ARE WOMEN FREE TO OPT OUT?
IMPLEMENTATION FIDELITY OF THE 'OPT-OUT' HIV TESTING FOR PREGNANT WOMEN IN GHANA

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ABSTRACT

In 2008, Ghana adopted WHO/UNAID's provider-initiated opt-out HIV testing policy and integrated it into all maternal services. The intervention's central principle was that women are free to choose whether or not to test for HIV (**C**onsent), assured of **C**onfidentiality, **C**orrect test results, **C**onnection to care, and **C**ounselling services(referred to as 5Cs). However, the weak healthcare infrastructure, low hospital staffing levels, hierarchical and paternalistic nursing and midwifery culture in sub-Saharan Africa were considered potential threats to achieving rights-based testing. Despite these concerns, much mainstream HIV testing research had focused on outcome-related to report high HIV test uptake among women attending the antenatal clinic. However, the reported high testing uptake had not produced the desired impact, as many women testing positive for HIV did not enter care. To date, no process evaluation exists to explain these outcomes. The current study recognises the need for a careful examination of the delivery process. Therefore, it has aimed to evaluate the antenatal clinic-based opt-out HIV testing programme's implementation fidelity to explain the observed outcomes.

Employing a mixed-methods design and guided by Carroll's seminal conceptual framework of implementation fidelity, the study collected quantitative and qualitative data from 12 antenatal clinics in Ghana. Adherence was measured quantitatively through brief facility surveys, healthcare provider and pregnant women self-reports and structured observation of counselling sessions at the antenatal clinic. Interviews with key informants, healthcare providers and women, and the keeping of field notes provided qualitative data. Descriptive statistical analysis of the quantitative data was used to describe the sample and antenatal clinic characteristics. To calculate fidelity scores, percentage means and standard deviation(SD) of components delivered were used. Qualitative data were analysed using framework analysis, aided by NVIVO data analysis software.

Routine testing of women for HIV was widely available in all the 12 antenatal clinics, and testing among pregnant women was high (98.1%). Many healthcare providers were, however, unaware of the opt-out approach for offering HIV test. Instead of group pre-test discussions, many clinics delivered information about HIV through individual pre-test

counselling. Adherence to the core principles of consent, confidentiality, counselling, and connection to care was low (38%) for direct observation, moderate (54%) for pregnant woman self-reports and moderately high (78.9%) for healthcare provider self-reports. Implementation of the opt-out intervention at the health facilities was fraught with challenges due to the complex nature of the opt-out intervention, lack of facilitation of intervention delivery, beliefs about autonomy that were not in line with the intervention's underlying principles, and antenatal contextual constraints. The outcome of this thesis is a proposed human rights framework supporting rights-based testing in the antenatal clinic. The framework provides a structured, comprehensive, and context-specific approach to support future rights-based interventions and research.

The study concludes that implementation fidelity was low to moderate for all the 5Cs of the opt-out intervention. Thus, in the context of this study, no claims can be made about the opt-out testing's ability to increase HIV testing uptake as widely reported. The absence of impact in terms of linkage to care and other behavioural outcomes is best explained by the low implementation fidelity, poor facilitation, complex and unfamiliar intervention, and a misfit between demands of the intervention and realities of the antenatal clinic setting. The findings highlight the need for culturally appropriate HIV testing guidelines that incorporate shared or relational decision-making approaches acceptable to women. The findings also generate new insights into the need to make programmes more straightforward, engage healthcare providers, and offer supportive supervision to equip them with the skills and knowledge needed to implement such complex intervention.

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AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Clinic
ART	Antiretroviral therapy
CDC	Center for Disease Control and Prevention
CFIF	Carroll's Framework of Implementation Fidelity
CHPS	Community-Based Health Planning and Services
CIA	Central Intelligence Agency
GAC	Ghana AIDS Commission
GHS	Ghana Health Service
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
HTS	HIV testing services
MDG	Millennium Development Goals
MNCH	Maternal Newborn and Child Health
MoH	Ministry of Health
MTCT	Mother-to-child transmission
NACP	National AIDS/STI control programme
NHIS	National Health Insurance Scheme
PITC	Provider-initiated Testing and Counselling
PMTCT	Prevention of Mother-to-child transmission
SDG	Sustainable Development Goals
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary Counselling and testing
WHO	World Health Organisation

Vignette

Ruth is in her late 20s and had been married for more than three years. She made several attempts at pregnancy but had been unsuccessful. On this day, Ruth found herself at the antenatal clinic (ANC), hoping to hear from the midwife that her baby was 'growing well'. The clinic was rather busy and overcrowded. Eventually, it got to her turn to see the midwife. The consulting room was no different from the waiting area. There were three other staff members in the room, each performing a different role. One midwife took her history and examined her. After this, a second midwife approached her:

> ***Staff:*** *Have you been tested for HIV in this pregnancy? (She asked this while standing in front of Ruth and looking down at her.)*
> ***Ruth:*** *'No'*
> ***Staff:*** *'As part of the government's policy to prevent the unborn child from getting HIV, we will test you for HIV. If you have the disease, you will receive treatment that prevents the diseases from getting to your child. Should I go ahead?'*
> ***Ruth:*** *(nodded in agreement).*

Ruth was too scared to say no, although she did not adequately understand what the midwife said. Moreover, she did not consider herself at risk for HIV. Fifteen minutes later, the midwife informed Ruth that she was HIV positive. The midwife offered instructions on what she must do, including antiretroviral drugs the same day. She then asked whether Ruth had any questions. Ruth was still in shock and trying to process what the midwife had told her. She sat there, reflecting on how the other women waiting in the queue would not be aware of her new HIV positive status and worried about informing her husband without getting divorced.

1 CHAPTER ONE: INTRODUCTION

1.1 Introduction

This vignette describes how HIV testing unfolds for many women in sub-Saharan Africa (SSA) and illustrates the process of opt-out HIV testing in Ghana. The testing approach assumes that every pregnant woman has agreed to test unless she explicitly says 'no'. Ghana has utilised this approach in testing pregnant women since 2008. This study evaluates the opt-out intervention's implementation to understand healthcare providers' adherence to the core principles of consent, confidentiality, correct test results, counselling, and connection to care (5Cs).

1.2 Background of the Study

The Joint United Nations Programme on HIV and AIDS (UNAIDS) estimates that in 2018, 37.9 million people were living with the human immunodeficiency virus (HIV) (UNAID'S Fact Sheets, 2019). The number includes 18.8 million women and 2.8 million children between 0 and 19 years. Each day in 2019, approximately 880 children became infected with HIV, and an estimated 310 children died due to AIDS-related causes (UNAIDS estimates, 2020). Sub-Saharan Africa, the epicentre of HIV, accounts for approximately 68 per cent of people of all ages and 90 per cent of the 1.1 million children (0-9 years) living with HIV. If left unchecked, paediatric HIV infections might reverse the recent gains in child survival rates. Nearly all infected children got HIV through mother-to-child transmission (MTCT)[1]. In Ghana, the Ghana AIDS Commission (GAC) (2019) estimated that 2,971 children acquired HIV in 2019 through MTCT. At 2%, Ghana has the fourth-highest rate of MTCT of HIV among the 23 high burden countries identified by UNAIDS and the second highest in West Africa (World Health Organisation [WHO], 2021). The high rate of MTCT of HIV was either because pregnant

[1] MTCT is the passage of HIV from a pregnant woman diagnosed with HIV to her unborn child or infant and usually mostly occurs around the time of delivery (Bertolli et al., 1996).

women did not know they were HIV positive or did not initiate treatment to interrupt transmission to their babies (Avert, 2017). Without treatment, a baby's chance of getting infected ranges from 15-25% in wealthy countries and 25-35% in resource-poor countries (WHO, 2018).

Before 1994, the chances of a mother transmitting HIV to her child ranged from 15% to 40% (Clark, 2006). Findings of the AIDS Clinical Trial Group Protocol 076 (ACTG 076), however, demonstrated that a woman infected with HIV could reduce the chances of transmitting the virus to the infants by as much as two-thirds by the administration of Zidovudine[2] (De Cock, Bunnell, & Mermin, 2006; Fetene & Feleke, 2010; WHO/UNAIDS, 2007a). It is now scientifically evident that transmission can be interrupted if a woman adopts MTCT prevention methods (Both & van Roosmalen, 2010; Horwood et al., 2012). In high-income countries, preventive interventions have demonstrated effectiveness in reducing the MTCT rate to about 2% (Reeves, 2011). No such improvements have been evident in SSA. To address this gap, the UNAIDS launched the Super Fast-Track Framework and Action Plan that targeted 23 priority countries, including Ghana (Figure 1). In 2016, these countries became home to 87% of new HIV infections among children (UNAIDS, 2017b). The Super Fast-Track Framework and Action Plan target included minimising the number of children newly infected with HIV to fewer than 40,000 by 2018 and fewer than 20,000 by 2020. There is also a significant commitment to ensuring 95% of pregnant women living with HIV receive antiretroviral therapy (ART) (Avert, 2020). The current global target is to end AIDS as a public health threat by 2030.

[2] An antiretroviral medication used to prevent and treat HIV/AIDS

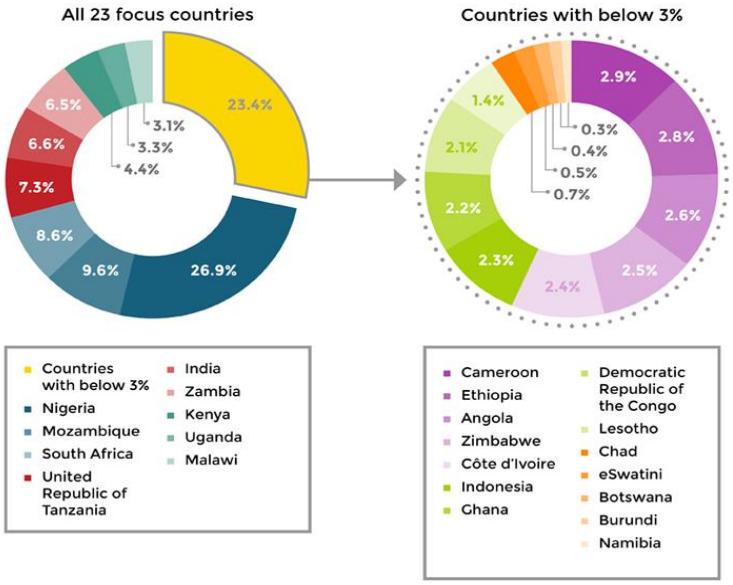


Figure 1: Distribution of children infected through MTCT, 23 focus countries, 2016

Source: UNAIDS (2017a) estimates.

The preventive measures of ART are promising. However, to benefit from these services, the pregnant woman must become aware of her HIV status and be connected and adhere to the prevention of mother-to-child transmission (PMTCT) processes (Ben-Natan & Hazanov, 2015). HIV testing and counselling (HTC) becomes a critical gateway to treatment, care, and support (Zakher, Blazina, & Chou, 2014). Becoming aware of one's HIV status may empower individuals to make informed personal decisions about using various prevention options, minimising HIV transmission, morbidity, and mortality (Rujumba, Neema, Tumwine, Tylleskar, & Heggenhougen, 2013a). The beneficial effects of HIV testing have resulted in efforts to get more pregnant women testing in the antenatal clinic (King, Maman, Wyckoff, Pierce, & Groves, 2013b).

In 2006, the Center for Disease Control and Prevention (CDC) produced new guidelines on HTC in the United States of America (USA) (Branson, 2006). Subsequently, in May 2007, UNAIDS/WHO revised these recommendations leading to its adoption by the United Nation's member countries (NACP, 2010; WHO/UNAIDS, 2007a). The Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities (from now on 2007 WHO/UNAIDS guidance) recommended that HIV testing be offered in settings with high HIV prevalence. The 2007

WHO/UNAIDS guidance document aims to scale up provider-initiated HIV testing and counselling to improve individuals' health through timely detection of HIV and management through ART.

1.2.1 Setting the scene: the rise and fall of HIV exceptionalism

Since its first description in 1981, HIV has been viewed differently from other infectious diseases (Bayer & Edington, 2009). For a disease that had no treatment options, a positive diagnosis meant death. People living with HIV at the time suffered widespread stigmatisation and discrimination before their death. These reasons caused many to argue that routinely testing individuals was dangerous, unnecessary, and inappropriate as it offered no immediate or long-term benefit. As claimed by human rights activists at that time, the population affected by HIV was primarily individuals who were already marginalised by their society (e.g. homosexuals) and therefore did not require the extra burden of knowing their status (Bayer & Edington, 2009). Conversely, others advanced the argument that HIV testing was the key to encouraging individuals to change their behaviour. Therefore, early debates about HIV testing and counselling were shaped by these two perspectives, which resulted in 'HIV exceptionalism' (Bayer & Edington, 2009).

Those who espoused HIV exceptionalism considered HIV a rare disease. Its association with human sexuality meant that one required specific guidelines to protect patient autonomy in the decision-making process (Bayer & Edington, 2009; Gruskin et al., 2008b). For this reason, healthcare providers did not routinely test individuals in hospitals except for blood donors and individuals volunteering to test (Voluntary Counselling and Testing [VCT]) (Bayer & Fairchild, 2006). Health care providers needed to take patients testing for HIV through a separate consent process, beyond the implied consent associated with health care delivery. The stringent consent process, which involved pre-and post-test counselling, informed consent and confidentiality, was meant to ensure patient rights (Granich, Gilks, Dye, De Cock, & Williams, 2009).

The exceptionalist view of HIV continued until the mid-90s, when evidence emerged that ART could radically reduce the transmission rate of HIV and change the clinical course of HIV and

AIDS (Connor et al., 1994; Pennisi & Cohen, 1996). While the availability of highly effective treatment was good news for the Western world, sub-Saharan Africa, the epicentre of the HIV infection, had no access to these treatments (Matovu & Makumbi, 2007). With only around one per cent of the population highly affected by HIV having access to ART in 2001, WHO declared a global emergency, leading to a series of initiatives that saw the expansion of ART access to developing countries (Macklin, 2005). Following this, the United States President's Emergency Plan for AIDS Relief and the Global Fund to combat AIDS, malaria and tuberculosis extended more funding to include ART access.

Despite the wide availability of ART in developing countries, many people living with HIV could not benefit from it, as only 10% of the population knew their positive status (WHO, 2007). People became aware of their HIV status only when they visited the hospital because they were seriously sick, by which time ART's administration was less useful (Becker, Tsague, Sahabo, & Twyman, 2009). Early detection and awareness of the HIV status, therefore, became a key HIV management strategy. The HIV exceptionalism argument was revisited to conclude that the exceptional approach to testing was no longer ideal. In effect, the UNAIDS and WHO decided to make HTC a standard clinical practice in all settings (Bayer & Fairchild, 2006). The two organisations also suggested that the elaborate process of pre-test counselling, written informed consent and exceptional handling of those testing positive could be seen as constituting a barrier in itself, as it drew attention to those testing positive (De Cock et al., 2006; WHO/UNAIDS, 2007a). These decisions resulted in the substitution of client-initiated testing and counselling (CITC) with provider-initiated testing and counselling (PITC) as the standard for offering HIV testing in health institutions (Makhunga-Ramfolo, Chidarikire, & Farirai, 2011).

1.2.2 Setting the scene: 'normalising' HIV testing through PITC opt-out

PITC emerged to address the concerns of low uptake of HTC. In PITC, the responsibility for initiating HIV testing shifted from the individual patient to the health care practitioner (Kennedy et al., 2013; WHO & UNAIDS, 2007). The UNAIDS and WHO promoted routine PITC together with client-initiated HIV testing policies (WHO/UNAIDS, 2007b). The approach

allowed governments to champion the public health goal of aggressively promoting increased testing while enabling the individual to remain in control of the choice to be tested (Rennie & Behets, 2006). Three categories of PITC exist; symptom-based, routine opt-in and routine opt-out testing. In symptom-based testing, the healthcare provider identifies and offers to screen patients who are symptomatic for HIV. In routine opt-in testing, providers ask patients visiting the health facility whether they would like to be tested, irrespective of their presenting symptoms. Routine opt-out testing occurs when healthcare providers inform patients that HIV testing is part of the health facility's standard test. Consent is assumed unless the individual declines explicitly (opt-out) (Ahmed et al., 2016; Branson et al., 2006; WHO/UNAIDS, 2007b). Routine opt-out takes away the need for prolonged and detailed pre-test counselling, replacing it with streamlined pre-test information that addresses the minimum standard for informed consent (WHO & UNAIDS, 2007).

The literature has linked increases in testing uptake to the adoption of the routine opt-out approach (Chandisarewa et al., 2007; Deressa et al., 2014; Staveteig, Croft, Kampa, & Head, 2017; Ujiji et al., 2011c). However, for a policy directed at women, such an increase in testing uptake has been met with some level of scepticism (King, Maman, Wyckoff, Pierce, & Groves, 2013a). For example, one cannot be sure that health care providers truly obtain informed consent in a setting characterised by power imbalance and unfavourable gender norms (Csete & Elliott, 2006; Gruskin, Ahmed, & Ferguson, 2008a; Sakyi et al., 2020). It is also unclear how the streamlined consent process and rapid testing implemented in a busy and often overcrowded clinic adequately prepare a pregnant woman to handle the challenges that naturally come with HIV testing (Galletly, Pinkerton, & Petroll, 2008). Further, midwives find it challenging to counsel women who test positive for HIV (Campbell & Bernhardt, 2003). There is indeed evidence that women who have tested positive for HIV have had to deal with stigma (Peltzer, Mosala, Shisana, Nqueko, & Mngqundaniso, 2007) and abandonment (Maman, Groves, King, Pierce, & Wyckoff, 2008; Maman et al., 2003; Pool, Nyanzi, & Whitworth, 2001). HIV remains an exceptional experience for pregnant women.

Policymakers anticipated these challenges and instituted measures to protect individuals who were offered testing through the opt-out approach. These measures developed by the

UNAIDS in conjunction with other human rights organisations underpinned 'the 3Cs' of HIV testing: *consent* that is informed and voluntary, adequate *counselling* services, and a testing process, including *confidential* results (UNAIDS, 1996). In 2013, the UNAIDS and WHO released its consolidated guidelines, incorporating measures to secure individuals' human rights. The guidelines recommended the rights-based approach to deliver HIV testing services. They included two more components to the 3Cs: *correct* test results and *connection* to care, treatment and prevention services (WHO, 2015a). Therefore, the five Cs of consent, counselling, confidentiality, correct test results and connection to care would constitute the human rights lens used in this research to assess the policy's implementation.

1.3 The rationale for undertaking this process evaluation.

In 2008, Ghana adopted the WHO/UNAIDS guideline for PMTCT and promoted a routine, 'opt-out' HIV testing approach in all antenatal clinics (GAC, 2008). In adopting the policy, Ghana aimed to increase testing uptake while ensuring that women enjoyed a rights-based testing process. However, achieving the public health interest of an increased test uptake and respecting women's rights has been deemed incompatible for many reasons, especially in the sub-Saharan African context (Evans & Ndirangu, 2009). For example, it has been of concern that making HIV testing routine in the antenatal clinic may reduce the healthcare providers' awareness of related ethical issues (Rennie & Behets, 2006). Commentators also cited the damaging impact of overcrowded hospitals, lack of private spaces and staff shortage on rights-based testing (De Cock et al., 2006; Durojaye, 2008; Gruskin et al., 2008a). Commentators further expressed doubt about how rights-based HIV testing could be advanced in many sub-Saharan African countries where nursing and midwifery practice is described as 'task-oriented' and operated within a 'hierarchical, paternalistic and authoritarian system' (Bennett, 2007b; Evans & Ndirangu, 2009, p. 728; Obi & Ifebunandu, 2006).

The opt-out approach for obtaining consent itself has been poorly and inconsistently described in policy documents (King et al., 2013b; Maman et al., 2008), making it difficult to put into practice (Francis-Graham et al., 2019; Grodensky, Rosen, Hino, Golin, & Wohl, 2016;

Montoy, Dow, & Kaplan, 2016a; Rosen et al., 2015). Such a situation may lead to the healthcare provider misinterpreting the policy and offering the test through either the opt-in approach or by engaging in other mandatory practices (de Zulueta & Boulton, 2007b; Francis-Graham et al., 2019; Montoy et al., 2016a).

Despite these concerns, mainstream HIV testing research from Ghana and other sub-Saharan countries has remained outcome-related and has reported high test uptake in the antenatal clinic (Ayisi Addo et al., 2018; Holmes, Preko, Bolds, Baidoo, & Jolly, 2008; Nyuzaghl, Ohene, & Odoi-Agyarko, 2011; Tetteh & Agyarko, 2017). These studies have recorded high but variable testing uptake, ranging from 29% to 87%; suggesting implementation differences across settings (Calderon et al., 2009; Haukoos et al., 2010; Lubelchek, Kroc, Levine, Beavis, & Roberts, 2011; Lyons et al., 2013; White et al., 2011). The reported desired impact of increased uptake is contingent on women being linked to and retained in the HIV care continuum (WHO/UNAIDS, 2007b). However, many women testing positive for HIV do not enter PMTCT services (Boateng & Awunyo-Vitor, 2012; Dako-Gyeke et al., 2016a; Sifa, Manortey, Talboys, Ansa, & Houphouet, 2019) and fail to disclose their new status to their partners (Poku, Owusu, Mullen, Markham, & McCurdy, 2017; Rujumba et al., 2012; Tam, Amzel, & Phelps, 2015; Wilkinson & Arora, 2015). Reasons for the lack of impact remains unclear in the HIV testing literature.

Two hypotheses may explain the apparent lack of impact: either the opt-out HIV testing intervention has been ineffective, or implementation was incorrect (Van den Branden, Van den Broucke, Leroy, Declerck, & Hoppenbrouwers, 2015). Researchers explore the latter through implementation fidelity, which involves comparing the intervention as contained in policy documents and the intervention as delivered. This helps differentiate intervention failure (i.e., lack of effectiveness) and implementation failure (i.e., incorrect delivery) (Pérez, 2016; Proctor, Powell, & McMillen, 2013). Therefore, insights from implementation fidelity studies help researchers, donors, and key stakeholders make sense of the effect of a programme and discern the intervention's strengths and weaknesses, leading to the continuous improvement of the interventions (Meyers, Durlak, & Wandersman, 2012). By facilitating the interpretation of the intervention’s implementation and its results,

implementation fidelity strengthens internal validity (Bodson, 2018). It helps avoid Type III errors in evaluation, where one mistakenly attributes a lack of effect to the intervention itself without considering the quality of implementation (Basch, Sliepcevich, Gold, Duncan, & Kolbe, 1985; Dobson & Cook, 1980).

