

**HUMAN IMMUNODEFICIENCY VIRUS AND DIABETES MELLITUS: A MISSED LINK
TO IMPROVE PREGNANCY OUTCOME IN ETHIOPIA**

by

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TO IMPROVE PREGNANCY OUTCOME IN ETHIOPIA**

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I further declare that I have not previously submitted this work, or part thereof, for an examination at Unisa for another qualification or at any other higher education institution.



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ABSTRACT

Introduction: Evidences indicate that human immuno-deficiency virus (HIV) and diabetes (DM) impact pregnancy outcomes but no experience on the integrated service delivery of HIV, DM and pregnancy care. This study explored the domains and levels of integration among DM, HIV and pregnancy care to prepare a service delivery model in Ethiopia.

Methods: A sequential exploratory mixed method and the integration theoretical framework guided the study. An exploratory qualitative phase used focused group discussion, in-depth interview and observation to explore the level of integration and to refine a questionnaire for the quantitative phase. The data were transcribed and coded for theme-based analysis. The descriptive quantitative phase described HIV, DM and pregnancy care services, and determined the burden of DM among HIV patients and the prevalence of pregnancy and pregnancy outcomes. Data was analysed using Epi-info. The findings were triangulated, discussed and interpreted.

Results: Seven themes were generated: joint plan, shared budget, monitoring system, structural location, the need of policy guide, the practice of integrated service delivery and suggested integration approaches. A coordinated HIV and pregnancy care services were noted. There was a linkage between diabetes and HIV, and diabetes and pregnancy care. The 1.5% of diabetes among HIV, the low number of pregnancies per a mother in diabetes (1.8) and HIV (1.3); the high adverse pregnancy outcomes among

HIV (13.4% abortion, 12.4% low birth weight (LBW), 3.5% pre-term birth, 2.1% congenital malformation) and diabetes (3.2% big baby, 3.2% LBW, 3.1% Cesarean-section); the respective absent and low (16.2%) diabetes screening service at anti-natal and HIV clinics, the absent pregnancy care service for diabetic females justified the development of the tripartite integrated service delivery model of diabetes, HIV and pregnancy care.

Conclusions: The model suggests active diabetes screening, evaluation and treatment at HIV and antenatal clinics. It considers the coordination between non-communicable diseases (NCD), HIV and maternal health units. Pregnancy care could be coordinated at HIV and NCD units. Full integration can be practiced between HIV and pregnancy care units. Preparing policy guide, building the capacity of health providers, advocating and piloting the model may be prioritized before the implementation of the model.

KEYWORDS: Diabetes care; HIV care; Integration; pregnancy care; linkage; coordination; tripartite model; pregnancy rate, adverse pregnancy outcome, pregnancy outcome

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Dedication

This study is dedicated to my life love and wife, Leelee G/Egzabher Bahata; my children, Tsinat Zewdu Gashu, Hiruy Zewdu Gashu and the new angel, Mariamawit Zewdu Gashu.

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LISTS OF ABBREVIATIONS AND ACRONYMS

ANC	antenatal care
APO	adverse pregnancy outcome
ART	anti-retroviral therapy
CSA	Central Statistic Authority
DM	diabetic mellitus
DPDP	disease promotion and disease prevention
FDRE	Federal Democratic Republic of Ethiopia
FGD	focus group discussion
FMOH	federal ministry of health
GDM	gestational diabetic mellitus
HAART	highly active anti-retroviral therapy
HCT	HIV counselling and testing
HCW	health care workers
HAPCO	HIV/AIDS prevention and control office
HIV	human immune-deficiency virus
HSREC	Health Studies Research Ethics Committee
IDF	International Diabetes Federation
IDI	in-depth interview
IRB	institutional review board

IUGR	intra-uterine growth retardation
LBW	low birth weight
MCH	maternal and child health
MTCT	mother to child transmission
NCD	non-communicable diseases
PITC	provider initiative HIV testing and counselling
PMTCT	prevention of mother to child transmission
PMR	perinatal mortality rate
RDS	respiratory distress syndrome
REC	review ethical committee
SGA	small for gestational age
VCT	voluntary HIV counselling and testing
WHO	World Health Organization

CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

In 2014, there were 0.79 million people living with Human Immunodeficiency Virus (HIV) in Ethiopia. About 40% of these have access to anti-retroviral therapy (ART) and more than half of pregnant women got ART to prevent mother to child HIV transmission (PMTCT) (Federal Democratic Republic of Ethiopia (FDRE) 2014:10). However, the improved treatment of HIV has translated into an increasing number of patients developing chronic complications, including DM (Kalra, Kalra, Agrawal and Unnikrishnan 2011:2; Young, Critchley, Johnstone and Unwin 2009:1). The risk of developing DM is related to HIV itself or its treatment (Alves, Oliveira & Brites 2008:342). The occurrence of diabetes in HIV infected patients has complicated adherence to the treatment of HIV and DM. There is also an interaction between HIV and DM medication leading to poor treatment outcomes of HIV and DM patients (Monroe, Rowe, Moore & Chander 2013:1).

Literature present the clinical complications of HIV and DM with limited information regarding their effect on pregnancy outcomes (DOS REIS, Araujo, Ribeiro, Da Rocha, Rosato, PASSOS & Mercon De Vargas 2015:111; Kim, Kasonde, Mwiya, Thea, Kankasa, Sinkala, Aldrovandi & Kuhn 2012:138). Nonetheless HIV and DM are related to fertility (Livshits & Seidman 2009:701) and can affect pregnancy outcome if they are not treated per the standard. HIV and DM services can be integrated to reduce adverse pregnancy outcomes. However, there are few experiences with the integration of HIV and DM services to deal with adverse pregnancy outcomes related to HIV and DM. This study, hence will explore and describe the level of DM and HIV service integration to reduce adverse pregnancy outcomes among reproductive age women in Addis Ababa Ethiopia.

1.1.1 Levels of integration

According to Pike and Mongan (2014:25) there are three levels of integration; namely, linkage, collaboration and full integration.

1.1.1.1.Linkage

Linkage is the system that services the whole population without relying on outside system. It is information sharing, which provides when asked and ask when needed. Multidisciplinary teams in health facilities can be established, but tends to focus on communication (linkage) rather than decision making, planning and coordination. It focuses on improving the link between providers. It depends heavily on education as a mechanism for change. The dissemination of information is difficult to sustain.

1.1.1.2 Collaboration

Collaboration is more structured referral linkage than only linkage. There are structures and individual to facilitate and coordinate. In collaboration, reports are defined and provided. It requires someone specifically designed to do the coordination. There is a formal arrangement such as protocols and a memorandum of understanding but are difficult to sustain.

1.1.1.3 Full integration

Full integration shares information using a common record as part of daily practice. It is applied when a new program or unit which pools resources from multiple system. It merges all cases.

1.1.2 Adverse pregnancy outcomes

Short-term maternal and perinatal complications, including diseases have been considered as they are consistent with the way in which maternal and perinatal outcomes are grouped for monitoring and research purposes. The following adverse pregnancy outcomes on the foetal sides will be evaluated: low birth weight (live infant

weighing <2500g at birth), preterm delivery (live infant delivered at <37 weeks' gestation), stillbirths (macerated and fresh stillbirths), severe neonatal conditions (neonates presenting with any of the following conditions: birth weight <1500g, gestational age <32 weeks and Apgar score at 5 minutes) and early neonatal death (deaths that occurred within 7 days after birth), preterm deliveries (deliveries before 34 weeks of gestation). Besides, Intra uterine growth retardation (IUGR), congenital malformation, Respiratory distress syndrome (RDS) and Sepsis were looked into (Ouyang, Zhang, Betrán, Yang, Souza and Merialdi 2013:357). As defined by Ouyang et al (2013:358), the maternal complication to be considered were caesarean section (C-section), pre-eclampsia, eclampsia, haemorrhage, gestational diabetes, maternal death, systemic infections and maternal near miss.

1.2 BACKGROUND TO THE RESEARCH PROBLEM

There has been an increase in fertility intention among HIV infected women following the expansion of ART in response to the HIV epidemic (Cooper, Moodley, Zweigenthal, Bekker, Gail, Shah, & Myer 2009:44; Finocchiaro-Kessler, Sweat, Darlotis, Trent, Kerrigan, Keller, & Anderson 2010:1106). Consequently, there are higher prevalence and incidence of pregnancy among HIV infected women (Kaida, Matthews, Kanters, Kabakyenga, Muzoora, Mocello, Martin, Hunt, Haberer, Hogg & Bangsberg 2013: e63411) and it is comparable with the general population (Kabami, Turyakira, Biraro and Bajunirwe 2014:81). On the contrary, there are evidences of reduced occurrence of pregnancy for HIV virus itself or ART can have a risk of infertility (FavotNgalula, Mgalla, Klokke, Gumodoka & Boerma 1997:414). A study conducted in Uganda shows that ART use did not affect pregnancy desire (Kipp, Heys, Jhangri, Alibhai & Rubaale 2011:27).

Maternal HIV infection in women who have not received anti-retroviral therapy (ART) is associated with preterm birth, low birth weight, small for gestational age and stillbirth in sub-Saharan Africa (Chekol 2011:10; Joseph, Biodun & Michael 2011:356; Wedi, Kirtley, Hopewell, Corrigan, Kennedy and Hemelaar 2016:E33). Though mother to child transmission (MTCT) is substantially reduced by ART, some of these pregnancies are

complicated by low birth weight (LBW) and pre-term or premature deliveries (DOS REIS et al 2015:111; Kim et al 2012:1). DOS REIS et al (2015:111) further state that the complications are highly prevalent among women on ART before or in the first trimester of pregnancy and receiving protease inhibitors.

Exposure to ART increases the incidence of DM (Isa, Oche, Kang'ombe, Okopi, Idoko, Cuevas and Gill 2016:ciw381; Karamchand, Leisegang, Schomaker, maartens, Walters, Hislop, Dave, Levitt & Cohen 2016; Tzur, Chowers, Agmon-Levin, Mekori & Hershko 2015:620). ART leads to an increase in metabolic dysfunction such as insulin resistance, dyslipidaemias and lip-dystrophy. High risk of DM also presents in patients with a high viral load and low CD4 (+) count, longer duration with HIV infection, advanced age, low socioeconomic status and the accumulation of visceral fats (Kalra et al 2011:1). DM is estimated to be four fold more in HIV infected patients on ART (Brown, Cole, Li, Kingsley, Palella, Riddler, Visscher, Margolick & Dobs 2005:1179).

Both pre-gestational and gestational DM is increasing; mainly, driven by a sharp increase in Type II DM (Bell, Bailey, Cresswell, Hawthorne, Critchley & Lewis-Barned 2008: 445). A high glucose level impairs implantation and affects the level of hormones essential for pregnancy leading to infertility or reduced incidence of pregnancy (Livshits & Seidman 2009:701). High blood glucose can also damage embryonic cells and thus pregnancy in DM is associated with an increase rate of adverse outcome for both mother and fetus (Kinsley 2007: S153). These are macrosomia, stillbirth, infant death, hypertension during pregnancy, increased frequency of C-section and spontaneous abortion (Bell et al 2008:445; Fernandes, Simões, Figueiredo, Ribeiro, Aleixo, Aragüés & Amaral 2012:494; Kinsley 2007: S153; Middleton, Crowther, Simmonds & Muller 2010:9; Verheijen, Critchley, Whitelaw & Tuffnell 2005:1500). Fetal congenital abnormalities and poor perinatal outcomes are related to glycaemic control in first trimester (Kinsley 2007: S153; Middleton et al 2010:9; Rowan, Gao, Hague & McIntyre 2010:9) and optimized metabolic control can reduce these complications. However, McCance (2011:954) indicates that perinatal mortality and congenital malformation

rates remains several fold higher in pregnancy in DM irrespective of improved management of maternal hyperglycaemia.

Therefore, HIV infection and its treatment increase the risk of DM. Conversely, a poorly controlled DM share immunosuppression state like HIV. Complications of DM and its treatment have challenged adherence in DM and HIV co-morbid patients (Young et al 2009:1).

Because HIV and DM are related, impact on each other and affect the pregnancy outcomes in reproductive age women, linking and collaborating the program management and clinical services of HIV and DM with maternal health seems paramount to reduce their complications (Gounder & Chaisson 2012: 1426). This is due to the fact that integration can improve coordination and service delivery by providing services together. Integration also ensures that services are managed and delivered together in an efficient and high quality service (Dudley & Garner 2011). In addition, integration addresses equitable access for people from different communities and socioeconomic backgrounds, a more convenient and satisfying service, and better health overall (Gounder & Chaisson 2012:1426). For instance, there is an integration experience between HIV and TB (World Health Organization (WHO) 2012), HIV and family planning (Baumgartner, Green, Weaver, Mpangile, Kohi, Mujaya and Lasway 2014: 570), TB and DM (WHO 2011), maternal and child health (Matthews 2005) where it is shown that integration of services improve quality of care for patients. However, with integration of care, health providers might become overloaded and loss specialized skills to manage specific diseases, which could lead to poor quality services and poor health (Gounder & Chaisson 2012:1428).

Experience from Cambodia (Janssens, Van Damme, Raleigh, Gupta, Khem, Soy Ty, Vun, Ford & Zachariah 2007:880) shows integrating HIV care with other chronic diseases such as DM and hypertension (HPN) is feasible, resulting in a satisfactory outcome for HIV patients and efficiency gains for the services. In Malawi (Gounder and Chaisson 2012) the need for integrated management of HPN and DM in HIV patients was assessed and suggested to develop initiatives for the integrated care for HIV with

HPN and DM. However, these studies did not consider the advantages of DM/HIV integration with pregnancy care. Irrespective of the presence of interactions between HIV and DM, impacting pregnancy and pregnancy outcomes, there has not been a practice of integration between HIV and DM in Ethiopia.

1.3 STATEMENT OF THE RESEARCH PROBLEM

Ethiopia is facing a rapidly emerging burden of DM, ranging within 0.5% to 1.2% (Misganaw, Mariam, Ali & Araya 2014:1). Simultaneously, the country is challenged with high HIV prevalence of 1.3% (FDRE 2014:6). HIV and its treatments are risk factors for DM, and HIV and DM can lead to clinical complications to the affected patients and can also impact pregnancy outcomes. In line with the emergence of DM as major diseases of public health importance among HIV infected patients in Ethiopia; however, DM and HIV service integration has got little attention.

Diabetes Mellitus and HIV services are vertically implemented in Ethiopia and are less frequently tied together to deal with their complications. There seems a missed link between DM and HIV to reduce adverse pregnancy outcomes related to them. That is, there is no defined and well-established level of integration between the two programs to deal with HIV and DM related adverse pregnancy outcomes. Therefore, it is high time to consider an integrated care of model linking HIV and DM to deal with adverse pregnancy outcomes in the affected women of child-rearing age.

The integration of HIV, DM and pregnancy care service is not specific as well. It is necessary to clarify on what level of HIV and DM integration is required at health facilities and different program management levels to improve pregnancy outcome among HIV and DM patients. It is also noted that clinicians primarily work on linking, with a few elements of coordination. There is no routine active screening and testing of HIV patients for diabetic patients and vice versa. There are health facilities with pregnancy counselling and a few contraceptive services at the HIV clinic. Others provided the full package of family planning and pregnancy counselling and testing at

HIV clinics. The collaboration and coordination between HIV, DM and pregnancy care seem absent or uneven differing in different settings, but critical to improve maternal and perinatal health.

In Addis Ababa city where this study is conducted, the rate of HIV prevalence declined from 8.5% in 2009 to 5.7% in 2011. However, the city is still one of the highest HIV prevalence in the country (CSA 2012:234). Besides, the burden of DM is high in the city and accounts for about 6.5 % of hospital admissions in Addis Ababa (Gizaw, Harries, Ade, Tayler-Smith, Ali, Firdu and Yifter 2015:74). Though HIV is decentralized to health centres, DM care is limited to hospitals and a few health centres. DM is integrated with other non-communicable diseases such as hypertension.

There is little and non-uniform link or collaboration of HIV, DM and pregnancy service across health facilities. HIV counselling and testing services at diabetic clinic are limited. The practice of active screening of diabetes at HIV clinics is absent. There are health facilities that provide pregnancy counselling, condom and oral contraceptive pills at the HIV clinic. However, these activities are not routinely recorded and registered. HIV counselling, testing and treatment are being given at antenatal care (ANC) clinics. However, the focused ANC recommends only the urine test for ketones to screen diabetes mellitus in pregnant women. Diabetic mellitus screening algorithms and registers are not available at ANC clinic. Nevertheless, a standardized and integrated HIV, DM and pregnancy care model is essential to improve the clinical complications and adverse pregnancy outcome.

Even though there is an established relationship between DM and HIV diseases and both are affecting pregnancy outcome among the reproductive age women, there has not been a theoretical framework or a model guiding an integrated service delivery in Ethiopia. Hence, the researcher in this study is interested in developing an integrated model addressing how a child-rearing age woman should obtain an integrated service inclusive of diabetes, HIV and pregnancy care in health facilities to prevent adverse pregnancy outcomes. To state in a sentence, during the period where maternal and

perinatal death is high in Ethiopia due to HIV and DM (Central Statistical Agency/CSA/Ethiopia and ICF. 2016), the authors aimed to develop an integrated model of care inclusive of HIV, DM and pregnancy care so as to guide a clinical care and policy of maternal care.

1.4 PURPOSE OF THE STUDY

The purpose of the study was to develop an DM/HIV integrated service delivery model to improve pregnancy outcomes for females in Addis Ababa, Ethiopia.

1.4.1 Objectives of the study

A research objective is a concrete, measurable end towards which effort or ambition is directed (Brink, Van der Walt & Van Rensburg 2018:85). The objectives of the study were listed under the two phases of the study.

Objective of Phase I of the study was to

- explore the functional, organizational and clinical integration of DM, HIV and pregnancy care service at federal, regional, sub city and health facility levels.

Objectives of Phase II of the study were to

- describe pregnancy care, HIV and DM services at ANC, DM and HIV clinics in Addis Ababa health facilities,
- determine the prevalence rate of DM among HIV females of childbearing age enrolled in HIV care during 2011-2016 in Addis Ababa health facilities,
- determine prevalence rate of pregnancy among HIV and DM childbearing age females enrolled to care during 2011-2016 in Addis Ababa health facilities, and
- determine prevalence rate of adverse events in pregnancy among HIV and DM childbearing females enrolled to care during 2011-2016 in Addis Ababa health facilities.

1.5 RESEARCH QUESTIONS

The research questions were based on the objectives of the study and were stated as follows:

- What is the level of integration of HIV, DM and pregnancy care services in Addis Ababa health facilities?
- What is the magnitude of pregnancy and adverse pregnancy outcome among HIV and DM patients?

1.6 SIGNIFICANCE AND CONTRIBUTION OF THE STUDY

This study will unfold critical evidences on the impact of diabetes mellitus and HIV on pregnancy outcome and the integration level of HIV, diabetes mellitus and pregnancy care. The findings will therefore be applicable in the improvement of the practical knowledge regarding the provision of an integrated standard care for HIV and DM to prevent adverse pregnancy outcomes. It can also assist program managers and policy makers to consider the interaction between HIV and DM to reduce pregnancy outcomes of childbearing women. The DM/HIV care of model in this study could optimize the control of DM and HIV among reproductive age women from preconception through pregnancy and minimize the risk of maternal and foetal complication due to the DM and HIV.

Understanding the interaction between HIV and DM and their impact on pregnancy outcome could assist in the planning programs of HIV and DM, and sexual and reproductive health policy formulation. The study assesses the prevalence rate of pregnancy and its adverse outcomes impacted by DM and HIV. This can help to improve counselling on fertility issues and strict antenatal care to avert adverse pregnancy outcome of mothers in Ethiopia. Recognizing the chronic nature of HIV and DM may also assist to come up with an integrated care of model, including routine screening of HIV and DM among pregnant women to deal with adverse outcomes due to DM and HIV.

1.7 DEFINITIONS OF KEY CONCEPTS

A concept is an abstraction based on observations of behaviours or characteristics. A conceptual definition presents the abstract or the theoretical meaning of the concepts being studied (Polit & Beck 2017:47 & 722). It was important to define concepts so that their right meaning in the study is clearly understood. Hence, defining them gives the reader a clear understanding in the context. The following concepts are defined in the context of this study.

1.7.1 Diabetes Mellitus

Diabetes mellitus is a disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood (Concise Oxford English Dictionary 2011, sv "diabetes"). It is also a chronic disease that occurs either when the pancreas does not produce enough insulin (Type 1 diabetes) or when the body cannot effectively use the insulin it produces (Type 2 diabetes) (WHO 2013b:2). In this research, the WHO diagnostic criterion for diabetes mellitus in women is used. It is when fasting plasma glucose ≥ 7.0 mmol/l (126mg/dl) or 2-hour plasma glucose ≥ 11.1 mmol/l (200mg/dl) (WHO 2006:1). Gestational diabetes (GDM) is diagnosed at any time during pregnancy if one or more of the following criteria are met: fasting plasma glucose 5.1-6.9 mmol/l (92 -125 mg/dl), 2-hour plasma glucose 8.5-11.0 mmol/l (153 -199 mg/dl) following a 75g oral glucose load (WHO 2013b:5).

1.7.2 Diabetes mellitus care

For the purpose of this study, screening for DM using urine or blood test of fasting or random sugar, treatment of DM and follow up are defining care of diabetes mellitus.

1.7.3 Human immunodeficiency virus

Human immunodeficiency virus is the type of virus that enters the body through blood or sexual activity and can develop into acquired immune deficiency syndromes (AIDS) (Longman dictionary of contemporary English, 2009 sv “HIV”). It also refers to human immunodeficiency virus and infects cells of the immune system, impairing their function. HIV infection results in progressive deterioration of the immune system, leading to AIDS (Goldman & Ausiello 2008:403; World Health Organization 2013: xiv-xv). HIV infection is diagnosed by routine blood test detecting antibodies related to HIV within 6-12 month after infection (Suthar, Ford, Bachanas, Wong, Rajan, Saltzman, Ajose, Fakoya, Granich, Negussie & Baggaley 2013: e1001496). In this study HIV infected women are those who are diagnosed and confirmed by routine blood test detecting antibodies related to HIV (Suthar, Ford, Bachanas, Wong, Rajan, Saltzman, Ajose, Fakoya, Granich, Negussie, and Baggaley 2013: e1001496).

1.7.4 HIV clinic

HIV clinic is a room or place where HIV infected people get care, adherence support and anti-retroviral therapy.

1.7.5 HIV services

In this study, HIV services include counselling on HIV prevention, testing of HIV, clinical and laboratory evaluations, adherence support, provision of ART and the follow-up care.

1.7.6 Integration

Based on Longman dictionary integration is “the combining of two or more things so that they work together effectively” (Longman dictionary of contemporary English, 2009 sv “integration”). Pike and Mongan (2014:7-8) defines integration as a search to connect the health care system with other human services to improve outcomes. Integration is a

concept which brings together inputs, delivery, management and organization related services of diagnosis, treatment, care, rehabilitation and health promotion as a means to improve access, quality, user satisfaction and efficiency (Pike & Mongan 2014:8).

In this study, the definition by Kodner and Spreewenberg (2002:4) is used: “integration is a set of methods and models on the functional, organizational and service delivery or clinical levels designed to create connectivity alignment and collaboration within and between HIV, DM and pregnancy care to enhance quality of care, quality of life, and system efficiency for patients with HIV and DM problems cutting across multiple service provider and setting”.

1.7.7 Pregnancy

Pregnancy, according to Concise Oxford English Dictionary (2011, sv “pregnancy”) is the condition or period of being pregnant. It is the state of carrying a developing embryo or fetus within the female body.

This condition can be indicated by positive results on an over-the-counter urine test, and confirmed through a blood test, ultrasound, detection of fetal heartbeat, or an X-ray (Ouyang et al 2013: 357).

1.7.8 Pregnancy care

This includes pregnancy counselling on conception/being pregnant, urine pregnancy test, provision of one of the modern family planning, all comprehensive antenatal care (ANC) and delivery service.

1.7.9 Pregnancy prevalence

This is defined as the number of pregnancies detected during 2011-2016.

1.7.10 Health care workers (HCW) are health care providers or clinicians at health facilities such as doctors, nurses and health officers working actively at HIV, NCD and ANC clinics.

1.7.11 Program managers are the focal persons or team leaders for NCD, MCH and HIV programs and are responsible for the respective programs at FMOH, RHB and sub-cities. The program managers could also be team leader. Therefore, team leader and program manager could be used interchangeably.

1.7.12 Program officers are health professionals who are supervised by the program managers and actively engaged in the planning, implementation, monitoring and evaluation.

1.8 ASSUMPTIONS OF THE STUDY

Assumptions are statements that are assumed to be true without necessitating proving them (Burns & Grove 2013:40). The assumptions for this study were as follows:

1.8.1 Ontological assumptions

Ontology means the nature of reality (Holloway & Wheeler 2010:21). According to Giacomini (2010:129), it is the examination of the nature of being real which is socially constructed by individuals involved in the research situation. In this study, integrating DM and HIV to improve pregnancy outcome is real and measurable. This means the level of DM/HIV integration can be observed, prevalence of adverse pregnancy outcome among HIV and DM patients is measurable as well. HCWs and program managers through in-depth interviews (IDI) and focus group discussion (FGD) can construct the level of DM and HIV integration. i.e., multiple realities about the integration of DM and HIV can be constructed.

1.8.2 Epistemological assumptions

According to Longman dictionary of contemporary English, “Episteme” is a Greek word meaning knowledge. Epistemology is about what can be known (Longman dictionary of contemporary English, 2009 sv “episteme”). This is how the researcher understands knowledge and how it is obtained (Holloway & Galvin 2016:21). The epistemological assumption in the pragmatic paradigm claims that knowledge arises out of actions, situations and consequences, and is socially constructed by the processes of institutionalization and legitimization. Socialization places managerial characteristics and perceptions at the core of any inquiry that seeks to understand organizational life (Yefimov 2014:5).

It was assumed that the integration of DM and HIV to improve adverse pregnancy outcomes could be studied and one could learn something useful about the DM/HIV integration. The DM and HIV integration was explored through capturing and documenting what HCWs and program managers had to say since they were the ones with experience of clinical service and program management of HIV and DM.

1.8.3 Methodological assumptions

Based on the above assumptions the researcher took certain methods that were workable for learning about integration of HIV and DM to improve adverse pregnancy outcome.

A mixed method research was used to answer the research question of this study. Johnson, Onwuegbuzie and Turner (2007:112) state that mixed method research combines elements of qualitative and quantitative research approaches for the purpose of breadth and depth understanding and corroborating. According to Creswell, Klassen, Plano Clark and Smith (2011:5) mixed method research focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or series of studies to investigate and understand the same phenomenon. Its central premise is that

the use of quantitative and qualitative approaches to provide a better understanding of the research problem than either approach alone. .

The mixed method in this study assisted to obtain a more complete picture of HIV, DM and pregnancy care service integration of HCWs at health facilities and program managers working in the ministry of health, Addis Ababa region and sub-cities on maternal health, non-communicable diseases (NCD) and HIV. In this study data abstraction checklist for quantitative data, observation, in-depth face to face interview and focus group discussion with open ended question guide were utilized. This allowed obtaining a deep and rich understanding of what the program managers and health care providers were thinking and doing regarding HIV and DM integration to prevent adverse pregnancy outcomes.

1. 9 THOERETICAL FRAMEWORK

Theory is the interpretive lens based on which one shape the study (National Institute of Health (NIH) 2005:4). This study was guided by an integration theory initially defined by Leutz (1999) (cited in Pike & Mongan 2014:10).

According Pike and Mongan (2014:10) integration has a sense of the 'glue' that holds the units together. In a health system, integration can occur in the policy, budgeting, organization, service and clinical delivery levels. Integration is also conceptualized as occurring on a continuum in which full integration anchors one end and full separation can chores the other. In between there is little structural arrangement (informal referral) to explicit formal structures, such as contractual agreements and formal referral protocols (Pike & Mongan 2014:11-12).

The concept of integrated care was initially used by primary care and was promoted as a means to address access, quality and continuity of health care services in efficient way particularly for peoples with multiple morbidities. It was developed to deal with the health service fragmentation due to specialization and differentiation, which results in

suboptimal care, higher cost and poor quality of care (Dudely & Ganer 2011:2). Thus, in a developing country with a population with multiple morbidities, an integrated health system has been promoted as a means to improve access, quality and continuity of services in a more efficient way (WHO 2008:2).

Accordingly, a conceptual framework is developed based on which this study is structured (figure 1.1). Its basis is the work of Shortell, Gilles and Anderson (1994) and Van Deusen Lukas and Desai (1999) and used in South Africa for TB and HIV integration (Uyei, Coetzee, Macinko, Weinberg & Guttmacher 2014:42) and recently described by Pike and Mongan (2014:26-27). This HIV, DM and pregnancy care integration conceptual framework is operationalised by three domains; functional, organizational, clinical or service integration.

1.9.1 Organizational Integration

This is the extent to which non-clinical program components are incorporated at the point of care or clinics. In this study it was assessed for the co-location of HIV, DM and pregnancy care services, combined DM and HIV patient services, HIV and DM information management, and joint training for HIV and DM to prevent adverse pregnancy outcomes.

1.9.2 Functional integration

This is a mechanism by which financing, information and management modalities are linked to coordinate and support accountability and decision making between organization and professionals to add the greatest overall value to the system. Functional integration supports organizational and clinical integration to occur (Van deusen Lukas and Desai 1999). In this study, it was a description of the extent to which key administration, financial operations and activities are combined at the managerial and policy level, such as strategic planning, budgeting and setting operation guidelines for joint HIV, DM and pregnancy care programs.

1.9.3 Clinical integration

Clinical integration is the extent to which diagnostic, treatment, care and health promotion are concurrently delivered to the patients. It ensures services do not fall between the cracks. It includes notions of continuity of care, coordination of care, disease management, good communication among caregivers, smooth transfer of information and records, elimination of duplicate testing and procedures (Pike & Mongan 2014:94).

In the clinical integration, service can be integrated structurally where there is formal HIV and DM related guidelines and protocols regarding the practice of joint service delivery. The process of clinical integration includes behaviour and practice of HCWs regarding the DM, HIV and pregnancy service delivery. Clinical integration also helps to explore whether there is a culture of workplace and personal identification with HIV, DM and pregnancy care integrated service delivery (Axelsson & Axelsson 2006:78-79).

The process in the service integration means to see whether there are HIV counselling and screening services at diabetes and ANC clinics. The process indicates whether there is screening of diabetes mellitus service in HIV and ANC clinics. The process also measures access and means of utilization. In the study, it meant the number of facilities with integrated DM, HIV and pregnancy counselling.

The integrated service delivery influences both output and impact. Output is performance of service generated and in this research it is the number or proportion of reproductive age mothers at HIV and ANC clinics counselled and screened for diabetes mellitus, the proportion tested for HIV at DM and ANC clinics and the number or proportion of mothers at ANC with DM and HIV screening and testing services. Impact on the integrated service models means patients' outcomes. In this study it meant the magnitude of DM among HIV patients, the prevalence of pregnancy and pregnancy outcomes among HIV and DM patients. The co-variate, the potential determinants for the output and impact, are age and sex, sugar level and CD4 count of the participants.

The co-variables are also used to describe the context of the study in terms of the prevalence and burden of DM, pregnancy and adverse pregnancy outcomes (Figure 1.1).

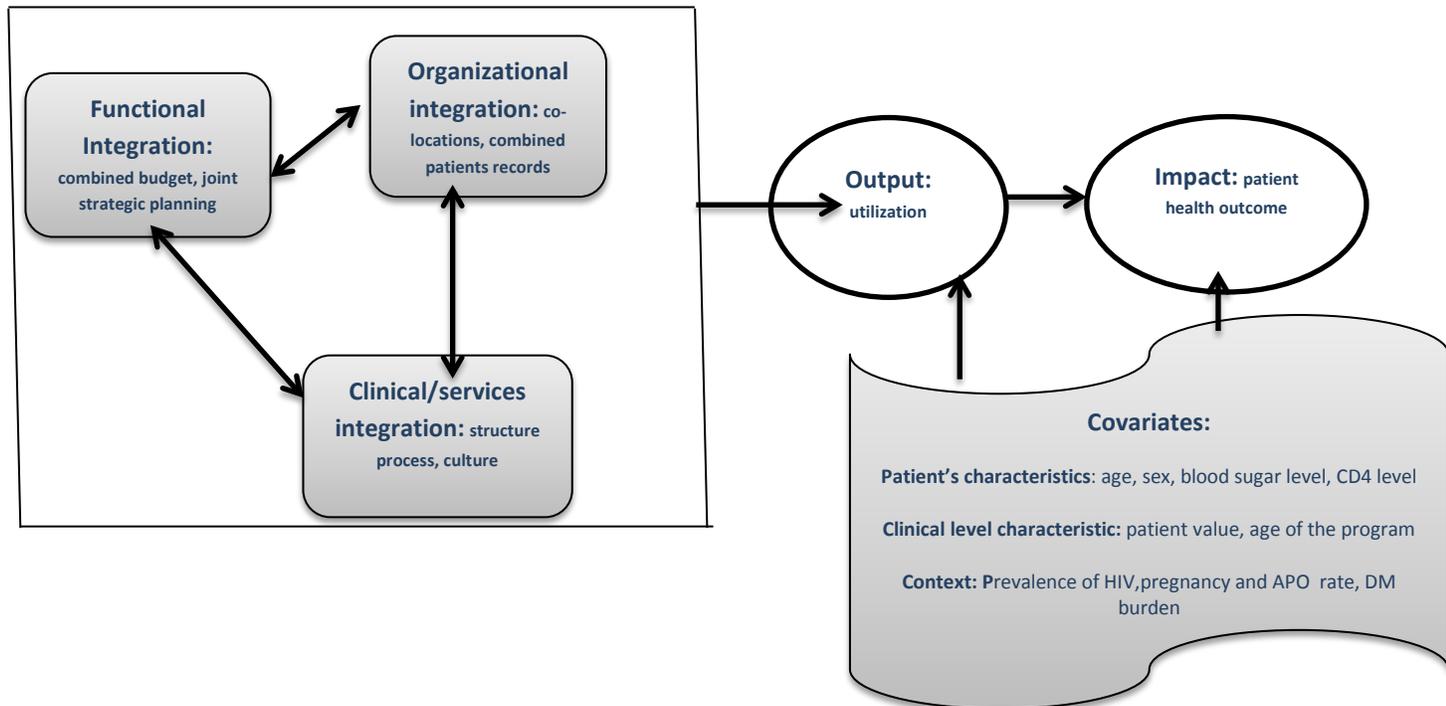


Figure 1.1: Integrated service delivery: conceptual framework

(Adapted from Pike and Mongan (2014:26-27))

The integration conceptual frameworks used here is a high-level conceptual categories and relationships that may not explain DM/HIV/pregnancy care integration, but identify the types of concepts that are likely needed to provide an explanation (Pike & Mongan 2014:25). In this study, the integrated theoretical framework developed based on theory of integration by Leutz (1999) (cited in Pike & Mongan 2014:10) was used to guide this study. In other words, the integration theory and the conceptual framework used in this study served as guidance for model development.

1.10 RESEARCH PARADIGMS

Paradigms is a 'world-views' that signal distinctive ontological, epistemological, and methodological perspectives. The paradigm of post-positivism emphasizes quantitative methods as opposed to interpretivists which focus on qualitative inquiry. Pragmatic paradigm embraces the two extremes normally espoused by post-positivism and interpretivist (Johnson et al 2007:112; Morgan 2007:48).

Pragmatic paradigm is concerned with applications and puts the research problem as central and applies all approaches to understanding the problem (Creswell 2014:39). Creswell (2014:39) further argues that, instead of methods being important, the research problem is the most important issue and individual researchers have freedom of choice regarding the methods, techniques and procedures of research that best meet their purposes. Pragmatism paradigm rejects the scientific notion that social inquiry was able to access the truth about the real world solely by virtue of a single scientific method (Mertens 2007:212). Thus, it provides the underlying philosophical framework for mixed method research (Creswell 2014:39). Therefore, pragmatism or mixing paradigms was preferred in this study to obtain a more complete picture of HIV, pregnancy care and DM service integration to improve pregnancy outcomes.

1.11 THE RESEARCH DESIGN

The research design, according to Burns and Grove (2013:209), is the overall plan of action of the study. It dictates the type of study planned and methods to be employed to produce and analyse data (Bowling 2014:158). Creswell et al (2011:72-73) classify mixed methods study designs into four; the convergent parallel design, the explanatory sequential design, the exploratory sequential design and the embedded design.

This study applied an exploratory sequential mixed method study design, with an exploratory qualitative design followed by a descriptive quantitative design in two phases of the study period (see Figure 1.2). This was to achieve the understanding of

how women in the reproductive age group could be offered integrated services of DM, HIV and pregnancy care services to improve the pregnancy outcomes and then to come up with the service delivery model. The quantitative phase utilized the instrument refined using the phase I findings to further enrich the model, assess the level and domains of the integration service inclusive of DM, HIV and pregnancy care.

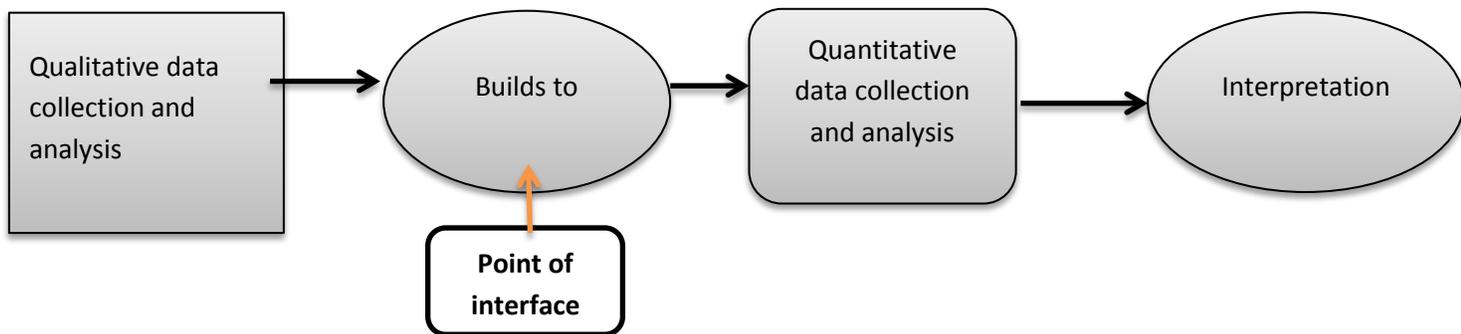


Figure 1.2: A mixed method exploratory sequential study design

(Adapted from Creswell et al (2011:2087))

1.12 RESEARCH METHODS

This study has two phases, phase I and phase II. In phase I, a qualitative data was collected using IDI, FGD and observation through video recording and field notes. The word was coded for theme analysis. In phase II, a quantitative data was collected using the abstraction checklist. Descriptive analysis was carried out. Purposive sampling for qualitative, and simple random sampling for quantitative phase were used. The research methodology is summarized in table 1.1 below. The detailed methods and data design quality are described and presented in chapter 3.

TABLE 1.1: SUMMARY OF STUDY OBJECTIVES, METHODS AND DATA ANALYSIS BY PHASES OF THE STUDY

Phases of the study	Objectives	Approach	Sample	Sampling method	Data collection	Data analysis
Phase-I	To explore the functional, organizational and clinical integration of DM, HIV and pregnancy care service at federal, regional, sub city s and health facility levels	Qualitative	NCD, HIV and Maternal health program managers at federal, regional, sub city levels and health facilities	Purposive	In-depth interview, focused group discussion and observation: audio record and fieldnote	Transcription, categorizing, coding and theme-based
		Qualitative	HCWs working at NCD, HIV and ANC	Purposive	Focused group discussion, observation: audio record and field note	Transcription, categorizing, coding and theme-based
Phase-II	To determine prevalence of DM among HIV patients among childbearing female registered during 2011-2016 in Addis Ababa health facilities	Quantitative	HIV infected patients	Sex based stratified Simple random sampling	Data abstraction and patient interview: data abstraction checklist/questionnaires	Prevalence rate
	To determine the prevalence of pregnancy among HIV and DM childbearing female registered during 2011-2016 in Addis Ababa health facilities	Quantitative	HIV infected patients and DM patients	Sex based stratified Simple random sampling	Data abstraction and patient interview: data abstraction checklist/questionnaires	Prevalence rate
	To determine the prevalence of adverse pregnancy outcomes among HIV and DM childbearing females registered during 2011-2016 in Addis Ababa health facilities	Quantitative	HIV infected patients and DM patients	Sex based stratified Simple random sampling	Data abstraction and patient interview: data abstraction checklist/questionnaires	Prevalence rate
	To describe mothers with a documented HIV and DM services at ANC clinics in Addis Ababa health facilities	Quantitative	Pregnant women with ANC follow up	Simple random sampling	Data abstraction and interview: data abstraction checklist/questionnaires	Number and percentage
	To describe females with a documented pregnancy care and HIV services at DM clinics in Addis Ababa health services	Quantitative	DM reproductive age women	Simple random sampling	Data abstraction and interview data abstraction checklist/questionnaires	Number and percentage
	To describe females with a documented pregnancy care and DM services at HIV in Addis Ababa health services	Quantitative	HIV infected childbearing women	Simple random sampling	Data abstraction and interview data abstraction checklist/questionnaires	Number and percentage

1.13 LAYOUT OF THE STUDY

The content of the thesis is organized into six interrelated chapters. The chapters in this study are as follows:

Chapter 1: Introduction and orientation to the study

Chapter 2: Literature review

Chapter 3: Research design and methods

Chapter 4: Description, analysis and triangulation of the findings

Chapter 5: Development of an integrated service delivery model for HIV, DM and pregnancy care

Chapter 6: Conclusions, limitations and recommendations

1.14 CONCLUSION

Chapter 1 presented an orientation to the study. The problem statement was derived from the given background. The purpose and objectives were also outlined. The research questions and an overview of the theoretical framework, the research method, and the research design were also presented. Definitions of terms were listed. The next chapter is the literature review.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Literature review assists to summarize and understand the existing knowledge regarding the topic under study (Sadler, Burgin, McKinney & Ponjuan 2010:235). The literature review in this study serves to identify any gaps in the existing pool of knowledge on the topic under study. In this chapter the literature review covers the main concepts related to the research topic; specifically, diabetes mellitus, HIV, the relationship between HIV and DM, pregnancy care, effects of DM and HIV on pregnancy, and outcomes of pregnancy. The review was guided by the research questions. Google scholar, pubmed, UNISA electronic articles and books, national policy guides and reports on DM, HIV and maternal health were the source for the literature review. After thorough reading of these sources, summary notes were taken, similar themes were summarized and organized to fit to the research questions.

2.1.1 Non-communicable and communicable diseases in developing countries

The significant increase in non-communicable diseases death in the next decade is expected in Africa, where NCD is likely to become the leading cause of death by 2030 (Dalal, Beunza, Volmink, Adebamowo, Bajunirwe, Njelekela, Mozaffarian, Fawzi, Willett, Adami & Holmes 2011:885). However, less attention has been paid to the extent to which NCD contributed to morbidity and mortality. The focus in sub-Saharan Africa region has been on communicable diseases and maternal, perinatal and nutritional causes of morbidity and mortality (Boutayeb 2006:191). These are countries where the burden of communicable diseases is still high. The convergence of NCD and communicable diseases in low and middle income countries has the potential to overstretch the already strained health systems. With some developing countries now focusing on major health system reforms, a unique opportunity is available to address

challenges by NCD and communicable disease with novel approaches. Therefore, integrating public health activities for communicable disease and NCD should extend beyond health care services to prevention (Remais, Zeng, Li, Tian & Engelgau 2013:221).

There are close relationships between communicable diseases and NCD in terms of causation, co-morbidity, and care. Oftentimes, both communicable diseases and NCD co-exist, and one can increase the risk or impact of the other (Norheim, Jha, Admasu, Godal, Hum, Kruk, Gómez-Dantés, Mathers, CD Pan, Sepúlveda and Suraweera. 2015:239). Diabetes, for example, can interact with and complicate a number of communicable diseases. HIV-infected patients with access to anti-retroviral treatments can now expect prolonged survival and ageing and hence accompanied by the emergence of diabetes and lipid disorders (Lo, Chen, Sheng, Hsieh, Sun, Liu, Wu, Wu, Hung & Chang, 2009:302).

Together, NCD and communicable disease can affect pregnancy outcomes. For instance, poor maternal nutrition before and during pregnancy together with smoking tobacco during pregnancy contribute to poor intrauterine growth, resulting in low birth weight which in turn predisposes to DM risk later in life. The problem is compounded by HIV/AIDS. Low birth weight and malnutrition are more frequent in HIV-infected children (DOS REIS et al 2015:111; Kim et al 2012:1). In this chapter DM, as an accelerating NCD; and HIV, as an impacting communicable disease will be discussed regarding their relationship and their impact on adverse pregnancy outcomes.

