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MSc. Thesis

ASSESSMENT OF MEDICINE USE AND ASSOCIATED OUTCOMES AMONG PREGNANT WOMEN VISITING ANTENATAL CARE UNITS IN PUBLIC HEALTH FACILITIES IN BUTAJIRA, SOUTH CENTRAL ETHIOPIA

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Assessment of Medicine use and associated outcomes among pregnant women visiting antenatal care units in Public Health Facilities in Butajira, South Central Ethiopia

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This is to certify that the thesis prepared by Deribe Woldesenbet Arficho, entitled: Assessment of Medicine use and associated outcomes among pregnant women visiting antenatal care units in Public Health Facilities in Butajira, South Central Ethiopia and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Pharmaco-epidemiology and Social Pharmacy complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Table of contents Pages

List of Tables pages

List of appendices **Pages**

Acronyms

ANC:	Antenatal care
AOR:	Adjusted odds ratio
APGAR:	Appearance, Pulse, Grimace response, Activity, Respiration
CEO:	Chief Executive Officer
CI:	Confidence interval
COR:	Crude Odds Ratio
CSA:	Central Statistics Agency
EDD:	Estimated date of delivery
Epi-info:	Epidemiological information statistical software
GDM:	Gestational diabetes mellitus
MCH:	Mother and child health
NTD:	Neural tube defect
OPD:	Outpatient department
OTC:	Over the counter
PIH:	Pregnancy Induced Hypertension
POM:	Prescription Only Medicine
SPSS:	Statistical Package for Social Sciences
STI:	Sexually Transmitted Infection
US FDA:	United States Food and Medicine Administration
UTI:	Urinary Tract Infection
WHO:	World Health Organization

Abstract

Introduction: Medicine use during pregnancy is a growing trend in the world. Medicines easily cross the placental barrier into the fetal body and are present also in the maternal milk. Exclusion of pregnant women from clinical trials has left questions about the safety of medicines in pregnancy. There were no such studies which assess the medicine use pattern and associated outcomes among pregnant women in Butajira. Hence this study attempted to fill such gaps.

Objective: To assess medicine use pattern and associated outcomes among pregnant women visiting antenatal care unit in public health facilities in Butajira.

Methods: Institution based prospective cohort study design was employed by interviewing pregnant women who were on routine antenatal care visit and waiting them until they give birth. Study participants were waited from March, 2018-November, 2018. Interview included recent medicine use history. Clinical data was obtained by abstracting the records of women who attended Antenatal Care follow up.

Result: A total of 399 pregnant women were included in this study, of whom 382(95%) of them had taken at least one medicine during pregnancy, and 24(6%) of them had self-medicated themselves. From prescribed medicines for pregnant women, Iron with folic acid was the most (937, 71.5%) prescribed medicine while Zingeber officinale; ginger was the most (4, 36%) used traditional medicinal herbs used by the pregnant women. Medicines were prescribed from all FDA pregnancy risk categories. In this regard, from the total of medicines used by pregnant women, 978(73.3%) were from FDA pregnancy category A, 194(14.5%) were from category B, 128(9.6%) were from category C, 25(1.9%) were from category D, and 1(0.08%) were from FDA pregnancy category X.

From 377 study participants with outcomes of pregnancy (Apgar score, birth weight and term of delivery); 56(15%) had poor pregnancy outcomes while 321(85%) had good pregnancy outcomes.

Conclusion: The majority of the study population used safe and appropriate medications. However, though low, a limited number of pregnant women were exposed to medications with potential risk for the fetus. Besides, although few, pregnant women reported the use of traditional medicinal herbs for which pregnancy risk level was not assigned. No statistically significant association was observed between medicines used in this study and pregnancy outcomes.

Keywords: Pregnancy, Apgar score, Medicine use, Birth weight, Term of delivery, Butajira.

1. Introduction

1.1. Background

Medicine use during pregnancy is a growing practice in the world. Medicines easily cross the placental barrier into the fetal body and are present also in the maternal milk. Therefore, it may affect the development of the child before and after birth (Ross et al., 2015).

The use of medications during pregnancy has been an issue of concern since the discovery of birth defects resulting from thalidomide use in early pregnancy during the 1960s. The medicine interfered with the babies' normal development, causing many of them to be born with phocomelia, resulting in shortened, absent, or flipper-like limbs (Fintel et al., 2009).

The majority of medicinal products administered to a pregnant woman could have effects on the fetus. Hence, medicine prescribing in pregnancy would require good knowledge of teratogenicity, fetal and neonatal effects that are associated with the medicines under considerations (Zachary et al., 2011).

Therefore, in order to optimize the knowledge about any potential teratogenic effects of a medicine and the doses at which such effects will develop, it is desirable to gather information about all medicinal products taken by pregnant women. There is an increased risk of reduced fetal growth (intrauterine growth restriction) in women who use medicines (Briggs et al., 2012).

Pregnant women are generally excluded, for ethical reasons, from randomized clinical trials in medicine development. This has left questions about the safety of new medications on the developing fetus unanswered, upon medicine approval and marketing (Petryna, 2009).

However, to guide safe medicine use during pregnancy, the U.S.A. Food and Medicine Administration (FDA) classified medicines into the following major categories; A, B, C, D, and X with categories D and X indicating evidence of risk in pregnancy (Mitchell et al., 2011).

Safety information regarding medicine use in pregnancy is gathered through case reports, epidemiological studies and animal studies, all of which have limitations. Results related to effect of medicine on pregnant animals cannot always be extrapolated in human population (Kebede et al., 2009).

1.2. Statement of the problem

For most medicines there is a serious lack of comprehensive and valid data concerning their teratogenic risk in human beings. Pharmacological treatment should be avoided in pregnancy, unless absolutely necessary (Eze et al., 2007).

Thus, administration of a medicine to a pregnant woman represents a unique problem for the attending physician, not only in alleviating maternal suffering but also not to harm the fetus. Regardless of the limited information on the safety of medicines in pregnancy, medicine use in pregnancy is common. Also pregnant women are prescribed medicines to treat pre-existing chronic conditions such as diabetes, hypertension or epilepsy or to treat pregnancy related disorders such as pregnancy induced hypertension and gestational diabetes (Gilboa et al., 2011).

Additionally more women taking any kind of medication have been doubled in the last 30 years. Current evidence suggests that between 65-94% of women take at least one prescription medicine during pregnancy. Nearly 70% of women are taking medication in the first trimester during organogenesis. On average, women are taking 3 medications in pregnancy with over 50% of women using four or more (Thall Bastow and Holmes, 2016).

In the developing world, including Ethiopia low level of educational status of mothers, lack of up to date information for health care providers, especially relatively for low level health institution workers like health centers and low level of training of health care providers at health center level could aggravate irrational use of medicines during pregnancy (Kebede et al., 2009).

Study conducted in Fiche primary hospital, Ethiopia, out of the total medicines prescribed, category A medicines comprised 20.83%, category B (26.34%), category C (24.34%), category C/D (9.65%), category D (9.43%) and category X (1.09%) (Fikadu et al., 2015).

It has been estimated that up to 10 % of congenital anomalies may be caused by environmental exposure i.e., exposures to medications, alcohol, or other exogenous factors that have adverse effects on the developing embryo or fetus. Hence it is necessary to avoid all potentially adverse exposures. Approximately 3-5 % of live births are complicated by a birth defect each year totaling around 120,000 babies. This is in part contributed by medicine and chemical exposure of women during pregnancy (Thall Bastow and Holmes, 2016).

In contrast to the marked decline in neonatal mortality, the rates of LBW and preterm births continue to increase. Therefore, it would be important to assess the extent to which prenatal medicine use would increase the risk of LBW, prematurity, and intrauterine growth restriction (Bada et. al., 2005).

Study which conducted in Addis Ababa, Ethiopia showed that Sixty-four new cleft lip and palate patients were recorded in the study institutions which gives an incidence of 1.49/1000 live births or 1 in 672 live births of which the exact cause is not elucidated (Eshete et al., 2011). Another study conducted in central and northwest Ethiopia, showed the magnitude of birth defects were common and making it a growing health problem (Afework et al., 2016). Low birth weight is a common health problem in developing countries. The Incidence of Low birth weight was 13.2% in Diredawa city, Ethiopia (Yemane, 2016). Therefore, judicious use of medicines, adequate knowledge, positive approach and awareness towards the medicine use are mandatory prerequisites for good maternal and child health (Adhikari et al., 2011).

1.3. Rationale of the study

Pregnancy management using medications has been challenging to both health care providers and pregnant women given the fear of teratogenic effects and the potential for fetal harm. It has been estimated that up to 10% of congenital anomalies may be caused by environmental exposure-that is, exposure to medications, alcohol, or other exogenous factors that have adverse effects on the developing embryo or fetus (Finnegan, 2013).

There were only a few such researches that describe the extent and type of medicines prescribed during pregnancy in Ethiopia and there were no such studies which assess the medicine use pattern and associated outcomes in pregnant women conducted in Butajira.

