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## RESEARCH ARTICLE

### Cotrimoxazole Prophylaxis Treatment Adherence and Associated Factors Among Human Immunodeficiency Virus (HIV) Exposed Children in Public Hospitals in Ilubabor Zone, Southwest Ethiopia, 2018

Dessalegn Nigatu<sup>1</sup>, Negalign Getahun Dinegde<sup>2,\*</sup> and Endalew Gemechu Sendo<sup>2</sup>

<sup>1</sup>Department of Nursing, Mettu University, Mettu, Ethiopia

<sup>2</sup>School of Nursing and Midwifery, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

#### Abstract:

##### Introduction:

Africa is the most affected region by HIV/AIDS in the world with about 26 million people living with HIV, of whom 2.3 million are children under the age of 15 years in 2015. The Human Immunodeficiency Virus (HIV) related estimates and projections for Ethiopia in 2017 revealed that 57,132 under 15 years children were living with HIV with about 1,276 children newly infected. Therefore, this study assessed cotrimoxazole prophylaxis treatment adherence and associated factors among HIV exposed children in public hospitals in Ilubabor zone, Southwest Ethiopia, 2018.

##### Methods:

The study design was a facility based, both a retrospective and descriptive study that involves a review of the records of children from PMTCT register books over the past 2 years, and the interview of health care workers and parents/guardian of all children at the follow up clinic. The study included a random sample of children born from HIV infected mothers and enrolled in the PMTCT follow up clinic. The total sample size was 293 and 99 for children (parents/guardian interviewed) and health workers, respectively, and the children's antiretroviral therapy (ART) registration books in each health facility were reviewed. The collected data was entered into the Epi-data software version 3.1 and then exported to SPSS version 20 for further statistical analysis. Descriptive statistics, bivariate analysis and multivariable logistic regression were used for analysis.

##### Results:

Among the total participants, a considerable number (83.3%) of them did not confirm their HIV status, and the majority (88.8%) of participants indicated that they had indeed suffered from one or more opportunistic infections. The common obstacles encountered in accessing care at the health facility were: lack of drugs (33.8%), long procedures in getting drugs (31.4%), unfriendly hospital staff (26.3%), and long distance to the health facility (8.5%). The study showed a significant association between compliance to cotrimoxazole prophylaxis and unfriendly health worker (OR=0.14, CI=0.03-0.78), follow-up (OR= 0.22, CI = 0.06-0.87) and the long procedure of getting drugs (OR= 0.08, CI= 0.01-0.45).

##### Conclusion:

The study revealed that a remarkable number of the participants were found to adhered to cotrimoxazole prophylactic treatment. Unfriendly health workers, follow-up and the long procedure of getting drugs were significantly and independently associated with compliance to cotrimoxazole prophylaxis.

**Keywords:** Adherence, Cotrimoxazole, HIV, Ethiopia, Children, Ilubabor zone.

#### Article History

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## 1. INTRODUCTION

Human Immunodeficiency Virus (HIV) continues to be a serious global public health problem in different parts of the world. The Center for Disease Control and Prevention [1]

reported that about 36.7 million people were and 1.8 million new cases of HIV were diagnosed in 2016 around the world. Sub-Saharan Africa, which bears the heaviest burden of HIV and AIDS worldwide, accounts for 64% of all new HIV infections. United Nations Programme on HIV/AIDS (UNAIDS) stated that in 2017, 21.7 million people were living with HIV on antiretroviral therapy [2]. In 2015, the World Health Organization indicated that [3] Africa is the most

\* Address correspondence to this author at the School of Nursing and Midwifery, College of Health Science, Addis Ababa University, Addis Ababa, Ethiopia; Tel: +251988729468; E-mail: [negalign999@gmail.com](mailto:negalign999@gmail.com)

affected region by HIV/AIDS in the world with about 26 million people living with HIV, of whom 2.3 million were children under the age of 15 years. In addition, 90% of the children in the world living with HIV were in sub-Saharan Africa. In 2015, 51% of people living with HIV in the African region knew their HIV status, and more than 12 million were receiving HIV treatment.

