ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF NURSING AND MIDWIFERY

Cotrimoxazole Prophylaxis Treatment Adherence and Challenges in Implementation among HIV Exposed Children in the Public Hospital in Ilubabor Zone, South West Ethiopia, 2018**.**

By: Dessalegn Nigatu (BSc)

A RESEARCH THESIS SUBMITTED TO SCHOOL OF GRADUATE STUDIES, ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCE, SCHOOL OF NURSING AND MIDWIFERY IN PARTIAL FULFILLMENT OF THE REQUIREMNTS FOR DEGREE OF MASTER IN CHILD HEALTH NURSING

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Acronyms and abbreviation

ART - Antiretroviral therapy

CPT - Cotrimoxazole preventive therapy

CTX - Cotrimoxazole

CD4 - Cluster of Differentiation

CDC - Communicable Disease Control

HIV - Human immune virus

HEI - HIV exposed infants

OI - Opportunistic infection

PCR/DNA - Polymerase Chain Reaction

PMTCT - Prevention to mother to child transmission

PJP - Pneumocystis Jiroveri

R LS -Resource Limited Setting

WHO - World Health Organization

LFTU -loss of follow up

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ABSTRACT

Background: Worldwide, over two million children are infected with HIV, ninety percent of who live in sub-Saharan Africa in 2011. 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 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 2 years. Ethiopia is one of low income county in sub-Saharan Africa that suffers a lot. For instance, out of an estimated 135,000 children who are in need of cotrimoxazole prophylaxis, only fifty six percent are currently receiving this intervention.

Objective: the aim of this study is to assess adherence and challenges in implementation of CPT among children born from HIV infected mother

Methods: Retrospective cross - sectional study design was conducted from January 2016 – April 2018. A total of 293 samples were collected using semi - structured data collection format. The data were cleaned manually, coded and entered into Epi – data version 3.1 and analyzed using SPSS version 20. Bivariate and Multivariate logistic regression, crude and adjusted odds ratio with their 95% confidence interval and p-value <0.05 were used to identify Variables which had significant association with CPT adherence and challenge in its implementation.

Result : The strongest predictors of poor adherence to CPT are long procedure in getting the drug (OR=9.913 (2.825-34.731), p=<O.000), shortage of drug availability (OR=3.917 (0.649-23.630), p=<O.013) and unfriendly hospital staff (OR=3.725(0.968-14.332,p=0.056). Care takers reason on CPT thought as a treatment of HIV (p=0.023) and reason for hospitalization (p=0.36), related medical problems like diarrhea (OR=4.324(1.067-17.530, p=0.040) and fever (p=0.067), occupation of care giver (p=0.033) significantly associated with poor adherence of CPT among HIV exposed children.

Conclusion: - Implementation of CPT guidelines should be central to the delivery of HIV care and treatment. In HIV exposed children, hospital management should put in place necessary mechanism to ensure that potentially poor adherent HEI are identified in a timely manner and that barriers to adherence are appropriately addressed during counseling sessions with health service providers. In addition, since the study identifies social support as key in promoting adherence, facility based strategy could be revised to help identify any barrier to non-adherence

Key words: Challenge, adherence, cotrimoxazole preventive therapy, exposed child

1. INTRODUCTION

1.1. Background

Human immunodeficiency virus (HIV) is a major global public health problem. In 2015, around 1.1 million people died from HIV-related causes diseases (1) and there were 2.6 million children living with HIV around the world, 90% of who live in sub-Saharan Africa (2).

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, antiretroviral therapy (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 2 years (1).

World Health Organization (WHO) endorses a comprehensive method for the Prevention of mother to child transmission (PMTCT) programs which includes, 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 (6).

PMTCT programs provide antiretroviral treatment to HIV-positive pregnant and lactating women to stop their infants from acquiring the virus. Without PMTCT interventions, the likelihood of HIV passing from mother-to-child is 15% to 45%. However, antiretroviral treatment and other effective PMTCT interventions can decrease this risk to below 5% (7). One-third of HIV positive infants are estimated to die before their first birthday and over one-half will die by their second birthday due to immature immune system. to prevent opportunistic infections during the early years of life, especially when the sero-status of the child is not yet confirmed, the use of antibiotic prophylaxis is commended (9).

All children should begin cotrimoxazole preventive therapy (CPT) after six weeks if there is no contraindication to cotrimoxazole use (e.g, severe anemia) (10). Cotrimoxazole is an important preventive element of HIV care and is recommended for the prevention of opportunistic Infections (OIs), notably Pneumocystis Jiroveci Pneumonia (PJP), some bacterial infections, some protozoan infections and Toxoplasmosis. It also reduces morbidity and mortality among HIV exposed infants if used consistently for this reason, greater advocacy for the use of cotrimoxazole prophylaxis in children is quickly required (11).

Lancet global health report (2017) states Virological test (DNA-PCR) for HIV exposed infants(HEIs) should be done as early as 6 weeks of age or at the first health care contact until 18 months of age breast feeding mother (12, 13). The infant should start HIV care for ART initiation further treatment HIV-positive on HIV virological test; or suspected of having likely severe HIV infection.in addition , refer children above 18 months of age if HIV antibody test is positive (12).

The recommendation on the use of cotrimoxazole prophylaxis for exposed children and adolescents living with HIV to prevent OI, complications and avoid simultaneous intermittent preventive treatment is maintained(14), based on a systematic review showing that (cotrimoxazole)CTX prophylaxis is not less important to intermittent preventive treatment of OI in children with respect to mortality, low birth weight, placental malaria (15), and severe adverse events (7) . However, this method also has its limitations in resource-limited settings, with potential for increased bacterial resistance due to inappropriate use of the cotrimoxazole (16).

According to pan African journal report that every day there are over 1,000 new HIV infections in children, with vast majority occurring in Sub-Saharan Africa(8). Evidence from trials on co-trimoxazole prophylaxis conducted in African countries show reductions in mortality between 25% and 46%, and a beneficial effect of co-trimoxazole in reducing morbidity in children living with HIV /AIDS (17).

In Ethiopia currently more than 135,000 children are living with HIV/AIDS (3) major mode of transmission is through the mother to child during pregnancy, labour, delivery or breast-feeding and it is the primary method of infection among children. Over 90 percent of new infections in infants and young children occur through MTCT**(4).**A higher percentage of HIV-infected children (70-80%) acquire the virus intrapartum, intrauterine infection accounts from 20 – 30% and breastfeeding is responsible for as much as 25-45% of infections in resource - limited countries (5)

According to 2016 Ethiopian PMTCT guideline; 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. (3). Co-trimoxazole prophylaxis is initiated at 4- 6 weeks and continue cotrimoxazole prophylaxis if the infant is HIV-infected or discontinue co-trimoxazole prophylaxis if HIV-infection is excluded. So identify CPT uptake and challenges in implementation has crucial role in reducing morbidity and mortality related to OI.

1.2. Statement of the problem

According to UNICEF estimate and projection in 2016 nearly 740,251 populations were positive for HIV among these 143,201were children and there were 4,800 new HIV infections among children less than 15 years (18).

CDC,2014 report HIV is the third common cause of death among children in Ethiopia (19). 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(20). Cotrimoxazole is an important preventive element of HIV care and is recommended for the prevention of Opportunistic Infections (OIs), but it remains challenging (21). due to the definite effectiveness and safety of cotrimoxazole for the management of opportunistic infections in children is mandatory, World Health Organization endorses that all children born to HIV-infected mothers should be provided with possible prophylaxis during 4–6 weeks after birth(14).

In the absence of PCR, prophylaxis should be continued for at least 1 year, when it can be confirmed that the child is not HIV-infected and no longer exposed to HIV. It also reduces morbidity and mortality among HIV exposed infants if consistently. Greater advocacy for the use of cotrimoxazole prophylaxis in children is urgently required (6), but in resource limited countries implementation of cotrimoxazole prophylaxis according to the guide line is challenging.

Challenge in implementation of CPT is particularly children born from HIV infected mother because they are relay on caregiver, who often provide medication .these challenge may be exacerbated in resource limited setting (RLS) and often elderly ,family members have to care for them and postponing disease progression and decreases morbidity and mortality of children associated with opportunistic infection and improve the quality of life in children infected with HIV (17).

Unlike treatment of chronic condition, cotrimoxazole requires very high levels of effective implementation to achieve the desired result and optimize the outcome of cotrimoxazole therapy to minimize early death of exposed children (11)**.**Cotrimoxazole prophylaxis can reduce morbidity and mortality due to opportunistic infection consistently (22).

Ethiopia is one of low income county in sub-Saharan Africa that suffer a lot (23). For instance, out of an estimated 135,000 children who are in need of cotrimoxazole prophylaxis, only 56 % are currently receiving this intervention(24, 25). Therefore, understanding CPT adherence and challenges encounter in the implementation of co-trimoxazole prophylaxis is essential for the successful use of the drug(26).