Therefore, this study was conducted to determine the type and extent of medicine use and associated outcomes among the pregnant women attending antenatal outpatient department (OPD) of public health facilities, which are found in Butajira and describe the pregnancy risk level of medications used during pregnancy according to the US-FDA pregnancy risk classification of medicines.

It was believed that, assessing the pattern of medicine use in pregnancy and informing the concerned body for possible intervention of the correct medicine utilization of pregnant women would have a paramount importance to improve service quality and also assessing association of medicine use in pregnancy with maternal and neonatal outcomes would also help to improve medicine utilization service in pregnancy and to formulate national policies depending on the study findings.

2. Literature review

2.1. Medicine and pregnancy

Pregnancy is special physiological conditions, where medicine treatment presents special concern. Pregnancy care is one of the great challenges in medicine because therapies and protocols may affect the life of mothers and babies. Diseases occurring during pregnancy are even more dangerous, because of the difficulties in their treatment strategy. Prevention must be emphasized using safe and natural medicines (Gilbert, 2010).

Pregnancy symptoms and complications can range from mild and annoying discomfort to severe, sometimes life-threatening illnesses. Sometimes it can be difficult for a woman to determine which symptoms are normal and which are not. Problems during pregnancy may include physical and mental conditions that affect the health of mother or baby. These problems can be caused by or made worse by being pregnant. Many problems are mild and do not progress; however when they do, they may harm the mother or baby. Anemia, urinary tract infection, mental disorder, hypertension, gestational diabetes mellitus (GDM), obesity and weight gain and hyperemesis gravidarum are common conditions which are caused or exacerbated by pregnancy (CDC, 2016).

Pregnancy is a unique period in a woman's life. Many changes are happening to her body that may affect the pharmacology of medications. During pregnancy, a woman's gastric pH is increased and gastric motility is reduced which may interfere with the rate and extent of medication absorption. Maternal plasma volume is increased leading to changes in the volume of distribution. In addition, increases in progesterone and estradiol levels may affect the hepatic metabolism of some medications. Glomerular filtration rate is increased due to increase renal blood flow which may affect renally cleared medications (Bulloch and Carroll, 2012).

Pregnancy is the most precious time period a woman goes through in her life. It constitutes special physiological changes that prevail a herculean task for the doctors in managing the disease condition and to ascertain the appropriate medicine management. Medicine treatment during pregnancy is always a special concern since every medicine is potentially harmful to fetus. In general, no medication is recommended during pregnancy unless it is indicated for any severe condition because many medicines used in maternal period can be teratogenic (Sasidharan and Kolasani, 2017).

Concern about the safety of medicines prescribed to pregnant women has been increasingly evident since the thalidomide crisis in the 1960's and the teratogenic effects of use of diethylstilbestrol in 1971, which led FDA to demonstrate safety and efficacy of any medicine before it is marketed However, pregnant women are generally excluded from clinical trials for fear of potential hazardous effects to the developing fetus (Sheffield et al., 2014).

2.2. Epidemiology of medicine use in pregnancy

Approximately 10% of infants are exposed to alcohol in utero, and 20% are exposed to nicotine. In addition, pregnant women may expose their fetuses to other legal medications (ie, nonsteroidal anti-inflammatory medicines, salicylates, angiotensin-converting enzyme inhibitors, warfarin, and others) that are not known to have abusive potential but that are known to adversely affect the fetus (Christensen et.al, 2015).

The prevalence of illicit medicine use among Canadian women of child bearing age is less but not insignificant. In United States population surveys approximately 5% of pregnant women reported illicit medicine use during pregnancy. Marijuana remains the most commonly used illegal medicine, followed by cocaine.

Women report higher rates than men of prescription medicine use, including pain relievers (23.1%), opioid analgesics (2.1%), sleeping pills (1.7%), tranquilizers (1.1%), and antidepressants (2.1%) (Wong et al., 2011).Illegal medicine use among pregnant women in USA in 2010 was 4.4% (Behnke and Smith, 2013).

According to a study conducted in India, medications which were commonly prescribed to pregnant women include vitamin and mineral supplements, intravenous fluids (IVFs), antiemetic medicines, antimicrobials, anthelmintic medicines and analgesic medicines (Sasidharan and Kolasani, 2017).

The study done in Ethiopia by Mohammed *et al*. (2013) showed that 55.2% had used at least one prescription only medications (POM) during pregnancy. Majority 56.3% of medications used were from category-C followed by category-B 48.7% and category-A, 35.4%. 16.8% and 7.1% were from category D and X respectively. Statins and warfarin were medications from category-X. The most commonly used medications were antibiotics (42.5%) and analgesics (40.1%).

Another study conducted in Southern Tigray region, north Ethiopia showed that 87.5% pregnant women were prescribed with at least one medication. As per the United States Food and Medicine Administration (US-FDA) risk classification system, 87.7%, 7.9%, 3.9%, and 0.5% of the prescribed medicine were from category A, B, C and D, respectively (Molla et al.,2017).

Study conducted in Addis Ababa showed that 95.2% pregnant women used at least one medicine during their pregnancy including iron/folic acid combination (excluding vaccination) and forty two different medicines were prescribed during all pregnancy stages (Etefa and Kahissay, 2015). Study by Kebede *et al*. (2009) in Addis Ababa also showed that 71.3% of study participants were prescribed at least one medicine during pregnancy.

2.3. Prescription of medicines in pregnancy

Prescribing medicines to pregnant women takes place in Antenatal Care Follow up (ANC),which is organized medical service including examination and advising a pregnant woman with the objective that every wanted pregnancy culminates in the delivery of a healthy baby without impairing the health of the mother (Gawde, 2013).

Antenatal care provides an opportunity to assess women's health and also provide some essential services such as tetanus toxoid injections (TTI), iron folate, malaria, STI and other treatments. It also serves as a gateway to inform and educate pregnant women on a variety of issues related to pregnancy complications, where to seek care if complication arises, and birth preparedness (Henok and Jelkeba, 2015).

Medicines taken by the pregnant mothers for therapeutic purposes may cause dangerous structural and functional adverse effects in the growing fetus. All the marketed medicines are not studied to a complete extent that they have proved to be safer in pregnancy, and hence, for this obvious ethical reason, most of the medicines are not recommended to be used during gestational period (Sasidharan and Kolasani, 2017).

Despite the common belief that the use of medications should be avoided in pregnancy, there are several conditions in which it is almost impossible to prevent medication use. There might be chronic conditions which are already present before pregnancy, such as epilepsy, psychiatric disorders and HIV/AIDS, which need continued treatment during pregnancy. There are also conditions which occur during pregnancy, such as nausea, diabetes mellitus and hypertension, which may also require treatment. Pregnant women may also develop acute illnesses which are short term and often self-limiting but which require treatment (Etefa and Kahissay, 2015).

2.4. Guidelines for assessing reproductive risk of medicines

In order to guide health care providers in prescribing medicines to pregnant women several classification systems have been developed based on human evidence, and when unavailable, on animal data. The commonly used classification was the U.S.A. Food and Medicine Administration (FDA) classification which classifies medicines into the following major categories; A, B, C, D, and X with categories D and X indicating evidence of risk in pregnancy. The purpose of these classifications is to give information to health care professionals about possible or established risk or safety of using medicines during pregnancy (Pollock et al., 2007).

Later on however, FDA learned that the pregnancy category letters were confusing and did not accurately and consistently communicate differences in degrees of fetal risk. To overcome that ambiguity FDA have started to replace the previous letter categories by pregnancy and lactation labeling rule. The new rule had expected to provide the prescriber with relevant information for critical decision-making when treating pregnant or lactating women, provide more complete statement of the known risks based on the available data, it takes in considerations of medical/disease factors, put animal data in context of human exposure and human data added when available and explicitly states when no data are available. FDA has been working to remove pregnancy medicines letter categories by June 2020, in a gradual manner. Prescription medicines approved on or after June 30, 2001 have an additional content and formatting requirements that reorganizes information in prescription medicine labeling to more clearly describe available data to aid decisions and counseling of patients using prescription medicines (Pernia and DeMaagd 2016).

2.5. Outcomes of medicine use in pregnancy

Medicines easily cross the placental barrier into the fetal body and are present also in the maternal milk. Therefore, it may affect the development of the child pre- as well as post-Nataly. The effects of prenatal medicine exposure are long-lasting and persist until adulthood (Slamberova, 2012).

The risks associated with substance use during pregnancy are well-known. Women who smoke cigarettes during pregnancy are more likely to experience ectopic pregnancy, placental abruption, placenta previa, and particularly, preterm birth, which alone causes more infant deaths than any other known cause. Children born to mothers who smoked during pregnancy are more likely to have a low birth weight, a condition associated with short- and long-term health consequences. Marijuana and alcohol use during pregnancy are associated with reduced gestational age, low birth weight, preterm birth, infant mortality, poor cognitive development, and behavioral problems (Gatny and Kusunoki, 2013).

Medicines can affect the fetus in multiple ways. Early in gestation, during the embryonic stage, medicines can have significant teratogenic effects. However, during the fetal period, after major structural development is complete, medicines have more subtle effects, including abnormal growth and/or maturation, alterations in neurotransmitters and their receptors, and brain organization. These are considered to be the direct effects of medicines. However, medicines also can exert a pharmacologic effect on the mother and, thus, indirectly affect the fetus (Behnke and Smith, 2013).