To date, no study in Ghana or elsewhere had examined implementation fidelity of the opt-out HIV testing intervention in antenatal settings. Implementation fidelity becomes essential as the world targets using an opt-out HIV testing approach to attain zero HIV infection by 2030 (UNAIDS, 2019). Examining the level of fidelity to the five human rights principles (5Cs) would offer essential insights into how women's rights are (or are not) addressed in Ghana's antenatal clinics while delivering the intervention. It also suggests ways in which the testing process can be improved operationally to promote rights-based testing. The current study moves beyond the outcome data to report the fidelity of implementation by assessing whether the opt-out intervention has been delivered as intended and ascertain the factors moderating the observed adherence levels.

1.4 Aim and questions of the process evaluation.

The study aimed to evaluate the extent to which healthcare providers delivered the antenatal-based opt-out HIV testing intervention as contained in the HIV testing guidelines (adherence) and the factors that moderated the observed adherence levels (moderators). The adherence dimension addressed was *content* and defined in this study as consent, confidentiality, counselling, correct test results and connection to care. *Moderating factors* considered in this study were the opt-out's complexity, level of facilitation, the responsiveness of both the health care providers and the women to the programme, and the antenatal clinic context. The two objectives (adherence and moderators) generated the following questions:

1. **Objective 1**: To examine the level of *adherence* to the opt-out intervention
    a. To what extent do healthcare providers understand and adhere to the opt-out approach when offering HIV testing?

b. To what extent do healthcare providers adhere to the recommended 5Cs when offering HIV testing?

2. **Objective2:** To examine factors that *moderated* the opt-out intervention delivery
    a. Is the policy adequately explained in programme guidelines?
    b. What is the level of support for healthcare providers in terms of guidelines, training, supervision, and feedback?
    c. How do healthcare providers and pregnant women perceive the experience of opt-out HIV testing in the clinic?
    d. What contextual factors influence the delivery of the opt-out intervention?

I have summarised the relationship between the rationale of the study and evaluation questions in Table 1. The relationship between study objectives, conceptual framework and methods employed in answering these questions is seen in Figure 2 (*pp.*12).

Table 1:Summary of rationale, objectives, and evaluation questions

Problem statement/rationale	Objective	Evaluation questions
Issue 1: the need to understand the process of opt-out intervention delivery in terms of adherence to the content of consent, confidentiality, correct test results, counselling, and connection to care	To examine the level of adherence to the opt-out intervention	a. To what extent do healthcare providers understand and adhere to the opt-out approach when offering HIV testing? b. To what extent do healthcare providers adhere to the recommended 5Cs when offering HIV testing?
Issue 2: the need to understand context-specific factors that affected the observed level of adherence	To examine factors that moderated the opt-out intervention delivery	a. is the policy adequately explained in programme guidelines? b. what is the level of support for healthcare providers in terms of guidelines, training, supervision, and feedback? c. how do healthcare providers and pregnant women perceive the experience of the opt-out HIV testing in the clinic? d. what contextual factors influence the delivery of the opt-out intervention?

5Cs= Counselling, confidentiality, correct test results, connection to care, and counselling

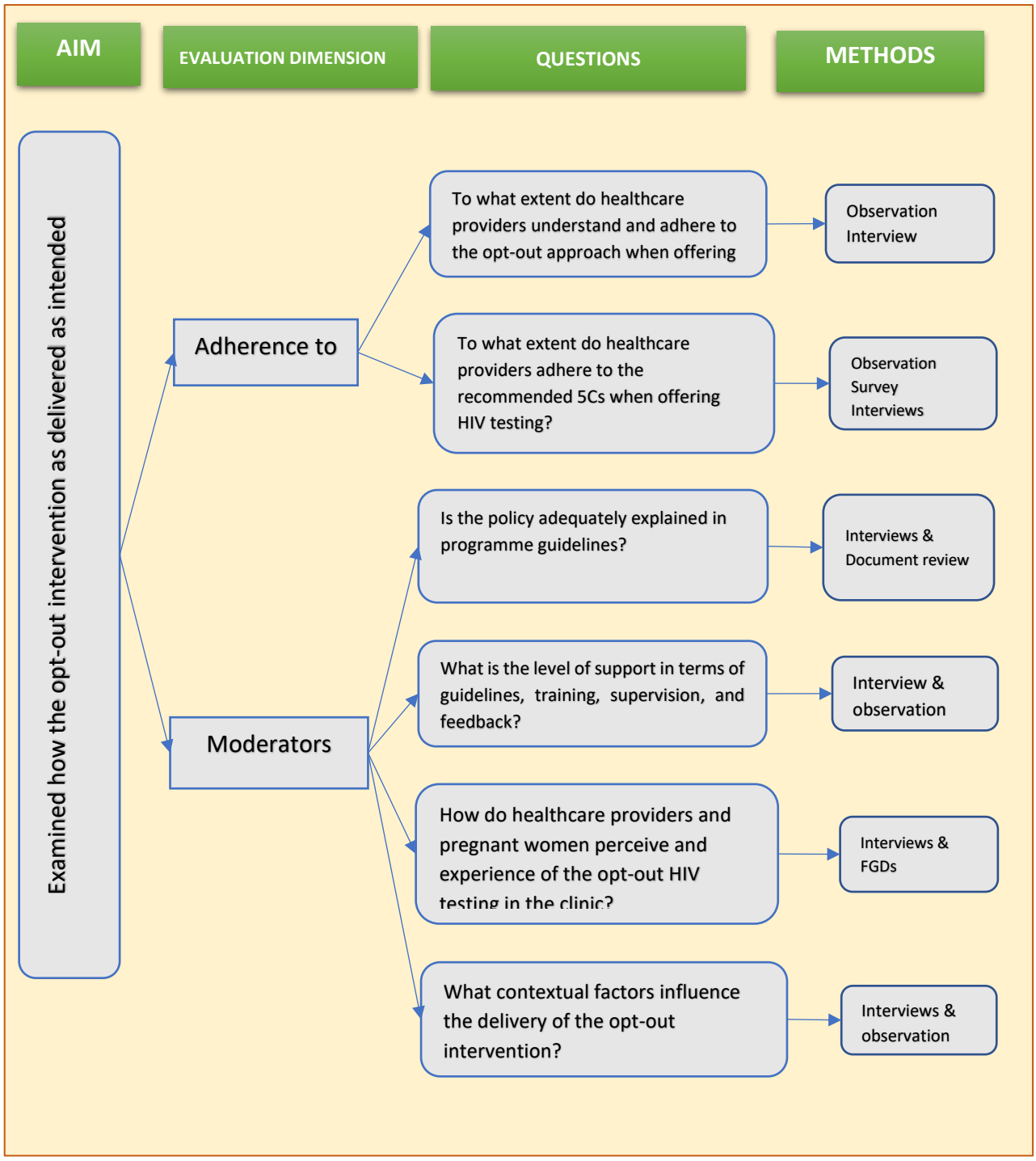


Figure 2: Summary of the aim, objectives, and methods

1.5 Defining concepts

Anyone new to the field of implementation fidelity would be confronted with several terms while reading this thesis. Such diversity of terminologies often used interchangeably is not unique to this study. Implementation fidelity is an emerging field and lacks the standardised vocabulary to explain some commonly used concepts (Carroll et al., 2007; Colquhoun et al., 2014; Dusenbury & Brannigan, 2003). In line with the conceptual framework used for this study (Carroll et al., 2007), the *fidelity of implementation* refers to how health care providers delivered the programme as intended by the programme developers and in line with the programme model (Carroll et al., 2007; Lee, Altschul, & Mowbray, 2008). The measure of adherence is a measure of implementation fidelity. I will use adherence from now on. Although nurses and midwives were the focus of this study, several other healthcare providers performed the test. Unless making specific reference to nurses or midwives, I will stick to the generic abbreviation healthcare providers. Lastly, until recently, midwifery was considered a specialty field for many nurses. To become a midwife, therefore, meant one had to have completed some nursing qualification. Many of the midwives encountered on the field were, thus, once nurses. The use of 'nurses' in this thesis would, in most cases, be referring to midwives as well.

1.6 Personal reflection

How did being 'me' and not anyone else affects the focus and decisions taken in this thesis? My professional life as a registered nurse started in 2003 at a mission hospital in Ghana. In 2017, when I began this doctoral study, I had accumulated 14 years of professional experience, both in direct patient care and in nursing education. Most patients I cared for at the start of my role were very ill HIV patients. Most of them got to know their HIV status only after being admitted to the hospital for an unrelated condition. HIV and AIDS were so highly prevalent that presenting with diarrhoea, cough and unexplained weight loss to the hospital would automatically lead to one being tested for HIV. Someone testing positive for HIV went directly to the isolation unit, a place akin to being ostracised. The nursing care for patients in

this unit was minimal, and visits from family members were rare. The non-availability of antiretroviral drugs in the hospital meant that the medical team managed patients symptomatically. Referral to one of the teaching hospitals was the only means for individuals to get ART. Therefore, a diagnosis of HIV often meant a death sentence, a perpetual stigma, and neglect from family members.

In 2009 after my undergraduate study, I took up a volunteering job in an HIV clinic. The role involved counselling newly diagnosed HIV patients and enrolling them on life-long ART. When I took up this role, I intended to help reduce the suffering that this patient group went through as they navigated the care trajectories. However, listening to newly diagnosed patients' stories became a turning point for how I viewed HIV testing and treatment. While my earlier experience with HIV was characterised by encountering acutely ill HIV patients, I now met patients who looked healthy, had access to treatment immediately after diagnosis and therefore had hope of living longer. Most of these patients were women who got to know their HIV status during routine antenatal visits. The stories of these women shaped my thinking about HIV testing and treatment. I began to understand that getting a diagnosis in the clinic was just the beginning of the challenging journeys for pregnant women.

I gained much experience and acquired a good knowledge of HIV infection among this population. One thing that struck me as surprising was many women's failure to return to the clinic for further treatment after receiving their first antiretroviral medications. Instead, after leaving the clinic, they shopped around for hospitals where HIV testing was not a routine part of the antenatal clinic services. Others sought spiritual support from pastors and other faith healers. The only time these women returned to the health system was when they were in labour. It is not enough just to inform women of their HIV status. Instead, women must be part of a testing process that supports their human rights.

I became interested in examining patient's adherence to ART medications and adherence studies when I enrolled for a master's in advanced nursing studies at the University of Nottingham in 2011. Because of the observed drop-out rates and non-adherence to antiretroviral drugs, I undertook modules in HIV adherence, with my dissertation focusing on

the use of mobile phone text messaging and voice calls to improve adherence to antiretroviral medications in low and middle-income countries. A systematic review and meta-analysis findings published in PLOS One (Amankwaa, Boateng, Quansah, Akuoko, & Evans, 2018) offered insightful recommendations regarding mobile phone use to improve ART adherence in a developing nation. Throughout my master's study, I concentrated on how to make women adhere to treatment without considering what might have caused the non-adherence itself.

However, my assumptions about adherence changed when I tested for HIV in 2013 as part of a procedure I had in the hospital. The hospital staff gave me no information about the test; neither did I recall consenting to the test. In writing the test, the doctor used the word 'spot test', which had been a way to prevent many patients from knowing that they had been tested for HIV. When the technician was about to take a blood sample for the laboratory test, I inquired about the test he was about to undertake. In an angry tone, he asked me to stretch my arm for him to take the sample or go back to the doctor who ordered the test to seek answers to my question. I acquiesced. I had similar experiences when I had to undergo a medical examination as part of my visa application to study in New Zealand.

From these interactions, it is evident that a patient's perspective on the testing process was often not considered, and no element of choice existed in practice. The test was simply part of the routine care package a patient receives. Despite my healthcare background, being educated and articulate, I was denied (and in some cases, I was afraid to ask) a fundamental right to make an informed decision. The practice appeared different from what the various guidelines and training manuals of the UNAIDS stipulate. Is it possible that many of these women never returned to the clinic and later reported not believing the test results went through similar experiences? Has attention been focused on getting people tested at the expense of their right to essential information, consent, and confidentiality?

1.7 Thesis overview

This thesis has seven chapters. The background of the study has been presented in this first chapter, drawing attention to debates that have culminated in the normalisation of HIV and adopting the routine opt-out HIV testing in the antenatal clinic. In stating the rationale for this study, I argued that the lack of process data makes it difficult to draw valid conclusions on the conflicting opt-out HIV testing outcome. I proposed the need to examine the process leading to the high testing uptake using implementation fidelity principles. I briefly described Carroll's framework of implementation fidelity to form the basis for the study's objectives and questions. This chapter ended with a reflection on personal experiences that shaped the decision to research this topic.

Chapter Two offers background information about Ghana, the healthcare delivery system, and the current HIV situation, focusing on PMTCT. In presenting the peculiarities of Ghana's health care system, I draw attention to gaps in healthcare delivery and how this might influence the opt-out intervention's implementation. The HIV epidemic, as has been recorded, is then presented. I also offer an insight into how, in this context, gender shapes and determines the acquisition of HIV. The chapter ends by describing problems associated with the opt-out intervention's target on women.

Literature relevant to the study's objectives is presented in **Chapter Three**. The chapter discusses patient autonomy, beneficence, and non-maleficence as crucial ethical issues surrounding women's HIV testing in the antenatal clinic. Following this, the literature review search process and thematic categorisation of identified studies are presented. I then summarise existing systematic reviews to draw attention to gaps in the literature and offer a rationale for further reviewing the empirical literature. The characteristics of empirical studies, a numeric summary of uptake, and the core components' delivery are then presented. The chapter ends with a discussion of factors that have influenced the implementation of the policy.

Chapter Four is in two sections; methodology and methods. The first section presents the philosophical rationale for decisions around process evaluation, implementation fidelity, and

mixed methods design. Pragmatism as the basis for using mixed methods is also presented. This culminates in the development of a process evaluation plan and the study's overall design. In the methods section, I present the procedures used to approach, recruit, and collect qualitative and quantitative data from various stakeholders. Analysis of the quantitative and qualitative approaches and key ethical issues encountered during data collection is presented to conclude the chapter.

The findings of the study are presented in **Chapter Five**. The chapter is in three sub-sections. In the first section, the characteristics of the included antenatal clinics and study participants are presented. The second section presents findings on the study's first objective; adherence, policy on paper, and policy as observed. I make links between these findings and the underlying human rights principles. **Chapters Six** discusses the main findings based on the study's objectives and the conceptual framework. **Chapter Seven** pulls the entire thesis together by revisiting the study's objectives and reiterating the findings. I then make recommendations for policy and practice consideration based on the proposed human rights framework.

2 CHAPTER TWO: BACKGROUND

2.1 Introduction

This chapter offers context-specific information needed to understand the peculiarities of HIV infection in Ghana. First, I provide an overview of Ghana and its uniqueness in governance, service delivery, maternal health indicators, and unique challenges. Following this, I present the country's HIV epidemic and how the Ghana AIDS Commission (GAC) and its agencies have responded. In describing the epidemic, I narrow down on women and the role of biological, socio-cultural, and customary practices in fuelling a disproportionate HIV infection among this population. I call attention to attempts made over the years in preventing HIV infection by targeting the female gender.

2.2 Ghana: an overview

Located centrally on the West African coast, Ghana shares a border with the Gulf of Guinea, Cote d'Ivoire, Togo and Burkina Faso. The country covers a land area of 238,533 km^2. Before the commencement of this study, Ghana had ten administrative regions. In 2018, the government reorganised the country from its ten regions to 16. One of the regions included in this study, the Brong Ahafo Region, was divided into Bono East, Bono West and Ahafo regions. Because this demarcation occurred after the data collection, I maintained the original ten administrative areas (See Figure 3). The Republic of Ghana is the first sub-Saharan African country where Europeans settled to trade in gold and slaves. The country was called the Gold Coast by the Europeans due to the massive gold deposit they found on the land. Led by a pan-African hero, Kwame Nkrumah, Ghana became the first black African nation to gain independence from its colonial powers on 6th March 1957. It became a commonwealth republic on 1st July 1960. In 1966, Ghana's first president was deposed in a coup, heralding years of predominantly military rule. In April 1992, a constitution that allowed a referendum approved multi-party democracy. The country has since enjoyed an increasingly stable and deepening democratic governance. Five successful elections in 2000, 2004, 2008, 2012, 2016 and 2020 have strengthened vital institutions.

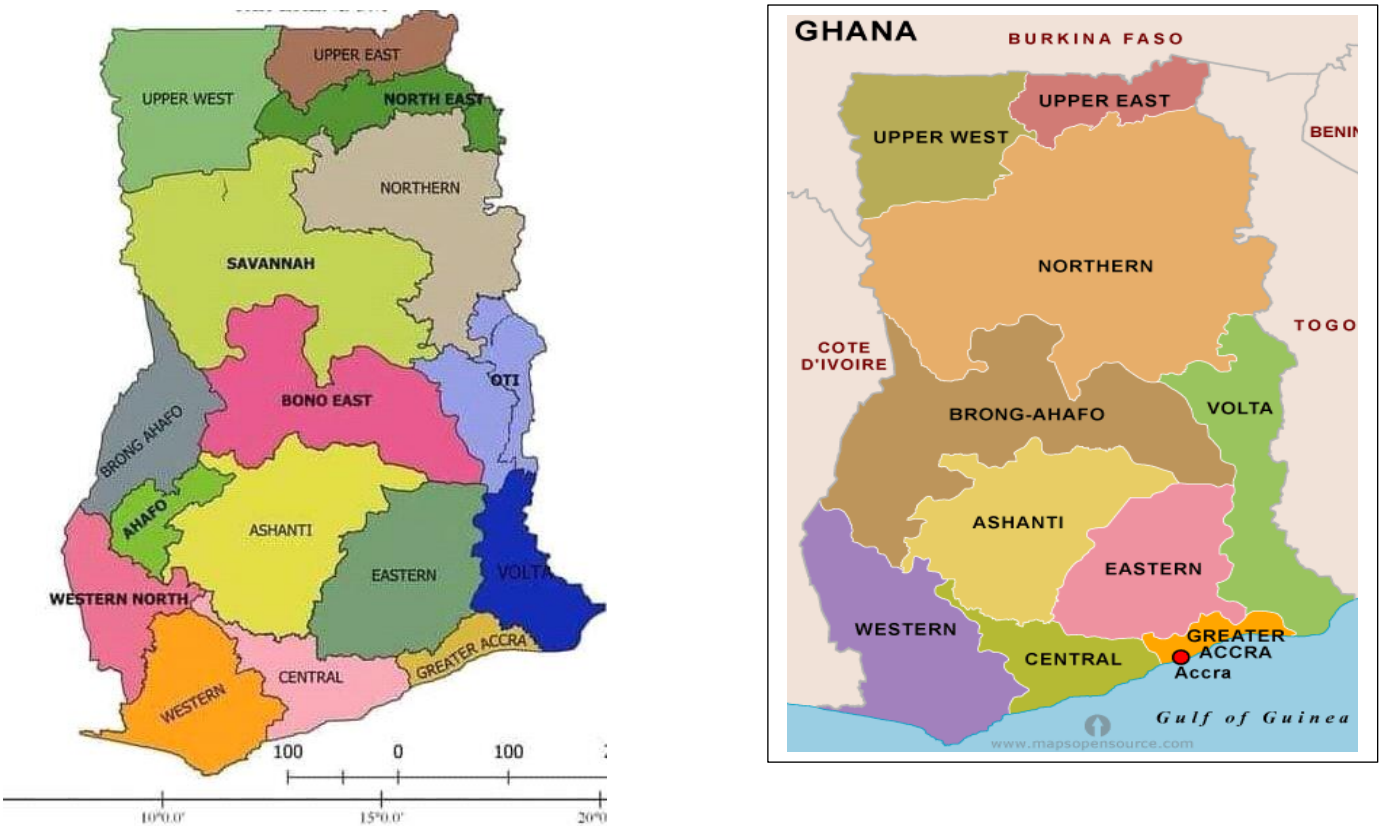


Figure 3: Map of Ghana showing new (left) and old (right) regions

In the early years after independence, Ghana became a country of immigration and attracted foreigners mainly from Nigeria and neighbouring countries to the mines and cocoa. During the 1970s, Ghana experienced a severe drought and a worsening economic downturn, leading to the country's transformation towards emigration. Many foreigners, mostly Nigerians, were deported. Ghanaians mostly travelled to neighbouring Cote d'Ivoire and Nigeria. In Nigeria, Ghanaians worked in the then-booming oil industry. However, between 1983 and 1985, most Ghanaians were deported from Nigeria when oil prices plummeted. Many Ghanaians then turned to more distant destinations, such as other parts of Africa, Europe, and North America. Since the 1990s, there had been increased emigration of skilled health professionals, mainly to the US and the UK.

Internally, developmental disparities continue to drive Ghanaians from the north to the south in search of job opportunities. The northern parts of the country, especially the rural settings, have remained underdeveloped due to unfavourable climate for agricultural production and post-independence political neglect. Historically, the colonial policy made northern Ghana

subordinate to the south in economics and politics by actively promoting labour migration and preventing investment. Also, the colonial masters settled along the coast (southern) because of the harsh and dry weather conditions. This saw the building of hospitals, schools, and road infrastructure in the south. Seeking better healthcare and education for their children, many healthcare providers, teachers and other government employees avoided working in many parts of the north. The situation had led to the vicious circle of poverty and underdevelopment in the north, and therefore poor health outcomes.

Ghana has more than seventy ethnic groups with a shared cultural heritage, language, and origin. The Akan constitutes the dominant ethnic group (47.5%) (Central Intelligence Agency, 2020). The country is multilingual, with about 80 languages spoken. English, inherited from colonial masters, is the official language and lingua franca. However, Twi is the most widely spoken (GhanaWeb, n.d.). Christians form the majority (71.2%) of the population (Central Intelligence Agency, 2020). The 2019 population density in Ghana was 134 people per km^2.