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 (25) Review current barriers to rapid, effective scaling up of co-trimoxazole preventive therapy, provide strategies and tools to facilitate scale up level of adherence cotrimoxazole is mandatory

In Ethiopia Infants and young children have an exceptionally high risk of poor outcomes from HIV related infection Up to 52% and 75% of children die before the age of two and five years respectively in the absence of any intervention(25). This is gap on the current CPT up take implementation and the current guidelines for CPT use among exposed children.

So the aim of this study was to assess adherence and challenges in implementation of CPT in children born from HIV infected mother in governmental hospitals in Ilubabor zone of Oromia regional state, Ethiopia

1.3. Significance of the study

The importance of studying adherence and challenges in implementation of cotrimoxazole preventive therapy (CPT) children born from HIV infected mother will assist for the country in prevention of morbidity and mortality of exposed children.

This study will be used as base line information for different stakeholders who are working in the prevention of mother to child HIV transmission, care takers and health professional. The identification of challenges will also be used as substantial value to program managers and policy makers for designing, proper adherence, implementation and evaluation of programs to achieve the national goals of reducing morbidity and mortality due to OI (27).

The finding of this study will provide evidence based and identify the most common challenges in implementation of cotrimoxazole in line with national guide line. It will also be used as base line information for future planning and challenges implementation of CPT for stalk holders, policy makers and researchers.

2. LITERATURE REVIEW

Cotrimoxazole preventive therapy is a feasible ,inexpensive and well tolerated way of using cotrimoxazole intervention for children living with HIV/AIDS to reduce HIV related morbidity and mortality(28)

WHO stated that the CPT has paramount value in reducing morbidity and mortality among HIV exposed infants the major barrier CTX implementation include supply chain and management issues leading to stock-outs; imposing costs on patients for medication and/or monitoring; inadequate training, supervision, and/or mentoring of health-care workers; low coverage of CTX and counseling; and lack of coordination across programs.(29).

The study done in south Africa showed that cotrimoxazole prophylaxis adherence among HEI is poor ,due to increase cost ,complexity of supply chain, health system problem, and side effect of the drug(4). According Ethiopian national guide line 2016,main barriers in cotrimoxazole prophylaxis up take among HIV exposed infants are families or guardians do not know the advantage of CTX , loss to follow up ,missing dose ,distance from health facility, and lack of clear information about the drug (25).

2.1. Global perspective on HIV related opportunistic infection

Globally all children infected with HIV are prone to infection with a myriad of opportunistic infections that would still be pathogenic to host individuals even in the absence of HIV infection. However, these opportunistic infections tend to be more common and severe in persons already infected with HIV (30).

AIDS info africa2016 stated ,HIV related infection increasingly is seen among HEI that substantially decreased survival(31).According Ethiopian National guide line some the most common opportunistic infection key co-infections among HIV exposed children are TB , hepatitis B and C and other comorbidities (25).

2.2. Cotrimoxazole adherence in the Africa situation and its challenge in implementation

Most recent works on CPT adherence and opportunistic infections involve a research conducted by the United States Centre for Disease Control (CD C) in eastern Uganda (32), where malaria is endemic, out that 72% of the 315 cases of fever reported by the study participants occurred

among those who had stopped taking cotrimoxazole prophylaxis, and they were also nearly twice more likely to report diarrhea. The direct implication of this study is that HIV -infected children, while on cotrimoxazole, have a lower rate of these infections and stopping the drug increases the rate(25, 33)

According to pan African journal over the last decade, the burden of HIV and AIDS have been documented as being greater in the sub-Saharan Africa than in any other region of the world. Approximately two thirds of the global total number of people living with HIV and AIDS are found within the Sub-Saharan Africa, In 2015, 1.1 million people died from HIV-related causes and there were 2.6 million children living with HIV around the world at the end of 2015 where majority were found in Africa (8).

The AIDS epidemic in sub-Saharan Africa remains to devastate communities, rolling back decades of development progress(14). According to the study done in Uganda Cotrimoxazole, which is also variously referred to as bactrim has been shown to be effective in preventing a number of these opportunistic infections including tuberculosis, bacterial pneumonia, malaria and PCP (32). In addition, the drug has also been shown to significantly reduce HIV related mortality among individuals being initiated into ARV (5). However, the shortage of the data and other issues special to the resource-limited settings make implementing cotrimoxazole prophylaxis difficult (34)

Over the past few years, a number of papers in leading medical journals have in several occasions raised pertinent question of why cotrimoxazole preventive therapy for opportunistic infections in patients living with the human immunodeficiency virus (HIV) has not been more widely scaled up in low-income countries (22).CPT is highly efficacious, cost-effective, and urgently needed has not become widely available(35). Combined analysis of the development of policy on cotrimoxazole prophylaxis and isoniazid preventive therapy raise concerns about the uptake of both interventions. While operationally the need to rule out active disease before initiating treatment creates problems that make isoniazid preventive therapy especially challenging (36).

In Ethiopia, similarities in the frustration were generated by the slow scale-up of both cotrimoxazole prophylaxis and isoniazid preventive therapy. They point out that at the national

level both adherence and its implementation policy on cotrimoxazole preventive therapy have been sluggish, and they argue "strong advocacy and dissemination of evidence-based information regarding the benefits of cotrimoxazole prophylaxis preventive therapy are urgently required at the national and international level(37). The study demonstrated a poor adherence of CPT (47.0%) among co-infected patients with 24% (359/1473) of CPT records missing. Since all HIV-positive patients are eligible for CPT, then only 36% (524/147"3) of the TB patients were on CPT. Also noted was a higher adherence in faith-based hospitals (65.8%) compared to the public hospital (35.2%), Considering the fact that CPT is a simple intervention with less strength eligibility criteria.

Higher CPT adherence linked to ART could have reasonably been expected(35). Incidences of inadequate supplies and rupture of CPT stocks have been reported and patients have been required to procure treatment personally and this might be another explanation for the low enrolment. The study recommends further research to explore the reasons for the above finding and address the operational challenges contributing to among others, the low CPT uptake. Various studies in Ethiopia have demonstrated that CPT reduces morbidity and mortality in HIV co-infection underscoring the importance of providing this simple but important CPT implementation to HIV -infected children and to vigorously monitor and report programed activities (34).

2.3. Cotrimoxazole up take in Ethiopian situation

Retrospective follow up study done in south west Ethiopia , several millions of children who are born from mother infected with the HIV and who need CTX especially those living in resource-poor and resource-limited settings have very limited or no access and prone to develop opportunistic infection (38). Even in situations where such drugs are available, there still remains the critical aspect of prevention and treatment of opportunistic infections. There is paramount importance attached to the right and timely intervention in treating such infections. It has, however, been observed that in certain circumstances it might be prudent to delay initiating treatment for HIV and instead offer treatment for the opportunistic infections when there are fears of unintended drug interactions and drug toxicities (39).

In Ethiopia out Of the 711 HEIs assessed, 95% were receiving cotrimoxazole prophylaxis. Most (86%) initiated cotrimoxazole between 45 and 60 days of birth (40).

2. 4. Cotrimoxazole Preventive Therapy Guidelines in Ethiopia

Despite the existence of the World Health Organization (WHO) and the joint United Nation Program on HIV and AIDS (UNAIDS) guidelines for CPT from as early as 2016, majority of countries are yet to implement the intervention widely enough to achieve full benefits of the therapy. Part of the concerns that have occasioned the slow implementation of the CPT guidelines mainly revolve around the differences in the burden of opportunistic infections particularly in developing countries, the potential of developing resistance to the drug, pill burden and in some cases lack of guidelines for the duration of the therapy. Thus far, a lot more effort has been geared towards the provision of antiretroviral therapy while overlooking the equally important aspect of scaling up the implementation of CTX prophylaxis (41).

Out of 442 patients, the overall of prevalence of OIs was 183(41.4%). Candidiasis, bacterial pneumonia, and upper respiratory infections were predominant OIs identified with prevalence of (n= 43/442, 9.7%), (n=39/442, 8.8%), and (n=25/442, 5.7%) respectively(15). In general prophylaxis, prevention of opportunistic infections in children with HIV is important because in all HIV -infected individuals, the risk of infections, both opportunistic and non-opportunistic increases as the absolute CD4 T-Lymphocyte count falls, especially to below350cells/ul (35).

Cotrimoxazole (CTX), also known as Sulfamethoxazole- Trimethoprim (SMX- TMP), is abroad-spectrum antimicrobial agent that targets a variety of aerobic Gram-positive and Gram-negative organisms and protozoa and has been shown to reduce the risk of early mortality from opportunistic infections in HIV/AIDS by 25-46 percent as well as rate of hospitalization, malaria, diarrhea and pneumonia(5). Provision of Cotrimoxazole (CTX) as primary or secondary prophylaxis for prevention of pneumocystis jiroveci pneumonia formerly Pneumocystis carni pneumonia (PCP) and toxoplasmosis has been part of the standard care in the management of HIV exposed infants in developed countries.

The antibiotic is also used in the treatment of a variety of bacterial infections. The drug is widely available in both syrup and solid formulations at low cost in most places, including resource -limited settings (42) . Over the past few years, more data from resource-limited settings have become available on the feasibility and the positive impact of CPT prophylaxis on the morbidity and mortality among adults and children infected with HIV. CPT has been shown to be effective

in preventing bacterial infections and malaria, despite the existence of variable levels of resistance to CPT (30).

