

Demand and supply side enablers and barriers of periconceptional folic acid supplementation among pregnant women in southern Ethiopia: A phenomenological qualitative study

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Abstract

Background: Folic acid deficiency during conception is linked to neural tube defects, small for gestational age, and low birth weight. Adequate periconceptional folic acid supplementation (PFAS) has been shown in most studies to significantly reduce the risk of neural tube defects. Thus, the aim of this study was to investigate the demand and supply side enablers and barriers of periconceptional folic acid supplementation among pregnant women in southern Ethiopia. **Methods:** A phenomenological qualitative study design was implemented among 35 purposively sampled pregnant women and 18 health professionals. We collected qualitative data through focus group discussions, in-depth interviews, and key informant interview techniques. Each of the collected data were transcribed verbatim and translated into the English language. The data were then entered into OpenCode software, which was used to manage the entire coding process and analyzed thematically.

Results: The study identified women's better health-seeking behavior and positive attitudes toward future PFAS use as enablers for service users. Service provider-side enablers include creating community awareness, health education, good perceptions of health professionals, integration with current health services, charge-free distribution of FAS, and application of the national supply management system. The main service user barriers were a lack of preconception care, an unplanned pregnancy, a late initiation of ANC follow-up, a lack of knowledge about PFAS, misconception of women, and financial constraints. We identified several service provider side barriers, including insufficient knowledge of health professionals, insufficient allocation of folic acid supplements, insufficient access, and ineffective supply stock management.

Conclusion: We must provide nutrition education about PFAS and its benefits for NTDs prevention, as well as engage in community activism and raise public awareness through mass media communication. Furthermore, PFAS should be integrated into health facilities and communities' current health care services across the country.

Key words: Enablers, barriers, periconceptional folic acid supplementation, neural tube defects, pregnant women, Southern Ethiopia

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INTRODUCTION

Folate is a very vital vitamin for gene expression, and it has a fundamental role in the synthesis and metabolism of proteins. It also acts as a cofactor in reactions that are determinants of cell division and cell maintenance through epigenetic mechanisms (Burdge and Lillycrop, 2012, WHO, 2015).

Folic acid deficiency during conception is linked with neural tube defects (Agopian et al., 2013, Detrait et al., 2005), small for gestational age and low birth weight (Hodgetts et al., 2015, Li et al., 2017). Likewise, folic acid deficiency relates to adverse pregnancy outcomes in the mothers, such as spontaneous abortion, preterm birth, and pre-eclampsia (Gaskins et al., 2014, Li et al., 2019, Kim et al., 2014, Wen et al., 2016).

Neural tube defects are multifactorial and preventable anomalies of brain and spinal cord neurulation that develop in humans between 21 and 28 days after pregnancy (World Health Organization, 2020, Pitkin, 2007). Every year, approximately 300,000 newborns worldwide are born with neural tube defects (NTDs), and the prevalence in Africa averages 11.7 and ranges (5.2–75.4) per 10,000 newborns (Zaganjor et al., 2016). In Ethiopia, the prevalence of NTDs ranges from 28.6 to 130.9 per 10,000 births (Mekonnen et al., 2021, Berihu et al., 2018).

Periconceptional folic acid supplementation (PFAS) is an intake of the folic acid supplement of 400 µg/d from preconception (4–12 weeks) until the end of the first trimester of pregnancy (8–12 weeks) (World Health Organization, 2006, Gomes et al., 2016). In most nations throughout the world, PFAS has been demonstrated to significantly reduce the incidence of pregnancies with neural tube defects (Dean et al., 2014, Liu et al., 2018).

Furthermore, a study revealed that adequate folate levels are difficult to attain only through diet. As a result, pregnant women must take five to ten times more folate than non-pregnant women (Wang et al., 2016). Even though, periconceptional use of FAS would be a simple and useful approach; this opportunity is frequently missed (Czeizel et al., 2013).

Multifaceted factors are identified as a challenge on PFAS including lack of awareness of women, unplanned pregnancies, late pregnancy diagnosis and higher number of pregnancies (Bitzer et al., 2013, Vieg and Bertini, 2018, Wegner et al., 2020, da Rosa et al., 2019). A study conducted in Adama Ethiopia showed that maternal age, early ANC registration, consultation about preconception, previous unsuccessful pregnancies and level of awareness were factors significantly associated with folic acid use for the prevention of NTDs (Dessie et al., 2017). Currently, iron folic acid tablets are being delivered in Ethiopia through the ANC platform of the health facilities. The main focus of IFA is the prevention of anemia among pregnant women (Molla et al., 2019, Gebremichael and Welesamuel, 2020, Federal Ministry of Health of Ethiopia, 2016). However, the effort to provide periconceptional folic acid supplementation to prevent NTDs is a recent development in Ethiopia. Moreover, there is paucity of research evidence on the operational enablers and barriers of PFAS in Ethiopia. Thus, this study explored the enablers and barriers of PFAS among pregnant women in Southern Ethiopia.

MATERIALS AND METHODS

Study Setting

The study was conducted at six hospitals in the Sidama Regional State (SRS) and Central and South Ethiopia Regions (former South Nation Nationality People Regional State) of Ethiopia.

Study Design and Period

A phenomenological qualitative design was applied to explore pregnant women's and health professionals' perceptions of demand and supply-side enablers and barriers to periconceptional folic acid supplementation. This study was part of the Ph.D. research project that ran from April 14, 2022 to March 27, 2023.

Recruitment and Sampling

In the study, we purposefully selected six hospitals from three regions, including Hawassa University Comprehensive Specialized Hospital located in Hawassa City, Arbaminch General Hospital, Jinka General Hospital, Halaba Kulito General Hospital, Konso Karat Primary Hospital, and Worabe Comprehensive Specialized Hospital. In the

selection, we tried to include primary, general, and specialized hospitals that serve both urban and rural populations.

Participants were purposefully selected. We recruited "service user women" from the client waiting areas of pregnancy follow-up clinics. Health care workers (medical doctors, midwives, and pharmacy professionals) and health decision-makers were recruited from selected hospitals and Sidama Regional State (SRS) and former South Nation Nationality People Region (SNNPR) health bureaus. Similarly, the Ethiopia pharmaceutical supply agency (EPSA) representative was recruited from Hawassa branch office.