Use of alcohol, illicit medicines and other psychoactive substances during pregnancy can lead to multiple health and social problems for both mother and child, including miscarriage, stillbirth, low birth weight, prematurity, physical malformations and neurological damage.

Dependence on alcohol and other medicines can also severely impair an individual's functioning as a parent, spouse or partner, and instigate and trigger gender-based and domestic violence, thus significantly affecting the physical, mental and emotional development of children (Finnegan, 2013).

Birth defects are structural and functional defects that develop during the organogenesis period and present at birth or detected later in life. They are one of the leading causes of infant and child mortality, morbidity, and long term disability. The magnitude of birth defects varies from country to country and from race/ethnicity to race/ethnicity, and about 40–60% of their causes are unknown. The known causes of birth defects are genetic and environmental factors including medicine exposure which may be prevented (Afework et al., 2016).

Structural abnormalities or teratogenicity may also result from in utero medicine exposure. The timing of medicine exposure in utero determines the effect. One possible adverse effect of any used medicine during the first week of pregnancy is miscarriage. The incidence of this complication is unknown because it may be difficult to determine the exact date of conception and exclude other factors that would cause termination of the pregnancy. It is well known that nearly all medicines of improper use have been associated with preterm birth. The second to eighth weeks of pregnancy compose the period of organogenesis, when medicines can produce structural abnormalities at the cellular level or interfere with growth of the developing fetus (Christensen et al., 2015).

Spina bifida is one of the birth defect observed by the use of medicines. Since 1998, FDA mandated that enriched grain products be fortified with folic acid, the estimated number of pregnancies affected by neural tube defects (NTDs) has declined by approximately 27%. However, a greater decline was predicted, raising the question of whether at least some of the remaining cases can be prevented through increased peri-conceptional supplementation or dietary folic acid intake (Ahrens et al., 2011).

In 1952, Dr Virginia Apgar devised a scoring system that was a rapid method of assessing the clinical status of the newborn infant at 1 minute of age and the need for prompt intervention to establish breathing. It is a method used as part of early assessment of a new born. A score of 0, 1 or 2 is assigned to each of the 5 physical signs at 1 and 5 minutes after birth. The maximum score that can be assigned is 10. Scores ranging from7-10 are considered as normal. If 5 the minutes Apgar score is abnormal (<7), appropriate measures should be taken. It is affected by gestational age, maternal medications, resuscitation, and cardiorespiratory and neurologic conditions (Polin and Spitzer, 2013).

Children born to mothers who smoked during pregnancy are more likely to have a low birth weight, a condition associated with short and long-term health consequences. Moreover, maternal smoking could be related to docosahexaenoic acid (DHA) supply to fetus. Indeed maternal smoking during pregnancy may progressively impair DHA synthesis and/or maternal transfer that has been associated with restricted fetal growth (Banderali et.al, 2015).

3. Objectives of the study

3.1. General objective

To assess medicine use pattern and associated outcomes among pregnant women visiting Antenatal Care Units in Public Health Facilities (PHF) in Butajira.

3.2. Specific objectives

- To determine the extent of use of medicines during pregnancy among Antenatal care attendees in Public health facilities of Butajira.
- To describe the pregnancy risk level of used medications according to the US FDA safety rating system.
- To assess association between medicine use in pregnancy and outcomes on pregnancy; Apgar score, birth weight and term of delivery.

4. Methods

4.1. Study area and setting

Butajira town is located 108km from the capital, Addis Ababa in the south. It has latitude and longitude of 8º07'N38º22'E and elevation of 2131 meters above sea level. According to the recent data, the town has total population of approximately 70,000 (CSA, 2015). It is also an area where Butajira Rural Health Program (BRHP) was located, which was initiated in 1986 with a collaboration between Addis Ababa University (AAU) and Umea University (Sweden).Since then, Butajira has been the site of regular demographic surveillance, with enumerators collecting data from households(Gaym, 2008). Currently, Butajira has one public hospital, one public health center and several privately owned medicine stores and clinics. This study was conducted in public health facilities. Mother and child health (MCH) unit of the hospital and health center are led by midwives. This unit provides antenatal care service and vaccination service. There are total of seventeen midwives and nurses in the MCH unit of the hospital and health center.

4.2. Study Design

Institution based prospective cohort study design was conducted by interviewing semi structured interview for pregnant women who had routine ANC follow up and waited until they gave birth. Socio-demographic, past medical history and self-medication practice was obtained by interviewing and clinical data were obtained from ANC follow up medical records. Study participants were waited from March, 2018-November, 2018 till all participants gave birth.

4.3. Source and study population

The source population constitutes all pregnant women who reside in Butajira and its surroundings and who were on ANC follow up during study period. The study population is pregnant women who came for antenatal follow up to the study sites during study period and who volunteered to participate in the study.

4.4. Sampling and sample size determination

The sample size for the study was determined based on single proportion formula (Suresh and Chandrashekara, 2012). Considering the prevalence of medicine use during pregnancy obtained in a study conducted in western Ethiopia, 55.2% (Mohammed et al., 2013).

$N = [(Z\alpha/2)^2 xP (1-P)] / D^2$ where;

N= desired sample size; $Z\alpha/2$=reflects the Standard score at 95% confidence interval (CI) which is 1.96; P= prevalence of medicine use during pregnancy; D= margin of error between the sample and population, 5% marginal error is admitted.

$N = [(1.96)^2 x0.552 (1-0.552)] /(0.05)^2 = 380$

By adding 5% contingency the total sample size was 399.

During the time of data collection, 1356 and 1163 pregnant women were on ANC follow up in the hospital and health center respectively. By proportionally allocating the calculated sample size to hospital and health center, 215 participants were obtained from hospital and 184 were obtained from health center totaling 399.

4.5. Data Collection Instrument

Semi-structured interview was used to capture data related to socio-demographics and self-medication practice. Data abstraction format was used to gather data regarding maternal disorders, the type of medicine prescribed, the gestational age at which the medicine was prescribed, the number of ANC visits the women had and the outcomes on the newborn.

Data was collected by nurses and midwives who work in the respective health facilities covered. Data collectors have been given one day training about the study procedures prior to data collection and pretest was done before actual data collection.

Antenatal care follow up medical records of the pregnant women were reviewed and medicines prescribed for them during their pregnancy starting from the date of the initial encounter were recorded and the outcomes of interest were assessed.

4.6. Study Variables

4.6.1. Independent variables: Socio-demographic characteristics, number of ANC visit and Medicines used at each trimester

4.6.2. Dependent variables: Apgar score, birth weight and term of delivery

4.7. Data Management, Quality Assurance and Analysis

Data entry and cleaning was done using Epidata version 7.2.1 and analyzed using SPSS version 24 statistical software. Description of the study population was done by analyzing the distribution of the participants by the variables in terms of frequencies and percentages. The frequency of medicines that were prescribed and the proportion of women to whom medicines were prescribed during each trimesters of the pregnancy were calculated.

The frequency of prescribed medicines to pregnant women with a potential for fetal harm during pregnancy (at each trimester) was evaluated based on the U.S. FDA pregnancy risk classification system and probable outcomes of medicine use on fetus were assessed in terms of Apgar score, birth weight and term of delivery. Association between medicines used by pregnant women and outcome variables were analyzed by logistic regression.

Ethical consideration

The study was ethically approved by Ethics Review Board of the School of Pharmacy (ERB/SOP/02/10/2018). Letter of cooperation from Department Pharmaceutics and Social pharmacy, Addis Ababa University was presented to Heads of the health facilities. Informed verbal consent was obtained from each study participant and the nature of the study, its purpose, and the potential benefits of the study was described. The participants were also been informed that the information would be kept confidential and it was assured by assigning code for each participants and analyzed in aggregates.

Operational definitions

1. Medicine: any substance or product including traditional herb that is used for prevention, treatment, or alleviation of disease.

2. Self-medication: Medicine use without prescription or recommendation by a physician or a traditional healer.

3. Trimester:

First trimester extended through the completion of 12 weeks of pregnancy.

Second trimester is extended from 13^{th} through 24^{th} weeks of pregnancy.

Third trimester include the 25th through 42nd week of pregnancy.

4. Parity: is the number of live births at any gestation or still births after 28 weeks

5. Gravidity: the total number of pregnancies regardless of how they ended.

6. Abortion: any interruption of human pregnancy prior to 28 week.

7. Still birth: the birth of fetus that has died at any time between 28th weeks of pregnancy.

8. Chronic diseases: hypertension, diabetes, Asthma, or other lung disease, thyroid disease, epilepsy, kidney disease, liver disease or HIV infection prior to pregnancy.

9. Apgar score: The Apgar score is a test given to newborns soon after birth. This test checks a baby's heart rate, muscle tone, and other signs to see if extra medical care or emergency care is needed.

10. Pregnancy term of delivery:

Pre-term: Preterm birth, also known as premature birth, is the birth of a baby at fewer than 37 weeks' gestational age.