Ghana has a market-based economy endowed with natural resources. Agriculture accounts for 20% of the Gross Domestic Product (GDP) and employs more than 50% of the workforce. Foreign exchange mainly comes from gold, oil, cocoa exports, and individual remittances. An estimated 6.8 million Ghanaians, representing 24.4%, could not afford to spend more than GH₵4.82 (US$1) a day in 2016/2017, as revealed by the Ghana Living Standards Survey Round 7 report by the GSS (Central Intelligence Agency, 2020). The report again indicates that 2.4 million Ghanaians, forming 8.2%, live in abject poverty as they cannot spend up to GH₵3 a day on food. Regionally, the three northern regions have the highest poverty rates.

2.2.1 Ghana's population

About a decade ago, the World Bank (2011) estimated that Ghana's population would increase to 33.8 million by 2030, representing a 39% increase. Available data suggested that the declining birth rates and rising life expectancy might reduce the proportions of those under 14 years from 32.1% in 2010 to 30.8% in 2030. Also, the percentage of those above 64 years would increase from 3.7% to 5.0%. A decade into this prediction, Ghana's population in

2020 was 31.1 million, representing a substantial growth from 8.74 million in 1970 (Knoema, 2019; Worldometer, 2020).

Ghana's age structure is young, with an estimated 57% of the population under 25, with a total dependency ratio of 67.4% (Central Intelligence Agency, 2020). At birth, the estimated sex ratio (male to female births) is 1.03 in 2020 (Central Intelligence Agency, 2020). Ghana's population, growing at the rate of 2.15% (2020 est.), is mainly concentrated in the southern half of the country, with 57.3% of the total population living in the urban areas of Accra (the capital) and Kumasi (one of the study sites). There was a reduction in the total fertility rate during the '80s and '90s, with the current estimated fertility rate at four children per woman. Fertility is generally higher in the north. The region also has lower school enrolment and higher illiteracy (Central Intelligence Agency, 2020).

Table 2: Trend in Life Expectancy at birth, Ghana, 1980-2013

Year	Life expectancy at birth in years
1980	52.3
1985	54.1
1990	56.8
1995	57.5
2000	57.0
2005	58.7
2010	60.6
2011	608
2012	61.0
2013	61.1

Source: UNDP Human Development Report, Ghana 2014

2.2.2 Health care profile

Ghana's health system has undergone significant changes since independence. Over the years, investment in public health services has improved health indicators such as life expectancy (Central Intelligence Agency, 2020; GHS, 2018a). Unfortunately, the improvement in lifestyle and living conditions has led to a gradual transition to new disease patterns. In 1957 when Ghana had independence, the disease burden was mainly infectious, maternal,

perinatal, and environmental-related (de-Graft Aikins & Koram, 2017). However, there has been a gradual shift towards a double burden of infectious and chronic, non-communicable diseases (NCDs) (see Table 3). Infectious diseases such as HIV, malaria, and diarrhoeal diseases, which once caused significant morbidity and mortality, have gradually given way to chronic, degenerative, non-communicable diseases (Aikins, 2014).

The 2017 population survey recorded infant and under-5 mortality rates of 37 and 52 deaths per 1,000 live births. Neonatal mortality stood at 25 deaths per 1,000 live births. However, the 2017 figure represents a decline in infant mortality from 77 deaths per 1,000 live births in 1988 to 37 in 2017.

Table 3: Top 10 causes of premature deaths and percentage change, 2007-2017

2007 ranking		2017 ranking		% change 2007-2017
1.	Malaria	1.	Neonatal disorders	-5.7%
2.	Neonatal disorders	2.	Malaria	-42.2%
3.	HIV/AIDS	3.	HIV/AIDS	-40.9%
4.	Lower respiratory infect	4.	Lower respiratory infection	-7.0%
5.	Diarrheal diseases	5.	Diarrheal disease	-5.5%
6.	Stroke	6.	Stroke	10.6%
7.	Congenital disabilities	7.	Ischemic heart disease	14.6%
8.	Tuberculosis	8.	Congenital defects	-1.2%
9.	Ischemic heart disease	9.	Road Injuries	24.0%
10.	Road injuries	10.	meningitis	-4.4%

Source: adapted from Institute for Health Metrics and Evaluation (IHME) (2018); (Larson et al., 2018).

2.2.3 Maternal, Neonatal and Child Health indicators

Globally, an estimated 289,000 women died during pregnancy and childbirth in 2013, a decline of 45% from the levels in 1990 (WHO, 2015b). Most of these women died because they had no access to skilled, routine, and emergency care (Gabrysch et al., 2019). However, it is satisfying to note that since 1990, some countries in Northern Africa and Asia have more than halved maternal mortality rates (The World Bank, 2015). The sub-Saharan Africa region has made some progress. However, unlike the industrialised countries where a woman's lifetime risk of dying during pregnancy and childbirth is 1 in 3700, maternal death is remarkably high at 1 in 38 in sub-Saharan Africa (Ronsmans & Graham, 2006; WHO, 2015b).

Progress towards Millennium Development Goal (MDG) 5, aimed at improving maternal health, was slow until its expiration in 2015 (Kyei-Nimakoh, Carolan-Olah, & McCann, 2016). The government of Ghana introduced several interventions to meet the MDG 5. Prominent among the interventions was free maternal health services and a Safe Motherhood Taskforce and Prevention of Maternal Mortality Programme (Dalinjong, Wang, & Homer, 2018); (PMMP) (UNDP Ghana, 2015). Unable to meet the MDGs at the end of 2015, Ghana enrolled in the Sustainable Development Goals (SDGs), aimed at 'sustaining' and improving the MDG targets' progress.

Ghana's maternal, neonatal, and child health indicators reflect efforts made towards attaining the MDGs. In terms of the total fertility rate, Ghana had 3.9 children per woman in 2017, representing a decline of 2.5 children from the 6.4 children reported in 1998 (Ghana Statistical Service (GSS), GHS, and ICF, 2018). Of all pregnancies recorded in 2017, 37% were unintended due to poor timing (23%) or unwanted pregnancies (14%) (Ghana Statistical Service (GSS), GHS, and ICF, 2018). There is also an indication that women are increasingly adhering to WHO's exclusive breastfeeding guidelines (Intiful, Osei, Steele-Dadzie, Nyarko, & Asante, 2017). The country has seen an increase in infants aged 0-6 months exclusively breastfed from 46% in 2011 (Ghana Statistical Service, 2012) to 52% in 2014 (Manyeh, Amu, Akpakli, Williams, & Gyapong, 2018).

Ghana has also seen increasing patronage of antenatal care. In 2017, about 98% of pregnant women received antenatal care from a skilled provider (Dickson, Darteh, & Kumi - Kyereme, 2017). In the same year, an estimated 79% of women benefited from skilled deliveries in health facilities. Women in the southern parts (92%) were more likely to benefit than their counterparts in the north (59%). In Ghana, doctors (16%), nurses/midwives (64%) and Traditional Birth Attendants (TBAs) or friends (18%) assist in deliveries (Ghana Statistical Service (GSS), GHS, and ICF, 2018). The opportunity to be delivered by skilled personnel in Ghana is linked to living in an urban area (91%), having a secondary education (99%), and living in the wealthiest households (98%). Approximately 84% of women received postnatal care two days after delivery (compared to 67% in 2007) (Ghana Statistical Service (GSS), GHS, and ICF, 2018).

Table 4: Key indicators for Maternal, Neonatal and Child Health, Ghana

Indicators	Residence		
	Ghana	Urban	rural
Total fertility rate	3.9	3.3	4.7
Median age at first birth for women age (25-49 yrs.)	21.5	22.7	20.3
Current use of any family planning (%)	31	30	31
Antenatal clinic visits with a skilled provider (%)	98	98	97
Births delivered in a health facility (%)	79	90	68
Birth assisted by a skilled provider (%)	79	91	69
Postnatal check during first two days after birth for mother	84	90	79
Postnatal check during the first two days after birth for a newborn (%)	81	88	76
Neonatal mortality	25	25	24
Infant mortality	37	36	38
Under-5 mortality	52	48	56

Source: Adapted from Ghana Statistical Service (GSS) (2018)

2.3 Health services delivery system

2.3.1 Governance

Ghana's health care system is divided into five functional levels; national, regional, district, subdistrict, and community. The Ministry of Health (MoH), working at the national level in partnership with its agencies, is responsible for the overall direction, policy formulation and priority setting (MoH, 2020). The ministry operates based on a hierarchical organisational structure from the central headquarters in Accra. The Ghana AIDS Commission, an agency of the Ministry of Health, is responsible for adopting and formulating HIV testing policies. Ghana Health Service (GHS), also an agency under the MoH, is mandated to implement the MoH policies (Ministry of Health, 2010). Its head, the Director-General, reports to the Council of GHS that also reports to the Minister of Health. Eight functional directorates operate under the GHS (Ministry of Health, 2010). One of these directorates oversees Public Health and

hosts the Ghana AIDS/STI Control Programme (NACP), an agency actively involved in this study (See Figure 4).

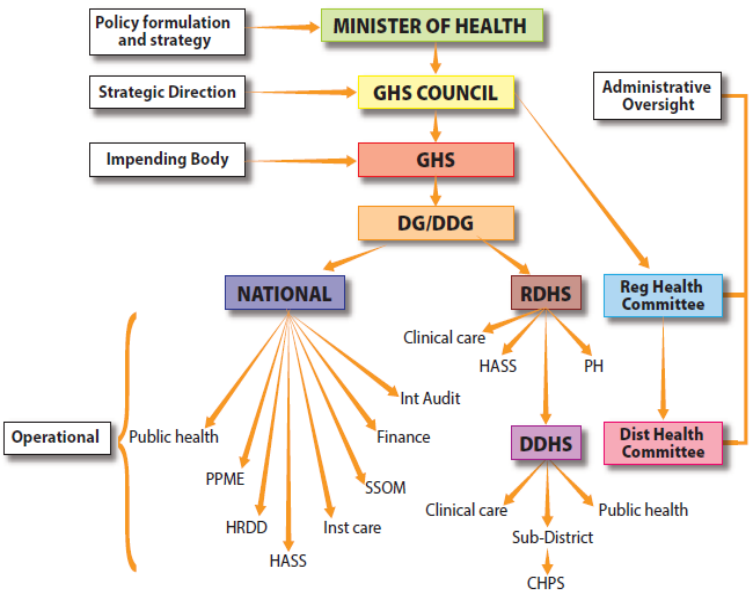


Figure 4: Health Sector Leadership and Governance Structure

Source: Ibrahim, Asampong, and Sackey (2018, p. 131)

2.3.2 Maternal health care delivery

Ghana's health service delivery is organised at the primary, secondary and tertiary levels. It has pluralistic service providers consisting of public, private, traditional and alternative service providers (Abor & Abekah-Nkrumah, 2008). The primary level of care constitutes the district, sub-district, and community. The sub-district/district level is the lowest level of health care championed by the Community-based Health Planning and Services (CHPS) compounds, health centres, clinics, and district hospitals. The CHPS delivers preventive and reproductive health services at the sub-district and community levels. CHPS compounds are there to bring health care and obstetric services to the doorstep of pregnant women and improve health outcomes (Atuoye et al., 2015; Kweku et al., 2020). Primary obstetric care of women with uncomplicated pregnancies is offered at the health centres. District hospitals form the apex of service delivery at the district level and provide advanced curative, preventive services, and obstetric services such as caesarean sections and blood transfusions. The district hospitals

often refer complicated cases to regional or teaching hospitals for specialised care. In addition to providing specialised care, the secondary and tertiary levels provide health professionals' training and conduct medical research (Figure 6).

The private health sector refers to non-governmental actors: self-financing private sector (also referred to as 'for profit'), not-for-profit and mission or faith-based institutions delivering health services. Among this group is the Christian Health Association of Ghana (CHAG), representing nearly all non-for-profit health service providers in Ghana who target hard-to-reach rural communities. They receive financial incentives and support from the government to support the payment of personnel. The self-financing private health sector is concentrated in the urban and periurban areas, with low rural penetration.

About 70% of Ghana's population depend on traditional, complementary and integrative therapies (Yarney et al., 2013). Traditional medicine in Ghana encompasses all health care practices, approaches, knowledge and beliefs incorporating animal, plant and mineral-based medicines, spiritual therapies, manual techniques and exercises applied to treat or prevent diseases. Ghana implemented the WHO strategy of integrating the traditional, complementary and integrative medicines into the formal healthcare system in September 2012(Gyasi et al., 2017). Already, traditional medical practices have been fused into 11 selected hospitals across Ghana. There is also a referral system to link the various levels of healthcare, though this had not worked very well over the years. The district hospitals often refer complicated cases to regional or teaching hospitals for specialised care. In addition to providing specialised care, the secondary and tertiary levels provide health professionals' training and conduct medical research (Figure 6).

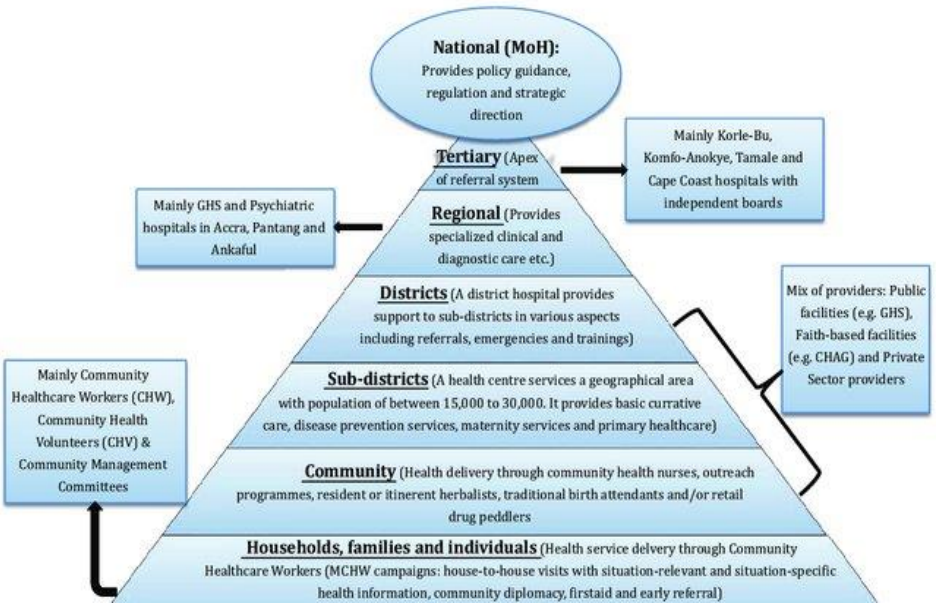


Figure 5: Health service provision from national to the community level in Ghana

Source: Ministry of Health, Government of Ghana: community Health Worker Programme, 2014.

2.3.3 Health facilities

Ghana has an estimated 3,500 private, public, and faith-based health care facilities. Of this number, 57% are public, 33% belong to the private sector, and 7% are operated by the Christian Health Association of Ghana (CHAG) (GHS Facts and Figures, 2017). See Figure 6.

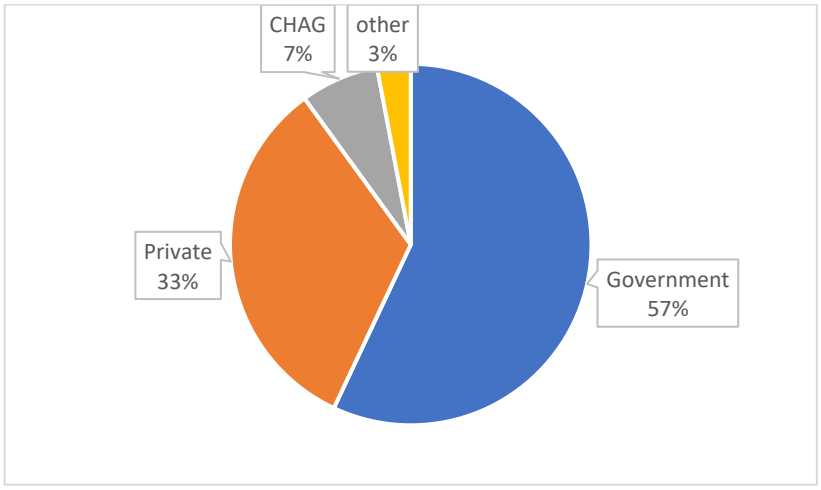


Figure 6: Health care facility, by ownership, 2016

Source: GHS Facts and Figures (2017)

The health facilities include CHPS compounds (61.4%), maternity clinics (14.7%), health centres (12.5%) and hospitals (3.9%). There are seven types of hospitals based on the level of care: district, municipal, metropolitan, regional, teaching, psychiatric and uncategorised.

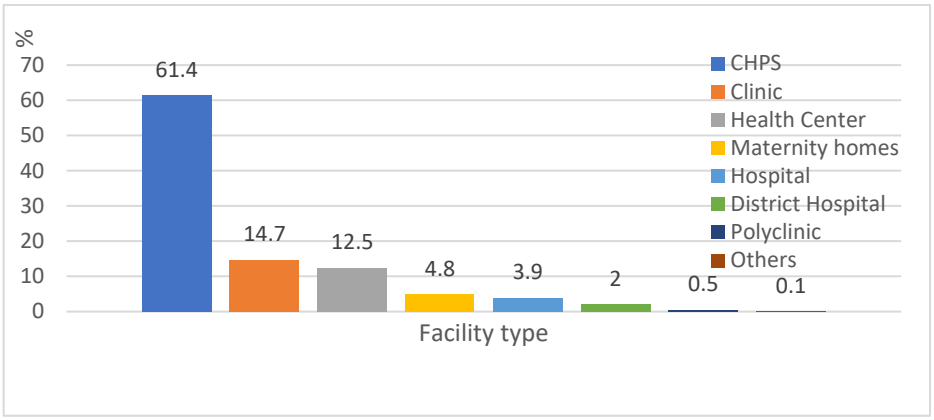


Figure 7: Distribution of health facilities by type, 2016

Source: GHS Facts and Figures (2017)

2.3.4 Human resources

The past decade saw an increase in Ghana's health workforce, resulting in improved nurses, midwives, and physicians' density from 1.07 per 1000 in 2005 to 2.65 per 1000 in 2017(GHS, 2018b). The efforts point to Ghana's good standing in universal health coverage and as a leading producer of nurses, midwives, and physicians in sub-Saharan Africa (Campbell et al., 2013). However, other reports indicate that human resources for health may not be optimal due to the maldistribution of skilled staff (Asamani, Amertil, Ismaila, Akugri, & Nabyonga-Orem, 2020; Asamani, Naab, & Ofei, 2016).

Greater Accra and Ashanti regions had the highest numbers of healthcare providers (Baird, Smith, & DeBacco, 2015; University of Ghana School of Public Health, 2018). In 2015, there were about 3,164 doctors in the country, with the Greater Accra and Ashanti regions having 2,228, representing 70.4%. The two regions also had 44.5% of nurses and 40.8% of all midwives in the country, respectively. In contrast, the Upper East and Upper West regions had fewer clinical staff (Ibrahim et al., 2018).

Such disparities compound women's health-seeking behaviour and make it impossible to obtain favourable maternal health outcomes (Sakeah et al., 2014). The 2018 Ghana statistical services (GSS) reported that 21% of women had no access to skilled birth attendants and therefore delivered home (GSS 2018). . MoH's introduction of Community Health Officers in the deprived regions has started showing some results (Sakeah et al., 2014).

2.3.5 Health financing

Ghana's health financing has been unstable since independence. In 2003, the government set a goal to provide health care to all by removing cost as a barrier. The decision led to the introduction of the National Health Insurance System (NHIS) in 2003. Before implementing this scheme, Ghanaians paid for health care services mainly through user fees which unquestionably disenfranchised the poor and vulnerable (Gwatkin, 2000). The insurance scheme is financed primarily through a 2.5% tax on goods and services and social security taxes for all formal sector workers (NHIA, 2013). Individuals then pay a relatively low premium of about 10 USD to benefit from the insurance. Vulnerable populations like the elderly and children under 18 do not pay a premium.

The Ministry of Health addressed women's financial challenges by introducing the maternal healthcare fee exemption policy (MoH, 2007). Pregnant women registered for national health insurance without paying a premium (Kodua, 2015) and free antenatal services, which include free medicines, two ultrasounds covering four to six clinic visits. They also benefit from free delivery, postnatal and neonatal care services (Asenso and Akanzige, 2011; Wang, 2017). The exemption initially affected women from the four most impoverished regions, which later extended to all regions in 2005 to give all women free delivery, including caesarean sections (Singh et al., 2015). A study by Bonfrer, Breebaart, and Van de Poel (2016) to determine the effects of Ghana's NHIS on maternal and infant health utilisation reported that the scheme significantly increased the proportion of pregnancies having at least four antenatal visits and had a significant effect on attended deliveries. Regardless of socioeconomic and demographic factors, women enrolled in NHIS made more antenatal visits than those not enrolled (Dixon, Tenkorang, Luginaah, Kuuire, & Boateng, 2014). Even though the intervention targets the

poor, Dixon and his colleagues reported that women with higher education, wealth and living in urban areas were more likely to register in NHIS and attend antenatal clinics.

2.3.6 The code of professional conduct for nurses and midwives

The decisions nurses and midwives make during their practice must take into account established laws and ethical standards. The International Council of Nurses (ICN) (2012:6) states that nurses have the mandate of providing care that respects human rights and is sensitive to people's values, customs, and beliefs. The international code of ethics for midwives acknowledges women as persons with human rights, seeks justice for all people and equity in access to health care and is based on mutual relationships of respect and trust and the dignity of all members of society (ICM, 2008). Nurses and midwives in Ghana achieve this mandate by adhering to the values, moral norms, and ideals of the Nursing and Midwifery Council of Ghana's (N&MC) codes of conduct document (NMC-Gh, 2007). The N&MC is an agency of the Ministry of Health that regulates the activities of nurses and midwives. They regulate nurses through the code of conduct. The code of conduct is succinct statements of ethical values, obligations, duties and professional ideals for these professional groups. The profession's non-negotiable ethical standards reflect the expression of nursing's understanding of its commitment to society. The code of conduct makes explicit the inherent duty for nurses and midwives to respect human rights, including cultural rights, the right to life and choice, to dignity and to be treated with respect (ICN, 2012). In other words, the ethical consideration and standards dictate what nurses and midwives can and cannot do. To ensure that nurses and midwives are competent in applying these professional codes of ethics, the council includes professional adjustment as a mandatory course during the first year of nursing training education. The NMC also works through local health authorities (agents) to ensure that nurses and midwives adhere to the professional codes of ethics.

