be implemented as planned (with fidelity) in a practical setting. Intervention fidelity is the degree to which an intervention is implemented as planned in the original implementation document(37).

So far, whether this FANC package intervention is implemented with fidelity or not and what are the facilitators and barriers for its implementation have not been assessed. Therefore, this study aimed at assessing focused antenatal care package intervention fidelity and factors influencing it in South Wollo Zone, Northeast Ethiopia. This study used standards for reporting implementation science guideline(38).

Methods
Design: Cross-sectional study design was used for evaluating the intervention fidelity of focused antenatal care package designed for the reduction of neonatal mortality.

Context: Focused antenatal care (FANC) package is a combined effective and efficient public health interventions which has been implemented during pregnancy. The main implementers are HEWs, at home-community service delivery platform, supported by family, health development army and skilled health providers working at health centers. HEWs are government-salaried, young local women with grade 10 complete plus one year certified training prior to employment. These HEWs have been
trained for family health services including FANC, diseases prevention and control, hygiene and environmental sanitation, health education and communication (39–41). HEWs have been working at health posts (the first level of health facility) under the supervision and support of health centers (42).

**Targeted sites and populations:** This study was conducted at South Wollo Zone which is 400 km far from the north of Addis Ababa. The zone has 900 rural and 150 urban health extension workers with 499 health posts, 126 health centers and 9 hospitals. The study population was all mothers who gave birth within six months prior to data collection, HEWs and health posts in the selected kebeles’.

**Intervention description:** Focused antenatal care requires a continuum of care provided at the household - health post - health center levels (Home-Community platform). The main goal of the intervention package is to transform evidence into action for reducing newborn mortality by increasing the reach to every pregnant mother and every newborn in the community. The services under this intervention package include provision of four antenatal visits, counsel about: nutrition, bed net use, pregnancy danger signs, mother to child transmission of HIV. It also includes birth preparedness and complication readiness planning, treatment of diagnosed STI, measure blood pressure, height and weight; identify maternal danger signs and referral, provision of maternal tetanus toxoid (2 doses) vaccination, promotion of institutional delivery, iron and folate supplementation and detection and management of complications. Health center staffs are expected to supervise and support health posts (or HEWs) weekly (36).

**Subgroup (Sampling):** Kebeles from South Wollo Zone were selected randomly using computer generated random numbers. All mothers who gave birth within six months prior to data collection (for individual level variables and fidelity assessment), all HEWs and all health posts in the selected kebeles (for cluster level variables) were measured. Mothers were interviewed in their home and HEWs were given the questionnaire when facility auditing was undergoing.

**Outcome:** The primary outcome of this study was FANC package intervention fidelity which had been computed by the weighted average of program reach (contact coverage), adherence to content and frequency. Program reach was measured by the proportion of mothers who visit or visited at least once by any health care provider at any health care delivery setting for recent pregnancy. The
number of antenatal visit and the number of components provided for the mothers, who were contacted, was considered as frequency and content respectively.

**Sample size:** The minimum sample size for this study was 422 computed using single population proportion formula considering a 52% of pregnant mothers received 4+ antenatal care and all the components of care during antenatal period (43), 95% confidence level, 5% margin of error and 10% non-response rate. But a total of 898 mothers who gave birth within six months were interviewed, sixteen HEWs and ten health posts were assessed.

**Analysis:** Antenatal care coverage, frequency and content were computed considering the recommended amount of care as a reference. Antenatal care coverage was computed as the proportion of mothers who have contacted health care providers during the recent pregnancy. Since the recommended number of focused antenatal care visits is at least four, getting antenatal care frequency less than four was weighed by considering \( \geq 4 \) as one (reference). For antenatal care contents, taking the total 17 antenatal care contents as maximum, mothers who received less than the recommended contents during the recent pregnancy were weighted accordingly. Since there was no any previous study in the same concept, equal weights was given for coverage, component and frequency to compute fidelity (44–46). Finally, FANC package intervention fidelity was computed by taking the weighted product of antenatal care coverage, frequency and contents. Maternal (service recipient) and health post (service provider) data were considered as facilitators and barriers for FANC package intervention fidelity. Because mothers are nested from the health post and the sampling method was cluster (kebeles) multilevel model was considered. SPSS were used for the exploratory data analysis and R statistical software were used for statistical modeling.