2.2 HUMAN IMMUNO-DEFICIENCY VIRUS

HIV belongs to the family of retroviruses that targets and weakens the immune system. The virus destroys immune cells with the CD4 (+) marker, often called T cells. Over time, HIV can destroy many of these cells to an extent that the body cannot fight off infectious diseases (WHO 2013a: xiv).

The advanced stage of HIV infection is AIDS. AIDS is defined by the opportunistic infections or cancers that take advantage of a very weak immune system. It takes from 2 to 15 years to develop AIDS depending on the individual (Goldman & Ausiello 2008:393).

2.2.1 Transmission of HIV

HIV can be transmitted via the exchange of a variety of body fluids. The infectious fluids are blood, breast milk, semen and vaginal secretions. Having unprotected anal or vaginal sex; sharing contaminated needles, syringes and other injecting equipment and drug solutions when injecting drugs; receiving unsafe injections, blood transfusions, tissue transplantation, medical procedures that involve unsterile cutting or piercing; and experiencing accidental needle stick injuries can lead to HIV infection (Goldman & Ausiello 2008:395). The transmission of HIV from an HIV-positive mother to her child during pregnancy, labour, delivery or breastfeeding is called mother-to-child transmission (MTCT). Without interventions, the rate of HIV transmission from mother-to-child can be between 15-45% (Tsague, Tsiouris, Carter, Mugisha, Tene, Nyankesha, Koblavi-Deme, Mugwaneza, Kayirangwa, Sahabo & Abrams 2010:753).

2.2.2 Anti-retroviral medications

HIV can be suppressed by anti-retroviral therapy (ART) consisting of a combination of three or more anti-retroviral (ARV) drugs. ART does not cure HIV infection, but controls viral replication within a person's body and allows an individual's immune system to strengthen and regain the capacity to fight off infections (Goldman & Ausiello 2008:396).

2.2.3 HIV/AIDS and Chronic illnesses

The wide use and effectiveness of Highly Active Anti-retroviral Therapy (HAART) has allowed the HIV infected population to live a longer and healthier life. Thus, they are now exposed to the same amount of risk factors (increased age, obesity and lack of physical inactivity) for NCD such as DM and premature cardiovascular disease as the non-HIV infected population (Baker, Henry & Neaton 2009:176; Young et al 2009:9). The rate of NCD is becoming higher among HIV patients due to the high prevalence of traditional risk factors such as smoking, alcohol and substance abuse, adverse effects of certain ARV drugs such as Abacavir and some protease inhibitors and the direct effects of HIV itself (Alvarez, Salazar, Galindez, Rangel, Castañeda, Lopardo, Cuhna, Roldan, Sussman, Gutierrez & Cure-Bolt 2010:256).

In people living with HIV (PLHIV), there is chronic activation of the innate immune system with excessive production of inflammatory markers that in turn are associated with an increased risk of atherosclerosis and coronary artery inflammation. HIV-mediated breakdown of the integrity of the gut mucosa and chronic translocation of gut microbial products into the systemic circulation contribute to the chronic inflammatory state (Rajasuriar, Khoury, Kamarulzaman, French, Cameron & Lewin 2013:1199). These all pave a way to the development of chronic illnesses like DM among PLHIV.

2.3. DIABETIS MELLITUS

Diabetes is a serious, chronic disease that occurs either when the pancreas does not produce enough insulin; a hormone that regulates blood sugar or glucose, or when the body cannot effectively use the insulin it produces (Wiener, Fauci, Braunwald, Kasper, Hauser, Longo, Jameson, Loscalzo & Brown 2012:1145).

2.3.1 Classification of Diabetes Mellitus

The WHO (2016:11) defines the following categories of diabetes mellitus:

- Type 1 diabetes (T1DM) which is characterized by deficient insulin production in the body. Type 1 diabetes patients require daily administration of insulin to regulate the amount of glucose in their blood. Symptoms include excessive urination and thirst, constant hunger, weight loss, vision changes and fatigue.
- Type 2 diabetes (T2DM) which is due to ineffective use of insulin. T2DM accounts for the vast majority of people with diabetes. It may go undiagnosed for several years, until complications have already arisen. For many years, T2DM was seen only in adults but it has begun to occur in children.
- Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) which are intermediate conditions that occur in the transition between normal blood glucose levels and diabetes (especially type 2), though the transition is not inevitable.
- Gestational diabetes mellitus (GDM) which occurs when a woman develops high blood sugar during pregnancy. It increases risk of infection and obstructed labour. If not properly treated, GDM can cause serious complications during pregnancy and childbirth. For instance, pre-eclampsia is three times more likely to occur in women with GDM (WHO 2016a:13).

Since GDM is associated with an increased risk for Type 2 diabetes for both the woman and child, it can also lead to serious health problems later in life. This can initiate a vicious cycle where the child will go on to have an increased risk of DM. This child also may pass this risk onto another generation (WHO 2016a:1).

2.3.2 Diabetes mellitus in Ethiopia

In Ethiopia, the International Diabetes Federation (IDF) 2015 report indicated an estimated DM prevalence of 3.4 % (IDF 2015:70). However, DM prevalence of as high

as 8% has been reported in 2013 on HIV/AIDS patients taking HAART (Sachithanan, Loha & Gose 2013:1). DM claimed 23,145 deaths in Ethiopia in 2015 (IDF 2015:70).

A systemic review by Gebre (2013:249) in Ethiopia showed that Major DM related complications have increased; hypertension (12.1% to 34.1%), neuropathy (27.7% to 34.1%), and DM foot disease (1.7% to 4.6%). However, the review did not look into the complication of HIV on DM, or DM and HIV on pregnancy outcome. Hence, the researchers concluded mentioning that no study has been conducted confirming whether DM increases infectious disease occurrences or vice versa.

2.4 HIV AS A RISK FACTOR FOR DIABETES MELLITUS

The chronic and repeated inflammatory reaction by HIV correlates with an increased risk for diabetes. Some HAART medications have either direct or indirect adverse actions to a patient's glucose metabolism, which makes them more likely to develop diabetes. Additional medications such as steroids given to treat some HIV-associated illness can cause altered glucose metabolism in healthy individuals (Tebas 2008:S86).

Another risk for insulin resistance in HIV-infected patients is Hepatitis C infection (White, Ratziu & El-Serag 2008:831). Due to the fact that both Hepatitis C and HIV are transmitted in the blood and risk factors for acquiring them are similar, some HIV-patients may be co-infected with hepatitis C (Operskalski & Kovacs 2011:12). Patients co-infected with both HCV and HIV had increased insulin resistance and higher diabetes rates versus HIV-infected patients without HCV infection after initiation of ART using a nucleoside reverse transcriptase inhibitor (NRTI) regimens with or without non-nucleoside reverse transcriptase inhibitor (NNRTI) (Butt, McGinnis, Rodriguez-Barradas, Crystal, Simberkoff, Goetz, Leaf & Justice 2009:1227).

The incidence of medication related diabetes increases as the duration of therapy increases. Protease inhibitors (PI) have a direct effect on glucose metabolism (hyperglycaemia) and then diabetes. Indinavir, ritonavir, and amprenavir are the PI's

commonly ascribed to diabetes (Ledergerber, Furrer, Rickenbach, Lehmann, Elzi, Hirschel, Cavassini, Bernasconi, Schmid, Egger & Weber 2007:111). Thus, the use of protease inhibitors has been associated with insulin resistance in pregnant and non-pregnant women. However, an association was not found between PI and Gestational diabetes (Jao, Wong, Van Dyke, Geffner, Nshom, Palmer, Muffih, Abrams, Sperling & LeRoith 2013: e141). The NRTI such as stavudine increases the risk for developing diabetes indirectly as well (Ledergerber et al 2007:111; Young et al 2009:9).

2.4.1 Incidence and risk factors of DM among HIV patients

According to the population survey in America, DM prevalence among HIV-infected adults was 10.3% and this was 3.8% (95% confidence interval (95% CI): 1.8% to 5.8%) higher in HIV-infected adults compared with general population adults. The survey shows that DM among HIV-infected persons may develop at earlier ages in the absence of obesity. Among HIV-infected adults with diagnosed DM, 3.9% had DM type 1 and 52.3% had DM type 2 and 43.9% had unspecified DM. Factors independently associated with DM among HIV-infected adults include increasing age, obesity, increasing time since HIV diagnosis, and geometric mean of CD4 (+) count. ART prescription in the past year is not associated with prevalent DM in the survey (Hernandez-Romieu, Garg, Rosenberg, Thompson-Paul and Skarbinski 2017: e000304).

In a prospective study by Puthachoen, Wattanachanya, Sophonphan, Siwamogsatham, Sapsirisavat, Gatechompol, Phonphithak, Kerr, Chattranukulchai, Avihingsanon and Ruxrungham (2017:1535), 123 patients developed new onset DM, resulting in an incidence rate of 7.6 (95%CI: 6.3-9) per 1000 per year follow up (PYFU). In this study, age >35 years, male sex, body mass index (BMI) ≥ 25 kg/m, family history of diabetes, abnormal waist circumference, lipodystrophy and exposure to didanosine (ddl) were significantly associated with incident DM. A prospective study in Nigeria, which determined the incidence of type 2 DM at baseline and after 12 months of ART initiation, indicates that the baseline T2DM prevalence was 2.3%, and an additional

5.3% had developed T2DM after 12 months of ART. In this study, newly developed diabetes was associated with BMI but not with age, CD4 (+) count, viral load, or type of ART (Isa et al 2016:ciw381).

In a study exploring the association between efavirenz exposure and incident diabetes, the crude incident of diabetes during the initiation of ART was 13.24 per 1000 PYFU. Treatment with efavirenz rather than nevirapine was associated with increased risk of developing diabetes (hazard ratio 1.27 (95% CI: 1.10-1.46)). Zidovudine and stavudine exposure were also associated with an increased risk of developing diabetes (Karamchand et al 2016: e2844).

A cross-sectional study conducted in Cameroon showed that that overall rate of GDM was 6.3%. This was 6.6% among HIV infected women. Family history of DM, HIV, and pre-pregnancy body mass index (BMI), only age ≥ 30 years were significant predictors of GDM. A significant association between use of ART and GDM was indicated in this study (Jao et al 2013: e141).

A systematic review done in Africa to investigate the incidence and prevalence of type 2 diabetes mellitus (T2DM) in patients with HIV infection reported that the incidence rates ranged from 4 to 59 per 1000 person years. However, this meta-analysis shows no association between T2DM prevalence and HIV infection or antiretroviral therapy (Prioreshi, Munthali, Soepnel, Goldstein, Micklesfield, Aronoff & Norris 2017: e013953).

2.4.2 Human immunodeficiency virus in Ethiopia

In a 2012/2013 cross-sectional study conducted at Hawassa University referral hospital in southern Ethiopia that aimed to determine the magnitude of metabolic syndrome, DM was diagnosed in 25% of patients receiving ART compared to 22.5% of the ART naïve group (OR: 1.14 CI: 0.71-1.84). Based on this study, patients receiving ART had significantly elevated Cholesterol, triglyceride, glucose and LDL-c levels, but lower CD4 (+) cell counts than the pre-ART groups. Being a female, having a body mass index

(BMI) of at least 25, older age of ≥ 45 years and having total cholesterol of at least 200mg/dl were significantly associated with the presence of metabolic syndrome. Taking stavudine (d4T) -lamivudine (3TC) - efavirenz (EFV) regimen was significantly associated with higher odds of metabolic syndrome (Tesfaye, Kinde, Medhin, megerssa, Tadewos, Tadesse, and Shimelis, Kinde, Medhin, Megerssa, Tadewos, Tadesse and Shimelis 2014:102).

A retrospective study done in Israel among HIV+ve Ethiopian immigrants shows that the prevalence of DM was 31% compared to 4% in HIV-infected non-Ethiopians and 8% in non-HIV-infected Ethiopians. The relatively increased prevalence of DM was age independent, but most noticeable in those under the median age (< 42 years). BMI was a predictor for DM (OR 1.263, CI 1.104-1.444, P = 0.001), although its values did not vary between the two ethnic groups. The researcher concluded that HIV-infected Ethiopians are more likely to develop DM at lower BMI values compared to non-Ethiopians (Tzur et al 2015:620).

An institution-based cross-sectional study done at the Jimma University Specialized Hospital in south-western Ethiopia demonstrates that the overall prevalence of DM among HIV+ people was 6.4% and it was associated with age, duration of highly active antiretroviral therapy, hypertension, and low-density lipoprotein cholesterol (Mohammed, Shenkute & Gebisa 2015:197). A Hospital-based cross-sectional study in north-western Ethiopia at HIV clinic of the University of Gondar Hospital by Abebe, Getachew, Fasika, Bayisa, Demisse and Mesfin (2016: e011175) also indicates that the overall DM prevalence was high (8%), particularly among subjects in the pre-ART group.

In short, studies in sub-Saharan African settings (Isa et al 2016: ciw381; Jao et al 2013: e141; Pioreschi et al 2017: e013953 & Karamchand et al 2016: e2844) including the studies among Ethiopian (Abebe et al 2016: e011175; Mohammed, Shenkute & Gebisa 2015:197; Tesfaye et al 2014:102 & Tzur et al 2015:620) have only look into the burden and risk factors of DM in HIV patients. However, there is limited information on

integrating the DM and HIV services to deal with the impact of the co-morbidity of the two diseases on pregnancy outcomes.

2.5 PREGNANCY AND MATERNAL HEALTH

According to WHO (2017: [SA]), maternal health refers to the health of women during pregnancy, childbirth and the postpartum period. Maternal mortality is a key indicator for maternal health. Despite a 44% reduction in maternal deaths between 1990 and 2015 (UNICEF 2014:3), about 830 women die each day due to complications in pregnancy and childbirth (WHO 2015a). In 2015, HIV/AIDS was the leading cause of death among women of reproductive age around the world (Abubakar, Tillmann & Banerjee 2015:117). One fourth of the pregnancy-related deaths in sub-Saharan Africa is attributable to HIV (Zaba, Calvert, Marston, Isingo, Nakyingi-Miir, Lutalo, Crampin, .., Robertson, Herbst, Newell & Todd 2013:1763). Women living with HIV in sub-Saharan Africa are at 6-8 times greater risk of dying during pregnancy or postpartum than their HIV-negative peers (Abubakar, Tillmann & Banerjee 2015:117).

The global sustainable development goal 3.1 is targeted to achieve less than 70 deaths for every 100,000 live births by 2030. This necessitates improving access to quality care before, during and after childbirth (Norheim et al 2015:239).

2.5.1 Preconception care

According to the WHO (2016:1) preconception care is one of the components of pregnancy care for women of childbearing age. It includes the clinical preventive services delivered to women during well woman visits. It is particularly essential to prevent complications of pregnancy due to chronic diseases such as HIV and DM.

2.5.2 Antenatal care

The WHO (2016:1) defines antenatal care (ANC) as the care provided by skilled healthcare professionals to pregnant women and adolescent girls in order to ensure the best health conditions for both mother and baby during pregnancy. Risk identification; prevention and management of pregnancy-related or concurrent diseases; and health education and health promotion are the components of the ANC. High quality health care during pregnancy and childbirth can prevent deaths from pregnancy complications, perinatal deaths and stillbirths (WHO 2016c:1).

According to the WHO (2016: xvi) indirect causes of maternal morbidity and mortality, such as HIV and DM, contribute to approximately 25% of maternal deaths and near-misses. To detect and address preventable complications related to pregnancy and childbirth such as HIV and DM, the WHO recommends an ANC model with a minimum of eight contacts. However, less than two-thirds of women receive antenatal care at least four times throughout their pregnancy in the world (Alkema, Chou, Hogan, Zhang, Moller, Gemmill, Fat, Boerma, Temmerman, Mathers & Say 2016:462).

The recommendation by the WHO (2016:1) is that pregnant women should receive comprehensive care at each of the contacts with the health provider. These include counselling on healthy diet and optimal nutrition, physical activity, tobacco and substance use; malaria and HIV prevention; blood tests and tetanus vaccination; foetal measurements including the use of ultrasound. The recommendation also advises to dealing with common physiological symptoms such as nausea, back pain and constipation.

2.5.3 Fertility, conception and HIV

Amongst others, an effect of HIV/AIDS on women is a change in fertility or conception levels. HIV/AIDS is related to conception or fertility due to behavioural change or biological mechanisms (Kushnir & Lewis 2011: 546).

Thackway et al (1997), and Stephenson and Griffioen (1996) (cited in Kushnir & Lewis 2011:548) describe that a new diagnosis of HIV is often followed by a decrease of sexual activity behaviour reducing pregnancy and birth rates among HIV infected women. This is because HIV-infected women terminate pregnancies in light of the challenges of pregnancy, birth, and parenting in the context of HIV infection (Kushnir & Lewis 2011:548). On the contrary, other behavioural influences may lead to higher fertility rates. In societies with high HIV/AIDS rates, some couples may desire larger families to ensure survival of children, though others limit family size due to concerns about leaving orphans behind after an early death (Loutfy, Hart, Mohammed, Su, Ralph, Walmsley, Soje, Muchenje, Rachlis, Smail & Angel 2009: e7925). In countries where HIV/AIDS treatment is widely available, such as South Africa, positive parenting is on the rise. The risk of mother-to-child transmission is as low as 2% in these areas, and treatment with ART medication has prolonged life expectancy for many potential parents with HIV (Myer, Carter, Katyal, Toro, El-Sadr and Abrams 2010: e1000229). This has resulted in the increase of fertility rate (Maier, Andia, Emenyonu, Guzman, Kaida, Pepper, Hogg & Bangsberg 2009:28). For instance, study from seven African countries demonstrates that the rate of new pregnancies was significantly higher among women receiving ART (9.0/100 PY) compared to women not on ART (6.5/100 PY) (Myer et al. 2010: e1000229). Nevertheless, Houle, Pantazis, Kabudula, Tollman, and Clark (2016:10) show that fertility patterns are not homogenous among different setting and countries.

Biological mechanisms also influence fertility rates in HIV-positive women. Research has shown that women with HIV may find it more difficult to conceive than their HIV-

negative counterparts due to ART-induced mitochondrial toxicity to embryo (Kushnir & Lewis 2011:550-51), hence reducing pregnancy rates. For example, HIV seroconversion was associated with a 0.02 (95% CI: 0.01-0.03) relative decreases in fertility for HIV- positive women (Marston, Nakiyingi-Miir, Kusemererwa, Urassa, Michael, Nyamukapa, Gregson, Zaba, Eaton, & ALPHA network 2017:S69). HIV/AIDS may induce sterility, increase foetal mortality, decrease production of spermatozoa, all contributing to a declining fertility (Ombelet, Cooke, Dyer, Serour & Devroey 2008:605). HIV also affects the placenta by interfering with the transfer of important nutrients to the foetus. The virus causes abnormal development of the embryo. These can lead to spontaneous abortion (Myer et al 2010: e100022).

Complications of HIV, such as increased risk of cervical abnormalities, early menopause, pelvic inflammatory disease-causing scarring of the Fallopian tubes, and severe wasting may also contribute to infertility in HIV infected women (Juhn, Kalemli-Ozcan & Turan 2008: w14248).

Since advanced HIV infection tends to decrease fertility, starting HAART can improve the likelihood of pregnancy. However, there are also indications that the drugs can have negative effects on fertility. Researchers from Uganda find out that the use of anti-retroviral therapy increased fertility in HIV-positive women (Maier et al 2009:28). On the other hand, women on HAART are less likely to conceive because of the use of some anti-retroviral, particularly zidovudine and other NRTIs that may affect fertility in women. These can damage the mitochondria in eggs leading to infertility (Kushnir & Lewis 2011: 546).

2.5.4 Fertility, conception and diabetes mellitus

There is a relationship between diabetes and fertility as well. Poorly controlled diabetes is associated with lower rates of fertility due to obesity, being underweight, having diabetic complications, having polycystic ovarian syndrome (PCOS) and having an autoimmune disease (Basmatzou & Konstantinos 2016:371; Livshits & Seidman

2009:701). The reproductive period of diabetic women may be reduced due to delayed menarche and premature menopause. During the reproductive years, diabetes has been associated with menstrual abnormalities, such as oligomenorrhea and secondary amenorrhea (Basmatzou & Konstantinos 2016:371).

High glucose levels are reported to increase a woman's chance of miscarriage by 30-60%. Even when implantation does occur, there is an increased risk of birth defects due to damage caused to embryonic cells from the high levels of glucose in the blood. A big baby (macrosomia) resulting in a C-section, which increases a mother's chance of infection is also another effect of hyperglycaemia in pregnancy (Gunatilake & Perlow 2011:106).

Young women with diabetes, either T1DM or T2DM, tend to start their menarche a little bit later in life than women without diabetes. On the other end of the spectrum, women with diabetes tend to go through menopause slightly earlier. This provides a slightly smaller window of fertility for women with diabetes (Livshits & Seidman 2009:703). In addition, many women with T2DM have an underlying syndrome called polycystic ovarian syndrome (PCOS). PCOS is associated with insulin resistance, which is a major player in type 2 diabetes. Because of the effects of PCOS on the ovaries, women with T2DM and PCOS may find a harder time with conception than women without diabetes (Basmatzou & Konstantinos 2016:371).

Women with T1DM were approximately twice as likely to have experienced menopause earlier than similar non-diabetic women. In particular, patients with early menopause were younger at T1DM onset (Livshits & Seidman 2009:703). In the same study, the age of menarche was found to be significantly older for Type 1 diabetic women compared with non-diabetic women. Taken together with premature menopause, this therefore reduces the reproductive period in T1DM women by 6 years. Premature menopause in women may also be related to the autoimmunity aspects of T1DM (Livshits & Seidman 2009:701).

2.6 ADVERSE PREGNANCY OUTCOMES

In 2015, at the start of the Sustainable Development Goals (SDGs) era, pregnancy-related preventable morbidity and mortality remains unacceptably high. In 2015, about 303 000 women and adolescent girls died as a result of pregnancy and childbirth-related complications (Alkema et al 2016:462). Around 99% of maternal deaths occur in low-resource settings and most can be prevented (WHO 2014:2014). Similarly, approximately 2.6 million babies were stillborn in 2015 mainly in the low-resource settings (Blencowe, Cousens, Jassir, Say, Chou, Mathers, Hogan, Shiekh, Qureshi, You & Lawn 2016: e98).

A survey data collected in 23 developing countries by WHO shows that women with an adverse outcome (i.e. stillbirth, neonatal death, infant with low birth weight and/or infant with very low birth weight) in their first pregnancy were found to be at increased risk of the adverse outcome in their second pregnancies. That is, a first pregnancy that ended in a stillbirth still appeared to be at increased risk of stillbirth at the end of their second pregnancy; women who had seen their first children die as neonates were at increased risk of seeing early neonatal death in their second pregnancies (Ouyang et al 2013:315). An analysis using facility-based cross-sectional data of the WHO Multi-country Survey on Maternal and Newborn Health in 29 countries demonstrates that adolescent pregnancy was associated with higher risks of adverse pregnancy outcomes (eclampsia, puerperal endometritis, systemic infections, low birth weight, preterm delivery and severe neonatal conditions) compared with mothers aged 20–24 years (Ganchimeg, Ota, Morisaki, Laopaiboon, Lumbiganon, Zhang, Yamdamsuren, Temmerman, Say, Tunçalp & Vogel 2014:40).

Pre-term labour, still birth, abortion, big baby are some of the adverse pregnancy outcome in diabetic mothers (Wendland, Torloni, Falavigna, Trujillo, Dode, Campos, Duncan & Schmidt 2012:32). HIV infected mothers could have abortion, still birth, IUFD, HIV infected neonates (Alemu, Yalew, Fantahun & Ashu 2015:31; Joseph, Biodun &

Michael 2011:356). In short, in patients with poorly controlled DM or HIV infection, there could be adverse pregnancy outcomes.

2.6.1 Risk factors for adverse pregnancy outcome

The risk factors of adverse pregnancy outcome include diabetes, hypertension, obesity, smoking, HIV/AIDS, heavy alcohol use, stress and depression. Unintended pregnancy and closely spaced births are also associated with adverse pregnancy outcome (WHO 2016c:xi). Hence, the WHO (2016:xiii) recommends the screening and testing of diabetes, HIV, tobacco smoking, substance use during preconception and antenatal care (ANC). In a Multi-country Survey on Maternal and New-born Health Laopaiboon, Lumbiganon, Intarut, Mori, Ganchimeg, Vogel, Souza and Gülmezoglu (2014:49) indicate that the prevalence of pregnant women with advanced maternal age of more than 35 years was 12.3% which significantly increased the risk of maternal adverse outcomes such as maternal near miss, maternal death, stillbirths and perinatal mortalities. A matched case control study conducted in Nigeria shows that a commencement of ANC attendance <4 months and number of pregnancies ≥ 4 months were found to be associated with adverse pregnancy outcomes (Sadiq, Poggensee, Nguku, Sabitu, Abubakar & Puone 2016:1).

There are evidences indicating HIV and DM are key risk factors for adverse pregnancy outcome. For instance, the prospective case record analysis of 212 HIV-infected women in India showed that HIV-infected women were more likely to have pre-term birth, intrauterine growth retardation, and anemia compared to uninfected women. Mean birth weight was significantly lower in neonates of HIV-infected women than HIV-uninfected women. The study also indicated that HIV-infected women on ART had decreased incidence of PTB and IUGR (Dadhwal, Sharma, Khoiwal, Deka, Sarkar, and Vanamail 2017:75). In addition, the survey in the Asian population reveals that pregnant women with type 1 diabetes are at increased risk of developing many adverse maternal and fetal outcomes such as preeclampsia, eclampsia, cesarean delivery, sepsis, and shock as compared to the pregnant women without the disease (Lin, Kuo, Chiou, and Chang 2017: 80679).

2.6.2 Pregnancy outcome in Ethiopia

Prevalence of adverse birth outcomes (still birth, preterm birth and low birth weight) is high and still a major public health problem in Ethiopian. For instance, study by Adane, Ayele, Ararsa, Bitew, and Zeleke (2014:90) at Gondar University Hospital, Northwest Ethiopia shows that about 23% of women had adverse birth outcomes (14.3% preterm, 11.2% low birth weight and 7.1% stillbirths).

Ethiopian women had a less favourable intra-partum outcome, according to the retrospective study by Salim, Mfra, Garimi and Shalev (2012:161). They had a higher incidence of pre-eclampsia (6.8% versus 4.0%, $P=0.01$) and early postpartum haemorrhage (4.3% versus 1.6%, $P=0.003$) than the control women, the general obstetric population in Israel. The incidence of vacuum or caesarean delivery was significantly higher among Ethiopian than among control women (odds ratio, 1.68; 95% CI: 1.28-2.20; $P=0.002$). Besides, Worku, Yalew and Afework (2014:1336) in northern Ethiopia indicate that skilled maternal care has reduced adverse pregnancy outcomes but the associations were not significant. Nevertheless, neither of these studies stratified the adverse pregnancy outcome by the status of DM or HIV status.

A descriptive study comparing birth outcomes of Ethiopian in Israel and non-Ethiopian women showed that Ethiopian women had about twice the incidence of very and extremely preterm births, compared with non-Ethiopians. In this study it was found that Ethiopian women had twice the odds for neonates who were either small for gestational age or had low 5-minute Apgar scores. Ethiopian women had about threefold increased risk of stillbirths (OR 2.9 [95% CI 1.87-4.49]) (Calderon-Margalit, Sherman, Manor & Kurzweil 2015:125).

2.6.3 Incidence of pregnancy and pregnancy outcomes among HIV infected patients

According to a retrospective cohort study among PLHIV in South Africa, the overall rate of pregnancy was 5.2 per 100 person-years and a cumulative incidence of first pregnancy was 22.9%. This indicates that women experience high rates of incident

pregnancy after HAART initiation. Also the study states that the strongest predictor of incidence of pregnancy was age, with women 18–25 having 13.2 times the rate of pregnancy of women ages 40–45 in adjusted analysis. CD4 (+) counts below 100 and worse adherence to HAART were associated with lower rates of incident pregnancy (Westreich, Maskew, Rubel, MacDonald, Jaffray and Majuba 2012:1).

Calvert and Ronsmans (2013:1631) indicates that an HIV-infected women has eight times the risk of a pregnancy-related death compared with HIV-uninfected women. The excess mortality attributable to HIV among HIV-infected pregnant and postpartum women is 994 per 100,000 pregnant women. It is also predicted that 12% of all deaths during pregnancy and up to 1-year postpartum are attributable to HIV/AIDS in regions with a prevalence of HIV among pregnant women of 2%. Another meta-analysis indicates that HIV-infected women has over three times the risk of a puerperal sepsis compared with HIV-uninfected women and this is increased to nearly six amongst studies only including women who delivered by caesarean (Calvert & Ronsmans 2013: e74848).

On the contrary, a retrospective cohort study in South Africa by Gibb, Kizito, Russell, Chidziva, Zalwango, Nalumenya, Spyer, Tumukunde, Nathoo, Munderi and Kyomugisha (2012: e1001217) indicates that ART or HIV infection does not have an adverse effect on pregnancy outcome. Gibb et al (2012:e1001217) further demonstrate that there is no significant difference in the occurrence of low birth weight and pre-term birth in pregnancies that occurred before and after ART. The consumption of illicit drug does not have any effect on the adverse effect of pregnancy as well.

A systematic review in developing countries shows that frequently observed ART related adverse birth outcomes included low birth weight (LBW), preterm Birth (PB), Small for Gestational Age (SGA), while still birth and congenital anomalies were infrequent. In the review, it is also indicated that type of regimen such as Protease Inhibitor (PI) based regimens and timing of initiation of ART are some of the factors associated with adverse pregnancy outcomes (Alemu et al 2015:31). A study conducted

in a teaching hospital in Nigeria indicates that untreated maternal HIV-infection in pregnancy may be associated with adverse pregnancy outcome such as intrauterine growth restriction (IUGR), pre-term birth, higher frequency of birth weight less than 2500g and caesarean delivery as compared with women who received HAART from early pregnancy (Joseph et al 2011:356).

The overlap between pregnancy and HIV is even more striking in Ethiopia, with very high rates of both HIV and pregnancy incidence reported among young women (Central Statistical Agency [Ethiopia] and ICF International 2012: 69,234). With a growing interest in “treatment-as-prevention” (Montaner, Hogg, Wood & Kerr 2006:531), an increasing incidence of pregnancy among women receiving HAART seems inevitable, especially in Addis Ababa, where there is wide access to HAART and a very large at-risk population of reproductive-age women. For instance, a facility based retrospective follow-up study in Addis Ababa in 661 women’s charts demonstrates that the incidence of pregnancy among women who enrolled in HIV care comprised of 21 incident pregnancies with the rate of 3.9 per 100 person-years in the pre-ART period and 67 incident pregnancies with the rate of 8.02 per 100 person years in the ART period. A facility based retrospective cohort study in northwest Ethiopia conducted over 4 years involving 1,239 women on ART indicates even a higher incidence of pregnancy, 49.2 per 1,000 person-years (Meseret, Shimeka & Bekele 2017:1). A facility based retrospective cohort study conducted in Gondar University hospital in northwest Ethiopia shows that adverse pregnancy outcome is also common among HIV –infected mothers. Accordingly, the prevalence of LBW and pre-term delivery were 89 (21.4%) and 69 (16.6%), respectively. The baseline maternal CD4 (+) counts below 200 cells/mm³, maternal body mass index (BMI) below 18.5 and maternal exposure to HAART were factors significantly associated with both LBW and preterm delivery (Kebede, Andargie & Gebeyehu 2013:254).

2.6.4 Pregnancy outcome and Diabetes Mellitus

A systematic review by WHO (Wendland et al 2012:32) find out that macrosomia, large for gestational age, perinatal mortality, preeclampsia and caesarean delivery are related to DM. The Indian study by Ellerbe, Gebregziabher, Korte, Mauldin and Hunt (2013: e65017) also demonstrates the association between maternal DM with increased weight in new-borns. However, a study done in Tanzania shows that DM doesn't significantly relate to low birth weight (Mitao, Philemon, Obure, Mmbaga, Msuya and Mahande 2016:75).

High serum blood glucose is a key cause of maternal and fetal complications in pregnancies of women with any type of diabetes. The review of adverse pregnancy outcome in Negrato, Mattar and Gomes (2012:41) indicates that fetal adverse outcomes found in pregnancies of women with diabetes are fetal and neonatal loss, congenital abnormalities and malformations, premature delivery, fetal growth acceleration. Women with type 1 diabetes have a four- to fivefold increase in perinatal death, and a four to six-fold in stillbirth compared to the general population. It is also shown that C-section, hypoglycemia and the worsening of any degree of a pre-existing renal insufficiency and retinopathy can be complications of DM among women. Rates of pre-eclampsia (12.7%), C-section (44.3%) and maternal mortality (0.6%) found among women with type 1 diabetes are considerably higher than in the background population.

2.7 CONCLUSION

This chapter provided a detailed literature review on DM and HIV as related to adverse pregnancy outcomes. It was shown that HIV and ART are risk factors for DM. Pregnancies among HIV infected or diabetic mothers could be complicated with adverse pregnancy outcomes impacting both maternal and child health. The next chapter will discuss the design and methodology used in this research.

CHAPTER 3

RESEARCH DESIGN AND METHOD

3.1 INTRODUCTION

This chapter presents details of the types of study design utilized to conduct the research. It also addresses the method used to collect data, means of analysing data and the ethical considerations in the study. The research's validity and trustworthiness are discussed as well.

3.2 RESEARCH DESIGN

Burns and Grove (2013:195) describe research design as "a blueprint for conducting the study that maximizes control over factors that could interfere with the validity of the findings". A research design is also defined as a comprehensive plan to answer research questions. It is a strategy adapted to develop accurate and meaningful evidence (Polit & Beck 2017:183).

This study applied a mixed method approach with exploratory and descriptive research design to achieve the aim and specific objectives of the study. Phase I of the study used the exploratory design as a part of qualitative approach, while phase II applied the descriptive design as part of the quantitative approach.

3.3 A MIXED METHOD APPROACH

Mixed methodology is a design for collecting, analysing, and mixing both qualitative and quantitative data in a single study to understand a problem (Clark & Creswell 2015:386). A key assumption in the use of the mixed methods is that neither quantitative nor qualitative research by itself is sufficient to understand a complex research problem.

Drawing on the strengths of quantitative and qualitative research adds up to a better understanding of the research problem (Creswell 2014:266).

Mixed method is also helpful to obtain different, multiple perspectives, validation, build comprehensive understanding, have better contextualised measures, whenever there is a need to explore and to further understand experimental results, process and outcome (Clark & Creswell 2015:386). It also helps to get a more comprehensive account of what's going on within the research. When used together as a mixed method, both qualitative and quantitative approaches enhance the integrity of the findings (Creswell 2014:267).

3.3.1 Application of mixed method in this study

In the HIV, DM and pregnancy outcome study, the researcher wanted to determine the level of integration of DM and HIV to deal with adverse pregnancy outcome, where descriptive design as part of quantitative research was applied. To find out the domains of the integration, the qualitative research was used to have a perspective of peoples working on the HIV and DM services and officers working on maternal health. Besides, the clinicians at health facilities were interviewed to know how they were delivering the service of DM testing and treatment at HIV and ANC clinics, HIV counselling and testing services at DM and ANC clinic and services of pregnancy care at DM and HIV clinics. Hence, these people were questioned to explore how they rendered the integrated services of DM, HIV and pregnancy care. The researcher tried to come up with an integrated model of care for DM, HIV and pregnancy care services which was augmented by the descriptive part of a quantitative design.

Moreover, to have in-depth understanding of the pregnancy care among HIV and DM patients, using qualitative approaches was critical. Also, this study needed to answer the question of the magnitude of pregnancy and adverse pregnancy outcomes among HIV and DM patients. The prevalence of DM among HIV patients was also determined. This warranted a quantitative study design. To further refine the model of care

developed in phase I from qualitative approach, it was also important to describe the level and domains of integration of HIV, DM and pregnancy care services.

3.3.2 Types of mixed methods

The classification of mixed method designs depends on timing, emphasis and mixing. Based on the timing, it is grouped as sequential where one built on the other and concurrent where both are collected at the same time.(Clark & Creswell 2015:389). In this study a sequential mixed methods; that is, an exploratory sequential mixed method was used (Clark and Creswell 2015:391; Creswell et al 2011:2108).

3.3.2.1 Sequential exploratory mixed method research

A sequential exploratory mixed method is characterized by an initial phase of qualitative data collection and analysis followed by a phase of quantitative data collection and analysis. Exploratory sequential design, meant for the exploration of a phenomenon, is aimed to generalize qualitative findings to a larger sample (Creswell et al 2011:2086). In this method the qualitative part is given a higher emphasizes than the quantitative (Clark & Creswell 2015:389). Basically, it is a two-phase research where qualitative results can help and inform the second quantitative method (Creswell et al 2011: 2086-87).

Using the sequential exploratory mixed method in this study, the phase one or exploratory section of the study had two key purposes; 1) to explore the integration of DM, HIV and pregnancy care services and to develop a servcie delivery model inclusive of DM, HIV and pregnancy care services, and 2) to modify or refine a draft instrument to be used for the phase II quantitative research. The second phase of the study not only descried the level of DM, HIV and pregnancy care service integration, it substantiated the finding during the phase II and enriched the developed a servcie delivery model of integrated DM, HIV and pregnancy care service delivery.

3.3.2.2 A rationale for applying the sequential exploratory method in this study

There was no data collection instrument which assisted to collate information regarding the level and domains of integration regarding DM, HIV and pregnancy care. Hence, it was important to explore the levels and domains of the integration and come up with a structured questionnaire and abstraction checklist to objectively investigate the level and the domains related to DM, HIV and pregnancy care in Ethiopia. Therefore, the sequential exploratory method was applicable, as this method helps to refine the data collection instrument.

The researcher used this study design because there was no model inclusive of DM, HIV and pregnancy care as a guide, though there is a relationship among the three health entities. Therefore, the researcher intended to explore what is on the ground and the potential suggestion from the experts and patients. Hence, a sequential exploratory type of mixed study design was used (Creswell et al 2011:2087).

3.4 QUALITATIVE RESEARCH APPROACH

Qualitative research is underpinned by interpretivism, constructivism, and critical theory research paradigms (Terrell 2012:257). The qualitative research is a holistic and striving for an understanding of the 'whole' part of the phenomenon being studied. It helped to develop a model based upon the data collected (Polit & Beck 2017:463). In a qualitative design, an inductive approach is used and unstructured interviews, focus groups, and participant observation are applied to collect data (Clark & Creswell 2015:54).

Therefore, in phase I of this study, qualitative study provided the opportunity to explore the level and domain of integration existed among HIV, DM and pregnancy care services from the perspective of HCWs and experts on HIV, DM and maternal health. The qualitative approach was utilized to develop an integrated model of care by interviewing the program officers and experts working on HIV, DM and pregnancy care.

3.4.1 Exploratory research design

Polit and Beck (2017:15) describe explorative research as a valuable way to yield new insights into a topic for research. According to Deforge (2010:1254), exploratory study is conducted when little is known about the phenomenon of interest with the goal to assess a relationship among variables within this little known phenomenon. The researcher in this study understands that DM and HIV can affect pregnancy outcomes. Nevertheless, the key question the researcher wanted to answer is, “How can DM, HIV and pregnancy care service among reproductive age women in Ethiopia be coordinated or integrated to improve pregnancy outcomes?”. That is, the researcher wanted to come up with an integrated model of service delivery linking HIV and DM to improve a pregnancy care. Thus, in phase I of this research, the researcher viewed the broader understanding of level and domain of integration of DM, HIV and pregnancy care which had not been explored so far. This assisted to come up with the HIV and DM service integration level that could address adverse pregnancy outcomes .i.e. services related to DM among HIV patients given at the HIV clinic, services related to HIV among DM patients given at DM clinic and HIV and DM services among pregnant women that are being given at ANC unit.

3.5 QUANTITATIVE RESEARCH APPROACH

Quantitative research is underpinned by positivist or post-positivist research paradigms. It is regarded as the traditions of the natural science which claims that knowledge is only created by following scientific methods of observation and testing (Terrell 2012:257). During phase II of this study, the quantitative approach was utilized to describe the DM, HIV and pregnancy care services at the study health facilities. It was further used to describe the number of pregnancies and pregnancy outcome occurred among HIV and DM patients. There is no information so far as to which level of DM/HIV/pregnancy service integration leads to a better pregnancy outcome and feasible for reproductive age mothers.

In phase II of this study, the findings in phase I were enriched to refine and develop data abstraction and questionnaire.

3.5.1 Descriptive research design

In descriptive research design a situation, a phenomenon, and events are observed by the researcher who focuses on what is happening or how much has happened rather than why it is occurring (Polit & Beck 2017:15; Tappen 2015:81). Descriptive designs can simply intend to report what is observed (Gratton & Jones 2010:7; Tappen 2015:78). In phase II of this research, the researcher's intent was to assess the level of DM, HIV and pregnancy care services in the study health facilities. In this study, the researcher wanted to describe burden of DM among HIV infected females, and to determine the prevalence of pregnancy and pregnancy outcomes among HIV and DM mothers using the descriptive quantitative design.

3.6 RESEARCH METHOD

Research method refers to the techniques the researcher uses to structure the study. It includes using a set of orderly disciplined procedures to obtain information to meet the objectives of a study (Polit & Beck 2017:11). In this section, the methods are outlined based on qualitative and quantitative approaches by referring to sampling techniques, data collection, data management and data analysis.

3.6.1 Research methods for qualitative approach (Phase I)

3.6.1.1 Setting and population

The settings for phase I study were federal ministry of health (FMOH), health bureau, sub-cities and public health facilities in Addis Ababa. The target population were experts at NCD, HIV and maternal and child health (MCH) at the federal ministry of health, regional health bureau, sub-cities and HCWs working at the study health facilities. That is, relevant information was obtained from experts and health care providers. Experts, program managers and officers, were those who are working on DM, HIV and maternal

health at different administrative levels (federal, region, and sub-cities in the Addis Ababa city). The health care providers were those from public health facilities working at HIV, DM and ANC units.

3.6.1.2 Sampling techniques

Purposive sampling entails selecting a particular subset of a population rather than making a random selection (Tappen 2015:115). The purpose of the study in phase I of this study was to gain an in-depth understanding of the level and domains of DM, HIV and pregnancy care (Burns & Grove 2013:352), hence purposive sampling was applied.

In a homogeneous type of purposive sampling, units are selected based on their having similar characteristics because such characteristics are of particular interest to the researcher (Clark & Creswell 2015:333). According to Clark and Creswell (2015:334), a homogeneous sample is often chosen when the research question being addressed is specific to the characteristics of the particular group of interest, which is subsequently examined in detail. Therefore, in phase I of this study, health providers and officers with similar experience of HIV, DM and maternal health were selected using a homogeneous purposive sampling. They were intentionally approached and selected to get a rich data on HIV and DM integration at federal, regional, sub-cities and facility level. Besides, during the IDI and FGD, the interview was started with small number of experts, and the selection of further participants was on the basis of the information gathered from earlier interviews, i.e. a theoretical sampling (Thornberg & Charmaz 2014:153).

3.6.1.3 Eligibility criteria

HCWs, program managers and officers working on DM, HIV and pregnancy care who gave their consent to participate in the study, were part of the study. To be a candidate for the study, HCWs and program managers and officers should have worked on DM, HIV and pregnancy care for at least 06 months.

3.6.1.4 Sample Size

Boddy (2016:432) states that an adequate sample size in qualitative research is one that permits the deep, case-oriented analysis that is a hallmark of all qualitative inquiry, and that result in a new and richly textured understanding of experience. Provided that a researcher remains faithful to the principles of qualitative research, sample size should follow the concept of saturation (Mason 2010 [Sa]). Saturation is when the collection of new data does not shed any further light on the issue under investigation. However, the objectives of the study are the ultimate driver of the sample size (Malterud, Siersma and Guassora 2016:1753). In this study, the sample size was 7 FGDs, 11 IDIs and 13 observations, after which the researcher could not appreciate new information.

3.6.1.5 Approach to data collection

The researcher was the data collector, who used the interview guide, audio record and also took notes of the observation. The study participants were informed about the IDI and FGD earlier to arrange the appropriate time for the interview. IDIs and FGDs were conducted at the places convenient for the study participants. IDIs were conducted in offices and clinics where there were no clients or patients. The FGD was carried out in mini-halls accomodating at least 10 individuals at a time. Also, there were times where FGD was perfromred inside the office of the health center, sub-cities, RHBs and FMOH. Amharic was the language of communication during the IDI, FGD and informal interview in the observaitons. Before the tape recording, verbal consent was obtained from the study participants. IDIs were mainly for program managers where as FGDs was among the program officer and HCWs.