2.3.7 Challenges and gaps in the Ghanaian health care system

Despite the interventions and policies to improve maternal, neonatal and child health outcomes, Ghana still grapples with a considerable burden of maternal and child mortality, with an estimated 343 deaths per 100,000 live births in 2017(MoH, 2020). WHO notes that

some of these deaths, often caused by severe bleeding, sepsis, pre-eclampsia, and childbirth complications, are often preventable (WHO, 2019). In 2007, the high maternal mortality ratio of 580 deaths per 100,000 live births caused the health minister to declare maternal mortality as a 'national emergency' (Der et al., 2013). The declaration led to the launch of a free health insurance policy for pregnant women

Adhering to WHO's minimum antenatal attendance recommendation ensures early detection and management of abnormalities (Sullivan & Hirst, 2011). However, nonadherence to this requirement is prevalent in sub-Saharan Africa (Pell et al., 2013; Villar et al., 2001). Close to half of women, especially those in rural parts of Ghana, initiate antenatal clinic visits after the first trimester of pregnancy (Manyeh, Amu, Williams, & Gyapong, 2020). A study conducted in Accra found that only about a quarter of the women adhered to the recommended four-time attendance of antenatal clinic (Asah-Opoku, Ameme, Yawson, Guure, & Aduama, 2019). Living closer to health facilities, higher income, and urban dwelling positively influenced the decision to attend the clinic. For women in rural settings, long distances coupled with limited and lack of transportation options have served as a deterrent for seeking ANC services (Anastasi et al., 2015; Dantas, Singh, & Lample, 2020). A study conducted in the Eastern region of Ghana found that each kilometre increase in distance to the clinic significantly reduced the prevalence rate of the number of women giving birth in a health facility by 6.7% (Dotse-Gborgbortsi et al., 2020).

The unfavourable socio-cultural environment had also influenced timely access to ANC services (Dako-Gyeke, Aikins, Aryeetey, McCough, & Adongo, 2013). Women from rural settings were often concerned that more privileged women might ridicule them for sub-standard clothing and poor personal hygiene. Other factors that deter women from seeking skilled perinatal care include poverty, cultural and religious beliefs, early marriages, and polygamy (Sumankuuro, Crockett, & Wang, 2018). The situation is not peculiar to Ghana. In Uganda, Kwagala (2013) reports that mothers were concerned about how providers treat them at the clinics (Dantas et al., 2020). Such concerns often cause women to patronise other forms of care instead of the biomedical, making it challenging to reach national health targets.

2.4 The HIV epidemic in Ghana

2.4.1 Ghana's response to HIV

Ghana recorded its first case of HIV in 1986. The discovery triggered a structured national response in 1987 that saw the creation of a medium-term plan supported by WHO and the Global Programme on AIDS. Later, the government established the National AIDS/STD Control Programme (NACP) in the Ministry of Health. NACP became in charge of prevention, management and coordination of HIV and AIDS activities in Ghana. In 2000, it became clear that HIV went beyond the mandate of the health sector. This realisation informed the decision to establish the Ghana AIDS Commission (GAC) through an act of Parliament. The GAC is a supra-ministerial body under the President's Office responsible for providing leadership in managing and coordinating the national response to Ghana's HIV and AIDS epidemic. Since its inception, the GAC has developed five National Strategic documents to guide the national response's deployment. The GAC developed the Strategic Plan for Comprehensive Response to Human Rights-related Barriers to HIV and TB Services (GAC, 2019c) as I was writing up this thesis. The realisation that human rights and gender-related inequalities serve as a barrier for the most vulnerable populations instigated the document's development. The document points to the new direction in the commission's effort to teach human rights issues in the continuum of HIV services.

2.4.2 The current situation - the epidemic

Ghana has made progress in curtailing the impact of HIV and AIDS on the general population. The country's ability to further reduce the incidence, prevalence and risk of HIV and AIDS has been challenged by prevailing programmatic and institutional difficulties. HIV is, therefore, still a significant threat. Like other sub-Saharan Africa countries, Ghana has a generalised HIV epidemic[3], with about 342,307 people with HIV/AIDS in 2019 (GAC, 2020). The country currently has an adult national HIV prevalence of 1.7%, representing a reduction from the

[3] A generalised HIV epidemic is an epidemic that is self-sustaining through heterosexual transmission. In a generalised epidemic, HIV prevalence usually exceeds 1% among pregnant women attending santenatal clinics.

2014 prevalence rates of 2.0%, and this is projected to reduce to 1.5% by 2025 (See Figure 8).

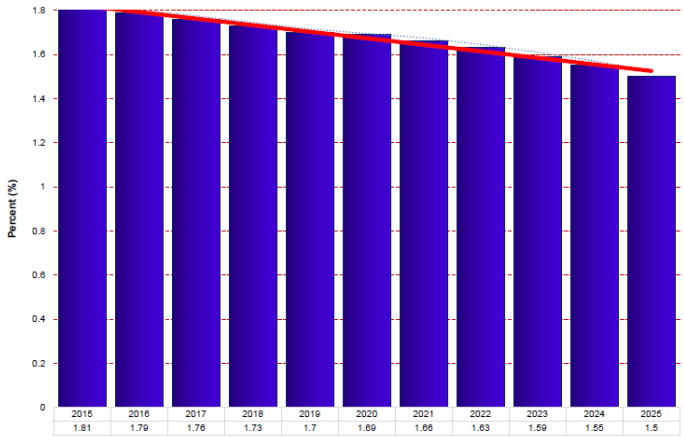


Figure 8:Adult HIV prevalence (15-49)

Source: GAC National Estimates (2019)

An estimated 342,307 individuals were living with HIV in 2019. The majority (64.3%) were females. Adults 15 years and above made up 316,352, representing 92.4%, and children aged zero to 14 years 25,514 or 7.5%. The estimated median number of new HIV infections increased from 19,931 in 2018 to 20,068 in 2019. About 14.8% (2,972) of the newly infected individuals in 2019 were aged less than 15 years. In 2019, an estimated 13,616 people died of AIDS-related morbidity. Out of this, 11,412 (or 83.8 %) were adults, 15 years and above, while 2,441 or 17.9% were children between zero and 14 years (Figure 9).

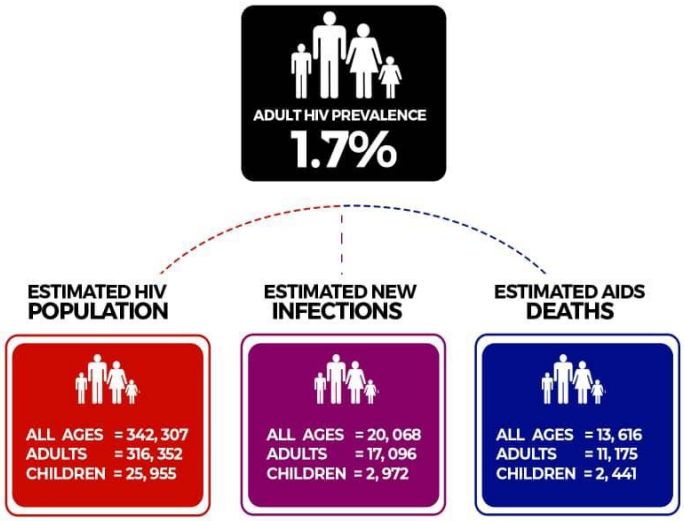


Figure 9: 2019 National HIV estimates.

Source: GAC National Estimates (2019)

There exist regional variations in the HIV prevalence rates, ranging from 2.66% in the Bono region with the highest prevalence rate to 0.24% in the North East region (GAC National Estimates, 2019). The Greater Accra region recorded the highest number of people with new infections (5,517) in 2019. The urban setting has higher prevalence rates (2.6%) than the rural settings (2.2%). HIV prevalence in Ghana's antenatal clinics declined from 2.9% in 2009 to 1.6% in 2014. Worryingly, there was an increase in HIV prevalence between 2015 and 2018 from 1.8% to 2.4% (GAC, 2019b).

2.4.3 A gendered analysis of Ghana's HIV epidemic

Epidemiological evidence points to an unacceptably high incidence and prevalence of HIV infection in women (Ramjee & Daniels, 2013b). The UNAIDS estimates that one young woman gets infected with HIV every minute in sub-Saharan Africa (UNAIDS, 2012). Women aged 15-24 years in the sub-Saharan Africa region are twice more likely to live with HIV than their male partners (NACP, 2018). In Ghana, females comprise 64% of the 342,307 people living with HIV (GAC, 2019a). Biological, socioeconomic, and specific cultural practices increase women's vulnerability to HIV transmission (Owusu, 2020).

The biological setup of women increases their risk of contracting HIV. The increased vulnerability is partly due to the wide mucosal surface area exposed to pathogens during coitus. The risk is higher in young women with an immature genital tract (Ackermann & de, 2002). Sexually transmitted infections (STI) are known to increase the chances of acquiring HIV in both sexes (Kalichman, Pellowski, & Turner, 2011), but the risk increases in women because of the difficulty in diagnosing and treating STIs in women (Ramjee & Daniels, 2013a). Progesterone, a hormone predominantly found in women and progestin-based contraceptives, also plays a role in women's susceptibility to HIV infection (Connolly, Ramjee, Sturm, & Abdool Karim, 2002). Women's vulnerability to HIV becomes even more significant during pregnancy due to high oestrogen and progesterone levels. Raised oestrogen levels cause cervical ectopy, further exposing the columnar epithelium to microorganisms (Jacobson et al., 2000; Nicolosi et al., 1994). In Ghana and other parts of sub-Saharan Africa, the practice of 'dry sex', which involves the insertion of agents believed to cause drying of the vagina to produce a tight, dry and 'hot' vagina, further increases women's biological vulnerability (Dlamini et al., 2007; Obiri-Yeboah, Amoako-Sakyi, Baidoo, Adu-Oppong, & Rheinländer, 2016).

A Ghanaian woman's low socioeconomic status is pervasive and correlates with vulnerability to HIV infection (Agyei-Mensah, 2006; Mill & Anarfi, 2002; UNAIDS Feature Story, 2012). The low status is partly due to the tendency for boys in this part of the world to be enrolled in school, while most females drop out when parents face financial difficulties (Mill & Anarfi, 2002). Without proper education, females invariably have fewer job opportunities and become economically dependent on men for sustenance. Such situations reduce a woman's ability to decide about their sexuality (Gillespie, Kadiyala, & Greener, 2007; Piot, Greener, & Russell, 2007), leading to risky sexual behaviours. For example, a young woman with low socioeconomic status is likely to have earlier first sex, seldom use a condom and may have multiple sex partners (Ramjee & Daniels, 2013b). There is also an increase in the chance that her first sex act was without her consent (Mabala, 2006), limiting her control over the male's condom use (Buvé, Bishikwabo-Nsarhaza, & Mutangadura, 2002; Duffy, 2005).

In Ghana, women's low socioeconomic status often causes them to marry early and to men who are many years older than themselves (Montgomery, Hosegood, Busza, & Timaeus, 2006). Because most of these young women are less likely to be infected with HIV, most men view the differential age favourably (Mill & Anarfi, 2002). Unfortunately, such unions have shifted the epidemiology of HIV illness, as the sudden change from being a virgin to frequent unprotected sexual encounters increases young girls' HIV risk (Owusu, 2020). Evidence exists that these women often engage in unprotected sexual relations outside the marriage context, as the men who marry them are often unemployed and unable to support them financially. The provision of sexual services by women in exchange for financial support from men is considered a strategy for economic survival in many parts of the country (Vandepitte et al., 2006). Such young women are often less educated, and therefore less likely to be concerned about prospects. Sex, thus, become a form of recreational activity (Buvé et al., 2002).

Married women also have an increased risk of HIV infection due to the risky behaviours of their partners. These women are usually unaware of their husbands' risky sexual behaviours and do not perceive themselves as being at risk for HIV (Owusu, 2020). Marriage has been cited as the primary risk factor for most HIV-positive women in low-income countries like India (Ghosh et al., 2011). When a financially dependent woman finds out about her husband's risky sexual behaviour, she will not be inclined to protect herself from HIV transmission, as this would often cause her to lose her financial security (Ghosh et al., 2011)

Traditional patriarchal values are still prevalent in most Ghanaian communities (Mill, 2001), leading to women's subjugation and susceptibility to HIV (Duffy, 2005; UNAIDS Feature Story, 2012). The social norms that demand culturally appropriate roles and conduct for men and women further perpetuate gender inequalities (Gupta, Parkhurst, Ogden, Aggleton, & Mahal, 2008). For example, the Ghanaian culture expects men to be masculine, which emboldens men to assume a patriarchal attitude that daughters, partners, and wives are their legitimate possessions (Gupta, 2002; Jewkes, Levin, & Penn-Kekana, 2003). Such a notion has received legitimacy due to the practice where a woman's family asks a prospective husband to pay vast amounts of money (bride price) to take the girl away from the family (Owusu, 2020). The

man becomes the head of the family and makes decisions, including those in the bedroom (Higgins, Hoffman, & Dworkin, 2010; Igulot & Magadi, 2018). A woman's attempt to initiate sex, suggest condom use, or decline sexual advances may generate violent consequences (Duffy, 2005). These women end up submitting to sexual advances that increase their risk of HIV infection (Go et al., 2003; Pulerwitz, Michaelis, Verma, & Weiss, 2010). The gender norms as described above promote multiple concurrent sexual partners for men, while women are required to be 'faithful' and unquestioning of their partner's behaviour (Gupta, 2002; Pettifor, Measham, Rees, & Padian, 2004).

2.4.4 HIV prevention strategies targeted at women

The factors above suggest women's vulnerability to HIV. Unsurprisingly, policymakers have directed behavioural, biomedical and structural interventions for preventing HIV in women. Biomedical interventions have involved the use of condoms (male and female). Even though female condoms are in abundance, the female still needs to negotiate their use. These difficulties have resulted in the promotion of female-initiated prevention methods, such as microbicide products with anti-HIV properties (McGowan, 2008). Other products containing antiretroviral properties have also been tested and used (Abdool Karim et al., 2010). For these biomedical approaches to work, the woman must adhere, but this has not proven easy.

Structural interventions attempt to alter the social and cultural practices that worsen HIV vulnerability among women. In Ghana, structural interventions have involved an increase in public campaigns to raise awareness about HIV and human rights, the scale-up of the 'Model of Hope', 'M-watchers' and other support groups, human rights education and paralegal training and 'bridging' to legal services (GAC, 2019c). Policy structural factors play an essential role in HIV transmission, and Ghana has made several improvements in its HIV policy environment over the years. The National HIV, AIDS and STI policy (GAC, 2013, 2019b) and the current strategic plan for a comprehensive response to Human Rights-related Barriers to HIV and TB Services in Ghana (GAC, 2019c) contain these policies. Behavioural interventions include HIV testing and counselling and peer education interventions (Ramjee & Daniels, 2013b). HIV testing helps identify women who are positive and subsequently put

them on treatment. HIV testing is, therefore, a critical behavioural intervention for HIV prevention (Grabbe et al., 2010).

2.4.5 Prevention of mother-to-child transmission of HIV

Prevention of mother-to-child transmission of HIV is a four-pronged intervention involving 1) the primary prevention of HIV infection among women; 2) preventing unintended pregnancies; 3) preventing transmission from women living with HIV to their infants and 4) providing appropriate treatment, care and support to mothers living with HIV (Wettstein et al., 2012; WHO PMTCT Strategic Vision, 2010). Ghana's adoption of the intervention in 2001 marked the country's commitment to halt the transmission of HIV to children under five (Dako-Gyeke et al., 2016a). WHO emphasises the third prong through its rapid advice guidelines, identifying and recommending life-long antiretroviral treatment to HIV-positive pregnant women (WHO RAPID Advice, 2010). In line with this, Ghana scaled up its PMTCT efforts, with a target of providing 95% of HIV positive pregnant women with effective PMTCT by 2015 (GAC/NACP, 2014). As of 2019, the estimated number of pregnant women needing PMTCT was 15,599, with an estimated 11,686 pregnant women living with HIV received ART for PMTCT. The figure brings the coverage of pregnant women living with HIV who received ART for PMTCT to 74.92% (GAC, 2019a). Integration of PMTCT services into standard antenatal clinic services became one strategy for scaling up HIV prevention efforts. Antenatal clinics offer an appropriate platform for screening women who might be positive for HIV and offering them treatment (Babalola & Fatusi, 2009; Haruna, Dandeebo, & Galaa, 2019). In Ghana, the integration of PMTCT services into antenatal care has occurred at the national, regional, and district health centre levels across all the administrative regions. The decentralisation efforts have, over the years, dictated the increased intervention coverage.

Ghana recorded an increase in PMTCT centres from 135 in 2005 to 1,656 in 2012. Currently, 2748 PMTCT centres offer HIV testing services in antenatal clinics (Ayisi Addo, 2018). The number of women testing as part of antenatal clinic attendance increased from 257,466 in 2008 to 492,622 in 2013. Over the years, antenatal clinic attendance has been high (87% of women had four or more antenatal clinic visits (GSS, 2018)). Correspondingly, PMTCT

numbers have also increased. However, studies have reported that women testing positive drop out of PMTCT services (Dako-Gyeke et al., 2016b). For example, in December 2009, HIV testing and counselling services were patronised by 53% of pregnant women in the country, 74% of whom were tested and received their results. However, this translates to only 39% of all pregnant women in the country. The HIV prevalence among those tested was 1.7%, and only 55% of those testing positive received ART to prevent vertical transmission of HIV (Ministry of Health, 2010).

Dako-Gyeke et al. (2016b) also described regional disparities and national trends in key PMTCT indicators by reviewing NACP regional disaggregated records of attendees across the country. The records reviewed covered three years (2011-2013). The review found an increase in clinic registrants who did not test from 17% in 2011 to 25% in 2013. The study further identified different missed opportunities for testing across the ten regions, leading to 487,725 untested pregnant women. The study pointed to the missed opportunities to test pregnant women for HIV and starting those testing positive on ART across all regions. The current study, aimed at ascertaining the process of HIV testing in some of these antenatal clinics, is not only timely but essential, given these issues.

2.5 Chapter summary

Ghana has a young population that is growing at a rate of 2.15% per annum. The country has seen improved life expectancy due to the increased availability of public health services. However, this has come with a gradual shift of the disease burden from mainly infectious during independence in 1957 to a double burden of infectious and chronic non-communicable disease. Ghana is a key contributor to HIV cases that position sub-Saharan Africa as the epicentre of HIV infection. Biological, socioeconomic, and specific cultural practices work separately and in synch to increase women's vulnerability to HIV transmission, with 64% of the population living with HIV being women. Through various strategic frameworks and ratification of different international conventions, Ghana has responded aggressively to the HIV epidemic. Testing women for HIV through the PMTCT programme integrated into all maternal services has served as the fulcrum of Ghana's fight against HIV. PMTCT was

introduced into antenatal clinics in 2001, with the adoption of routine opt-out HIV testing in 2008 intended to increase testing uptake and prevent mother to child transmission of HIV. This study focuses on assessing how well healthcare providers adhered to the core principles of these guidelines.

3 CHAPTER THREE: LITERATURE REVIEW

3.1 Introduction

This section of the thesis explores the academic literature that frames and guides the process evaluation and serves as a foundation for the current study. The chapter introduces the key ethical arguments for and against the provider-initiated opt-out prenatal screening. I argue that ascertaining the ethical reasons for or against using the opt-out approach is central to providing a thorough understanding of the need for assessing implementation fidelity. In the last section, I review primary studies that have evaluated the opt-out intervention implementation from 2006 to date. To offer a broader perspective of existing evidence, I first provide a summary of existing systematic reviews. In reviewing the empirical studies, I focus on previous researchers' approaches to examining the intervention's core components. Throughout the literature review, I reiterate the need to understand how the opt-out approach in the antenatal clinic addresses (or does not address) pregnant women's autonomy and other human rights issues and the evidence for the need for process-focused research. This review ends with synthesising key findings, drawing attention to crucial gaps and how the current study addresses these.

3.2 Ethical issues surrounding the opt-out prenatal HIV testing

It has been about three decades since the Second International Consultation adopted the Guidelines on HIV and Human Rights in 1996 as a direct response to the discovery of antiretroviral therapy that has made HIV/AIDS a chronic disease. In 2001, having access to life-saving antiretroviral treatment was considered a human rights issue, as contained in the Commission on Human Rights resolutions (de Bruyn, 2005). In 2002, OHCHR and UNAIDS sponsored the Third International Consultation on HIV/AIDS and Human Rights to revise Guideline 6 to reflect the human rights dimensions of access to HIV prevention, treatment, care and support (Bayer, 2009). Since this time, human rights have taken centre stage in HIV related issues.

Many of the conventions formulated by WHO and UNAIDS took inspirations from the United Nations Declaration of Human Rights (1948), the Universal Declaration on Bioethics and Human Rights (2005). Under these international treaties, every person has a right to health, access to HIV, and other healthcare services. People also have a right to equal treatment before the law and a right to dignity. WHO has explicitly enumerated the human rights protections required for HIV testing (WHO, 2012). WHO and UNIADS addressed HIV-related human rights issues through the 'three Cs' of counselling, confidentiality, and informed consent. The need for a more expansive notion of respecting, protecting, and fulfilling human rights led to the inclusion of two other essential elements: connection to care and correct test results. Based on Beauchamp and Childress's works on ethics, I highlight some of the rights-based arguments that underpin HIV testing.