**Results**

**Socio-demographic characteristics of study subjects**
The mean age of mothers at the time of interview was 30.96 ± 7.215 years. Fifty percent of mothers were between 25 and 36 years of age. Concerning educational status, 638 (71.4%) of mothers did not attend formal education. Seven hundred sixty eight (85.5%) of mothers were married and 662 (74%) of mothers were housewife.
A total of sixteen HEWs who are working in 10 health posts were included in the study. The mean age of these HEWs was $26 \pm 3.67$ years and 13 (81.3%) of them were married. The average walking distance from health post to furthest home were $2:55$ (95% CI: $1:10$ – $3:20$) hours.

**Coverage of FANC**

In this study, 752 mothers visit or visited by any kind of health care providers at least once making the overall antenatal care coverage of 83.7% (95% CI: 81.28 – 86.12). HEWs contacted 397 or 44.2% (95% CI, 40.95 – 47.45) mothers and the rest contacted by skilled providers. The mean time of first antenatal care visit was $4.14 \pm 2$ months with 259 (42.7%) of mothers had seen by health care providers within the first trimester (12weeks) of gestation.

**Frequency of FANC service utilization**

The mean number of antenatal visit was $3 \pm 1.6$ and on average 34.97% (95% CI: of 31.56 - 38.39) of mothers received at least four antenatal care visit for their recent pregnancy (See figure1). Increasing the number of antenatal visit results in increasing the contents delivered to mothers in this study which was indicated as one, two, three and four plus antenatal care visit was accompanied by two, eight, sixteen and twenty mothers who received the whole contents of FANC (See figure 1 for the detail).

**Components of FANC**

On average 46 or 6.12% (95% CI: 4.40-7.83) of mothers received all the components of focused antenatal care. In this study, mothers who received all the required components of focused antenatal care by health extension workers were 33(4.3%) while by skilled providers were 13(1.7%) (See table 1).

The overall weighted average FANC package intervention fidelity was 49.78% (95% CI: 47.73 - 51.83). Only 20 (2.2%) of mothers received all the recommended FANC package intervention with full fidelity. The weighted average FANC intervention fidelity by HEWs were 62.02% (95% CI: 59.71 – 64.32) and by skilled providers were 56.57% (95% CI: 53.94 – 59.19).

**Provider related factors**
Twelve (75%) of the health extension workers ever trained on FANC package while 2 (12.5%) received current refreshment training within the last three months prior to data collection. Only two of the health posts were supervised weekly from the catchment health center and 9 (56.3%) of the health extension workers got on gob assistance for difficult cases. The average time to walk from the health post to furthest house by HEWs is 2:30 hours with the maximum of 4:00 hours. Nine of the health extension workers believe that they are able to give FANC (self-efficacious).

HEWs were asked about the implementation of support/facilitation strategies set by the ministry of health. These support strategies were assessed from health center, woreda health offices, community and development army perspectives. Seventy percent of the HEWs reported that the implementation of support from the community, health development army and Woreda health office were lower than expected.

Quality of service delivery

One hundred (16.3%) of mothers didn’t receive antenatal care, of whom 489 (65.03%) and 706 (93.88%) of mothers did not get the required number and contents of FANC package respectively. 

Customer perspective

Only 180 (20%) of mothers are within 15 minute walking distance while 333 (37.1%) of them walked more than 45 minutes to reach to health post. Of those mothers who received antenatal care service, 685 (91.1%) was self-referral. One hundred eighty seven (20.8%) of mothers encountered pregnancy related problem in their previous pregnancy.

Organizational perspective

No health post were having all the required functional equipment and medical supplies for focused antenatal care services. Birth preparedness and complication readiness form (80%) supervision checklist (70%), blood pressure cuff (50%), pregnant women registration book (30%), stethoscope (40%) and tape measure (40%) were the most frequently mentioned unavailable equipment in the respective health posts.