- Pre-testing the data collection instrument

The advantage of conducting a pretest as described by Polit and Beck (2017: 57 & 268) is to assess the appropriateness of data collection instrument, and method, potential problems that will be encountered, and identify confounding variables to control.

In this study, 2 IDIs and 01 FGD were conducted prior to the main study in order to determine whether the interview guide would bring the intended information or not. The study pretest helped to identify weakness, ambiguity or lack of clarity of the questions in the interview guide. Questions that were not clear during the pretest study were clarified, rephrased, and modified before the main data collection process. Questions in the question guide were rearranged: the sequence of the questions was ordered in a logical way. Probing questions modified, addressed and added. However, there were no changes to the methodology. The results of the pretest were not included in the final findings of the study.

3.6.1.6 Method of data collection

An interview guide for IDI and FGD was developed and used in phase I of the study (see Annexure H). Polit and Beck (2017:732) defined interview as “ the data collection method in which an interviewer asks a question(s), either face-to-face or by telephone”. Interviews are designed to generate participant perspectives about ideas, opinions, and experiences (Polit & Beck 2017:506).

The interview guide for IDI and FGD was drafted based on the integration theory and was modified based on the finding during the interviews. The drafted interview guide depended on the domains of integration such as organizational, financial, administrative, functional, and clinical and service integration. The functional, financial and administrative integration section was utilized while interviewing experts at the ministry of health, regions and sub-cities in the Addis Ababa. It was also applied during the FGD of HCWs at DM, HIV and ANC clinics. The organizational and clinical integration part was asked for HCWs working at DM, HIV and ANC clinics. In short, the interview guide was an initial draft and was further refined and developed based on the subsequent IDI and FGDs (see Annexure H).

- In-depth interview

An IDI is a technique designed to elicit a vivid picture of the participant's perspective on the research topic. IDIs are usually conducted face-to-face and involve one interviewer and one participant. Interview data consists of tape recordings, typed transcripts of tape recordings, and the interviewer's notes (Mack, Woodson, MacQueen, Guest and Namey 2005:29-30). A classical IDI was utilized in this study. It was particularly useful for exploring a topic broadly; in this case, the integration status of DM, HIV, and pregnancy care. It also helped to understand details of services of DM, HIV and pregnancy care being carried out at the respective service outlets and also explored the domains and level of integration of HIV, DM and pregnancy care in the Addis Ababa city. Field notes were kept as well.

- Focus group discussion

FGD is one component of unstructured interview and it was an interaction of study participants and the interviewer to explore specific issues and develop a better idea as a group (Tappen 2010:240). Similarly, Polit and Beck (2017:729) argue that FGD is a kind of group interview intended to explore information taking the advantage of group dynamic. It can be used for many topics, however, it is believed very good for sensitive topics. The FGD sessions were tape recorded in this study. A principal advantage of focus groups was that they yielded a large amount of information over a relatively short period of time. FGD assisted to encourage the participants to share views and experiences and also to debate issues

In phase I of this study, FGDs were chosen as a data collection approach to obtain an opinion deeper as one capitalized others' ideas or assistive on information recall. In this study, the researcher obtained a detailed opinion regarding the relationship between DM and HIV, their impact on adverse pregnancy outcome and the status of HIV and DM integration to address pregnancy outcome in Addis Ababa. The FGDs were facilitated by the researcher.

- Observation

The researcher observed how HIV, DM and pregnancy care were being rendered in the 06 public health facilities during the real clinical practice. The observation was done at DM, HIV and ANC clinics. Participants' observation was also done at FMOH at NCD, MCH and HAPCO units. The observations focussed on the linkage, coordination or collaboration of these services. It also looked into the interactions among patients and HCWs, and the communication among the HCWs working at DM, HIV and pregnancy care while serving their patients. The researcher took notes during the observation.

Therefore, the IDIs, FGDs and the observations assisted to explore organizational and functional integration of DM, HIV and pregnancy programs and services at the ministry of health, Addis Ababa regional health bureau, sub-cities and the study health facilities during the phase I of this research. There were a total of 11 IDIs, 7 FGDs and 13 observation carried out in this study. IDIs included 11 study participants. Each FGD involved 6-8 participants. The observation was carried out at the 6 health facilities, three sub-city, at the Addis Ababa region and 3 units in FMOH. The interviews and the observations were stopped when no new dominant issues emerged in the dataset. Data saturation reached after 11IDIs, 7 FGDs and 13 observations (See chapter 4, table 4.1).

3.6.1.7 The process of data collection

- Sources of data

As there was little information regarding the formal integration of these three items (DM, HIV and pregnancy care), the researcher in this study collected a primary information using interviews and focus groups involving the experts, HCWs and the patients themselves. Hence, the recorded IDI & FGD, the field notes from the observations and the written memos were the sources of data.

- Phase I data collection

Data were collected by the researcher using IDI and FGD. The HIV, DM or ANC programs managers took part in the face-to-face IDI while other program officer and other clinicians were brought together for the FGD. The introductory statement during the IDI and FGD was;

“I am Zewdu Gashu Dememew. I am a student at UNISA. Thank you for taking your time to take part in FGD/IDI. I am a principal investigator of this study. This is a discussion on the integration service related to HIV, DM and pregnancy care. There is no right or wrong answer. You are free to withdraw from interview any time in the middle of the interview should there is any inconvenience. Is that clear? So, I will start the interview.”

The study participants were interviewed through the local language, Amharic. The interviews were recorded, except in one case where consent was refused and the researcher only took notes.

- Topic guide

The interview guide was drafted for both the IDI and FGD based on the integrated theoretical framework. After 2 IDIs and 1 FGD, it was modified especially the sequence and the probing questions (Annexure H).

- Data collection at the federal ministry of health (FMOH)

Participant observation and interview were carried out. The researcher undertook an interview with the team leader and the officer of NCD unit. Both of them were males. The same visit was paid to HIV/AIDS prevention and control office (HAPCO) and MCH unit and observation was done where a female officer gave information on the collaboration and coordination activities. Field notes were taken after the visit to these units at FMOH.

Key Notes:

1. **HAPCO** is the office at federal ministry level that is responsible for the national prevention, care, treatment and support of HIV/AIDS. At the region and sub-cities, the structure that can handle HIV/AIDS is under disease promotion and disease prevention (DPDP) core process. There are also sub-cities that has standalone HIV unit focusing on the prevention while the care and treatment of HIV is under the core process of medical service.
2. **Family health** is the unit at federal, region and sub-cities that addresses MCH. PMTCT, ant-natal care and family planning are under this unit.
3. **Non-communicable diseases unit** at federal regional and sub-cities is a unit that concerns with all kinds of cancers, DM, HPN, cardiac illnesses, chronic renal problems, liver diseases and other similar disease. NCD is under the medical service core process with a focal person at regional health bureaus and some cities. However, there are sub-cities where NCD is under the disease promotion and disease prevention core process.
 - Data collection at Addis Ababa regional health bureau

Three IDIs were conducted with participants each from the HIV, NCD and pregnancy care in the family health unit. Two of the participants were females; aged 37 years and 45 years; and were a family health officer and the HIV focal person respectively. The third was a 38 years old male who was a program manager of the NCD unit in the

RHB. The IDIs took approximately 30-45 minutes. One FGD was undertaken with 6 experts, 2 each from the three units.

- Data collection at the sub-cities

Three sub-cities were involved to conduct IDIs and FGDs. Three IDIs were conducted with a 45 years old female HIV focal person, 50 years old female family health officer, and a 46 years old female NCD focal person. One FGD was conducted with a group containing 6 members; two from HIV unit (male 35 years and female 36 years), two from family health unit (36 years old female team leader, 35 years male officer) and another two from NCD (29 years female team leader and 37 male NCD officer). The IDIs took approximately 25- 40 minutes while the FGD took 45 - 60 minutes.

- Data collection at health facilities

Five IDIs and 05 FGDs were conducted at six health facilities. The IDIs was conducted with officers from HIV (Female, 46 years; and male 23 years), NCD (Two females, 26 years; 40 years) and ANC unit (Male, 25years; female 35 years) . The IDIs took 25-45 minutes. The FGDs took 45-85 minutes each, with 6-8 individuals involved.

- Participant observation

Prior to the appointment for the IDIs and FGDs, observation was performed at regions, sub-cities and health facilities. Memo and field notes were captured. During the observation the coordination, collaboration and referral linkage among NCD, HIV and maternal health or ANC, integration behaviors of the HCWs were the focus area. The observation tried to address the administrative structure where HIV, DM and pregnancy care were included. An example of observation was done where a young female officer was giving information on the collaboration and coordination activities. Observation field notes were written after the visit to these units. An observation took a duration of 20-35 minutes.

TABLE 3.1: SUMMARY OF DATA COLLECTION LEVELS AND METHODS USED

Level of data collection	FGD	IDI	Observation (and Informal interview/ participant observation)	Checklist/Questionnaires' (Quantitative: ANC, DM, HIV/ART data)
Health facilities	<ul style="list-style-type: none"> ❖ Summit health center (HC) (6[#]) ❖ Woreda 19 Kolfe keranio HC (7) ❖ Goro HC (8): ❖ GMH (6), ❖ ZMH (7) 	<ul style="list-style-type: none"> ❖ Lafto HC W-12, HIV (1) ❖ Woreda-12 nefas silk Lafto HC, ANC (1) ❖ Woreda-9 Kolfe Keranio HC, HIV (1) ❖ GMH, MCH (1) ❖ ZMH, NCD (1) 	5 Observations	<ul style="list-style-type: none"> ❖ Gandhi memorial hospital (GMH), ❖ Zewditu Memorial Hospital (ZMH), ❖ Woreda -19 kolfe keranio health centre (HC), ❖ Woreda-12 Nefas-silk, ❖ Goro HC, and ❖ Summit HC
Sub-cities	<ul style="list-style-type: none"> ❖ Nefas silk Lafto sub-city (6) 	<ul style="list-style-type: none"> ❖ Bole-HIV (1), ❖ Bole-MCH (1), ❖ Kolfe keranio-MCH (1) 	3 observations	
RHB	<ul style="list-style-type: none"> ➤ AACHB (6) 	<ul style="list-style-type: none"> ❖ NCD/DM (1) ❖ MCH (1) ❖ HIV officer (1) 	1 observation	
FMOH			Done at <ul style="list-style-type: none"> ❖ HAPCO (once) ❖ MCH (once) ❖ NCD/DM (once) 	
<i>Total</i>	<i>7 FGD</i>	<i>11 IDI</i>	<i>13 observations</i>	

Numbers in the brackets after the name of study health facility, region or sub-city show the number of participants involved in the IDI and FGD.

- Concerns and challenges during the data collection

During the conducts of interview and discussions, the following issues and challenges were encountered:

1. The need to have FGD at sub-cities and the region was noted to be vital to appreciate the group dynamics. This was done accordingly. The initial proposal was to carry out only IDIs at sub-cities and region and FGD at health facilities.
2. A fewer numbers of FGD participants due to working hours, 6-8 participants per FGD. The discussion was carried out during the “free and non-rushing hours”, after 3:00 pm in the afternoon yet a fewer clinicians were involved. The interviews were also made at the end of the mornings before lunch where the participants might be exhaustive to fully show their ideas.

3. The interview was done in the office, at ART, ANC or NCD. The interview in the afternoon was with the assumption of little workload. Nevertheless, there were occasions where clients in need of the service were knocking or opening the door interrupting the interview. Other staff member in need of the interviewer were also interrupting the interview process
4. The challenge of getting enough time, HCW and patients in private health facilities due to the working nature of the facility (profit making) where they wanted to keep the privacy of the their clients. It was also difficult to get a room or an office for the IDI and FGD, and the difficulty of appointing the busy HCW and experts working in the private health facilities. Hence, the private health facilities were left out. To compensate for the left out private health facilities, three public health facilities were added after re-requesting the IRB's of Addis Ababa ethical clearance committee.
5. At the federal ministry level, data collection using formal IDI and FGD could not be carried out. This is because the Addis Ababa city IRB could not write a support letter to the federal ministry of health. This is because; structurally, FMOH is not accountable for Addis Ababa. However, informal observation and interviews were carried out regarding the coordination, collaboration and the structure regarding the DM, HIV and pregnancy care services at federal level.
6. The researcher used the mobile phone to record the interview. In one FGD and two IDIs, the sound of the incoming calls interrupted the recording and affected the discussion or interviews.

3.6.1.8 Coding and analysis

Coding is attaching labels to segment of data that depicts what each segment means (Thornberg & Charmaz 2014:159). During the coding process, according to Thornberg and Charmaz (2014:160), the researcher interrogated the data to identify units of analysis (categories). Interviews and discussions were made using the widely spoken Amharic language. However, the translation was done while transcribing the audio recorded data. Initially, the researcher familiarized himself with the data through

listening to all audio records; then reading and rereading of transcripts before coding and categorizing. The researchers used an iterative approach to analyse IDI and FGD. Field notes for observation were written using English language. The field notes and memo of the observation were coded, categorized and put to similar theme. This allowed pursuing emergent themes in subsequent data collection. In this study, key points in each interview were highlighted. The researcher gave each key point a code to describe the data. The codes revealed patterns across the data and then grouped the patterns into categories. Each category was given a title. New codes and sub-categories emerged as themes.

3.6.1.9 Rigor in qualitative research

In qualitative research, rigor is associated with openness, adherence to a philosophical perspective, thoroughness in collecting data and thoroughness in the consideration of all the data. Evaluation of the rigor of a qualitative study is based upon the logic of the emerging theory and the clarity with which it sheds light on the phenomenon under investigation (Polit & Beck 2017: 557 & 747). To enhance the trustworthiness of the qualitative part of this study, the researcher used the criteria formulated by Lincoln and Guba (1986:73) namely, credibility, transferability, dependability and confirmability.

- Credibility

The credibility of the research can be improved through triangulation. Triangulation enriches understanding of a phenomenon by viewing from different perspectives. It ensures that different sources and mixed methods lead to similar results. Triangulation ensures credibility through cross-checking two or more sources and methods (Lincoln and Guba 1986:73-74). In this study, findings from observation, IDI and FGD were triangulated and interpreted. Member checks were used to address credibility by asking the HCWs and program managers of DM, HIV and maternal health to review the researchers' interpretation of that interview and observation.

Additionally, DeForge (2010:125-126) describes triangulation as the use of multiple references to draw conclusions about what constitutes the truth. Triangulation can involve the use of different data collection tools with the same sample of participants, different qualitative methodologies to answer the same research question (Clark and Creswell 2015:490). As applied to this study, to describe and explore about the level and domain of HIV, DM and pregnancy care integration, both observation and interview were applied. At the end, findings from observation and interview were triangulated, interpreted and discussed together.

Data triangulation - involves the use of multiple data sources in the study in order to get diverse views to aid in validating the conclusions (Creswell et al 2011:2103; Mateo and Foreman 2013:293). HIV, DM or pregnant women, and health providers and program managers of DM, HIV and maternal health were different data sources used in the qualitative part of this research.

- Transferability

This is the degree of similarity between the original situation and the situation to which it is transferred. According to Lincoln and Guba (1986:74-75), purposive sampling helps to ensure transferability. In this research, transferability was addressed by using purposive sampling of HCWs and program managers. In purposive sampling, specific information is maximized in relation to the context in which the data collection occurs. The aim of this study was not generalizing the finding to another setting as it was carried out in only 06 health care facilities. The transferability of this study depends on the future studies in similar contexts.

- Dependability

Dependability examines both the process and the product of the research for consistence (Mateo &Foreman 2013:193). In this research, dependability was ensured

by the employment of “overlapping methods”. That is, the level of DM/HIV integration with pregnancy care was looked into during the qualitative data collection.

- Confirmability

This relies on interpretation and is admitted value-bound. It reduces the influence of the researcher’s thoughts, hence reduces a degree of bias (Polit & Beck 2017:723). To reduce the distance between the interviewee and interviewer, the finding of this study were supported by evidence from different literature. In addition to the extensive literature review, confirmability was ensured by the seeking a critic from experts in the field of DM, HIV and maternal health during the evaluation of the model developed.

3.6.2 Research methods for quantitative approach (phase II)

3.6.2.1 The study setting

According to Streubert and Carpenter (2011:27), setting is a place where the phenomenon of interest actually exists. The setting can be homes, health facility, community or sites selected (Streubert & Carpenter 2011:28).

- Addis Ababa

Addis Ababa is a dominant political, economic, cultural and historical city of the country established in 1887 by emperor Menilik II. It has the status of both city and state. It is the capital of the federal government of Ethiopia. The African Union is based in Addis Ababa. The city also hosts the headquarters of the United Nations Economic Commission for Africa (UNECA) and other continental and international organizations. The city is divided into ten sub-cities which are the second administrative units next to city administration.

According to Central Statistical Agency of Ethiopia (CSA) (2007:17), Addis Ababa harbours about 3 million people. Altogether, there are 52 hospitals in the metropolis of which 6 are owned by Addis Ababa City Administration Health Bureau (AACAHB), 5 by the federal ministry of health, 2 by non-governmental organizations (NGOs), 3 by

Defence and Police and the remaining 36 by the private owners. There are also 100 health centres owned by the city administration. Furthermore, there are an estimated 760 private clinics in the city (Addis Health 2013:32).

A total of 82 health facilities is providing ART services in Addis Ababa, of which 60 are public, 16 private and 6 are non-governmental facilities (FDRE 2014:43-44). In these facilities 124,983 people living with HIV/AIDS were enrolled into care. About 76,035 patients started ART of which only 49,807 are currently on ART (Addis Health 2013:32). During the current research, the researcher obtained the list of all public health facilities in Addis Ababa. Then, the health facilities were stratified as health centers and hospitals providing HIV, DM and ANC services. Of these, 04 health centers and 02 public hospitals were randomly selected.

3.6.2.2 Research population

A population refers to the entire individuals in the certain group that has common binding characteristics to be studied (Babbie 2008:211). It is from this large population that a sample is drawn to make an inference about the population. LoBiondo-Wood and Haber (2014:232) described a population as an entire aggregate of care in which a research is interested. In this study, these were individuals with HIV, DM and ANC care and follow up in Addis Ababa.

- Target population

These are parts of cases about which an investigator wants to generalize (LoBiondo-Wood and Haber 2014:233). Target population is also known as theoretical population. According to Polit and Beck (2017:250), it's an entire group of individuals or objects to which researchers are interested in generalizing the conclusion. In this research, diabetes and HIV infected female patients with a childbearing age on care in public health facilities of Addis Ababa city, and those mothers on ANC follow up were the population of interest.

- Accessible population

They are also called study or source population and are the subset of target population to which the researchers can apply their conclusion. It is from here that one draws a sample (LoBiondo-Wood and Haber 2014:233). Diabetic and HIV infected patients within reproductive age groups and those attending ANC at a selected 06 health facilities in Addis Ababa were approached to obtain information during the period of data collection.

3.6.2.3 Sample and Sampling Techniques

In the HIV, DM and pregnancy care study a random sampling applied after stratifying the diabetic and HIV infected patients based on their gender where only the female patients in the reproductive age group were select as the study participants. Random sample relates to a randomly selected sample from a population. A random sample is assumed to be a representative of the larger population. Therefore, every member of the study participants in this study was independently chosen and has equal non-zero chance of being selected into the sample (Babbie 2008:212).

- Sampling frame

Polit and Beck (2017: 334) defined sampling frame as “a list of all the elements in the population from which the sample is drawn”. In this study the framework was all lists of HIV infected, diabetic and pregnant mothers in care who fulfil the eligibility criteria in the study health facilities.

A sampling frame was prepared from patients’ list that was appointed to care on the dates of data collection. The date of appointment for each patient was electronically registered in the computer at HIV clinic and manually documented at DM and ANC units. It was from patients’ appointment list that random table was produced. Study participants were selected randomly from the table using the lottery methods in the Exel after stratifying based on their gender. Therefore, a probability sampling was used. The

probability sampling forms a basis of random sampling (Babbie 2008:224). In this case, individuals in sampling frame would have an equal chance of being chosen (Bonita, Beaglehole and Kjellström 2006: 51).

- Eligibility criteria

Eligibility criteria are criteria set by the researcher to define the target population included in the study. Inclusion criteria are the characteristics of a person to include in the study based on specific criteria (LoBiondo-Wood & Haber 2014:233). Those criteria that ruled out certain population not to be participated in the study because of they do not possess or meet the inclusion criteria are called exclusion criteria (Polit & Beck 2017:231).

Inclusion criteria: Health facilities with ART, DM and anti-natal care (ANC) services since 2011 were part of the study site. Study participants were females, in a childbearing age of 18-49 years, who have already enrolled to DM and HIV care during 2011-2016 and those in ANC care during the data collection. They should have confirmed HIV and DM have at least one visit in the last three months before data collection. Only data of documented and confirmed pregnant mothers was abstracted at ANC.

Exclusion criteria: Severely sick patients who cannot give consent during interviewing and patient with incomplete information in the register were excluded from the study. Women with age over 49 years, in whom pregnancy is rare, were excluded.

- Sample Size

The sample size determination for HIV infected mothers was based on the assumption of the prevalence rate of diabetes mellitus and the pregnancy rate among HIV positives in the previous studies (see table 3.2). The sample size determination for diabetes mellitus was based on the 10% pregnancy rate among diabetes mellitus women. These

assumptions are with a 5% margin of error and 95% confidence interval ($\alpha=0.05$). A non-response rate was assumed to be 20%. It was also assumed that the population of DM and HIV infected is large and unknown. Thus, the actual sample size for each objective was determined using a formula for a single population proportion (Daniel 2009:192).

$$N = \frac{(Z/2)^2 p(1-p)}{d^2}$$

Where:

N=the required sample size

Z= standard score corresponding to 95% CI

p= Assumed proportion of DM, pregnancy outcome

d= the margin of error 5%

TABLE 3.2: SAMPLE SIZE CALCULATION BASED ON THE OBJECTIVES OF PHASE II STUDY

Ser. No	Objectives	Assumed power and confidence level	Assumed prevalence rates	Computed sample size	20% non-respondent rate	Total sample size for prevalence rate study
1	To determine prevalence of DM among HIV patients among childbearing female registered during 2011-1016 in Addis Ababa health facilities	Power=90%, Confidence level=. 95	0.34 (IDF 2015:70)	345	69	414 HIV +mothers
2	To determine the prevalence of pregnancy among HIV childbearing female registered during 2011-1016 in Addis Ababa health facilities	Power=90%, Confidence level=. 96	0.32 (Degife et al 2013:S34)	334	67	401 HIV+ mothers
3	To determine the prevalence of pregnancy among DM childbearing female registered during 2011-1016 in Addis Ababa health facilities	Power=90%, Confidence level=. 97	0.1	138	28	166 diabetic mothers
4	To determine the prevalence of adverse pregnancy outcomes among HIV childbearing females registered during 2011-1016 in Addis Ababa health facilities	Power=90%, Confidence level=. 98	0.68 (Adaneet al 2014:90)	334	67	401 HIV+ mothers
5	To determine the prevalence of adverse pregnancy outcomes among DM childbearing females registered during 2011-1016 in Addis Ababa health facilities	Power=90%, Confidence level=. 99	0.1	138	28	166 diabetic mothers
6	To describe mothers with a documented HIV and DM services at ANC clinics in Addis Ababa health facilities	Power=90%, Confidence level=. 99	0.2	300	57	357 pregnant ANC attendants

3.6.2.4 Procedure of enrollment and sampling

The sampling frame was prepared from the appointed clients on the specified date of data collection. In the study health facilities, there was a register database installed on the computer. All the patients' information is available from this registration database, including the date of the appointment of the patients. Thus, those clients who would be coming on a certain date could easily be listed early in the morning of the date of appointment. This is a routine activity of every ART clinic. However, this was manually done at the ANC and DM clinics. In all clinics, the list was made based on their medical registration number and sex. It was from this sample frame that the participants were randomly selected using excel in the computer. The randomly selected DM, HIV infected and pregnant mothers on ANC follow up were approached till the intended amount of sample was selected.

3.6.2.5 Development of data collection instruments and data collection procedures

According to Polit and Beck (2017:266) data collection refers to ways to which information can be obtained systematically to answer the research question. According to LoBiondo-Wood and Haber (2014:273), data collection is a crucial stage in the planning as well as during conducting the study. Data collection tools in pragmatic paradigm use both from post-positivist and interpretivism paradigm (Polit & Beck 2017:577). In this research, the draft data abstraction checklist and questionnaire was developed based on the integration theoretical frame with its different levels of domains; functional, organizational, and service or clinical integration (Uyei et al 2014:42).

- Development of data collection instruments

Babbie (2008:272) described data abstraction questionnaire as a document containing the questions and other types of items designed to solicit information appropriate for analysis. Though producing a high quality structured data collection instrument is challenging and time taking, research requirements must be analysed, related construct

needs to be clustered into a separate area of questions and the instruments must be done to reduce bias (Polit & Beck 2017:302). In this research, data abstraction and the questionnaire was drafted based on relevant literature on the phenomenon under study with due consideration of the research problem and the research question. It was further refined and enriched after the qualitative study finding in phase II of this study. To ensure the reliability and full capture of information, thorough conceptualization and operationalization of the construct was carried out.

The conceptualization in this study mainly came from the exhaustive literature review, specifically the integrated theory by Leutz (1999) and systemic review of TB/HIV integration study in South Africa by Uyei et al (2014). The data abstraction and questionnaire was prepared in English and then translated to the Amharic. Prior to data collection, the data abstraction and questionnaire was reviewed by experts that were epidemiologists, statisticians, researchers and program officers who had at least master level of educational levels. It was also pretested on a total of 15 participants (5 HIV, 4 DM and 6 ANC attendant females) who did not form part of the sample for this study. Redundant items were avoided. For instance, items used to determine the level of integration was supposed to be the fourth section of the data collection part. This information was also part of the other section of the data abstraction and questionnaire and was not used (see Annexure F).

- Characteristics of the data collection instrument

The data abstraction and questionnaire was close-ended. Close-ended questions provide a greater uniformity of responses and are more easily processed than open-ended ones (Babbie 2008:272). To ensure the standardized recording, accuracy and usefulness of the data for data analysis (Polit & Beck 2017:314), each category on the instrument was assigned a numeric value and responses were coded. The data collection tool was named 'data abstraction checklist and questionnaire' because one data collection tool was used to obtain data from patients medical file and register and from the interview of patients' themselves. There were medical data, such as clinical

complications and pregnancy outcomes, which needed to be extracted from their files and register. The patients' current information, such as socio-demographic and family history of DM, should have obtained from the patients themselves. Hence, this is one tool serving as abstraction and questionnaire and hence the name 'data abstraction checklist and questionnaire'. Three data collecting tools were prepared for HIV infected, diabetic and ANC attendant females (see Annexure E)

- Methods of data collection

The structured data collection is obtaining data by formal instruments and protocols that dictate what to collect and how to collect and record the needed information (Babbie 2008:278; Polit & Beck 2017:297). In phase II of the study, structured data abstraction checklist was utilized to collect data on pregnancy, adverse pregnancy outcomes, documented HIV, diabetes and pregnancy counselling and testing services. The tool was refined based on the findings from a phase I study. Diabetic and HIV infected female patients were approached and interviewed to obtain additional information from the study participants and to countercheck key information from the abstraction checklist. This helped to have an accurate, valid and interpretable data, responding to the research question (Polit & Beck 2017:297). The structured data collection was applied to collect very precise information. (Burns & Grove 2013:507; Polit & Beck 2017:298). In this study, numerical data were collected with the same structured plan implemented in all study health facilities. By doing so, all data were collected in similar way (Polit & Beck 2017:301). The quantitative data was collected by the trained clinicians at the health facilities and the researcher himself. It took 5-10 minutes per the clients and upto 30-40 minutes including the abstraction of the clients' files. It was structured and face-to-face interview that was performed.

- Data collection procedures

The researcher served as the data collector. The following is the summary of procedure that was followed during the data collection.

- a) After the UNISA and Addis Ababa city administrative ethical committee approved the research protocol, a support letter was sought and written to the health facilities requesting permission to conduct the study. The letter indicated the need to access HIV, DM and ANC attendants' files and registers, and to interview the patients as part of the study.
- b) Each HIV or DM patients and mothers having a follow up at ANC was approached and asked for a written consent for the interview and to access to their files and clinical information.
- c) Data abstraction of the clinical information from the files of those patients who gave the written consent and fulfilled the inclusion and exclusion criteria was conducted.
- d) The data were obtained from DM, HIV and ANC attendants' files. DM, ART, delivery and ANC registers were looked into for the abstraction.
- e) A structured interview was conducted to counter-check some information during data abstraction and to obtain additional data.

3.6.2.6 Validity and reliability of measurement in quantitative research

Validity and reliability are the two important technical considerations used to evaluate a research instrument in terms of adequacy and quality (Babbie 2008:157; Burns & Grove 2013:393 & 394).

- Reliability of a measurement

LoBiondo-Wood and Haber (2014:290) describes reliability, as the ability of an instrument to measure the attributes of a variable or construct consistently. As stated by Burns and Grove (2013:389) reliable instrument enhances the power of a study to detect a significant difference or relationship occurring in the study population. Thus, responses to a question would give same data in repeated observations (Babbie 2008:157).

LoBiondo-Wood and Haber (2014:291) mentioned the following techniques for increasing the reliabilities of a measurement and reducing the likelihood of measurement error or bias due to random factors.

i). Administration of standardized instruments: this allows the occurrence of measurements consistently across all participants. In this research a uniform data abstraction was conducted all over (Burn & Grove 2013:390). HIV and DM patients themselves were interviewed to counter check some information with data extraction checklist for the purpose of consistency. Also, quality assurance checks for outliers, consistency and duplicates were carried out before data analysis.

ii). Making sure that the instructions and the content of the instrument are well understood. This would easily avoid bias. In this research, clarity on the questions in the data abstraction and the questionnaire were dealt with during the orientation of the research, pre-testing and data collection process. The specificity was given an emphasis to each question.

iii). Training of researchers or data collectors in the use of the instruments. Ample practice and repeated training over the course of the study to maintain consistency is critical. The researcher practiced the data collection process before the real data collection. That means, the data extraction checklist was pretested prior to the study. The supervision was done by the researcher. Though the researcher was also collecting data, assistant data collectors were recruited in the health facilities after orienting on the purpose of the researcher and the data collection instruments for the quantitative data.

iv). Ensuring that data are recoded, compiled and analysed accurately. Data entry should be closely monitored and audits should be conducted regularly (Babbie 2008:159). In this study, there was a continual monitoring and supervision during data abstraction and face-to-face interview during the quantitative data collection to ensure that the researcher coded data accurately and in a timely manner.

- Validity of a measurement

Validity is what the test or measurement strategy measures and how well it does so (Burns & Grove 2013:393). The same authors indicate that validity seeks to answer the question: “Does the instrument or measurement approach measure what it is supposed to measure?” The concept addresses the appropriateness, meaningfulness and usefulness of the specific inference made from instrument scores (Burns & Grove 2013:394). Validity has to do with truth, strength and value. It can be inferred that if the measurement of the concepts improves then validity also improves by reducing systematic error.

According to LoBiondo-Wood and Haber (2014:292) content validity starts with the development of questionnaires where experts have to review for appropriateness, accuracy and representativeness. The experts were epidemiologist , statistician and three program managers with masters level of education. Based on the 4 scale rating of the experts (or likert scale), the instrument could be 1 not relevant, 2 need modifications, 3 relevant, but need minor modification, or 4 very relevant and succinct. As the determination of content validity starts with operationalization of the construct of instrument (LoBiondo-Wood & Haber 2014:292); the DM, HIV & pregnancy care study had both conceptual and operational definitions based on the literature review and integration theory. That is, the study variables are operationalized so that the underlying theme of the study should have a strong conceptual basis and well validated constructs (Burns & Grove 2013:217-219). Thus, it accurately captures the content from the construct.

In this study, the development of the data abstraction and the questionnaire were preceded by extensive literature review, and further revised by experts who gave their comments by rating and modified per their comment. The data abstraction and questionnaires were translated to Amharic and back to English with the assistance of language experts.

3.6.2.7 Data analysis

Babbie (2008:443) defined a quantitative analysis as “the numeric representation and manipulation of observation for the purpose of describing and exploring the phenomena that those observations reflect”. According to Marczyk, DeMatteo and Festinger (2005:198) the process of data analysis involves data preparation and management; analysis of the data; and interpreting the data; testing the research hypothesis and drawing valid inference.

- Data preparation and management

In addition to ensuring the confidentiality and security of personal data, Tappen (2015:283-284) suggests that the researcher should be able to track and enter the data, and organize the data into a database. Setting up a data, recruitment and tracking system on a computer database provides with up to date information throughout the study, saves time and easily be ready for analysis (Tappen 2015:288). Data checking or screening can be done manually or electronically (Marczyk, et al 2005: 200) to ensure data accuracy and completeness (Tappen 2015:297). In this study manual data checking was done soon after the data was abstracted to screen for plausible ranges; for instance of age, implausible codes for gestational age. In case of inaccuracy, medical records were re-abstracted or study participants were contacted again. Further data screening was done in the DM, HIV & pregnancy care study to ensure that responses were legible and understandable; within acceptable ranges, complete and accurate.

After corrections were made through data screening, data were entered into a well-structured database. In this study, the Epi-info version 3.5.3 of 2011 was used to prepare the data entry format from pre-tested data abstraction and questionnaires. With the inclusion of names, descriptions and abbreviations of the variables codebook was developed before initiation of data collection. To ensure the accuracy of data entry, double entry was applied. Here, data were entered into the database twice and then

compared to determine whether there were any discrepancies. Two data entry clerks were recruited and involved in the data entry and cleaning. One carried out the primary data entry and the second person did the second data entry and cleaning

After this double data entry, each abstracted data and questionnaire were stored in folders per the name of the health facility. The data were stored in a personal computer. Second copy of data were filed as a backup data on CD-ROM. At the end of the data entry, the original data were coded for safeguard, as recommended by Burns and Grove (2013:452). Epi –info statistical package of 2011 was used which assisted in ignoring cases in which variables are missing. Before analysis, variables were checked for normal distribution in order to avoid overestimation (Type I error) by examining skewness (Marczyk, et al 2005:205).

- Analysis of data analysis

Once the data were screened, entered, cleaned and coded; it was easy for analysis. Frequency distribution in a frequency tables were used to describe variables in this study. Categorical variables were summarized by numbers and percentage. Numerical variables such as age and number of births etc. were summarized using means, median and mode based on the symmetry of the data (Polit & Beck 2017:721). Means, ranges, quintiles, variance and standard deviations were used for variables such as gestational age. In addition to table, graphic displays of the variables were applied for description in this study. The proportion test (with p-value less than 0.05 as significant) was also used to compare two proportions such as prevalence of pregnancy and pregnancy outcome between DM and HIV, ANC attendant pregnant mothers and DM, and HIV and ANC attendant pregnant mothers. The findings are presented in chapter 4.

3.7 ETHICAL CONSIDERATION

Research ethics is associated with morality governing research from inception to completion and publication of results (Babbie 2008:66-67). The trust in research results

in the trust in the integrity of researchers and the reliability of the result of their scientific works. Thus, if science is to remain trustworthy, researchers must observe basic moral principles (Rivera & Borasky 2009: 5-6).

3.7.1 Fundamental Principles of Human Research Ethics

There are three basic ethical principles that guide all research involving human subject. These are respect for person, beneficence and justice (Rivera & Borasky 2009: 5-9).

3.7.1.1 Respect for person

Respect for person involves autonomy and privacy, self-determination, confidentiality, the capacity to decide, make a choice, the dignity of people and the individuals (Rivera & Borasky 2009: 5). Sigh (2007:32) described the two moral requirements of respect for persons; the need to acknowledge autonomy and the requirement to protect those with diminished autonomy. Autonomy person, cited by Sigh (2007:32), is an individual capable of deliberating about personal goals and acting under the direction of such deliberation.

To show respect is to give weight to autonomous persons' opinions and choices. To deny individual respect is to show a lack of the freedom to act on considered judgments and withhold information necessary to make judgments when there is no reason to do so, according to Sigh (2007:32). In this study, it was with respect that study participants were approached. It was with their self –decision that they were part of the study. That means, the participants were made clear about the aim of the study and procedure of the data collection so that it was with their self-determination that they became part of the study.

3.7.1.2 Privacy and anonymity

There was a reasonable expectation of guaranteeing the privacy of study participants. So, there was no identifying information of individuals participating in this study that would be revealed in written or other means of communication. The interview questions

were coded with numbers rather than names. The information for the study was meant for academic purposes only, and therefore the information was shared with the supervisor of the study only.

3.7.1.3 Confidentiality

Information that would be given by interviewees was treated in a confidential manner so that the study participants were entitled to privacy of information. The information of the study participants was kept in the private or locked (with code) database.

3.7.1.4 Beneficence

Rivera & Borasky (2009:7) indicate that beneficence is risks reduced (non-maleficence) to ensure physical, mental and social well-being. As complementary expressions of beneficence, Sigh (2007:32) formulates two general rules of beneficence; maximizing possible benefits and minimizing possible harms. As this was a non-experimental study there was no risk of intervention to the study participants. The way the outcome of the study could be beneficial for HIV infected and DM patients and pregnant mothers was explained to them before the interview.

3.7.1.5 Justice

According to this principle, all research participants should be treated equitably (Sigh 2007:33). Justice is also a fair recruitment of research participants and distribution of risks and benefits (Rivera & Borasky 2009: 9). This offers special protection for vulnerable groups. As this was not an intervention or experimental study, there was no major expected risk to study participants. However, as the disease entities were socially sensitive; specifically, HIV, stigma issue was potentially expected to deal with. Yet, all the ethical principles were strictly adhered to while approaching HCWs, program managers, officers, patients, accessing their files and conducting interviews.

3.7.1.6 Obtaining informed consent

One of the foundations of research ethics is the idea of informed consent. Council for International Organizations of Medical Sciences and World Health Organization (CIOMS/WHO) (2002) Guideline 4 stated the informed consent as: "... for all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject. A waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee." Accordingly, both UNISA and Addis Ababa ethical review committees approved the written consent form for this study.

The individual has to receive the necessary information and should understand the information adequately and ought to arrive at a decision. S/he ought not to be subjected to coercion, undue influence or inducement or intimidation (Rivera & Borasky 2009:26; Sigh 2007:35). In this study, essential information was addressed during the process of informed consent. These include the purpose of the research, the methods being used, the possible outcomes of the research, confidentiality, voluntary participation, associated demands, discomforts, inconveniences as well as risks that the participants may face (Nuffield Council on Bioethics 2005:11-15; Sigh 2007:35).

Another component of informed consent is the principle that participants should be volunteers, taking part without having been coerced and deceived. (Nuffield Council on Bioethics 2005 11-15). During the interview process, in this research, the interviewees explicitly explained a person who may have access to the information. They were told that there was no penalty for refusal to participate. Rather, it was absolutely voluntary, with the right to discontinue at any time (Nuffield Council on Bioethics 2005 11-15; Rivera & Borasky 2009:37).

In summary, during the interview and FGD, study participants' informed written consent was sought and obtained for the interview, and to access to their medical record. The confidentiality of personal medical information was kept (Nuffield Council on Bioethics 2005:11-15; Sigh 2007:35). The study participants were explained to about

study purpose and significance. They were informed that it was their right to refuse to participate in the study any time (Nuffield Council Bioethics 2005:11-15; Rivera & Borasky 2009: 37).

In this study the informed consent form was translated into local language, Amharic. It was pre-tested. Subjects were made to participate in the study only after they had read the statement for them and signed on it (Babbie 2008:47).

3.7.1.7 The institution/site

Guideline 2 of CIOMS/WHO (2002) states: “ All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees”. The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review. The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.” Scientific review must consider the study design, including the provisions for avoiding or minimizing risk and for monitoring safety (Rivera & Borasky 2009:52).

The initial review of research protocol was obtained from the Health Studies Research Ethics Committee (HSREC) of the Department of Health Studies at UNISA (REC-012714-039). The committee approved the protocol after reviewing informed consent documentation and data collection instruments in addition to the research protocol (see Annexure J1).

The approved protocol of this study was submitted to Institutes of Review Board (IRB) of the Addis Ababa Health Bureau for a complementary local scientific review and permission to conduct the study (see Annexure J2-J4). After ethical review was obtained from Addis Ababa IRB, then, permission letter to conduct letter from the regional health bureaus was obtained to communicate with the experts (DM, HIV &

maternal health) at regional health bureaus and sub-cities. The letter was written to the heads of study health facilities to observe the service delivery of HIV,DM and ANC and to access to records and registers of patients' files as well as to interview the HCWs(see Annexure J3 & J4). In addition, study participants' informed written consent was sought and obtained to access to their medical files, to participate in the interview and focus group discussion (see Annexure C & D). Throughout the process of the study, the supervisor of the study and the IRB committee monitored and confirmed that the protocol was followed as approved (Rivera & Borasky 2009:53). To effect this, the researcher reported and updated the progress and the process of the study every month until the end of the study.

3.7.1.8 Scientific integrity of the research

Research results might be influenced by conflict of interests and the publication of fabricated data (Bonita, et al 2006:59). To maintain scientific integrity and eliminate the possibility of scientific misconduct and plagiarism, the researcher in the HIV, DM and pregnancy care study followed the steps mentioned in Rivera & Borasky (2009:61). Hence, the researcher preserved primary data and documentation during the study. When citing ideas, words, processes, findings and results obtained by other authors, a clear reference was made to the respective sources. Important results which were contrary to the researchers' results and conclusions were cited and discussed. Besides, the limitation of the research methods were recognized and properly documented and reported in chapter 6.

- Scientific integrity on the part of the researchers

Rivera and Borasky (2009:61) indicates that researchers are responsible for ensuring that no participant will be involved in the research before getting informed consent. The CIOMS guideline also states that the researcher has the duty to communicate to the prospective subject all the information necessary for adequate informed consent. Above all, the researcher had an obligation to protect the confidentiality of the study participants (Rivera & Borasky 2009:61). In this study, the researcher was honest to

accomplish the integrity of the research by adhering to study procedures, and by being transparent in the identification and management of conflict of interest (Rivera & Borasky 2009:60).

3.8 CONCLUSION

In this chapter, the study design and methods were discussed. The chapter also addressed ethical issues related to sampling and data collection. Study rigor and validity were dealt with as related to the study design. The next chapter, chapter 4, deals with description, triangulation and idscussion of the study findings.

CHAPTER 4

PRESENTATION, DESCRIPTION AND TRIANGULATION OF THE FINDINGS

4.1 INTRODUCTION

This chapter presents and describes the details of the findings in phase I and phase II . At end, the triangulation of the two findings is summarized and discussed.

4.2 PHASE I

The objectives of the phase I was to explore the functional, organizational and clinical integration of DM, HIV and pregnancy care service at regional, sub city levels and health facility levels.

In phase I of the study, the collection and analysis of qualitative data was carried out simultaneously. The data collection using IDI, FGD and observations was carried out at the administrative level (sub-cities, regional health bureau and FMOH). Also, the phase I undertook the IDI, FGD and observation at the selected health facilities of Addis Ababa city.

4.3 PHASE II

The objectives of the phase II were to:

- describe pregnancy care and DM services at HIV, DM and HIV services at ANC, and pregnancy care and HIV services at DM clinics in Addis Ababa health facilities,
- determine the prevalence rate of DM among HIV females of childbearing age enrolled in HIV care during 2011-2016 in Addis Ababa health facilities,
- determine prevalence rate of pregnancy among HIV and DM childbearing age females enrolled to care during 2011-2016 in Addis Ababa health facilities

- determine prevalence rate of adverse events in pregnancy among HIV and DM childbearing females enrolled to care during 2011-2016 in Addis Ababa health facilities.

Phase II dealt with the data collection using checklist and questionnaires. The data were collected from females in reproductive age groups attending ANC, HIV and NCD or DM (NCD/DM) clinics at the study health facilities.

4.4 COMBINED FINDINGS OF FGDs, IDIs AND OBSERVATIONS

Based on the aforementioned analysis, a total of seven themes were merged from the combined codes and categories from IDI, FGD and observation. Hence, guided by the domains of the integrated service, similar themes and categories were summarized in the table below (Table 4.1).