Full-term: A full-term pregnancy lasts between 38 weeks, 0 days and 40 weeks, 6 days.

11. Birth weight: Birth weight is the body weight of a baby at its birth.

Low birth weight: a birth weight of infant of less than 2.5kg regardless of gestational age.

Normal birth weight: a birth weight of infant term delivery is 2.5kg–4.2kg

Over weight**:** a birth weight of infant weight at term delivery is above 4.2kg

12. Pregnancy outcomes include Apgar score, birth weight and term of delivery.

5. Results

5.1. Socio demographic characteristics of the participants

As shown in Table 1, majority of the study participants 334(83.7%) were in the age group of 20–34 years; with the mean age of 25.0 ± (SD 4.7) years. In terms of level of education, those who attended elementary school constituted the majority 190 (47.6%) followed by those who completed secondary/preparatory school 89 (22.3%) and those who are unable to read and write 69 (17.3%). Nearly two third, 245 (61.5%) of the participants were housewives, 52 (13%) were merchants, 46 (11.5%) and 21 (5.3%) were government and non-government employees respectively and 21(5.3%) were farmers, 10 (2.5%) were unemployed and 4 (1%) were students.

Three hundred seventeen (79.5%) were willing to disclose their family income; of whom 99 (31.2%) were with monthly income of below 1000 Eth. Birr, followed by 94 (29.6%) with monthly income 1001-2000 Eth Birr. Only 39 (12.3%) study participants claimed to have monthly income more than 4000 Eth Birr.

Table 1.Socio demographic characteristics of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Variables	Number (n=399)	Percentage (%)
Age		
15-19	42	10.5
20-34	334	83.7
34-49	23	5.8
Marital status		
Married	385	96.5
Never married	9	2.3
Widowed, divorced	5	1.3
Educational status		
Unable to read and write	69	17.3
Primary	190	47.6
Secondary/preparatory	89	22.3
College/University	51	12.8
Occupation		
Gov. Employee	46	11.5
Non.Gov employee	21	5.3
Merchant	52	14.8
House wife	245	61.4
Others	35	8.8
Monthly income		
<1000	99	31.2
1001-2000	94	29.6
2000-4000	85	26.8
>4000	39	12.3

*Others include Students, housemaids, and unemployed.

5.2. Obstetrics and medical history of the participants

5.2.1. Past obstetric history

Two hundred and thirty four (58.6%) of the pregnant women had two to four pregnancies, 153(38.4%) pregnant women were Primi-gravida and 190 (50.4%) had given 2-4 births and 56 (14 %) had history of abortion (Table 2).

Table 2**.** Past obstetrics history of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Variable	Number (n=399)	Percentage (%)
Ever had illness in the past two years		
Yes	70	17.5
No	329	82.5
Gravida		
1	153	38.4
2-4	234	58.6
≥5	12	3
Parity		
0-1	197	49.4
2-4	195	48.8
≥5	7	1.8
Ever had abortion		
Yes	56	14
No	343	86

5.2.2. Present obstetric and medical history of the participants

Three hundred forty three (86%) of the pregnancies were planned and wanted; while 40 (10%) were not planned but wanted and 16 (4%) were neither planned nor wanted. The average weight of the 373 participants with weight recorded at the first visit of ANC was 54.3 kg and for the 360 women for whom the weight during their last visit, the mean weight was 58.8 kg.

At the time of interview, fourty three of the study participants were in the first trimester and the remaining participants were at second and third trimester of pregnancy. Two hundred and eighty three (71%) of the study participants had at least four visits of ANC and one hundred and sixteen (29%) had less than four ANC visits up until the date of delivery (Table 3).

Table 3. Present obstetrics history of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Variable	Number (n=399)	Percentage (%)
Is this pregnancy planned?		
Yes	343	86
No	56	14
Hospitalized during current pregnancy		
Yes	17	4.3
No	382	95.7
No. of Antenatal visit		
<4 times	116	29
≥4 times	283	71

5.3. Maternal disorders during pregnancy

Most of pregnant women 340(85%) had attended obstetric OPD on account of routine ANC follow-up on the days of interview; whereas, 59(15%) visited health institutions because of perceived illness. Card review of the study participants showed that 204 (51%) of pregnant women were presented with at least one maternal disorder during the current pregnancy. The maternal disorders most frequently presented and recorded in the ANC follow up medical records of the study participants were nausea and vomiting 35(11.7%), intestinal parasites 33(11%), urinary tract symptoms 31(10.4%), dyspepsia 29(9.7)%, backache/headache 27(9%) and respiratory tract infections 24(8%) (Table 4).

Table 4. Common maternal disorders of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Maternal disorders	Cases (n=272)	Percentage (%)
Nausea and vomiting	35	12.8
Intestinal parasites	33	12
Urinary tract disorders	31	11.4
Dyspepsia	29	10.6
Backache/headache	27	10
Respiratory tract infections/cough	24	8.8
Pushing down pain	18	6.6
Abdominal cramp	16	5.8
Anemic symptoms	11	4
Others	48	17.6

Others include: Typhoid, diarrhea, skin disorders, hemorrhoid, diabetes, HIV, hypertension, typhus, eye diseases, traumatic injury, parasites, toothache, thyrotoxicosis, constipation and loss of appetite.

5.4. Medicine use during pregnancy

5.4.1. Extent and types of medicines prescribed during pregnancy

A total of 382 (95.7%) pregnant women used at least one medicine during their pregnancy. Iron with folic acid or ferrous gluconate was the most commonly prescribed medicine. Excluding those pregnant women who received only iron with folic acid or ferrous gluconate, a total of 212 (53.1%) pregnant women received at least one medicine during current pregnancy. Second trimester of pregnancy is the gestational age when most medicines where prescribed followed by third and first trimester.

Total of sixty six items of medicines were used by pregnant women; of which 24(36%) were over the counter (OTC) medicines and the remaining 42 (64%) of the medicines were prescription only medicines. Next to iron with folic acid, paracetamol, amoxicillin, antacids, ceftriaxone, mebendazole and Iron with vitamins and minerals syrup were found to be the most frequently prescribed medicines during pregnancy (Table 5).

Table 5.Commonly prescribed medicines for the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Generic medicine	Prescriptions (n=1310)	Percentage (%)
Iron with folic acid	937	71.5
Paracetamol	43	3.2
Amoxicillin	41	3.1
Aluminum-Magnesium hydroxide	38	2.9
Mebendazole tab/syrup	37	2.8
Vitamins (other than Folic acid)	24	1.8
Ceftriaxone	20	1.5
Diclofenac inj/tab	18	1.3
Omeprazole	16	1.2
Metoclopramide inj/tabs	13	1.0
Oral rehydration salt	12	0.9
Clotrimazole pessary/cream	10	0.7
Iron with vitamins and minerals syrup	10	0.7
Others	91	7

Table 6. Commonly prescribed class of medicines for the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Therapeutic class	**Trimesters**			
	First(n)	Second (n)	Third (n)	Total
Anti-anemic preparations	197	372	390	959
Antibiotics	20	38	11	69
Analgesics	12	25	24	65
Antacids and ulcer healing medicines	26	17	11	53
Anthelmintic	10	13	16	39
Antiemetics	8	9	8	25
Vitamins other than anti-anemic	7	9	8	24
Antihistamines	3	6	8	17
Antifungals	5	6	5	16
Medicines used in diabetes	4	3	3	11

5.4.2. Medicines used by pregnant women in relation to U.S. FDA pregnancy risk classification

From total of 1,335 of medicines used by pregnant women, 978(73.3%) were from FDA pregnancy category A, 194(14.5%) were from FDA pregnancy category B, 128(9.6%) were from FDA pregnancy category C, 25(1.9%) were from FDA pregnancy category D and 1(0.08%) were from FDA pregnancy category X.

Three hundred eighty two (39%) of FDA category A medicines were used in third trimester of pregnancy followed by second (36.6%) and first (21.8%) trimester of pregnancy while majority (37.1%) of category B medicines were used in second trimester of pregnancy followed by first (36.8%) and third (26%) trimester of pregnancy respectively. Majority (52.4%) of category C medicines were used in second trimester of pregnancy followed by first (29%) and third (18.7%) trimester of pregnancy while majority (44%) of category D medicines were used in third trimester of pregnancy. Tetracycline, prophylthiouracil, phenytoin, phenobarbitone, doxycycline, and cotrimoxazole were pregnancy category D medicines while warfarin was class X medicines used by study participants.