From the 34 FGD participants approached, 29 agreed to participate in the FGDs and IDIs, but five were unable to participate because of a time shortage and busy home duties. In this qualitative study, we performed four focus group discussions, and a total of 29 participants were involved, with 6–9 participants in each FGD. Six (6) in-depth interviews among pregnant women, one per selected hospital were conducted. In the current study, twelve (12) in-depth interviews were done with health care workers (six antenatal care service heads and six pharmacy heads), and three (3) KIIs were conducted with medical directors representing the selected hospitals. Additionally, three (3) KIIs were conducted among health decision-makers, two from the maternal, child, and nutrition directorate SRS and former SNNPR health bureaus, and one from the supplier (EPSA-Hawassa branch).

Data Collection Procedure

We collected qualitative data using three different data collection techniques, which include focus group discussions (FGDs), in-depth interviews (IDIs) and key informant interviews (KIIs). Among pregnant women, the focus group discussions lasted 60 to 80 minutes, and interviews lasted 20 to 30 minutes. The focus group discussions were done using a semi-structured discussion guide, and for IDIs and KIIs, we used an interview guide as a tool of data collection, which was adopted after reviewing different literature (Tong et al., 2007, O'Brien et al., 2014). The data was collected by the principal investigator and two trained research assistants with MSc degrees in maternity and

reproductive health who had experience in qualitative research.

All interview questions were written in Amharic, and one health worker from Konso Primary Hospital served as a local language translator on-site. To recruit study participants, the data collection team contacted pregnant women in the ANC follow-up clinic waiting area and requested their agreement to participate in IDIs and FGDs. The study purpose and approaches were explained during recruitment, and then informed, verbal, and written consent to participate in the study was obtained from all the participants. The interviews were conducted in one of the consultation rooms at the MCH to minimize interruptions and enhance the privacy of the participants. Each interview was audiotaped after securing permission from each participant. These audio recordings were complemented by field notes. Interviews were continued until all categories were well defined and thoroughly researched.

Interviews with health professionals, decision-makers, and suppliers were also done using a semi-structured interview guide by the principal investigator. After receiving written consent, health care workers (HCWs), decision-makers, and supplier were interviewed in a private room, mostly at their offices. A standard for reporting qualitative research was employed.

Trustworthiness

In this qualitative study we maintained trustworthiness criteria of credibility, transferability, dependability, and conformability (Korstjens and Moser, 2018). To maintain the study's credibility, discussions were made with the principal investigator and study participants to establish confidence. We spoke with managers and hospital-level facilitators. Using the participants' words in the final report boosted credibility. The researchers assured the study participants that they were not involved in the provision or management of health care services. The study's dependability was ensured by rigorously reviewing the transcribed data against the audio recorded files. More information regarding the concerns was obtained through probing and elaboration. Independent assistant and lead researcher discussed the coded results, and any

conflicts in interpretation were debated and resolved.

To ensure data transferability, the study involves both pregnant women and health professionals, allowing for insight and rich information from both service users and providers. To maintain the finding's confirmability, we did peer debriefing and member checking to ensure that the findings were objective and unaffected by any biases or preferences of the researchers.

Data Analysis

The audio files of the interview data were transcribed verbatim and then translated into English by the principal investigator. The translated text was imported into OpenCode 4.02 software to facilitate the coding process. Coding was carried out by picking pertinent elements of the study participants' statements as they emerged. First, principal investigator and two research teams read each transcript multiple times to become acquainted, and the technique of inductive coding was employed.

Themes and sub-themes were created by looking for linkages between categories based on frequency of occurrence. We included critical and unexpected information provided by participants that appears in many papers, as well as any additional remarks relevant to this study. The data derived from the original transcripts was then organized into charts with headings and subheadings and built into a thematic framework (Green and Thorogood, 2018).

Operational Definitions

Periconception Period: is a time that lasts 4-12 weeks before conception and extends from the last menstrual period to 12 weeks of pregnancy.

Periconceptional Folic Acid Supplementation: is the practice of taking folic acid supplements 4-12 weeks before conception and from the last menstrual period until 12 weeks of pregnancy to reduce the risk of neural tube defects (NTDs).

RESULTS

Socio-demographic Characteristics of Pregnant Women

A total of 35 pregnant women (29 in FGDs and 6 in IDIs) participated in this study. The majority of pregnant women were between the ages of 25 and 34, with 20 of the research participants being urban women.

The majority of the women who participated had at least a secondary education, and housewives made up more than half of the women's occupations. A total of twenty-one pregnant women who participated in the study had pregnancies three or more times, and the majority of the women had less than three children (Table 1)

Table 1:- Socio-demographic characteristics of pregnant women who participated in the study, Southern Ethiopia, 2023.

Characteristics	FGD (N=29)	IDI (N=6)
Age group (Yrs.)		
<25	12	1
25-34	17	5
Resident		
Rural	13	2
Urban	16	4
Educational status		
Cannot read and write	7	0
Primary school	4	1
Secondary school	8	2
Higher education	10	3
Occupational status		
Housewife	17	3
Government employee	7	2
Self-employee	3	1
Student	2	0
Gravidity		
Less than three	13	1
Three and more	16	5
Children Alive		
None	7	1
Less than three	14	4
Three and more	8	1

Socio-demographic Characteristics of Health Service Providers

In this qualitative study, 18 health professionals (12 in IDIs and 6 in KIIs) participated. The study included 14 health professionals aged 25 to 34.

Whereas about half of IDI and KII professionals have diplomas and MSc/MPH degrees, respectively. Half of the study participants had at least seven years of experience providing health services (Table 2).

Table 2:- Sociodemographic characteristics of health service providers who participated in the study, Southern Ethiopia, 2023.