TABLE 4.1: SUMMARIZED FINDINGS FROM THE COMBINED FGDs, IDIs, AND ONSERVATION BASED ON THE DOMAINS OF INTGRAITON

Domains	Themes	Category: FGD	Category: IDI	Category: Observation/field notes
Functional	1. Plan	1. 1 One plan document from higher level	1.1 One plan document from FMOH and RHB	1.3 Isolated planning process at FMOH for HIV, MCH and NCD
		1.2 Woreda/District based planning	1.2 Woreda/District based planning	
	2. Budget	2.1 A separate budget at core process	2.1 The budget is for the core processes; of DPDP, medical service and family health.	2.1 Isolate budgeting process
		2.2 No program based budget	2.2 No earmarked budget for each program-for TB, HIV, NCD	
Organizational	3.0 Monitoring system and information management	3.1 A separate supportive supervision	3.1 No program based supportive supervision	3.1 A separate supportive supervision and monitoring.
		3.2 different supervision checklist	3.2 Different supervision checklist	
		3.4. HIV result registration at NCD clinic & ANC	3.3 Monitored intra-referral linkage	
		3.5 s FP registration at HIV, not for DM screening/testing registration	3.4 Separate recording and reporting for NCD	3.7 The NCD register does not have HIV screening or pregnancy testing result column
		3.6 Absent registration and reporting of DM at HIV and ANC		
	4.0 The structure and location of services	4.2 Separate DM, HIV and pregnancy care service outlets	4.2 Stand-alone HIV, ANC and NCD	4.1 The structure of HIV, DM and pregnancy care
Clinical integration-structural integration	5. Policy guideline, training manuals, protocols and algorisms	5.1 Policy guidelines, protocols and algorism of joint service delivery	5.1 Policy guidelines, protocols and algorism of joint service delivery	5.1 Policy guidelines, protocols and algorism of joint service delivery
		5.2 No training manual combining DM, HIV and maternal care	5.2 Absent training manual combining DM, HIV and maternal care	
Clinical integration-process integration	6.0 Integrated practice of DM, HIV and pregnancy care service	6.1 PMTCT (HIV service at ANC)	6.2 HIV service at DM	6.2 HIV service at DM
		6.3 Pregnancy care service at HIV clinic	6.4 Pregnancy care at ANC	
		6.5 DM service at HIV	6.5 DM services at HIV	6.5 DM service at HIV
		6.6 DM services at ANC	6.6 DM services at ANC	6.6 DM services at ANC
		6.4 Pregnancy care at DM	6.7 Health care providers collaboration/linkage	6.3 pregnancy care at DM
Clinical integration-service delivery	7.0 Suggested service	7.1 Routine DM screening and diagnosis at HIV		

(Suggestions)	integrated approaches	7.2 Pregnancy care and FP service at HIV clinic		
		7.3 Related service integration (One-stop-shopping for related services)	7.4 One-stop-shop mentality	
		7.5 Policy guideline and training manual	7.5 Policy guideline and training manual of integrated service	
			7.4 Integration mentality of HCWs (One-stop shopping mentality)	
		7.6 Integrated monitoring: Joint supportive supervision, the feedback and supervision checklist	7.6 Integrated monitoring system	7.5 Policy guideline and training manual of integrated service

Hence, under the four main domains of integration, seven main themes were identified.

These are:

Theme 1: Joint plan

Theme 2: Shared budget

Theme 3: Monitoring system and information management

Theme 4: The structure and location of services

Theme 5: Policy guideline, training manuals, protocols and algorithms

Theme 6: The practice of an integrated DM, HIV and pregnancy care service delivery

Theme 7: Suggested service integrated approaches

The following section presents the themes and the categories. The description of each theme and categories is also supported by the field notes captured during the data collection and observations. This is again justified by the relevant quotes from the study participants.

Theme 1: Joint plan

Category 1.1: An integrated and joint plan

A framework plan for all core process (Medical care, DPDP, family health, HPACO etc) comes from FMOH or RHB. The officers and the heads of each core process usually cascade their plan based on what has come from the higher up. The plan is a common

and comprehensive plan out of which the heads of the core process would take their own for the detailed plan related to family health (pregnancy care), DM & HIV. Though there is a joint planning, each program focuses on its own program related activities rather than the interrelated issues. During the interview one of the participants indicated:

35, F, FGD, NCD unit: *“As an office, there is one planning... all core process will meet and there will be one joint and common planning. Then after, each core process will come up with their activities ... Otherwise, as a health office (sub-city health office), there is one plan”.*

Category 1.2 Woreda or district based planning

The health offices in regions and sub-cities have one health plan. All core process meet for a common and comprehensive planning related to family health, DM & HIV, Tuberculosis, Malaria and others. The meeting is prepared at district level and it is named as a district or woreda based planning. The 34 years old HIV officer during the IDI in the Addis Ababa city health bureau (AACRHB) mentioned:

34, F, IDI, HIV officer: *“Yes, joint planning is done; there is what we call woreda based planning. This is a joint planning...ehee... (interrupted).”*

Similar to the federal or regional planning, each core process at sub-cities or districts focuses on the program based activities. It was observed that pregnancy care or DM team give an emphasis on the pregnancy care or DM. Issues binding HIV with DM or pregnancy care with DM are given little attention. It is named joint or common planning because the forum of planning is planned and cascaded simultaneously. Otherwise, there is little attention paid to the planning of cross-cutting issues among the programs or the units.

In short, it was noted that at federal level, HIV, NCD and MCH unit are working differently. There was no integration of the plan at least in the cross cutting issues. Even though FMOH has one annual plan document for all units or program, the related

services are not put together during the planning process. For instance, NCD unit do plan on the DM, HPN, cancers and etc. It does not consider the related issue such as HIV or maternal health as related to DM.

Theme 2: Budget allocation at federal level

Category 2.1: A separate budget at core process

At federal level, the budgeting exercise is done separately for HIV, NCD and MCH. There is no common budgeting. In fact, the ministry has one budget from where earmarked budget is allocated for each directorate or unit. For instance, the DPDP has its own budget where it allocates the earmarked budget for NCD unit, TB program, and malaria programs. In addition, the ministry allocates a budget for MCH unit or directorate where the unit assigns earmarked budget for maternal or child care. HAPCO is standalone office with its own plan and budget for one program, that is, HIV.

The interviewers at the regions and sub cities mentioned that every core process has its own budget. Hence, the budget is allocated for the core process of DPDP core process (HIV), medical service (DM/NCD) core process and for family health (pregnancy care) core process. During the interview in a sub-city, this was described as:

32, F, FGD, NCD officer: *“Regarding the budget, every core process has its own budget...The core process can utilize its own budget for any activity planned...”*

Category 2.2: No program based budget at regions and sub-cities

There is no program based budget. That is, there was no mentioning of earmarked budget for each program of pregnancy care or ANC, HIV and DM or NCD. The 34 years old NCD focal person from AACRHB said:

34, M, IDI, NCD team lead: *“There is no a program budget. No assigned budget for each program; for TB, HIV, NCD etc.The budget is for the core process of DPDP, curative and medical core process... for family planning. Otherwise, no budget ...emhee...not for the program”.*

However, it was noted that in sub-cities where HIV is an independent unit or core process, there is HIV related budget on HIV prevention activities. In others where HIV prevention is under DPDP and medical care of HIV/AIDS is under medical care core process, the budget allocation is for all activities under the core process, not only for HIV/AIDS care and support.

One of the key challenges to integration of DM, HIV and pregnancy care services lies in the fact that both international funding and local government health structures still tend to be siloed separately (Kiersten, Varallyay and Ametepi 2012:09-10). For instance, PEPFAR, USAID and Global fund are the main source of budget for HIV; whereas, government budget are the financial source for NCD or maternal health. Besides, Malinda gate and Save the Children or UNICEF is the other financial source for maternal health. Hence, such different source of fund need alignment for the success of integrative DM, HIV and pregnancy care services. The donor institutions have been equally slow to relinquish the vertical orientation of funding mechanisms for HIV and maternal health that may impede the efforts to integrate these services (Kiersten et al 2012:10).

Theme 3: Monitoring system and information management

Category 3.1: No program based supportive supervision

At the level of ministry, there was no joint supportive supervision (JSS) and joint mentoring. That is, there noted an isolated supportive supervision and monitoring. Besides, supervision and mentoring are vertical; HAPCO to HIV program, MCH unit to ANC and NCD unit to DM care and support units.

The interviewers at the region and sub cities also reported a separate supportive supervision (SS). Each core process is doing the supportive supervision separately. The integrated supervision is undertaken occasionally when there is activity in need of joint monitoring. Otherwise, each core process does the monitoring of its own program. The feedback of the SS is also a discrete. The interviewers reported:

35, M, FGD, HIV officer: *“During the supportive supervision, all the core processes are doing it separately...”*

35, F, FGD, FP officer: *“Emee... feedback is given in separate. It is a separate feedback system.”*

The thinking that the core process under which HIV, DM and pregnancy care are assigned is different contributed for non-integrated and an isolated supportive supervision and monitoring. Same is true of the reporting system of these programs. This was supported by the following quotes during interview:

F, 26, IDI, NCD officer: *“I (NCD/DM officer) am under the medical service core process...HIV is standalone under the HIV/AIDS core process... Yes, we (NCD and HIV team lead or officers) are not going together (for supervision)”*

35, M, FGD,HIV Officer: *“Yes, ehee...HIV has its own core process... same is true with reporting. Similarly, the unit reporting to me is the one that I am going to... (Door knocking).... (silent)... and supervise”.*

35, F, FGD, family health officer: *“There is a unit which is mainly dealing with pregnant mothers...that is, emee...regarding the mother it is up to the family health core process”.*

According to the officers and team leads, as long as the FMOH or RHB does not direct to do joint supportive supervision, they are not doing so. Hence, the officers or team leads at sub-cities and RHB were not mentoring or doing the supervision together.

Category 3.2: Different supervision checklists

The officers and team leads at all levels mentioned that not only is the supervision carried out separately, but also the supportive supervision checklist does not incorporate the related services of HIV, DM and pregnancy care. Pregnancy care or DM related item does not exist in the HIV supervision checklist. The supervision checklist of NCD does not have HIV or pregnancy care items. One of the interviewees indicated:

45, F, IDI, HIV officer: *“... there is no checklist alignment here.... at supportive supervision... eh?”*

Category 3.3: Monitored intra-referral linkage

Even though there was rarely a joint supportive supervision, the study participants reported that the referral of patients from NCD to ANC, from NCD to HIV and from ANC to HIV is monitored during the assessment or the outreach joint activity using the internal referral forms. They looked at the referral papers to ensure the internal referral linkage. One of the officers explained:

40, F, IDI, NCD officer: *“We check... the internal referral ...we looked at these papers (internal referral forms) what is being done at reproductive health on a mother. When we look at the referral papers we can assess how much we worked together.”*

Category 3.4: HIV service and pregnancy test result registration at NCD clinic

The NCD register is prepared and being used in some selected hospitals. The register does not have HIV screening or pregnancy testing result recording column. However, there is HIV test result register at NCD clinic but registration for pregnancy care service. One of the interviewee described:

46, F, FGD, NCD officer: *“We might make a line (a column) by ourselves (on NCD register); otherwise, we do not have an isolated register (for pregnancy test)”*.

Category 3.5: Pregnancy care service registration at HIV

There were pregnancy counseling, testing and FP service registration at HIV clinic. The registration is not available for DM screening or testing. This was described by the FGD participants as:

37, F, FGD, ART officer: *“Yes, I do have register (for pregnancy care including family planning service at ART)”*.

25, M, FGD, PMTCT officer: *“Yes, regarding pregnancy testing and... ehee...inclusive of family planning, we make a report monthly (with ART clinic).”*

Category 3.6: Registration and reporting of DM at HIV or ANC

It was generally observed that there is no registration or reporting on the screening /testing of DM at HIV or ANC.

Health information systems or monitoring and evaluation, infrastructure, referral systems, are important in determining the success of integration efforts (Adamchak, Janowitz , Liku and Munyambanza I 2010:6). This is also mentioned by the study participants as the details of recording and reporting and joint mentoring and supervision are essential. However, this is challenged by; the increased burden of collecting and reporting on additional indicators for the integrated services; addressing need for increased supportive supervision to ensure quality of integrated services, establishing functional referral systems that can handle integrated services, establishing adequate monitoring and evaluation systems, as there are no standard indicators for integration, addressing the need for interlinked patient monitoring systems and data quality (Kiersten et al 2012:09). Hence, as indicated by the study participants, there were no recording or reporting systems established for the related services of HIV, DM and pregnancy care.

Theme 4: The structure, organization and location of HIV, DM and pregnancy care services

Category 4.1 The structure and organization of HIV, DM and pregnancy care services at administrative levels

At federal level, HIV care and treatment is a unit under DPDP; whereas, the HIV prevention activity is under the unit of HAPCO. HAPCO has its own president. It is the responsibilities of HAPCO concerning HIV prevention in the country. DM is one of the programs in the NCD unit. At federal level, NCD is a unit under the DPDP directorate. It is thus accountable for DPDP directorate in the ministry. NCD is well established with the policy and guideline, together with the commonest NCDs in Ethiopia such as DM,

HPN, breast cancer, cervical cancer and etc. Team leader of the NCD is assigned. The officers of DM, HPN and different cancers have already been employed. The health extension workers (HEW) are also included in the community awareness of DM, HPN, cervical cancer and etc. MCH is another directorate in the ministry. The pregnancy care is in the family health or MCH directorate. The maternal care, neonatal and child care are all the responsibilities of MCH. There are officers for child health, family planning, community care of mother and children.

NCD is young program in regions and sub-cities. There is a team lead for NCD at region under the medical care core process. In these administrative levels, the MCH or family health unit addresses PMTCT and FP while HIV is under the DPDP core process.

Nevertheless, there is an inconsistency structure and assignment of HIV, NCD and maternal health in different sub-cities. At some sub-sites, the structural organization of DM, HIV and ANC is that all are located in the same building and in the same floor. In other sub-cities the NCD is under the medical service - the unit that is responsible for all the health services at health facilities- while in other sub-cities the NCD unit is under the DPDP. HIV or ART is under the DPDP in almost all sub-cities. The family health unit which deals with pregnancy care is under the medical service while the PMTCT is under the HIV program. In the other sub-cities, HIV related prevention activities are under the DPDP while HIV care and treatment is under the medical service. This uneven arrangement can pose the risk to integrative service provision, planning, budgeting, monitoring and evaluation activities of these related programs.

Category 4.2: Standalone HIV, ANC and NCD clinics at health facilities

It was noted that ANC/PMTCT, HIV or ART clinics are located separately in all health facilities during the study period. NCD is also stand-alone clinic. There are also officers for NCD. One of the interviewee described:

30, F, FGD, NCD officer: *“Yes, like other clinics (for HIV and ANC), there is an isolated room for it (NCD). That is, standalone clinic (NCD). It is an OPD but only DM, HPN and other chronic illness together...”*

Theme 5: Policy guideline, training manuals, protocols and algorithms

Category 5.1: Policy guidelines, protocols and algorithm of joint service delivery

Guideline, policy direction and algorithms on HIV and DM related pregnancy care are not in place and considered in the country. Also, the officers at all levels do not have an awareness to practice an integration of DM, HIV and pregnancy care services. The study officers and team leads confirmed that there is no guideline thus far that addresses DM, HIV and pregnancy care services all together.

Pregnancy counseling and testing, and family planning provision guidelines and algorithm are available at ART and ANC/PMNTCT clinics. However, there was no guideline or algorithm that is comprehensive enough to contain DM, HIV, and pregnancy care services. The interviewees and the discussants said that:

45, F, FGD, ART officer: *“No, not at all (combined guideline or protocol)”.*

30, F, FGD, PMTCT officer: *“No direction from sub-city or FMOH regarding guidelines/algorithm of DM/HIV”.*

35, M, IDI, NCD focal person: *“No, this guideline (NCD guideline) is for the general population. No specific group (HIV or pregnant women) is addressed. The DM/ANC, DM/HIV etc... are not addresses in the NCD guideline”*

45, F, FGD, NCD officer: *“No guideline or algorithm related to HIV and DM.”*

However, it was noted that the guideline & algorithm for HIV testing and counseling is available in all service outlets including ANC and NCD. Also, the pregnancy counseling and family planning provision guidelines and algorithm are available at ART and ANC clinics. This was described as:

35, F, IDI, NCD, officer: *“PITC (provider initiated HIV testing and counseling) is common algorithm. One can get PITC algorithm at NCD, HIV, ANC...You also get PITC algorithm”.*

50, F, FGD, NCD officer: *“I have (guideline & algorism) for HIV... but not for DM”.*

Category 5.2: Training manual combining DM, HIV and pregnancy care

Trainings at federal levels are not designed in such a way to addresses HIV or pregnancy care with NCD. This was justified as:

40, F, FGD, HIV officer: *“No, there is no (training manual combining DM, HIV and maternal care), but PMTCT (HIV with pregnancy care and family planning)”.*

26, M, IDI, NCD officer: *“No, not at all (No direction from RHB, sub-city or FMOH) regarding the joint training of DM/HIV”.*

40,F, FGD, ART officer: *“No, I have not trained (on DM/HIV)”.*

The need of the policy guide and training manuals as well as the practice of integrated HIV and family planning has been widely implemented in countries hard-hit by HIV in sub-Saharan Africa including Ethiopia (Kiersten et al 2012:xi). Hence, as stated by the study participants there are a need of policy guidance and development of training manuals from FMOH so that the integration will be successful.

It was also stated by Kiersten et al (2012:4) that renewed attention of policy makers and politicians is critical on the potential for integration to save money or achieve better, more cost-effective outcomes with existing resources. The existence of clear targeted national policies outlining guidance and strategies are required for implementation of integration efforts particularly in contexts where vertical approaches are still pervasive throughout the health sector. Therefore, that need of direction from higher up (FMOH and RHB) is paramount for the effective implementation of DM/HIV/pregnancy care integration at the sub-city, district or health facility levels. Nevertheless, the development of integrative police guideline can be challenged by the revisions to update service delivery guidelines and norms.

Theme 6: The practice of integrated HIV, DM and pregnancy care services

Category 6.1 HIV screening, care and treatment at ANC

Pregnant mothers are one of the priority groups in Ethiopia for HIV testing and counseling. That is, a universal HIV testing and counseling for pregnant women is a policy in Ethiopia where all pregnant mothers visiting ANC are offered free and confidential HIV counseling and testing. The HIV testing service is inclusive of their partners. In addition, after the adoption of option B+ PMTCT, a pregnant mother with HIV infection will have a preventive ART for her and her newborn until one and half year after birth . The study participants have described:

M, 25, FGD, PMTCT Officer: *“We do PITC for all pregnant mothers and their partners”.*

F, 30, FGD, ANC Officer: *“...after they get pregnant, they will stay at PMTCT for 1 and ½ years”.*

50, F, IDI, family health officer: *“If the mother is HIV+, we offer full PMTCT service to have HIV free child”.*

Category 6.2: HIV service at NCD clinic

The researcher also noted that PITC is offered should the DM patients show signs and symptoms of immunodeficiency. HIV counseling and testing is not routinely done for every clients visiting NCD clinic. The following were the reflections during IDI and FGD:

IDI 29, F, NCD officer: *“Here PITC can be done at NCD clinic if they (clinicians) suspect HIV. If positive at DM, they will be linked to HIV clinic.”*

F, 50, FGD, NCD officer: *“Like other OPD, here (at NCD) PITC is done.”*

Category 6.3: Pregnancy care at HIV clinic

Pregnancy counseling was reported to be a routine advice in HIV clinics. HIV infected females are told not to get pregnant though on ART. This is because the chance of MTCT is not nil. If HIV infected clients want to be pregnant, the HIV officer advice to

have unprotected sexual intercourse during a high risk period of getting pregnant. This was justified as:

30, F, FGD, PMCT officer: *“We cannot prevent them from getting pregnant. With very low CD4, they might want to get pregnant. Here, we tell them it is a problem both for their mother and fetus”.*

25, M, FGD, ART officer: *“We tell that there are cases where they can give HIV infected child ... ehee....I mean...even with follow up due to high viral load”.*

45, F, FGD, ART officer: *“They want to get pregnant. We advise them to do mating during the ovulation rather than doing sex all over the month... We advise them on the timing of sexual intercourse”.*

It was noted that clients were routinely provided with dual family planning, hormonal and a barrier (condom) methods. Short-term family planning such as pills and injections were provided in all HIV clinics. However, the long term family planning service including Implanon had just been started at HIV clinics of a few health facilities. Otherwise, it was observed that it is a routine practice to refer clients for long term family planning to FP unit. The study participants said:

35, M, FGD, HIV officer: *“We counsel and advice on the use of family planning and it is integrated with HIV”.*

45, F, FGD, ART officer: *“We give short term FP in this (HIV) clinic...When they need a long term FP, we link to FP clinic”.*

45, F, FGD, ART officer: *“..... Condom and DEPO, we will give them here (at HIV clinic)”.*

45, F, IDI, ART officer: *“For Implanon and IUCD we refer them to FP clinic”.*

35, F, FGD, Family health officer: *“At HIV, we render FP including long term FP...just started...Our clinicians have trained recently”.*

46, F, IDI, ART officer: *“In this clinic (HIV); mainly, mother uses dual FP”.*

35, F, FGD, Family health officer: *“We have a plan to start the long term (FP), just trained health care providers a month back”.*

Pregnancy test using a urine sample is another service at HIV clinic. This is provided when mothers complain about the sign and symptoms of pregnancy or delayed menses. The pregnancy test is also provided whenever the females in the reproductive age are enrolled to HIV clinic and started ART. If mothers are confirmed to be pregnant, they will be linked to PMTCT. The interviewees reported:

36, F, IDI, ART officer: *“Depends on the women complaint (if she has signs of pregnancy, morning sicknesses, and if she reported the monthly menses is absent), I will send (for pregnant test); specially, if she is amenuric.... (Long silence). Emhhee...ehhee... If it is confirmed, I will link to PMTCT”.*

Category 6.4: Pregnancy care at NCD clinic

The pregnancy test at DM is rarely entertained. It is only when the patients requested the test that it is offered.. Whenever they need the service of pregnancy care, they are referred to family planning. However, for a diabetic pregnant mother, her pregnancy and DM is taken care of at hospital setting. The study participants described:

F, 46, FGD, NCD officer: *“If the young girl/women come, of age 18 or 19, we will give her the detail counseling and advice (regarding pregnancy)...”*

29, FGD, NCD officer: *“As an institute, based on the symptoms by the DM mother, we can do an investigation (pregnancy test (PT))”.*

F, 50, FGD, NCD officer: *“... we ask for amenuria (absence of menses) and if we suspect for pregnancy, we send for pregnancy test”.*

Category 6.5: DM service at HIV

Unlike the routine HIV test for all pregnant mothers at ANC clinic, there was no routine DM screening at HIV clinic. The DM screening and investigation is based on the symptoms and signs reported by the clients.

M, 30, FGD, HIV officer: *“Regarding DM...ehee... if the symptoms of DM are detected, we will investigate the clients (laboratory tests)”*.

45, F, FGD, ART officer: *“We ask about feeling thirst, weakness, fatigue, dry mouth, urine in the night; then, we do laboratory tests (fasting blood sugar)”*.

50, F, FGD, ART officer: *“Based on the symptoms (of DM), random blood sugar (RBS) may be done. Otherwise, like HIV, there is no emphasis... or routine test for DM.”*

The HCW are not also well aware of how HIV or ART are a risk factor for DM. Therefore, the practice of routine DM screening at HIV is absent. The active and routine DM screening for HIV infected patients was not noted during the observation or interview as well. The HCWs justified this as:

28, M, participant’s observation/ informal interview: *“...no convincing evidence that HIV or ART is a risk factor for DM”*.

It was also noted that there were some HIV clinics that order FBS before the initiation of ART and reported as:

46, F, IDI, ART officer: *“Before putting our clients of ART, we usually do baseline investigation such as FBS, hemoglobin, CD4 ...”*

M, 30, FGD, HIV officer: *“DM test (is done) per the complaints on the follow up, monthly. In fact, we assess for any new event... including DM, in the follow up”*.

Whenever HIV infected females are confirmed to be diabetic, they are linked to NCD for treatment and follow up. One of the participants said:

35, F, IDI, HIV officer: *“If HIV+ infected clients of ours becomes diabetic, this will be linked to DM clinic”*.

It was observed that DM screening and evaluation is done based on the patient’s complain at the study health facilities. DM is usually diagnosed at the general OPDs. DM suspects at ANC or HIV clinics are usually referred to OPD or DM/NCD clinicians

for confirmation. If DM is diagnosed, referral is made to chronic care. At DM clinic, if HIV is confirmed, s/he is sent to ART using the intra-facility referral form.

Category 6.6: DM services at ANC

During the initial visits of pregnant mothers to ANC, a urine dipstick is done. When glucose 2 or 3 plus results are found, FBS or RBS is sent to confirm DM, in addition to the clinical evaluation. If no glucose is detected, active screening of DM is not a practice in the subsequent visits or ANC follow up. It is only when the pregnant mothers come up with the signs and symptom of DM that DM evaluation is done. The interviewees said:

30, F, FGD, PMTCT officer: *“In the initial visit, we will send urine dip stick, if plus 2 or 3, that is the indication for DM, we will send for FBS, then after”.*

45, F, FGD, PMTCT officer: *“If she (pregnant mother) comes up with... dehydration, frequent urination...in the subsequent ANC follow up...that we will do FBS...otherwise, DM testing is not a routine service for pregnant mother”.*

The knowledge of the effect of poorly controlled DM on pregnancy outcome was not optimal among the study participants. Besides, the focused ANC is not emphasizing the DM screening at ANC. The participants indicated:

30, F, FGD, PMTCT officer: *“If we see ANC, DM screening is not in the focused ANC, or not implemented.”*

50, F, IDI, Family health officer: *“As far as I am concerned...no risk factors related to DM (on pregnancy) are considered at ANC”.*

Therefore, HCWs were not thinking of the need of the routine DM screening at ANC. One of the interviewee's confirmed:

25, M, FGD, PMTCT officer: *“No routine screening service of DM in ANC... No pregnant mother is specifically screened for HPN or DM”.*

Mothers with DM and pregnancy have a follow up at hospitals. The DM mothers without pregnancy or other comorbid illnesses can have follow up at health centre (HC). There

is a focal person at health facilities who can decide whether mothers can have a follow up at HC or Hospitals. They can be started on medication at hospitals and then referred back to health centre for follow up. This is because there could be birth complications during a labour or then after. These are supported by the interviewees as:

50, F, FGD, NCD officer: *“Pregnant mother with DM are having a follow up at Hospital”.*

30, F, FGD, NCD officer: *“If she has both HIV and DM, she will be linked to hospitals, especially for DM and potential birth complication...may be to control the sugar”.*

29, F, IDIs, NCD officer: *“Yes, after birth she (DM and pregnant mother) will be having a follow up here (at health centre)”.*

Category 6.7: Health care providers’ collaboration

It was observed that there are occasional shared forums where the NCD is collaborating with HIV or MCH unit. Neither the pregnant women are screened for DM or are offered a routine DM testing at ANC and HIV, nor do they get a combined ART treatment with diabetic medications. Hence, if a mother has both HIV+ and DM, they (health care providers) talk together and decide whether the patients should be treated here or should be referred to better health facility. An NCD officer during the IDI described:

F, 29, IDI, NCD officer: *“For diabetic pregnant mother, the clinicians communicate and discuss together and might refer to hospital for better follow up and treatment...”*

In some health facilities, there is no capacity of diagnosing DM at ANC and ART clinics. There is a thinking that the diagnosis of DM is a work of clinicians at DM or OPD. So there is usually a referral of DM suspects to OPD, NCD clinics or other health facilities with NCD clinics or NCD experts.

Theme 7: Suggested Service Integrated Approaches

The key guiding question asked to explore the possible and feasible level of integration was, ***“How do you think should HIV and DM be integrated to prevent adverse pregnancy problems?”***

Sub category 7.1 DM service at ANC

NCD officers commented that the pregnancy counseling and advice before conception for female in the reproductive age group can be beneficial. In addition, building the capacity of clinicians working at DM clinics to enable them give a follow up care for diabetic and pregnant women at health centers could be feasible. The officers said:

50, F, FGD, NCD officer: *“... there is a limited capacity of HCWs and the health center...but mothers can have a follow up at health center to take care of diabetic and HIV infected mothers without other complication... emhee... [silent]... this can be beneficial for mothers...Also, a routine pregnancy counseling and provision of at least short term family planning is essential at chronic care unit”.*

35, F, FGD, Family health officer: *“At ANC it is also important to have a routine FBS/RBS, like a routine HIV testing and counseling at ANC. It could be practiced. However, this has to come to health facilities in the form of ... direction or guideline from FMOH”.*

Subcategory 7.2: Routine DM screening and diagnosis at HIV

The clinicians at health facilities suggested creating the awareness of clinicians on the fact that HIV infected individual on ART could potentially develop DM and hence the need to make the routine DM screening practice for PLHIV. However, they emphasized the need to have the direction from higher level that convinces the importance of active DM screening and diagnosis at HIV clinic. Diabetic mother can be linked to NCD clinics for treatment and follow up using the standardized referral form. Mentioning the existing threat for the suggested activities, the HIV officers commented:

50, F, FGD, HIV officer: *“That is sound and preferable, the routine (of DM screening at HIV clinic) is important, but the supply (reagents or supplies for DM testing such as glucometer) is challenging”.*

35, F, IDI, HIV focal person: *“That (the routine DM screening) is good, but clients are not comfortable to give blood repeatedly (in every follow up period)...ehee... may be at interval at a time...”*

Subcategory 7.3 Pregnancy care HIV clinic

In addition to the counseling and the advice on the family planning and period of conception, all kinds of family planning were commented to be rendered at HIV clinic. This is because the long term FP has already been initiated in some health centers and they suggested that it should be scaled up to other health facilities. In fact, this warrants the training of HCWs and revision of the guideline and protocols/algorithms on pregnancy and HIV care and support. The interviewees at region and sub-cities described:

37, F, IDI, family health team leader: *“Health care provider should be trained in short and long term (on FP methods)... So, they could give all methods (of FP) at ART clinic (HIV clinic)”.*

50, F, IDI, MCH officer: *“...referral to FP for long term might be stigmatizing. [mobile calling and interrupted the IDI]... (Silent)...It is better to finalize and give all FP service at ART clinics”.*

45, F, IDI, ART officer: *“On ART (HIV) training, this (pregnancy care and including all methods of FP) can be integrated so that they could be given by HCW at ART (HIV clinic)”.*

Subcategory 7.4 Related service integration (One-stop-shopping mentality for related services)

The program team leaders and officers said that it is better to serve a patient with multiple problems at a time and give all related service. As much as possible, in terms of time, resource and human power, the combined approach of giving a comprehensive service that are related together can be cost effective. Moreover, this is beneficial for the patients. The approach of screening and evaluating a single patient for HIV at ART clinic, for DM at NCD clinic and for pregnancy at ANC creates inconvenience for the patient. Advanced and complicated care of HIV, DM or pregnant problem might warrant referral to relevant clinic or it might need consultation of the expertise. Otherwise, the active and routine screening and diagnosis of HIV at ANC and NCD, or DM at HIV or ANC and pregnancy testing and counseling at HIV or NCD is feasible and practical to do. This necessitates the revision of policy guide or development of protocols and algorithms. The comprehensive service packages of interlinked items (DM, HIV, pregnancy care) for a patient was reflected by the study participants as follow:

35, M, FGD, family health team leader: *“All programs that are related should be integrated...ahaa...ehee...such services should be interlinked”.*

50, F, IDI, family health officer: *“A mother coming for ANC can be screened for both (DM & HIV)”.*

37, F, FGD, family health team leader: *“Though there is a (issue of) resource, cost and times, if that happens (DM screening at HIV and ANC clinics), early detection of these diseases is possible”.*

35, M, FGD, HIV team lead: *“Only disease consideration needs to be left out....We needs to treat patients...the patient centered approach. Just think of patient, not disease entity... Better if managed (related problems of a patient) once... sound for patient satisfaction,”*

50, F, FGD, HIV officer: *“Like ANC with HIV (i.e., PMTCT) similar guideline for similar services can be prepared to render similar service at a time”.*

45, F, IDI, HIV officer: *“HCWs at ART can be trained and can give a comprehensive pregnancy care & DM services at ART (HIV clinic)”.*

37, F, FGD, family health team leader: *“Whenever you deal with health, a separate disease entity approach is not useful...Because NCD cases can have HIV, pregnant females can have DM or HIV...”*

In order to overcome problems of low coverage of active HIV screening and pregnancy care at DM clinic in Ethiopia, ministry of health may practice community based DM/pregnancy/HIV health services integration at primary health care (PHC) level. There are several advantages to treating related diseases like HIV, DM and pregnancy problems in primary care and other priority health care programs. Integrated treatment programs in which medical providers are supported to treat related health problems offer a chance to treat ‘the whole patient’, an approach that is more patient-centered and often more effective than an approach in which mental health, acute and chronic physical health, reproductive health, and chronic pain problems are each addressed in a different ‘silo’ without effective communication between providers. This was also well described in the mental health integration into PHCU in Ethiopia (Ayano 2016:1)

Category 7.5 Policy guideline and training manual of integrated service

It was suggested that the practice of DM screening and diagnosis at HIV and ANC/PMCTC, pregnancy care and family planning provision including long term FP at HIV and DM clinics can be included in the policy guideline, training manuals, protocols and algorithms. The FMOH or RHB are expected to prepare such policy guideline, training manual, algorithm or protocols so that sub-cities and health facilities will make use of it. Direction or guidance that is not coming from the higher administrative could not be implemented at lower administrative level. These issues were explained as:

30, F, FGD, family health team leader: *“HIV guideline when prepared, it should include other related burden like DM at the same time”.*

35, M, IDI, NCD team leader: *“The guideline should clearly state what to do if a diseases entity occurred with HIV...Guideline should be standardized & comprehensive”.*

36, F, FGD, family health team leader *“Police or guideline should guide a full and a comprehensive health service for a client.”*

29, M, IDI, NCD team leader: *“The integration should be started from higher up (FMOH and RHB)... Things from federal should have an integrated service delivery approaches”.*

30, F, FGD, family health team leader: *“... So, rather than... these things (related item like DM, HIV and pregnancy) come in separate, it is better as one together... Hence, works from higher administrative level (FMOH and RHB) should come down together”.*

Though such kinds of integration are suggested, the study participants emphasized that there should be bold evidences indicating that integration is efficient, cost effective and useful for patients. Otherwise, activities should be prioritized. That is, HIV screening and diagnosis has already been prioritized among pregnant women. Similarly, for there is a hidden but accelerating DM burden in Ethiopia, the screening and diagnosis of DM should be prioritized among the population with high risk such as HIV or patients on ART where poorly controlled DM could cause harmful events among the pregnant women.

Category 7.6 Integrated monitoring: Joint supportive supervision, the feedback and supervision checklist

The supportive supervision can be integrated and the supervision checklist could include the content of DM, HIV and pregnancy care. The register and reporting of DM can include HIV and pregnancy care services. Same is with ANC/PMCTC register where DM screening and diagnosis could be included.

45, F, FGD, HIV officer: *“DM symptoms can be one question in the HIV intake form... Had it been incorporated into intake form, HIV mentors could have mentored the testing of DM for HIV infacted patients...”*

45, F, IDI, HIV officer: *“Mentors can see whether the DM being also screened at HIV care”.*

29, F, FGD, family health team leader: *“Feedback is given in separate...It would have been better to do together and give the feedback at the same time on one paper”.*

29, F, IDI, NCD team leader: *“It could have been better to organize the checklist together and do the feedback simultaneously”.*

35, M, FGD, HIV team leader: *“Disease prevention, medical service and HIV should have done it (SS) in common, including the preparation of the supervision template”.*

4.5 LEVEL OF DM, HIV AND PREGNANCY CARE INTEGRATION

As described in Chapter One, there are three degrees or levels of health service integration. These are linkage, collaboration and full integration. **Linkage** focuses on improving the link between providers. **Collaboration** is more structured referral linkage than only linkage. In collaboration reports are defined and provided and there is a formal arrangement such as protocols, but are difficult to sustain. **Full integration** has the ideology of one-stop-shopping where a client obtains all health services in a clinic. In this section, the findings from the observation, IDIs and FGDs are used to determine the

degree of integration among DM, HIV and pregnancy care services at administrative (FMOH, RHB and sub-city) and health facility levels.

Kiersten et al (2012:3) indicate that the integration can occur at the levels of administration or health facility down to community. The services can be co-located at the individual service provider, the consultation room, other facility levels. The integrated service can also be provided through referral services to other providers or separate facilities, which often provide more specialized or standalone services. In this study, the degree or the intensity of integration at FMOH, RHB and sub-cities or districts is described as **administrative level of integration**. This is because these levels are playing a role of management, program monitoring and evaluation. The level or intensity of integration at the hospital, health center or community level is assigned as **facility level integration**. It is also noted that the mere coexistence of services in the same facility does not constitute integrated services (Kiersten et al 2012:3). Accordingly, the degree or intensity of integration at administrative and facility level is described in this section.

4.5.1 Level of DM, HIV and pregnancy care integration at administrative levels (FMOH, RHB and sub-cities)

According to theme 1-5, at administrative level, there was an isolated maternal and child health (ANC), HIV and NCD supportive supervisions, registrations and reporting system. There are occasional joint and integrated SS, financing and planning inclusive of all programs. However, the family planning and HIV has an integrated registration and reporting system.

Supervision and mentoring from federal, region or sub-cities are vertical, so HCWs do not believe it is important to give routine DM screening testing at ANC and HIV. However, they are well aware of the accelerating burden of DM in Ethiopia. They think that DM program, NCD in general, is not well funded, recognized and decentralized. That might hide the need for efficient and effective integration of related service such as DM, HIV and pregnancy care.

During the planning or budgeting process at FMOH, RHB and sub-cities, there is no issue of HIV related activities at DM, no issue of DM related duties in HIV or PMCTC and no comprehensive pregnancy related issues on HIV or DM. There existed the policy or guideline or training manuals regarding the integration of HIV care with pregnancy care. Otherwise, there is no policy guideline or training manuals addressing DM in HIV, DM in pregnancy care or the three items all together. Therefore, at administrative levels the collaboration type of integration was witnessed between HIV (HAPCO) and pregnancy care (MCH). The level of integration between HIV (HAPCO) and NCD and between NCD and family health or MCH is a linkage.

4.5.2 Degree of DM, HIV and pregnancy care integration at health facilities

The responses to address the level or intensity of DM/HIV/pregnancy care at health facilities were the one described under the themes 6 and 7 above. The table below (Table 4.2) summarizes the degree of integration based on the themes.

At ANC clinic, HIV infected mothers and the newborn get full care and treatment of HIV. Hence, full integration of maternal and newborn care, and HIV care and treatment are provided at least during the pregnancy and two years after giving birth.

Nevertheless, HIV testing is provided at NCD clinic for clients who shows symptoms and signs indicating HIV or AIDS. If an HIV infection is detected, the clients are referred to ART HIV clinic. There are no standard protocol for the referral linkages between NCD and HIV clinic. Therefore, the type of linkage between NCD and HIV program is taken as a linkage. HIV testing and counseling algorithm was available in all service outlets including ANC and NCD. However, no protocol or algorithm includes DM with HIV or DM with pregnancy care and family planning.

TABLE 4.2: SUMMARY OF EXPLORED LEVEL OF INTEGRATION AMONG HIV, DM, AND PREGNANCY CARE AT HEALTH FACILITIES OF ADDIS ABABA, 2018

Service outlets	NCD clinic	HIV clinic	ANC clinic
HIV service	<ul style="list-style-type: none"> • PITC • Symptom based testing and counseling • Referral of the confirmed HIV infected female to HIV clinic = LINKAGE		<ul style="list-style-type: none"> • Routine HIV testing and counseling • ART for 1 &1/2 years at ANC/PMTCT • Register and reporting available • Guideline and algorims on HIV, pregnancy care, • FP available =FULL INTGRATION
DM service		<ul style="list-style-type: none"> • Symptom based evaluation and treatment • Referral for the treatment and follow up to HIV clinic =LINKAGE	<ul style="list-style-type: none"> • Symptom based evaluation • Referral for treatment and follow-up =LINKAGE
Pregnancy care	Pregnancy test(PT) si available and refer PT positive to ANC and referral for FP =LINKAGE	Pregnancy counseling and advice available PT available and positive PT referred to ANC. Short term FP and pregnancy counseling available =COORDINATION	Pregnancy counseling and advice available. Referral for FP =COORDINATION

In addition to the signs and symptoms, it is mentioned that dipstick test, FBS and RBS are the commonly used methods of screening DM patients. At HIV clinic, DM screening is done only when the clients reported the signs and symptoms indicative of DM. Otherwise, there was no active and routine DM screening for HIV infected patients.

Besides, there is no direction or policy guideline recommending that routine and active DM screening for HIV infected individual. Hence, during the study period, linkage is the type of integration practiced between NCD and HIV clinics. The linkage degree of integration is noted between NCD and ANC. This is because the DM screening for pregnant mothers' depends on the report from the clients and linkage to NCD clinic is done for diabetic mothers.

The pregnancy counseling and testing service as well as family planning counseling and family planning service provision are routinely given at HIV clinic. The long term family planning was just started to be given at a few health facilities. There is a formal registration and reporting of pregnancy care and family planning service at HIV clinic. However, pregnant mothers are referred to ANC. In addition, females with the need of long term family planning are linked to family planning unit. At ANC/PMCT, counseling on family planning and future pregnancy is also given. Hence, the level of integration between pregnancy care service and HIV clinic and between pregnancy care and PMCTC/ANC is coordination.

At NCD clinic, DM female patients are rarely given pregnancy counseling while they are referred to FP unit for the all kinds of family planning services. If they show the signs and symptoms of pregnancy, pregnancy test service is given. If they are positive for pregnancy test, they will be referred to ANC/PMCT. If it is at the health center level that pregnant and diabetic mothers are sent to hospital for better follow up. Hence, at NCD clinic, the DM and pregnancy care service has a linkage level of integration.

4.5.3 Suggested integrated approaches of HIV, DM and pregnancy care at administrative levels

According to the theme 8, at administrative levels the integration between HIV and ANC is full integration; between HIV and DM and between DM and ANC is collaboration.

4.5.4 Suggested integration approaches of HIV, DM and pregnancy care at Health facility level

Theme 8 is also the theme that indicated the suggested integration level at health facilities. Accordingly, table 4.3 summarizes the suggested integration level at health facilities among pregnancy care, HIV and DM to address the adverse pregnancy outcome among the reproductive age mothers. Therefore, it seems feasible to have a routine HIV testing at DM clinic, supported by the DM and HIV care SOPs and guideline. These SOP and the guideline should direct the key activities which can be

practiced at DM clinic that is related to HIV. Hence, the coordination level of integration is feasible and practical. However, the full packages of integration where HIV testing and comprehensive HIV treatment follow up can be implemented at ANC clinic. This has got an already developed guidelines and algorithms in favor of full integration where clinicians at ANC room are trained on HIV care and treatment, pregnancy care and family planning services for reproductive age women.

For HIV clinicians working at HIV clinic, the DM/HIV integrated guidelines, algorithm and SOP are suggested to be prepared addressing routine and active DM screening among HIV infected mothers, treatment follow up for the DM/HIV comorbidity, counseling on the preventive methods of DM (dietary practice, exercise and smoking), and a formal referral and consultation services between HIV clinicians and DM expert. Therefore, almost all services relates to DM at HIV clinic could be addressed so that DM/HIV comorbid patients can obtain all services for both, except the referral or consultation for complex cases at health centers. In fact, the clinicians should be trained on the integrated HIV and DM care to address adverse pregnancy outcome in the females. Similarly, these full packages of DM preventive and treatment service could be offered at ANC by revising the PMCTC guideline and SOPs where DM is addresses clearly in pregnant mothers with HIV infected or otherwise. Here, counseling, testing, treatment and follow up services of both DM and HIV could be rendered for mothers at ANC as far as they are at ANC clinics—full integration.

TABLE 4.3: SUMMARY OF FEASIBLE AND PRACTICAL LEVEL OF INTEGRATION AS SUGGESTED DURING THE IDI AND FGD FOR ADDIS ABABA HEALTH FACILITIES, 2018

Service	Chronic/DM care	ART/HIV care	ANC/PMTC
HIV services	<ul style="list-style-type: none"> Routine HIV testing and counseling HIV testing algorithm can be availed HIV and DM care guideline or SOP is possible =COORDINATION		Option B+ is already available =FULL INTGRATIONB
DM services		<ul style="list-style-type: none"> Routine FBS Health education (HE) on preventive measures Treatment and follow up of DM/HIV co-morbidity DM/HIV guideline, algorism Referral/consultation for complicated and specialty care to chronic care =FULL INTGRATION	<ul style="list-style-type: none"> HE on preventive measures Routine FBS/RBS/DIPSTICK Treatment and follow ay ANC/PMTC till post-partum period and refer to chronic clinic Referral consultation to chronic care if complications DM screening, diagnostic algorism can be available at ANC clinic =FULL INTEGRATION
Pregnancy care	<ul style="list-style-type: none"> Counseling and HE on pregnancy care PT available FP: Short term Referral for long term FP DM + Pregnancy acre =COORDINATION	=FULL integration	

However, the coordination level was suggested per the current health facility structure in Addis Ababa for pregnancy care at NCD clinic. This is because; at DM clinics females could be routinely counseled on the pregnancy care including the family planning. Pregnancy care can be offered whenever the clinician suspects or the clients requested. Short term FP services could also be offered and referral could be practical for long family panning service to FP clinic. Hence, the pregnancy care and DM SOPs and

algorithm could be prepared considering these feasible and practical services related to pregnancy care at DM; thus, the coordination level of integration.