2.5. Challenge in implementation of cotrimoxazole preventive therapy

WHO stated some of the major barriers to implementing co-trimoxazole prophylaxis for HIV exposed children are supply chain and management issues leading to stock-outs, imposing user charges for medication, inadequate training of health-care workers; and lack of coordination across programs (43).

WHO consolidated management ,2016,The consequences of poor or non-adherence to treatment regimen is not only limited to poor treatment outcome with respect to the individual care giver, but most importantly has been related with the emergence of multi-drug resistant strains and subsequent transmission of such strains to the general population which is raising a serious public health concern (6) refer to as the extent to which an individual sticks to the prescribed drug regimen. Conversely, amenability has been defined as the overall evaluation of how well an individual sticks to the prescribed regime (15).

The study done in south Africa showed that cotrimoxazole prophylaxis up take among HEI is weak ,due to increase cost ,complexity of supply chain, health system problem, and side effect of the drug(4). According Ethiopian national guide line 2016,main barriers in cotrimoxazole prophylaxis are loss to follow up ,missing dose ,distance from health facility, and lack of clear information (25).

2.5.1 Provision of cotrimoxazole prophylaxis

Cotrimoxazole is relatively inexpensive. Provision of CTX prophylaxis is among the most cost-effective, logistically feasible interventions to reduce morbidity and mortality in patients with HIV(44). Co-trimoxazole in all HIV exposed infants significantly reduces the rate of PCP and other bacterial infections and in turn reduces infant morbidity and mortality rates. Start co-trimoxazole to all HIV exposed infants from 6weeks of age. CPT for HIV exposed infants should be continued until the child is confirmed not to have HIV infection using antibody test after 18 months of age (25).

2.5.2 Demographic characteristics

A study conducted in Brazil to detect factors associated with MTCT of HIV in using retrospective cohort study with 1200 HIV - exposed children resulted that maternal age, educational level of mother, birth weight were not significantly associated (45). The retrospective study done in Tanzania 80% of children was initiated with co-trimoxazole prophylaxis within 2 months after birth. 299 (58.4%) children initiated using co-trimoxazole within 4 weeks after birth. Majority (n=458, 91.8%) of the children were given 120 mg of co-trimoxazole per day, whereas 39 (7.8%) received 240 mg per day. Only a small proportion (n=1, 0.2%) of children received 480 mg/day. Dose determination was based on the child's age rather than body weight(17).

Parents and guardians stated that 42 (13.1%) children had missed one or more doses of co-trimoxazole during the course of prophylaxis. The majority of health care workers (89.7%) reported that co-trimoxazole is very effective for the prevention of opportunistic infections among children, but frequent shortage of co-trimoxazole in the health facilities was the main problem (46).

2.5.3 Socioeconomic status.

Cotrimoxazole has been demonstrated to be one of the most cost-effective interventions in HIV treatment and has been associated with improved personal and family health outcomes. According to the study done the coverage of such preventive approaches are still limited in resource-limited setting. Study suggests that the cost of CTX is likely to be outweighed by benefit, not only in terms of improved prevention of infections (9).

2.5.4 Psychological stress, social relationship and activities

According to Ethiopian national guide line a number of underlying social and personal issues challenge implementation of CPT. Retrospective study done in Addis Ababa a great proportion of children born from HIV infected mother had received ARV prophylaxis from birth, about 31% of them were eventually lost to follow up and their co-trimoxazole treatment had been interrupted(25). One of the reasons for this could be that the infants' mothers were being faced with various difficulties while following a specific care program laid out for the child, and perhaps a fear that treatment in the facility would lead to stigmatization and discrimination by

the community or their partners. Another reason might be that when the infants' first PCR/DNA HIV test result (at 45 days of age) is negative, the mother may decide that it is not necessary to continue follow up further, or may change their address without informing the facility. A further reason could be lack of charge free co-trimoxazole drug supply in the stock of the facility, so treatment cannot be provided regularly without interruption by the presence of such inherent psychosocial issues as resentment, anxiety and guilt was shown to be significantly challenging (3).

2.5.5 Health facility service delivery factors

Studies conducted in Aksum St Marry Hospital, Mizan Aman General Hospital, Jimma University Specialized Hospital and University of Gondar(47) reported that the proportion of LTFU was 9.8%, 26.7%, 28% and 31.4%, respectively. Additionally, a retrospective study from Ethiopia reported that retention of patients in care was a major challenge and varied across health facilities (48).

2.5.6. Care giver/family related factor

One critical aspect closely associated with adherence revolves around the patient knowing the correct dosage of medication to take and the importance of sticking to that dosage especially for chronic conditions such as HIV(8). According to the findings, precise patient knowledge of the role that the prescribed regimen plays in one's medical condition was significantly associated with increased adherence. Closely associated to this is the understanding that better progress and change in clinical response in one's condition is tied to the level of adherence. Given the chronic nature of HIV/AIDS, it is imperative that patients be equipped with necessary knowledge on the benefits of continued medication especially during the asymptomatic period (49).

2.5.7. Health care provider and patient communication

UNAIDS 2015 reported that healthcare providers play a pivotal role with regard to the dissemination of patient information particularly on the correct use of medication. Even with the correct dosage information, several studies have shown that majority of patients often forget the timings of medication which calls for innovative strategies to incorporate reminders such as timed pill dispensers, alarm clocks and friends/relatives (50).

Twenty-four of the 682 children who had been on follow up had not been tested. Records for 12 of the infants cited unavailability of health personnel to take the sample, missed appointment, lost to follow up, negligence of health worker, refusal by the mother, and transfer out as reasons why the test had not been given. The reason was not recorded for the other half of the infants. numerous additional studies have also pointed to the need for a more robust approach in providing patients with information regarding adherence and challenge in implementation to medication including more hospital visits and facility based provision services for HIV prophylaxis (29).

2.6. Conceptual framework

This conceptual framework was developed after reviewing different literatures (4, 6, 9, 15, 20, 25, 24, 26, 29, 43, 46, 48, and 49). The diagram shows the relationship between adherence and challenges in implementation of cotrimoxazole prophylaxis treatment with socio-demographic, health worker, guardian/family, drug and health facility related factors linkage.

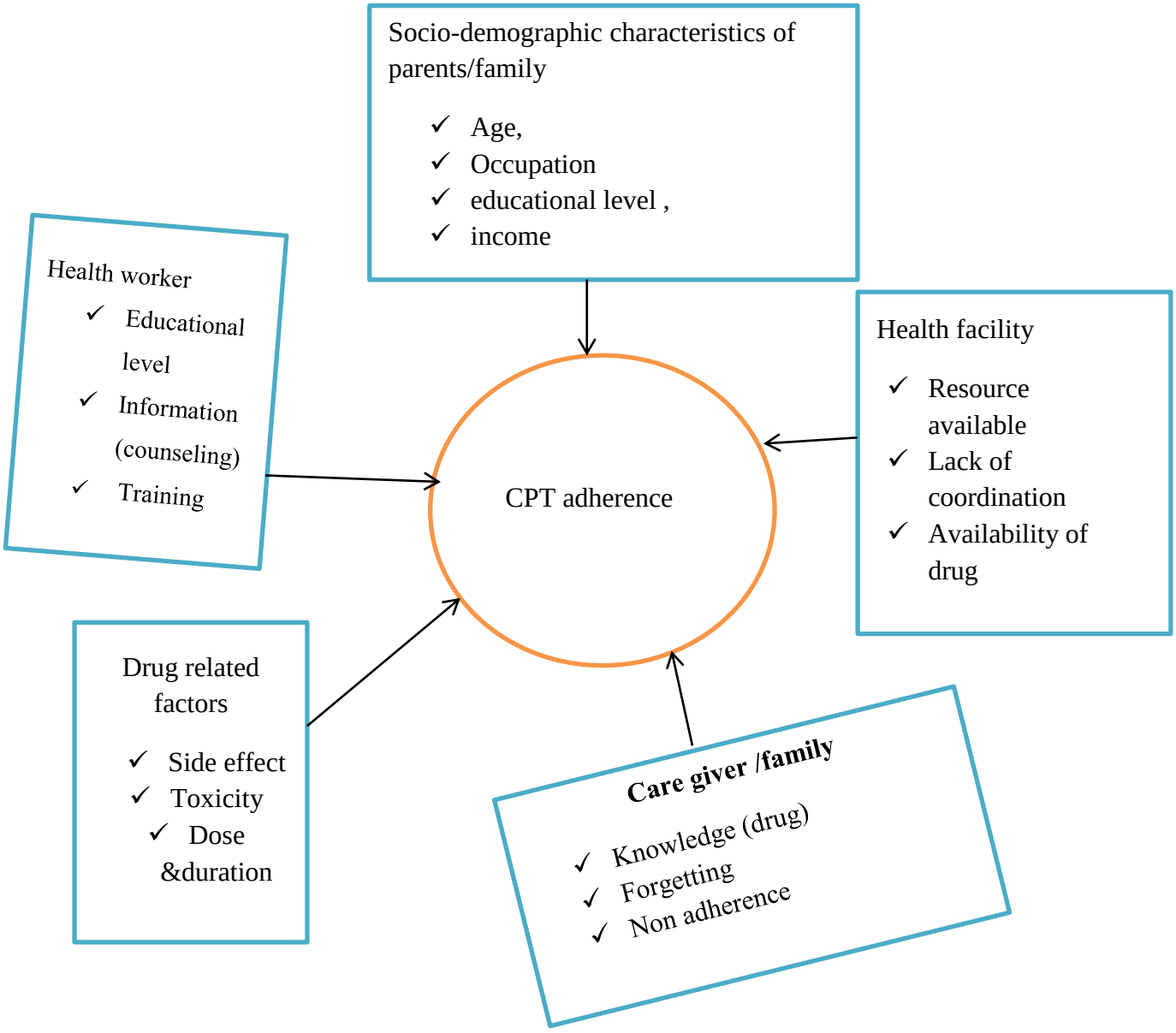

Fig1. Conceptual frame work on adherence and challenge in Implementation of CPT developed from literatures.