Facilitators’ and barriers’

To select the appropriate statistical model for the hierarchal nature of the data, intra-class correlation
coefficient (ICC) was computed by running the intercept only model. The ICC in this model was 17.73% indicated that 17.73% of the variation in FANC package intervention fidelity is explained by health post (cluster) level factors. Therefore, multilevel linear regression model was appropriate. In the first level model, maternal age, distance from the health post, maternal education, problems in the previous pregnancy, husband’s education and total number of abortion were considered. Support/facilitation strategies, distance from the farthest household and availability of supplies in the health post were considered in the second level model. Finally, three variables were found to be statistically significant facilitators for FANC package intervention fidelity (See table 2 for the detail). In the final model the ICC was reduced to 4.7% and both AIC and BIC was decreased from 334.6 and 349.0 to 147.3 and 180.4 respectively from the initial model.

Discussion
The antenatal care coverage was 83.7% with 6.12% of mothers received all the recommended components and 34.97% received at least four ANC visits. Moreover, 91.1% of mothers who have got antenatal care visit were self-referral. The weighted average FANC package intervention fidelity by HEWs was 62.02% and by skilled providers was 56.57%. The overall weighted average FANC package intervention fidelity was 49.78%. Statistically significant facilitators for FANC package intervention fidelity were maternal pregnancy related problem in previous pregnancy, a mother having formally educated husband, implementation of supportive/facilitation strategies.

In this study, the weighted average FANC package intervention fidelity score was too low as per the expected to be. According to Joseph A. Durlak & Emily P. DuPre, the level of an intervention implementation around 60% could produce a positive result but the level of FANC package intervention fidelity in this study was significantly below this level (47). This implies that the FANC package intervention fidelity, according to the finding, is too low to result in reduction in neonatal mortality. This might indicate that the stagnation of neonatal mortality reduction might be partly due to the low fidelity of the FANC packages intervention implementation as planned. The current study shows that the level of FANC frequency was 34.97% and a component of 6.12%. This implies that though reaching the target audience was optimal (83.7%), non-conformity with the prescribed
frequency and content is evident. In this study, the increase in antenatal care visit (frequency) was accompanied with reception of the recommended FANC contents which is comparable with the reanalysis of 41 countries demographic and health survey data (48). The present study suggests that the mere increase in the contact coverage does not warrant the increase for the provision of expected contents and intervention fidelity of FANC package.

In the current study, mothers’ who encountered pregnancy/delivery related problems in their previous pregnancy have a 0.0889 times higher level of FANC package intervention fidelity in their recent pregnancy than mothers who did not encounter any problem. This may indicate that the pregnancy related risk perception of mothers play an important role for their adherence to the recommended of FANC package intervention implementation.

In this study, mothers having formally educated husbands have 0.0751 times higher levels of FANC package intervention fidelity in their recent pregnancies than mothers having husbands’ not attending formal education. Husbands’ attendance of formal education facilitates FANC package intervention fidelity but not mothers in the same level of educational status. This indicate that paternal education, even in the lowest level (elementary), will contribute for service uptake and adherence to the recommended package of care. Besides, this may indicate that maternal and child (MCH) health care uptake decision making might still be depend on the husband especially for women in the low level of educational status.

An increase in the implementation of health post level supportive/facilitation strategies resulted in a 0.0375 times increase in the level of FANC package intervention fidelity of their affiliated mothers. When the facilitation strategies that put in place to optimize the implementation of FANC package intervention increased, the intervention fidelity of FANC will be optimized to the expected level of the affiliated mothers. This statistically significant result indicate that the measured facilitating effects of supportive strategies for optimizing and harmonizing the FANC package intervention implementation as described by Carrol C. (49). An implication of this is the possibility that the weakness in the facilitation/supportive strategy might be the main possible reason for the low level of FANC package intervention fidelity thereby the stagnating high level of neonatal mortality.
Though data collectors were not health professionals and the data were collected at mothers’ home without any personal identifier, this result should be interpreted with caution for the possibility of social desirability bias which may inflate the focused antenatal care package intervention fidelity.