Therefore, the level of integration at health facility level could be full integration among DM, pregnancy care and HIV at ANC; coordination among DM, HIV and pregnancy care at DM clinic. Table 4.4 summarizes the explored level of integration and the suggested level of integration for the HIV, DM and pregnancy care services at the three service outlets.

TABLE 4.4: LEVEL OF INTEGRATION AMONG DM, HIV AND PREGNANCY CARE SO FAR AND THE SUGGESTED APPROACHES AT HEALTH FACILITIES OF ADDIS ABABA, 2018

Ser No.	Integration between	Intensity of integration so far	Suggested level integration
1	HIV service at DM	LINKAGE	COORDINATION
2	HIV service at and ANC	FULL INTEGRATION	FULL INTEGRATION
3	DM service at ANC	LINKAGE	FULL INTGERATION
4	DM service at HIV	LINKAGE	FULL INTEGRATION
5	Pregnancy care at DM	LINKAGE	COORDINATION
6	Pregnancy care at HIV	COORDINATION	COORDINATION

According to Leutz (1999) (Cited in WHO 2008:112-13), one size of integrated care does not fit all'. It is therefore vital to consider the context; that is, different care settings and perspectives in which a specific integrated care initiative develops. In other words, one can integrate all of the services for some of the people, some of the services for all of the people, but one cannot integrate all of the services for all of the people. That is could be why different degree or intensity of integration were noted and suggested.

A comprehensive approach towards the integration of DM, HIV and pregnancy care can shape the whole health system and allow for services to be integrated at various

levels of intensity depending upon the different needs of services users. For instance, though DM is one of the NCDs considered in this study other related NCDs such as HPN could be part of the NCD, HIV and pregnancy care integration, provided that there is a good evidence that HPN can also affect pregnancy and common among HIV infected females.

Vertical integration in the health system is the ownership of the various stages of the production process (Kodner 2009:13). For instance, HIV or NCD and MCH are vertical program in Ethiopia. Daily integrated maternal health services where the record cards, registers, procedures and training courses of the separate 'vertically' organized services (of HIV, DM and pregnancy care) need to be brought together to enable the development of the model fully integrated service. This will improve accessibility, acceptability and output of the services including the reduction in adverse pregnancy outcome. In fact, the service ought to be evaluated by a joint and integrated supportive supervision and the integrated supervisory checklist.

Integrated care aims to address fragmentation in patient services, and enable better coordinated and more continuous care, frequently for an ageing population which has increasing incidence of chronic disease in the western health system (Nuffield trust 2011:9). In Ethiopia there is the experience of the integration of mental health into the primary health units through the training of nurses and supportive supervision (Ayano 2016:1). The other integrative models piloted in Ethiopia were mental health into the chronic HIV care (Wissow et al 2015), and HIV service into family health (Kiersten et al 2012). In addition, the linkage of sexual and reproductive health (SRH) and HIV front-line services (Rebecca, Tamil, Ana and Till 2014) is a well-documented practice of integration. The integration of mental health/substance abuse in primary care unit is a patient centered integration and improves and saves lives and reduces health care costs (Carey, Crotty, Morrissey, Jonas, Thaker, Ellis, Woodell, Wines and Viswanathan 2013:345). Kuramoto (2014:44) and Dall (2011) showed that integration of mental health and behavioral change with primary health care is efficient and effective with a

sound outcome. Grazier, Smith, Song and Smiley (2014:67) indicated that the integration of depression into primary health care is feasible as well.

However, as compared to the suggested DM and HIV integration to address pregnancy outcome, the aforementioned integrations are the integration of a new initiative into an already established primary health system. These integrations are not described based on the leutz theory of integration and could be tough as compared to the potentially easy integration of DM, HIV and pregnancy care at primary health units. This is because, the DM, HIV and pregnancy care services have already been established at the primary health units but with loose collaboration and linkage. Therefore, it could be more feasible to strengthen the linkage and integration of the already established services as compared to the introduction and integration of new initiatives into the health system.

4.5.5 Summary of Phase I study findings

The combined findings of IDIs, FGDs and observations at the administrative level and at health facility level data produced seven key themes. The process by which the themes developed was assisted by the integrated theoretical frame work. The session answered the key objective of the study; exploring the functional, organizational and structural integration of DM, HIV and pregnancy care (Theme 1-5). Also, the researcher determined the intensity or level of integration of DM, HIV and pregnancy care (theme 6). Eventually, this section assisted to bring about the suggested level of integration among DM, HIV and pregnancy care at administrative and health facility level (theme 7), the basis for the development of service delivery model of care including DM, HIV and pregnancy care. The next section describes the finding in phase II of the study.

4.6 PRESENTATION AND DESCRIPTION OF FINDINGS IN PHASE II

The **objectives** of phase II were to:

- describe pregnancy care, HIV and DM services at ANC, DM and HIV clinics in Addis Ababa health facilities,
- determine the prevalence rate of DM among HIV females of childbearing age enrolled in HIV care during 2011-2016 in Addis Ababa health facilities,
- determine prevalence rates of pregnancy among HIV and DM childbearing age females enrolled to care during 2011-2016 in Addis Ababa health facilities, and
- determine prevalence rates of adverse events in pregnancy among HIV and DM childbearing females enrolled to care during 2011-2016 in Addis Ababa health facilities.

Based on the theoretical and conceptual framework of the study (Chapter I, Figure 1.1), the following section are addressed – the output and the impact part of the conceptual framework.

i) Output

This addresses the description of HIV and DM services at ANC clinic, HIV and pregnancy care services at DM/NCD clinic and DM and pregnancy care services at HIV clinic. That is, it deals with the performance of service generated and in this research it is:

- the number or the proportion of reproductive age mothers at HIV and ANC clinics counselled and screened for diabetes mellitus,
- the number or the proportion tested for HIV at DM and ANC clinics and,
- the number or the proportion of mothers at ANC screened and tested for DM and HIV.

ii) Impact

On the conceptual framework of the study, impact means patients' outcomes. In this study it means:

- The prevalence of DM among HIV patients,
- The prevalence of pregnancy among HIV and DM patients, and
- The prevalence of pregnancy outcomes among HIV and DM patients.

In the quantitative phase of this study, the data were collected using the checklist and the questionnaires where data source was the patients' themselves and their clinical records. Data was collected at ANC, DM and HIV clinics by the orientated clinicians on the data collection tools for 11/2 days.

The initially proposed data collection tool was refined and modified based on,

1. The finding from the phase I or qualitative part of the study. Here, the flow and content were revised. For instance, to describe the HIV and DM services being given to mothers at the ANC, DM screening service at HIV, and HIV service the questionnaires and the checklist was modified accordingly to address these issues. Therefore, there were three data collection tools for the quantitative phase of the study. These were for HIV, DM and ANC/PMCTC (see Annexure E & I).
2. The pre-test of the checklist where the order of the questions was rearranged. Repetition and redundancy of the some variables such as pregnancy and family planning and DM and HIV complications were removed.

4.6.1 HIV and DM services at ANC

To answer the objective; “to describe the DM and HIV services at ANC” about 326 pregnant mothers attending ANC at 06 health facilities (about 54 pregnant mothers each) in Addis Ababa were randomly selected and approached.

4.6.1.1 Socio-demographic Characteristic

The mean age of the pregnant mother during the data collection was 28.7 years with standard deviation (SD) of 4.5 years. About 46.0% of them were Gravida 2 while 51.1% were Para 1 (Table 4.5).

TABLE 4.5: PARITY AND GRAVITY OF PREGNANT MOTHERS HAVING A FOLLOW UP AT THE ANC OF ADDIS ABABA HEALTH FACILITIES, FEBRURAY- MAY, 2018

Variable	Number of Gravity or Parity						
	0	1	2	3	4	5	6
Gravity (N=326)		62	150	81	25	4	4
Percent (%)		19.0	46.0	24.8	7.7	1.2	1.3
Parity (N=319)	73	163	60	20	3		
Percent (%)	22.9	51.1	18.8	6.3	0.9		

The mean Gestational age in weeks during the data collection (n=297) was 32.3 weeks with the maximum of 42 weeks and the minimum of 1 week.

Most of the study participants (98%) were married. About 80% of them had attended at least a junior secondary school. Close to 56% were housewives (see table 4.6).

TABLE 4.6: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PREGNANT MOTHERS ATTENDING ANC AT ADDIS ABABA HEALTH FACILITIES, , FEBRUARY-MAY 2018

Variables	Frequency	Percent
Marital status		
a. Married	315	98.1
b. Single	1	0.3
c. Divorced	2	0.6
e. Non-married with a partner	3	0.9
Total	321	100
Highest educational level		
a. Unable to read and write	29	9.0
b. Primary school (1-6 grades)	32	9.9
c. Junior Secondary school (7-8)	65	20.2
d. High School (9-12)	107	33.2
e. Above high school	89	27.6
Total	322	100
Occupation		
a. Unemployed	48	14.9
b. Student	2	0.6
c. Housewife	180	55.9
d. House servant	1	0.3
e. Daily laborer	4	1.2
f. Merchant	86	26.7
commercial Sex worker	1	0.3
Total	322	100
Family history of DM		
a. yes	47	14.5
b. no	277	85.2
c. I do not know	1	0.3
Total	325	100

4.6.1.2 HIV counselling and testing service at ant-natal (ANC) care clinic

The documented HIV testing and counselling was reported for 313 of the pregnant mothers (96%). Twenty-four (7.7%) of them were HIV positive. Almost all of HIV infected pregnant mothers were on ART as PMTCT option B+ (Table 4.7).

TABLE 4.7: HIV RELATED SERVICE AT ANC CLINIC FOR PREGNANT MOTHERS IN ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY 2018

HIV test result	Frequency	Percent
a. HIV+ve	24	7.7
b. HIV-ve	289	92.3
Total	313	100
ART started		
a.No	1	8.0
b.Yes	312	92.0
Total	313	100
ART regimen type		
a.AZT ETC NVP	3	8.7
b.AZTETCEFV	1	4.4
c.TDFETCEFV	306	78.3
d.TDF 3TC NVP	2	8.7
Total	312	100

4.6.1.3 DM services at ANC clinics

Dip stick urine test, a comprehensive test for proteins, sugar, was the only DM related service reported that was reported for all mothers. Otherwise, there were no objectively recorded DM related services given to the pregnant mother. There was no report of RBS or FBS done and recorded in the patients' files. Hence, there was no reported DM mother during the study period from 313 approached study participants.

4.6.1.4 Pregnancy outcomes

The respective 238, 100, 25 and 3 pregnant mothers on ANC reported that they had at least one, two, three and four pregnancies thus far. Those mothers who had the experience of at least one pregnancy reported a 6.1% spontaneous abortion while 4.8% had induced abortion. C-section was done for 37% of them. Hypertension during pregnancy was 7.7% (see table 4.8).

TABLE 4.8: GESTATIONAL AGE (GA) IN WEEKS AND THE NUMBER OF BIRTHS AMONG PREGNANT MOTHERS HAVING ANC FOLLOW UP AT ADDIS ABABA HEALTH FACILITIES, 2018

Ser no.	Gestational age during delivery	No of first pregnancy (%)	No of second pregnancy (%)	No of third pregnancy (%)	No of fourth pregnancy (%)	All pregnancy (%)
1	<32 weeks	47 (25.7)	33 (25.6)	23 (29.1)	8 (53.3)	111 (27.3)
2	32-36 weeks	40 (21.9)	23 (17.8)	18 (22.8)	1 (6.7)	82(20.1)
3	37-40 weeks	80 (43.7)	50 (38.8)	34 (43.0)	4 (26.7)	168 (41.2)
4	41-42 weeks	11 (6.0)	16 (12.4)	4 (5.1)	2 (13.3)	33 (8.1)
5	>42 weeks	5 (2.7)	7 (5.4)	0	0	12 (2.9)
6	Total	183	129	79	15	406

Among the total of 406 total births (from first to fourth births experienced), about 20.1% and 2.9% were preterm and post term pregnancies respectively. In about 51.1% of births the gestational age was within a normal limit of 37-40 weeks (Table 4.9).

There were 12(4.1%), 22(7.4%) and 14 (4.7%) very low birth weight, low birth weight and big baby reported in the total of 296 birth (Table 4.9). The proportion of deliveries with the normal birth weight 84%, the highest proportion of 94.4% in the third pregnancy.

TABLE 4.9: SUMMARY OF BIRTH WEIGHT AMONG PREGNANT MOTHER HAVING ANC FOLLOW UP IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser no.	Birth weight	First pregnancy (%)	Second pregnancy (%)	Third pregnancy (%)	Fourth pregnancy (%)	Total pregnancy (%)
1	<1500	7(3.5)	5 (6.4)	0	0	12 (4.1)
2	1500-2499	15(7.8)	6(7.7)	1 (5.6)	0	22 (7.4)
3	2500-4000	165(83.3)	64(82.1)	17 (94.4)	1000	248 (83.8)
4	>4000	11(5.6)	3(3.8)	0	0	14 (4.7)
5	Total	198(100)	78(100)	18(100)	2 (1000)	296 (100)

Although the majority (46%) of the births were spontaneous vaginal delivery, especially in third pregnancy (68%), there were spontaneous or induced abortions (11.7%),

caesarean or instrumental deliveries (36.4%) and HPN during pregnancy (5.6%). Stillbirth was reported in 8.4%, 9.3% and 4.2% of the respective first, second and third pregnancies. Miscarriage was indicated in the 10% of the first pregnancy, 10.3% of the second pregnancy and 16.7% of the third pregnancy. Congenital malformation was also reported in 0.8% and 3.1% of the first and the second pregnancy among the mothers having ANC follow up in Addis Ababa health facilities (Table 4.10).

TABLE 4.10: MATERNAL AND FETAL BIRTH OUTCOMES AMONG ANC ATTENDANTS' MOTHERS IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser No	Pregnancy outcomes	Number (%) in the first pregnancy	Number (%) in the second pregnancy	Number (%) in the third pregnancy	Number (%) in the fourth pregnancy	Total number (%) of the pregnancy
Birth outcome, maternal						
1	Spontaneous vaginal delivery	107 (42.2)	49 (49)	17 (68)	1 (33.3)	174(46.3)
2	Spontaneous abortion	15 (6.1)	9(9)	2 (8)	1(33.3)	27(7.2)
3	Induced abortion	12 (4.8)	3 (3)	2 (8)		17(4.5)
5	Instrumental delivery	8 (3.2)	1 (1)			9(2.40)
6	C-section	87 (35.1)	36 (36)	4 (16)	1(33.3)	128(34.0)
7	Pre-eclamsia	15 (6.1)	2 (2)			17(4.5)
8	Eclamsia	4 (1.6)				4(1.10)
	Total	248 (100)	100 (100)	25(100)	3(100)	376 (100)
Birth outcome, fetal						
1	Alive/normal birth	194 (77.3)	75 (77.3)	19 (79.2)	2 (66.7)	290 (77.3)
2	Still birth	21 (8.4)	9 (9.3)	1 (4.2)		31(8.3)
3	Miscarriage	25 (10)	10 (10.3)	4 (16.7)	1 (33.3)	40(10.7)
4	Congenital Malformation	2 (0.8)	3 (3.1)			5(1.3)
5	Other	9 (3.6)				9(2.4)
	Total	251 (100)	97 (100)	24 (100)	3 (100)	375 (100)

4.6.2 DM and pregnancy care services at HIV clinic

4.6.2.1 Socio-demographic characteristic of the study participants

The mean age of HIV positive study participants was 32.5 years with SD of 5.3 years. It ranged from 19-45 years. The majority of them were married (65.6%), literate (96.7%) and housewives (29%) (Table 4.11).

TABLE 4.11 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF HIV+ MOTHERS IN ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY 2018

Variable	Frequency	Percent
Marital status		
a. Married	236	65.6
b. Single	62	17.4
c. Divorced	26	7.3
d. Widowed	18	5.05
e. non-married with a partner	18	4.6
Total	360	100
Educational status		
a. Unable to read and write	14	3.7
b. Primary school	61	17.1
c. Junior school	29	7.9
d. High school	144	44.4
e. Above high school	108	26.9
Total	360	100
Occupation		
a. Unemployed	20	5.5
b. Student	36	10.1
c. Housewife	103	28.9
d. House servant	22	6

e. Daily laborer	6	1.8
f. Merchant	12	3.2
h. Government employee	62	17.1
i. Private employee	91	25.4
k. Others	8	2.3
Total	360	100

4.6.2.2 HIV Counselling and testing service outlet

The majority of HIV+ mothers (67.5%) on follow up were tested at HIV counselling and testing (HCT/VCT) or ANC clinics. At an outpatient department about 23.3% of the HIV+ mothers knew their HIV status (Table 4.12).

TABLE 4.12: SERVICE OUTLETS WHERE HIV COUNSELLING AND TESTING WAS DONE FOR HIV+ MOTHERS IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser No	Where was HIV diagnosis made?	Frequency	Percent
1	HCT/VCT clinic	129	37.2
2	ANC	105	30.3
3	Family planning	3	0.9
4	Outpatient Department (OPD)	81	23.3
5	Inpatient Department (IPD)	6	1.7
6	Others	23	6.6
	Total	347	100

Among the HIV+ mothers, fourteen cases of TB (4.0%) and three case of HPN (0.8%) mothers were reported

4.6.2.3 Pregnancy rate among HIV+ mothers

Among the 280 (77.8%) mothers having an experience of pregnancy thus far, 275 (98.2%) were successful delivered live births while 271(96.8%) children were alive during the study. About 78.4% of the HIV+ females had at least one pregnancy while 21.6% had never got pregnant (Table 4.13).

TABLE 4.13: NUMBER OF PREGNANCIES EXPERIENCED BY THE HIV+ MOTHERS ON HIV CARE AND TREATMENT AT ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY, 2018

No of pregnancy	Number females get pregnant thus far (%), N=357	Number females with live deliveries (%), N=343	Number of females having alive child/ren (%), N=342
0	77 (21.6)	82 (23.9)	86 (25.2)
1	117 (32.8)	122 (35.6)	121 (35.4)
2	86(24.1)	93 (27.1)	90(26.3)
3	45 (12.6)	32 (9.3)	33 (9.7)
4	24 (6.7)	11 (3.2)	9 (2.6)
5	4 (1.1)	1 (0.3)	2 (0.6)
6	1 (0.3)	1 (0.3)	1 (0.3)
7	2 (0.6)		
8	1 (0.3)	1 (0.3)	

4.6.2.4 DM services at HIV clinic

The following bar graph shows that only 16.2% of HIV+ mother were tested for DM. About 8.4 % of HIV+ mothers were tested for DM at the study health facilities, while 7.8% of them were evaluated at other health facilities (Figure 4.1). Fasting blood sugar (FBS) was the main means of DM testing (32 out of 41 tested, 78%), the other being random blood sugar and urine dipstick. Five cases of DM (1.5%) were reported among HIV+ mothers.

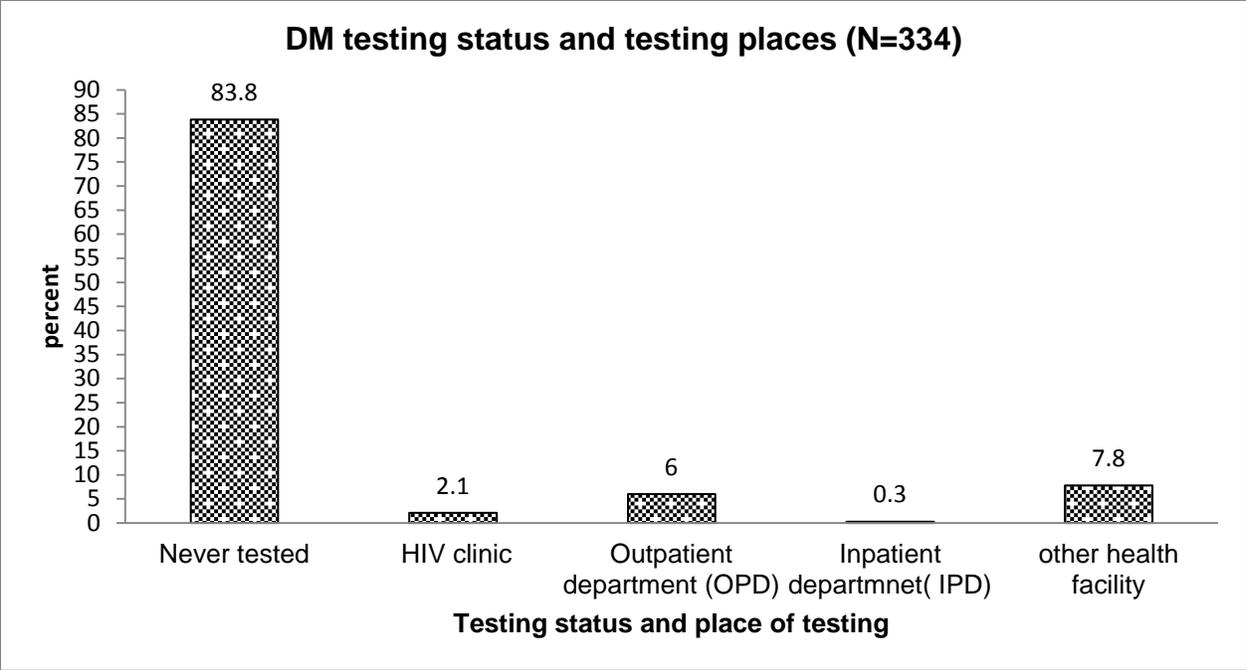


Figure 4.1: DM testing status and testing service outlets in Addis Ababa health facilities, 2018

4.6.2.5 Pregnancy outcome among HIV positive mothers

4.6.2.5.1 Maternal birth outcome

About 80.5% and 7.6% of the total pregnancies ended in term (37-40weeks GA) and post-date (41-42 weeks of GA) deliveries respectively. Twenty-nine (7.8%) pregnancies reported to be delivered before 32 weeks of GA, and 13 (3.5%) were pre-term deliveries. Two deliveries (0.5%) were post term (Table 4.14).

TABLE 4.14: SUMMARY OF GESTATIONAL AGE OF DELIVERIES AMONG HIV INFECTED MOTHERS IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser no.	Gestational age during delivery	No of first pregnancy (%), N=216	No of second pregnancy (%), N=105	No of third pregnancy (%), N=38	No of fourth pregnancy (%), N=11	All pregnancies (%), N=370
1	<32 weeks	12 (5.6)	8 (7.6)	6 (15.8)	3 (27.3)	29 (7.8)
2	32-36 weeks	6 (2.8)	4 (3.8)	2 (5.3)	1 (9.1)	13 (3.5)
3	37-40 weeks	176 (81.5)	88 (83.8)	28 (73.7)	6 (54.5)	298 (80.5)
4	41-42 weeks	21 (9.7)	5 (4.8)	1 (2.6)	1 (9.1)	28 (7.6)
5	>42 weeks	1 (0.5)	0 (0)	1 (2.6)	0 (0)	2 (0.5)

In the first to fourth pregnancy, 326 (74.1%) of the pregnancies were normal deliveries while 63 (14.3%) ended in abortion. Eighteen (4.1%) pregnancies were assisted through instrumental deliveries or C-section. The HPN during pregnancy was 23 (5.2%); ranged from 2.1-10.7%. Two (0.5%) and 8 (1.8%) pregnancies were complicated by systemic infection and haemorrhage respectively (Table 4.15).

TABLE 4.15: MATERNAL DELIVERY OUTCOME AMONG HIV INFECTED MOTHERS IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser No.	Maternal delivery outcome	Number of first pregnancy (%)	Number of second pregnancy (%)	Number of third pregnancy (%)	Number of fourth pregnancy (%)	Total pregnancy (%)
1	Spontaneous vaginal delivery	188 (76.1)	98 (77.8)	31 (64.6)	9 (47.4)	326 (74.1)
2	spontaneous abortion	23 (9.3)	17 (13.5)	13 (27.1)	6 (31.6)	59 (13.4)
3	Induced abortion	2 (0.8)	0(0)	1 (2.1)	1 (5.3)	4 (0.9)
4	Instrumental delivery	6 (2.4)	6 (4.8)	1 (2.1)	1 (5.3)	14 (3.2)
5	pre-eclamsia	20 (8.1)	2 (1.6)	1 (2.1)	0(0)	23 (5.2)
6	C-section	1 (0.4)	2 (1.6)		1 (5.3)	4 (0.9)
7	APH	2 (0.8)	0(0)		0(0)	2 (0.5)
8	Systematic infection	5 (2)	1 (0.8)	1 (2.1)	1 (5.3)	8 (1.8)
9	Total	247	126	48	19	440

4.6.2.5.2 Foetal birth outcome

The mean birth weight were 2999.3, 3136.5, 2659.8, 2327.6 grams for the respective first, second, third and fourth pregnancies. Overall, 4.6% of very low birth weight and 7.8% of low birth weight were reported. Big baby was 2% of the pregnancies. The normal birth weight was in the range of 62.5% and 87.4% (Table 4.16).

TABLE 4.16: BIRTH WEIGHT IN HIV INFECTED MOTHERS IN ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY, 2018

Ser no.	Birth weight	Number of first pregnancy (%)	Number of second pregnancy (%)	Number of third pregnancy (%)	Number of fourth pregnancy (%)	Total pregnancy (%)
1	<1500	6 (4)	2 (2.7)	2 (8)	2 (25)	12 (4.6)
2	1500-2499	13 (8.6)	5 (6.8)	2 (8)	0 (0)	20 (7.8)
3	2500-3999	132 (87.4)	63 (85.1)	21 (84)	5 (62.5)	221 (85.7)
4	>4000		4 (5.4)		1 (12.5)	5 (2)
5	Total	151	74	25	8	258

There were a total of 74 (17.1%) stillbirths or miscarriage. Congenital malformations (down syndrome and mental retardation) was reported in 9 (2.1%) of the births; high (42.9%) in the fourth pregnancy and low during the first pregnancy (1.8%). Otherwise, 345 (80%) of the births were normal deliveries (Table 4.17).

TABLE 4.17: FOETAL BIRTH OUTCOME AMONG BIRTHS OF HIV+ MOTHERS IN ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY, 2018

Ser No	Fetal birth outcome	First pregnancy (%)	Second pregnancy (%)	Third pregnancy (%)	Fourth pregnancy (%)	Total number of deliveries
1	Live/normal birth	198 (80.5)	106 (85.5)	31 (67.4)	10 (55.6)	345 (79.7)
2	Still birth	4 (1.6)	4 (3.2)	1 (2.2)		9 (2.1)
3	Miscarriage	32 (13)	14 (11.3)	13 (28.3)	6 (33.3)	65 (15.0)
4	Congenital malformation	8 (3.3)			1 (5.6)	9 (2.1)
5	Other	3 (1.2)		1 (2.2)	1 (5.6)	5 (1.2)
6	Total	245 (100)	124 (100)	46 (100)	18 (100)	433 (100)

4.6.3 Diabetes Mellitus

The mean age of the 158 diabetic women involved in the study was 43.5 years (95% CI, 42.5-44.7 years) ranging from 24 to 47 years. About 96.7% of the study participants were diagnosed at out-patients department (OPD) of the study health facilities. The rest (3.3%) were diagnosed and referred from other health facilities. Forty-one (27.2%) of the females had type I DM, and type II DM was reported in 109 (72.2%) the females. Sixty-one out of 103 study participants (59.2%) said at least one of their close relative or family had DM as well. History of DM in the family was reported by 72.5% of type II DM mothers while 9.1% of the type I DM reported presence of DM in the family. The average FBS during the data collection period was 194mg/dl and the range was 293mg/dl (103-386 mg/dl). The mean weight of the DM females during the data collection was 66.4 kg ranging from 53-80 kg. As shown in the bar graph below, about 27.2% of DM females were over-weight or obese.

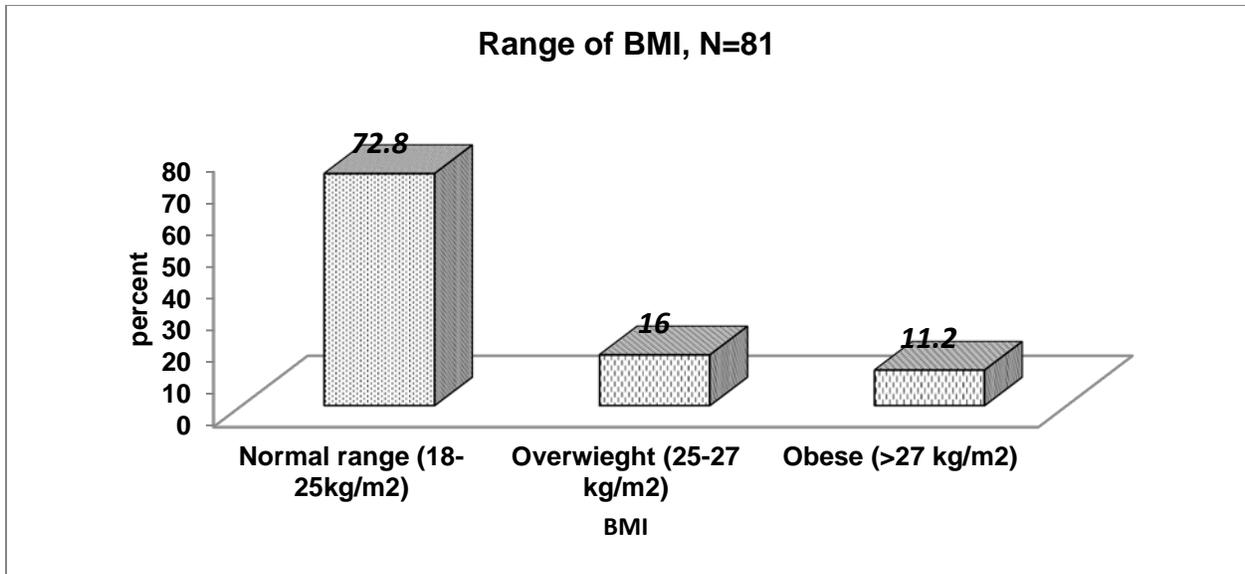


Figure 4.2: The summary of BMI based on WHO definition among Addis Ababa diabetes females, 2018

About 7% (11) DM patients documented to have TB disease and 5.7% (9) of them were hypertensive.

4.6.3.1 HIV service at DM

Out of the 152 diabetic patients, 67.8% of them were offered PITC at NCD, whereas 25% were referred to HIV counselling and testing clinic or outpatient department for testing and counselling service. About 7.2% of diabetic patients had not given HIV testing and counselling service (Figure 4.3). Two (1.4%) DM patients were found to be HIV positive.

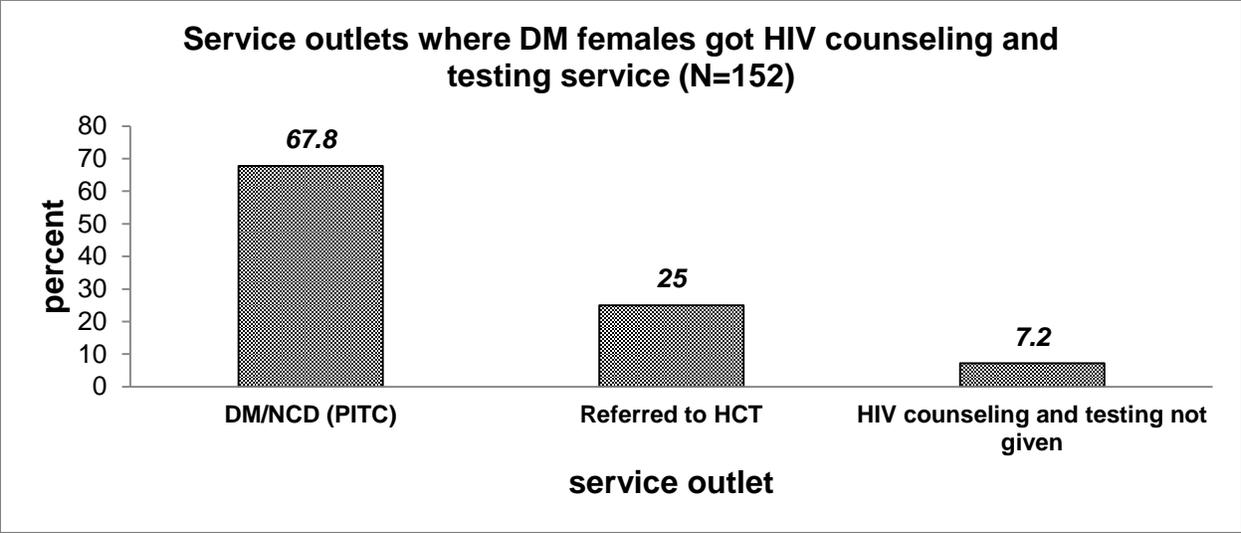


Figure 4.3: Service outlets where HIV counselling and testing was provided for DM females in Addis Ababa health facilities, 2018

Among the DM females who responded for the question of “Have you ever got pregnant?”, about 79% said they had experienced at least one pregnancy so far. About 20% of them had not got pregnant thus far (Figure 4.4). Two (1%) of them were pregnant during the data collection, the GDM.

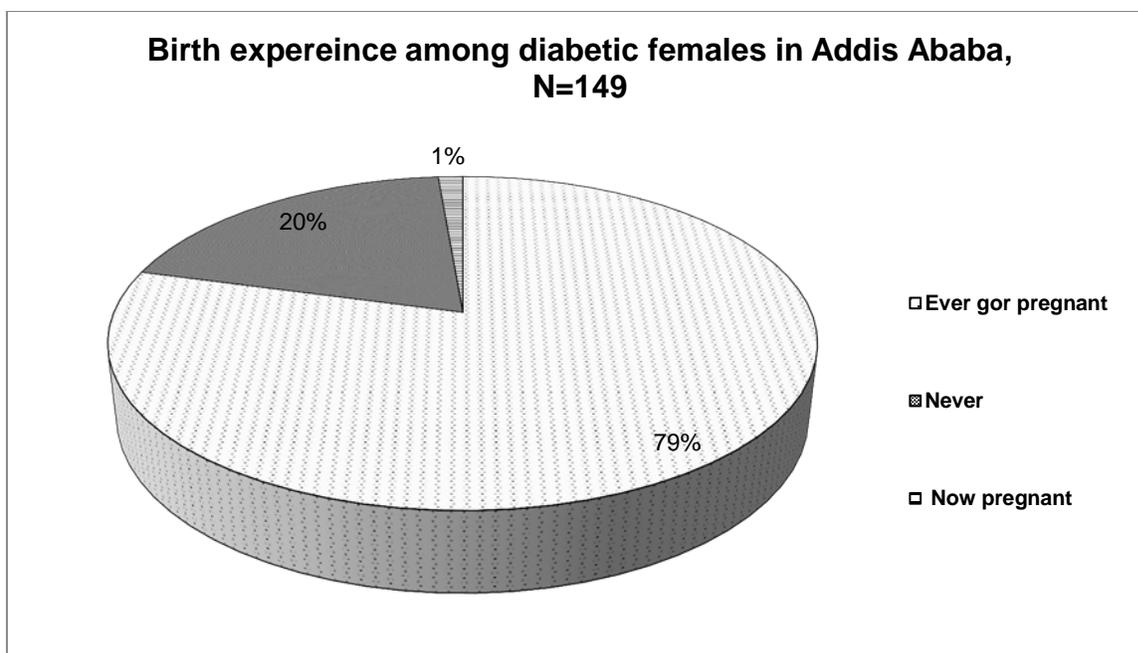


Figure 4.4: Experience of pregnancy among DM females in Addis Ababa health facilities, 2018

4.6.3.2 Pregnancy outcome among diabetes mothers

There were a total of 93 reported pregnancies with identified gestational age, 35-43 weeks at birth. Two (2.2%) were preterm deliveries and three (3.2) were post term (Table 7.18).

TABLE 7.18: GESTATIONAL AGE IN WEEKS AT BIRTH FOR DIFFERENT STAGES OF PREGNANCY AMONG DM FEMALES IN ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY 2018

Ser No.	Stage of pregnancy	Number of pregnancy	Mean GA in weeks	Minimum GA in weeks	Maximum GA in weeks
1	First pregnancy	78	39.6	37	43 [#]
2	Second pregnancy	30	39.4	37	42.3
3	Third pregnancy	7	38	35*	40

*Two pregnancies was reported to be born at 35 and 36 gestational age)

Three pregnancies ended in post term (GA>42weeks)

The mean birth weight in the first, second and third pregnancy in grams were reported as 2886, 3010 and 3083 respectively. As shown the table below, the proportion of low birth weight and big baby was 3.2% each.

TABLE 4.19: BIRTH WEIGHT AMONG THE DM FEMALES IN ADDIS ABABA HEALTH FACILITIES, FEBRUARY-MAY, 2018.

Ser No	Birth weight in gram	First pregnancy (%), N=57	Second pregnancy (%), N=29	Third pregnancy (%), N=7	Total N=93 (%)
1	<2500	3.5	3.4	0	3.2
2	2500-4000	96.5	89.7	85.7	93.5
3	>4000	0	6.7	1	3.2

More than 90% of pregnancies were normally delivered without a complication. However, still birth was 1.5% with the highest in the third pregnancy. Abortion was reported in 2.1% of the deliveries. Besides, 2 (1%) of the cases were congenital malformation and 4.6% was delivered by instrumental or caesarean-section (Table 4.20).

TABLE 4.20: PREGNANCY OUTCOME AMONG DM MOTHERS IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser No.	Birth Outcome	First pregnancy (n=111) , %	Second pregnancy (n=60) , %	Third pregnancy (N=25) , %	Total (N=196) , %
Fetal birth outcome					
1	Alive normal	96.4	95.0	91.7	95.4
2	Still birth	0.9	1.7	4.2	1.5
3	Miscarriage/ abortion	1.8	3.3	0.0	2.1
4	Congenital malformation	0.9	0.0	4.2	1.0
Maternal Birth outcome					
5	Spontaneous vaginal delivery	96.4	95	92	95.4
6	Instrumental delivery	0.9	1.7	4	1.5
7	C-section	2.7	3.3	4	3.1

4.6.4 Summary

This section described the DM, HIV and pregnancy care services at HIV, DM and ANC clinics. It also tried to respond for the objectives of determining the magnitude of DM among HIV, prevalence of pregnancy and pregnancy outcome among HIV and DM patients. The next section summarizes, describe and triangulate the findings in phase I and phase II.

4.7 DESCRIPTION AND TRIANGULATION OF PHASE I AND PHASE II FINDINGS

4.7.1 Introduction

This section addresses the combined findings in phase I and phase II. These findings deal with the DM, HIV and pregnancy care services at the study health facilities. It also presents the magnitude of DM among HIV, the prevalence of pregnancy and pregnancy outcome among HIV and DM patients.

4.7.2 DM testing service at ANC and HIV clinics

As shown in table 4.21, there was no pregnant mother at ANC and only 16.2% of PLHIV that were tested for DM. This shows a routine DM service at both HIV and ANC clinics is minimal or absent. During the interview (Theme 7, Category 7.2) it was also indicated that the lack of awareness of the fact that DM could cause APO in pregnant mothers is a reason for the HCW not to practice the routine DM screening ANC/PMCTC clinics. In theme 5 and Category 5.1, the interviewees commented that such direction should have come from FMOM or RHB.

A systemic review by Tieu, McPhee, Crowther, Middleton and Shepherd (2017:1) comparing the universal screening of DM among pregnant women with risk factor-based screening leads to more women being diagnosed with GDM. Therefore, more mothers with DM could be found out if DM screening is active and routine. Yet, the cost effectiveness and resource issue should be taken into consideration. Therefore, if the

universal DM screening is not feasible, at least risk profile based screening can be considered in Ethiopian setting.

In the Theme 7 and category 7.4, it was also mentioned that there was not routine screening of PLHIV for DM, because HCW are not well aware of the fact that HIV or ARV could be a risk factor for DM. However, DM evaluation for HIV infected mother would be done if there are signs and symptoms of DM. This might explain the lower proportion of HIV infected mother were tested for DM.

4.7.3 HIV testing and counselling service at ANC and NCD clinics

HIV testing counselling service was done for 95% pregnant mothers. As indicated in phase I of the study, HIV testing and counselling is universal for all pregnant mother at ANC (Theme 6, category 6.1). That might be the reason why the higher proportions of pregnant mothers were tested for HIV. Similar to this study, Mayer et al (2018: e1002547) found that integrating HIV services into the MCH platform during the postnatal period was a simple and effective intervention, and this should be considered for improving maternal and child outcomes in the context of HIV.

Though the HIV testing service at ANC is higher than the 67.8% for diabetic females ($p=0.00$), the HIV service at DM clinic seems more of the PITC approach rather than the routine or universal one (Category 7.3). The high rate of HIV testing for DM mothers is because diabetes mother could be offered HIV testing and counselling at other OPDs.

4.7.4 Prevalence of DM among HIV patients

About 1.5% of the HIV infected mothers were found to be diabetic. This might be a low figure because complaint based DM evaluation is given for PLHIV (Theme 7, category 7.4). That is, DM screening is not routine for all PLHIV at HIV clinic. Yet, the 1.5% of DM burden among PLHIV is higher or equivalent to the prevalence of 0.5-1.2% reported by Misganaw, Mariam, Ali & Araya (2014:1) in the general population. However, with

minimal or symptom based DM screening, the burden of DM among HIV infected mothers is not low indicating that there could be missed or hidden DM cases among HIV patients. That is why the proportion is still much lower than the prevalence rate of 6.5% at hospital settings in Addis Ababa (Gizaw et al 2015:74) and the 25% in Hawassa (Tesfaye et al 2014:102). In fact, these studies are among all ages and both sex at referral hospitals as compared to this study that included only female in their reproductive ages from two hospitals and 4 health centers. Hence, the need of routine DM screening among is unquestionable and need to be part of the clinical care.

However, the prevalence of 1.5% among HIV infected mother is lower than the 10.3% in United States of America (U.S.A) (Hernandez-Romieu et al 2017: e000304). The difference might be due to the difference in the study setting and population, where DM is highly prevalent in the general population of U.S.A as compared to the population in Ethiopia, specifically among the reproductive age females in this study. According to the systematic review in Africa (Pioreschi et al 2017:e013953), there is no association between the prevalence of T2DM and HIV infection or ART. Other evidences indicated that the probably increase in the burden of DM among HIV could be age dependent (Mohammed, Shenkute & Gebisa 2015:197).

TABLE 4.21: SUMMARY OF DM AND HIV SERVICES AND PREVALENCE RATE OF DM, PREGNANCY AND APO IN ADDIS ABABA HEALTH FACILITIES, 2018

Ser No.	Variables	Among pregnant mother on antenatal care N (%)	Among diabetic females (%)	Among HIV infected females (%)
1	DM testing service	0	NA	54 (16.2)
2	HIV testing and counseling service	313(96)	103(67.8)	NA(Not applicable)
3	Prevalence of pregnancy (ever get pregnant)	NA	111(69.8)	280 (77.8)
4	Prevalence of DM	0	NA	5 (1.5)
5	Key adverse pregnancy outcome identified			
5.1	<i>Spontaneous abortion or miscarriage</i>	27(7.2)	4 (2.1)	59 (13.4)
5.2	<i>Pre-term</i>	82 (22.2)	2 (2.2)	13 (3.5)
5.3	<i>Low birth weight</i>	12 (4.1)	3(3.2)	32 (12.4)
5.4	<i>Big baby</i>	14 (4.7)	3 (3.2)	5 (2)
5.5	<i>still birth</i>	31 (8.3)	3 (1.5)	9 (2.1)
5.6	<i>c-section</i>	127 (34)	6 (3.1)	4(0.9)
5.7	<i>Congenital malformation</i>	5 (1.30)	2 (1.0)	9(2.1)
5.8	<i>HPN during pregnancy</i>	21 (5.6)		23 (5.2)
5.9	<i>systemic infection</i>			8(1.8)

4.7.5 Prevalence of pregnancy among DM and HIV infected females

Among the 360 HIV infected mothers, there were a total of 280 mothers that reported they had ever got pregnant (77.8%). There were a total of 370 pregnancies from the 280 HIV infected mothers. Each mother had an average of 1.3 children.

Among the 111 diabetic mothers, there were a total of 196 reported pregnancies. Hence the pregnancy rate was 69.8% .Each DM mother had 1.8 children.

In both diabetic and HIV infected mother, the number of children per women is lesser than the fertility rate in Urban Ethiopia of 2.3 (Central Statistical Agency/CSA/Ethiopia and ICF 2016:13). This might be due to the evidence of reduced occurrence of pregnancy because HIV virus itself or ART can have a risk of infertility (Kushnir & Lewis 2011:550-51; Marston et al 2017:S69; Ombelet 2008:605). Similarly, a high glucose level impairs implantation and affects the level of hormones essential for pregnancy paving a way for infertility or reduced incidence of pregnancy (Livshits & Seidman

2009:701). Nevertheless, studies from African countries demonstrate that the rate of new pregnancies was significantly higher among women receiving ART (9.0/100 PY) compared to women not on ART (6.5/100 PY) (Myer et al. 2010: e1000229). On the other hand, Houle et al (2016:10) show that fertility patterns are not homogenous among different setting and countries.