3.Objectives

3.1.Generalobjective

To assess adherence and the challenges in implementation of co-trimoxazole prophylaxis among children born to HIV-infected mothers in the governmental health facility ,Ilubabor zone, southwest,Ethiopia,2018.

3.2. Specific objectives

1. To determine level of the CPT adherence in line with standard treatment guidelines among children born to HIV-infected mothers in the governmental health facility, Ilubabor zone south west ,Ethiopia
2. To assess the association between the CPT adherence and associated factors among children born to HIV-infected mothers in the governmental health facility ,Ilubabor zone ,south west Ethiopia
3. To describe challenges in the implementation of co-trimoxazole prophylaxis in line with standard treatment guidelines among children born to HIV-infected mothers among children born to HIV-infected mothers in the governmental health facility, Ilubaborzone ,south west Ethiopia .

4. METHODS AND MATERIALS

4.1. Study area and setting

The study area was governmental hospitals in Ilubabor zone. One of oromia region which is located 600 km away from the capital city, Addis Ababa, Ethiopia. It is bordered on the south by the south nation , nationality and Peoples , on the southwest by the Gambela , on the west by kelem welega zone , on the north by mirab wellega zone , and Benishanigul –gumuz Region, on the northwest by misirak welega zone , and on the east by Jima zone . with an area of 15,135.33 square kilometers.

There are two public hospitals (mettu karl referral hospital and darimu hospital) which are delivering PMTCT service.

4.2. Study design

The study design was a facility based both a retrospective and descriptive study that involve review of the records of children from PMTCT register books of at for past 2 years, and Interviewing health care workers and their parents/guardian of all children at follow up clinic in two public hospital of Ilubabor zone.

4.3. Study period

The study was conducted from March 1 to31, 2018

4.4. Source population

All children born from HIV infected mother and enrolled at PMTCT follow up clinic in the zone governmental public hospital over the last two years.

4.5. Study population

All HIV exposed children from six week to five years of age those enrolled at PMTCT follow up clinic in zone governmental public hospital over the last two years.

4.5.1. Inclusion criteria

Children born from HIV infected mother from 6wk-five years of age and on CPT, Health workers, PMTCT, ART included. Infants whose mothers were not available but their guardian included in the study.

4.5.2. Exclusion criteria

HIV exposed children mother with missed maternal or infant records (chart), and any mother who transferred out of the District before or during the study will be excluded. Mothers who refused to consent or assent their involvement in the study will be excluded and if either of the mother/ guardian or child is critically sick.

4.5.3 Sampling frame

This consisted of all mothers-infant pairs who were within the catchment area of the health facilities and confirmed HIV positive during pregnancy and found in the registers

4.5.4 Sample size determination and sampling procedure

Sample size was calculated using single population proportion formula. retrospective study done in Addis Ababa 56% of infants adhered to cotrimoxazole with 95% CI and 5% marginal error (3).

$ni=(Z_{a/2})^2 \times p(1-p)/W^2$ where ni = initial sample

α =confidence interval

ni= (1.96)2×(0.56) ×(0.44)/ (0.05)2 =378 p= proportion of HEC

w= margin of error

Since the sample has taken from the total population of 420 who have been taking CPT, i.e., <10,000, the final sample size was determined after using the correction factor. So that,

$$nf = \frac{ni}{1+\frac{ni}{N}}$$

nf = 378/1+378/420

= 378/1.916667

= 198

By considering 10% incomplete data = **218**

Sample Size for health worker was calculated as the following by using proportion 89%.

ni= (1.96)2×(0.89) ×(0.11)/ (0.05)2= 150

Correction formula $nf = \frac{ni}{1+\frac{ni}{N}} = \frac{150}{1+\frac{150}{230}} = 90$

By considering 10% non-response rate the final sample size will be **99**

Schematic presentation of sampling procedure

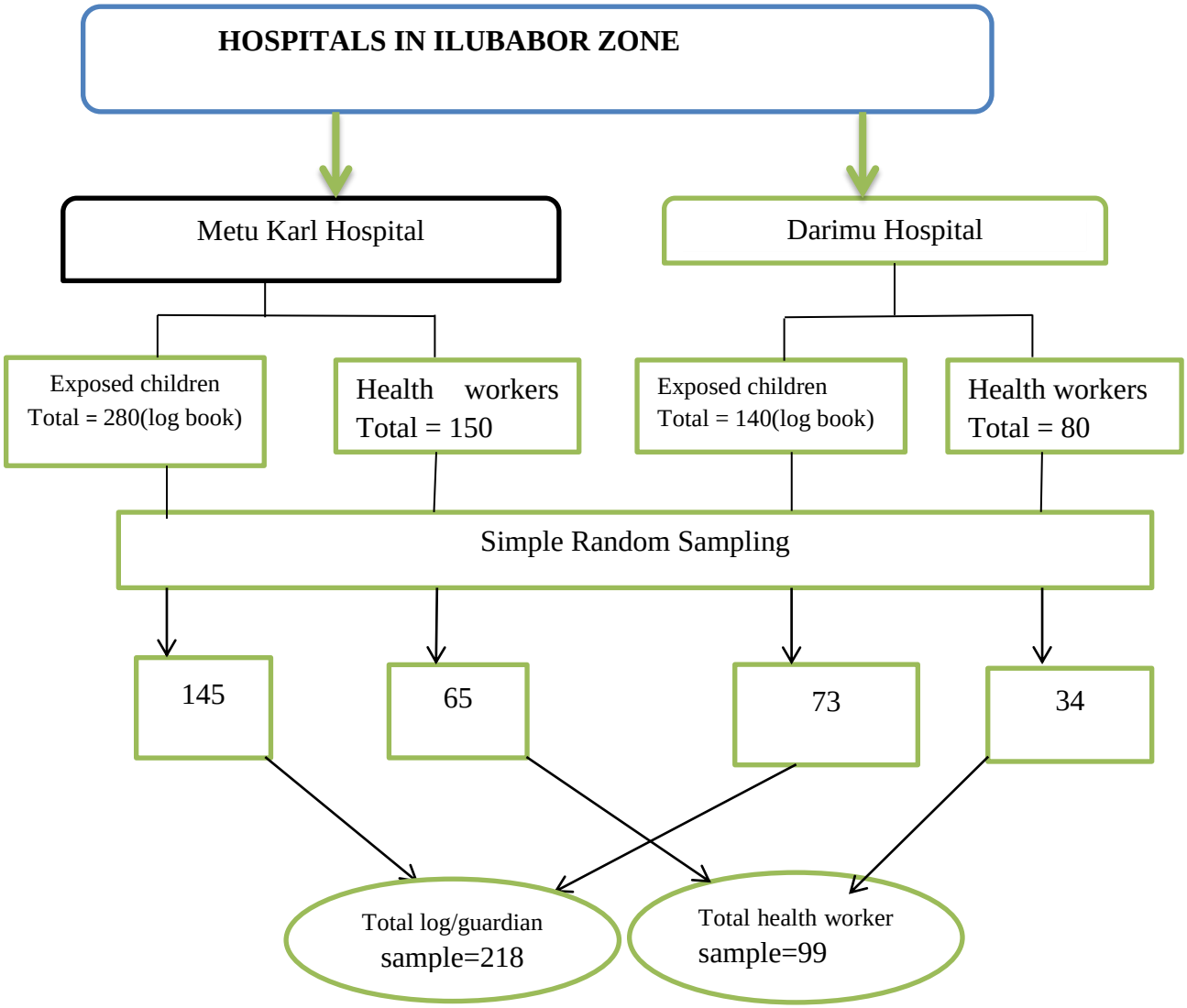

Figure 1. Schematic presentation of sampling procedure

4.6. Sampling technique

Simple random sampling was used to select study units from the sampling frame for both (mother-infant pairs found in the Exposed Infants Register) and Health care workers who were interviewed in this study, directly who were involved in the management of children those born from HIV infected mother.