Conclusion
In conclusion, notwithstanding this limitation, the study suggests that the FANC package intervention fidelity is too low to achieve the expected level of neonatal mortality reduction. Multilevel multiple regression analysis revealed that maternal previous pregnancy/delivery related problem, paternal education and implementation of facilitation strategies emerged as statistically significant facilitators of FANC package intervention fidelity. This result implies that, apart from other facilitators, paternal education and implementation of facilitation strategies plays a significant contribution for improvement of focused antenatal care package intervention fidelity. Further studies, which take why facilitation strategies were in a paucity of implementation and how it facilitates neonatal mortality reduction into account, will be needed.

Abbreviations
FANC – Focused Antenatal Care
HEWs – Health Extension Workers
HIV – Human Immunodeficiency Virus
ICC – Intra-class correlation coefficient
AIC – Akaike Information Criteria
BIC – Bayesian Information criteria
SPSS – Statistical Package for Social Sciences
ANC – Antenatal Care
MCH – Maternal and Child Health

Declarations
Ethical approval and consent to participate
Ethical clearance was secured from the ethical board of University of Gondar (Ref. No O/V/P/RCS/05/810/2018), then, permission letter was sought from Amhara regional state health bureau, South Wollo Zone and respective Woreda health offices. Information sheet was attached to
data collection instrument and written informed consent was obtained from participants.

Confidentiality and anonymity of the participants were secured.

Consent for publication
Not applicable

Availability of data and materials
The dataset used and analyzed for this study are available from the corresponding author on reasonable request.

Competing interest
The authors declare that they have no competing interests.

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Authors contribution
AM generating the concept, develop the proposal, analyzed and interpret the data under the supervision of AG, SM, KA and ZT. AG, SM, KA and ZT read, review and comment on the proposal and report. AM developed the manuscript and all of the authors read and approved the final manuscript.

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Tables

Table 1. The components of focused antenatal care package provided for pregnant mothers by providers qualification in South Wollo Zone, Ethiopia.