According to spectrum preliminary estimates by the President's Emergency Plan for AIDS Relief (PEPFAR), HIV prevalence in Ethiopia in 2016 was estimated to be 1.5%. It was estimated that there were 4.2 million orphans in Ethiopia, of which, 18 percent were orphaned due to HIV/AIDS [4]. As stated by the Ethiopian Public Health Institute, in 2017, HIV related estimates and projections for Ethiopia revealed that 57,132 under 15 years children were living with HIV with about 1,276 children newly infected [5]. With the expansion of HIV care and treatment services in the country, a remarkable uptake has been achieved in HIV counseling and testing (HCT) services. In 2014, on average, per year more than 10 million people were tested for HIV, with 27% HIV testing and counseling coverage among the adult population. In the same year, about 339,043 adults with 65% ART coverage were receiving ART. However, pediatric ART coverage was below 15% (22,955) which is an issue to be concerned [6].

Many HIV-infected infants and children die from HIV-related causes without their HIV status being known or receiving HIV care. Without access to cotrimoxazole prophylaxis, ART and supportive care, about a third of all HIV-infected infants die by 1 year of age and about half of all HIV-infected infants die by age of 2 years [7, 8]. The World Health Organization (WHO) endorses a comprehensive model for the Prevention of Mother to Child Transmission (PMTCT) programs which include preventing new HIV infections among women of childbearing age, preventing unplanned pregnancies among women living with HIV, preventing HIV transmission to the baby and providing right treatment, care and support to mothers living with HIV, their children and families [9].

According to the 2016 Ethiopian PMTCT guideline: the follow-up schedule of HIV exposed infants (HEIs) is at 7 days, 6 weeks, then monthly for 6 months, then every 3 months until HIV infection is excluded. Cotrimoxazole prophylaxis is initiated at 4-6 weeks and is continued if the infant is HIV-infected or is discontinued if HIV-infection is excluded [8, 10, 11].

Mortality is very high among untreated infants infected with HIV in the first year of life, making early HIV testing, prompt return of results and rapid initiation of treatment imperative [12, 13]. Ethiopia is among the top ten countries in the world with the highest burden of HIV infections among children due to mother to child transmission. In addition, HIV is the third commonest cause of death among children in Ethiopia [14, 15]. In Ethiopia, infants and young children have an exceptionally high risk of poor outcomes from HIV related infection as up to 52% and 75% of children die before the age of two and five years, respectively, in the absence of any intervention [13].

Due to the definite effectiveness and safety of

cotrimoxazole for the management of opportunistic infections in children, the World Health Organization endorses that all children born to HIV-infected mothers should be provided with possible prophylaxis during 4-6 weeks after birth [16]. In the absence of PCR, prophylaxis should be continued for at least 1 year, when it is confirmed that the child is not HIV-infected and is no longer exposed to HIV [9]. However, in resource-limited countries, the implementation of cotrimoxazole prophylaxis according to the guideline is challenging. For instance, out of an estimated 135,000 children who are in need of cotrimoxazole prophylaxis, only 56% are currently receiving this intervention in Ethiopia [13, 17]. Therefore, this study assessed cotrimoxazole prophylaxis treatment adherence and associated factors among Human Immunodeficiency Virus (HIV) exposed children in public hospitals in Ilubabor zone, southwest Ethiopia, 2018.

## 2. MATERIALS AND METHODS

### 2.1. Study Design and Setting

The study design was facility-based, being both a retrospective and descriptive study that involves a review of the records of children from the Prevention of Mother-to-Child Transmission of HIV (PMTCT) register books over the past 2 years, and the interview of health care workers and parents/guardian of all children at the follow up clinic in two public hospitals of Ilubabor zone, Ethiopia. The study involved all mother-infant pairs who were within the catchment area of the health facilities and confirmed to be HIV positive during pregnancy and found in the registers.

### 2.2. Sampling Technique and Procedure

The study included a random sample of children born from HIV infected mothers and enrolled at the PMTCT follow up clinic in the zonal governmental public hospital over the last two years. Children born from an HIV infected mother with 6 weeks to five years of age and undertaking CPT have been included in the study. In addition, health professionals working in PMTCT and ART departments were participants of the study. The sample size was calculated using single population proportion formula by using a retrospective study conducted in Addis Ababa, which showed that 56% of infants adhered to cotrimoxazole with 95% CI and 5% marginal error [18]. The total sample size was 293 and 99 for children (parents/guardian interviewed) and health workers, respectively. In addition, the children's ART registration book in each health facility was also reviewed.