3.2.1.1 Autonomy and HIV testing

Autonomy is the cornerstone of bioethics and the main principle that health care providers can abuse while pregnant women access HIV testing services (Csete & Elliott, 2006; Gostin, 2006; Schuklenk & Kleinsmidt, 2007). It refers to individuals' ability to make an informed decision after weighing specific factors and choices presented to them. Such an exercise of autonomy recognises the right to liberty of action and self-directed decisions. Offering the right amount of HIV-related information had been a cornerstone of an autonomous decision (Beauchamp & Childress, 2009). Since the opt-out approach de-emphasises the consent process and limits the amount of information, many ethicists have raised questions regarding autonomous decision-making, especially women's ability to make a genuine informed consent(Csete & Elliott, 2006; Gostin, 2006; Schuklenk & Kleinsmidt, 2007).

The opt-out testing represents an example of the positive framing effect, whereby a healthcare provider frames a wish in such a way as to guide the patient to make a specific decision as an apparent positive gain (Abhyankar, Summers, Velikova, & Bekker, 2014). Individuals opposed to framing effects have referred to it as a barrier to informed consent (Beauchamp & Childress, 2009). The approach minimises women's opportunity to decline the test, thereby potentially eroding their right to autonomous decision-making (Bennett, 2007a; Fields & Kaplan, 2011) and debasing their humanity and sense of dignity (Durojaye, 2008). To

respect women's autonomy, the provider must have the required training and expertise to deliver the information within the limited amount of time at her disposal (Wocial & Cox, 2013). It remains unclear how these preconditions are met in many parts of sub-Saharan African countries.

Several studies in the region have reported that women undergoing testing in clinics are unaware of their rights to refuse an HIV test. Women in these studies reported feeling coerced to undertake the test as a pre-requisite for receiving care (de Zulueta & Boulton, 2007a; Groves, Maman, Msomi, Makhanya, & Moodley, 2010; Kwapong, Boateng, Agyei-Baffour, & Addy, 2014; Obermeyer, 2014; Rujumba, Neema, Tumwine, Tylleskär, & Heggenhougen, 2013b). Women in other studies reported that providers did not give them the chance to agree or voluntarily opt out of HIV testing (Johansson, Pedersen, & Andersson, 2011). Such practices may be disempowering for most women, causing them to say yes, even if they intended to say no, since they might feel obliged to consent. Acquiescing to a test instead of voluntarily consenting is common among women with low socioeconomic and educational status (Bain, Dierickx, & Hens, 2015; Durojaye, 2008). Most of these women are ready to do anything to protect their unborn children if they are adequately counselled and informed about the benefits and risks involved in the test (Durojaye, 2008).

3.2.1.2 Beneficence and HIV Testing

The beneficence principle seeks to the benefits and the harms that may result from an action to ascertain whether, on balance, the action is beneficial (Kass, 2000). Early opt-out HIV testing literature rated the potential risks of routinely offering HIV testing at the ANC above its benefits (Bain et al., 2015). In the era of voluntary testing and counselling, patients decide to test for reasons they consider to be in their best interest. Beneficence is, therefore, inherent in such autonomous decision-making. Providers would be doing good professionally by identifying HIV positive pregnant women and offering them treatment (Cook, 1993; Durojaye, 2008). The woman takes the necessary measures to prolong her life while also preventing the spread of the disease to the unborn child, and the wider society is benefitted (Durojaye, 2008; Seloilwe, 2011). While this is the ideal situation, the routine opt-out testing does not make room for beneficence for the woman undergoing the test, as it is rooted in

seeking the public's best interest. The Siracusa Principle has often been used to support the need to downplay women's rights to autonomous decision-making (United Nations Economic and Social Council, 1985). The principle states that an individual's human rights are not absolute, and society may curtail them for its greater good. The discovery of antiretroviral medications capable of preventing transmission of HIV to unborn children further entrenched this position (Slavin, 2016).

Those in support of opt-out testing have argued that when individuals become aware of their status, they can initiate treatment early, which minimises the risk of transmission in society (Maartens, Celum, & Lewin, 2014). Some have argued that if left alone, women may not make rational decisions to take advantage of the benefits of antiretroviral drugs for themselves, the unborn child, and society. For this reason, society has a responsibility to encourage or even coerce individuals to undertake such health promotion activities to produce the desired outcomes (Clark, 2006; Schuklenk & Kleinsmidt, 2007). Therefore, the breaching of respect for autonomy has been deemed acceptable based on libertarian paternalism (Bain et al., 2015; Bennett, 2007b; Durojaye, 2008).

3.2.1.3 Non-maleficence and HIV testing

Closely related to the ethical principle of beneficence is non-maleficence. Non-maleficence in bioethics entreats health care providers to do no harm to the person, or at least do not leave the person worse off than before you started to intervene (Jonsen, 1975). It is an essential ethical principle for the health care provider to consider when disclosing a positive test result to a woman who had no plan to test for HIV. It is essential to reflect on the difference for the pregnant woman between voluntarily deciding to have an HIV test versus being told by a health care provider that she would be tested for HIV unless she refuses. Massive detection of individuals with HIV may overwhelm the health system, especially in sub-Saharan Africa. Such a lack of capacity to accommodate women testing positive, or a lack of guaranteed linkage to care or preventive services, may lead to untold damaging social and psychological trauma, partner violence and physical abuse (April, 2010; Seloilwe, 2011; Wocial & Cox, 2013).

Besides not getting the care needed, women testing positive for HIV in the sub-Saharan context often have no means of keeping their diagnosis confidential. For example, in many parts of Ghana, an individual's disease becomes a joint disease of the family (Drake et al., 2015; Seloilwe, 2011). A family member or a friend may even accompany a woman attending the antenatal clinic. These individuals would often become aware of the woman's HIV positive status, which leads to stigma and stress (Stuber, Meyer, & Link, 2008). Even when women do not experience discriminatory behaviours, they still endure internalised stigma, causing them to focus their lives around managing information about their new status rather than their health (Flowers et al., 2006).

The discussed ethical challenges associated with opt-out testing become even more pronounced when applied to a poorly-resourced context such as Ghana, where weak healthcare infrastructure, extreme poverty, gender inequality, and stigma threaten the test's beneficial effects (Rennie & Behets, 2006). For this reason, one needs to understand whether healthcare providers are enabled to implement the intervention as intended, in such a way that upholds the underlining human rights attributes discussed above. Without adequate adherence to these fundamental human rights principles, the opt-out approach and the reported increased uptake may be counterproductive, erode the trust between the woman and the provider and even turn the pregnant women away from the hospital (Fang et al., 2010).

3.3 Review of related literature

3.3.1 Literature search and data management

The review's inclusion and exclusion criteria were determined a priori and included studies involving a population of pregnant women (18 years and over) who tested for HIV in the antenatal clinic. I excluded studies conducted in high-income countries as they have slightly different testing guidelines and policies (Bell et al., 2016). Other exclusion criteria included not having access to the full-text article and studies conducted outside the antenatal clinic. I limited the search to studies published between 2006 and 2019 to coincide with the time CDC released the opt-out testing guidelines.

A search of the databases MEDLINE, Psych Info, Google Scholar and CINAHL, was undertaken in June 2017 using the following search terms: 'HIV or AIDS', 'pregnant women', 'testing and counselling', 'Provider-initiated or opt-out', 'adherence or compliance or intervention fidelity'. I extended the search to include HIV testing interventions reported under 'Prevention of Mother-to-Child Transmission or PMTCT'. Search strategies of existing reviews (Baggaley et al., 2012b; Ibekwe, Haigh, Duncan, & Fatoye, 2017a; Tudor Car et al., 2013) guided the final search strategy (Appendix 20). I made an effort to broaden the search strategy by including as many relevant articles as possible through subsequent manual screening (grey literature). I searched the reference list of the eleven systematic reviews retrieved and other primary articles. Identification and retrieval of articles were improved using mapped searches (Medical Subject Heading Terms) and Boolean operators ('AND', 'OR', and 'NOT'). I narrowed the search by applying the following filters: 1) English full text, 2) peer-reviewed articles, and 3) published after 2006. Automatic updates were set up in MEDLINE and CINAHL to ensure regular updating of newly published studies.

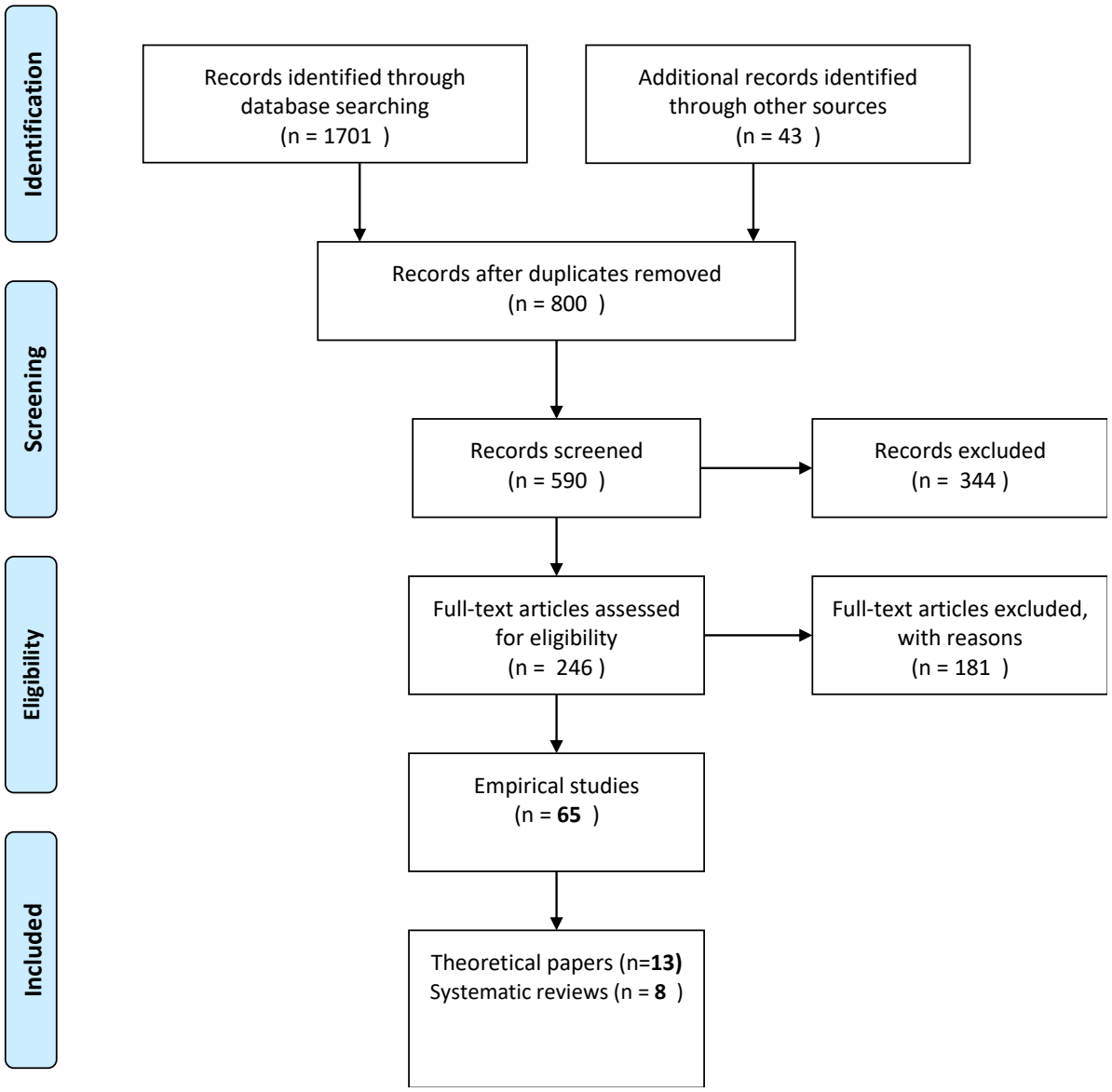


Figure 10: PRISMA flow diagram for study selection

Source: Liberati et al. (2009).

Figure 10 shows the PRISMA flow diagram of the systematic search. A search of databases and grey literature identified 1744 potentially relevant articles. These articles were imported into Endnote X9 bibliographic software to facilitate further management. After the removal of duplicates, 800 articles remained.

Only 590 of these articles were screened, leading to the exclusion of 344 studies that did not meet the inclusion criteria. I then reviewed the full-text articles of the 246 studies, leading to the further removal of 181 studies. Eighty-six (86) full-text articles, comprising 65 primary studies, 13 ethical review or theoretical studies and eight systematic reviews were included in the final narrative synthesis (Figure 10).

3.3.2 Summary of existing systematic reviews on opt-out HIV testing

The search identified eight systematic reviews involving 172 individual studies published between 2006 and 2019, including mostly (91.0%) observational studies on the opt-out approach to testing offer. Close to half of the individual studies included in these reviews were published before the CDC released the opt-out testing guidelines (2007). This means their content may not reflect the current opt-out guidelines. The lack of recent reviews makes reviewing of empirical studies published after 2006 timely. The eight reviews identified mainly focused on clinical outcomes, economic impact and implementation experiences of the opt-out HIV testing intervention.

Reviews have reported on the beneficial effects of using the opt-out approach. Three systematic reviews (Hensen et al., 2012b; Ibekwe et al., 2017a; Tudor Car et al., 2012; Wettstein et al., 2012) reported an overall testing uptake of 66-99.9% for provider-initiated opt-out screening, compared with 58-78.7% for patient-initiated opt-in testing. Mean uptake rates were highest in reviews that had a global focus (94%), followed by studies focusing on sub-Saharan Africa (85%) and then studies that concentrated on lower and middle-income countries LMICs (81%). The included studies did not explore reasons for the lower uptake in LMICs. Furthermore, the reported increased testing uptake reported in most studies did not improve behavioural outcomes such as linkage to care, disclosure, and treatment adherence. Ibekwe et al. (2017a), for example, reported that only 12.9% to 77.2% of pregnant women testing positive for HIV were linked to HIV care. Hensen et al. (2012b) have reported a similar lack of linkage to care. While it is not clear why women fail to enter, it is evident that many women who become aware that they are positive for HIV do not benefit from ART.

The reviews by Ibekwe, Haigh, Duncan, and Fatoye (2017b) and Bert and Gualano (2017) reported that routine antenatal HIV screening for pregnant women is both cost-effective and cost-saving. Examining a wide variety of economic evaluations studies, Ibekwe et al. (2017b) reported that the opt-out approach used resulted in a cost-saving of between 5,761.20 and 3.69 million United States dollars per case of previously undiagnosed maternal HIV infection. In the same year, Bert and Gualano (2017) reviewed 21 individual studies. They found that antenatal screening at any stage of pregnancy was cost-effective. It averted many HIV newborn cases and resulted in life expectancy gains for infected mothers and babies. The 31 individual studies, including the two reviews discussed above, were all conducted in high-income settings. The scope of the studies make generalising the findings to sub-Saharan Africa, and therefore Ghana, challenging.

Blackstone, Nwaozuru, and Iwelunmor (2017) systematically examined the barriers and facilitators of routine antenatal HIV testing in sub-Saharan Africa. The review focused on articles published between 2000 and 2015 and only studies that included women's perspectives. The 27 studies published in 11 African countries reported barriers such as the difficulty of communicating a positive test result to male partners, client convenience and accessibility, HIV-related stigma, the burden of other responsibilities at home and the perception that the antenatal clinic is a 'woman's job'. The authors emphasised the multifaceted problem of HIV testing that required community and system-wide intervention's approach. No review has assessed these barriers from the perspective of providers.

Hensen et al. (2012b) assessed provider-initiated testing and counselling's contribution in achieving universal testing of pregnant women. The review further assessed whether the PITC adoption adhered to the pre-test information, post-test counselling procedures and linkage to treatment. Including only ten studies, the review reported a testing uptake that ranged from 5.5% to 78.7%. The uptake increased by 9.9% to 65.6% following the introduction of PITC. Eight studies recorded testing uptake of ±85%. The review further reported that pre-test information was provided between 91.5% and 100% and post-test counselling between 82% and 99.8% of pregnant women. Though individual studies reported

high testing uptake, linkage to care was lower, ranging from 53.7% to 77.2%. The studies did not examine the reasons for many women testing positive but failing to enter HIV testing care has not been explored. More importantly, very little is known about providers' adherence to the principles that underpin the opt-out testing approach. The lack of evidence on the processes leading to the high testing uptake makes it difficult to explain the poor linkage to care.

3.3.3 Empirical literature

Reviewing primary studies became necessary as many of the reviews described above had studies carried out before the opt-out testing guidelines were released. This section involves a description of the included studies' distribution and focus, a numeric summary of HIV testing uptake from 2006 to 2019 and a synthesis of key findings on the delivery of the opt-out intervention. This will be followed by a description of contextual issues that affected implementation.

3.3.3.1 Characteristics of included studies (general)

Countries of included studies: The current review identified studies across different LMICs, with many studies (88%) undertaken in sub-Saharan Africa. Four countries recorded the highest number of studies (Figure 11). The large numbers of primary studies in sub-Saharan Africa may reflect the magnitude of HIV infection in this region and the corresponding HIV preventive interventions to reverse the trend (Chopra et al., 2009). Three studies (Gunn et al., 2016; Hardon et al., 2012; Obermeyer, 2014) were conducted in multiple countries. Three studies were conducted in Ghana (Kwapong et al., 2014; Nyuzaghl et al., 2011) (Figure 11).

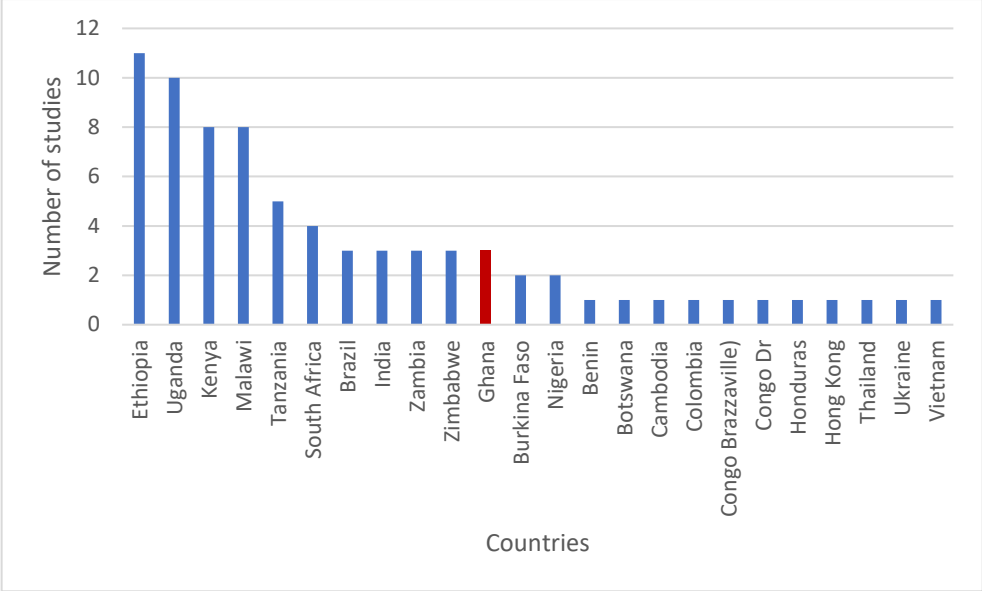


Figure 11: Distribution of studies across countries

Source: Included studies

Year of publication: The sixty-five publications included in this review involved empirical work in LMICs, published between 2006 and 2020. The distribution of studies, according to the year of publication, has been summarised in Figure 12. Unsurprisingly, the number of studies on the opt-out intervention was highest between 2011 and 2015, coinciding with the active periods of the millennium development goals (MDGs) (Prendergast, Essajee, & Penazzato, 2015). The need to understand the attainment of MDG6 with the HIV commitments of halting the spread of HIV by 2015 and ensuring antiretroviral access by 2010 might explain this surge. After 2015, there was a gradual decline in the number of studies reporting on opt-out testing of pregnant women. While the decline in the number of studies may be due to a change from MDG to Sustainable Development Goals (SDGs), one cannot ignore the near-complete routinisation and embedding of the opt-out intervention antenatal clinic.

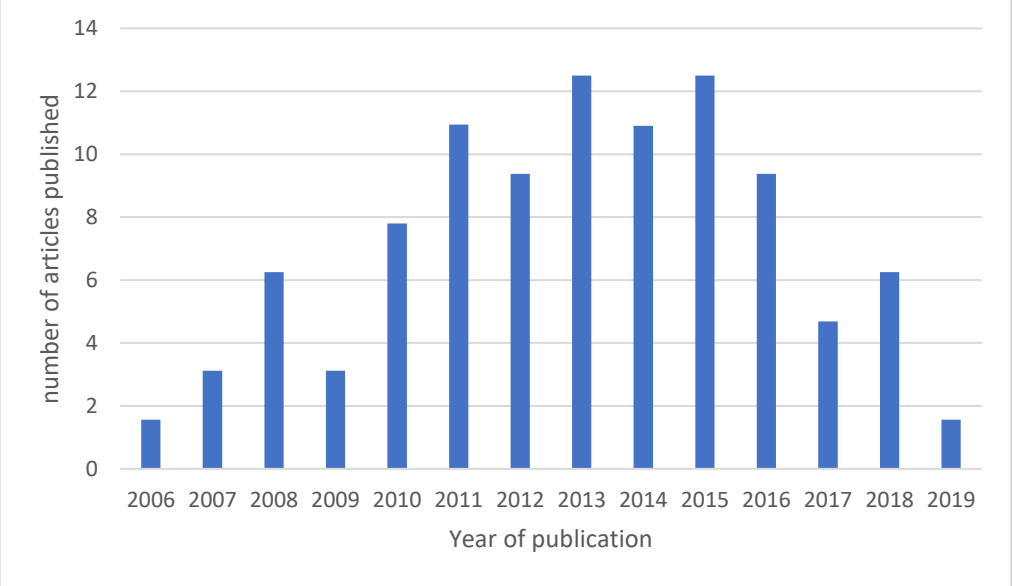


Figure 12: Distribution of studies according to years of publication

Source: Included studies

Data collection methods: Studies employed unique designs and data collection methods. The majority of studies evaluated the opt-out intervention using some form of quantitative design (n=37; 56.9%) followed by qualitative (N=22; 33.8%) and hybrid designs (n=5; 7.7%) (Figure 13). Studies were predominantly cross-sectional (n=45; 70.5%), with just one longitudinal study identified. The cross-sectional approach is relatively cheaper and faster to conduct. However, overly relying on cross-sectional studies offers just a one-time measurement of exposure to the opt-out intervention without an opportunity to establish causal relationships between the opt-out testing and increased testing uptake. Most studies mainly recruited pregnant women (256,984 women vs 984 health care providers) using non-probability sampling (n=34; 65.3%) approaches such as convenient and purposive sampling.