| Contents                      | Number of mothers (%) | By HEWs (%) | By ski (%) |
|-------------------------------|------------------------|-------------|-----------|
| Weight measured               |                         |             |           |
| Yes                           | 629 (83.6)             | 296 (47.1)  | 3:        |
| No                            | 123 (16.4)             | 101 (82.1)  | 2         |
| Height measured               |                         |             |           |
| Yes                           | 488 (64.9)             | 252 (51.6)  | 2:        |
| No                            | 264 (35.1)             | 145 (54.9)  | 1:        |
| Blood pressure measured       |                         |             |           |
| Yes                           | 558 (74.2)             | 305 (54.7)  | 2:        |
| No                            | 194 (25.8)             | 92 (47.4)   | 1:        |
| Counseled for institutional delivery |             |             |           |
| Yes                           | 686 (91.2)             | 372 (54.2)  | 3:        |
| No                            | 66 (8.8)               | 25 (37.9)   | 4         |
|                                      | Yes               | No               | No               | Total |
|--------------------------------------|-------------------|-------------------|-------------------|-------|
| **Counseled for BPCR**               |                   |                   |                   | 21    |
|                                      | 645 (85.8)        | 350 (54.3)        | 295 (45.7)        | 6     |
|                                      | 107 (14.2)        | 47 (43.9)         | 60 (9.3)          | 2     |
| **Counseled on danger signs during pregnancy** |                   |                   |                   | 3     |
|                                      | 606 (80.6)        | 327 (54.0)        | 279 (46.0)        | 2     |
|                                      | 146 (19.4)        | 70 (47.9)         | 107 (17.4)        | 1     |
| **Advised on personal hygiene**      |                   |                   |                   | 3     |
|                                      | 695 (92.4)        | 372 (53.5)        | 223 (33.8)        | 1     |
|                                      | 57 (7.6)          | 25 (43.9)         | 57 (8.6)          | 0     |
| **Advised for PMTCT**                |                   |                   |                   | 4     |
|                                      | 633 (84.2)        | 320 (50.6)        | 313 (48.2)        | 2     |
|                                      | 119 (15.8)        | 77 (64.7)         | 42 (6.4)          | 1     |
| **Advised and screened for STI**     |                   |                   |                   | 4     |
|                                      | 622 (82.7)        | 308 (49.5)        | 313 (46.8)        | 2     |
|                                      | 130 (17.3)        | 89 (68.5)         | 49 (6.8)          | 1     |
| **Advised for bed net use**          |                   |                   |                   | 2     |
|                                      | 527 (70.1)        | 299 (56.7)        | 228 (57.1)        | 1     |
|                                      | 225 (29.9)        | 98 (43.6)         | 81 (22.9)         | 0     |
| **Mothers tested for HIV**           |                   |                   |                   | 2     |
|                                      | 678 (90.2)        | 345 (509)         | 333 (49.1)        | 1     |
|                                      | 74 (9.8)          | 52 (70.3)         | 22 (30.6)         | 0     |
| **Advised for nutrition during pregnancy** |               |                   |                   | 7     |
|                                      | 634 (84.3)        | 350 (55.2)        | 284 (42.1)        | 2     |
|                                      | 118 (15.7)        | 47 (39.8)         | 70 (10.8)         | 1     |
| **Told to sick care for pregnancy danger signs** |             |                   |                   | 3     |
|                                      | 669 (89.1)        | 363 (54.3)        | 306 (45.7)        | 2     |
|                                      | 82 (10.9)         | 34 (41.5)         | 48 (7.2)          | 1     |
| **Number of TT* vaccine received**   |                   |                   |                   | 3     |
|                                      | 58 (7.7)          | 23 (39.7)         | 35 (55.6)         | 1     |
|                                      | 287 (38.2)        | 185 (64.5)        | 192 (52.9)        | 2     |
|                                      | 407 (54.1)        | 189 (64.6)        | 118 (32.5)        | 1     |
| **Iron folic acid received**         |                   |                   |                   | 2     |
|                                      | 425 (56.5)        | 203 (47.8)        | 122 (29.4)        | 1     |
|                                      | 327 (43.5)        | 194 (52.2)        | 171 (40.6)        | 0     |
| **Referred for institutional delivery** |                |                   |                   | 1     |
|                                      | 475 (63.2)        | 284 (59.8)        | 191 (40.2)        | 1     |
|                                      | 277 (36.8)        | 113 (40.8)        | 134 (59.8)        | 0     |
| **Expected date of delivery told**   |                   |                   |                   | 2     |
|                                      | 462 (61.4)        | 228 (49.4)        | 134 (38.6)        | 1     |
|                                      | 290 (38.6)        | 169 (50.6)        | 134 (38.6)        | 0     |

*BPC - Birth preparedness & complication readiness, PMTCT - Prevention of mother to child transmission of HIV, STI - Sexually transmitted infection, TT - Tetanus toxoid
Table 2. Significant level one (maternal level) variables with the corresponding effect size and confidence intervals.

| Variables                                  | Estimate | 95% Confidence interval |
|--------------------------------------------|----------|-------------------------|
| **Level 1 variables**                      |          |                         |
| Age of mothers (in years)                  | 0.0044   | 0.0003 - 0.008          |
| Maternal problems in previous pregnancy    |          |                         |
| No                                         | 1        |                         |
| Yes                                        | 0.0618   | 0.0111 - 0.112          |
| Total number of abortion                   | 0.0135   | 0.0050 - 0.021          |
| Husband education                          |          |                         |
| No formal education                        | 1        |                         |
| Attend formal education (1-8)              | 0.09731  | 0.0470 - 0.147          |
| **Combined model**                         |          |                         |
| Maternal problems in previous pregnancy    |          |                         |
| No                                         | 1        |                         |
| Yes                                        | 0.0889   | 0.0235 - 0.154          |
| Husband education                          |          |                         |
| No formal education                        | 1        |                         |
| Attend formal education (1-8)              | 0.0751   | 0.0162 - 0.134          |
| Implementation of supportive/ facilitation strategy | 0.0375 | 0.0218 - 0.053 |

Figures
Skilled providers - Nurses, midwives and physicians

Figure 1

Percentage of frequency of antenatal care visit by providers in South Wollo Administrative Zone, Ethiopia.

Supplementary Files

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