### 2.3. Measurements

Data were collected by a structured pre-tested questionnaire which was adopted from different studies [9, 17, 19]. Data was collected by using the structured questionnaire form to gather the information of infants from the PMTCT register books. The data collected through the review of the PMTCT register books and the interview of parents, guardians/caregivers, and health care workers. The content of the questionnaire included: socio-demographic characteristics (age of the child, sex of the child, age of the caregiver, educational status, occupational status of the caregiver); socio-economic

conditions (monthly income, financial support for the child, grant for the child); medication-related factors; health care delivery systems related factors, health care provider related questions, caretaker related factors, and register books review (as per the national guidelines). The independent variables were: health care provider-related factors, health facility-related factors, drug-related factors, and caregiver /family-related factors.

#### 2.4. Data Analysis and Processing

The collected data was entered into the Epi-data software version 3.1 and then exported to the SPSS version 20 for further statistical analysis. Descriptive statistics were used to describe the study participants major independent and dependent variables. The bivariate analysis used to analyze the association between predictors and dependent variables. Multivariable logistic regression analysis was used to see the impact of the variable of interest on the outcome variable. Odds ratio and p-value were computed to see whether any relation exists between the two variables. A P - value less than 0.05 will be considered as statistically significant.

#### 2.5. Operational Definitions

Good adherence: taking greater than 95% prescribed dose or Missed 3 and less doses/30doses [9].

Poor adherence: less than 95%, missed greater than 3 doses per 30 doses.

HIV Exposed children: children who were born from confirmed HIV infected women [20].

#### 2.6. Ethical Consideration

Ethical clearance was obtained from the Research Ethics Committee (REC) of Addis Ababa University, College of Health Science, School of Nursing and Midwifery. Permission from the Ilubabor zone health bureau, and then informed written consent of individual participants were obtained after being fully informed of the study purpose and procedures. During the consent taking process, they were provided with information regarding the purpose of the study, why and how they were selected for this study and the opportunity given to ask questions if they had. Participants also were assured of the confidentiality of the information obtained from them during the data collection by not using personal identifiers and analyzing the data in aggregates. Confidentiality and anonymity were ensured. No name and other identifying information were asked.

### 3. RESULTS

#### 3.1. Study Population Characteristics

Most of the (272 (93%)) of the care giver respondents were female and 196 (66.9%) of them were living with a partner. The majority of the care givers 223 (76.1%) were less than 30 years of age and almost half of them 157 (53.6%) were Christians. The majority of the respondents (64.5%) attended the secondary school and 57.7% of them reported an average annual household income of less than 15,000. ETB. In addition, the results indicated that the majority (280 (95%)) of the respondents were unemployed.

A total of 293 HIV exposed children from recorded data

for the past 2 years in the data registry were enrolled in the study. Review of the records indicated that amongst all the infants who were registered in the PMTCT register books and born from confirmed HIV-infected mothers, more than half [158 (54%)] of them were in the 13-18 month age group. The mean age of the children was 10.6 Kg. The majority of the health care worker respondents were nurses (62.8%), followed by physicians (27.7%) and health officers (9.5%). Table 1 provides the socio-demographic characteristics of the study participants.

**Table 1. Sociodemographic characteristics of study participants in public hospitals, Ilubabor, Ethiopia, April, 2018 (n=293).**

Variables	Category	N	%
Age (Child)	≤15 months	174	59.4
	>15 months	119	40.6
Age (Care giver)	≤30 years	223	76.1
	>30 years	70	23.9
Weight (Child)	≤10 Kg	159	54.5
	>10 Kg	133	45.5
Cohabitation	Living with partner	196	66.9
	Living alone	97	33.1
Education	Below secondary school	104	35.5
	Secondary and above	189	64.5
Religion	Christian	157	53.6
	Muslim	136	46.4
Income	≤1500 ETB	169	57.7
	>1500 ETB	124	42.3
Hospitalization	Yes	44	15
	No	249	85
Facility support	Yes	115	39.2
	No	179	60.8

#### 3.2. Exposed Children's Health Status

Among the total (293) HIV exposed children, a considerable number of them (83.3%) have not confirmed their HIV status yet. The vast majority (92.2%) of the children adhered cotrimoxazole prophylactic treatment. The result indicated that nearly half of HIV exposed infants (44.1%) were hospitalized within the last one month and the causes of admission to hospital were: pneumonia (43.2%), diarrhea (18.4%), and 9.6% reported to have been admitted for various other reasons. The majority of the participants (88.8%) indicated that they had indeed suffered from one or more opportunistic infections. The study showed that the majority (90.1%) of the children were on stage one WHO HIV staging followed by 4.8% at stage two, 3.4% at stage four and 1.7% at stage three.