Table 7. Prescribed medicines with reference to US-FDA pregnancy medicine safety category and gestational age of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

US. FDA safety	Trimesters			
	First n (%)	Second n (%)	Third n (%)	All
A	213(21.8%)	358(36.6%)	382(39%)	978
B	71(36.8%)	72(37.1%)	51(26%)	194
C	37(29%)	67(52.4%)	24(18.7%)	128
D	8(32%)	6(25%)	11(44%)	25
X	1(100%)	0	0	1
N	6(66.7%)	1(11.1%)	2(22.2%)	9

N: Medicines not classified by FDA pregnancy safety category

5.4.3. Self-medication practice during pregnancy

Twenty four of the pregnant women reported that they self-medicated at their current pregnancy; of these 13 of them took modern medication; while 11 of them used traditional medicine. The commonly reported illnesses, for which the study participants took self-medication, were: Headache, cough and cold, back pain and dyspepsia respectively. Retail medicine outlets (pharmacies or medicine stores), household and left over from past prescriptions were reported as their source of medicines for self-medication. Practice of self-medication was due to the fact that they used the medicine before, considered the perceived illness as minor and long waiting time at health institutions. Traditional medicinal herbs used by the pregnant women were Zingeber officinale; ginger (4), Allium sativum; garlic (3), Ruta chalepenisis;fringed rue (1), Lepidium sativum; garden cress (1), Echinops kebericho Mesfin, Kebericho (1) and Cinnamomum verum; cinnamon (1). Paracetamol was the most commonly used OTC medicine for self-medication and omeprazole was from prescription only medicine.

Table 8.Self-medication practice of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=399)

Study parameters	Number	Percentage
Medicines used for self-medication:		
Traditional herbs	11	46
Modern medications		
OTC medicines	8	33
Prescription medicines	5	21
Reasons for self-medication:		
Used the medicine before	14	58
Minor illness	7	29
Long waiting time at health institutions	3	13
Source of medicine for self-medication:		
House hold/ Left over from past prescriptions	18	75
Pharmacy/medicine store	6	25

5.5. Outcomes of pregnancy

From recorded 377 outcomes of pregnancy, 44(11.6%) were preterm deliveries and 333(88.4%) were full term deliveries while 334(89.9%) had Apgar score of >7 and 42(11%) had Apgar score of ≤7 and 347(88%) had normal birth weight and 45(12%) of the newborns had low birth weight. By merging the three outcomes, 56(15%) had poor pregnancy outcomes while 321(85%) had good pregnancy outcomes.

5.5.1. Associations between medicine use during pregnancy and birth outcomes.

Analysis was done using logistic regression and correlation to assess association between socio demographic, obstetric and health related variables and medicines prescribed at each trimester with Apgar score, baby birth weight and pregnancy term of delivery. The result showed that there was no statistically significant association between medicines used and Apgar score, birth weight and term of delivery. But it has showed a positive relation between medicines used in each trimester and Apgar score, baby birth weight and pregnancy term of delivery. In the multinomial logistic regression model, however, statistically significant association was observed between women age of teenage pregnancy (15-19) years with pregnancy outcomes (Apgar score, birth weight and term of delivery) P<0.05; (OR 3.20; 95%CI: 1.34-5.04), (AOR 1.90; 95% CI: (1.29-4.47) (Table 9).

Table 9. Statistical association between medicine use and pregnancy outcomes (neonates Apgar score, birth weight and pregnancy term of delivery) of the study participants at public health facilities, Butajira, Ethiopia, between March to November, 2018 (n=377).

Variables	Pregnancy outcomes (Apgar score, birth weight and term of delivery)				
	Poor n (%)	Good n (%)	COR 95% CI;	AOR 95% CI)	P-value
Age category					
15-19	9(3%)	31(8%)	3.20(1.34-5.04);	1.90(1.29-4.47)	0.032
20-34	44(12%)	287(76%)	1.38(0.39-4.87);	0.96(0.19-3.23)	0.615
35-49	3(0.8%)	19(5%)	1.00	1.00	
Education level					
≥secondary	16(4%)	124(33%)	0.55(0.90-1.59);	0.35(0.83-1.77)	0.525
≤primary	40(11%)	214(57%)	1.00	1.00	
Occupation					
Employed	19(5%)	89(27%)	2.51(0.86-1.12);	1.10(0.40-137)	0.236
Not employed	36(9.5%)	213(56.5%)	1.00	1.00	
No of ANC visit					
≥4 times	42(11%)	251(66.5%)	1.40 (0.30-0.99);	0.64(0.20-1.25)	0.271
<4 times	13(3.5%)	83(22%)	1.00	1.00	
Medicines used at					
1st trimester	14(4%)	87(23%)	1.51(0.90-1.14);	1.12(0.73-1.769)	0.635
3rd trimester	20(5.3%)	121(32%)	1.00(0.93-1.52);	0.72(0.90-1.46)	0.335
2nd trimester	21(6%)	130(35%)	1.00	1.00	

Statistically significant at $P < 0.05$.

COR: crude odds ratio, AOR: Adjusted odds ratio, CI: Confidence interval

6. Discussion

The use of prescribed and over-the -counter medications in pregnancy is on the rise (Werler et. al, 2005). In addition, pregnancy is associated with profound changes in the physiology of virtually every organ in the body, which affect medications' pharmaco-kinetics and pharmacodynamics (Ansari et.al, 2016). Despite all of these, pregnant women are still considered therapeutic orphans, as the majority of current therapeutics were never studied in pregnancy (Ilekis et.al, 2016).

In this study, a total of 358 (95%) pregnant women used at least one medicine during their pregnancy. This is nearly comparable with multinational study by Thomas and Yates (2012), where more than 80 % of pregnant women in Europe, Australia, and the Americas use at least one medication during pregnancy.

The finding of this study is also in line with another study conducted in Addis Ababa, Ethiopia (Etefa and Kahissay, 2015), Bishoftu, Ethiopia (Gadisa and Guyo, 2014) and Southern Tigray, Ethiopia (Molla et al., 2017). But it is higher than the findings by (Mohammed *et al*., 2013) and (kebede et al., 2009). This might be due to inclusion of self-medication practice in this study and increased visit of pregnant women to ANC.

Average number of medicines used by participants in this study was 3.35. This is in line with study done multinationally (Thomas and Yates, 2012) but slightly higher than the finding from Bishoftu, Ethiopia (Gadisa and Guyo, 2014). This could be inclusion of self- medication and increased visit of participants to ANC but the finding of this study is slightly lower than study conducted in India (Sasidharan and Kolasani, 2017). This might be due to increased habit of using medicines in that study participants.

In this study Iron with folic acid or ferrous gluconate was the most commonly prescribed medicine.The results are also coincides with the findings reported from India by (Gawde et al., 2013), India (Sasidharan and Kolasani, 2017), Addis Ababa (Etefa and Kahissay, 2015), Addis Ababa (Kebede et al., 2009), this is because it is recommended to be used by pregnant women to protect iron deficiency anemia.

This study also revealed that the proportion of women with medications used were higher in their second trimester followed by the third and first trimesters. This could possibly be explained by the fact that, the majority of the pregnant women in our study started their antenatal follow-up early in the second and third trimester of pregnancy and prescribers might be aware of the risk of prescribing medicines during the first trimester of pregnancy than other trimesters; which is in contrast with the study conducted in Addis Ababa (Etefa and kahisay 2013), which showed that the number of women taking medicines decreased across the trimesters from first to third.

Moreover this study also showed that, pregnant women use medications from across all the FDA medicine risk categories with decreasing proportion from category A to X, which coincides with a study conducted in Southern Tigray (Molla et al., 2017), Addis Ababa (Etefa and Kahissay 2015), Addis Ababa (kebede et al., 2009), but it is in contrast with the study done from western Ethiopia (Mohammed *et al.*, 2013), and India (Sasidharan and Kolasani, 2017).

The most commonly used medications in this study were anti anemic preparations, antibiotics, analgesics and anti-ulcer medicines which is expected because antianaemic preparations are recommended as prophylaxis of anemia in pregnancy and others are used for the treatment of pregnancy related disorders. Number of participants who self-medicated themselves was low. This might be underestimated because some participants reported that they self-medicated themselves but did not remember the name of the medicine they had taken.

This study showed that there were no statistically significant association between medicines used by pregnant women and pregnancy outcomes such as neonates' birth weight, Apgar scores and pregnancy term of delivery. This could be most medicines prescribed and used by pregnant women in this study were from relatively safe class of FDA pregnancy category and the potential teratogenic class of medicines (category D and X) are small in number.

This is supported by study conducted in Ghana by Mensah et.al (2017), which showed that antibiotic exposure in pregnancy did not significantly affect the birth weight, incidence of congenital birth defect and mean Apgar scores.

Antiepileptics, antipsychotics, antidepressants are common class of medicines which have negative effect on pregnancy. Prenatal exposure to antiepileptic medicines was associated with increased risk of being born with a low Apgar score (Christensen et al., 2015). But this current study found that only few number of pregnant women were exposed to those potential medicines which is impossible to detect its impact on pregnant women and newborns.

pregnant women who smoke and use hard illicit medicine gave birth of babies whose birth weight lesser at delivery than those women who did not smoke and did not use illicit medicines (Baily et.al., 2012) and (Rachidi et al., 2013). But this current study did not come up with illicit medicines like alcohol, cigarette and chat.

In this study women with teenage pregnancy were significantly associated with poor pregnancy outcomes. This is in line with study: Mekelle, Ethiopia (Tela et al., 2019), Nigeria (Isiugo-Abanihe and Oke, 2011), India (Aras 2016), UK (Marvin-Dowle et al., 2018). This might be due to interplay of biological, health and social factors on age but the current finding was in contrast to study Georgia state university (Jonson, 2014). This might be due to age and socio economic variation in the studies.