4.7 Data collection method

Data was collected by using structured questionnaire form to gather information of infants from the PMTCT register books. The data collected through the review of the PMTCT register books and interview parents, guardians /care giver, and health care workers.

4. 8 Study variables

4.8.1. Dependent variables

- adherence of cotrimoxazole prophylaxis
- Challenges in Implementation 0f CPT among children born from HIV infected mother in line with standard treatment guide line.

4.8.2. Independent variables:-

- ✓ Health care provider
- ✓ Documentation
- ✓ Counseling

Health facility related factor

- ✓ Resource availability
- ✓ Availability of drug

Drug related factors

- Side effect
- Dose &duration

Care giver /family

- ✓ drug Information
- ✓ Forgetting
- ✓ Adherence

Socio-demographic characteristics of health care workers, parents/family

- ✓ Age,
- ✓ sex ,
- ✓ educational level , and
- ✓ income

4.9. Data Collection Procedure and Quality Control methods.

Structured questionnaire was prepared in English after reviewing literatures of similar study. The final modified English questionnaire was translated to Afan Oromo. Questionnaire was adapted from research done in Tanzania one supervisor and three data collectors was diploma and BSc holders in health respectively who have experience on it. The supervisors were trained for two days on components of data collection which were data collection procedure, accuracy and completeness of the data .After the training, pretest was carried out on the 5% of the sample done in similar population that were in other health facility, to ensure the quality and validity of the data.

There was frequent supervision and checking of the questionnaire by the supervisors, for its completeness. The principal investigator was also there to handle any problem during data collection. The collected data was reviewed and checked for completeness before data entry.

4.10 Operational definition

Challenge in implementation of CPT: -The factors that hinder implementation of CPT.

Good adherence: taking $\geq$95% a prescribed dose or missed less than 3doses/30 doses (6)

Poor adherence; < 95%, missed $\geq$ 3 doses /30 doses

HIV Exposed children:-children who born from confirmed HIV infected women (51)

4.11. Data analysis

Collected data was entered into and cleared using Epi-data software version 3.1 and then exported to SPSS version 20 for further statistical analysis. Descriptive statistics were used to describe the study participants with major independent and dependent variables. Frequency distribution, bar chart (descriptive statistics) used to describe the major variables of the study. Tables and figures were used to summarize data. Bivariate analysis used to look for association between predictors and dependent variables. Multivariable logistic regression analysis used to control for confounding and to see for the impact of variable of interest on

outcome variable. Odds ratio and p- value was computed to see whether any relation exist between the two variables. P-value less than 0.05 will be considered as statistically significance.

4.12. Ethical Consideration

Ethical clearance was obtained from Research Ethics Committee (REC) of Addis Ababa University, college of Health science , school of nursing and midwifery. 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.

4.13. Dissemination of Results

The result of the study will be disseminated to different organizations; AAU, school of allied health, department of nursing, Ilubabor zone health bureau and other concerned bodies.

The information will be disseminated to the respective bodies (Federal Ministry of Health, Oromia regional state Health Bureau and Ilubabor zone health bureau) and the results will be presented on the scientific forum and published in peer reviewed and internationally reputable journals.

5:-Results

5.1 Socio-demographic characteristics of the study participant

A total of 293 respondents were involved in this study and were drawn from Mettu Karl and Darimu hospital. Concerning the sex, most 272(93%) of the respondents were female and196 (66.9%) of the respondents were married. The result showed that 223 (76%) of the respondents were aged between 24-30 years of age and 141 (48%) of the respondents were orthodox Christians. Regarding education level only 92 (3.4 %) of respondents had primary school education and 80% of the respondents reported an average monthly household income of less than 3000 Ethiopian birr. The results indicated that the majority 280 (95%) of the respondents were non-employed. Some form of non-employed engaged in private business about 94 (32.4%). 70 (24%) of the respondents reported being casual laborers performing various jobs with the least being unemployed representing 33 (11.3%) and 12 (4.5 %) governmental employed and 2 %(6) professional employed NGO (MFM). See (**Table 1.Socio** demographic characteristics of study participants in Mettu Karl and Darimu Hospitals, IAB, Ethiopia, April, 2018 (N=293**)**

Table 1.Socio demographic characteristics of study participants in Mettu Karl and Darimu Hospitals, IAB, Ethiopia, April, 2018 (N=293**)**

Variable	**Category**	**N**	**%**
Age group(years)	24-30	223	76
	30-40	69	23
	>40	1	0.34
Educational status	Primary school and below	92	3.4
	Secondary school	142	48.5
	College and above	47	16
	No formal Education	12	4.1

Marital status	Married	196	66.9
	Divorced	96	32.8
	Widowed	2	0.3%
Religion	orthodox	141	48
	Muslims	136	46
	Protestant	25	8.5
	Others	16	6.0
Occupation	Non-employed	280	95
	Employed	12	4.5
Income(annual)	500-3000	235	80
	>3001-5500	49	16.6

Notes: 24 with incomplete data excluded.

5.1.2 Exposed infants demography

A total of 293 HIV exposed children from recorded data for the past 2 years in the data registry were enrolled into the study. Review of the records indicated that all infants who were registered in the PMTCT register books were born from confirmed HIV-infected mothers in which more than half 158 (54%) of them were in the 13-18 month age group. See fig.3

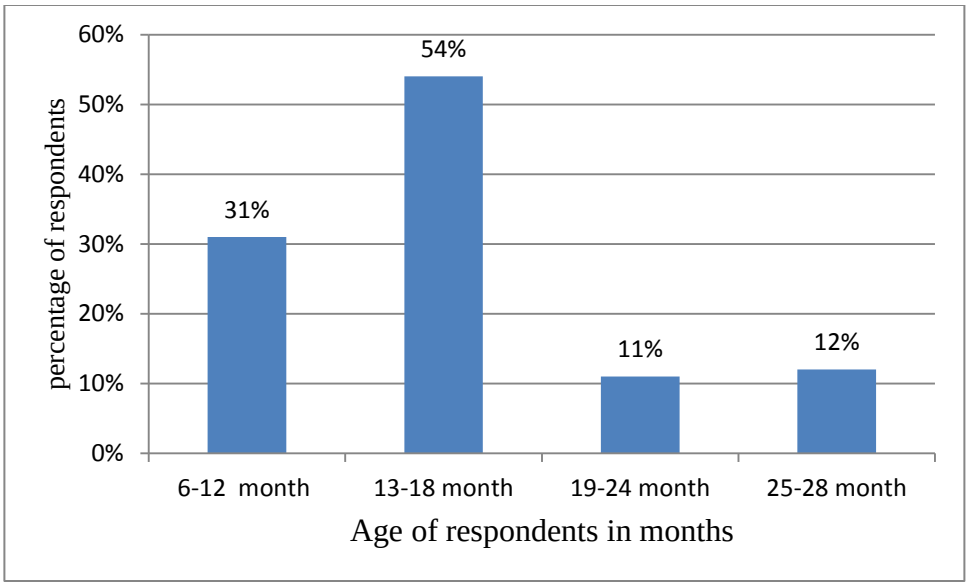

Figure 2: Age distribution of HIV exposed infants

5.2 Awareness of guardians/care takers on opportunistic infections

Regarding the awareness of caretakers towards opportunistic infection related problems only 191(65.5%) of the care taker was aware of opportunistic infections related problems while 75(25.6%) of the respondents were not aware. The majority of participant 88.8% indicated that they had indeed suffered from one or more opportunistic infections**.** See table 2

5.3 CPT use and associated factors.

98.3% of the respondents reported that CPT was part of their current treatment regime while 1.7% indicated that they were not on CPT (do not know) and 60% of the respondents reported that they had missed at least two dose of CPT, 40% had not missed any dose, 20.6% of the respondents had missed one dosses, 28.1% had missed two doses and 9.3% reported missing more than three doses within the one month. See table 2

5.4 Hospitalization and health facility related factors.

The results indicate that nearly half of HIV exposed infants 44.1% had been hospitalized within the last one month and the cause of admission to hospital, diarrhea (18.4%), pneumonia (43.2%) while 9.6% reported having been admitted for various other reasons. 80.5% of the respondents has received regular supply of CPT and 19.5% of respondents reported being unable to acquire the drug when they needed it. see table 2

The most common problem encountered in accessing CPT and other related care at the health facility was frequent drug out of stock (33.8%), followed by long hospital procedures(31.4%) , Unfriendly hospital staff and long distance to the health facility(8.5%). Others like provision of social support 60.8% of respondents were reported not received any form of social support from the hospital while 115(39.2%) had received hospital based social support during their course of treatment. The reported social support consisted of counseling on positive living and nutritional advice**.** See Table 2

Table 1 Measures adopted to increase awareness through counseling on OI and related medical problem n=293

Variables	Category	Frequency	%
Awareness	Appropriate	166	56.7
	Inappropriate	75	25.6
	Others	52	17.7
Related medical problem	Persistent /recurrent diarrhea	54	18.4
	Fever one month and above	70	23.9
	Pneumonia	128	43.7
	Others	41	14.0
Age at which CPT	In Weeks	Frequency	%
	4	8	2.7
	5	6	2.0
	6	95	32.4
	7	26	8.9
	8	130	44.4
	9	15	5.1
	10	9	3.1
	11	2	0.7
	18	1	0.3
No of missed dose	No	frequency	%

	0	108	36.9
	1-3	170	58.5
	>3	15	5.1
Hospitalization	Admitted	44	15.0
	Not admitted	249	85.0

Notes: age at which CPT initiated in weeks

Number of missed doses 0=do not missed the dose

5.5 Health care workers related factors

A total of 94 health care workers were interviewed and majority (99.2%)of the respondents got counseling during treatment in which the patients informed about their drug instructions, benefits of adherence and related issues on CPT. more than half (66.7%) of the health care workers reported to have experienced unavailability of co-trimoxazole pediatric formulations in the health facilities. One -third (28.6%) of the health care workers reported that scarcity of the drug as the main reason for poor adherence and (19.0%) reported a lack of funds to purchase the drug in the hospitals has strong association with poor adherence. In the absence of co-trimoxazole syrup, approximately one-quarter (23.8%) of health care workers gave instructions to parents and guardians to prepare co-trimoxazole suspension using crushed tablets at home. Some health care workers (17.5%) were able to assist parents and guardians by making co-trimoxazole suspension using co-trimoxazole 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.