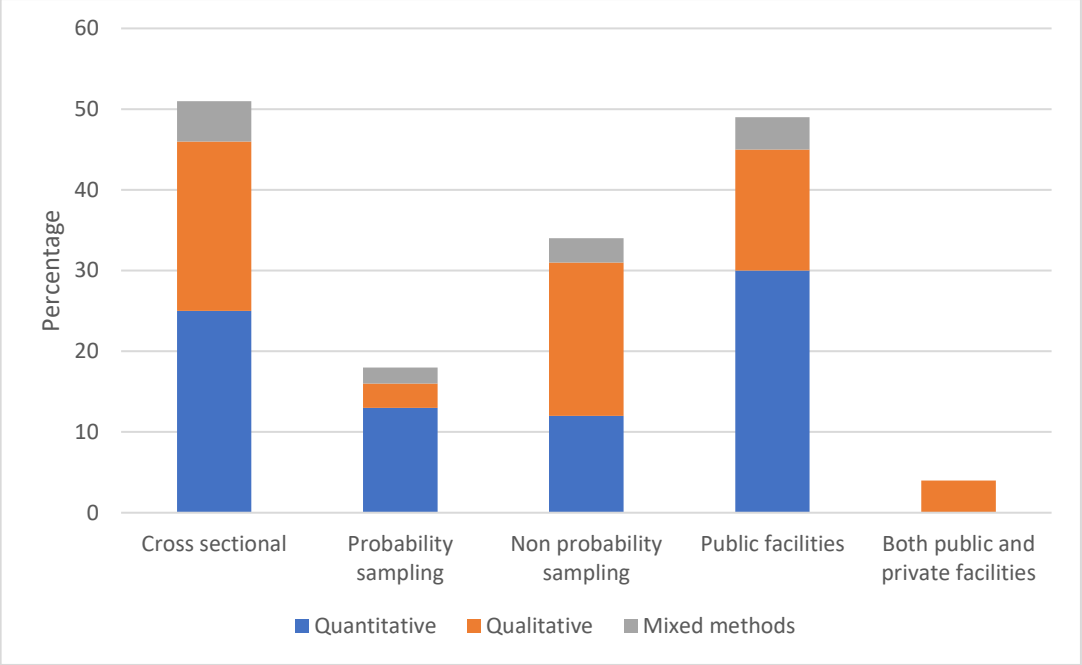


Figure 13: Characteristics of included studies

Source: Included studies

The use of data collection instruments varied across studies. Studies used one (84.4%), two (10.9%), and three form(s) (4.7%) of instruments to collect data from participants. The data collection instruments were interviews (37%), questionnaires (34%), observation guides/checklists (16%) and archival documents/hospital records (13%) (See Figure 14). The finding that only 7.7% of studies used mixed methods may suggest that authors could not confirm contradictory findings.

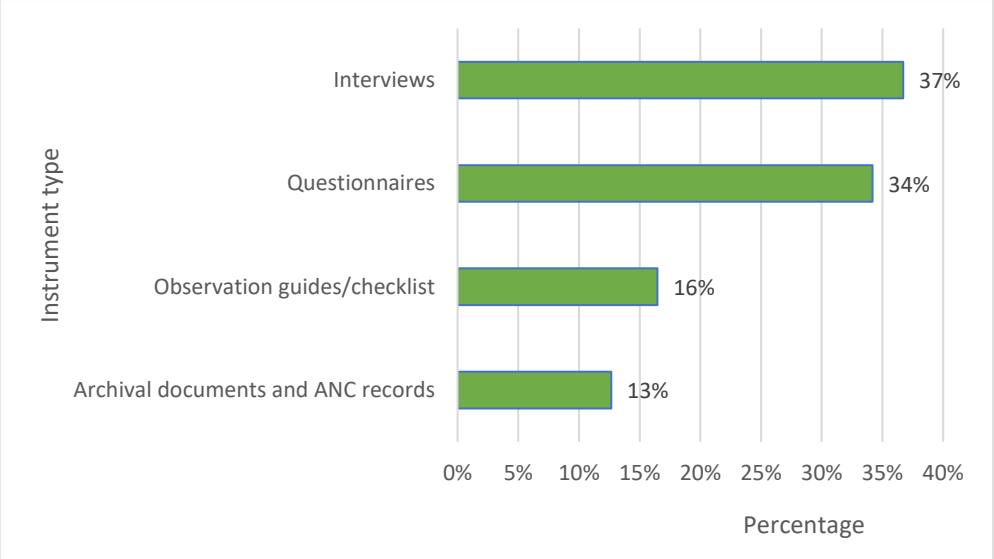


Figure 14: Data collection instruments employed in included studies

Source: Included studies

Characteristics and findings of the studies (n=3) conducted in Ghana: The three identified studies were conducted between 2011 and 2016 and determined implementation challenges (Osei, Fosu, & Der, 2016); health facility-related factors influencing testing (Kwapong et al., 2014) and acceptability of the routine offer of HIV testing in the antenatal clinics (Nyuzaghl et al., 2011). Consistent with the studies previously described, all the three studies were cross-sectional, with the authors relying on survey questionnaires and interview guides to obtain numeric and textual data from women (n=135-300) and health care providers (n=6-12).

Findings from the three studies were mixed. Osei et al. (2016) reported a high testing uptake (134; 99.3%), with 97% of women reporting privacy and confidentiality adequacy during counselling. Nyuzaghl et al. (2011) also reported that almost all 270 pregnant women favoured the opt-out policy as it helped them know their HIV status and facilitated the prevention of mother to child transmission of HIV. In contrast, a study in Kumasi (Kwapong et al., 2014) reported that 24% of the 300 pregnant women attending the antenatal clinic said they did not test because the midwives failed to provide information about the test. It is crucial to note that the study sites' differences might have influenced these studies' testing

uptake. The first two studies reporting increased uptake took place in relatively small cities, with most of the study participants likely to have travelled from remote locations to seek healthcare. Beyond these outcome-related studies, it is essential to understand how providers delivered the intervention, the level to which they adhered to the core elements, and factors that might have influenced the observed level of adherence. It is only then that some of these discrepant findings can be understood.

3.3.3.2 The objectives of the reviewed studies

Included studies were classified based on their primary objectives and main results (see Figure 15). Most studies had more than one focus. The majority of studies (n=27) focused on how study participants perceived and engaged in the opt-out intervention (responsiveness). A similar number (n=26) also reported on the uptake in acceptance and testing for HIV. The content of the intervention (delivering any of the five core ingredients) was the focus of 24 studies. Thirteen studies addressed contextual factors such as clinic environment, stigma, and cultural differences that influenced the implementation process. Seven studies addressed how agencies facilitated the intervention. There was no study from Ghana that examined the actual delivery of the opt-out intervention.

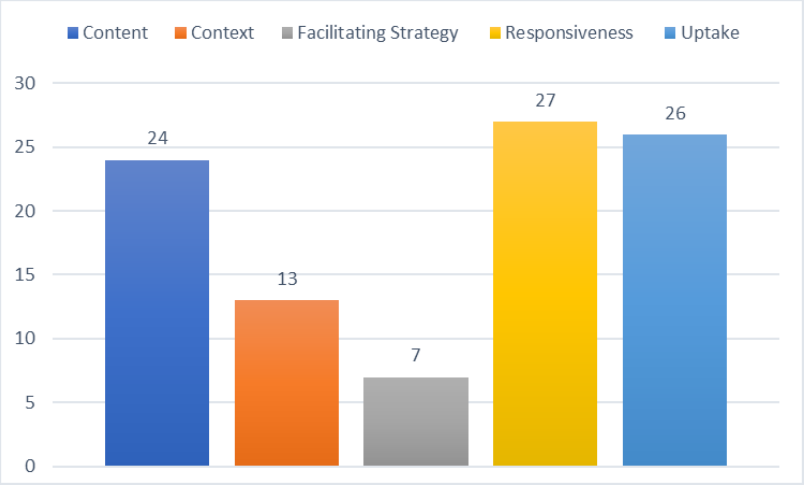


Figure 15[4]: Focus of primary studies on opt-out testing activities (2007-2019)

[4] Some studies had more than one focus' has been inserted, and the label now reads 2007 to 2019.

3.3.3.3 Numeric summary of uptake of HIV testing services

Figure 16 summarises the uptake of HIV testing services. Uptake, defined as a pregnant woman's acceptance of the intervention, was exceptionally high (85%, range 62.7% to 100%) for HIV testing, moderate for retesting in 34 weeks (67.3%) and considerably lower for HIV positive women on ARV treatment (36.7%). The testing uptake recorded in the current review is consistent with the earlier reported uptake by Hensen et al. (2012a), who reported an average of 85% testing uptake in eight studies but slightly higher than the 81% recorded by Tudor Car et al. (2013). The difference may be due to Tudor's study's global focus, compared with the current review that included studies only from LMICs. Only three studies reported test refusal rates, averaging 11.2% (range 6.2% - 17.5%). One study (Mandala, Kasonde, Badru, Dirks, & Torpey, 2019) reported that 67.3% of pregnant women who tested negative during their first antenatal visit retested in the third trimester. The mean prevalence of HIV infection among pregnant individuals attending antenatal clinics was 7.5% (range: 0.4-20.3%).

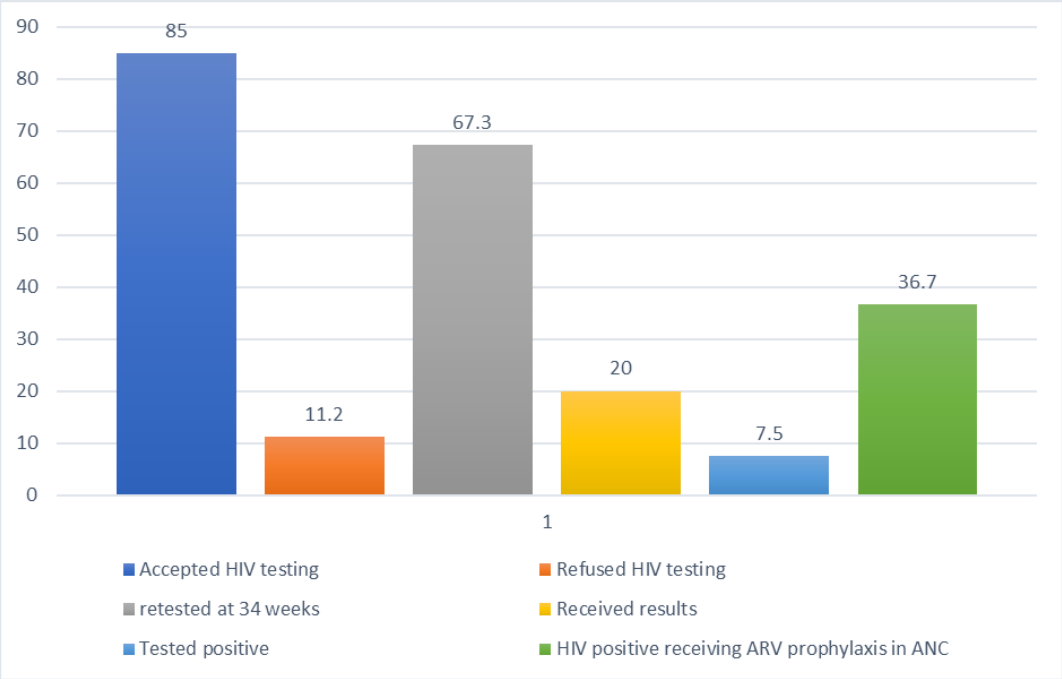


Figure 16: Summary of antenatal HIV testing and PMTCT uptake in the LMICs (2007-2018).

Source: Calculated from 28 individual studies.

3.3.3.4 The delivery of the opt-out intervention

The delivery of the opt-out intervention in any clinic must follow the human rights principles of informed consent, confidentiality, counselling, connection to care and correct test results. Figure 17 shows how reviewed studies have addressed these issues. Informed consent and the voluntary nature of consent was the most reported component (28% and 24% respectively), followed by a general adherence to the policy guideline (16%), post-test counselling (16%) and linkage to care (8%). However, most reviewed studies concentrated on just one aspect of the 5Cs, making it difficult to understand how pregnant women experienced the receipt of these core elements in their complete form. Studies also ascertained the receipt of these components from pregnant women, mainly using exit interviews. Therefore, the perspective of providers on how the core elements are delivered is lacking. The identified gap needs attention.

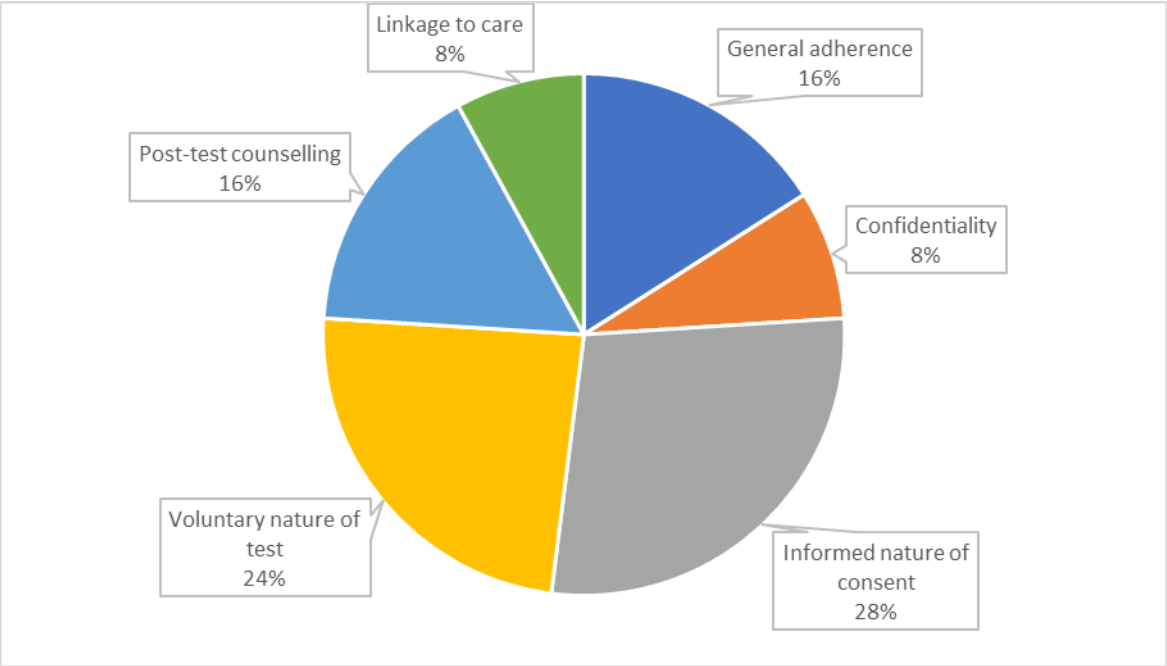


Figure 17: Distribution of the core principles of opt-out across studies; 2007-2019

3.3.3.4.1 Nature of informed nature of consent

For consent to be considered informed, a woman requires comprehensive and understandable information about opt-out. Five studies reported on the information delivered or received by pregnant women before an HIV test. These studies' findings indicate that providers' information was often either low, of short duration or absent. Crozier, Chotiga, and Pfeil (2013) explored factors related to HIV screening diagnosis and reported that pregnant migrant women in Northern Thailand mainly heard about AIDS from the media and friends and not from the healthcare provider. No study reported on prior knowledge of pregnant women before coming to the clinic or other sources of learning about HIV testing in the clinic. Mugore, Engelsmann, Ndoro, Dabis, and Perez (2008a) reported on the adequacy of information delivered. Ninety-five per cent of pregnant women taking part in the cross-sectional survey said that information offered to them was enough to make an informed decision.

However, half of the women mentioned that they were unaware that they could request individual pre-tests counselling. Also, studies did not report on details of the information women received. Neither did any study report on the receipt or delivery of the full complement of the minimum amount of information women are expected to receive before consenting. Studies have reported on making women aware of the testing process (Delva, Mutunga, Quaghebeur, & Temmerman, 2006; Groves et al., 2010); the meaning of MTCT (Ujiji et al., 2011b) and the meaning of a positive or negative HIV test (Hardon et al., 2012; Ujiji et al., 2011b). Two studies reported women's awareness of the test's importance (Mitiku, Addissie, & Molla, 2017; Ujiji et al., 2011b). Studies also reported providers' correcting misunderstandings (Ismail & Ali, 2009), encouraging partner testing (Ujiji et al., 2011b) or allowing women to ask questions (Delva et al., 2006; Ismail & Ali, 2009). These studies have mainly reported receipts of one or two components of the pre-test information from either the provider or the pregnant women's perspective. Such an approach makes it challenging to conclude whether women receive the intervention's full component.

3.3.3.4.2 Voluntary nature of consent

Besides delivering the information needed to make informed consent, pregnant women must consent or voluntarily opt out of the test. For consent to be voluntary, pregnant women must be aware that the test is optional and can opt out without any consequences. Findings from studies included in this review depicted instances where there might have been breaches of this requirement. Three studies (Kedote, Brousselle, Champagne, & Laudy, 2011; Mugore, Engelsmann, Ndoro, Dabis, & Perez, 2008b; Veloso et al., 2008) reported that healthcare providers tested pregnant women without their prior knowledge or consent. Though 128 (94%) of pregnant women attending antenatal clinic in Zimbabwe became aware of being tested, the test's voluntary nature remained unclear. Ujiji et al. (2011a) report that only 17% of women knew that testing was optional, while other studies have reported that pregnant women perceived the test as compulsory or coercive (Hardon et al., 2012; Kapembwa & Mubita-Ngoma, 2018). No study reported on the consent process.

3.3.3.4.3 Ensuring the confidentiality of testing services

Three studies reported on adherence to the content of privacy and confidentiality. Pregnant women reported being anxious about confidentiality issues as providers gave no assurance of the test's confidential nature (Tripathi, King, Finnerty, Koshovska-Kostenko, & Skipalska, 2013). The fourteen HIV positive women in the study by Madhivanan et al. (2014) recounted a violation of their right to privacy and confidentiality. In Ghana, Nyuzaghl et al. (2011) revealed that 97% of pregnant women reported privacy and confidentiality concerns during counselling. Beyond these pregnant women self-reports, the HIV literature has nothing on measures that institutions put in place to ensure a private testing process; neither do we know how healthcare providers understand and ensure confidentiality. Also, little to no information is available regarding the suitability of the antenatal environment for such confidentiality practices.

3.3.3.4.4 Ensuring correct or quality test results

The time spent delivering the opt-out intervention components is the proxy for the testing quality in this review and the entire thesis. Three studies gave a global picture of the time spent delivering the opt-out intervention, which differed across studies. These studies

reported inadequate time for women to decide (Mtumbuka, Maluwa, Malata, Pindani, & Bultemeier, 2012). For example, individual pre-test counselling lasted 6.6 minutes (range 20mins-34mins) in a study by Delva et al. (2006). Delivering group information lasted for 15 minutes (10-33 mins) in other studies (An et al., 2015). Similarly, the duration of post-test counselling differed between pregnant women testing negative (7.5 minutes) or positive (38 mins) for HIV (Delva et al., 2006). Spending more time counselling women who test positive in the clinic is crucial, even though the literature does not report how such an extended time affects the clinic flow or provider workload. The estimated time for counselling, undertaking rapid testing and delivering test results reported by two studies were 55 (Ahmed et al., 2016) and 39.8 minutes (Ismail & Ali, 2011). Despite testing guideline availability to ensure standardisation, the varying degree of time used across studies supports Maddox et al.'s (2017) concerns. The authors state that providers may not adhere to the test running period (5 min) or the required waiting time (10 min) before interpreting the results.

3.3.3.4.5 Delivering post-test counselling and connecting women to services

Pregnant women testing positive or negative for HIV must receive post-test counselling and be connected to care. The review identified no individual study that has reported on the full complement of post-test counselling services. Studies have instead reported on providers making women aware of: the meaning of a positive or negative test result (Ismail & Ali, 2009; Veloso et al., 2008); the window period and retesting during the third trimester (Delva et al., 2006) and the disclosure of HIV status to partners (Amboko & Brysiewicz, 2015; Delva et al., 2006; Hardon et al., 2012). However, only three studies reported that healthcare providers gave women ample time to ask questions (Hardon et al., 2012; Ismail & Ali, 2011; Kumar, Singh, & Kusuma, 2015). Tripathi et al. (2013) reported general inadequacy of post-test counselling, while others reported that women missed the opportunity to hear about preventive measures (Delva et al., 2006; Hardon et al., 2012; Veloso et al., 2008). Post-test counselling messages' incomplete nature made it unclear whether women who tested negative or positive for HIV benefited from preventive or treatment services, respectively. Besides two studies (Gupta et al., 2015; Madhivanan et al., 2014) that offer evidence on healthcare providers' effort to link women to HIV care, no study in this review addresses this

subject. The gap in evidence supports the notion that the interest in HIV testing intervention has been on the uptake, with little interest or attention to the testing process and connection to care.