Participants	Age	Gender	Educational status	Profession	Work experience (Yr.)
Health professionals					
ANCH-1	30	Female	BSc, Degree	Midwife	3
ANCH-2	27	Female	Diploma	Midwife	4.5
ANCH-3	30	Female	BSc, Degree	Midwife	10
ANCH-4	28	Female	Diploma	Midwife	3
ANCH-5	28	Female	BSc, Degree	Midwife	8
ANCH-6	26	Male	BSc, Degree	Midwife	6
PSH-1	40	Female	Diploma	Druggist	9
PSH-2	25	Male	Diploma	Druggist	4.5
PSH-3	32	Male	Diploma	Druggist	12
PSH-4	28	Male	Diploma	Druggist	6
PSH-5	30	Male	BSc, Degree	Pharmacist	8
PSH-6	35	Male	BSc, MPh	Pharmacist	8
MD-1	32	Male	Medical doctor	General practitioner	3
MD-2	27	Male	Medical doctor	General practitioner	3
MD-3	27	Male	Medical doctor	General practitioner	3.6
Health Decision Makers and Supplier					
SRS-HB	42	Male	BSc, MPh	MCHN, Directorate	20
SNNPRS-HB	38	Female	BSc, MPh	MCHN, Directorate	15
EPSA-H	32	Male	BSc, MPh	Branch Representative	8

ANCH: Antenatal care head; PSH: Pharmacy service head; MD: Medical director; SRS-HB: Sidama Regional State-Health Bureau; SNNPRS-HB: South Nation Nationality Peoples Regional State-Health Bureau; EPSA-H: Ethiopia Pharmaceutical Supply Agency Hawassa; MCHN: Maternal Child Health and Nutrition

Folic Acid Supplement Types and Forms Delivered at the Facility

The types and forms of folic acid supplements delivered by the health facilities, as confirmed by the service providers, are iron-folic acid tablets and folic acid-only tablets. However, since the current supplementation focuses on iron-deficiency anemia, most people receive ferrous sulfate tablets without folic acid. In the focus group discussions, the majority of participants said that they took "iron" or "key kinine" to represent iron tablets or a combination of folic acid and iron. Likewise, there were fewer women who reported to have consumed folic acid from multiple micronutrient supplements with the name "Prenatal," which is expensive, and only those women who could afford to buy it from private pharmacies consumed it during their pregnancies.

Pregnant women reported:

"I took anemia correction tablets during my current pregnancy; the tablet is red and round-shaped." (FGD, 25 years old, rural woman).

"During my current pregnancy, I took red and round tablets in a plastic cup from the hospital" (IDI, a 25-year-old mother of a child).

"I am taking iron tablets, and I thought the name was prenatal." (IDI, 25 years old, merchant).

In addition, the service providers who were respondents to IDIs and KIIs indicated that, at their facilities, a combination of iron-folic acid tablets and non-enteric-coated forms are predominantly available, and women are receiving these supplements. For instance, one respondent said,

"In our facility pharmacy, we have both folic acid and iron combination oral tablets, commonly known as Fifol, and folic acid alone tablets." (IDI, PSH-2)

Another participant added,

"Folic acid is available in a combined form with iron (iron-folate tablets) and non-enteric-coated tablets." (IDI, ANCH-4)

Practice of Periconceptional Folic Acid Supplementation (PFAS)

It is internationally recommended that women receive folic acid supplementation from the moment they are trying to conceive until 12 weeks of pregnancy, which is the recommended period to prevent congenital anomalies, including neural tube defects. However, this study found that almost all pregnant women had not received FAS during the periconceptional period, and that regional health facilities do not implement periconceptional folic acid supplementation. Most of the women who participated in the FGDs and in the IDIs started to consume folic acid after the third month or within the second trimester, which is outside of the PFAS period.

A pregnant woman stated,

"After confirming my pregnancy, I began taking tablets in the fourth month of my current pregnancy." (IDI, 30 years old, housewife)

The service providers working in the facility and decision makers affirmed that,

"Most of pregnant woman didn't took folic acid within periconceptional period." (IDI, ANCH-4)

"Folic acid supplementation is not being given in a timely manner; if it is taken during this period, it is good for the fetus and the mother." (IDI, PSH-1)

"Provision of supplementation for women within the internationally accepted and recommended intake period for folic acid tablets is not being implemented in our facility." (KII, MD-2)

"Based on our regional current situation, we are delivering folic acid during the pregnancy period, and it is not much before pregnancy." (KII, SNNPRS-HB)

"Mothers take folic acid pills after confirmation of their pregnancy status, not before." (KII, SRS-HB)

Thematic Analysis Findings

The study's findings were thematized, with nine sub-themes identified as enablers and thirteen as barriers to periconceptional FA supplementation (Table 3).

User side Enablers for Periconceptional Folic Acid Supplementation

Better Health-seeking Behavior

A few women with better health-seeking behaviors received advice and a prescription to take folic acid before pregnancy or in the earlier months within the first trimester. Since they have had better health-seeking behavior, they started taking folic acid tablets within the recommended period. For instance, a woman reported that,

"I started taking with the first month of pregnancy because I received an instruction from a health worker. But I don't have any knowledge about the standard period" (FGD-3, a 23-year-old government employee).

On top of that, two IDI participant women stated,

"I visited a hospital in a nearby town and received information from health workers on the advantages of taking 'werja tekelay kinine,' or abortion protective tablets, before pregnancy. I then received the tablets and continued taking them today" (IDI, a 27-year-old housewife).

"I started taking the tablets during the second month of my current pregnancy after receiving health care providers' advice. In addition, I went to the facility because my husband and I were planning to have a child, and the pregnancy was planned" (IDI, 32 years old, mother of two children).

Positive Perception of Women

The majority of the pregnant women who participated in the FGDs and IDIs indicated they were willing to receive FA during the recommended period by the health professionals, which could be before pregnancy or within the first 3 months of their pregnancy. Almost all FGDs affirmed the possibility of receiving FA within the recommended time frame if information is provided by HPs. Participants in the FGD and IDIs assert,

"I think it is much better to take within 3 months before and after conception I will take for the future because folic acid will help for unborn

baby health” (FGD-3, a 27-year-old government employee woman).

“I’m not sure about this period, but if the health workers tell me to obey, I’ll take whatever pills they give me as long as it doesn’t harm my unborn baby” (IDI, a 25-year-old mother of three children)

“I think it is possible to begin and finish an iron tablet during this time period, as recommended by health workers. Therefore, it is possible for all women, not just those affected by “werja” abortion frequently” (IDI, a 27-year-old housewife)

Table 3:- Thematic analysis of demand and supply side enablers and barriers of periconceptional folic acid supplementation among pregnant women in southern Ethiopia, 2023.