7. Strength and limitation of the study

In this study interview using semi structured questionnaires and also a record review of the same pregnant women were done thus, one complementing the other and making the required information, especially the socio-demographic and obstetric history of the pregnant women complete. It also includes self-medication practice in addition to prescription only medications.

The extent of medicine use during pregnancy documented in this study might be underestimated as majority of study participants started their antenatal follow up in their second trimester of the pregnancy and participants' recall of non-prescription medicine use was low. Another limitation of this study is that sample size was not large enough to associate the outcome variables with the outcome variable and it does not include the use of illicit medicines like cigarate smoking and chat.

Regarding self-medication use, information was obtained from maternal report as there was no other means of obtaining that information, and as such could have been subject to recall bias.

In this study, since the use of category D or X medicines was relatively uncommon, thus led to limited statistical power to examine the association between medicine use and pregnancy outcomes such as Apgar score, baby birth weight and pregnancy term of delivery, thus sample size should have been larger for such analysis.

8. Conclusion

Majority of the study population used safe and appropriate medications according to US-FDA risk classification system. However, though low, limited number of pregnant women was exposed to medications with potential risk for the fetus and also study population were also used traditional herbs for which pregnancy risk level was not assigned by US-FDA.

Furthermore, pregnant women self-medicated themselves with modern medications and/or traditional herbs. In this study, prophylactic Iron with folic acid or Iron gluconate was the most commonly prescribed medicine while Paracetamol was most commonly used OTC medicine and garlic was most commonly used traditional medicine. There were no statistically significant association between medicines used in this study and pregnancy outcomes such as mean birth weight, Apgar score and pregnancy term of delivery.

9. Recommendation

Continuing medical education of health care providers on the effects of medications on both the pregnant women and the developing fetus is recommended. In addition, health care providers must be persuaded that not all symptoms should necessarily be treated with medications and that the therapeutic restraint may be the best interest for both mother and infant.

Pregnancy medicine use or substance use registry with outcomes should be implemented and studied in health facilities or at a national level.

Case control studies should be conducted at referral or special maternal and neonatal health facilities to see the cause of specific birth related outcomes.

National study with large sample size is needed to assess the safety of exposure to medicines during pregnancy. Potential and specific class of medicines should be selected to correlate medicine use during pregnancy and associated birth outcomes.

Prescribers must weigh the therapeutic benefits of the medicine to the mother against its risk potential to the developing fetus before prescribing any medicine to the pregnant women. They also should assess past and present medical and medication history of pregnant women and should discontinue past medications which has been taken by pregnant women if they are contraindicated.

Health care providers should routinely inquire about the women's self-medication practice with over the counter medicines or prescription medicines including traditional herbs and warn against the use of these safety unproved medications during pregnancy.

Educating pregnant women and women of reproductive age group regarding the risk of self-medication using modern and traditional medicines during pregnancy is very important.

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Annex I: Verbal Informed Consent

Hello! My name is ……..and I work in this health institution. I represent Mr.Deribe W/senbet who is working his thesis research project for MSc. Study in Pharmaco-Epidemiology and Social Pharmacy at School of Pharmacy, Addis Ababa University.

This study is designed to assess the medicine use pattern and associated outcomes among pregnant women among pregnant women attending antenatal care unit in Butajira, Ethiopia. You are kindly requested to be included in this study, which will help rationalize the medicine use during pregnancy and attain the health care synthesis initiative in making pregnancy safer. The whole process of this interview will take 30-45 minutes.

You will be asked some personal questions that are related to your pregnancy and your honest answers to these questions will help better understand the subject under study. Your participation is voluntary and you have options not to answer any of the questions or quit the interview if you are not comfortable. Your participation or refusal to respond some or all of the questions have no consequence on the service you or any member of your family receives. I would also like to assure you that you answers will be kept confidential and your name will not appear anywhere in this form or in the final study document.

Are you willing to proceed with the interview? If yes, thank and continue interviewing. If no, thank and stop interviewing.

Result: 1. completed 2. Refused 3.partially replied 4.other

Interviewers name……signature ……date……

Principal investigators name…….signature……..date……..

Annex II. Interview questions for the assessment of medicine use in pregnancy.

1. Socio demographic data

Socio demographic characteristics are believed to affect medicine use during pregnancy.

No	Question	Code	Skip to
1	Questionnaire code	_____	
2	Age in years	_____	
3	Ethnicity	□1.Guraghe □2.silte □3.Hadiya □4.Oromo □5.others specify----------	
4	Religion	□1.Muslim □2.Orthodox □3.Protestant □4.Catholic □5.Other (specify)_____	
5	Marital status	□1.Married □2.single,Never married □3.Widowed □4.separated	
6	Educational level	□1.unable to read and write □2.1-8th □3.9-10th □4.11-12th □5.college/University completed	

7	Occupation	□1.government employee □2.farmer □3.non government employee □4.merchant □5.student □6.house wife □7.unemployed □8.others (specify)	
8	Number of family members	Total _____No of Male_____ No of Female_____	
9	Monthly income (estimated)	_____Eth. Birr	

2. past obstetric and medical history

No	Questions	Code	Skip to
1	Past medical/surgical/medication history (two years prior to current pregnancy if any:	□1.Tuberclosis □2.Typhoid □3.Typhus □4.Urinary tract infection □5.Pneumonia □6.Heart disease □7.surgical operation including C/S □8.diabetes □9.hypertension □10.renal disease □11.medicine allergy □12.none □13.others(specify)	
2	Is there any medicine you have been taking or have taken for the above mentioned health problem?	□1.yes □2.No	If the response is No, skip to Q. No 5.
3	If response for Q.No 2.is Yes, what type of the medicine is it?	□1.Modern □2.Traditional □3.I do not remember	
4	Describe the name, dosage and dose of the medicine you have been taking or have taken and show me if you have it		
5	Gravida		
6	Para		
7	No of abortions if any:		
8	Was there problems you faced in the past pregnancies?	□1.yes □2.No	If No, skip to the next part
9	If yes, what was the problem?		

3. Present obstetric history

No	Question	Code	Skip to
1	Health facility where you have antenatal care follow up	□1.Hospital □2.Health center	
2	Card No of ANC follow up		
3	Is this pregnancy	□1.planned □2.untimely but wanted □3.unwanted	
4	Gestational age	_____months	
5	How many times do you feed per day		
6	Have you hospitalized during this pregnancy?		
7	Have you faced any health problems during this pregnancy?	□1.yes □2.no	
8	If yes, what was the health problem you faced?		
9	Is there any medications that you have taken or have been taking during this pregnancy?	□1.Yes □2.No	Skip to Q. No 6.
10	If yes, the kind of medicine is	□1.Modern □2.traditional □3.both	
11	what is the name, dosage and dose per day of the medicine that you are taking (if the woman has medicine with her please ask her and record the required information)		
12	Where did you get the medicine from?	□1.prescribed from health practitioner □2.traditional healer □3.pharmacy/medicine store □4.the left over medicines □5.friends/relatives	

		□6.self-prescribed □7.others (specify)	
13	Did the pharmacist or the traditional healer or your friends asked you whether you are pregnant or not before giving the medication?	□1.yes □2.no	
14	Did you inform the dispenser or the traditional healer or your friends that you are pregnant before taking the medication?	□1.Yes □2.No	
15	If No for Q. No 14, what was your reason?	□1.I do not think it is important □2.I was anxious to get the medicine □3.I used to do it before □4.others (specify)_____	Skip to the next part
16	If you took the medicine without prescription, what was your reason for self-medication?	□1.less costly □2.minor illness □3.long waiting time at modern health facilities □4.used to take the medicine before □5.others (specify)	
17	What is the reason you come this health institution today?	□1.I am not feeling well and seek health □2.I have an appointment □3.to check for pregnancy □4.Reffered to this health institution □5.others (specify)_____	

18	Is any medication prescribed to you today?	□1.yes □2.No	
19	If yes for Q.no 19,please show me the prescription paper or if you took the medicine show me and tell me its dose		

Thank the study participant again!!!