5.6 Independent predictors of adherence to CPT

Bivariate analysis was used to look for association between predictors and dependent variables. Multivariable logistic regression analysis was done to control for confounding and to see for the impact of variable of interest on outcome variable. Odds ratio and p- value will be computed to see whether any relation exist between the two variables. P-value less than 0.05 were considered as statistically significance.

The strongest independent predictors of poor adherence to CPT are long procedure in getting the drug (OR=9.913 (2.825-34.731), p=<O.000)and kinds of barriers in implementation strongly associated with poor adherence are shortage of drug availability (OR=3.917 (0.649-23.630), p=<O.013) and unfriendly hospital staff (OR=3.725(0.968-14.332,p=0.056). some missed dose greater than three doses (p=<0.022).Other predictors of poor adherence to CPT were care takers reason on CPT thought as a treatment 0f HIV (p=0.023). Other reason for hospitalization were related medical problems like diarrhea (OR=4.324(1.067-17.530, p=0.040) and fever (p=0.067), occupation of care giver (p=0.033) significantly associated with poor adherence of CPT among HIV exposed children. See table 3

Table 3 Factors associated with CPT adherence among HIV exposed children attending Mettu karl and darimu hospital, Ilubabor, Ethiopia, 2018 (N=293).

Variables	**Adherence level n(%)**		**COR** (95%CI)	**AOR**(95%CI)	[p]
	Good	Poor			
Respondents' educational status					
Not able to read	11(91.7%)	1(8.3%)	0.238	0.153(.027-.863)	0.33
Occupation					
Government	7(58.3%)	5(41.7%)	3.649	.153(0.027-0.863)	0.033*
Kind of barrier provision of CPT					
Unfriendly hospital staff	73(94.8%)	4(5.2%)	0.288	3.725(0.968-14.332)	0.056
Long procedure in getting drug	81(88.0%)	11(12.0%)	0.713	9.913(2.829-34.736)	0.00*
lack of drug	67(67.7%)	32(32.3%)	2.507	3.917(0.649-23.630)	0.013*
long distance from home	21(84.0%)	4(16.0%			
facility support yes	90(78.3%)	25(21.7%)	1.624	0.746(0.340-1.638)	0.465
Reason taking CPT					

To Cure from HIVAIDS	39(72.2%)	15(27.8%)	0.833	0.331(0.128-0.858)	0.023*
To Alleviate symptom ,feel heal	190(86.4%)	30(13.6%)	0.342	2.867(0.599-13.708)	0.187
Missed cotrimoxazole					
Yes	137(78.7%)	37(21.3%)	2.026 1.o71	2.692(1.157-6.262)	0.022*
No	105(88.2%)	14(11.8%)		1	0.980
Related medical problem					
Persistent diarrhea	50(92.6%)	4(7.4%)	0.284	4.324(1.067-17.530)	0.040*
Fever	56(80.0%)	14(20.0%)	0.889	3.378(.921_12.397)	0.066
pneumonia	104(81.2%)	24(18.8%)	0.821	3.349(.711-15.772)	0.126
candidiasis	32(78.0%)	9(22.0%	0.002	1.9 68 (o.324-1.753)	0.653
syrup availability					
using crushed tablet	189(81.1%)	44(18.9%)	1.763	0.674(0.243-1.866)	0.447

** Significant at p<0.05, AOR = adjusted odds ratio, OR = Odds ratio, CI = Confidence intervals.*

6. Discussion

The study set out to establish the implementation and determinants of adherence to cotrimoxazole preventive therapy among exposed children on treatment. Initially, this study was conducted to assess the level of adherence to cotrimoxazole preventive therapy and factors associated by using validated tools. This finding of quantitative study in which two health facilities involved indicated, patient self-report and document review indicated that adherence in the month prior to the interview was good (82.6%) while the rest had poor adherence. This proportion of good adherence was higher than that of retrospective study in Addis Ababa 56% (3). This is possibly due to that almost all, [99.5% and 98.2%] of the respondents of this study had good knowledge of CPT and good attitude towards CPT respectively. In addition to this, 99.2% of the respondents got counseling during treatment in which the patients informed about their drug instructions, benefits of adherence and related issues on CPT. But the above stated factors are not significant predictors of good adherence in the final multivariable analysis which may be due to confounding factors in the final model and The probable reason may be; there could be difference in the study population as well as different methods used. Occupation, long procedure in getting the drug, scarcity of the drug, number of missed dose, unfriendly hospital staff, related medical problems and admission to hospital, care takers/guardians knowledge on CPT, and presence of opportunistic infection were statistically significant predictors of adherence in multivariable logistic regression analysis.

Multiple variable Regration was employed to assess whether there was any association between the various socio-demographic variables like age, level of education, occupation and adherence to CPT up take. There was no significant association between socio-demographics factors and adherence to CPT except for occupation ($p<0.033$).occupation is strongly associated with adherence of CPT but not significant with the study done in Tanzania ($p=0.428$) and was align with the study done in South Africa (26). The availability and affordability of CPT and treatment services for opportunistic infections was variously noted as a major factor promoting its utilization is similar with study done in Tanzania (17). Most importantly, the fact that the drug was offered free of charge during HIV related care and management promoted a wider acceptability among care givers. However, occasional drug

stock-outs compounded by long procedure (8.5%) for health services within the hospital were noted as the major barriers to poor adherence the utilization of HIV related care at the hospital which was higher than study done in Kenya (1.6%) this variation may be due to socio economic status or confounding effect. In addition, some of the respondents reported shortage of the drug (33.8%) to get to the facility only to be met by drug stock-outs at the hospital and this was a big contributor to poor adherence more higher than the study done Kenya and Tanzania 6.8%and 0.6% respectively may be due to economic status of the country and confounding effect of other variables (17).

Regarding counseling on awareness of opportunistic infections suffered as a result of HIV related diseases like diarrhea 18.4% (p=0.040,AOR 4.324(1.067-17.530) i.e. those individuals who got counseling was about 4.32 times more likely adherent to their counter parts but it was lower than the study done in Kenya 28.9% may be due to confounding effect of other variable (53, 31, 33)

The main reason for admission to hospital (15%) were care takers awareness on use of CPT about 25.6% do not know what to treat. it was higher than the study done in Tanzania (13.1%).

The finding of this study indicated the number of missed dose was 60% which was higher than the study done in Tanzania (33%) that resulted in suffered from one or more an opportunistic infection (17). When asked about the cause of admission to hospital within the last one month, 43.9% of the respondents reported URTI as the cause of admission with 18.4% reporting diarrheal related diseases. The remaining 9.6% had been hospitalized from other. This can be attributed to the fact that non-adherence to cotrimoxazole is usually associated with increased rates of diarrhea, and hospitalization due to missed dose (53, 17, 31, 12).

Regarding challenges implementation of CPT health workers reported that shortage of drug (p=0.013.AOR=3.917(0.649-23.030) in the health facility, lack support group AOR=0.746(0.340-1.638) and guardians not awareness on reason CPT use P=0.023, AOR=0.33(0.128-0.858) may be due to barriers of adherence not appropriately addressed during counseling.

7. Strength and limitation of the study

7.1. Strengths of the study

This study considered associated factors related to health facility, health workers and guardians/care takers which could potentially be associated with adherence to CPT. Backward stepwise Logistic regression analysis was used to control for the effect of possible confounders.

7.2. Limitations of the study

In this study, only dose adherence of the patients was assessed. Since the patient adherence to CPT level was assessed over the last month prior to the interview, there could be recall bias. Also, since data collectors were health professionals in the respective institutions, social desirability bias could also appear. These study findings were not generalized to all children born from HIV infected mother**.**

8. Conclusion

The adherence level HIV exposed children through guardian self-report and document review indicated that adherence in the month prior to the interview was 82.6%.