Major Themes	Sub-themes	Categories
Enablers for PFAS	User (demand) side	<ul style="list-style-type: none"> - Better health seeking behavior - Positive perception of women to use PFAS in the future
	Provider (supply) side	<ul style="list-style-type: none"> - Creating awareness in the community - Health/nutrition education - Good perception of HPs on PFAS - Post-miscarriage service delivery experience - Integration with current health services - Charge-free distribution of supplement - Use of national supply management system
Barriers for PFAS	User (demand) side	<ul style="list-style-type: none"> - Low preconception care service use - Unplanned pregnancy - Late initiation of ANC follow-up - Lack of knowledge about PFAS among women - Misconception of women about FAS benefits - Non-compliance of women to FAS intake - Financial constraints of women to buy FA tablets
	Provider (supply) side	<ul style="list-style-type: none"> - Inadequate knowledge of HPs on PFAS - Unavailability of PFAS guidelines - Procuring non-enteric FAS - Insufficient access to FAS supply at HFs - Ineffective stock management of supply at HFs - Improper allocation of FA supply by RHB and EPSA

Provider Side Enablers for Periconceptional Folic Acid Supplementation

In this thematic analysis, creating awareness in the community, health education, good perception of HPs, FAS service delivery experience after miscarriage, integration with current health services, charge-free distribution of FAS, and use of the national supply management system were the identified service provider enablers.

Good Perception of Health Professionals

Most health professionals working in health facilities have a positive perception and attitude toward the effectiveness of implementing PFAS. The health facility workers and an EPSA representative who took part in the IDIs and KIIs reported on the issue that,

"I think it is possible to implement PFAS, and definitely if we work on this recommendation, we will achieve a lot because I am observing and hearing an increase in the birth of infants with cases of congenital anomalies, including NTDs, in recent years in the health facility" (IDI, ANCH-6)

"In our hospital, the folic acid pill was not being given in the internationally accepted time frame. But I think there is a possibility if there is a sufficient supply of folic acid pills" (IDI, PSH-4)

"The internationally accepted and World Health Organization (WHO) recommended intake period for folic acid tablets is not being implemented. Thus, until now, we have not worked with dedication to deliver supplements at this time frame, but it is good to work on it in the future" (KII, MD-2)

"It is possible to be implemented, and in the case of folic acid tablet distribution at the time recommended by the WHO, we can say it is possible. It is better to fully include them in the report and requisition form (RRF) format so that they can take the health plan as per their needs" (KII, EPSA-HB).

Creating Awareness in the Community

The findings of this study indicated that awareness creation about PFAS in the community was one of the enablers for most health professionals and regional health decision-makers who participated in both the IDIs and KIIs. The main issues raised include awareness about folic acid and its prevention benefits for

congenital anomalies through communication media with extensive advocacy, and sensitization by involving couples and the community at large. Four health workers who participated in the IDIs and KIIs reported that,

"All healthcare professionals must take part in raising awareness about folic acid. Congenital abnormalities and inadequate folic acid intake are issues that need intervention in our society. For a mother to deliver a healthy baby at nine months of pregnancy, she needs to be aware of the advantages of taking folic acid" (IDI, PSH-1).
"It is better if women are made aware of pre-pregnancy and taking folic acid through communication media, because mothers in cities that are close to health professionals and those who use social media may have awareness, but most rural mothers may not have awareness. Therefore, it is good if awareness is created through mass media" (IDI, ANCH-5).

"Periconceptional folic acid supplementation can be applicable if awareness creation is implemented well using campaigns to give folic-acid pills at the international standard and by involving the community starting from health posts, health centers and to the hospitals" (KII, MD-1).

"It is necessary to remember that it is crucial to involve the users of folic acid pills as a couple (husband and wife) in the awareness-creation activities that will serve as a reminder and help to avoid commitment diverting factors" (KII, MD-3).

In addition, regional decision maker stated,

"There should be extensive advocacy and sensitization activity, focusing on taking the right folic acid supplement during the recommended time window" (KII, SRS-HB).

Health/Nutrition Education

The service providers who participated in this study pointed out that providing health/nutrition education on PFAS focusing on reproductive-age women who planned to be pregnant encouraged them to start taking it timely for the prevention of NTDs. The main approach should be to use visual teaching aids and to educate the women with practical examples to enhance their consumption of PFAS. Health workers from the facilities that participated in IDIs and KII asserted,

"We should give health education for all reproductive-age women to take folic acid supplementation before pregnancy if they planned it and to encourage women who suspect they are pregnant to start taking folic acid tablets within the recommended period." (IDI, ANCH-2)

"Health education is a key to bringing behavioral changes among pregnant women. So we should provide health education about the health benefits of folic-acid supplementation and what congenital anomalies, including NTDs, mean both at the community level by health extension workers and by midwives and nurses at the facility level" (IDI, ANCH-6)

"During health education sessions, we have to use the child with NTDs as an example and explain to the mothers why the child has this issue. We should clarify that the mother's failure to take folic acid prior to conception and during her pregnancy is what caused the baby's problem. We must so warn them that they will also experience this issue if they refuse to take it" (KII, MD-3).

Post-miscarriage Service Delivery Experience

Health professionals revealed that health facilities are providing FAS after a woman miscarries or gives birth to a fetus with congenital anomalies in the facility. A pregnant woman who participates in IDI also witnessed receiving the service after fetal loss. For instance, a pregnant woman from IDI stated that,

"I started and completed taking tablets three months before this pregnancy and am still taking iron tablets received from a health worker at the hospital after traveling to a nearby town." (She cried and then continued narration). "I lost my fetus two times previously, and I want to thank the health workers because, currently, both I and my fetus are doing well" (IDI, 27-year-old woman, housewife).

Additionally, two ANC health workers from IDIs affirmed that,

"Rarely, women who have a planned pregnancy, who are aware of the benefits of folic acid, and those who have experienced a miscarriage take the pills prior to pregnancy" (IDI, ANCH-3)

"Those pregnant mothers who gave birth in our hospital and encountered congenital

anomalies, as well as women who had a miscarriage, take the iron-folate tablets for 3 months after the incident" (IDI, ANCH-4).

Integration with Current Health Services

In this qualitative study, some of the health professionals and regional decision-makers indicated that to promote effective implementation of PFAS, it is better to use the family planning service as a contact area, implement projects, and also use existing community-based health intervention approaches. Health workers who participated in the IDIs and a KII participant regional decision maker stated that,

"We should carry out awareness-raising activities mainly among reproductive-age women by giving family planning service provision as the main starting point for the initiation of folic acid supplementation when they remove their contraceptive methods at the facility level. However, many women get pregnant without planning it" (IDI, ANCH-1)

"I believe the family planning service division should start by advising the use of folic acid pills when clients come to receive family planning services. This is because early pregnancy initiation is a problem" (IDI, PSH-1)

"To address preconception folic acid supplementation using women in one to five groups to identify and reach those women who have a pregnancy plan in the community. Also, we have to engage the HEWs and health development army" (KII, SNNPR-HB).