በአ.አ.ዩ ፋርማሲ ት/ቤት

በቡታጅራ የሚገኙ የነፍሰጡር እናቶች ላይ ለሚካሄደው ጥናት የተሳታፊዎች የቃል ስምምነት

መግቢያ

እንደምን አሉ

እኔ ስሜ…….. ይባላል፡፡ የምሰራውም በዚህ ጤና ድርጅት ውስጥ ሲሆን በአ.አ.ዩ ፋርማሲ ት/ቤት የፋርማኮፒድምሎጂና የሶሻል ፋርማሲ ተማሪ የሆኑት አቶ ደርቤ ወ/ሰንበት በእርግዝና ወቅት ስለሚኖር የመድኃኒት አጠቃቀም ሁኔታና ተያያዥ ዉጤቶች ላይ ለሚያደርጉት ጥናት መረጃ ለመሰብሰብ ነው፡፡

የጥናቱ ዓላማ በእርግዝና ወቅት አግባብ ያለው የመድኃኒት አጠቃቀም ሥርዓት እንዲኖርና እርግዝናን ጤናማ እና ጉዳት አልባ ለማድረግ በጤና አገልግሎት ዘርፍ እየተደረገ ላለው ጥረት የበኩሉን አስተዋጽዎ ለማድረግ ሲሆን እርሱዎም በዚህ ጥናት በመሳተፍ የድርሻዎን እንዲወጡ በትህትና እጠይቃለሁ፡፡ ይህም ቃለመጠይቅ ከ20 እስከ 30 ደቂቃ የሚወስድ ይሆናል፡፡

በዚህ ቃለመጠይቅ ውስጥ ለጥናቱ ጠቃሚ ናቸው የሚባሉ ከእርግዝናዎ ጋር የተያያዙ ጥያቄዎችን አቀርብሎታለሁ፡፡ እውነተኛ እና ቀና ምላሽዎ ለሚደረገው ጥናት ከፍተኛ ጠቀሜታ ይኖረዋል፡፡ ተሳትፎም ሙሉ በሙሉ በፈቃደኝነትዎ ላይ የተመሰረት ስለሆነ ለሚቀርብልዎትም ጥያቄዎች በሙሉም ሆነ በከፊል መልስ ያለመስጠትና ያልተስማማዎት ነገር ካለ መልሱን ማቋረጥ ይችላሉ፡፡

የእርስዎም በዚህ ጥናት አለመሳተፍም ሆነ ቃለ መጠይቁን ማቋረጥ አሁንም ሆነ ወደፊት እርሶም ሆኑ በተሰቦዎችዎ ሊያገኙት የሚገባቸው የጤና አገልግሎት ላይ ምንም ዓይነት ተጽዕኖ እንደማይኖረው በቅድሚ ላረጋግጥልዎት እወዳለው፡፡

በተጨማሪም ለጥያቄዎቹ የሚሰጧቸው ምላሾች በሚስጥር የሚጠበቁና ስምም በመጠየቂያ ቅጹ እዲሁም በጥናቱ የመጨረሻው ጽሑፍ /ህትመት/ ላይ የማይጠቀስ መሆኑን ላሳውቅዎ እወዳለሁ፡፡

በዚህ መሠረት ለቃለመጠየቁ ለመቀጠል ፈቃደኛ ነዎት

መመሪያ፡- ለቃለመጠይቅ አድራጊው

ፈቃደኝነታቸውን ከገለፁ በማመስገን ወደ ቃለመጠይቁ ይግቡ

ፈቃደኛ ካልሆኑ አመስግነው ያሰናብቷቸው

ውጤት፡- 1. ሙሉ በሙሉ የተሳተፈ 2. ያልተሳተፈ

3. በከፊል የተሳተፈ 4. ሌላ

የቃለመጠይቅ አድራጊው ስም…… ፊርማ…… ቀን ……

የዋና ተመራማሪ ስም…… ፊርማ ……ቀን……..

1. አጠቃላይ የመሰብሰብ መረጃ

ተ.ቁ	ጥያቄ የመጠየቂያ ቅጽ መለያ	መለያ	መዉጫ
1	የመጠየቂያ ቅጽ መለያ	☐☐☐	
2	አሁን ዕድሜዎ ስንት ይሆናል	□1…… ዓመት □2……. አላውቀውም	
3	ብሄር	□1.ጉራጌ □2.ስልጤ □3.ሃድያ □4.ኦሮሞ □5.ሌላ (ይጠቀስ)----------	
4	ሃይማኖት	□1.ሙስሊም □2.ኦርቶዶክስ □3.ፕሮቴስታንት □4.ካቶሊክ □5.ሌላ (ይጠቀስ)……	
5	የጋብቻ ሁኔታ	□1.ያገቡ □2.ያላገቡ □3.የትዳር ጓደኛቸው በሞት የተለዩ □4.ከትዳር ጓደኛቸው የተለያዩ	
6.	የት/ት ደረጃዎን ብገልጹልኝ /መደበኛ ት/ት የተከታተሉ ከሆነ የት/ት ደረጃቸውን ይጥቀሱ/	□1.ያልተማረ፣ ማንበብ እና መጻፍ የማይችሉ □2.1ኛ-8ኛ ክፍል □3.9ኛ-10ኛ ክፍል □4.11ኛ-12ኛ ክፍል □6.ኮሌጅ ወይም ዩንቨርስቲ ያጠናቀቁ	
7.	ሥራዎ ወይም የገቢ ምንጭዎ ምንድነው? /መተዳደሪያቸውን ይጠይቋቸው	□1.የመንግስት ሠራተኛ (ተቀጣሪ) □2.አርሶ አደር □3.የግል ድርጅት ተቀጣሪ □4.ነጋዴ □5.ተማሪ □6.የቤት እመቤት □7.ሥራ አጥ (ሥራ የሌለው) □8.ሌላ (ይጠቀስ)……	
8	የቤተሰብ ብዛት በቁጥር	----------ወንድ-------ሴት--------	
9.	ወርሃዊ የቤተሰብዎ የገቢ መጠን ቢገልፁልኝ /በወር የሚያገኙት የገቢ መጠን ይጠይቋቸው/	…….. ብር	ስራ የሌላቸዉ ከሆና ይህን ጥያቄ ይለፉ

2. ከዚህ በፊት ያለዎት የእርግዝና እና የጤንነት ሁኔታ

ተ.ቁ	ጥያቄ የመጠየቂያ ቅጽ መለያ	መለያ	መዉጫ
1	ከዚህ አርግዝና በፊት በነበሩት ሁለት ዓመታት ዉስጥ ያጋጠመዎትና የሚያስተዉሱት ህመም ካለ ብገልጹልኝ	□1.የሳንባ ነቀርሳ በሽታ □2.ተይፎይድ □3.ተሲቦ □4.የሽንት ቱቦ እንፌክሽን □5.የልብ በሽታ □6.ቀዶ ጥገና አድርገው ከሆነ □7.የሥኳር በሽታ □8.የደም ብዛት (ግፊት) □9.የኩላሊት ሕመም □10.የመድኃኒት አለመስማማት (አለርጅ) □11.ምንም ዓይነት ሕመም አልነበረብኝም □13.አላስታዉሰዉ ም □12.ሌላ (ይጠቀስ)……	
2	ከላይ ለተጠቀሰው ህመም የወሰዱት ወይም አሁን እየወሰዱ ያሉት መድኃኒት አለ?	□1.አዎ □2.የለም	ምላሽዎ የለም ከሆና ወደ ጥያቄ ቁጥር 5 ይለፉ
3	የወሰዱት ወይም አሁን እየወሰዱ ያሉት መድኃኒት (ምርጫዉ ይነበብ)	□1.ዘመናዊ □2.ባህላዊ □3.አላስተዉሰዉም	
4	የወሰዱት ወይም አሁን እየወሰዱ ያሉት መድኃኒት ስሙንና መጠኑን እና በቀን ምን ያህል እንደሚወስዱ ቢገልፁልኝ (ይዘዉት ከሆና ቢያሳዩኝ)		
5	የአሁኑ እርግዝናዎ ስንተኛ ነዉ	…….	
6	የወለዱአቸዉ ልጆች ቁጥር	…….	
7	የውርጃ ብዛት ካለ	……	
8	ከአሁን በፊት በነበረዉ እርግዝና ጊዜ ችግር ገጥሞት ያዉቃል	□1.አዎ □2.የለም	
9	ችግር ገጥሞት ከሆና የገጠመዎትን ችግር ቢገልጹልኝ		

3. በዚህ ወቅት ያለዎት የእርግዝና እና የጤንነት ሁኔታ

ተ.ቁ	ጥያቄ የመጠየቂያ ቅጽ መለያ	መለያ	መዉጫ
1	የእርግዝና ክትትል የሚያደርጉበት ጤና ተቐም መለያ	□1.ሆስፒታል □2.ጤና ጣቢያ	
2	የእርግዝና ክትትል የሚያደርጉበት ካርድ ቁጥር		
3	ይህ እርግዝና (ምርጫው ይነበብ)	□1.የታሰበበትና የታቀደ ነው □2.ያልታሰበ ግን የምፈልገው ነው □3.ያልተፈለገ እርግዝና ነው	
4	እርግዝናዎት ስንተኛ ወር ላይ ነዉ?		
5	በቀን (24 ሰዓት ዉስጥ) ስንት ጊዜ ይመገባሉ		
6	በዚህ እርግዝና ወቅት በሆ/ል ወይም ሌላ ጤና ድርጅት ተኝተዉ ያውቃሉ	□1.አዎ □2.የለም	
7.	በዝህ እርግዝና ጊዜ የጤና እክል ገጥሞት ያዉቃል?	□1.አዎ □2.የለም	ምላሽዎ የለም ከሆና ወደ ጥያቄ ቁጥር 6 ይለፉ
8	ከላይ የተጠቀሰዉን ህመም ብገልፁልኝ	□1.ትኩሳት □2.ሳል □3.ማቅለሽለሽና ማስመለስ □4.የአንጀት ትላትል(ኮሶ) ተይቶኝ □5.ከማህፀን የሚወጣ ፈሳሽ □6.የሽንቴ ቶሎ ቶሎ መምጣት □7.የራስ ህመም ስለነበረኝ □8.ሌላ (ይጠቀስ)……..……..	
9.	በዝህ እርግዝና ወቅት የወሰዱት ወይም እየወሰዱት ያለ መድኃኒት አለ?	□1.አዎ □2.የለም	ምላሽዎ የለም ከሆና አመስግነዉ ያሰናብቱአቸዉ
10	ይህ የወሰዱት ወይም እየወሰዱት ያለው መድኃኒት (ምርጫው ይነበብ)	□1.ዘመናዊ መድኃኒት ነው □2.ባህላዊ መድኃኒት ነው □3.1 እና 2	
11.	እየወሰዱት ያለውን መድኃኒት ስሙን፤ መጠኑንና አወሳሰዱን ብናግሩኝ? መድኃኒቱን አሁን ይዘውት ከሆነ እባክዎ ቢያሳዩኝ		