3.3.3.5 Factors moderating adherence

3.3.3.5.1 Contextual or organisational characteristics influencing implementation

After more than ten years of its implementation, the opt-out intervention has become fully embedded in the antenatal social systems, structures and sub-cultures (Hasson, Blomberg, & Duner, 2012; Lipsey & Cordray, 2000). This makes it imperative to understand how the clinic setting supports the delivery of the intervention. Already, enough evidence exists that limited health care staff affects the delivery of the opt-out intervention (Ahmed et al., 2016; Ahumuza, Rujumba, Nkoyooyo, Byaruhanga, & Wanyenze, 2016; Crozier et al., 2013; Sprague, Chersich, & Black, 2011). The inadequate staffing levels might make delivery of rapid HIV testing difficult. Studies have reported that healthcare providers often resorted to limiting the amount of information delivered to women to deal with the excessive workload (Ahumuza et al., 2016; Crozier et al., 2013). A South African study reports that in Eastern Cape hospitals, a single nurse was in charge of all counselling related services, in addition to their assigned core roles (Sprague et al., 2011). The nurse's need to perform her core function meant that she could provide only five counselling sessions in a day (Sprague et al., 2011). On days that she fell sick, there usually would be no counselling activities. Ahmed et al. (2016) reported similar staffing challenges.

Studies have also reported the lack of adequate testing spaces that allow for private testing and sufficient protection of women's HIV positive status. For example, a study in Uganda reported that the lack of suitable rooms pushed healthcare providers to use examination rooms for testing and counselling (Medley & Kennedy, 2010). In addition, the use of such makeshift spaces to deliver HIV testing services affected the delivery of critical components of the intervention, such as adequate pre-test information sessions (Ahumuza et al., 2016).

Another important contextual factor that influences programme implementation is the level of facilitation. Facilitation involves the provision of precise, explicit guidelines, training, and

leadership. Smooth intervention delivery requires strong leadership, implementation support and appropriate accountability mechanisms (Leon, Lewin, & Mathews, 2013). Little is known about the level of facilitation of the HIV testing intervention, especially in Ghana. However, this had been addressed in other settings, such as the school environment by Gottfredson and Gottfredson (2002) (Payne, 2009). Two studies have reported the non-availability of guidelines and protocols to guide testing activities in some selected antenatal clinics (Gupta et al., 2015; Mwangome et al., 2017). A Tanzanian study reported that clinic staff relied on outdated guidelines to guide their practice. Studies have also noted the lack of supplies such as test kits needed to test pregnant women (Ahmed et al., 2016; An et al., 2015; Mwangome et al., 2017). Mwangome et al. (2017) reported using an outdated version of testing guidelines in a clinic.

In most of these studies, the lack of stock was attributed to misuse of test kits and inadequate documentation, leading to under-forecasting supply needs. Reasons external to the antenatal clinic included insufficient stock at the national medical stores, delays in delivering orders to facilities, and delivery of only a component of the HIV testing algorithm requirement. Providers employed several strategies to deal with such shortages, including prioritising which clients to test and borrowing supplies from other facilities. However, providers also felt unsupported in their roles. Such concerns involved not receiving adequate training to carry out counselling services (Medley, 2009; Tripathi et al., 2013). Tripathi et al. (2013) report that providers' most profound concern was providing counselling services for women testing positive for HIV. However, Kim et al. (2013) reported that including performance standards and ensuring provider training may increase provider skills from 67% to 74% at intervention sites, compared to a decline from 65% to 59%. No study reported on provider supervision.

Other contextual factors at the individual level were power imbalances (n=4); disrespectful care (n=1), anticipated stigma (n=3), psychological distress (n=1) discordant couples (n=1), barriers in communication (n-1) and male non-involvement in antenatal care (n=1). Narratives from pregnant women revealed that power imbalances often favoured providers and resulted in directed counselling and limited shared decision with providers (An et al.,

2015; Gourlay et al., 2014; Groves & Eyakuze, 2010; Vernooij & Hardon, 2013). A study involving rural women in Tanzania reported that pregnant women often viewed their social status as below that of the provider and, therefore, often failed to question providers even when unhappy with the care provided (Gourlay et al., 2014). Narratives of Ugandan health care providers included in Vernooij and Hardon (2013) study revealed two hegemonic discourses: 'protecting the child's health' and 'the health worker knows best'. Such a notion often resulted in a directive form of counselling within the clinic.

Stigma was another contextual issue that affected how women viewed the intervention (An & Kim, 2016; Turan & Nyblade, 2013). For example, a study has reported that 32% of women anticipated a collapse of their relationship if they tested positive for HIV, while 45% felt they could lose their friends (Turan et al., 2011). Similar findings emerged from the narratives of pregnant women in rural and peri-urban settings in Tanzania who reported that stigma surrounding HIV often led them to seek health services in other facilities (An & Kim, 2016). Needing permission from partners before testing (Medley & Kennedy, 2010) and disrespectful care from providers were other factors women mentioned (Gourlay et al., 2014). Providers were also concerned about difficulties that came with disclosing test results to discordant couples (Medley & Kennedy, 2010), language barriers (Crozier et al., 2013) and stigma (Oosterhoff, Hardon, Nguyen, Pham, & Wright, 2008). The above contextual challenges make it imperative to understand the antenatal clinic's testing processes and how the clinic's context impinges on attaining a rights-based testing outcome.

3.3.3.5.2 Individual factors influencing implementation

The antenatal-based HIV testing intervention revolves around healthcare providers and pregnant women. The success of the opt-out testing hinges much on how these individuals perceive and engage with the intervention. Individuals' perceived need for an intervention, confidence in carrying out the intervention (self-efficacy), belief that the intervention would succeed and possessing skills to implement the intervention impacts intervention's delivery and success (Durlak & DuPre, 2008). Not much evidence exists in the antenatal clinic on how healthcare providers view the fit between the clinic practices and the opt-out intervention. Instead, researchers have reported pregnant women's perceptions (n=14), attitudes (n=5);

satisfaction (n=5); anxieties or fears that come with the offer of a test (n=2). Pregnant women in eight studies perceived the routine offer of HIV in the antenatal clinic as compulsory, as they had no choice to decide whether to test or not (An & Kim, 2016; Angotti, 2012; Kapembwa & Mubita-Ngoma, 2018; Larsson et al., 2012; Mitiku et al., 2017; Obermeyer, 2014; Rujumba et al., 2013a; Ujiji et al., 2011a).

Other pregnant women have perceived the intervention more favourably (Abtew, Awoke, & Asrat, 2015; Byamugisha, Tumwine, Ndeezi, Karamagi, & Tylleskär, 2010; Maddox et al., 2017; Wangwe, Nyasinde, & Charles, 2014). Having a positive attitude increased the test acceptance rate significantly (Abtew et al., 2015). A positive attitude correlates with the woman considering beneficial aspects of status awareness, such as the chance to receive antiretroviral therapy (An et al., 2015; Malaju & Alene, 2012; Mitiku et al., 2017). Five studies included in this review reported that women were primarily satisfied with the overall counselling services (Chandisarewa, 2007), immediate counselling received (Rujumba et al., 2013a), and the privacy of testing and counselling process (Kevin, Mutugi, & Wanzala, 2014).

3.3.4 Implications for the current research

The current review has identified gaps worth exploring further. Firstly, this review reveals a discrepancy between policy debates in the HIV literature and the focus of antenatal HIV testing research identified in this review. The contention of commentators and ethicists concerns how the opt-out approach may impinge upon the pregnant woman's autonomy. For many, the core human rights of consent, confidentiality and counselling are incompatible with the busy antenatal clinic environment. Based on this assumption, the expectation is that empirical research would focus on determining how, in practice, healthcare providers address these concerns. To date, no study has assessed the implementation process. The review, however, identified studies that have mainly focused on testing uptake. Researchers' primary interest appears to be on the uptake rather than how the intervention was delivered (the process). Reasons for not addressing implementation fidelity are many.

Second, and closely related to the above findings, is the fact that while theoretical models of process evaluation and implementation fidelity exist and are used widely, no study involving

antenatal HIV testing relied on any conceptual framework when assessing the delivery of the opt-out intervention. The lack of attention to fidelity and conceptual frameworks in the reviewed studies is not peculiar to this review. For example, a scoping review found that only 5% of studies addressed implementation fidelity or utilised a fidelity framework in motivational interventions (Quested, Ntoumanis, Thøgersen-Ntoumani, Hagger, & Hancox, 2017). The finding is similar to other behavioural studies (Gearing et al., 2011; Schinckus, Van den Broucke, & Housiaux, 2014; Schoenwald & Garland, 2013). A similar finding has been reported by Durlak and Dupree (2008) after they reviewed 500 studies of health promotion and prevention programmes. In addition, Perepletchikova, Hilt, Chereji, and Kazdin (2009) have suggested that researchers often feel they do not have sufficient knowledge to measure implementation success. Cox et al. (2019) have also attributed the general lack of fidelity studies to the sophisticated nature of methods needed to measure fidelity, such as audio recording, tailored observation checklists and detailed analysis of adherence levels.

Although researchers employed a wide variety of data collection techniques, the qualitative approach was the most predominant in 84.4% of studies (Figure 14). The qualitative method was used either in isolation or in combination with a questionnaire. In instances where researchers used more than one data collection technique, there was no evidence of appropriate data triangulation, and it was not often measured on two or more levels (i.e. pregnant women, provider, and national-level officers). A possible explanation could be that high-quality primary studies may not always be practical in the busy antenatal clinic environment. Researchers, therefore, need to balance the complexity of the antenatal clinic environment with high-quality methods. I have addressed these gaps by conceptualising the study as a process evaluation using an implementation framework. The approach ushers in a new direction for HIV testing research to improve rigour and replicability and systematically describe how various stakeholders adhere to the intervention's core principles. It is only through this that researchers can link the observed uptake to the opt-out intervention.

3.4 Chapter summary

With the increasing reliance on the antenatal clinic and health care providers to deliver evidence-based HIV prevention intervention, research must examine the processes by which nurses and midwives implement a programme. Such a research approach will help explain observed outcomes while identifying barriers. In this chapter, I have outlined the intellectual rationale for this thesis. I achieved this by making connections between what I intended to study and the broader area of evidence-based practice, the ethics of opt-out HIV testing and the empirical literature. This chapter revealed the empirical evidence regarding the HIV testing intervention in the antenatal clinic and the ethical arguments surrounding the intervention's introduction. Existing systematic reviews included studies mainly conducted before the WHO/UNAIDS' policy guidance was introduced, making it unsuitable for this study. Of the empirical studies conducted after the policy guidelines were introduced in 2007, only three were found in Ghana, and all these focused on testing outcomes. These studies relied on pregnant women responses and used cross-sectional designs to determine perceptions about the intervention.

4 CHAPTER FOUR: EVALUATION METHODOLOGY

4.1 Introduction

The previous chapter positioned this evaluation study within HIV testing and implementation research literature. The review findings partly informed the chosen philosophical underpinnings and the broad decisions made in the current chapter. The chapter is in two parts. The first part, the process *evaluation methodology*, describes the overarching evaluation strategy and the general philosophical underpinnings that informed the subsequent decisions. The second part, the *evaluation methods*, outlines what I did in the field. Specifically, it offers insight into the specific tools and procedures I used to collect and analyse the data. After this introduction, I describe the evaluation methodology by providing a brief historical perspective on evaluation as a field of inquiry and why I focused on '*process'*. I then present the conceptual framework and its utility in holding the entire thesis together. After this, I describe the stages involved in developing the process evaluation plan, followed by how pragmatism as a philosophical perspective informed my choice of mixed-methods design. The section ends with a description of the overall design and evaluation plan.

4.2 Process evaluation methodology

In its simplest form, Scriven (1991) defined evaluation as determining the relative merit, worth or value of something. Even though the American perspective has dominated the field of evaluation, the emergence of different actors with competing interests has led to diverse definitions, approaches and concepts (Rossi et al., 2004)). Attempts to have a unified definition and classification of the various evaluation approaches have led various scholars (Alkin & Christie, 2004; Chen, 2005; Mouton, 2007; Rossi, Lipsey, & Freeman, 2004; Stufflebeam & Shinkfield, 2007) to organise the existing approaches into a meaningful order. For example, Alkin and Christie (2004) introduced an evaluation tree concept, with use, methods, and valuing representing the branches. Rossi et al. (2004) and Mouton (2007) suggested a classification system that linked evaluation to the program cycle (design, implementation and outcomes). Similarly, Owen (2007) identified proactive, clarificative,

interactive, monitoring, and impact evaluation. Stufflebeam and Shinkfield (2007) introduced the five evaluation approaches system. Unfortunately, the confusion surrounding approaches to evaluation may persist for some time to come.

The focus of this evaluation study is '*process'* (Moore et al., 2015). Process evaluations are concerned with monitoring, documenting and analysing how, why and what conditions must be available for an intervention to happen (Dehar, 1993; Harachi, Abbott, Catalano, Haggerty, & Fleming, 2004), while impact evaluation focuses on efficacy or effectiveness (Moore et al., 2015). Process evaluations offer explanations for success, failure and changes to the programme over time (Patton, 2008) and the components that caused the positive or negative effects (Harachi et al., 2004; Strijk, Proper, van der Beek, & van Mechelen, 2011). For example, Van den Branden et al. (2015) evaluated the implementation fidelity of oral health promotion intervention in preschool children. Relying on Carroll's implementation framework and mixed-methods approach, the study found that whereas 88% of all parents attended all home visits, only 57% received at least 9 out of 11 planned consultations. Whereas outcome evaluation reported high attendance (88%), process evaluation allowed us to deliver intervention components (planned consultation).

The routine opt-out testing process is a complex intervention with multiple components (Campbell et al., 2000; Francis-Graham et al., 2019; Montoy, Dow, & Kaplan, 2016b) and, therefore, unlikely to be implemented as planned (Dusenbury & Brannigan, 2003). The complexity is particularly true in antenatal settings, where adaptations may be inevitable and even beneficial (Movsisyan et al., 2019). The reviewed HIV testing literature clarified that past efforts to evaluate the programme's implementation have been outcome-focused and have often produced variable findings. The lack of process data in the HIV literature makes it challenging to explain why a pregnant woman will refuse to enter HIV care or take an antiretroviral drug after testing positive for HIV. With the overreliance on outcome data, one cannot determine whether the lack of impact is due to poor implementation or inadequacies inherent in the design (opt-out) itself, the so-called Type III error (Bonde, Stjernqvist, Sabinsky, & Maindal, 2018; Dobson & Cook, 1980; Linnan & Steckler, 2002).

Focusing on the process was therefore driven by the need to explore context-specific barriers, facilitators and modifications or adaptations (Sandars, Brown, & Walsh, 2017; Strijk et al., 2011; Young et al., 2008) and also to improve the internal validity of impact evaluations (Byng, Norman, Redfern, & Jones, 2008; Craig et al., 2008; Hulscher, Laurant, & Grol, 2004; Murta, Sanderson, & Oldenburg, 2007; Saunders, Evans, & Joshi, 2005).

4.2.1 The conceptual framework

Early implementation researchers relied on empirically driven research approaches that paid little or no attention to an implementation's theoretical underpinnings (Nilsen, 2015). As revealed in this study's reviewed literature, no study employed frameworks[5] or theories[6] to interpret their findings. Such a gap exists against the backdrop of the recent call for implementation researchers to improve their results through the use of frameworks and theories (Nilsen, 2015). The lack of framework utilisation may not, however, be peculiar to HIV prevention interventions. Schaap, Bessems, Otten, Kremers, and van Nassau (2018) assessed how researchers assessed fidelity in a school-based obesity prevention programme by reviewing studies published between January 2001 and October 2017. The study found that out of the 63 different studies reporting on implementation fidelity, only 17 authors relied on a theoretical framework. Failure to report on implementation frameworks may be due to the multiplicity of frameworks and the poorly defined terminologies used to describe them. The description of the various frameworks is above the scope of this section. Tabak, Khoong, Chambers, and Brownson (2012) and Nilsen (2015) offer comprehensive taxonomy to improve our understanding.

[5] Frameworks have descriptive purposes, point to factors believed to influence implementation outcomes and provide a systematic approach to develop, manage and evaluate interventions (Nilsen, 2015).

[6] Theories offer a systematic way of comprehending events or behaviours by revealing definitions, concepts, and propositions that specify the relationship between concepts, thereby helping to explain or predict events (Glanz & Bishop, 2010).

4.2.1.1 Carroll's Framework of Implementation Fidelity

I relied on the conceptual framework of implementation fidelity developed by Carroll et al. (2007) to organise this evaluation study. The framework, outlined in Figure 18, depicts elements of implementation fidelity and their relationship with each other. In this framework, the measurement of implementation fidelity is the measurement of adherence (and therefore, the two terms are sometimes used interchangeably in this thesis). As the principal component of the framework, adherence includes sub-categories of content, frequency, duration, and coverage. An evaluator examines fidelity by measuring how implementors adhere to the intervention's intended coverage, content, frequency and duration. Coverage in this study refers to the proportion of pregnant women exposed to the opt-out intervention as intended (i.e. offered and tested for HIV). The other three adherence measures include how much of the intervention's prescribed content is delivered by implementers, how frequently (frequency), and how long (duration). Fidelity is high if the programme implementation adheres to the original intervention model (in the case of this study, the opt-out approach and the core human rights principles).

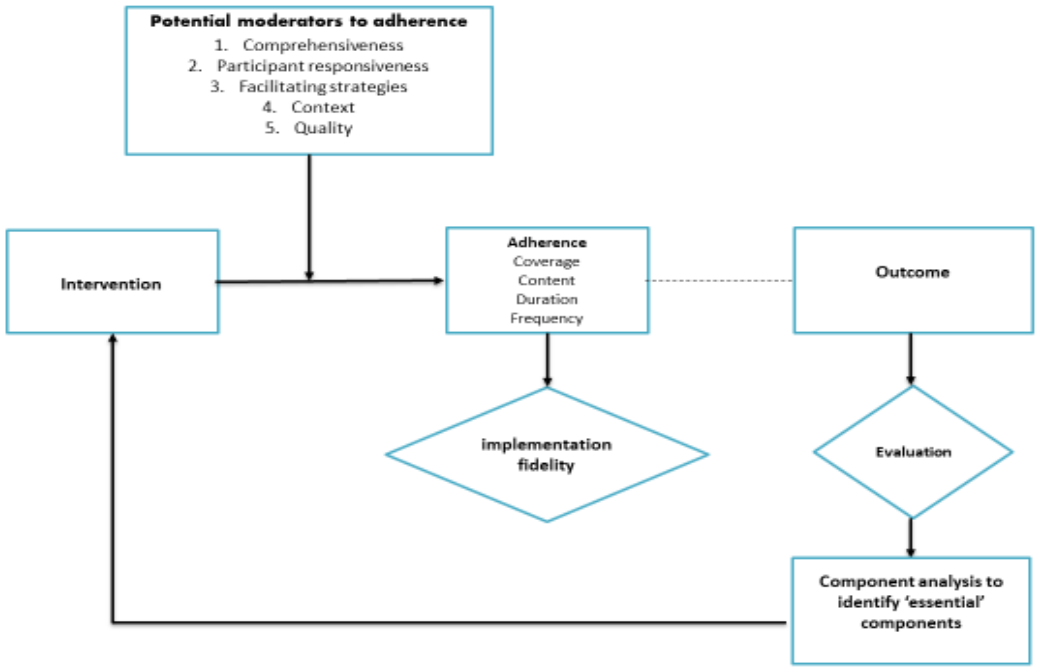


Figure 18: Carroll's Conceptual Framework of Implementation Fidelity

Source: Carroll et al. (2007)

The framework suggests four factors that moderate the four interrelated variables. The first moderator is intervention complexity. The more complex an intervention, the harder it is to implement it fully. Implementers will achieve higher fidelity levels if policy documents offer a detailed and precise description of the intervention. The second moderator is facilitating strategies, which include training, guidelines, supervision and feedback. Facilitating strategies optimise and standardise the fidelity of implementation. The third moderator is quality of delivery, defined as how (the manner) an implementer delivers a programme. Participant responsiveness is the fourth moderator. It refers to how participants of an intervention engage in the intervention in terms of perceptions and attitudes. When participants are enthusiastic about an intervention, they can achieve higher implementation.

Hasson (2010) suggested two extra moderators, namely context and recruitment. The former involves the organisational structure and the culture in which healthcare staff delivers the intervention. Recruitment refers to selecting or inviting participants, the reason for nonparticipation and the presence of sub-groups.

4.2.1.2 The adapted framework

I adapted Carroll's framework to guide the analysis of the qualitative and quantitative findings. This study aimed to assess the antenatal clinic-based opt-out HIV testing implementation fidelity and identify factors that moderated the observed fidelity levels. The study addressed questions such as: to what extent do healthcare providers understand and adhere to the opt-out approach when offering HIV testing?; to what extent do healthcare providers adhere to the recommended 5Cs when offering HIV testing?; is the policy adequately explained in the programme guidelines?; what is the level of support for providers in terms of guidelines, training, supervision, and feedback?

Ideally, process evaluation should include all the elements described in the framework. This study aimed to evaluate the implementation fidelity of the opt-out intervention using the framework explained. To my knowledge, this is the first study to investigate the implementation fidelity of the opt-out intervention systematically. Using this framework, I retained adherence to the intervention's content and duration and potential moderators

used in the original framework. Therefore, this study has omitted the frequency of the intervention's delivery, quality, and recruitment components. I used the duration of rapid testing as a proxy for quality of delivery or correct test results. Also, assessing the quantitative relationship between fidelity levels and outcomes, as indicated in Carroll's framework, was not assessed. I reviewed Ghana's policy documents to identify the 'essential' component of the intervention.