Charge-free Distribution of Supplement

In the health facilities, folic acid, either in iron-folic acid or folic acid-only supplements, is delivered charge-free to pregnant women. This practice may help as one of the facilitators for the success of periconceptional folic acid supplementation. Health professionals who participated in the IDIs affirmed that the delivery of FAS for women during ANC follow-up is free of charge if sufficient supplies are available at the health facilities. A pregnant woman who participated in IDI witnessed that,

"I received the iron-folate tablets from the public hospital for free" (IDI, 32 years old, housewife).

In addition, a midwife and pharmacy professional who participated in the IDIs confirmed the issue that,

"When there are adequate folic acid tablets available at our hospital pharmacy, we offer free folic acid tablets to all pregnant women. However, sometimes there is a lack of supplementation in the middle of the service provision. Thus, if iron-folic acid tablets were not available in the institution, women were forced to obtain them after buying them from a private pharmacy" (IDI, ANCH-5).

"Folic-acid pills are available free of charge from the pharmacy while supplies are available. Currently, women are given a prescription to purchase folic acid, which they then purchase from a private pharmacy" (IDI, PSH-4).

Use of the National Supply Management System

Nationally, Ethiopia uses a national drug and supply management system with a RRF filling process across the nation, including folic acid supplements. Regional decision-makers who participated in the KIIs, reported that FAS is delivered based on requests from the health facilities. A regional decision maker stated that,

"Folic acid tablets and other medical supplies are requested from the Drug Fund and Supply Agency in accordance with what we call the RRF format. Thus, the distributions to the health facilities are done on a request basis by the Ethiopia Pharmaceutical Supply Agency (EPSA). That is why we see it as having a strong and positive side" (KII, SNNPR-HB).

User Side Barriers for Periconceptional Folic Acid Supplementation

Service users' barriers were one of the sub-themes. In the discussions and interviews, lack of preconception care service use, unplanned pregnancy, late initiation of ANC follow-up, lack of knowledge about PFAS among women, misconception of women about FAS benefits, non-compliance of women to FAS intake, and financial constraints of women to buy FA tablets were the main barriers identified by users.

Lack of Preconception Care

Lack of preconception care (PCC) use is one of the barriers to the effectiveness of periconceptional folic acid supplementation. The majority of the pregnant women in the FGDs and IDIs indicated they had never accessed health care services before their current pregnancy. Two pregnant women who took part in the IDIs affirmed that,

"I didn't use pre-pregnancy health services concerning pregnancy preparation" (IDI, 25 years old, mother of a child).

"I didn't use health services to learn about pregnancy preparedness before becoming pregnant" (IDI, 30 years old, housewife).

Unplanned Pregnancy

In the study, one of the barriers mentioned was having an unplanned pregnancy. A midwife who participated in an IDI reported that,

"I believe it is possible to use folic acid during the periconceptional period if we implemented it correctly; however, the main issue is that most pregnancies are unplanned" (IDI, ANCH-1).

Late Initiation of ANC Follow-up

Late antenatal care initiation during pregnancy was one of the hindering factors for periconceptional supplementation. As most of the women witnessed, they started their first follow-ups between the third and fourth months of their pregnancy. The women's late beginning of pregnancy follow-up was confirmed by the health professionals involved in this study.

A pregnant woman who participated in an IDI reported that,

"I started using the pregnancy follow-up service in the fourth month of my pregnancy, and today is my third follow-up visit. I am now in the eighth month of my pregnancy" (IDI, 25 years old, mother of a child).

Also, HCWs who took part in an IDI and KII affirmed that,

"I think the main problem is that almost all women come to the ANC service late or after the recommended period" (IDI, ANCH-4).

"Most women visit our hospital in the second three months of pregnancy; before that, they get services at the health center and first-level hospital. They come to us mainly when they

suspect that there may be a problem related to their pregnancy” (KII, MD-3).

Lack of Knowledge

Lack of knowledge about PFAS is an important barrier among service users. All of the women didn't have any knowledge or information about preconception folic acid supplementation. Health professionals affirmed that most women are not aware of the benefits of folic acid and about PFAS. For instance, a woman who participated in one of the FGDs stated that,

“I didn't take folic acid tablets at the indicated time since I didn't have any information about the period because health workers are responsible for guiding us” (FGD-1, a 26-year-old housewife).

Furthermore, a midwife and pharmacy professionals that participated in IDIs confirmed that,

“Most women don't have adequate knowledge about the recommended period and the periconceptional folic acid supplementation service” (IDI, ANCH-5).

“Folic acid supplementation is not being given in a timely manner; if women receive FA tablets during this period, it is good for the fetus and the mother, but usually none is taken before pregnancy due to a lack of awareness” (IDI, PSH-1).

Non-compliance of Women

We discovered that non-compliance of women with taking the prescribed dose of FAS is one of the hindering factors of PFAS. The health professionals who participated in the IDIs affirmed that some women started FA before pregnancy but didn't complete taking it, and some women complained about physical illness for the non-compliance as indicated during the FGD. In addition, a pharmacy head reported women's fear of harm to the fetus and herself when taking drugs for a longer period of time. For instance, a pregnant woman who participated in a FGD reported that,

“I faced problems often because of gastric irritation, and still, I am taking folic acid and iron tablets” (FGD-4, a 30-year-old mother of two children).

Additionally, health workers who participated in IDIs stated that,

“Most of the women come after conception, so we provide for them during the pregnancy period. We usually provide them with Iron-Folic Acid (IFA) tablets after 4 months of their pregnancy because they complain about gastric illness and hyperemesis; as a result, they refuse to take the supplements earlier than 4 months” (IDI, ANCH-6)

“Among pregnant women, the inability to take the prescribed amount of folic acid pills is one of the problems. To name a few of the issues that keep away women from taking folic acid, including nausea and stomach irritation after taking the pill, we advise them to take the medicine with food” (IDI-PSH-3).