#### 3.3. Factors Associated with Children's Treatment Adherence

##### 3.3.1. Health Facility Factors

In this study, most of the respondents (80.5%) stated that they encountered barriers in accessing cotrimoxazole therapy. The common obstacles encountered in accessing care at the

health facility were lack of drugs (33.8%), long procedures of getting drugs (31.4%), unfriendly hospital staff (26.3%), and long distance to the health facility (8.5%). The study showed that the majority of (60.8%) the health care facilities providing care for the HIV exposed children did not offer any form of social support services (counseling on positive living, nutrition *etc.*) for the clients.

**3.3.2. Cotrimoxazole Related Factors**

The study indicated that nearly all 98.3% of the respondents reported that CPT was part of their current treatment regime, among which 35.2% had not missed any dose, 20.6% of the respondents had missed only one dose, 27.2% had missed only two doses and 9.2% had missed only three doses and 7.8% reported missing more than three doses within the one month. More than half (66.7%) of the health care workers reported to have experienced unavailability of cotrimoxazole pediatric formulations in the health care facilities. In the absence of cotrimoxazole syrup, approximately one-quarter (23.8%) of health care workers gave instructions to parents and guardians to prepare cotrimoxazole suspension using crushed tablets at home. Some health care workers (17.5%) were able to assist parents and guardians by making cotrimoxazole suspension using cotrimoxazole crushed tablets and (19.8%) requested parents and guardians to come back to the health facilities the next day with anticipation that the drug will be available during that time. Moreover, 80.5% of the respondents had received regular supplies of CPT and 19.5% of respondents reported being unable to acquire the drug when they needed it. The most frequently experienced side effects were vomiting (57.7%), nausea (25.6%), rash (13.7%) and other reason (3.1%).

**3.3.3. The Health Care Provider Related Factors**

The study indicated that the majority (99.2%) of the respondents received counseling during treatment in which the patients informed about their drug instructions, benefits of adherence and related issues on CPT. Among the clients receiving CPT, the common factors for missing the CPT dose were unavailability of the drug, forgetfulness, difficulties in understanding its usage, and distance from health facilities, being 32.1%, 23.2%, 23.2% and 21.2% respectively.

**3.3.4. Caretaker Related Factors**

The caregiver participants were mothers, fathers and guardians with 45.7%, 7.8% and 46.4%, respectively. The study revealed that only 191 (65.5%) of the caretakers were aware of opportunistic infections related problems.

**3.3.5. Independent Predictors of Adherence to Cotrimoxazole Prophylactic Treatment**

Table 2 depicts factors that can predict and impose an impact on acquiring good adherence about cotrimoxazole prophylactic treatment using binary logistic regression. Accordingly, after controlling the effects of other variables, two variables were found to be significantly associated with adherence to CPT in children. As shown in Table 2, the follow-up was significant and participants with scheduled follow-up more strictly adhered to cotrimoxazole prophylactic treatment (OR= 0.22, CI = 0.06-0.87). In addition, children who faced barriers in getting CPT drugs were less likely to adhere to CPT than those who did not encounter any problem; the barriers included unfriendly health worker (OR=0.14, CI=0.03-0.78), long procedure of getting the drug (OR= 0.08, CI= 0.01-0.45), and unavailability of the drug (OR= 0.11, CI= 0.02-0.61).