The strongest predictors of poor adherence to CPT are long procedure in getting the drugs and kinds of barriers in implementation strongly associated with poor adherence are shortage of drug availability and unfriendly hospital staff. Some missed dose greater than three doses. Others related medical problems like diarrhea and fever were significantly associated with poor adherence of CPT among HIV exposed children

Implementation of CPT guidelines should be central to the delivery of HIV care and treatment. Given the critical role played by CPT in the management of opportunistic infections. In HIV exposed children , hospital management should put in place necessary mechanism to ensure that potentially non-adherent client/patient are identified in a timely manner and that barriers to adherence are appropriately addressed during counseling sessions with health service providers. In addition, since the study identifies social support as key in promoting adherence, facility based strategy could be revised to help identify any barrier to poor adherence.

9. Recommendations

9.1. For health institutions:

- They need to strengthen screening of opportunistic infections and take appropriate management at each visit.
- They need to strengthen counseling of the patient about the importance CPT to their families, parents or guardians to get social support and nutritional education.

9.2. For zonal health

- The health office needs to facilitate the services of CPT use according to the guide line

9.3. For Regional Health Bureau:

- Closer supervision in the implementation of existing guidelines that would enhance adherence to CPT.
- Where applicable, social support can be used (e.g, providing food) and enhanced through incorporating referrals to community based health care workers and NGOs for close monitoring and reminders.
- Documentation during each visit should be improved through continuously updating the health professionals and implementing and adhering strictly to the updated national guidelines.
- Health care workers as the main source of information should be exposed for regular training programme by the hospital to update their skills and knowledge on PMTCT update provide quality care to their clients/ patients

9.4. For Researchers:

- To use different research design to assess the level of adherence to CPT.
- To consider factors related with long-term adherence, which require longer follow-up than this study.

9.5 Non-governmental organizations

To improve community awareness on the importance of adherence to regimen among HIV exposed children should be sustained and improved through social mobilization and advocacy.

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ANNEXES

ANNEXES I. INFORMATION SHEET

English version consent form and questionnaire
Information sheet

Introduction: Hello! My name is _____. I am doing a study on cotrimoxazole prophylaxis up take and challenges in implementation among HIV exposed children

Procedures: We are going to ask you for information concerning about your demographic background characteristics, as well as other topic related to Cotrimoxazole prophylaxis treatment adherence and challenges in implementation among HIV exposed infants .the interview takes approximately 20 minutes to complete.

Confidentiality: I want to assure you that all of your answers will be kept strictly secret. I will not keep a record of your name or address.

Risks and Benefits of the Study: By participating in this study, you will not receive any direct benefit. However, you will help to increase our understanding towards CPT awareness and its associated factors and the result of the study will hopefully serve as an important input to intervention programs that aim at improving HEI health by reducing Opportunistic infection related morbidity and mortality. Your participation in this study will have no risk.

Rights: Your participation in this study is voluntary and you have the right to stop the interview at any time, or to skip any questions that you don't want to answer.

If you need additional information use address; cell phone: - 0912002398,

E-mail :- dessalegnnigatu@yahoo.com.

ANNEXES II. INFORMATION SHEET

Consent Form

I have read the above information, or it has been read to me. I was given the opportunity to ask questions and the question that I have asked have been answered to my satisfaction. I consent voluntarily to participate in the study and understand that I have the right to withdraw from the study at any time.

Signature of volunteer: _____ Date: _____

Name of data collector	Signature	Date
_____	_____	_____

Questionnaire

Name of location._____
Date of interview._____

SEMI-STRUCTURED INTERVIEW SCHEDULE

Interviewer's name ……..

Date of interview ……..

PMTCT site name …….

Questionnaire No . …….

Status of Respondent

Tick appropriate box

Case (indicate PMTCT No.) _____

Date of Delivery_____ Day/Month/Year

part 1 Demographic Characteristic of guardian or parents

Q101	**Marital Status**	❑ Married ❑ Divorced ❑ Widowed ❑Single
Q102	Level of Education	❑ Primary(1-8)

		❑ Secondary(9-12) ❑ diploma ❑Degree ❑ Others
Q103	Religion	❑ Protestant ◘Catholic ❑ orthodox ❑ Muslim ❑ Others (specify)……
Q104	How old are you?	----------in year.
Q105	What is the age of the child?	……years and months
Q106	Current Weight of the child	---------kg
Q107	HIV status of the child	Confirmed HIV status Unconfirmed HIV status
Q108	How much income do you earn per month ? In ETB	◘ Less than 1000 ◘ 1000- 5000 ❑ 5001-10,000 ◘ Above 10,000
PART 2: Health facility factors		
Q201	Did you encounter any barriers accessing cotrimoxazole preventive therapy?	❑Yes ❑No ❑I do not know
Q202	If yes, what kind of barriers did you face with provision of drug?	❑ Unfriendly hospital staff

		❑ Long procedure in getting drugs ❑ Lack of drugs ❑Long distance from home ❑Lack of drug information from the clinic staff ❑ Lack of privacy and confidentiality ❑ any other (specify)_____
Q203	Does the facility offer any support group services for HIV exposed child?	❑Yes ❑ No
Q204	If yes, What types of services?	----------
Q205	**How you get cotrimoxazole?**	**☐ free** **☐ fee** **☐ others (specify)**
Q206	Why taking this drug	☐To cure me from HIV/AIDS ☐To alleviate the symptom and feel healthy ☐Other specify ……..
Q207	Have missed co-trimoxazole at the health facilities in one or more occasions?	**☐yes** **☐No**
Q208	**If ,yes**	☐ Lack of transport facilities to attend scheduled clinic visits . ☐ Lack of pediatric co-trimoxazole formulation in the hospitals ☐ lack of refrigerators **☐Other specify**
	Have you changed the dose?	**☐Yes** **☐No**

Q209	If yes,What was the main reason for altering the doses of co-trimoxazole?	☐**Specify**
Q210	What are the main challenges for the provision of co-trimoxazole prophylaxis to children at home?	**specify**
Q211	The most frequently experienced side effects	☐**Rash** ☐**Vomiting**
Part 3 Health care provider related question		
Q300	**profession**	☐ physician ☐ nurse ❑ Health officer ☐ others
Q301	**Place of work**	☐Under five OPD ☐PMTCT ☐in patient /WARD/ ☐ANC ☐ART Other _____
Q302	Which category of HIV infected persons are most at risk of dying from opportunistic infections? Why?	
Q 304.	What messages on opportunistic infections are available to those infected?	
Q305.	What measures can be adopted to increase awareness and uptake of Cotrimoxazole preventive therapy by HIV /AIDS infected child?	❑Appropriately according to the guideline ❑Inappropriately ❑other specify…….
Q306	What are the challenges in provision of care and treatment child born from HIV infected mother in this hospital?	❑Lack of pediatric formulation ❑Unavailability of pediatric guide line ❑ Difficulty in determination of weight of the child ❑Heavy patient load

Q307	What facility factors influence availability of cotrimoxazole pediatric formulation ?	❑Scarcity of the drug from the central medical stores department ❑Lack of funds to purchase essential medicines in the hospitals ❑Others(specify)_____
Q308	Is there Any contra indication CTX ?	Yes No
Q309	How you solved syrup unavailability in health facility?	❑Using crushed tablets at home ❑Come back to the health facilities the next day with anticipation that the drug will be available during that time ❑Other specify
Q310	What play major role in poor adherence?	❑ Distance ❑Forget fullness ❑Unavailability of drug ❑difficulties in understanding how to use the drug ❑Other (specify)
Q311	which are considered by health care workers as a prerequisite for the initiation of co-trimoxazole prophylaxis	❑Weight of the child ❑ age of the child, ❑commitment of parents and guardians to administer co-trimoxazole to a child at home, ❑confirmed HIV status of the mother and ❑commitment of parents or guardians to follow the scheduled visits to the clinics
Q 312	What are Barriers for effective implementation of co-trimoxazole prophylaxis in HIV exposed children.	❑These included lack of pediatric co-trimoxazole formulations ❑unavailability of upto-date treatment guidelines for co-trimoxazole prophylaxis ❑difficulties in the determination of the weights of children for calculation of doses ❑heavy patient load ❑Others

Q313	How effective against many opportunistic infections in children?	
Q314	What are the major barriers?	
Q315	What are contributing factor to failure in adherence to CPT?	❑Lack of knowledge among parents and guardians regarding the use of co-trimoxazole ❑shortage of co-trimoxazole ❑ attitude of parents and guardians regarding the use of co-trimoxazole for the prevention of opportunistic infections in children
Part 4	**care taker related factor**	
Q400	Who is care provider?	❑Mother ❑Father ❑Guardian /sibling
Q401	Does the child Know his/her HIV status?	❑Yes ❑NO
Q402	If yes, does he/she know that you are taking cotrimoxazole	❑Yes ❑NO
Q403	What the advantage of taking cotrimoxazole? Specify…….	
Q404	Do you pay for cotrimoxazole?	❑Pay ❑free
Q405	Why taking this drug?	❑To cure me from HIV/AIDS ❑To alleviate the symptom and feel healthy ❑Other specify ……..
Part 5	Register books review(As per national guide line)	
Q 501	Age of the child	
Q 502	Weight of the child	