Misconceptions among Women

One of the barriers mentioned by some of the women was the misconception of women in the community about the effects of taking iron with folic acid tablets during pregnancy. Women taking iron folate tablets will increase blood pressure, lower fetal movement, make our child thinner, and delayed growth are some of the misconceptions raised by women from FGDs. Furthermore, health workers saw several misconceptions, such as the belief that ingesting FAS will make our child thinner and hinder growth, as well as neglect and some traditional community beliefs. Pregnant women who participated in the FGDs stated on the matter that,

“I experienced low fetal movement within a few days after taking the tablets, then a health worker told me it returned to normal and became well. I wonder if many women, like me, ask what the benefits of taking tablets during their pregnancies are because our moms and grandmothers didn't use them, but they gave birth to normal babies.” (FGD-1, a 24-year-old housewife)

“Since a pregnant woman gains weight as a result of pregnancy, taking a tablet may increase the amount of blood, and blood pressure will increase too. Due to these reasons, there are some women who are not willing to take it in the community.” (FGD-1, a 23-year-old high school student)

On top of that, a midwife and medical doctor who took part in IDI and KII, respectively, reported that,

“Among women, the misconceptions reported during our counselling session include that taking the pill can increase blood pressure, make our child thinner, and delay his growth” (IDI, ANCH-1).

“Factors preventing pregnant mothers from taking folic acid pills include negligence, some negative traditional perceptions in the community about taking medicine during this time, and a belief that it is not useful for pregnant mothers” (KII, MD-2).

Financial Constraints

Most of the women witnessed that they were unable to purchase the FAS from a private pharmacy because they had financial difficulties; as a result, they were unable to take or continue FAS. Women participating in FGDs and IDIs, and service providers reported that women were forced to buy tablets or supplements when there was an unavailability of supply at the health facility pharmacy. Pregnant women who participated in FGD and IDIs stated that,

“I have children to take care of, and I don't have enough money to buy folic acid pills from a private pharmacy, so I couldn't take them” (FGD-2, a 29-year-old housewife).

“I received only a month of tablets free of charge, but the other two months doses I purchased from a private pharmacy. Because of financial difficulties, I faced challenges in completing the full dose” (FGD-3, a 23-year-old government employee).

“The tablets were not available in the facility; as a result, I bought the tablets from a private pharmacy for 350 Ethiopian Birr for 30 tablets. It was expensive” (IDI, 22 years old, merchant woman).

In addition, a midwife who participated in an IDI reported that,

“Folic acid capsules are often not available at the hospital pharmacy; thus, a client receives a prescription to purchase from a private pharmacy, and the cost is expensive. Because of this, even if we prescribe it to them, they will not be able to afford to buy it” (IDI, ANCH-4).

Provider Side Barriers for Periconceptional Folic Acid Supplementation

Service providers play a crucial role in the success of PFAS. However, the main barriers were inadequate knowledge of HPs on PFAS, lack of national guidelines and protocols, procuring low-efficacy FAS by HPs, insufficient access to FAS supply, improper stock management of supply at HPs, and inadequate allocation of FA supply by RHB and EPSA.

Inadequate Knowledge of HPs

Health professionals having poor knowledge of the importance of implementing periconceptional FAS was one of the main barriers from the service provider side. Some service providers indicated that low knowledge about taking folic acid within the periconceptional period is one of the barriers to effective PFAS. A regional decision maker and pharmacy professional affirmed that,

“I think the health professionals themselves need to be knowledgeable and must understand the protocol well. Previously, health workers advised using only iron-folate supplements when pregnant. The community's view and habit of solely taking folic acid tablets during pregnancy, health professionals' lack of awareness on the topic, and timely folic acid tablet administration are among the challenges” (KII, SRS-HB).

“Folic acid supplementation is not being given in a timely manner; there is a lack of proper knowledge regarding the timing and benefits of folic acid intake among health professionals” (IDI, PSH-1).

Unavailability of PFAS guidelines

One of the barriers is the lack of national PFAS implementation guidelines. A regional decision maker who took part in a KII commented about the matter,

“Based on our regional current situation, we are delivering folic acid during the pregnancy period, and it is not much before pregnancy. A guideline for PFAS is not available, and currently it is being prepared and endorsed at the federal ministry of health (FMOH) level” (KII, SNNPR-HB).

Procuring Non-enteric FAS

The form of folic acid supplement, which is a non-enteric-coated tablet with increased side effects, is one of the service provider's barriers. In addition, a

HP who participated in the IDIs indicated that because enteric-coated FAS with better efficacy were not available in the HF pharmacy, those who complained of side effects were encouraged to buy from a private pharmacy. A pregnant woman who took part in an IDI stated that,

"The tablets that are delivered from the hospitals have caused gastric irritation and discomfort. It is preferable to have the hospital provide us with the safest tablets so we can consume the prescribed dose completely" (IDI, 32 years old, housewife).

In addition, a pharmacy head, a regional health decision maker, and an EPSA representative who were involved in this interview reported that,

"Some pregnant women didn't take all of the folic acid pills that are recommended for them. Uncomfortable feelings and gastric irritability are a few of the complications that keep women from taking folic acid. We advise pregnant women to buy enteric-coated folic acid tablets from private pharmacies since they are expected to finish all the prescribed folic acid tablets" (IDI, PSH-1).

"Enteric-coated folic acid tablets or iron folate tablets would be better if distributed instead of the non-coated pill... It is preferable to deliver enteric-coated folic acid tablets to all health facilities in place of the non-enteric-coated pills that were previously distributed to some facilities for a brief period before being discontinued" (KII, EPSA-HB).

Insufficient Supply

In this study, insufficient FAS supply at the health facilities was identified as one of the barriers. Women who participated in the IDIs and KIIs indicated that they faced lack of supply or poor access to the tablet, shortage and inconsistency of the FAS tablets from the facility pharmacy. The supply scarcity of folic acid pills was evidenced by health workers in the facility and regional health decision-makers who participated in IDI and KIIs, respectively, saying,

"There is a lack of sufficient supply of folic acid pills in the middle of service provision, supply loss (stock-out), and interruption of supply in our hospital" (IDI, PSH-6).

"Folic acid pills are being given at the hospital, and supplies are available as much as possible. Since there are users of the service in the hospital from the neighboring zone, when there is a large number of users,

the supply from the EPSA is not sufficient for our hospital and is not commensurate with our needs" (KII, MD-2).

"It's hard to argue there is a real supply scarcity; more accurately, there is an artificial supply shortage. There may occasionally be a shortage in some portions of a zone or district, even though there is an adequate supply of tablets in some locations" (KII, SNNPR-HB).