4.7.6 Adverse pregnancy outcomes among HIV and DM female patients

The outcomes are grouped as follows:

4.7.6.1 Spontaneous abortion or miscarriage

Among HIV and DM females, the proportion of spontaneous abortion was 13.4% and 2.1% respectively. The interviewees also confirmed that pregnancy among DM mother could end in miscarriage or abortion. They also indicated that the recurrent abortion is common.

Gunatilake & Perlow (2011:106) indicated that a high glucose levels are reported to increase a woman's chance of miscarriage by 30-60%. Even when implantation does occur, there is an increased risk of birth defects due to damage caused to embryonic cells from the high levels of glucose in the blood.

4.7.6.2 Pre-term birth

The preterm birth was computed to be 3.5% among HIV infected females and 2.2% among the diabetic mothers and there is no significant difference in the proportion ($p=0.53$).

All the HIV infected mothers in this study were on ART due to the already implemented 'test and treat' strategy. According to the studies by DOS RIES et al (2015:111) and Kim et al (2012:1), pregnancies among mothers on ART can be complicated by pre-term or premature deliveries.

The study in a teaching hospital in Southwest Ethiopia shows that the preterm among HIV infected mothers was 16.6%, much higher than the finding of 3.5% in this study (Kebede, Andargie & Gebeyehu 2013:254). The difference in the rate of preterm could be due to the difference in the study design, setting and population type yet warrants an investigation. On the other hand, Gibb et al (2012:e1001217) demonstrate that there is no significant difference in the occurrence of pre-term birth in pregnancies that occurred before and after ART.

The preterm delivery among diabetes mothers in this study is lower than the reported to preterm of 13.7% by Soliman, Salama, Al Rifai, De Sanctis, Al-Obaidly, Al Qubasi and Olukade (2018:11). The difference could be due to the variation in the study design and sample size.

4.7.6.3 Low birth weight

The low birth was 12.4% among HIV infected mothers and 3.2% among diabetic mothers ($p=0.01$). During the interview, the study participants mentioned low birth weight as one of the APO among HIV patients. They reasoned out that HIV infected mothers could face nutritional problem which could also affect their fetus. Hence, they justified that the low birth weight is inevitable among HIV pregnant mother if the mother get birth.

Studies have indicated that LBW and malnutrition are more frequent in HIV-infected children (DOS REIS et al 2015:111; Kim et al 2012:1). The research at Gondar University Hospital in Northwest Ethiopia by Kebede, Andargie & Gebeyehu (2013:254) indicated the higher (21.4%) LBW among HIV infected mother as compared the rate in this study (12.4%). Adane et al (2014:90), in similar setting, shows 11.2% low birth weight rate among the ANC attendants. However, Gibb et al (2012:e1001217) further demonstrate that there is no significant difference in the occurrence of low birth weight in pregnancies that occurred before and after ART.

In this study almost all of the HIV infected mothers were on ART that could attribute to the higher proportion of LBW. Snijdewind, Smit, Godfried, Bakker, Nellen, Jaddoe, Van Leeuwen, Reiss, Steegers and van der Ende (2018: e0191389) showed that the use of ART prior to conception is associated with intrauterine growth restriction resulting in LBW.

4.7.6.4 Big baby

The birth weight of more than 4000gm, the big baby, was reported in 4.5%, 3.2% and 2% of births among mothers on ANC follow up, diabetic mothers and HIV infected mothers respectively. There is no significant statistical difference among these proportions ($P>0.05$). Nevertheless, the HCW were explaining that overweight is the typical characteristic of births from diabetic mothers as compared to other births. They indicated that this could lead to other APO such as obstructed labor and shoulder dystocia

The lower sample size of DM female might contribute to the lower rate of big baby. Otherwise, high glucose levels can lead to a big baby or macrosomia (Gunatilake & Perlow 2011:106). Soliman et al (2018:11) also showed that macrosomia was more prevalent in babies of DM – about 6.4%.

4.7.6.5 Still birth

The interviewees worried about the potential high rate of HIV and DM associated perinatal death. They attributed the death to intra-uterine fetal death among HIV infected mothers and hypoglycemia induced death soon after birth in diabetic mothers. The respective 8.3%, 1.5% and 2.1% of births ended in death at term among ANC attendant mothers, diabetic and HIV infected mothers (Table 4.20). There is no significant statistically difference in the birth death among birth of diabetic and HIV infected mothers ($p=0.6$).

The study by Adane et al (2014:90) in Gondar University Hospital, Northwest Ethiopia shows there was 7.1% stillbirth which is lower than the finding among ANC attendants

(8.3%) and higher than the reported still births among DM (1.5%) and HIV infected mothers (2.1%) in this study. This might be due to the difference in the study design, setting and population.

A systematic review in developing countries shows that frequently observed ART related adverse birth outcomes included low birth weight (LBW), preterm Birth (PB), Small for Gestational Age (SGA), while still birth and congenital anomalies were infrequent (Alemu et al 2015:31). Nevertheless, Sunjaya, and Sunjaya (2018:1031) showed that diabetes mothers with poor glucose control in pregnancy has been found to increase rates of infant mortality suggesting early detection of DM pregnant mother so that adverse pregnancy outcomes such as death would be averted.

4.7.6.6 Caesarean section

As expected, the proportion of C-section among mothers on ANC follow up (34%) was greater than the same procedure among DM (34% versus 3.1%, $p=0.00$) and HIV infected mothers (34% versus 0.9, $p=0.00$). Besides, more C-section was done among DM mothers as compared to HIV infected mother (3.1% vs 0.9%, $p=0.04$).

The lower C-section procedure in this study might be due to the fact that spontaneous vaginal delivery is usually recommended among PLHIV pregnancies to avoid C-section induced MTCT and post operation complications which are higher among HIV infected mothers in developing countries (Jamieson, Read, Kourtis, Durant, Lampe and Dominguez 2007:S96; Kourtis, Ellington, Pazol, Flowers, Haddad and Jamieson 2014:2609). Hence, in these settings, C-section or instrumental deliveries are avoided as much as possible, except in the form of elective delivery procedures (Kennedy, Yeh, Pandey, Betran, and Narasimhan 2017:1579). However, a population based cohort status in USA indicated that there is a higher rate of cesarean delivery (OR 3.06, 95% CI 2.79-3.36) as compared to non-HIV infected mothers. This is because in USA there is a better facility and infrastructure including infection control so that C-section is preferable to vaginal delivery for HIV infected mothers (Arab, Spence, Czuzoj-Shulman and Abenhaim 2017:599).

A big baby (macrosomia) resulting in a c-section, which increases a mother's chance of infection is also another effect of hyperglycemia in pregnancy (Gunatilake & Perlow 2011:106). Unlike this study, the proportion of DM women who underwent Cesarean section in the study of Soliman et al (2018:11) was significantly higher in the DM, i.e 51.9%. The difference might be due to the variation in the settings where western health facility is well facilitated to do elective C-section for DM pregnant mothers.

4.7.6.7 Congenital malformation

The reported congenital malformations were Down Syndrome and mental retardation. Among the ANC attendants this was 1.3%, and it was 1% among the births of diabetic mothers and 2.1% among HIV infected mothers. Nevertheless, there was no significant difference in the proportion of the reported congenital malformation between ANC attendance and HIV ($P=0.36$), DM and ANC attendance ($p=0.14$) and HIV and DM females ($p=0.32$). The occurrence of possible congenital malfunction among HIV females was indicated during IDI and FGD. The interviewees mentioned that HIV could affect the growth of the brain, and thus leads to congenital anomalies.

A systematic review in developing countries shows that frequently observed ART related adverse birth outcomes included low birth weight, preterm Birth, Small for Gestational Age (SGA), while still birth and congenital anomalies were infrequent (Alemu et al 2015:31).

Regarding DM, however, Soliman et al (2018:11) indicated that the prevalence of congenital anomalies does not differ between DM and non-diabetic patients. The difference with this study could be due to the design and sample size difference. However, the IDI and FGD participants stressed that the congenital malformation among in birth from diabetic mothers with a poorly controlled blood glucose level is inevitable.

Hypertension during pregnancy (Pre-eclamsia and Eclamsia) was reported only among HIV infected mothers and mothers with ANC attendance. Hence, the proportion of HPN

during pregnancy were 5.6% among the ANC attendance mothers and 5.2% among the HIV infected mothers on ART, without a statistical difference in the proportion ($p=0.8$).

4.7.6.8 Systemic infection

The systemic infection or infection after birth was reported among HIV infected mother on ART as a complication of birth. This was reported in 8 births (1.8%).

In the quantitative data analysis, there were no reports of HIV infected children of HIV infected mothers or diabetic infants or children of diabetes mothers. This could be due to the implementation of the strong PMTCT option B+ and too early to detect diabetic children from diabetic mothers. The risk of mother-to-child transmission is as low as 2% in settings where treatment with ART medication has prolonged life expectancy for many potential parents with HIV (Myer et al 2010: e1000229). However, during the phase I study, the HCWs commented there could be MTCT among births of PLHIV and diabetic children among diabetic mothers later in their life.

In fact there were participants who confidentially spoke out that there will not be any APO due to HIV, ART or DM.

4.7.7 Conclusion

It was shown that the DM screening service is at infancy level at HIV and ANC units though these are units where high risk mothers and their pregnancy for DM have a follow up at. The magnitude of DM among HIV patients is a bit higher than the general population in need of integrated routine DM screening among HIV and pregnant mothers in the reproductive age. All sorts of APO were also noted and witnessed by the HCW. Hence, not only should the HIV and DM considered to be screened but also other causes of APO among DM and HIV infected mothers should be explored and looked into so that the higher APO is addressed. The following chapter, therefore, is aimed to develop the integrated DM/HIV/pregnancy care services to deal with APO.

CHAPTER 5

DEVELOPMENT OF AN INTEGRATED SERVICE DELIVERY MODEL FOR HIV, DM AND PREGNANCY CARES

5.1 BACKGROUND TO THE MODEL DEVELOPMENT

According to Walker and Avant (2005:28) theory is defined as, "... an internally consistent group of relational statements that presents a systemic view about a phenomenon that is useful for description, explanation, prediction and prescription or control". Chinn and Kramer (2011:155) defined empiric theory as a creative and rigorous structuring of ideas that projects a tentative, purposeful, and systematic view of a phenomenon. Walker and Avant (2005:28) described a model as a graphic representation of a theory. Models are delivery strategies that prescribe specific ways in which professionals will work together to provide healthcare services. Citing Baltes, Reese, and Nesselroade (1977:17) walker and Avant (2005:28) also indicate that a model is any devise used to represent something other than itself. Hence, the parts of the theory should correspond to the parts of the theory they represent, Walker and Avant (2005:28) (citing Brodbeck 1968:583). The authors also stated that description, explanation, prediction and prescription/control are the phase of theory building.

According to Walker and Avant (2005:29), a model can be drawn schematically using symbols and arrows or a mathematical model. In addition, Chinn and Kramer (2011:157) described a model as a symbolic representation of an empiric experience in the form of words, pictorial or graphic diagrams, mathematical notation or physical materials. The schematic drawing is used to develop a model in this study. Chinn and Kramer (2011) and Walker and Avant (2005) are the basis for the development and evaluation of the model in this study.

5.2 PURPOSE OF THE MODEL DEVELOPMENT

As explained in chapter 1 and chapter 4, the HIV and DM are a missed link to address APO and there is a loose collaboration between HIV and DM though both are the risk factors for the APO. Hence, the development of the service delivery model inclusive of HIV and DM could be a better strategy to deal with pregnancy related complication in the reproductive age females having the two disease conditions. The developed model aimed to guide the program managers, program officers and HCWs to prevent the APO in HIV and DM mothers.

5.3 COMPONENTS OF THE MODEL

There are two main components of the model. These are,

1. Administrative level integration of DM, HIV and pregnancy care, and
2. Facility level integration of DM, HIV and pregnancy care.

5.3.1 Administrative level integration of DM, HIV and pregnancy care

This is the model that can be applicable at the federal ministry, region, sub-cities or zones, districts or *woredas*.

5.3.2 Facility level integration of DM, HIV and pregnancy care

This is the model that works at hospitals, health centers and health posts.

5.4 BUILDING THE MODEL

This model was developed through a process of literature review, findings in phase I and II, observing clinical practice and expert consultation. Therefore, the development of the model mainly depends on the theme 6 where the integration status among HIV, DM and pregnancy care was explored at administrative and health facility levels. The

process of the model development is also using the Theme 7 where integrated approaches are suggested by HCWs at facility level and program officer and managers at administrative levels (FMOH, RHB, sub-cities and districts). Hence, inductive reasoning was applied where findings of phase I and phase II were combined to find the pattern; in this case the parts of the model (Heit and Rotello 2010:805). While developing the model the intensity or degree of integration by Leutz (1999) (cited in Nuffield trust (2011) and domains of integration (Kobner 2009) are taken into consideration.

5.4.1 Organizational integration

Organizational integration refers to the extent that services are produced and delivered in a linked-up fashion. It is an inter-organizational relationship by pooling the skills and expertise of the different organizations (Kodner & Spreeuwenberg 2002:3). In this study this is taken as an integration relationship between health care organization or **administrations** such as FMOH, RHB, sub cities and district levels (Kodner 2009:11) and assigned by the following diagram (Figure 5.1).



Figure 5.1: Organizational integration

5.4.2 Clinical or service integration

Clinical or service integration refers to the coordination of services in a single process across time, place and discipline (Kodner 2009:11-12). Also, Kodner and Spreeuwenberg (2002:4) described clinical integration as the coordination of person-focused care in a single process across time, place and discipline. This is considered at health facility level in this study. Based on Theme 7, clinical integration in this study is

among DM, HIV and pregnancy care at facility level. The facility level integration is indicated by the following box in the model (Figure 5.2).

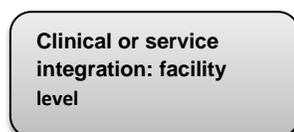


Figure 5.2: A box representing the clinical or service integration

5.4.3 Program or service types

The NCD, MCH or family health and HIV or HAPCO are currently standalone units both at administrative and health facility levels. That is why they are shown with the full border lined box and in different colours below.

5.4.3.1 At the administrative level

At the FMOH, RHB or sub cities DM is under DPCP directorate or medical service process owner, pregnancy care is within MCH or family health directorate or core process and HIV is within HAPCO or DPCP core process or directorate.



Figure 5.3: Three different units at administrative levels

5.4.3.2 At the facility level

At the health facilities DM is within NCD clinic, pregnancy care service is delivered at ANC and family planning clinic and HIV prevention, care and support is rendered at HIV clinic. Hence, these are represented in box as follows.



Figure 5.4: Three different units at facility level; NCD, ANC and HIV

5.4.4 Linkage

Linkage is taking place between existing organizational units with a view to referring patients to the right unit at the right time, and facilitating the communication between professionals involved in order to promote continuity of care. Responsibilities are clearly aligned to different groups with cost shifting. While exploring the existing intensity of integration, this degree of integration was noted between DM and ANC or between HIV and DM (Table 4.2). However, it is not applied in the development of the mode because it was not suggested to be degree of integration to be practised among DM, HIV and pregnancy care (Table 4.3). Linkage was reported to be a poor collaboration (theme 6). It is represented by the following dotted straight line.



Figure 5.5: Broken line representing linkage level of integration

5.4.5 Coordination

Citing Leutz (1999), Kodner (2009:12) described coordination as structured, inter-organizational response involving defined mechanisms to facilitate communication, information sharing and collaboration while retaining separate eligibility criteria, service responsibilities and funding. The implementation of the coordination is inside the existing organizational units so as to coordinate different health services, share clinicians' information and manage transition of patients between different units (Kodner & Spreeuwenberg 2002:5). It is shown with a dotted line to indicate that there are some services that need consultation or formal referral. The service at the blunt side is to be coordinated at the service outlets at end of the arrow end. The double arrow is to show a bilateral coordination.

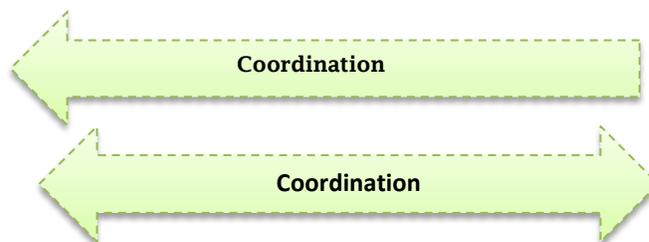


Figure 5.6: Diagram indicating unilateral and bilateral coordination of integration

5.4.6 Full integration

According to Kodner (2009:12), full integration refers to a 'new' entity that consolidates responsibilities, resources and financing in a single organization. The same authors also indicates that full integration pools resources, allows a new organization to be created alongside development of comprehensive services attuned to the needs of specific patients group. According to Theme 7, it is suggested that almost critical services of DM and HIV could be given at ANC and also important services of pregnancy care and DM services could be rendered at HIV unit. Funding, planning, monitoring and evaluation, capacity building and policy guideline could be arranged in such way that HIV and pregnancy care could be fully integrated.

The representation of full integration is an arrow with the bold border and written internally as 'Full integration'. The service at the blunt edge is to be fully given in the service outlet shown with the arrow (Figure 5.7).



Figure 5.7: Diagram indicating unilateral and bilateral full integration

5.4.7 Horizontal integration

Horizontal integration is improving the overall health of people and populations by cross-sectorial collaboration (Kobner 2009:13). Horizontal integration in this study is suggested to be among HIV, DM and pregnancy care at health facility level. It is represented with the following symbol.

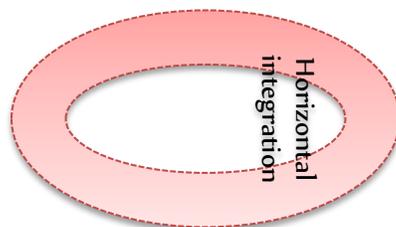


Figure 5.8: Diagram representing horizontal integration

5.4.8 Virtual integration

Virtual integration takes the form of alliances, partnerships and networks created by a number of organisations (Nuffield trust 2011:9). This is exemplified by the alliance between HAPCO, DPCP and MCH directorate at FMOH. The dotted line is to show that there are other stakeholders other than the aforementioned.

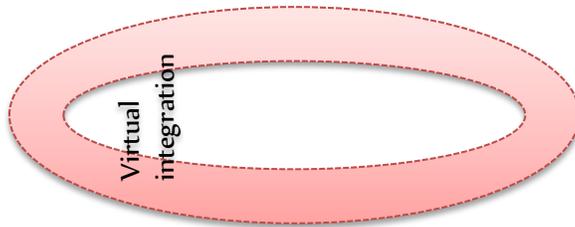


Figure 5.9: Figure representing virtual integration

5.4.9 Components of the tripartite

The tripartite is the term used to describe the three health care conditions such as DM, HIV and pregnancy care. At the administrative level, these represent the unit that address each of these health conditions. The three units are HAPCO for HIV, DPDP for DM, MCH or family health for pregnancy care. Thus, at the administrative level, the tripartite is indicated by the following diagram (Figure 5.10)

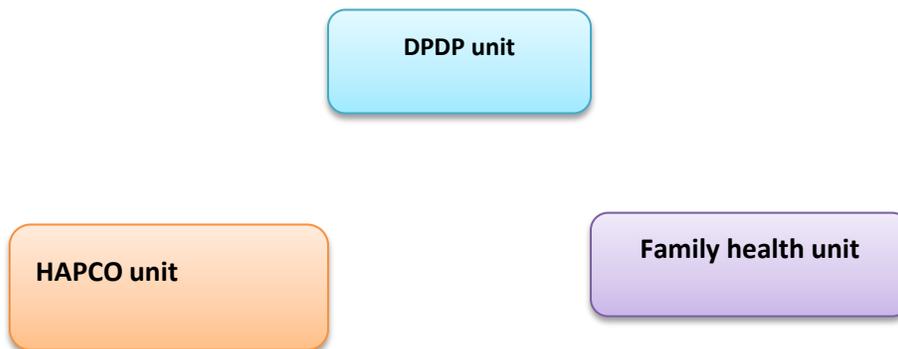


Figure 5.10 : The components of tripartite at the administrative level

The three items at the facility level are HIV clinic for HIV, NCD clinic for DM and ANC clinic for pregnancy care, and shown by the following diagram (Figure 5.11).

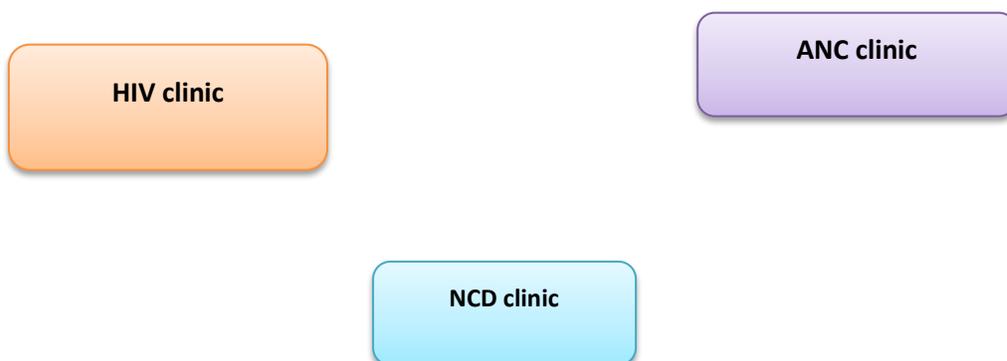


Figure 5.11: The component of tripartite at the health facility

In the health facility level integration, coordination is exemplified by the integration of HIV service at DM clinics. All the HIV related services could be given at DM clinic except treatment and follow up. The SOPs on the HIV prevention and testing and HIV testing registers could be put at DM clinic. In addition, the pregnancy care service at DM and HIV clinic could be taken as coordination kinds of integration. This is because referral of pregnant mothers to ANC is inevitable though HIV testing, counselling services are given at DM or HIV units. Also, pregnancy care services such as pregnancy counselling and testing and short term FP services could be given at NCD and HIV clinics. Hence, guidelines, protocols, recording and reporting tools related to the pregnancy care could be developed and put at NCD and HIV. However, for the full follow up of pregnancy and for the special consultation, one can make a referral to ANC. All the comprehensive HIV care and treatment and care could be offered at ANC as PMCTC at facility level and represented by a single arrow. Also, all the packages of DM services could be rendered at ANC or HIV that warrants full integration of DM in to HIV and ANC (Figure 5.12).

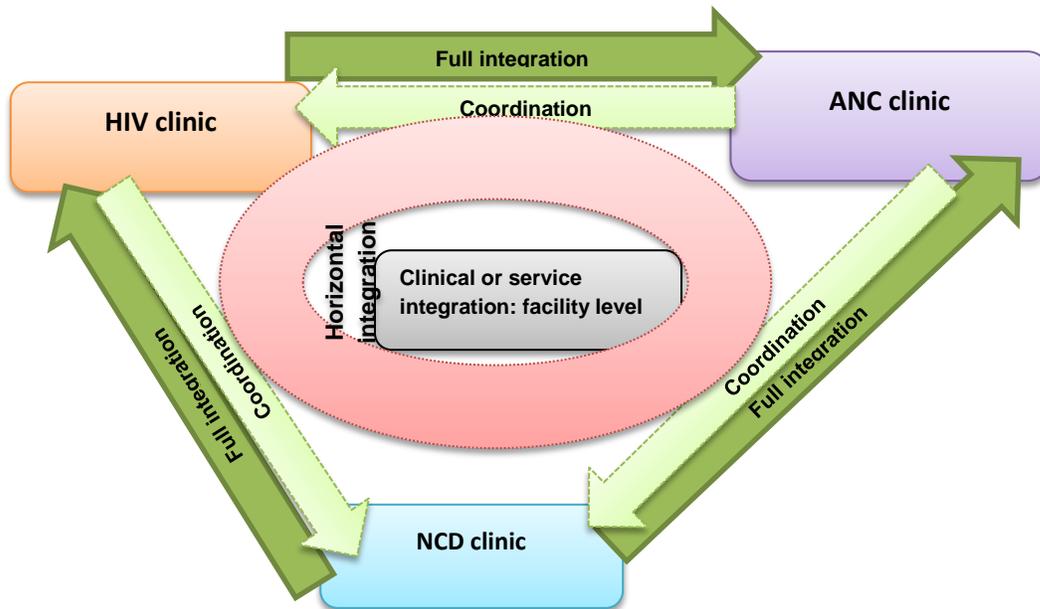


Figure 5.12: Integration at facility level: clinical service and horizontal integration

In the administrative level, common financial, planning, capacity building, policy guideline development and monitoring and evaluation related to HIV could be implemented at MCH/family healthy and vice versa. This is shown with green double arrow. Policy guides need to be produced encompassing DM, HIV and pregnancy care together with joint funding, planning and monitoring system.

The joint financing, planning, supportive supervisions related to HIV and DM care could be coordinated among HAPCO and NCD units or NCD and family health unit at administrative level that is represented by the double arrows of the coordination (Figure 5.13).

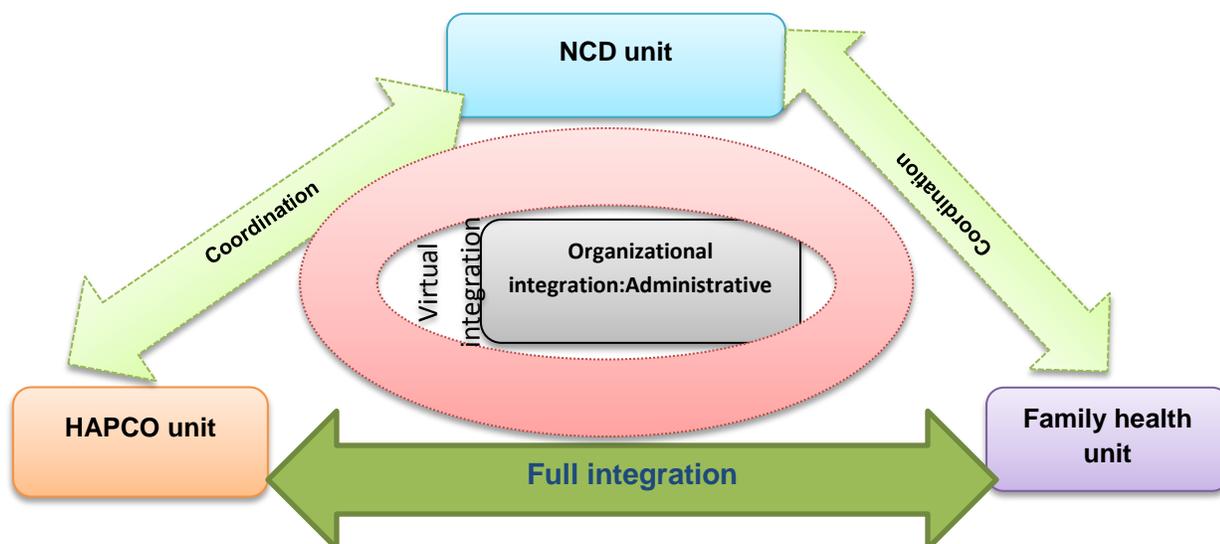


Figure 5.13: Integration at administrative level: organizational and virtual integration

5.4.10 Functional integration

The functional integration defined as a mechanism by which financing, information, and management modalities are linked to add the greatest overall value to the system (Kodner & Spreeuwenberg 2002:4; Kodner 2009:12). It supports clinical and professional integrations (See sections 5.4.12 and Figure 5.16). In this study, functional integration includes the coordination of developed policy guidelines and protocols, financial and human resource management, strategic planning and information management (Themes 1,2, 3 and 5) that bridge the gap and links administrative level or organization integration (see Figure 5.13) and facility level or clinical integration (see section 5.4.12). The double arrow shown in figure 5.14 shows that there is a bilateral coordination played by the functional integration (Kodner 2009:12). This is drawn between facility and administrative integration level (Figure 5.15).



Figure 5.14: Diagram of functional integration

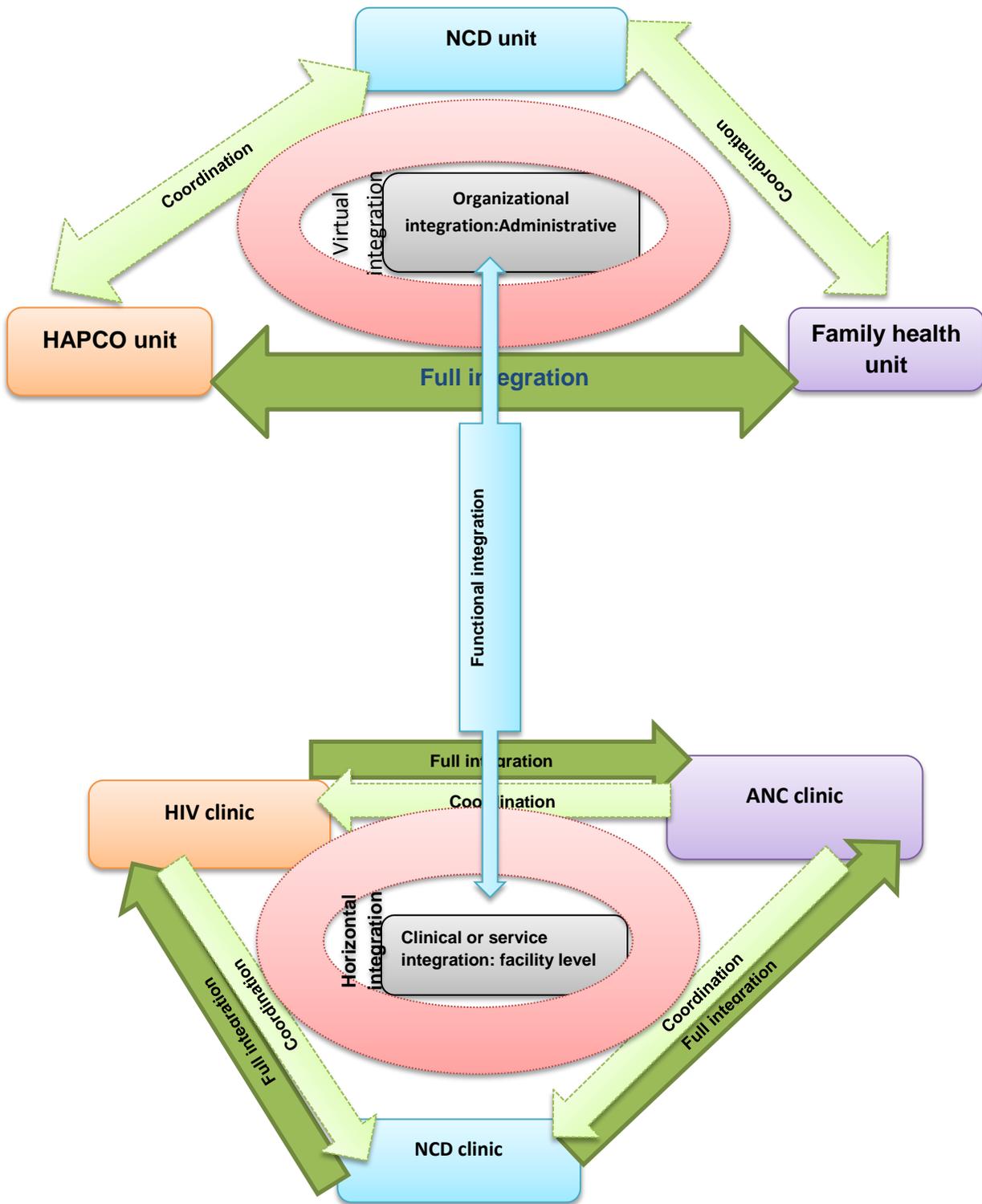


Figure 5.15. The diagram showing the bilaterla coordination played by the functional integration between facility and administrative level

5.4.11 Vertical integration

Kodner (2009:13) related vertical integration to the idea that diseases are treated at different (vertical) levels of specialization and the integration of care across sectors, e.g., integration of primary care services with secondary and tertiary care services. In this study it is the integration between administrative and facility levels services. Hence, vertical integration is among FMOH, RHB, sub-cities; and among health facilities such as between hospitals and health centers. The connection is through planning, training, funding, and monitoring and evaluation and already represented by the functional integration (see section 5.4.10). Therefore, the mechanisms of vertical integration, as represented in the functional integration in this model development, are monitoring and evaluation such as supportive supervision and recording and registration, budget or financing, joint planning and police guides and protocols or algorithms inclusive of DM, HIV and pregnancy care (Theme 1-5).

Both vertical (Section 5.4.11) and horizontal integration (Section 5.4.7) are paramount to counteract the fragmentation of services in a health system (Nuffield trust 2011:8-9). Hence, in the development of this model, both vertical and horizontal integration are used. Firstly, this is because incorporating vertical and horizontal integration can improve the provision of continuous, comprehensive, and coordinated services across the entire care continuum. Secondly, partnerships across traditional organizational and professional boundaries are needed in order to improve the efficiency and quality of a system (Kodner 2009:12; Kodner & Spreeuwenberg 2002:4).

5.4.12 Professional integration

Kodner (2009:12) defined professional integration as a health care provider's relationship within and between administrative/organization and clinical unit or health facilities. Professional integration could be practiced at facility level for the clinical integration in the form of horizontal integration. This is the communication among HCW at DM, HIV and pregnancy care (Theme 6 and category 6.7). Also, it is taken as a

partnership between health care officers that are expertise of HIV, DM and pregnancy care (Theme 6 and Category 6.7). Professional integration is a cross-cutting at health facility or administrative level. Hence, this is represented by the symbol of wider line (Figure 5.16). It surrounds and connects administrative/organizational and clinical/facility level integration (Figure 5.17).

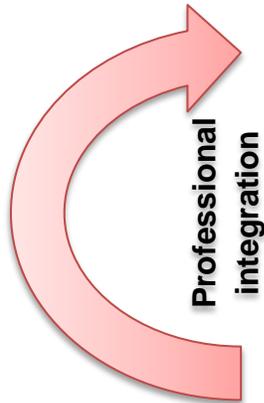


Figure 5.16: The figure representing the professional integration

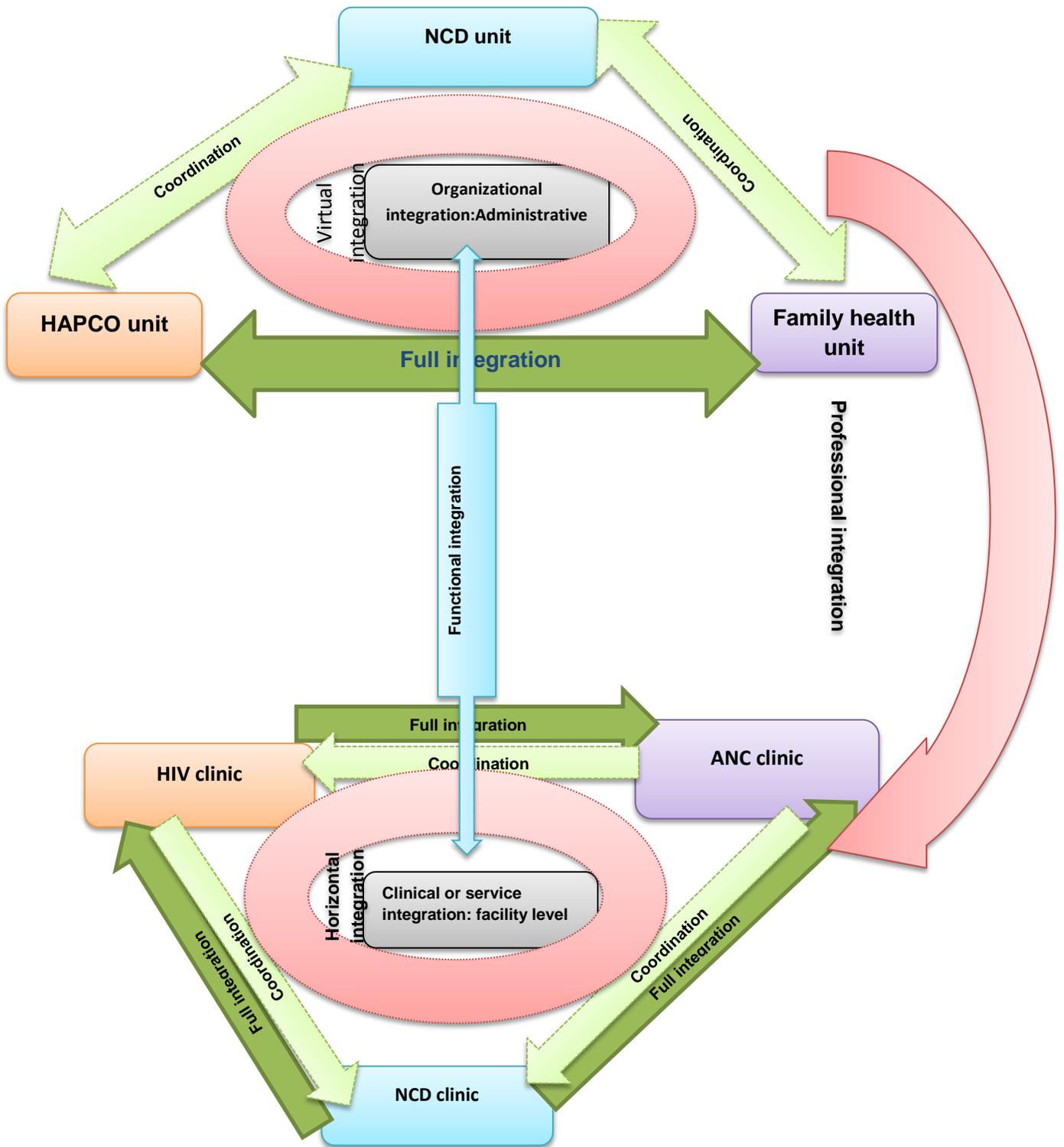


Figure 5.17 : Professional integration surrounding and connecting administrative and facility level integration

5.4.13 The tripartite integrated model of care:DM/HIV/pregnancy care

As described through sections 5.4.1 to 5.4.12, the overall model related to DM/HIV/pregnancy care is represented by the following diagram (see Figure 5.18). It is named **tripartite integration model** because three programs or health entities such as DM, HIV and pregnancy care are involved. The entire model could be named as **The Tripartite Integration: DM/HIV/Pregnancy care service delivery model**.

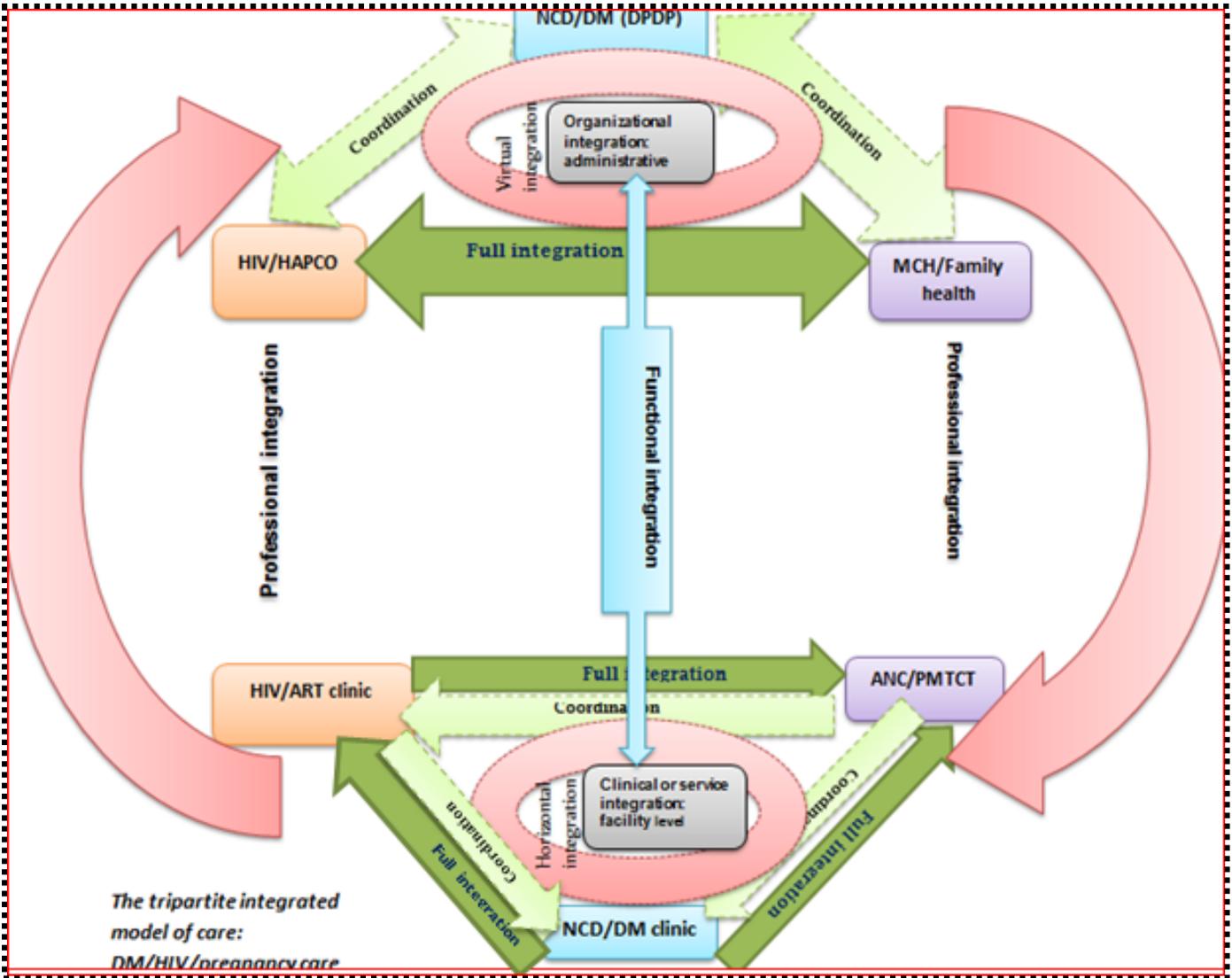


Figure 5.18: the tripartite integrated model of care: DM/HIV/pregnancy care

5.5 EVALUATION OF THE TRIPARTITE DM, HIV AND PREGNANCY CARE SERVICE DELIVERY MODEL

The HIV, DM and MCH experts were approached to look into and evaluate the model. The experts used the following criteria to evaluate the model.

- a) **Clarity:** to check whether the model is easily understandable.
- b) **Simplicity:** to check whether it is not complex to look at.

- c) **Consistency:** to check whether the model can service similarly at all levels.
- D) **Generalizability/Transferability:** to check whether it could be applicable in other regions of Ethiopia, other than the study region.
- e) **Importance:** to check that the model is paramount for Ethiopia.
- f) **Practicality:** to check whether it is suitable and works in Ethiopia.
- g) **Feasibility of the model:** to check whether the model feasible in the health finance and health policy of Ethiopia.

A brief aim of the model, how the model was developed and the description of the model was summarized and given to the experts. After reading the summary and looking into the diagram of the model, the experts were asked to evaluate the model using the table at end of the summary with the aforementioned criteria. Each criterion was assessed as, 1) Totally disagree 2) Disagree 3) Just agreed and 4) Totally agreed. That is, the Likert scale was used to evaluate the model using the aforementioned criteria. The evaluators were also asked to put their remark about the model. They were also requested to criticize, put any suggestion and recommendations regarding the model (see Annexure K). Accordingly, the following section presents and discusses the finding of the evaluation, including the remarks and recommendations by the experts.

5.5.1 Experts participated in the evaluation of the model

Describing the aim of the model and the purpose of the evaluation, the DM, HIV and MCH experts were approached at FMOH (3), RHB (2), and stakeholders or partners working on HIV program (4).

The experts were nine in number. Four were working on HIV program, three on NCD and two on MCH. The age of the evaluators ranged from 33-59 years. Seven were males. They did have 11-26 years of work experience. Almost all of them had a minimum of 3 years work experience at health facilities. Eight of them had at least a second degree or specialization in pediatric or internal medicine.

5.5.2 The findings of the evaluation

The following table summarized the finding from the experts' evaluation of the tripartite model. All in all, there were 60 responses (95%) that indicated that the experts at least agreed with the developed model using the 7 criteria (See Table 5.1).

TABLE 5.1: THE RESULT OF THE EVALUATION OF THE TRIPARTITE SERVICE DELIVERY MODEL OF HIV, DM AND PREGNANCY CARE, ADDIS ABABA 2018

Ser No.	Criteria	Totally disagree	Disagree	Agree	Totally agree
1	Clarity			4	5
2	Simplicity			7	2
3	Consistency		1	3	5
4	Generalizability or transferability			7	2
5	Importance			7	2
6	Practicality			4	5
7	Feasibility		2	5	2
8	Total out of 63	0	3	37	23

5.5.2.1 Clarity of the model

All of the experts commented that the model is clear and understandable. However, an expert commented the writing of the professional integration should have been inside the arrow.