Q503	Duration of treatment	
Q 504	Any drug interaction	
Q 505	CD4 count of the child	
Q 506	Age at which CTX started	
Q 507	Dose of the drug (current)	
Q 508	Discontinuation of CTX	❑Yes ❑NO
Q 509	If yes, why?	❑Side effect of the drug ❑Scarcity of drug ❑Toxicity ❑Other (specify)
Q 510	HIV infection WHO staging	❑Stage 1 ❑Stage 2 ❑Stage 3 ❑Stage 4
Q 511	CD4 count within 6month	_____/mm^3
Q 512	Follow up HIV exposed the children	Scheduled Unscheduled
Q513	If un scheduled ,duration?	❑<01 month ❑01-2. month ❑> 3month of loss of follow up
514	Documentation related to adherence /tolerance to CTX	❑Good ❑Fair ❑Poor
515	Is the child breast feeding currently?	❑Yes ❑NO
516	If yes, Do you know the status of the child?	Negative ❑ Ag ❑ Ab Positive ❑Ag ❑Ab
517	Do you know when you miss the drug is there effect on your health	❑Yes ❑NO

518	If yes .how many dose you miss in one month	
519	Why , you miss the dose (challenge)?	
520	Did the baby suffer from any of these conditions?	❑ Persistent recurrent, diarrhea: 2 loose stools/ day for more than 30days ❑ Fever lasting more than one month recurrent/ continuous ❑ Pneumonia ❑ Candidiasis: oral____ ❑ Delayed milestones ❑ Regression of attained milestones

ANNEXES III. INFORMATION SHEET
Afaan oromo version

Gucaa gaafii fi deebbii Afaan oromoo

Waraqaa ibsa

Gafii Waraqaan gafii kun kan qopha'e ragaa hojiira olma qorcha kotrimoxazoli guufuu ka taa'aan qorachuu ta'aa

Waligaltee

Nagaa

Seensa;

Maqaan koo _____ jedhama. Ani kan hojjachaa jiru ragaa qoranaa Univarsitii Finfinne,

fakalitii sayinsii fayyatti walin ta'uun matta dure "hojira olma qorcha kotrimoxazolii gufuu ta'aan " irratti gageefamuuf ragaa funanuu dha.

Maqaan keessan guca kana irratii hin-bareefamu, akkasummas ragaa naa keenitan walin qabsifamees itti hin-fayyadamamu. Gafiin isin deebisuu hin-barbanne yoo jiratee dhisuun mirga keessan ta'e yeroo barbaadanis gafii fi debii gageesinu dhabbu ni-dandeessu.

Haa ta'u malee, gafilee hundaaf deebiin sirii ta'e kayoo qoranaa kanaf bahee ni-barbachisadha.

Hirmaachuudhaaf fedhii qabduu?

❑Eyee ❑ lakkii

Gafii fi deebi kana xumuruuf sa'aa walakaa ta'u nutti ni-fudhata.

Mallattoo gaafaataa, Namni gaafatamu kun waligatee issa jechaan ibsu isaa mirkaneessuuf

_____

001. Lakkoofsa waraqaa gafii /_____/_____/

002. Maqaa nama gaafatuu _____

003. Guyyaa gafii fi deebbi _____

004. Teesso; 1. Magaala 2. Badiyaa

005. Frii: 1. Hundi guutame 2. Walakaa guutame. 3.kan biraa (Ibsi)

To'ata hordofe; Maqaa _____, Mallattoo___

Tick sanduka kessat malato kana fayyadama ☑

Lakkofsa kardii (PMTCT No.) _____

guyyaa itti dessee _____ guyaa /ji'aa/wagaa

Kutaa,1 :- seenaa haadhaa mucaa

Q101	Halaa fudhaa fi heeruumaa	❑ kan abbaa mana qabduu ❑ kan abbana hiikte ◘ kan abba malee jiratu
Q102	Sadarkaa barnootaa	❑ kutaa 1-8 ❑ kutaa 9-12 ❑ diplooma ❑Digrii ❑ gara biraa
Q103	Amantii	❑ Protestanti ◘katolic ❑ ortodoxi ❑ Muslima ❑ gara biraa (ibsii)……
Q104	Umurii haadhaa …….waggaatin	_____
Q105	Umurii mucaa	……waggaa and ji'aan
Q106	Ulfatina qaama mucaa	---------kg
Q107	Fayyaa mucaa	
Q108	Maalaqa ji'aan argatu ?	◘ < 1000 jia'an ◘ 1000- 5000 ❑ 5001-10,000 ◘ 10,000 oli
Kutaa 2: haalawwan dhabataa fayyaa kessati		

Q201	Qoricha kotrimoxazle jedhamu argachuuti rakkoon simudate jira?	❑eyye ❑lakkii
Q202	Maaltu simudate?	❑ walitti dhufeenya hojeettota fayyaa qabdu ❑ halli qorch itti argataan dheerachuu ❑ qorcha hinjiruu ❑karaa dheera ta'uu ❑wa'ee qorchaa isaa hubannoo dhabuu ❑ ofti amanamuumaa ❑ kan biraa yoo jiratee?
Q203	Hospitaalich karaa gara biraa ittin singargaruu jiraa?	❑eyyee ❑ lakkii
Q204	Yoo jiraatee maalifaadha? ibsii	----------
Q205	kotrimoxazoli kan argata jirtuu?	☐ eyyee ☐ lakkii
Q206	kotrimoxazoli kan akkamitti argata jirtuu?	☐ bilisa ❑ kafaltii
Q207	Qoricha kana hospital kessa argacha jirtu?	☐lakki ☐eyee
Q208	Yoo argacha hinjirtan ta'ee, Sababa isaa ibsa	☐hinjiruu ☐giddutti citeet ☐rakkin dhiyyessa/ waaligaltee dhabuu
Kutaa 3 haala hojjeetaa fayyaadhan walqabate kan jiru		
Q301	Ogumaa	☐ Doktori ❑ laboratori ☐ narsi ❑qondala fayyaa ☐ farmasi ❑ogeessa gorsa
Q302	Dhukuboota caraa argachuudhaan ijoolee midhaan kessaa isa kami? ? maalif?	
Q 304.	Gorsa akkamiit isaan barbachisa?	
Q305.	Hubannoo itti fayyadama kotrimoxazoli guddisuuf ,barsisa kennite?	

Q306	Gufuu gurguddaa kan ta'aan isa kamii?	❑formulaa ijoolee qophaayee dhibuu ❑ guide line(qajeelifama dhibuu irra kan ka'ee ❑ ulfatina qaama mucaa ❑ bayyina dhukabusatoota
Q307	Rakkoon hospitala kessa walqabatee jiruu, ibsi?	
Q308	Qorcha akkan hinfudhanee danqaa kan ta'ee jira?	
Part 4 maati ijooleen walqabatan kan jiru		
Q401	Dhukbaa mucaa beeka/taa?	❑eyee ❑lakkii
Q402	Guyaati akkamin fudhata,laataaf?	❑eyee ❑lakii
Q403	Fayidaan kotrimoxazoli maalii? ibsi…….	
Q404	Qoricha kana akkamiin argata?	❑kafaltii ❑bilisa
Q405	Maaliif qorcha kana fudhata?	❑HIV irra fayyisuuf ❑dhukkboota garagaraa irra fayyisuuf ❑kan biraa yojirate ibsii ……..
Part 5 Gucaa galmee irraa ittin guutamuu		
501	Umurii mucaa	
502	Ulfatina qaama mucaa	
503	Lakkofsa CD4	
504	Umurii itt kotrimoxazoli jalqabde	
505	Ungami laatama	
506	Yoo gargar kutee?	❑eyee ❑lakkii
507	Sababa ittin gargari kutee?	❑dhibuu qorchaa ❑dhibee qorchaan dhufuu ❑kan biraa (ibsii)
508	Sadarkaa isaa(WHO staging)	❑Sadarka1 ❑sadarka 2 ❑sadarka 3 ❑Sadarka 4
509	Lakk CD4 ji'aa 6 kessat	_____/mm^3

510	Deedebisa akkami ittin	❑Yeroodhaan/guyyaa beelamameen) ❑Irra dabareee
	Guyyaa beelama irra dabarste?	❑<01ji'aa ❑01-2ji'aa ❑> ji'aa
511	Galmee ittifufinsa qorcha	❑gaaridha ❑umami tokko gaaridha ❑gad aanaadha
512	Harma haadha osisa jirta??	❑eyyee ❑lakkii
513	Kan faayyaa mucaa beekataa?	
514	Yoo gargar kutee waan simmudatu beekta?	❑Eyyee ❑lakkii
515	Sababa ittin gargari kuttuu maalifa?	Ibsii
516	Ji'aa kessat meeqa dhista?	
517	Akka gargar kuttu rakkina kan ta'ee maalifafa?	
518	Yeroo bayyee dhukubaa maaliin dararama?	❑ gadbaasaa ji'aa oli ❑ ho'aa qaamaa ❑ qufaasisaa ❑ dhukubaa afaan kessa ❑ gudina qaamaa