12.	መድኃኒቱን ከወዴት እንዳገኙት ቢነግሩኝ	□1.በዘመናዊ ሃኪም ታዞልኝ □2.ከባህል መድኃኒተኛ □3.ከመድኃኒት ቤት /መደብር/ □4.እቤት ውስጥ ተርፎ የተቀመጠ መድኃኒት ነበረ □5.ከጓደኛ (ዘመድ) ሰቶኝ □6.እኔ እራሴ እንደሚያሽለኝ ስለማውቅ ነው □7.ሌላ (ይጠቀስ)…….	
13.	መድኃኒቱን የሰጠዎት የመድኃኒት ባለሙያ፤ ባህል መድኃኒተኛ ወይም ጓደኛዎ መድኃኒቱን ከመስጠታቸዉ በፊት ነፍሰጡር መሆንዎን ጠይቀዎት ነበር?	□1.አዎ □2.የለም	
14.	መድኃኒቱን ለሰጠዎት የመድኃኒት ባለሙያ፤ የባህል መድኃኒተኛ ወይም ለጓደኛዎ ስለ እርግናዎ ነግረውት ነበር?	□1.አዎ □2.የለም	
15.	ያልተናገሩ ከሆነ ያልተናገሩበትን ምክንያት ቢነግሩኝ	□1.አስፈላጊነቱ ስላልተያኝ □2.እኔ ጭንቀቴ ቶሎ መድኃኒት ማግኘት ብቻ ስለነበረት □3.ሁል ጊዜ የማደርገው ነገር ስለሆነ □4.ሌላ…… ይጠቀስ	
16.	መድኃኒቱን ያለሃኪም ትዕዛዝ ወስደዉ ከሆና የወሰዱበትን ምክኒያት ቢገልጹልኝ	□1.በቀላል ዋጋ ስለማገኘው □2.ሕመሜ ቀለል ያለ ስለነበር □3.ሃኪም ጋር ወረፋ-ከመጠበቅ ብዬ □4.ከዚህ በፊት የምጠቀምበት መድኃኒት ስለሆነ □5.ሌላ…….. ይጠቀስ	
17	ዛሬ እዝህ ጤና ተቐም የመጡበትን ምክንያት ብገልጹልኝ	1. ጤንነት ስለማይሰማኝ ህክምና ፈልጌ 2. ቀጠሮ ስላለኝ ነው 3. የመጀመሪያዬ ነው የእርግዝና ክትትል ፈልጌ መጣሁ 4. ከሌላ ጤና ድርጅት ወደዝህ ለክትትል ተልኬ መጣሁ 5. ሌላ (ይጠቀስ)…….	

18	አሁን የምሰማዎትን የህመም ስሜት ብገልጹልኝ	1. ሳል 2. ማቅለሽለሽና ማስመለስ ነው 3. የአንጀት ትላትል (ኮሶ ተይቶኝ) 4. የማህፀን ፈሳሽ አለኝ 5. ሽንቴ ቶሎ ቶሎ ይመጣል 6. የራስ ምታት 7. ወገቤን ያመኛል 8. ሌላ…… ይጠቀስ	
19	በዛሬው ዕለት መድሐኒት ታዘሎታል?	1. አዎ 2. የለም……››››	ምላሽዎ የለም ከሆና አመስግነዉ ይሸኙአቸዉ
20	የታዘዘሎትን መድኃኒት ማዘዣ ብያሳዩኝ ወይም መድኃኒቱ ተሰቶት ከሆና ብያሰዩኝና አወሳሰዱን ብገልጹልኝ		

ጊዜዎን ወስደው ለጥያቄዎች ምላሽ ስለሰጡኝ በጣም አመሰግንዎታለሁ፤፤

Annex III. Data abstraction format used for extraction of information from Antenatal care follow up card

No.	Question	Code
1	Code of health institution	☐☐☐
2	Code of data collector	
3	Date of data collection	
4	Card No	
5	No of total antenatal care visit	
6	Gestational age at the time of first visit	_____weeks
7	Gestational age at the last visit	_____weeks
8	Weight at the 1st visit (kg)	_____kg
9	Weight at last visit (kg)	_____kg
10	Height of the woman	_____Cm
11	BMI	_____
12	Hct or Hgb level	1. _____% 2. _____g/dl 3. Not done

13	Complaints/diagnosis at the 1st trimester	1. Nausea/vomiting 2. Dyspepsia 3. Headache or pain 4. Spotting/bleeding per vag. 5. Skin disorders 6. Hypertension 7. Fever and chills 8. Genital infection 9. UTI 10. Diabetes mellitus 11. Cough and cold 12. Others(specify)_____ 13. Not recorded 14. None
14	Complaints/diagnosis at the 2nd trimester	1. Nausea/vomiting 2. Dyspepsia 3. Headache or pain 4. Spotting/bleeding per vag. 5. Skin disorders 6. Hypertension 7. Fever and chills 8. Genital infection 9. UTI 10. Diabetes mellitus 11. Cough and cold 12. Others(specify)_____ 13. Not recorded 14. None

15	Complaints/diagnosis at the 3rd trimester	1. nausea/vomiting 2. dyspepsia 3. headache or pain 4. Spotting/bleeding per vag. 5. Skin disorders 6. Hypertension 7. Fever and chills 8. Genital infection 9. UTI 10. Diabetes mellitus 11. Cough and cold 12. Others(specify)_____ 13. Not recorded 14. None
16	Were there any medication given	Yes_____ No_____
17	**If yes for Q No 17,** Medication given at the 1st trimester of pregnancy	**Medicine name, Dose, Frequency, Duration** 1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____
18	Medications given at the 2nd trimester of pregnancy	**Medicine name, Dose, Frequency, Duration** 1. _____ 2. _____ 3. _____ 4. _____ 5. _____

19	Medications given at the 3rd trimester of pregnancy	**Medicine name, Dose, Frequency, Duration** 1. _____ 2. _____ 3. _____ 4. _____ 5. _____
20	How many times have she been pregnant?	1.gravida_____ 2.parity_____
21	Term of delivery	_____weeks 1.Normal 2.Preterm 3.Post term 4.Discontinued
22	Weight of baby in gram	_____ 1.Normal 2.Low birth weight 3.Extreme low birth weight 4.Over weight
23	APGAR Score	_____

Annex IV: medicines used by pregnant women and their U.S. FDA pregnancy category

Medicines prescribed	FDA pregnancy category
Albendazole	C
Allium sativum; garlic	N
Aluminum hydroxide	N
Amoxicillin	B
Anti-D	C
ART medicines	C
Aspirin	C
Azithromycin	B
Bisacodyl	B
Ceftriaxone	B
Chlorpheniramine	B
Chlorpromazine	C
Cimetidine	B
Cinnamon	N
Ciprofloxacillin	C
Clarithromycin	C

Clotrimazole cream/pessary	C
Cloxacillin	B
Cotrimoxazole	C/D
Dextromethorphan	C
Diclofenac	D
Diphenhydramine	B
Doxycycline	D
Echinops kebericho Mesfin	N
Fringed rue	N
Furosemide	C/D
Glibenclamide	C
Glucose	C
Heam up syrup	C
Hydrocortisone	C
Hyoscine	C
Ibuprofen	B
Isoniazide	C
Insulin	B

Iron with folic acid	A
Lepidium sativum; garden cress	N
Magnesium hydroxide	N
Mebendazole	C
Metformin	C
Methyl dopa	B
Metoclopramide tab/inj	A
Metronidazole	B
Multi-vitamin	A
Nifedipine	C
Norfloxacillin	C
Normal saline 0.9%	N
Omeprazole	C
Oral rehydration salt	N
Paracetamol	B
Phenytoin	D
Prednisolone	C
Promethazine	C

Prophylthiouracil	D
Pylocaine	C
Salbutamol	C
Spironolactone	C
Tetanus antitoxin	C
Tetracycline	D
Theoephedrine	C
Tinidazole	C
Tramadol	C
Vitamin A	A
Vitamin B complex	A/C
Warfarin	X
Zingeber officinale; ginger	N