5.5.2.2 Simplicity of the model

Again all of the evaluators stated that the model is simple to read but the organizational/administrative and facility/clinical level integration are not easily identified in the first look. Hence, they should be bold to be seen easily and was corrected as suggested.

5.5.2.3 Consistency of the model

Eight of them reported the model is consistent while describing the degree of relevant integration. However, one of the experts was not agree as to the consistency of the model because the way coordination was explained at administrative and facility level was not the same.

5.5.2.4 Generalizability/Transferability

The experts rated this criterion as just agreed justifying that the model could be used in all administrative levels in Ethiopia, and in all kinds of health facilities including private health facilities. One of the experts said that the HIV and DM issue as related to MCH is cross-cutting and so the model could be applicable all over.

Nevertheless, they commented that advocacy work need to be done to convince decision makers as to the importance of the integration so that it would be applicable in other regions of the country.

5.5.2.5 Importance

All of the experts did not have a doubt on the importance of the model; seven of them rating this as just agreed and the rest totally agreed. The experts commented that the model helps to reduce the workload of HCWs including the work of laboratory technicians as it assists to deal with diseases conditions of a patient at once. The importance of the model is unquestionable as far as there is a sound communication among the HIV, DM and MCH clinicians where the model serves as a time and resource efficient. In addition, the experts said that the model addresses the challenge faced by the young pregnant women who could have HIV or DM.

5.5.2.6 Practicality of the model

One of the experts doubted the immediate implementation of the model. This is because the health structure and health system of Ethiopia might not accommodate the model. Thus, the pilot work was suggested before putting the model into practice. Otherwise, the remaining experts rated the practicality of the model as at least just agreed.

They suggested that the practicality should be assessed before the wider scale up of the model. The other practical challenge to the practical implementation of the model, as stated by the NCD expert, is that the full integration could be hindered by the challenging financial system where MCH and NCD have an isolated resource or budget. To address such kinds of issue the role of relevant organization, stakeholders and donors is critical.

5.5.2.7 Feasibility of the model

Again two of the experts doubted the implementation of the model as it is now. They said that HIV and maternal and child health programs are a matured and well-funded program, unlike the NCD. That is, NCD is a young program in Ethiopia and just being decentralized. The attention given and the financing of the NCD program are limited as well. On top of these, the national health policy in Ethiopia is geared towards the prevention and control of communicable diseases and on the health of maternal and child health (The Federal democratic Republic of Ethiopia Ministry of Health 2015:12). Hence, the integration of HIV and DM may be challenged unless otherwise it is piloted. Policy revision may consider the roaring burden of NCD in Ethiopia. Hence, it was commented that feasibility needs discussion with the stakeholders.

The other HIV expert also pointed out that the model could be used as the opportunity to strengthen the health system so that the direction should be coming from the FMOH for the feasibility of the integration.

All in all, the experts gave their opinion that the optimal integration and coordination of the DM, HIV and pregnancy care in the form of tripartite model is clear, simple and consistence as described with minimal modification of the original model. The current health system, health policy of the country, joint financing, shared planning and monitoring may consider the integration approach of service delivery. For the effective implementation of the model advocacy works, building the capacity of the HCWs and program leads, revising policy guides to accommodate the integration of NCD services to communicable diseases prevention and control are the key area of revisions.

5.6 THE COMPARISON OF THE INTEGRATED THEORETICAL FRAMEWORK AND THE TRIPARTITE SERVICE DELIVERY MODEL FOR HIV, DM AND PREGNANCY CARE

As indicated throughout this study, the integration theoretical framework applied in this study is well fit to guide this study. It was also used as a sound directing tool to come up with the tripartite service deliver integration model of DM/HIV/pregnancy care.

The model developed here is not serving as theoretical model upon which feature studies are relying on, but it supports the practical quality improvement, care and treatment of DM, HIV and pregnancy care so that mothers could give birth to a healthy baby. The model, if rightly adopted and practiced, could also address clinical and pregnancy complications among DM and HIV patients could be averted.

5.7 CONCLUSION

An integrated care deals with the coordination for the betterment of the patient care. A single model could not be a suitable for all situations and contexts; however, the analysis of of various integrative processes are essential to support the integration within a certain circumstance.

It is also paramount to have a know-how of the dynamics between different degrees or intensities of integration that can happen in both ways, like in the case in figure 5.18, in terms of fully integration and potentially fragmenting services. As Leutz points out, 'one man's integration is another's fragmentation' (Leutz, 1999). In other words, integration within one part of a health system may well facilitate movement along the continuum, but it can also result in fragmentation elsewhere. In short, this chapter presented the process of the tripartite model development and evaluation. Chapter 6 wraps up the study by conclusions, limitations and recommendations.

CHAPTER 6

CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

The objective of this chapter is to provide the study conclusions, limitations and recommendations. The purpose of this study was to develop a model for integration of DM, HIV and pregnancy care services.

6.2 RESEARCH DESIGN AND METHOD

The researcher applied a sequential exploratory mixed method under the pragmatic paradigm to achieve the objective of the study. Phase I of the study explored the intensity and the domains of integration among HIV, DM and pregnancy care using IDI and FGD among HCWs and program officers, and observation at health facilities and departments of where HIV, DM and pregnancy care are addressed in the FMOH, AACHB and sub-cities. An open code and theme based data analysis was carried out. Phase II of the research applied a descriptive quantitative design where DM, HIV and pregnancy care services were described and the burden of DM among HIV and the prevalence rate of pregnancy and pregnancy outcome among DM and HIV patients were determined. At end, both qualitative and quantitative data were triangulated to assist in the development of the integrative service delivery model of DM/HIV/pregnancy care among the reproductive age females.

6.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

6.3.1 The burden of DM among HIV females

There was scarce knowledge among the HCW as to where HIV and its treatment are risk factors for chronic illness such as DM. However, the 1.5% burden of DM among

HIV patients in Addis Ababa is higher than the general population in Ethiopia in the background of absent routine and active screening of DM among HIV patients.

6.3.2 The prevalence of pregnancy and APO among DM females

The prevalence of pregnancy (70%) among DM mothers (or 1.8 per diabetic mother) was lower than the general population of 2.5 per woman. LBW (3.2%), big baby (3.2%), C-section (2.2) and pre-term birth (2.2%) are the main APO among DM mothers.

6.3.3 The prevalence of pregnancy and APO among HIV females

HIV infected mothers had also a pregnancy rate of 78%, or 1.3 per mother, and a high APO such as abortion (13.4%), LBW (12.4%), still birth (2.1%), pre-term birth (3.5%), congenital malformation (2.1%). These necessitate strengthening the pre-conception counseling for HIV infected females.

Hence, the higher APO among DM and HIV infected mothers warranted an integrated model of care to improve the pregnancy outcome.

6.3.4 An integrated DM, HIV and pregnancy care services at facility level

Except the notable integration service between pregnancy care and HIV care, the DM service at HIV and ANC, and pregnancy care at DM were not more than the linkage level of integration. However, these were the gray area for the better intensity of integration. Thus, HCWs and program managers suggested the possible full integration of DM and HIV services at ANC, and DM services at HIV clinics. Also, coordination can be practiced for pregnancy care at DM and HIV clinics and also for HIV service at NCD clinic.

6.3.5 The integrated DM, HIV and pregnancy care service at administrative level

At administrative level, HIV and pregnancy care services could fully be integrated between HAPCO and MCH units. Bilateral coordination is feasible for pregnancy care and DM services between MCH and NCD units; and for HIV and DM services between HAPCO and NCD/DPCP.

6.3.6 The tripartite DM/HIV/pregnancy care service delivery model

The model developed is termed as the tripartite integration model of DM, HIV and pregnancy care. It was developed based on the triangulated findings from phases I and II, literature review and evaluation from the experts. It aims to improve pregnancy outcome among DM and HIV infected mothers. The model has two main components: the integration at facility and the administrative levels. The tripartite model at facility levels tells us that a routine HIV testing, counseling and referral could be done at DM clinics. An active and a routine DM screening, diagnosis and treatment services could be given at HIV and ANC clinics for diabetic and HIV positive pregnant mothers. At least, pregnancy counseling and testing, and the provision of short term family planning services could be given at DM or HIV clinics.

The tripartite model of service delivery at administrative level assists the practical implementation of the model at facility levels by developing policy guidelines, SOP and algorithm containing the integrated service delivery among HIV, DM and pregnancy care. This is through the joint planning, financing or budgeting, supportive supervision, monitoring and mentoring as well as building the capacity of officers and clinicians on the integrated service delivery of DM, HIV and pregnancy care.

There is a place for stakeholder and other partners that need to give a hand technically and financially on the integrated service delivery both at facility and administrative levels. Above all, the model also deals with the need to have an integrated mentality

among professionals working both at facility and administrative levels to address the APO through the integrated HIV and DM services.

6.4 CONTRIBUTION OF THE STUDY

The model was designed to provide an integrated DM, HIV and pregnancy care service to improve a pregnancy outcome for reproductive age females. The tripartite model would fill the gap of the missed link between the HIV and an accelerating DM in Ethiopia in terms of reducing APO. In addition, the model could contribute to the effort of reducing the current higher child and maternal mortality and morbidity rates in Ethiopia. That is, the application of the model could play a role in improving APO and hence morbidity and mortality among mothers and children. It could be used by both clinicians and program managers at all levels.

6.5 LIMITATIONS

1. The concept of integration is a complex idea, and the researcher could not explain and describe the whole set of the integration but tried to describe as it was practically applied to the related items of DM, HIV and pregnancy care or outcome. Hence, the 'co-variates' and preconception part of the integration theoretical framework was not addressed in this study. Hence, future studies could explain factors associated with APO among DM and HIV infected mothers using the framework.
2. This study does not include the district level interview or structured data collection. This is because the district health office is near to the primary health care unit or health centers and the structure and the staff is similar.
3. From the NCDs, only DM was included in this particular study. Together with DM, the integration of other NCDs, such as HPN, to HIV or pregnancy care may be possible. DM was given due attention because it has an objective relation with both HIV and its treatment, and the pregnancy care. As far as there is strong scientific

evidence of the relation of other NCD, that are given together with DM at NCD, with HIV and pregnancy care they could be part of the tripartite integration model.

6.6 RECOMMENDATIONS

The recommendations for this study are as follows:

6.6.1 Recommendation to the HCWs

HCWs could use the model to practice an active and routine DM screening and evaluation at HIV and ANC units; to give routine pregnancy care service at DM and HIV clinics. They may consider the comprehensive disease entity rather than having separate clinics for a patient with multiple and related illnesses for the effective and efficient approach of rendering health service. This necessitates the mentality of integrated service delivery. However, these all necessitated the direction from FMOH or RHBs.

6.6.2 Recommendation to program managers and policy makers (FMOH, RHB, Zones/sub-cities, district/woreda)

1. There is a need to prepare the policy guide on the routine and active screening of DM at HIV and ANC. They might also prepare SOPs, implementation guidelines and algorithm regarding the integrated service delivery of DM/HIV/pregnancy care. Hence, advocacy work to the decision makers may be done on the need of integrated service delivery model among the related communicable and non-communicable diseases to address the maternal and child morbidity and mortality in Ethiopia.
2. The officers and team leaders working on DM, family health and HIV could make use of the tripartite DM/HIV/pregnancy care service delivery model to address the maternal and child morbidity and mortality associated with HIV and DM through a joint annual planning, financing, and joint supportive supervisions.

3. To support the scale-up of an integrated DM/HIV/pregnancy care in Ethiopia, there is a critical need to strengthen leadership and co-ordination at the national, regional, zonal and district levels. Expanding indicators for routine monitoring of HIV and DM pregnancy care and addressing the clinical complication associated with HIV and DM, mainly the adverse pregnancy care among HIV and DM patients, are critical.

6.6.3 Recommendation to the stakeholders or partners

Donors and stakeholders working on the NCD, MCH and HIV ought to take into consideration the interrelated disease entities such as HIV and DM and effects of HIV or DM on pregnancy. This could assist them to give a hand to the government health structure in the integrated manner so that their financial and technical support will be efficient and cost-effective and also helps in the strengthening of the health system in general. All in all, the non-governmental stakes and donors working on health should consider the chronic nature of HIV and an accelerating burden of DM in Ethiopia, being a double burden to impact pregnancy outcome, to focus their support in an integrative manner. Together with the government, this model could be piloted by the stakeholder and guide the scale up of the integrated HIV, DM and pregnancy care in Ethiopia.

6.6.4 Recommendations to the researchers

1. This is the first of its kind model developed and there is a need to explore the challenges or barriers to the integration of HIV, DM and pregnancy care in the Ethiopian context.
2. The client's side perspective as to whether DM/HIV/pregnancy care is practical and feasible could be explored in the future studies.

6.7 CONCLUDING REMARKS

In the face of the high burden of both communicable and non-communicable diseases affecting maternal and child health in Ethiopia, the ANC, HIV and DM services can be reorganized into an integrated format, replacing separate clinics and service records. Currently, mothers have to attend on separate days for DM, ANC, family planning and HIV services. The tripartite integration can be started with the preparation of joint registers, training manuals after the ministry gives direction on the integrated approach and prepared the training manual on the DM/HIV/pregnancy care. An integrated checklist can be made for supervision and inventory supplies. This integrative approach could be institutes after when, the attendance is expected to increase and clients more readily accept the routine and active screening, evaluation and treatment of HIV and DM so that the pregnancy outcome may be improved. This should be done simultaneously with capacity building of HCW using the integrated DM/HIV/pregnancy training manual. Direction and policy guide on the tripartite integration model of DM/HIV/pregnancy care should first be developed and come from the ministry of health.

6.8 COMMUNICATING THE FINDINGS

Communicating the findings involves the development and distribution or giving out of a research report to appropriate audiences (Brink et al 2014:50). The researcher will communicate the results of the study to others who may find it useful. The findings of the study will be communicated through the research report which will be set to the FMOH in Ethiopia and the health facilities where the study was conducted. Also, dissemination of the findings will be done through publication of the research in the scientific journals or even presentation at relevant for such as workshops, conferences, congresses and updates.

MY JOURNEY THROUGH THIS RESEARCH

As a public health professional in Ethiopia, I have been assisting the health system to deal with infectious diseases such as Tuberculosis and HIV for the last one decade. I had been worried about the increasing burden of DM in the background of the epidemic state of HIV. Besides, the nation faces the high level of maternal and child death. Soon after I completed MPH at UNISA, I was so eager to join the next level of education so that I become part of a solution to improve DM and HIV services to deal with maternal and child death. My dream came true when I joined UNISA. Throughout the course, it was my duty to manage a big family of 8-12 members and to manage my course at UNISA in my spare time. I learnt time management, being disciplined and facing frequent stressful period. It was a tough time writing chapter after chapter, collecting data at FMOH, RHB, sub-cities and health facilities amid the terrific traffic in Addis Ababa. Above all, transcribing and translating the interviews and rearranging related literature was tiresome. Stamina, perseverance and hope were the life principles I have learnt as experiences for the future life of mine.

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ANNEXURE A: DETAILED THEMES AND CATEGORIES IDENTIFIED FROM FGDs AND IDIs BASED ON DOMAINS OF INTEGRATION

Domain: Functional integration; financial and administrative

Type of approach: Focuses group discussion

Program	Main theme	Category	Units
HIV, DM/NCD, Pregnancy care/family health	Joint planning	<input type="checkbox"/> One plan from the higher level of administration <input type="checkbox"/> Woreda based planning (Joint and one plan)	<p>It usually comes from higher up, RHB</p> <p>We usually cascade what has come from higher up (RHB).</p> <p>As an office there is one planning</p> <p>All core process will meet and there will be one plan/joint common planning</p>
	Budget	<input type="checkbox"/> A separate budget	<p>Every core process has its own budget.</p>
	Supportive supervision (SS)	Separate/isolated SS	<p>There is no direction from above (RHB/FMOH) to do (SS) together</p> <p>DM or maternal health is not under our core process (diseases promotion and prevention)</p> <p>we are not mentoring or supervising them to do a routine DM test or screening,</p> <p>there is no direction for higher up (FMOH) to do joint supervision</p> <p>all the core process are doing it (SS) separately.</p> <p>It is a separate feedback system, after SS</p>

Domain: Functional integration; financial and administrative

Type of approach: in-depth interview

Program	Main theme	Category	Units
DM/NCD	NCD structure	Presence of focal person at sub-city	like HIV there is a focal person (for NCD at sub-city and FMOH)
		Standalone NCD unit	HPN, DM, etc are made to be seen in isolated room A follow up from our side as medical service core process (to stand alone NCD/DM clinic)
		NCD/DM gained emphasis recently	NCD is a new unit. It is very young. Previously, there was a lesser focus or no structure so far. The emphasis was on communicable diseases.... just currently NCD becomes a problem. An emphasis is gained It is considered in the structure
NCD/HIV/ANC	Plan	Joint plan	There a common plan A common and comprehensive plan out of which we will take ours related to (family health, NCD/DM & HIV) Joint planning is done; there is what we call woreda based planning
	Budget	Common budget	There is no a program budget. No earmarked budget for each program-for TB, HIV, NCD/DM The budget is for the core process of DPDP core process (HIV), medical service (DM/NCD) core process and for family health (pregnancy care).
	Monitoring system and tools	Program specific SS	we do an integrated supervision occasionally when there are activity in need of joint monitoring. We (NCD supervisors) do not get into that (ANC or HIV). The works (SS of HIV, DM, ANC) can be done in different times. I (NCD/DM) am under the medical service core process. HIV is not under medical service. HIV is standalone under the HIV/AIDS core process... we are not going together (for supervision). ... Same is true with reporting. Similarly, the unit reporting to me (NCD/DM) is the one that I am going to and supervise.

		<p>There is a unit which is mainly dealing with pregnant mothers...</p> <p>Regarding the mother it is up to the family health unit...</p> <p>Mother/pregnancy related issues are for family health core processes</p> <p>There is collaboration at health facilities among health care process...</p> <p>There is no routine DM test you do not also tell the HCW at health facility to do it routinely</p> <p>No direction from FMOH on joint SS</p>
	Supervision checklist	<p>...But here there is no joint supervision or checklist alignment.</p> <p>DM related item does not exist in my checklist (of the family health supervision checklist)</p>
	Shared activity on intra-referral activity	<p>We assess the outreach joint activity using the internal referral; the referral from NCD to ANC, from NCD to HIV, ANC to HIV</p> <p>we looked at the referral papers to ensure the internal referral linkage.</p> <p>What is being done at reproductive health on mother, on family planning, when looked into the referral papers, we can assess how much we worked together.</p>
	combined DM/HIV/ANC guidelines	<p>there is no guideline thus far</p> <p>there should be a guideline</p> <p>It should come in the form of guideline/direction</p> <p>We do have a good experience on syphilis/VDRL so long... like syphilis if emphasis is given we can handle DM together with ANC</p> <p>If the focus on HIV were extended to DM,</p>

Domain: Organizational integration

Type of approach: Focused group discussion

Program	Main theme	Category	Units
DM/HIV/ANC	Combined information management	Common recording and reporting mechanism	<p>We make a line ourselves (on NCD register); we do not have an isolated register (for pregnancy test and HIV test register)</p> <p>If we are to do it we can do it on HMIS register (e register for all diseases entity)</p> <p>Yes I do have register (for family planning service at ART).</p> <p>There is HIV result registration at NCD clinic</p> <p>there is FP registration at HIV, not for DM screening/testing registration</p> <p>No registration or reporting on the screening /testing of DM at HIV</p>
	Co-location of services	Service and location	There are NCD day of NCD stand-alone clinics
	Joint Trainings	Common family planning (FP) and ART/HIV training	There is no training on FP in ART training

Domain: Organizational integration

Type of approach: In-depth interview

Program	Main theme	Category	Units
DM/HIV/pregnancy care	Co-location of services	NCD/DM service outlet	<p>Yes, there is an isolated room for it (NCD/DM). Standalone clinic (NCD/DM). It is OPD but only DM and HPN together</p>
		NCD/DM service outlet	There is a trained person at health center as focal person (on NCD/DM).
	Combined information management	Common register/recording	<p>there is (a family planning register) at ART clinic</p> <p>Yes I have a register of family planning at ART clinic.</p>
		Common reporting system	<p>Not on CND report.. but through family health, ANC, in the DP</p> <p>I have for HIV (reporting) but not for DM</p> <p>Yes, with family planning unit we make a report monthly (with ART clinic).</p>
	Joint Trainings	Joint training manual and activity	No I have not (not trained on DM/HIV)

			<p>No, there is no (a training manual combining DM, HIV and maternal care), but PMCTC (HIV and pregnancy care, family planning).</p> <p>No, not at all (No direction from sub-city or FMOH) regarding the joint DM/HIV training of DM/HIV)</p>
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Domain: Clinical integration-structural

Type of approach: Focused group discussion

Program	Main theme	Category	Units
DM/HIV/Pregnancy care	Guidelines and protocols regarding joint service delivery	Common guideline/algorithm	<p>No, not at all (combined guiding or protocol)</p> <p>No direction from sub-city or FMOH regarding guidelines/algorithm of DM/HIV</p> <p>I have (guideline & algorithm) for HIV,, but not for DM</p>

Domain: Clinical integration-structural

Type of approach: In-depth interview

Program	Main theme	Category	Units
DM/HIV/Pregnancy care	Guidelines and protocols regarding joint service delivery	Common guideline/algorithm	<p>No guideline or algorithm related to HIV and DM.</p> <p>No, this guideline is for the general population. Not specific group is addressed.</p> <p>The DM/ANC, DM/HIV etc... are not addresses in the NCD guideline</p> <p>On can get PITC algorithm at NCD, HIV, ANC you also get PITC algorism.</p> <p>PITC is common algorithm</p>

Domain: Clinical integration-process integration

Type of approach: Focus group discussion

Program	Main theme	Category	Units
HIV/pregnancy care	Integrated HIV/pregnancy care service delivery	PMTCT	<p>... And if pregnancy occurred we link or refer to ANC.</p> <p>After they get pregnant they will stay at PMTCT for 1 and ½ years.</p> <p>We do PICT for all pregnant mothers and their partner.</p> <p>If the mother is HIV+, we offer full PMCT service to have HIV free birth</p>
		Family planning service	<p>We counsel and advice on the use of family planning (FP) and it is integrated with ARR.</p> <p>We give short term FP in this (HIV) clinic</p> <p>When they need a long term FP, we link to FP clinic.</p> <p>Condom, depo-, we will give them here (HIV clinic)</p> <p>For Norplant and IUCD we refer them to FP</p> <p>At HIV we render FP including long term FP</p> <p>In this clinic (HIV); mainly, mother uses dual FP</p> <p>We just planned to start the long term, just trained health care providers very recently</p>
		pregnancy counseling, testing	<p>Depends on the women complaint (if she has signs of pregnancy, morning sicknesses, and if she reported the monthly census is absent. I will send (for pregnant test); specially, if she is amenuric. If it is confirmed, I will link to PMTCT.</p> <p>We cannot prevent them from getting pregnant. With very low CD4, they might want to get pregnant. Here, we tell them it is a problem both for their mother and fetus.</p> <p>We tell that there are cases where they can give HIV infected child even with follow up due to high viral load.</p> <p>They want to get pregnant. We advise them to do mating during the ovulation rather than doing sex all over the month, advice on the timing.</p>
DM/pregnancy care	DM service integrated to pregnancy care and HIV	DM service at HIV	<p>if HIV+ have DM, this will be linked to DM clinic</p> <p>We ask about feeling thirst, weakness, fatigue, dry mouth, urine in the night, then we do lab tests (fasting blood sugar).</p> <p>Before initiation of ART, we usually do baseline investigation such as... FBS.</p> <p>DM test per the complaints on the follow up, Monthly. In fact, we will assess for any new event, including DM.</p> <p>Regarding DM... If the symptoms of DM are detected, we will send investigate for the client.</p> <p>No, such service (routine DM screening) at HIV</p>
		DM services at ANC	<p>DM testing is not a routine service for pregnant mother.</p> <p>DM screening can be routine.</p> <p>In the initial visit, we will you send urine sugar, if plus 2 or 3, that is the indication for DM, we will send for FBS.</p>

			<p>If she comes up with history of DM, dehydration, frequent urination, we will do FBS</p> <p>There is such service (counseling service on family planning or pregnancy care).</p>
		Pregnancy care at DM	<p>If the young girl/women come, of age 18 or 19, we will give her the detail counseling and advice (regarding pregnancy)..</p> <p>It is better if the mother gets counseling service on FP (at NCD/DM).</p> <p>Before birth, she should get counseling or advice to prevent complications.</p> <p>As an institutes, based on the symptoms by the DM mother, we can do an investigation (pregnancy test (PT)) we ask for amenuria (absence of menses) and if we suspect for pregnancy, we send for PT.</p>
DM/HIV/ANC	Behavior and practice of integrative service delivery	Long term FP at HIV clinic	<p>We do not have such service (family planning). We will send to FP.</p> <p>It need standardized procedure (on long term FP).</p> <p>It needs special training (on long term FP).</p>
		DM services for pregnant mothers	<p>Mothers with DM and pregnancy will have a follow up at hospitals.</p> <p>The other can have follow up at health center (HC). There is a focal person at health center who can decide whether mothers can have a follow up at HC or Hospitals.</p> <p>They can be started on medication at hospitals and then referred to health center for follow up</p> <p>Pregnant mother with DM are having a follow up at Hospital.</p> <p>If she has both HIV and DM she will be linked to hospitals, especially for DM.</p> <p>(Because there could be delivery problems: Macrosomia (Big baby), obstructed labor, and dystocia and birth complication).</p> <p>Yes, after birth she will be having a follow up here (at health center).</p>
		HIV services at NCD/DM clinic	<p>If any patients come to chronic OPD we do PITC. if HIV+, will send to ART</p> <p>I do PITC, occasionally.</p>
		Pregnancy care at HIV clinic	<p>Even then they come up with getting pregnant irrespective of the advice, we send them to PMCTCT.</p>

Domain: Clinical integration-process integration

Type of approach: In-depth interview

Program	Main theme	Category	Units
DM/HIV/ANC	Integrated service delivery	DM service at ANC	No pregnant mother specific screening for HPN or DM In the focused, ANC there are basic tests , but things related with DM ,nothing is being done
		HIV service at DM	HIV screening and testing is not done daily for every mother at NCD/DM But PITC is done, symptom based HIV testing and counseling. Here PICT can be done at NCD clinic if they suspect for HIV, if positive at DM, they will link to ART. Like other OPD there PITC is done. For only the suspected one for HIV
		DM services at HIV	There is no DM screening service, but if the patient complains with symptoms, not routine testing, however, at chronic HIV clinic. There is a linkage. Based on the symptoms (of DM), random blood sugar (RBS) may be done. Otherwise, like HIV, there is no emphasis or routine test for DM.
		DM services at ANC	If we see ANC, DM screening is not in the focused ANC, or hardly implemented. DM is not integrated into ANC No risk factor related to DM are considered at ANC No routine screening service of DM in ANC May be previous history or sign and symptoms of DM
	Behavior and practice of service delivery.	Health care providers collaboration/linkage	Not all pregnant women are screening for DM currently No such activity of routine offer of DM testing at ANC If a mother with HIV+ is DM, they (health care providers (HCP)) will talk together and decide whether the patients should be treated here or should be referred to better health facility. For diabetic pregnant mother, the HCPs communicate and discuss together and might refer to hospital for better follow up and treatment. There is a linkage.

4.7.9 Domain: clinical integration-service delivery (Suggestions)

Approach: Focused group discussion

Program	Main theme	Category	Units
DM/HIV/ANC	Suggested integrated approach	Routine DM screening and diagnosis at HIV	That is sound and preferable, the routine (of screening DM for HIV infected people) is important but the supply (reagents for DM testing) is challenging.

		Pregnancy care and FP service at HIV clinic	Health care provider (HCP) should be trained in short and long term, so, they could give all methods (of FP) at ART. Referral to FP for long term might be stigmatizing.
		Integrated monitoring: Joint supportive supervision, the feedback and supervision checklist	It would have been better to do (the supportive supervision) together and give the feedback at the same time on one paper (a common checklist). It could have been better to organize the checklist together and do the feedback together. Disease prevention, medical service and HIV should have done it (JSS) in common, including the preparation of the supervision template.
		Policy guideline and training manual	Police guideline should guide a full and a comprehensive health service for a client. The integration should be started from higher up, FMOH and RHB Things from federal should have come on integrated service delivery Hence, works from up from the (FMOH/RHB) should come down together
		Related service integration (One-stop-shopping for related services)	Like PMTCT with HIV similar guideline for similar service, can be prepared to render similar service at one. HCW at ART can be trained and can give FP & DM service at ART Related services can be integrated.

4.7.10 Domain: clinical integration-service delivery (Suggestions)

Approach: In-depth Interview (IDI)

Program	Main theme	Category	Units
DM/HIV/pregnancy	Suggested service integration	Integrated monitoring	Mentors can see whether the DM being also screened at HIV care.

	Integration behavior among HCWs	Internal consultation, internal referral, internal communication....should be there
	One-stop-shop mentality	<p>All programs that are related should be integrated</p> <p>Services should be interlinked</p> <p>Only diseases consideration have to be left out</p> <p>We have to treat patients... just think of patient, not disease entity.</p> <p>Comprehensive packages of interlinked diseases for a patient.</p>
	Policy guideline and training manual of integrated service	<p>HIV guideline when prepared, it should include other related burden like DM at the same time</p> <p>The guideline should clearly state what to do if a diseases entity (DM) occurred with HIV</p> <p>Guideline should be standardized & comprehensive</p>

ANNEXURE B: SAMPLE OF FIELD NOTES AND MEMOS

Observation

Observation on the structural organization at FMOH, region and sub-cities

At sub-sites, the structural organization of DM, HIV and ANC is that all are located in the same building and in the same floor. There is a difference in the structure. In some sub-cities the NCD is under the medical service with the unit that is responsible for all the health facility services' while in the other sub-cities the NCD unit is under the diseases promotion and diseases prevention (DPDP). HIV or ART is under the disease prevention and promotion in almost all sub-cities. The family health unit which deals with family planning pregnancy care is under the medical service while the PMTCT is under the HIV program. There is an inconsistency structure and assignment of HIV, DM/NCD and maternal health in different sub-cities. In the other sub-cities HIV related prevention activities are under the diseases prevention and promotion while ART/HIV care treatment is under the medical service. This uneven arrangement can pose the risk of integrative service provision, planning, budgeting, monitoring and evaluation activities of these programs.

At federal level NCD is well established with the policy and guideline, including the commonest NCDs in Ethiopia such as DM, HPN, breast cancer, cervical cancer and etc. NCD at Federal level is under the disease prevention and control directorate and established as a unit. Team leader of the NCD is assigned. The officers on DM, HPN, different cancers are already recruited. The health extension workers (HEW) are also included in the community awareness of DM, HPN, cervical cancer and etc.

The NCD register, without HIV testing or pregnancy care testing/counseling, is prepared and being used in some selected hospitals. There are cancer centers at regions as well. However, there is no joint supportive supervision (JSS), joint mentoring, budgeting or annual planning at the federal ministry of health (FMOH). There is an isolated planning, budgeting, supportive supervision, monitoring, and capacity building at FMOH.

Trainings at federal levels are not designed in such a way to address HIV or pregnancy care with NCD. The NCD register does not have HIV screening or pregnancy testing result column. There are rarely shared forums where the NCD is collaborating with HIV or maternal and child health (MCH) unit.

At health facilities DM screening and evaluation is done based on the complain of the patients. DM is usually diagnosed at the general OPDs. DM suspects at ANC, and some ART clinics are usually referred to OPD clinicians or DM/NCD clinician for confirmation. There are three scenarios by which DM service is given at the study health facilities- NCD clinic with all weekday, NCD clinic with NCD day and NCD integrated into OPDs in the country as a whole

- I. The follow up and DM medical service is given together with other chronic illness such as HPN, cervical cancer, chronic live diseases, breast cancer and etc. This is given at standalone NCD clinics where there are trained physician and a nurse at the study health facilities. Here, there is NCD register where all necessary data set related to common NCD are recorded. However, there are no columns addressing the HIV or pregnancy screening. The NCD service in this scenario is given throughout the week. The report is generated to sub-cities quarterly relating to the NCDs.

- II. In the second scenario the health facilities have got NCD day at NCD room or clinic. Patients with DM, HPN, and different cancers having a follow up are usually appointed in specific day in a week. For example, there were health centers where Thursday is NCD day at NCD clinic. These days and clinics are usually meant for follow up. In these scenarios the diagnosis is usually made at OPD and referrals are from other health facilities.
- III. In the third scenario, patients with all types of NCD can come at their own day of appointment at any days in a working day for the follow up. There are no specific days in a week designated for the NCD or there is no NCD clinic. All clinicians at OPD or to her give about lets can suspect, screen, evaluate and confirm the diagnosis. Here all HCWs are expected to have a capacity of identification of DM suspect, evaluate and investigate DM, confirm the diagnosis and put on the appropriate treatment, and refer the DM case to NCD clinics for the follow up.

In some health facilities there is no capacity of diagnosing DM at ANC and ART clinics. There is thinking that diagnosis of DM is a work of clinicians at DM or OPD so there is usually a referral of DM suspect at OPD, NCD clinics or other health facilities with NCD clinics or NCD experts.

The pregnancy testing at DM is rarely entertained. It is only when the patients requested the pregnancy test that pregnancy test might be ordered or counseling on the pregnancy care. Whenever they need the service of pregnancy care, they are referred to family planning. However, pregnancy care and DM is usually taken care of at hospital setting for better care.

Observation at Health facilities

DM/NCD clinics: they are old peoples who were having a follow up. The pregnant mothers with DM, on insulin are referred to hospitals for the better treatment and care. DM at HIV clinic is investigated if the patients show up with symptoms and if s/he self-reports. Otherwise, there is no routine screening of DM at HIV clinics for HIV infected patients. During the informal observation or interview, the reason was mentioned as,

1. *“ There is no as such direction from the federal level “ and*
2. *“ there is no convincing evidence that HIV or ART is a risk factor for DM”*

Participants/ Informal observation

Health care workers (HCW) are not well aware of how HIV or ART are a risk factor for DM, so they do not believe on the fact that DM screening should be a routine at HIV clinic. Also, there is no awareness of adverse pregnancy outcome (APO) by HIV/ART on mother, thinking that PMTCT is optimal. So, pregnancy counseling might not be routinely given. So, most mothers come to ART getting pregnant without the knowledge of HCW. Knowledge of the effect of poorly controlled DM on pregnancy outcome is not optimal. So, DM routine screening is not thought of.

Guideline, policy direction, algorithms on HIV &DM related APO is not being considered and not in place in the country. They are not also well aware to practice optimal integration of service of these items. Besides, supervision and mentoring are vertical so HCW does not believe it is important to give routine DM screening testing at ANC and HIV. HCW are well aware of the accelerating and increasing magnitude of DM in Ethiopia. However, they think that is not well funded, well recognized and integrated with chronic illness such as HPN, cancer illness etc. That might hide the attention needed by DM.

Memo or field notes of Health center: FGD

Participants: ANC, PMTCT and chronic care/DM focal person

DM officer coordinated and at ANC and the FGD was carried out. ART focal person could not be part of the FGD. Four of us carried out the discussion which took 45 minutes.

Suggestions

DM officers: counseling and advising on pregnancy at DM before they get pregnant

Give all follow up and care for DM/Pregnant care at HC after capacitating the HCWs at health centers. "... limited capacity of mothers to have a follow up at HC to take care of diabetic and HIV infected mothers without other complication will be beneficial for mothers...also routine pregnancy counseling and provision of at least short term family planning is essential at chronic care unit".

"At ANC it is also important to have a routine FBS/RBS, like HIV, can be a practice. ...however, this has to come to health facilities in the form of policy or direction guideline from FMOH".

DM screening and treatment or evaluation algorithm and guidelines are not available at DM/ANC or ART/HIV clinic. However, pregnancy counseling and family planning provision guidelines and algorithm are available at ART and ANC/PMNTCT clinics.

HIV screening algorithm is available at all service outlets

No guideline or algorithm that is a comprehensive DM, HIV, and pregnancy care in all service outlets

DM, HIV and pregnancy care algorithm, guidelines and pregnancy care are important if available, designed, availed and implemented in the country and feasible and practical.

Routine FBS/RBS, DM counseling on prevention, algorithm of screening and treatment are feasible, acceptable and practically if implemented at ANC, ART clinics.

"...HIV program is well funded...ehhe.. With rich resource....guideline are available with supply policy...but the magnitude is decreasing...ehheee..While DM is silently affecting a lot of people "

The member of the FGD stressed the fact that DM is a 'silent killer', as there are a lot of asymptomatic, undiagnosed DM patients. Hence, one of the members of the FGD described. "...the silent nature of the diabetic mellitus... can be identified...if we are in high index of subspecies...emmmm. ,to identify the underdiagnosed DM among HIV and pregnant mothers... routine screening of DM is a solutions..."

HIV at DM: "PITC" whenever the DM patients should show signs and symptoms of immunodeficiency. HIV counseling and testing is not routine done for every clients visiting DM/NCD clinic.

DM at ANC: Whenever the mother comes up with the signs and symptom of DM. FBS/RBS is not a routine investigation/screening at ANC.

DM at HIV: the same as at ANC or HIV. If DM is diagnosed, referral is made to chronic care. At DM if HIV is confirmed , s/he is sent to ART using the intra-facility referral form.

ANNEXURE C: WRITTEN CONSENT FORM FOR PATIENTS INTERVIEW (English Version)

My name is ----- . Here at Hospital HIV care unit/Diabetic clinic/ANC or Delivery clinic, I am abstracting clinical data from patients files and registers. I am also interviewing women who know their HIV/diabetic status. This is to evaluate the impact their disease condition brought about on pregnancy outcome. We believe that this study would help to indicate a model of care linking diabetic and HIV care to pregnancy outcomes among diabetic and HIV positive others. We would like to assure you that your name will not be mentioned in the data abstraction form or questionnaire and the information that you give us will be kept confidential and only used for research purposes. You have a full right to refuse to take part or to interrupt the interview at any time. But the information that you will give us is quite useful to achieve the objective of the study. It will take 20-25 minutes to respond to the interview. Are you willing to participate in the study?

1- Yes

2 - No

(If the answer is yes, thank the patient. Then have the signature and conduct the interview. Otherwise, the patient is not forced to participate)

Name and signature.....Date.....

Name and signature of interviewer.....Date.....

ANNEXURE D: WRITTEN CONSENT FORM FOR PATIENT INTERVIEW (Amharic version)

በጥናት ለመሳተፍ የፍቃድኝነት መግለጫና የፈቃድኝነት ስምምነት ቅጽ

የጥናቱ ርዕስ:- በአድሳ አበባ ሆስፒታሎች የምወለዱት ህፃናት ገጠና ለማሻሻል የኤች ኤይ ቪና ስኳር ህመምን ስለማጣመር

ሰሜ ሲሆን፡ እኛ ጋ ለየሌች.አይ.ቭና የስኳር ህመም የህክምና ክትትል ያላቸውን እናቶች ቃለ-ምልልስ እያደረግን ነዉ።ምክንያቱም የሁለቱ ህመም ተጠቂ የሁኑት እናቶች ጤናማ ህጻን ስለመወለዱ ጥናት እተደረገ ነዉ። የጥናቱ ዋና ዓላማ በሁለቱ በሽታ ምክንያት የምክሰተዉን የጽንሰ ችግር ላመሰወገድ የምቻልበትን መላ ለማበጀት ነዉ።

በግምት 5-10 ደቂቃ የሚወስድ ቃለ መጠይቅ የማደርግልዎ ሲሆን የሚሰጡኝ መልስ በሚሰጥር እንደሚያዝ ላሳውቅዎ አወዳለሁ። እርሰዎን የምሠጡን መረጃ በዚህ ጥናት ከሚሳተፉ የጤና ባለሙያዎች ውጭ ለማንም አይሰጥም። ውጤቱም ስንጽፍ በዚህ ጥናት የተሳተፉ ሰዎች ስምና ሌሎች መለያዎች አይካተትም።በዚህ ጥናት መሳተፍ ካልፈለጉ ለመተው ወይም ለማቆም መወሰን ይችላሉ።በጥናቱ ለመሳተፍ ለሚያደርጉት ትብብር የላቀ ምስጋናየን አቀርባለሁ።

ስለዚህ በዚህ ጥናት ለመሳተፍ ተስማምቻለሁ-----

አልተስማማሁም-----

በጥናቱ የሚሳተፈው ሰው ፊርማ-----ቀን-----

እኔም ለጥናቱ ተሳታፊ ስለ ጥናቱ አላማ በዝርዝር ማስረዳቱን አረጋግጣለሁ።

ቃለ-መጠይቁን የሚያካሂደው ሰው ስም:- ----- ፊርማ-----ቀን-----

ለማንኛውም ዝርዝር ጥያቄዎች የጥናቱ ዋና ሐላፊን በምክተለዉ አድራሻ መግኘት ይቻላል።

ዶ/ር ዘዉዱ ጋሹ ደመመዉ: የኔሳ፤ደቡብ አፍሪካ ዩኒቨርሲቲ

ስልክ ቁጥር:+251911768081

44934599@mylife.unisa.ac.za

አዲስ አበባ

ANNEXURE E: DATA ABTRACTION CHECKLIST AND QUESITONARRIE

Human Immunodeficiency Virus and Diabetes Mellitus: A Missed Link to Improve Pregnancy Outcome in Ethiopia

Patient Instruction: You have been selected to take part in this interview. It will take a few minutes. Because the Diabetes and HIV can affect the outcome of pregnancy, it is important to ask you some questions about your fertility and the outcomes of your pregnancy outcomes. Your name, address or any identification will not be collected. Your answers will remain confidential so please be honest.

A. Data abstraction- ANC

ALL PREGNANT MOTHERS

Name of health facility..... MRN_____

Type of health facility a. Public Hospital b. Private Hospital

I. Socio-Demographic Characteristic (Pregnant women)

5 What is your current marital/relationship status?

1. Current age in years

2. Gravidity.....

a. Married

b. Single

3. Parity

c. Divorced

d. Widowed

4. Gestation age in weeks..... (For current pregnancy)

e. Non-married with partner

5. History of diabetes mellitus in the family: a) yes b) no

c) I do know f. No response

6.

No of ANC visit Toxoid	Iron folate	FBS /urine test (result)	T est for HIV (result)	VDRL (result)	Tetanus
1st pregnancy____ Yes No	Yes NO	Yes NO (-----)	Yes NO (-----)	Yes No (-----)	Yes No (-----)
2 nd pregnancy____ Yes No	Yes NO	Yes NO (-----)	Yes NO (-----)	Yes NO (-----)	Yes NO (-----)
3 rd pregnancy____ Yes No	Yes NO	Yes NO (-----)	Yes NO (-----)	Yes NO (-----)	Yes NO (-----)
4 th pregnancy____ Yes No	Yes NO	Yes NO (-----)	Yes NO (-----)	Yes NO (-----)	Yes NO (-----)
Current Pregnancy ----- Yes No	Yes NO	Yes NO (.....)	Yes NO (.....)	Yes NO (.....)	Yes NO (.....)

II. DM services at ANC clinics (Health care workers **at the HIV clinic ONCE!**)

1. If the DM diagnosed,

1.1 Date diagnosed with DM

1.2 Type of DM

a. Type I

b. Type II

c. GDM

d. Other type

##Maternal survival/ Complication

- 1. Alive
- 2. Spontaneous abortion
- 3. Induced Abortion
- 4. Not recorded or unknown
- 5. Spontaneous vaginal delivery

- 16. Systemic infections
- 17. Eclampsia
- 18. ant-partum Haemorrhage
- 19. Systemic infections
- 20. Maternal near miss
- 21. Others specify.....
- 22. No complication

****Infant survival/Complication**

- 1. Live/normal birth
- 2. Stillbirth
- 3. Miscarriage

- 4. Congenital malformation (from live births)
- 5. Other, specify.....