**Table 2. Factors associated with CPT adherence among HIV exposed children attending at Mettu Karl and Darimu hospital, Ilubabor, Ethiopia, 2018 (N=293).**

Variables	Adherence Level n (%)		COR (95% CI)	AOR (95%CI)
	Good	Poor		
<b>Age (Child)</b>	-	-	-	-
≤15 months	158 (90.8)	16 (9.2)	1.62(0.65-4.1)	1.93(0.7-5.7)
>15 months	112 (94.1)	7 (5.9)	1	1
<b>Cohabitation</b>	-	-	-	-
Living with partner	178(90.8)	18(9.2)	1.86(0.67-5.2)	2.7(0.81-8.97)
Living alone	92(94.8)	5(5.2)	1	1
<b>Education</b>	-	-	-	-
Below secondary school	96 (92.3)	8 (7.7)	0.97(0.39-2.36)	1.63(0.52-5.1)
Secondary and above	174 (92.1)	15 (7.9)	1	1
<b>Income</b>	-	-	-	-
≤1500 ETB	159 (94.1)	10 (5.9)	0.54(0.23-1.27)*	0.38(0.13-1.1)
>1500 ETB	111 (89.5)	13 (10.5)	1	1
<b>Follow up</b>	-	-	-	-
Scheduled	239 (93.4)	17 (6.6)	0.37(0.14-1.0)*	0.22(0.06-0.87)*
Unscheduled	31(83.8)	6 (16.2)	1	1
<b>Medical Problems</b>	-	-	-	-
Persistent diarrhea	48(88.9)	6(11.1)	0.9(0.25-3.2)*	1.34 (0.28-6.44)
Fever	63(90)	7(10)	0.8(0.24-2.71)*	1.65(0.38-7.16)
Pneumonia	123(96.1)	5(3.9)	0.3(0.08-1.1)	0.35(0.08-1.57)

(Table 2) contd....

Variables	Adherence Level n (%)		COR (95% CI)	AOR (95%CI)
	Good	Poor		
Candidiasis	36(87.8)	5 (12.2)	1	1
<b>Barriers</b>	–	–	–	–
Unfriendly health worker	72 (93.5)	5 9 (6.5)	0.28(0.7-1.1)*	0.14 (0.03-0.78)*
Long procedure in getting drug	86 (93.5)	6 (6.5)	0.28(0.08-1.0)*	0.08(0.01-0.45)*
Drug unavailable	92 (92.9)	7 (7.1)	0.3(0.09-1.06)*	0.11(0.02-0.61)*
Long distance from facility	20 (92.2)	5 (7.8)	1	1

Note: \* refers to P-value <0.05

#### 4. DISCUSSION

The World Health Organization (WHO) issued global recommendations for the use of CTX in children exposed to HIV as well as children, adolescents and adults infected with HIV in an effort to extend and improve the quality of life for people living with HIV, including those on ART [21 - 23]. The primary purpose of CTX prophylaxis in all HIV exposed children is to provide added protection against other opportunistic infections in infants who are HIV infected and who would only be diagnosed much later.

Strict adherence is pivotal to the successful Cotrimoxazole Prophylactic Treatment (CPT). Adherence is the extent to which a client's behavior matches the prescribed health care regimen in terms of care (correct date and time for clinic appointment) and treatment (correct drug, timing, dosing, compliance with food restrictions and no missed doses). As with any drug use, drug efficacy is directly proportional to the patient's level of adherence. Although exposing children to CTX for a longer period is more likely to affect adherence to CTX, good adherence levels are required to obtain a successful treatment outcome [24, 25].

In this study, challenges encountered during the provision of cotrimoxazole prophylaxis in children born to HIV-infected mothers were assessed through the review of PMTCT files and by interviews of caregivers of children and health care providers in the public hospitals. Overall, the majority (92.2%) of the children adhered to cotrimoxazole prophylactic treatment. The study conducted in public hospitals of Tigray, northern Ethiopia, on HIV-positive pregnant women showed that the level of adherence of respondents to Option B+ PMTCT drugs was 87.1%, which is in line with this study [26]. According to Gokarn, Narkhede [27], a study conducted on adherence to antiretroviral therapy in India with 97% adherence rate showed outcomes similar to this study. To the contrary, a cross-sectional study conducted on HIV exposed infants in Chikankata District in Southern Zambia showed that 78.7% of the respondents were non-compliant with cotrimoxazole prophylaxis [28]. In addition, according to a retrospective quantitative study conducted in Addis Ababa, Ethiopia, only 56% of the infants were found to adhere to cotrimoxazole prophylactic treatment [10]. Moreover, different studies conducted in Ethiopia, India and Tanzania revealed lower adherence level being 7%, 63.7%, and 16.7% respectively [19, 29, 30].