Ineffective Stock Management

Ineffective stock management is one of the barriers to effective PFAS. The providers of the service, including health professionals, regional decision-makers, and EPSA, witnessed the facilities' improper use of folic acid supplements. The national supplier EPSA recommended that facilities should make sure that supplies are delivered to consumers promptly. A pharmacy head who participated in IDI indicated that,

"Sometimes the folic acid supplements are available in the pharmacy store of a facility, but without proper stock management they may expire. Additionally, some facilities may have an overstock of the folic-acid tablets, so the responsible bodies should make redistribution to the nearby health facilities to solve the supply problem" (IDI, PSH-6).

In addition, the regional health decision maker and EPSA representative who participated in the KIIs stated that,

"Folic acid supplements are being misused in some medical facilities, which causes them to expire. If folic acid tablets are widely available in a healthcare facility in large quantities, it is advisable to distribute them to other facilities that are in need because this will be more beneficial to society at large. Likewise, there is a shortage of supplement supply occasionally in some facilities as a result of inappropriate requests or improper RRF filling." (KII, SNNPR-HB)

"After the tablets reach the health facilities, it is not necessary to keep them in the store; rather, it is necessary to distribute the supplements. Furthermore, it is mandatory to ask the mothers what they want, give advice, and motivate the women to take the supplements. This is necessary so that the folic acid pill does not expire" (KII, EPSA-HB).

Improper Supply Allocation

Mismatching of the folic acid supplement service users demand against supply distribution to health facilities was also another barrier. A gap in the supply distribution against MOH-approved quotas to HFs is one of the barriers from the EPSA side. A pharmacy head and medical director who participated in an IDI and a KII stated that, *"We asked EPSA for the supply of iron-folic acid pills but could not find them. It's possible that folic acid pills are hardly available at their national drug store due to a supply shortage. But there was no problem before. In fact, it used to expire because no one was interested in taking the tablets, but now it disappears when users start to take the tablets"* (IDI, PSH-4).

"At the national level, there are discrepancies in the EPSA side's supply distribution. We faced an inadequate supply compared to demand because the supply is allocated to users who reside beyond the hospital's catchment area" (KII, MD-2).

On top of that, a regional health decision maker who took part in a KII reported that,

"In the case of the supply of folic acid tablets, there is no problem with supply at the moment, but in the middle of service provision, there are shortages of supply and sometimes the distribution of expired folic acid tablets. As a result, we were experiencing supply shortages" (KII, SRS-HB).

DISCUSSION

Folic acid supplementation during the periconceptional period plays a pivotal role in the prevention of neural tube defects (Silva et al., 2017). However, in the study, we discovered that periconceptional folic acid supplementation was not frequently provided in health facilities, despite the fact that this is the recommended period to avoid neural tube defects. Almost all pregnant women did not receive FAS at the recommended time. Women's better health-seeking behavior and positive perceptions of future PFAS use were identified as facilitators among service users. This finding, supported by other research, found that women's health-seeking behavior was substantially related to maternal health care (Vincent et al., 2017, Machira and Palamuleni, 2018).

Women who exhibited strong health-seeking behavior received guidance and were given a

prescription to take folic acid prior to pregnancy or throughout the first trimester. Women's positive perceptions of utilizing PFAS in the future were potential facilitators, most women were prepared to take folic acid supplements prior to or during the first three months of their pregnancy, as advised by health professionals.

In contrast, one of the barriers to periconceptional folic acid supplementation cited by service users was a lack of preconception care services. The majority of the pregnant women who took part in the study had never received preconception care services before their current pregnancy. Similarly, research conducted in Ethiopia revealed that women's awareness and usage of preconception care were significantly low (Wegene et al., 2022, Ayele et al., 2021).

As reported by health professionals, one of the most challenging aspects of consuming PFAS during the periconceptional period is that the majority of pregnancies are unplanned. Another study from Italy found that women who do not plan their pregnancy use the least preconception FAS (Nilsen et al., 2016). Similarly, late antenatal care initiation by women was one of the barriers to PFAS. Most participants reported that they began their initial ANC visits between the third and fourth months of their pregnancies. The results are in line with research conducted in Southwest Ethiopia, which showed that 66% of pregnant women initiated their first antenatal care late (Tesfaye et al., 2017).

Another barrier that women faced was a lack of knowledge regarding PFAS. The majority of women who participated in the FGDs and IDIs in the present study found that they had no knowledge or information on folic acid intake before or during the first trimester of pregnancy. Likewise, studies in Germany (Wegner et al., 2020) and Japanese women (Obara et al., 2017) indicated that a lack of understanding of the necessity of folic acid for good pregnancy outcomes is associated with a failure to use periconceptional FA supplements. Furthermore, our study identified another barrier: women's misconceptions regarding the effects of iron-folate tablets during pregnancy. Some women and service providers suggested that taking iron-folate tablets causes elevated blood pressure, lowers fetal movement, makes infants thinner, and delays growth. Misconceptions about FAS

have been reported in other countries as well. For instance Nigerian women said that taking iron-folate tablets endangers both the mother and the child, causes newborns to grow too big, and makes childbirth difficult for mothers (Siekman et al., 2018).

We also investigated women's noncompliance with the prescribed dose of FA as one of the barriers. According to health professionals, some women started taking FA prior to pregnancy but stopped, while others complained about gastrointestinal discomforts and hyperemesis as a reason for noncompliance. Moreover, women were concerned about the danger to the fetus and themselves if they used drugs for an extended period of time. A similar result from South Africa indicated that because women were not experiencing physical disease, they were demotivated to adhere to supplements and considered they did not need them (Silubonde et al., 2022). Further, the present exploratory study revealed that the majority of the study's female participants were unable to obtain the FAS from a private pharmacy due to financial limitations. As a result, they were unable to use FAS or discontinued them.

Folic acid, either alone or in combination with other micronutrients, lowers the occurrence of neural tube abnormalities. Similarly, a study found that folic acid supplementation reduced the likelihood of pregnancy termination due to fetal abnormalities (De-Regil et al., 2015). The current study found that raising community awareness regarding PFAS was one of the facilitators. The emphasis should be on increasing public awareness of folic acid and its benefits in reducing congenital abnormalities, particularly NTDs, through advocacy and communication channels, as well as sensitization through the engagement of couples and society at large.

The service providers in this study emphasized the criticality of providing health education for women of reproductive age about PFAS, particularly those who intend to become pregnant; this can motivate them to begin taking it on time in order to prevent NTDs. To improve women's consumption of PFAS, we should include visual aids and practical scenarios in the sessions. Health professionals and regional decision-makers have identified integration of PFAS with current health services as a very

crucial enabler. In order to properly implement PFAS, the service providers suggested that we use the family planning service as a point of contact, to carry out projects, and to make use of already-existing community-based health intervention services.