8. Second pregnancy

- 8.1 date confirmed.....
- 8.2 date delivered.....
- 8.3 Gestational Age-----
- 8.4 Birth weight-----

8.3. Outcome

8.3.1 ##Mother:-----

8.3.2 **Foetus:-----

9. Third pregnancy

- 9.1 date confirmed.....
- 9.2 date delivered.....
- 9.3 Gestational age-----
- 9.4 Birth weight-----

9.5. Outcome

9.5.1 ##Mother:-----

9.5.2 **Foetus:-----

10. Fourth pregnancy

- 10.1 date confirmed.....
- 10.2 date delivered.....
- 10.3 Gestational age-----
- 10.4 Birth weight-----

10.5. Outcome

10.5.1 ##Mother:-----

10.5.2 **Foetus:-----

B. Data abstraction-DM clinic

All Females 15-45 during enrollment

At least 3 months of follow-up

Name of health facility..... MRN_____

Type of health facility, a. Public Hospital b. Private Hospital

I. Socio-Demographic Characteristic (Baseline data, at enrollment, 18-45 years females)

1. Ageyears

2. Date DM diagnosed (DD/MM/YY) -----

3. DM diagnosed at:

- a. OPD
- b. DM/NCD clinic
- c. IPD
- d. HIV clinic
- e. Other health facility

4. Type of DM

- a. GDM
 - b. TYPE I
 - c. TYPE II
 - d. Other, specify.....
5. History of diabetes mellitus in the family: a) yes b) no c) I do know

6. Date diabetic treatment started (DD/MM/YY)-----

Regimen	Time Period
-----	-----
-----	-----
-----	-----

	0 month	12 months	24 months	36 months	the latest/Current
7. Height	_____	_____	_____	_____	_____
8. Weight	_____	_____	_____	_____	_____
9. FBS	_____	_____	_____	_____	_____

10. Documented Clinical complications

Date Detected/Diagnosed

11. Other co-morbid Infectious diseases

Check TB yes NO -----

Others -----

Date (DD/MM/YY)

12. Other non-communicable/ **Chronic illnesses**

Check for HPN Yes No-----

Others -----

Date (DD/MM/YY)

II. HIV service at DM (Health care workers at DM +PATINETS+ FILE+REGISTER)

1. HIV counselling and testing offered at DM

- a. Yes
- b. Referred to HCT/OPD for counselling and testing
- c. Not at all

2. Date tested for HIV (DD/MM/YY).....

3. HIV test result

- a. HIV+
- b. HIV-ve
- c. Unknown

0 month 12 months 24 months 36 months The latest/Current

4. Viral load _____ (HIV+)

5. CD4 (+) count _____ (HIV+)

6. Have you started ART? (HIV+)

a. Yes, I have started ART

b. No, I haven't started ART yet.

7. If ART started, date it is started (DD/MM/YY E.C)? (HIV+)

Regimen type

Date (DD/MM/YY)

8. Documented Clinical complications

Date-Diagnosed

9. Other Infectious diseases

Date-Diagnosed

Check TB yes NO -----

Others -----

10. Other non-communicable diseases

Date-Diagnosed

Check for HPN Yes No-----

Others -----

III. Family planning and Pregnancy care at DM/NCD clinic

1. Have you ever got pregnant a. Yes

b. Never

c. Now pregnant

2. First pregnancy

2.1 Date confirmed.....

2.5. Outcome (*more than one option is possible*)

2.2 Date delivered.....

2.3 Gestational age at birth.....

2.5.1 ##Mother:-----

2.4 Birth weight.....

2.5. 2 **Fetus:-----

Pregnancy outcome

##Maternal survival/ Complication

1. Alive

2. Dead

4. Spontaneous abortion

5. Induced Abortion

6. Not recorded or unknown

7. Spontaneous vaginal delivery

8. Instrumental delivery (vacuum extraction or forceps)

9. Breech delivery

10. Caesarean section

11. Pre-eclampsia

12. Eclampsia

13. Postpartum haemorrhage

14. Puerperal endometritis

15. Eclampsia

16. Ant-partum haemorrhage

17. Maternal near miss

18. Others specify.....

19. No complication

****Infant survival/Complication**

4. Live/normal birth

5. Stillbirth

3. Miscarriage

- 4. Congenital malformation (from live births)
- 5. Other, specify.....

3. Second pregnancy

- 8.1 date confirmed.....
- 8.2 date delivered.....
- 8.3 Gestational age at birth-----
- 8.4 Birth weight-----

8.5 Outcome

8.5.1 ##Mother: -----

8.5.2 **Fetus: -----

4. Third pregnancy

- 9.1 date confirmed.....
- 9.2 date delivered.....
- 9.3 Gestational age at Birth-----
- 9.4 Birth weight-----

9.5 . Outcome

9.5.1 ##Mother:-----

9.5.2 **Foetus:-----

5. Fourth pregnancy

- 10.1 date confirmed.....
- 10.2 date delivered.....
- 10.3 Gestational age.....
- 10.4 Birth weight-----

10.5. Outcome

10.5.1 ##Mother-----

10.5.2 **Foetus-----

C. HIV CLINIC

All Females 15-45 during enrollment

At least 3 months on follow-up

Name of health facility..... MRN_____

Type of health facility, a. Public Hospital b. Private Hospital

I. Socio-Demographic Characteristic ((Baseline data, at enrollment, 18-45 years females)IN Take

1. Ageyears

3. History of diabetes mellitus in the family: a) yes b) no c) I do know

II. HIV AND ART HISTORY (PRE-ART/ART REGISTER)

1. Date diagnosed with HIV (DD/MM/YY Ethiopian Calendar (E.C).....

2. Where HIV diagnosis made?

- a. HCT/VCT clinic
- b. DM/NCD clinic
- c. ANC/PMTCT
- d. Family planning
- e. Outpatient department
- f. In-patient department
- g. Other, specify.....

	0 month	12 months	24 months	36 months	The latest/Current
3. Height	_____	_____	_____	_____	_____
4. Weight	_____	_____	_____	_____	_____
5. Viral load	_____	_____	_____	_____	_____
6. CD4 (+) count	_____	_____	_____	_____	_____

8. ART initiation status? a. Started ART b. Not started, yet

9. If ART started, date started (DD/MM/YY E.C)

Regimen type Time Period (DD/MM/YY)

10. Documented Clinical complications Date Detected/Diagnosed (DD/MM/YY)—**HIV/AIDS related**

Check For TB a. YES b. NO

Others -----

11. Other Infectious diseases (co-morbidity) Date Detected/Diagnosed (DD/MM/YY)--**HIV/AIDS related**

12. Other non-communicable diseases —**chronic illnesses** Date detected/Diagnosed

Check HPN a. yes b. No

Others -----

III. FERTILITY HISTORY (=PATIENTS)

- How many pregnancies have you had?pregnancies
- So far, how many live births/deliveries have you had? live births/deliveries
- How many are alive now? Children

IV. DM status for HIV infected women at HIV clinic (PATIENTS + register + HCW)

1. Tested for DM at

- a. HIV clinic c. IPD
b. OPD d. other health facility e. Never tested

2. If tested for DM, tested by

- a. Symptoms or clinical screening d. FBS
b. Urine dipstick e. 2 hour Oral glucose tolerance test (OGTT)
c. RBS f. Glycosylated Haemoglobin IC (Hb1C)

3. If the DM diagnosed, date (DD/MM/YY E.C)..... (**DM+HIV PATIENTS**)

Regimen	Time Period
-----	-----
-----	-----
-----	-----
0 month 12 months 24 months 36 months The latest/Current	
4. FBS _____	_____
5. Documented clinical complications (PATIENTS FILES, REGISTER, PATIENTS) _____	
Clinical Complications	Date
Check for TB yes No ----	-----
Check for HPN Yes No-----	-----
Others-----	-----
-----	-----

V. Family planning and Pregnancy care at HIV clinic (Health care workers at HIV clinic)

1. **(PATINETS at HIV clinic)** Have you ever got pregnant a. Yes b. Never. c. Now pregnant

2. If yes, date first pregnancy confirmed..... (E.C)

2.1 Date gave to birth..... (E.C)

2.2 Gestational age at delivery.....

2.3 Birth weight.....

6.4. Birth outcome *(more than one option is possible)*

6.4.1 ##Mother: _____

6.4.2 **Foetus: _____

Pregnancy outcome

##Maternal survival/ Complication

- 1. Alive
- 2. Dead
- 3. Spontaneous abortion
- 4. Induced Abortion
- 5. Not recorded or unknown
- 6. Spontaneous vaginal delivery

- 11. Instrumental delivery (vacuum extraction or forceps)
- 12. Breech delivery
- 13. Caesarean section
- 14. Pre-eclampsia
- 15. Eclampsia
- 12. Postpartum haemorrhage
- 13. Puerperal endometritis

- 14. Eclampsia
- 15. Ante-partum haemorrhage
- 16. Systemic infections
- 17. Maternal near miss
- 18. Others specify.....
- 19. No complication

****Infant survival/Complication**

- 6. Live/normal birth
- 7. Still birth
- 3. Miscarriage
- 4. Congenital malformation (from live births)
- 5. Other, specify.....

7. Second pregnancy date confirmed.....

7.1 Dates delivered.....

7.2. Gestational age at delivery.....

7.3 Birth weight.....

8. Third pregnancy date confirmed.....

8.1 Date delivered.....

7.4 Outcome

7.4.1 ##Mother:_____

7.4.2 **Fetus:_____

8.4 Outcome

8.4.1 ##Mother:_____

8.4.2 **Fetus:_____

- 8.2 Gestational age at delivery.....
- 8.3 Birth weight.....
- 9. Fourth pregnancy date confirmed.....
- 9.1 Date delivered.....
- 9.2 Gestational age at delivery.....
- 9.3 Birth weight.....

9.4. Outcome

9.4.1 ##Mother: -----

9.4.2 **Fetus: -----

ANNEXURE F. LEVEL OF INTEGRATION ASSESMENT: DM/HIV/Pregnancy care

(ONE TIME INTERVIEW QUESTION FOR EACH STUDY HEALTH FACILITY)

I. DM services at HIV clinics (Health care workers *at HIV clinic*)

1. Screening service of HIV infected mother for DM
 - a. Yes, always for every HIV infected patients
 - b. Occasionally
 - c. Only when they come with symptoms of DM
 - d. No, not at all (skip to 3)
2. If responded a-c, means/tools of screening (More than one option is possible)
 - a. Symptoms or clinical screening
 - b. Urine dipstick
 - c. Random blood sugar (RBS)
 - d. Fasting blood sugar (FBS)
 - e. 2 hour Oral glucose tolerance test (OGTT)
 - f. Glycosylated Hemoglobin IC (Hb1C)
3. Documented DM testing for HIV infected females (Verify)
 - a. Yes, always
 - b. No, not at all.
 - c. Occasionally
4. Is there a register for DM screening and testing at the HIV clinic (verify) a. Yes b. No
5. Column with DM screening and testing in pre-ART or ART register a. Yes b. No
6. Where is the full evaluation of DM being done
 - a. At HIV clinic
 - b. Referred to DM/OPD for evaluation
 - C. Other, specify_____
7. Treatment and follow up for DM among HIV patients is
 - a. Done at HIV clinic
 - b. Refer to DM/OPD
 - c. Other specify_____

II. DM services at ANC clinics (Health care workers *at ANC clinic*)

1. Screening service of pregnant mother for DM
 - c. Yes, always for every HIV infected patients
 - d. Occasionally
 - d. No, not at all (skip to 3)
3. If responded a-c, means/tools for screening (More than one option is possible)
 - d. Symptoms or clinical screening
 - e. Urine dipstick
 - f. Random blood sugar (RBS)
 - d. Fasting blood sugar (FBS)
 - e. 2 hour Oral glucose tolerance test (OGTT)
 - f. Glycosylated Hemoglobin IC (Hb1C)
3. Documented DM testing for pregnant mothers (Verify)
 - a. Yes, always
 - b. No, not at all.
 - c. Occasionally
4. Is there a register for DM screening and testing at ANC clinic (verify) a. Yes b. No
5. Column with DM screening and testing in ANC register a. Yes b. No
6. Where is the full evaluation of DM being done
 - a. At ANV clinic
 - b. Referred to DM/OPD for evaluation
 - C. Other, specify_____
7. Treatment and follow up for DM among pregnant women is
 - a. Done at HIV clinic
 - b. Refer to DM/OPD
 - c. Other specify_____

III. Family planning and Pregnancy care at the HIV clinic (Health care workers *at HIV clinic*)

1. Counselling on family planning and pregnancy
 - a. Available
 - b. Not available at all
 - c. Only for those who asked actively

**ANNEXURE G: CONSENT TO PARTICIPATE IN IDI and FGD for the STUDY
ON ‘HUMAN IMMUNODEFICIENCY VIRUS AND DIABETES MELLITUS: A MISSED
LINK TO IMPROVE PREGNANCY OUTCOME IN ETHIOPIA’**

You are asked to participate in a research study conducted by “Zewdu Gashu Dememew”, a doctoral student at the University of South Africa (UNISA).

If you have any questions or concerns about the research, please feel free to contact the investigator: ‘Zewdu Gashu Dememew’ (Tele: +251 911768081).

PURPOSE OF THE STUDY

The purpose of the study is to develop an integrated model of care regarding HIV, DM and pregnancy care

PROCEDURES

If you volunteer to participate in this study, you will be asked to participate in an in-depth interview which will take not more an hour. You cannot be identified through your responses.

POTENTIAL RISKS AND DISCOMFORTS

The study will not impose any significant risk for participants expect minimal discomfort that might be encountered while dealing with organizational process. If you experience discomfort and wish to receive psychological support, please contact the investigator of the study for a referral.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

There will no direct benefit that would be gained by you from attending in this study. However, the results of this study can contribute to the development of integrated DM/HIV model of care essential for mothers with HIV and DM diseases.

PAYMENT FOR PARTICIPATION

There is no payment for participating in this study.

CONFIDENTIALITY

The principal investigator is responsible for ensuring confidentiality at any time. The completed data will be stored in a locked cabinet for five years and will be destroyed after five years. Only electronic copies of the data will be kept with passwords after five years. The result of the study will be communicated through journals or other outlets.

PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time.

RIGHTS OF RESEARCH PARTICIPANTS

You have full right to withdraw your consent at any time and discontinue participation without consequence. This study has been reviewed and received ethical clearance through the UNISA and Addis Ababa Health Bureau. If you have questions regarding your rights as a research participant, please contact the investigator of the study.

SIGNATURE OF RESEARCH PARTICIPANT/LEGAL REPRESENTATIVE

I have read the information provided for the study as described herein. My questions have been answered to my satisfaction, and I agree to participate in this study.

Signature of the Participant _____ Date: _____

Signature of the Witness _____ Date: _____

ANNEXURE H: QUESTION GUIDE FOR IDI AND FGD

In-depth Interview (IDI): federal ministry of health, regional health bureau and the sub-city

1. What is the effect of HIV infection on the occurrence of DM in HIV infected mothers? (Probe :How does HIV affects the occurrence of DM? OR mention if HIV can lead to DM or ARV affects the occurrence of DM among HIV infected mothers) What is the effect of HIV infection to the pregnancy of HIV infected mother? (Probe: In terms of fertility, stigma and discrimination, on pregnancy, during delivery, outcome of pregnancy).
2. What is the effect of DM on the pregnancy of the pregnant diabetic mother? (Probe:In terms of fertility, stigma and discrimination, on pregnancy, during delivery, outcome of pregnancy).
3. What is the effect of DM and HIV on the pregnancy of mothers having both diseases at the same time? (Probe: In terms of fertility, stigma and discrimination, on pregnancy, during delivery, outcome of pregnancy) What is the problem of screening and diagnosing DM or/and HIV in the health facilities? (Patients factor, Health care worker factors, health facilities factors)
4. How should Health care workers, health system, etc. handle HIV and/or DM?
5. What should the HIV and DM integration look like (probe: To what level should both be integrated?)
6. What should be done at DM/HIV/ANC/delivery room to reduce perinatal complication due to HV/DM?
7. *Why do you think pregnancy rate is high/low among HV/DM as compared to non-DM/HIV?*
8. *Why do you think.....? (Adverse pregnancy outcome) is so frequent among DM/HIV as compared to DM/HIV?*

Functional, financial & administrative integration: FMOH, regions and Sub-city program officers

A. NCD program	B. HIV program	C. Family/maternal health
1. Describe joint planning of NCD with HIV program	1. Describe joint planning of HIV with NCD program	1. Describe joint planning of family planning with HIV program
2. Describe joint planning of NCD with Family planning program	2. Describe joint planning of family planning with HIV program	2. Describe joint planning of family planning with NCD program
3. Describe joint planning of NCD, HIV program, and family planning	3. Describe joint planning of NCD, HIV program, and family planning	3. Describe joint planning of NCD, HIV program, and family planning
4. Can you tell us about the common budget for NCD/DM, HIV and maternal health	4. Can you tell us about the common budget for NCD/DM, HIV and maternal health	4. Can you tell us about the common budget for NCD/DM, HIV and maternal health

5. Can you describe the presence of guidelines, training materials, screening and diagnostic algorithm of HIV and pregnancy care	5.Can you describe the presence of guidelines, training materials, screening and diagnostic algorithm of NCD and pregnancy care	5. Can you describe the presence of guidelines, training materials, screening and diagnostic algorithm of HIV and DM care
6. How is the HIV, DM and pregnancy care integrated during supportive supervision	6. How is the HIV, DM and pregnancy care integrated during supportive supervision	6. How is the HIV, DM and pregnancy care integrated during supportive supervision
7. Describe joint needs assessment of DM, HIV and pregnancy care	7.Describe joint need assessment of DM, HIV and pregnancy care	7. Describe joint needs assessment of DM, HIV and pregnancy care
8. Can you please tell us about joint recording and reporting system of DM/NCD, HIV and pregnancy care	8. Can you please tell us about joint recording and reporting system of DM/NCD, HIV and pregnancy care	8. Can you please tell us about joint recording and reporting system of DM/NCD, HIV and pregnancy care
9. How do you see the inter-sectoral planning with regard to HIV, NCD and maternal health programs	9. How do you see the inter-sectoral planning with regard to HIV, NCD and maternal health programs	9. How do you see the inter-sectoral planning with regard to HIV, NCD and maternal health programs

A. Focused group discussion (FGD): Health care workers at DM, HIV and ANC workers

1. What is the effect of HIV infection on the occurrence of DM in HIV infected mothers? (Probe: How does HIV affects the occurrence of DM? OR mention if HIV can lead to DM or ARV affects the occurrence of DM among HIV infected mothers) What is the effect of HIV infection to the pregnancy of HIV infected mother? (Probe: In terms of fertility, stigma and discrimination, on pregnancy, during delivery, outcome of pregnancy).
2. What is the effect of DM on the pregnancy of the pregnant diabetic mother? (Probe: In terms of fertility, stigma and discrimination, on pregnancy, during delivery, outcome of pregnancy).
3. What is the effect of DM and HIV on the pregnancy of mothers having both diseases at the same time? (Probe: In terms of fertility, stigma and discrimination, on pregnancy, during delivery, outcome of pregnancy) What is the problem of screening and diagnosing DM or/and HIV in the health facilities? (Patients factor, health care workers factors, health facilities factors)
4. How should Health care workers, health system, etc. handle HIV and/or DM?
5. What should the HIV and DM integration look like (probe: To what level should both be integrated?)
6. What should be done at DM/HIV/ANC/delivery room to reduce perinatal complication due to HV/DM?
7. Why do you think pregnancy rate is high/low among HV/DM as compared to HIV.DM?
8. Why do you think.....? (Adverse pregnancy outcome) is so frequent among DM/HIV as compared to DM/HIV?

Organizational Integration

A. DM	B. HIV	C. ANC
<p>1. How do you provide HIV counselling and testing service at NCD/DM clinic? -(Probe: Is there HIV counselling and testing? How do you record the results?)</p>	<p>1. How do you provide NCD/DM counselling and testing service at HIV clinic? (Probe: Is there HIV counselling and testing? How do you record the results?)</p>	<p>1. How do you provide HIV counselling and testing services at ANC clinic? (Probe: Is there HIV counselling and testing? How do you record the results?)</p>
<p>2. How is the pregnancy care service being issued at NCD/DM clinic for females in reproductive age group (probe: Is there family planning counselling and provision? How is the recording and registration, reporting of family planning service?)</p>	<p>2. How is the pregnancy care service being issued at HIV clinic for females in reproductive age group (probe: Is there family planning counselling and provision? How is the recording and registration, reporting of family planning service?)</p>	<p>2. How is the NCD/DM service being issued at ANC clinic for females in reproductive age group (probe: Is there NCD/DM counselling and provision? How is the recording and registration, reporting of NCD/DM service?)</p>

Clinical Integration

Structure

A. DM	B. HIV	C. ANC
<p>1. Describe the presence of HIV Protocol, guideline, training materials to address HIV among diabetic mothers</p>	<p>1. Describe the presence of HIV Protocol, guideline, training materials to address HIV among diabetic mothers</p>	<p>1. Describe the presence of HIV Protocol, guideline, training materials to address HIV among diabetic mothers</p>

2. Describe the presence of a pregnancy care protocol, guideline, training materials to address pregnancy care among diabetic mothers	2. Describe the presence of NCD/DM Protocol, guideline, training materials to address NCD/DM among HIV infected mothers	2. Describe the presence of HIV Protocol, guideline, training materials to address HIV among pregnant mothers at ANC clinic
3. How do you communicate with HIV or ANC clinic if you get HIV+ pregnant mother/ (Probe: referral linkage, feedback system)	3. How do you communicate with NCD/DM or ANC clinic if you get NCD/DM or pregnant mother (Probe: referral linkage, feedback system)	3. How do you communicate with HIV or NCD/DM clinic if you get DM pregnant mother (Probe: referral linkage, feedback system)

Service delivery

A. DM	B. HIV	C. ANC
1. What do you think regarding joint training among DM, HIV and pregnancy care? (Is there joint training inclusive of all the three entities? Do you think it is feasible? Is it important?)	1. What do you think regarding joint training among DM, HIV and pregnancy care? (Is there joint training inclusive of all the three entities? Do you think it is feasible? Is it important?)	1. What do you think regarding joint training among DM, HIV and pregnancy care? (Is there joint training inclusive of all the three entities? Do you think it is feasible? Is it important?)
2. How do you think multidisciplinary team should work regarding the integration of DM, HIV and pregnancy care? (Probe: is there such MDT discussion/working about HIV, DM and pregnancy care? Do you think it is important to have such team?)	2. How do you think multidisciplinary team should work regarding the integration of DM, HIV and pregnancy care? (Probe: is there such MDT discussion/working about HIV, DM and pregnancy care? Do you think it is important to have such team?)	2. How do you think multidisciplinary team should work regarding the integration of DM, HIV and pregnancy care? (Probe: is there such MDT discussion/working about HIV, DM and pregnancy care? Do you think it is important to have such team?)

<p>3. What do you feel about the importance of putting screening and diagnostic algorithms of DM at HIV and ANC clinic? (Probe: Is there such service so far? Do you think it is usefully? Is it feasible to do so?)</p>	<p>3. What do you feel about the importance of putting screening and diagnostic algorithms of DM at HIV and ANC clinic? (Probe: Is there such service so far? Do you think it is usefully? Is it feasible to do so?)</p>	<p>3. What do you feel about the importance of putting screening and diagnostic algorithms o DM and HIV at ANC clinic? (Probe: Is there such service so far? Do you think it is useful? Is it feasible to do so?)</p>
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Process

A. DM	B. HIV	C. ANC
<p>1. What is your opinion regarding the experience and culture of having HIV counselling and testing at DM</p>	<p>1. What is your opinion regarding the experience and culture of having NCD/DM counselling and testing at HIV</p>	<p>1. What is your opinion regarding the experience and culture of having NCD/DM counselling and testing ANC?</p>

Access

A. DM	B. HIV	C. ANC
<p>1. What are the HIV related services being provided at DM? (Probe: counselling, testing, linking, treatment, follow-up)</p>	<p>1. What are the NCD/DM related services being provided at HIV? (Probe: counselling, testing, linking, treatment, follow-up)</p>	<p>1. What are the HIV related services being provided at ANC? (Probe: counselling, testing, linking, treatment, follow-up)</p>
<p>2. What are the pregnancy care related services being provided at DM clinic? (Probe: counselling, testing, linking, treatment, follow-up)</p>	<p>2. What are the pregnancy care related services being provided at HIV clinic? (Probe: counselling, testing, linking, treatment, follow-up)</p>	<p>2. What are the NCD/DM related services being provided at DM clinic? (Probe: counselling, testing, linking, treatment, follow-up)</p>

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C. HIV CLINIC

All Females 15-45 during enrollment

At least 3 months on follow-up

Name of health facility.. XICHOHMC MRN 91218

Type of health facility, a. Public Hospital b. Private Hospital

I. Socio-Demographic Characteristic ((Baseline data, at enrollment, 18-45 years females) IN Take

- 1. Age 33 years
- 3. History of diabetes mellitus in the family: a) yes b) no c) I do know

II. HIV AND ART HISTORY (PRE-ART/ART REGISTER)

- 1. Date diagnosed with HIV (DD/MM/YY Ethiopian Calendar (E.C.) 5/13/98
- 2. Where HIV diagnosis made?
 - a. HCT/VCT clinic b. DM/NCD clinic c. ANC/PMTCT d. Family planning
 - e. Outpatient department f. In-patient department g. Other, specify.....

	0 month	12 months	24 months	36 months	The latest/Current
3. Height		<u>153</u>			<u>153</u>
4. Weight		<u>53</u>			<u>57</u>
5. Viral load					<u>570</u>
6. CD4 (+) count		<u>279</u>			<u>279</u>

- 8. ART initiation status? a. Started ART b. Not started, yet
- 9. If ART started, date started (DD/MM/YY E.C.) 5/13/98
 - Regimen type 1C
 - Time Period (DD/MM/YY) for 2 month

- 10. Documented Clinical complications Date Detected/Diagnosed (DD/MM/YY)—HIV/AIDS related
 - Check For TB a. YES b. NO
 - Others _____

- 11. Other Infectious diseases (co-morbidity) Date Detected/Diagnosed (DD/MM/YY)—HIV/AIDS related
 - _____
 - _____

- 12. Other non-communicable diseases —chronic illnesses Date detected/Diagnosed
 - Check HPN a. yes b. No
 - _____

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B. Data abstraction-DM clinic
All Females 15-45 during enrollment
At least 3 months of follow-up

Name of health facility M.I.S.H. MRN 30983

Type of health facility, a. Public Hospital b. Private Hospital H. center

I. Socio-Demographic Characteristic (Baseline data, at enrollment, 18-45 years females)

1. Age 39 years

2. Date DM diagnosed (DD/MM/YY) 12/5/06

3. DM diagnosed at:
 OPD c. IPD
b. DM/NCD clinic d. HIV clinic e. Other health facility

4. Type of DM
a. GDM b. TYPE I TYPE II d. Other, specify.....
5. History of diabetes mellitus in the family: yes b) no c) I do know

6. Date diabetic treatment started (DD/MM/YY) 17/06/06
Regimen Metformine 500mg po bid for 2 months Time Period

	0 month	12 months	24 months	36 months	the latest/Current
7. Height					<u>1.55 m</u>
8. Weight					<u>67 kg</u>
9. FBS					<u>182 mg/dl</u>

10. Documented Clinical complications - CHF Date Detected/Diagnosed

11. Other co-morbid Infectious diseases Date (DD/MM/YY)
Check TB yes NO
Others

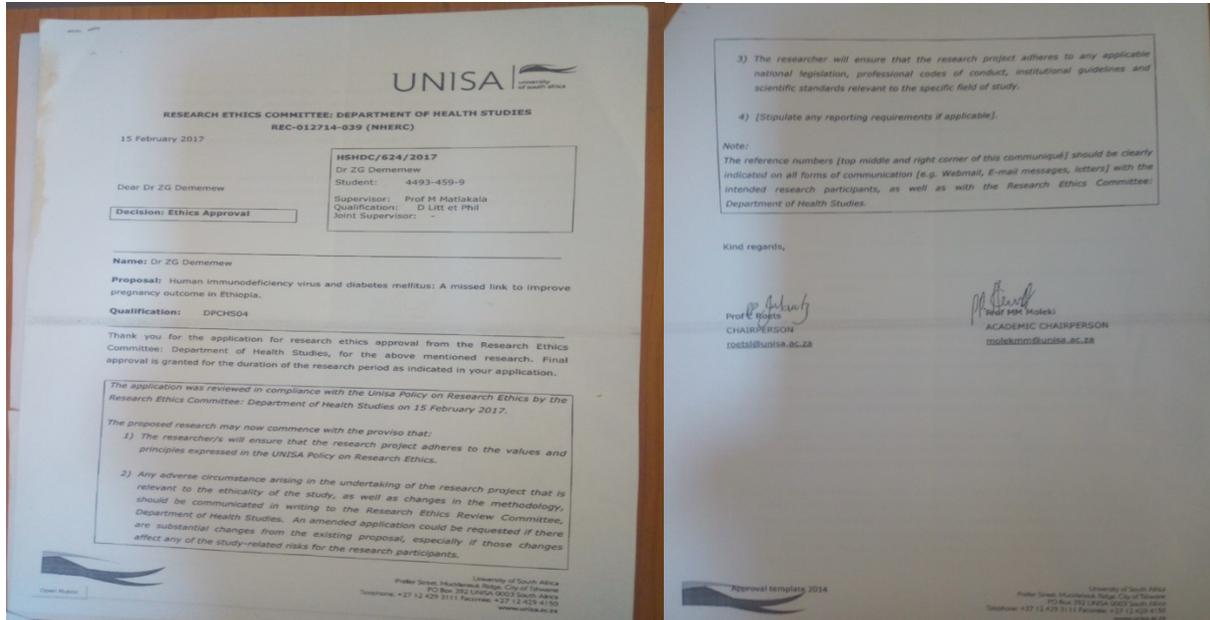
12. Other non-communicable/ Chronic illnesses Date (DD/MM/YY)
Check for HPN yes No
Others

II. HIV service at DM (Health care workers at DM +PATINETS+ FILE+REGISTER)

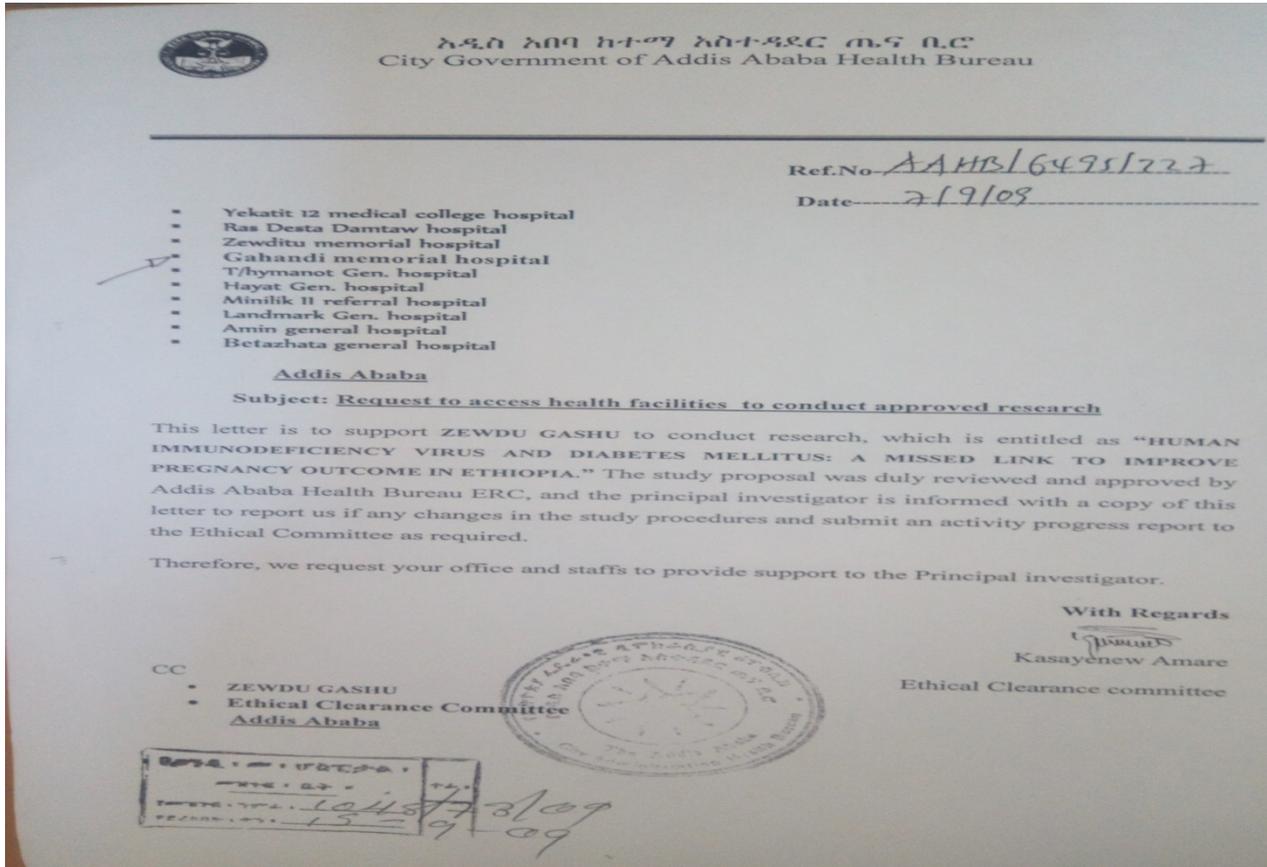
1. HIV counselling and testing offered at DM
a. Yes b. Referred to HCT/OPD for counselling and testing c. Not at all
2. Date tested for HIV (DD/MM/YY) 18/03/10
3. HIV test result a. HIV+ b. HIV-ve c. Unknown

ANNEXURE J: ETHICAL CLEARANCE AND SUPPORT LETTERS

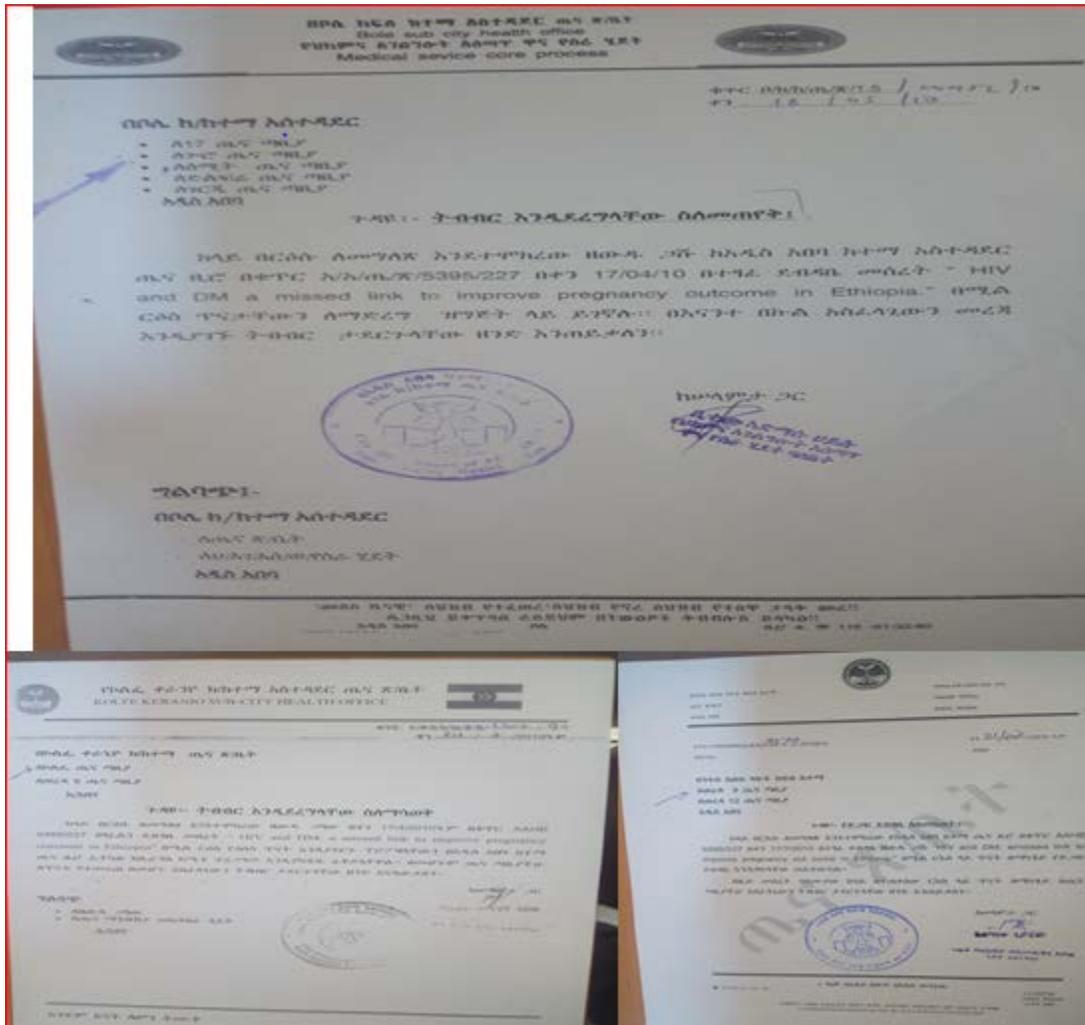
ANNEXURE J 1: Ethical clearance letter from REC of UNISA



ANNEXURE J3: Ethical clearance and support letter from Addis Ababa IRB to study hospitals



ANNEXURE J4: Ethical clearance and support letter from Addis Ababa IRB to study health centers



ANNEXURE K: EXPERTS' EVALUATION OF THE "THE TRIPARTITE SERVICE INTGRATION MODEL OF DM, HIV ANAND PREGNANCY CARE

Experts' Evaluation of the "The Tripartite Integration: DM/HIV/Pregnancy care model".

Date: -----

Educational status (just circle) ----- (Diploma, first degree, second degree, speciality, third degree)

Age: -----

Sex/Gender -----

Year of experience (in year): -----

- ◆ At health facility (working as a clinician) -----

The clinic or department you spend most of your time as a clinician-----

- ◆ On the program -----

Mention the name of the program you spend most of your time-----

Dear peer,

This is a newly suggested model of care at **administrative level (FMOH, region and sub cities) and health facility level** at A.A.

Aim of the evaluation to check (with you as an experienced health care worker) whether the suggested care of model is applicable as it is or need to be revised or not applicable at all. After reading the following section you are asked to evaluate the model based on the criteria mentioned in the table. **THANK YOU FOR TAKING YOUR TIME TO EVALUTE!**

Objective of the model

The model is developed based on the suggestion from HCW and program officers at FMOH, AACHB, sub-cities and health facilities in A.A. The main objective of the model is to reduce or minimize adverse pregnancy outcome among reproductive age group females with DM and HIV by integrating the pregnancy care, DM and HIV services at all levels.

Definition of terms

Pregnancy care: counselling on conception/being pregnant, urine pregnancy test, provision of one of the modern family planning, all comprehensive anti-natal care (ANC) and delivery service.

HIV services: counselling on HIV prevention, testing of HIV, clinical and laboratory evaluations, adherence support, provision of ART and the follow-up care.

DM care:, screening for DM using urine or blood test of fasting or random sugar, treatment of DM and follow up care.

The model: description of the model

Please put "X" inside the box you think you grade/evaluate the item based on the criteria (You may look at the model/diagram again before evaluation).

Ser No.	Criteria	Totally disagree	disagree	Agree	totally agree
1	Clarity				
2	Simplicity				
3	Consistency				
4	Generalizability or transferability				
5	Importance				
6	Practicability				
7	Feasibility				

General comment (Brief suggestion and area for improvement) -----

THANK YOU AGAIN FOR TAKING YOUR TIME TO EVALUTE!

ANNEXURE L: CONDENSED CV DEMEMEW, Zewdu Gashu Dememew

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E-mail: zewdugashudememew@yahoo.com, zgashu@msh.org
Skype: hiruy.gashu

Education

1997-2004: Doctor of Medicine (MD), Addis Ababa University, Ethiopia
2010-2014: MPH, UNISA-University of South Africa University, Department of Health Studies.
2016-till now: a candidate of Doctor of literature and philosophy at University of South Africa University, Department of Health Studies.

Research and publication experience

1. **Zewdu Gasu** et al. The Yield of Community-Based "Retrospective" Tuberculosis Contact Investigation in a High Burden Setting in Ethiopia. (<http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0160514>)
2. **Dememew, Z.G.**, et al., 2016. Trends in tuberculosis case notification and treatment outcomes after interventions in 10 zones of Ethiopia. *The International Journal of Tuberculosis and Lung Disease*, 20(9), pp.1192-1198. (<http://www.ingentaconnect.com/contentone/iatld/ijtd/2016/00000020/00000009/art00014>).
3. **Zewdu Gashu et al.** 2018. Seasonal patterns of tuberculosis case notification in the tropics of Africa:A six-year trend analysis in Ethiopia. *PloS one*.
4. Joanna L, **Gashu Z**, et al. 2018. Provider barriers, enablers, and incentives associated with the use of Isoniazid Preventative Therapy among HIV Patients in Ethiopia. *The Union J*.
5. Asfaw Ayelew, **Zewdu Gashu** et al. 2018. Improvement in tuberculosis infection control practice via technical support in two regions of Ethiopia. *BMC Infectious Diseases*
6. Yirdaw, K.D., Jerene, D., **Gashu, Z** et al. 2014. The beneficial effect of isoniazid preventive therapy and antiretroviral therapy on the incidence of tuberculosis in people living with HIV in Ethiopia. *PloS one*,9(8), p.e104557. (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4126726/>)
7. Tadesse, Y., Gebre, N., Daba, S., **Gashu, Z** et al. 2016. Uptake of Isoniazid Preventive Therapy among Under-Five Children: TB Contact Investigation as an Entry Point. *PloS one*, 11(5), p.e0155525. (<http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0155525>)
8. Habte, D., Melese, M., Hiruy, N., **Gashu, Z.**, et al. The additional yield of GeneXpert MTB/RIF test in the diagnosis of pulmonary tuberculosis among household contacts of smear positive TB
9. Trends in Treatment Outcome of New and Retreatment Tuberculosis Cases in Two Regions of Ethiopia (Poster presented on The Union conference 2015/Cape Town)
10. The additional yield of GeneXpert MTB/RIF test in the diagnosis of pulmonary tuberculosis among household contacts of smear positive TB cases. *International Journal of Infectious Diseases*, 49, pp.179-184. ([http://www.ijidonline.com/article/S1201-9712\(16\)31109-2/fulltext?rss=yes](http://www.ijidonline.com/article/S1201-9712(16)31109-2/fulltext?rss=yes))
11. The experience of scaling up a decentralized, ambulatory model of care for management of multidrug-resistant tuberculosis in two regions of Ethiopia (<http://www.sciencedirect.com/science/article/pii/S2405579416300407>)
12. Use of indicators of standards of care to improve tuberculosis program management in Ethiopia <https://www.sciencedirect.com/science/article/pii/S2405579417300438>
13. **Dememew ZG** & Phaladz N. Fertility Desire, Intention and Associated Factors Late in HIV Epidemic among People Living with HIV: A cross-sectional study in Southern Ethiopia (UNISA Library).

Short-term trainings

- Certificate of the 28th Annual Graduate Summer Institute of Epidemiology and Biostatistics, including two weeks workshop I & II of data analysis using STATA and Conducting Epidemiologic Research, at Johns' Hopkins University Bloomberg School of Public Health, July 2010.
- A Certificate on "*PH207x: Health in Numbers: Quantitative Methods in Clinical & Public Health Research with STATA*", a course of study offered by Harvard, an online learning initiative of Harvard University through edX. October 1, 2012-February 1, 2013. (Four month course with STATA software)
- Credit Certificate on Qualitative and Mixed Method (QMM) of research using Nvivo software in Belgium, Antwerpen, and January 27-February 22, 2014.
Research Ethics Training Curriculum, FHI June 21, 2012
- Certificate on From Research to Practice: Workshop on SRH including STI/HIV Research, Geneva, Switzerland August 27-September 2, 2012.
- Certificate on From Research to Practice: Training Course on SRH Research Adolescent. The Geneva Foundation for Medical Education and Research in collaboration with WHO, May-November 2011

Work experience

1. May 3, 2016-Till now: Senior TB/HIV and Childhood TB adviser, Challenge TB/USAID

2. June 16, 2014 – April 30, 2016: Implementation Research Coordinator (M/E and Operational Research Unit), Heal TB/MSH/USAID

2. November 1, 2011-December 30, 2013: Lead TB/HIV Advisor, Technical Support for the Ethiopian HIV/AIDS ART Initiative (TSEHAI), Addis Ababa, Ethiopia

3. October 12, 2010- Nov1, 2011: TB/HIV and ART Advisor, Technical Support for the Ethiopian HIV/AIDS ART Initiative (TSEHAI) HAWASSA, Ethiopia.

4. June 6, 2007-October 12, 2010: HIV/AIDS Clinical Advisor (Mentor) and Site Support Team Lead, Technical Support for the Ethiopian HIV/AIDS ART Initiative (TSEHAI) Hawassa, Ethiopia.

5. September 11, 2004--June 1, 2007: Attat Hospital (Rural Hospital in SNNPR)

Language:

Amharic (Speak, read and write)

English (Speak, read and write)

Oromiffa (speak, read and write)

Basic computer skills

Introduction to computer, MS Word, MS Excel, MS Access, PowerPoint, STATA and EPI-INFO, Nvivo, SPSS