However, cotrimoxazole is relatively inexpensive, cost-effective, with logistically feasible interventions to reduce morbidity and mortality in patients with HIV. Majority (66.7%) of the health care workers reported to have experienced

unavailability of cotrimoxazole pediatric formulations in the health facilities. This was the finding reported in other studies [19, 21, 24, 28, 31 - 34]. Confirming HIV status in HIV exposed individuals remains a challenge as a considerable number of them (83.3%) have not confirmed their HIV status yet. This was at variance with findings which showed a better confirmatory status [10, 25]. This could be due to PCR testing being resource-limited in countryside health facilities.

The study showed a significant association between compliance to cotrimoxazole prophylaxis and unfriendly health workers at health facilities (OR=0.14, CI=0.03-0.78), follow-up (OR= 0.22, CI = 0.06-0.87) and the long procedure of getting drugs (OR= 0.08, CI= 0.01-0.45). Prior studies conducted in Zambia and other WHO regions have found similar results [21, 28].

Lack of adequate supply of cotrimoxazole in health facilities was among the factors causing poor implementation of cotrimoxazole prophylaxis. This result is similar to studies conducted in India and Tanzania [19, 29]. The study indicated that the most frequently experienced side effects were vomiting (57.7%), followed by nausea (25.6%), rash (13.7%) and others (3.1%). This is in line with a study conducted in Tanzania which revealed that 37.3% of the participants mentioned cotrimoxazole-induced side effects, including nausea, vomiting, and skin rashes, as the reasons for skipping prescribed doses [19].

In this study, the majority of the participant (88.8%) indicated that they had indeed suffered from one or more opportunistic infections: 43.9% of the respondents reported pneumonia, followed by diarrhea (18.4%) and others (9.6%) as the cause of admission. This can be attributed to the fact that poor adherence to cotrimoxazole is usually associated with increased rates of opportunistic infections and hospitalization due to missed doses [35].

#### CONCLUSION

In summary, the study revealed that the remarkable number of participants were found to adhere to cotrimoxazole prophylactic treatment. An unfriendly health workers at health facilities, follow-up and the long procedure of getting drugs were significantly and independently associated with compliance to cotrimoxazole prophylaxis. Among the total participants, a considerable number of them did not confirm their HIV status, and the majority of participants indicated that they had indeed suffered from one or more opportunistic infections.

## LIST OF ABBREVIATIONS

<b>AOR</b>	= Adjusted Odds Ratio
<b>ART</b>	= Antiretroviral Therapy
<b>COR</b>	= Crude Odds Ratio
<b>CPT</b>	= Cotrimoxazole Prophylaxis Treatment
<b>CTX</b>	= Cotrimoxazole
<b>HCT</b>	= HIV Counseling and Testing
<b>HEIs</b>	= HIV Exposed Infants
<b>HIV</b>	= Human Immunodeficiency Virus
<b>OR</b>	= Odds Ratio
<b>PCR</b>	= Polymerase Chain Reaction
<b>PEPFAR</b>	= President's Emergency Plan for AIDS Relief
<b>PMTCT</b>	= Prevention of Mother to Child Transmission
<b>REC</b>	= Research Ethics Committee
<b>UNAIDS</b>	= United Nations Programme on HIV/AIDS
<b>WHO</b>	= World Health Organization

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical clearance was obtained from the Research Ethics Committee (REC) of Addis Ababa University, College of Health Science, School of Nursing and Midwifery.

## HUMAN AND ANIMAL RIGHTS

No humans/ animals were used for the studies that are basis of this research.

## CONSENT FOR PUBLICATION

Permission from Ilubabor zone health bureau, and then informed written consent of individual participants was obtained after being fully informed of the study purpose and procedures. During the consent process, they were provided with information regarding the purpose of the study, why and how they selected for this study and opportunity given to ask questions if they had. Participants also assured about confidentiality of the information obtained from them during the data collection by not using personal identifiers and analyzing the data in aggregates. Confidentiality and anonymity was ensured. No name or other identifying information included in the instrument.

## AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on request.

## FUNDING

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## CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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zonal and woreda health departments.

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