In this study, we found that delivering folic acid supplements following miscarriage or fetal loss with congenital malformations (CMs) is one of the enablers from the care provider's perspective. A study on the effects of folic acid supplementation on abortion risk found that consuming more folate from supplements was linked with a reduced incidence of spontaneous abortion (Gaskins et al., 2014).

In addition, the majority of health professionals working in healthcare facilities suggested that administering PFAS within the time frame given is advantageous. Thus, the majority of HPs are optimistic about the feasibility of periconceptional FA supplementation. Despite supply issues in many health facilities, iron-folic acid or folic acid-only supplements, may be available to pregnant women free of charge in the pharmacy. This practice may be a facilitator for the success of periconceptional folic acid supplementation. All participants and service providers agreed to deliver free FAS to women during ANC follow-up if adequate supplies were available at the health facilities.

The broad use of uniform medication, medical logistics, and reporting tools is crucial for effective healthcare supply chain management. Within the findings, a regional health decision maker stated that the EPSA distributes folic acid tablets and other medical supplies to health facilities nationwide on a request basis using the RRF format. This delivery method is seen as a strong and positive experience. A qualitative study in Bahir- Dar confirmed that almost all respondents felt that a credible and detailed RRF report is crucial for accurate forecasting and optimal distribution performance when supplied on time (Tilahun, 2022). The folic acid supplementation program is included within the Ethiopian antenatal care standards, which indicate that every pregnant woman should consume 60 mg of elemental iron (ferrous sulfate, ferrous fumarate, or ferrous gluconate) and 0.4 mg of folic acid per day for six months (180 tabs) (Ministry of Health Ethiopia, 2022). If she did not

finish and, the entire dose was not consumed throughout pregnancy; the remainder was completed after delivery. If the area is prone to anemia, iron supplements may be continued for an extra three months. As a result, the emphasis is mostly on preventing maternal iron deficiency anemia during pregnancy but fails to provide periconceptional folic acid supplementation, which prevents neural tube defects and other congenital anomalies.

One of the most significant concerns identified in our qualitative study was the lack of national-endorsed guidelines or working protocols for PFAS, despite efforts to develop them. This study revealed that there are substantial policy gaps in administering PFAS. Another key barrier to appropriate PFAS was the inadequate knowledge of health professionals about PFAS. A study conducted in China supports the finding that health professionals' knowledge regarding periconceptional folic acid consumption was insufficient in certain areas (Cui et al., 2021). Similarly, research in Northern Ethiopia found that approximately 50% of health workers lacked adequate knowledge of folic acid during the periconception period (Demilew and Asres, 2017). Enteric coating is a typical process used in the creation of oral medicinal dosage forms. The primary benefit of enteric coating is that it protects the drug from acidic pH and enzymatic destruction in the stomach, as well as mitigating the negative effects of certain drugs (Maderuelo et al., 2019).

One of the challenges noted for HFs in our study was receiving FA supplements that are non-enteric coated and which have high side effects. A study in India showed that among iron-folic acid supplements, enteric-coated or delayed-release ferrous sulfate preparations can trigger less nausea and lower adverse gastrointestinal effects (Iqbal et al., 2015). Some health professionals who participated in IDIs stated that because enteric-coated FA tablets were not provided at the HF pharmacies, pregnant women were advised to purchase from private pharmacies. Improper allocation of FA supply by RHB and EPSA was identified in this investigation as another significant barrier. The majority of service providers stated in their response that there is an imbalance between the supply of folic acid to healthcare facilities and the demand for supplements. The supply distribution

disparity between MOH-approved quotas for health facilities and the verified EPSA-related mismatch was also confirmed by specific healthcare specialists and regional health decision-makers.

A study in northwestern Tanzania revealed that women who received an iron-folate supplement at each appointment were more likely to continue using IFA supplements than women who did not access supplements at each visit (Lyoba et al., 2020). However, in this qualitative study, insufficient access to FA tablet supply at HFs was one of the main challenges explained as a barrier to PFAS.

The majority of participants indicated the absence, shortage, and supply inconsistencies of the FAS tablets from the facility pharmacy. Studies in Pakistan (Nisar et al., 2014) and Uganda (Kiwunika et al., 2017) reported that women with inadequate access to iron and folic acid supplements had lower adherence to the doses. Inventory management contributes to maintaining a consistent supply for patients and preventing product stock outs for essential medical supplies (Kefale and Shebo, 2019).

Overall our study found that poor stock management and misuse of FAS at the health facility level are challenges to successful PFAS. Key informants, including regional health decision-makers and an EPSA official, confirmed that folic acid supplements are overstocked in some health facilities, causing them to expire. Furthermore, EPSA, who are the FAS suppliers, urged that health facilities should distribute supplies to users as soon as possible.

The study's strengths and limitations include the lack of evidence from qualitative studies on the barriers and facilitators of PFAS in Ethiopia; as a result, the findings will assist programmers and policymakers in developing an effective strategy for reducing neural tube defects and other birth defects that can be prevented with folic acid supplements. The study attempted to include the perspectives of medical experts and pregnant mothers. The study's limitations include its focus on only six healthcare facilities, nearly all of which are general hospitals or higher, as well as its failure to include inputs from health centers and health posts. More research is needed to

address some of the issues that this study failed to consider.

CONCLUSIONS

Periconceptional folic acid supplementation guidelines and protocols should be implemented as a priority to prevent neural tube defects and other adverse birth outcomes across the country. Nutrition education on PFAS and its benefits for NTD prevention needs to be delivered targeting women of reproductive age, adolescent girls, and newlywed couples. Although we must engage in community activism and attempt to raise public awareness through mass media communication. Furthermore, PFAS should be integrated into the current health care services provided by healthcare facilities and communities. In addition, substantial donor support is required to maintain consistent access to safe and high-quality folic acid supplements.

ETHICAL CONSIDERATIONS

The Institutional Review Board of Hawassa University granted ethical permission for the study (Ref No. IRB/025/14). We then obtained a permission letter from the college as well as approval letters from the medical directors and administrators at each study facility. We received both oral and written consent from the study participants. All gathered information and medical records were kept private and confidential.

CONFLICTS OF INTEREST

The authors declare that they have no conflicting interests.

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