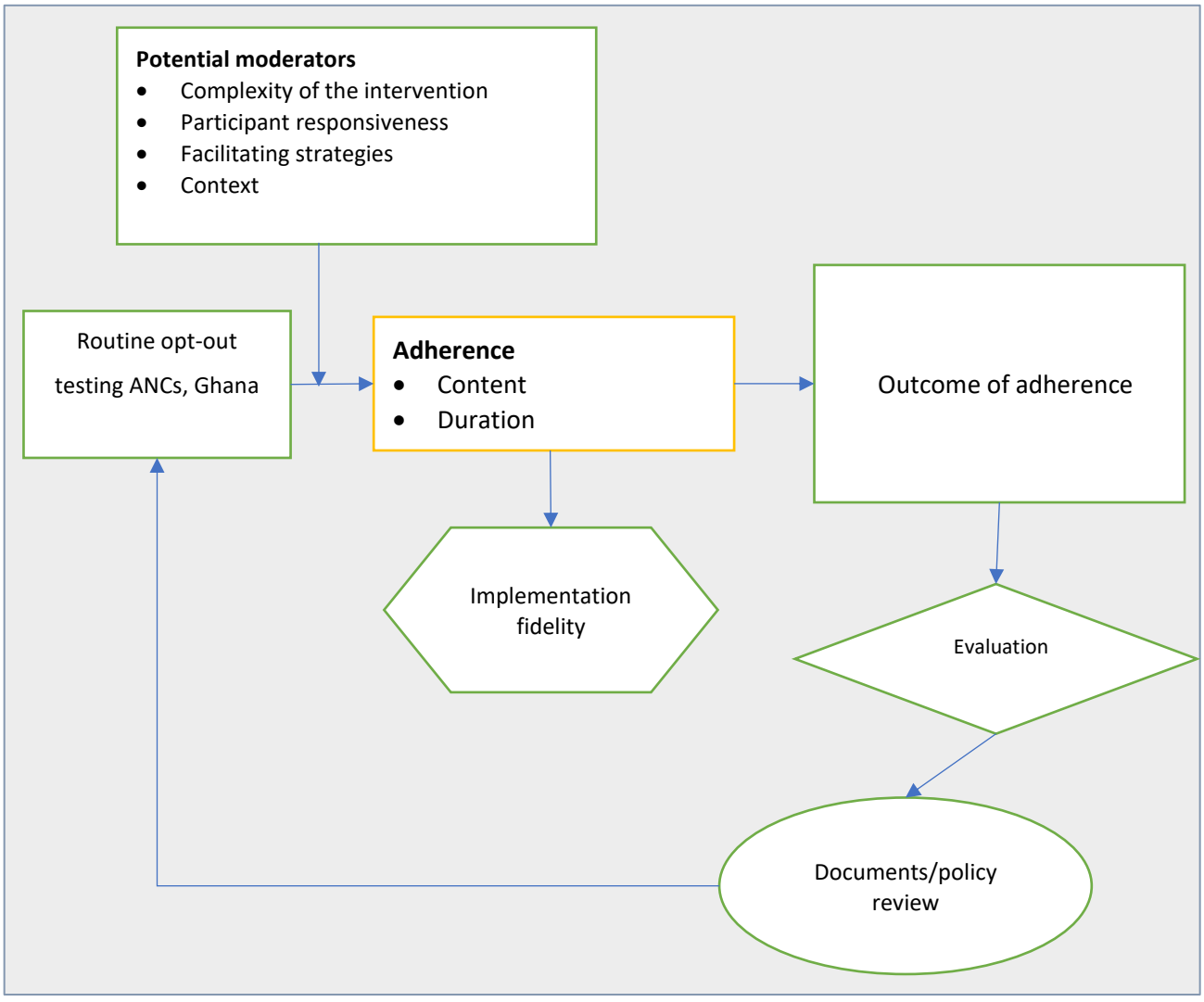


Figure 19: An adapted conceptual framework of implementation fidelity

Source: Carroll et al. (2007)

4.2.2 Process evaluation plan

In this section, I describe the logic behind opt-out intervention and its expected delivery. Then, based on Carroll's framework and concepts, I develop the constructs or dimensions measured, which informed the process evaluation questions. The last part would address the plan itself.

4.2.2.1 Theoretical underpinnings of opt-out testing

The opt-out testing involves a subtle shift in obtaining consent (Montoy et al., 2016a). Midwives inform all women about the inclusion of HIV testing in the routine antenatal care test. Offering a test this way means the midwife presents the test as a default option (e.g. 'we will be testing you for HIV unless you decline') (Branson et al., 2006; Rosen et al., 2015). Default is a component of the nudge theory that capitalises on well-established shortcomings of human decision making to influence behaviour (Jagosh et al., 2015). By aligning the default option of the HIV testing programme with the public health objective (women taking the test), the public health experts hypothesised that the opt-out approach would increase uptake (Bayer & Fairchild, 2006; Halpern, Ubel, & Asch, 2007; Johnson & Goldstein, 2004). For example, pregnant women could incur a cost (justifying decision) when deciding to opt out of a test. If the cost exceeds the benefit of opting out, then it becomes unreasonable for her to do so (switching cost) (Thaler & Sunstein, 2009).

Also, pregnant women compare perceived losses against equivalent gains (e.g. preventing infection in an unborn child versus psychological discomfort of testing). Opt-out testing, acting on the default principles, weighs the loss of benefits heavily against potential gains of not testing (loss aversion) (Keller, Harlam, Loewenstein, & Volpp, 2011). The very act of making an active choice requires some effort in thinking (see Figure 20). By making HIV testing the clinic's default option, the opt-out testing approach exploits the pregnant woman's bias not to use this effort, thereby encouraging her to actively opt for the test (cognitive effort) (Thaler & Sunstein, 2009). The last explanation offered for how the opt-out work is the power of recommendation by a person of authority.

Default options act as a powerful tool to influence a decision and, therefore, need to be used wisely by individuals in positions of power. Using defaults in the antenatal clinics must not preclude free choice or impinge unnecessarily on the pregnant woman's right to autonomy (Halpern et al., 2007). Because individual autonomy is compromised when they are unaware of the decisions confronting them, health care providers were instructed to precede the test offer with brief group pre-test information or discussion (WHO/UNAIDS, 2007a). At all times, the testing must be rights-based.

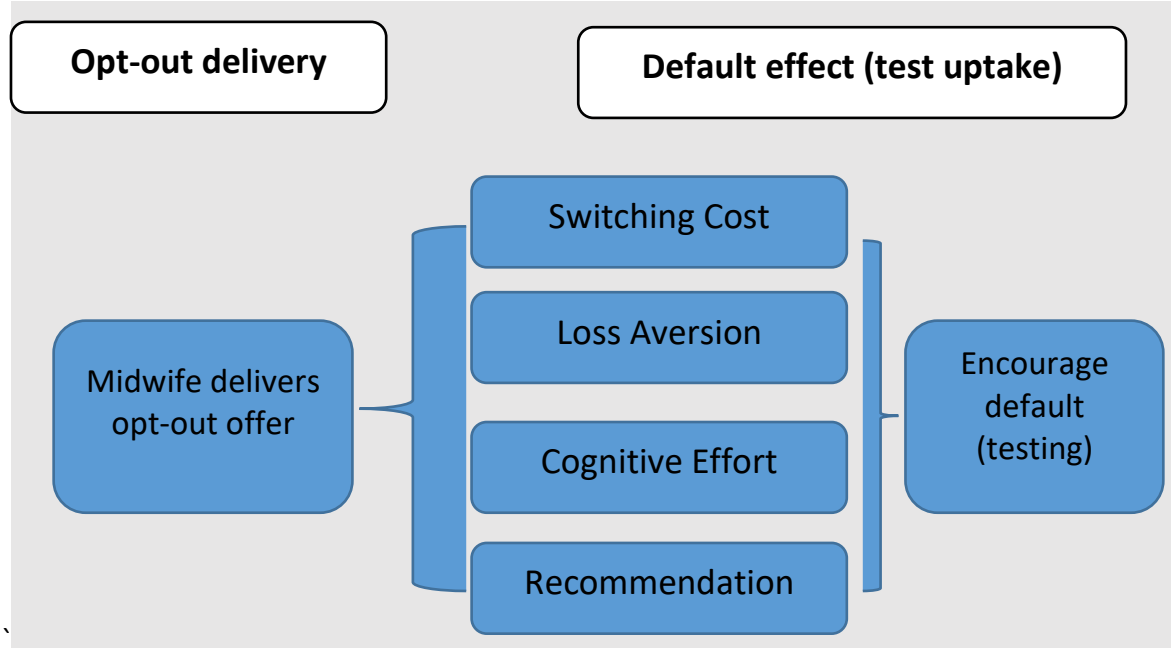


Figure 20: How the opt-out intervention affects decision making

Source: adapted from Francis Graham (2019).

4.2.2.2 The intervention as specified by GAC's HIV Testing and Counselling Guidelines

Women attending the antenatal clinics for the first time should receive streamlined pre-test counselling or information delivered during the 15-20 minutes of group education. During this time, the midwife informs them of general pregnancy issues in addition to HIV testing. The information to be delivered should be adequate and must make women aware of the testing process, mother-to-child transmission, the meaning of positive or negative test results, PMTCT and HIV preventive measures. Next, the midwife offers individual pre-test

counselling to women requiring further information. After receiving the information, the women go through the usual antenatal clinic screening process and then see the midwife in the consulting room. Here, the midwife reiterates the earlier information and makes the women aware that HIV testing would be part of the day's routine test. Consent is presumed unless a pregnant woman explicitly refuses the test (opts-out). Women who do not refuse and thus give verbal informed consent would have the blood drawn for rapid HIV testing. Women testing negative then receive brief post-test counselling covering preventive measures, partner testing and the need to retest during the 3rd trimester. However, for positive test results, providers must commit much time to provide detailed post-test counselling that addresses immediate concerns. Women testing positive receive detailed post-test counselling and then offered antiretroviral therapy. (see ***Figure 21)***

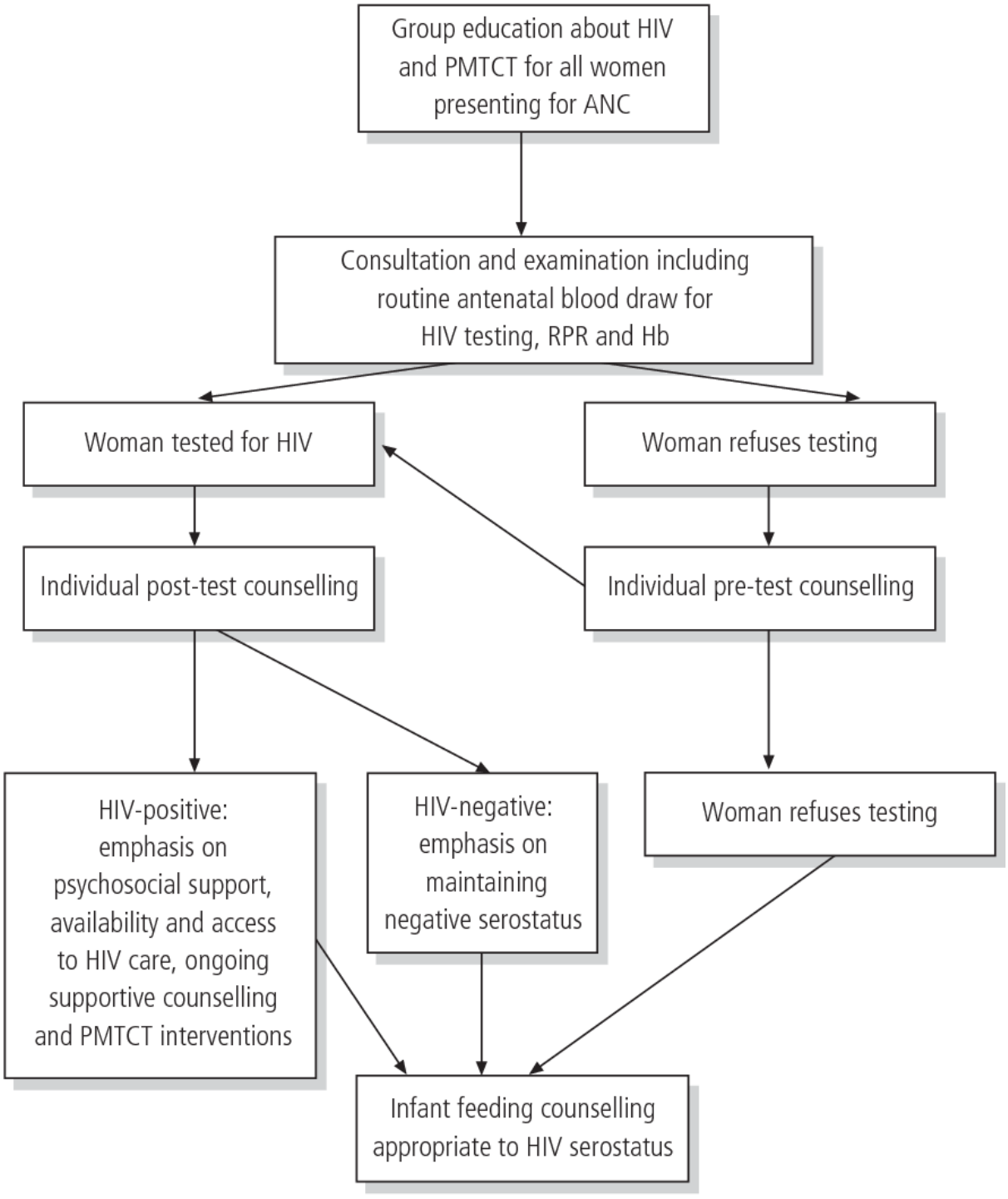


Figure 21***: The intervention as specified by GAC's HIV Testing and Counselling Guidelines***

Photo credit: Chandisarewa (2007)

Table 5: Planned delivery of the opt-out HIV intervention

component	Activity
Pre-test information	The provider delivers information in groups, with the opportunity for individual pre-test information
	Provider explains the HIV testing process to pregnant women
	Mother made aware of how HIV is transmitted from mother to child
	Provider explains what it means to be positive or negative for HIV
	Mother made aware of preventive options for HIV
	Mother is given ample time and opportunity to ask questions
Informed consent	Pregnant women informed that HIV test is part of a panel of tests and that she has the right to refuse
	The provider ensures that pregnant woman voluntarily want to undergo the test
Rapid testing	Women tested for HIV using the recommended algorithm
	Provider waits for 10-15 minutes before reading test results
Post-test counselling and connection to care	Meaning of test result explained to pregnant women
	Information on prevention given
	Provider discusses partner testing with women
	The window period and the need to retest during the 34th week is explained
	Available support services explained to pregnant women
	Provider allows time for questions

4.2.2.3 Constructs or dimensions for evaluation

The second step for planning the process evaluation involved the identification of the dimensions for evaluating the intervention. I relied on Carroll's Conceptual Framework for implementation fidelity discussed in Section 4.2.1 (Figure 18) to achieve this step. Based on the described intervention and the conceptual framework, I evaluated two main evaluation dimensions: adherence and moderating factors. As depicted in the conceptual framework, adherence represented the intervention's actual delivery in terms of content and duration. I identified 16 measurable indicators based on the activities expected to be delivered in the clinic. Then, I quantitatively measured these indicators. Further, I categorised levels of

adherence for a specific component as 'high fidelity', within the range of 80-100%; 'moderate fidelity', within 51-79% and 'low fidelity', 0-50% as reported in other studies (Borrelli et al., 2005; Nurjono et al., 2019; Toomey, Matthews, & Hurley, 2017). To measure duration, I calculated the time it took for providers to undertake specific intervention sessions.

4.2.2.4 Develop a list of process evaluation questions

Through the combination of the steps described above, I systematically developed the process evaluation questions:

Adherence

1. To what extent do healthcare providers understand and adhere to the opt-out approach when offering HIV testing?
2. To what extent do healthcare providers adhere to the recommended 5Cs when offering HIV testing?

Moderators

1. Is the policy adequately explained in programme guidelines?
2. What is the level of support for healthcare providers in terms of guidelines, training, supervision, and feedback?
3. How do healthcare providers and pregnant women perceive and experience the opt-out HIV testing in the clinic?
4. What contextual factors influence the delivery of the opt-out intervention?

The final process evaluation plan is summarised in Table 6.

Table 6: The Process evaluation plan

Area of measure	Sub-component	General process questions	Core information sought	Data type	Data sources
Adherence	Content	Do healthcare providers adhere to the opt-out approach when offering test?	• How familiar healthcare providers find the intervention • The approach used to obtain informed consent	• Observation • Document analysis • Interviews	• Antenatal clinic (ANC) register • Observation guide • ANC managers
	Content and duration	Do healthcare providers follow the recommended human rights principles (5Cs) when testing women?	• Component of consent, confidentiality, counselling, correct test results and connection to care	• Observation • Survey	• ANC registers • Pregnant women • Providers
Potential Moderators	Women Responsiveness	How did women perceive the testing process in terms of respect for their autonomy and human rights?	• Perceptions, views, satisfaction, and engagement with the intervention	• Interviews	• Pregnant women
	Provider responsiveness	What is the perception of providers' experiences with the intervention?	• Perceptions, views, satisfaction, and level of engagement	• Interview • FGDs	• Provider
	Facilitation	How well is the intervention delivery supported in terms of resources, training, and supervision?	• Availability of manuals, guidelines, training, monitoring and feedback	• Interviews • Unstructured observation	• Policy documents • Guidelines • Providers • ANC environment
	Complexity	How well is the opt-out intervention explained in guidelines and policy documents?	• Providers' knowledge of opt-out, • Description of the intervention in policy documents, guidelines and manuals	• Interviews • Unstructured observation • Document review	• Policy documents • Guidelines • Providers
	Context	What factors at the organisational level affected implementation?	• Clinic environment and culture	• Interviews • Unstructured observation	• Women • Clinic managers • Providers • Clinic

4.2.3 Process evaluation design – mixed-methods approach

I conceptualised the process evaluation as a mixed-method study based on the questions in Section 4.3.3 (page 77). The term 'mixed-methods' research has generally been described as integrating quantitative and qualitative data within a single study (Creswell & Plano, 2011). This definition opens a qualitative-quantitative continuum whereby researchers bring qualitative and quantitative elements together to produce a fuller account of the evaluation problem (Glogowska, 2011). This section presents arguments on the links between mixed-methods and pragmatism as the adopted theoretical perspective. Following this, I describe the concurrent mixed-methods design in terms of purpose, independence, status, and implementation timing.

4.2.3.1 Using pragmatism to justify the choice of a mixed-methods approach

Health services research has seen an upsurge in the use of a mixed-methods approach (O'Cathain, Murphy, & Nicholl, 2007) due to the complex healthcare arena, the nature of questions asked and the multidimensional factors that influence health and illness (Glogowska, 2011; Ong, 1993). The questions about human interaction and responses are often encountered (Glogowska, 2011; Pope & Mays, 1995). To answer such complex questions, an evaluator must rely on methods that address all dimensions of the problem at hand (Andrew & Halcomb, 2009; Creswell & Plano, 2011). Researching HIV testing in the antenatal clinic reflects such complexity, given the multiple stakeholders and the now chronic nature of the once 'deadly HIV and AIDS' disease.

Johnson and Onwuegbuzie (2004) first championed pragmatism as the philosophical partner of mixed-methods. They argued that pragmatism as a philosophical lens for mixed-methods is cognizant of the natural and social world, allowing the researcher to work between the two extremes of quantitative and qualitative research instead of treating them as independent entities (Patton, 1990). The pragmatist epistemological stance informed the decision to put the evaluation questions at the centre of the research process. In doing so, the study emphasised what was practically workable in the field, rather than concentrating on scientific research's ideal or theoretical demands (Mackenzie & Knipe, 2006).

The overall purpose of the mixed-methods approach was complementarity. The mixed-methods approach ensured an in-depth, broader, and nuanced understanding of opt-out's delivery. The qualitative component (moderating factors) added significant depth to understanding contextual issues that influenced observed adherence (Halcomb, 2015). In process evaluation, mixed-methods research has been used to assess contextual issues and determine factors that moderate programme outcomes (Glasgow & Emmons, 2007). The hallmark of the mixed method purpose was to focus on various methods (e.g. surveys, interviews and structured observation), the same phenomenon (i.e. fidelity) to gain greater insight and understanding (Greene, Ion, Kwaramba, Smith, & Loutfy, 2016).

With pragmatism as a philosophical perspective, I employed an abductive reasoning process to move back and forth between an inductive and deductive reasoning process to address the connection between theory and data in this study (Morgan & Mills, 2007). This position contrasts the existing positivist and interpretivist views of scientific discovery. The former utilises deductive reasoning to confirm the well-established theory, and the latter draws on inductive reasoning to develop a theory. Furthermore, in response to the pragmatist's position, I adopted a notion of intersubjectivity (rather than objectivity or subjectivity) to capture what Morgan and Mills (2007) referred to as the phenomenon's duality. This approach facilitated the acceptance of the external reality (observed level of adherence) while helping pay attention to the explanations from different stakeholders (moderating factors) (Johnson & Onwuegbuzie, 2004).

4.2.3.2 The dimensions of a mixed-methods design

Mixed-methods research involves four critical issues during the design stage: timing, weighting, mixing and theorising (Creswell, 2009). Timing refers to whether the qualitative and quantitative data will be in phases (sequentially) or gathered at the same time (concurrently). This study employs a concurrent design, meaning quantitative data collection and analysis occurred (almost) simultaneously with qualitative data (Creswell & Clark, 2007; Shorten & Smith, 2017). This decision was taken a priori in consultation with my supervisors based on our understanding of the often busy and overburdened antenatal clinic settings

intended for the study. Therefore, the decision was to collect all quantitative and qualitative data and move on to the next clinic.

The second design dimension of the mixed-methods design is the weighting or theoretical drive of the study. This study employed the concurrent explanatory mixed-methods approach. When analysing this study's findings, I used the qualitative results (potential moderators) to explain and interpret the quantitative results (adherence level). Such designs typically assign primacy to the quantitative data. However, Creswell and Clark (2007) note that researchers may regard both methods as equal components: qualitative and quantitative components were considered equal in this study because they offered a unique perspective.

The last design dimension is the point of integration. In using a mixed-method approach, I had the option to merge the two strands or combine them at some point during the research process (Morse, 2009). In this study, I kept the quantitative strand (levels of adherence) separate from the qualitative strand (moderators) during data collection, analysis, and presentation. Merging occurred during the discussion chapter, where I relied on the moderating factors to explain quantitative findings. The adapted Carroll's conceptual process guided this process. Using a theoretical or programme framework to integrate a mixed-methods study has been recommended (Creswell, 2009).

4.3 Process evaluation methods

This section will describe the practical steps I took to execute the mixed-methods design. After describing the setting for this study, I offer an insight into how I gained access to the various stakeholders, especially pregnant women, through the gatekeeping process. Next, I describe the data collection approach, management, and analysis. In keeping with Carroll's conceptual framework and this study's aims, the methods section has been put into two main domains; adherence (mainly quantitative) and moderating factors (mainly qualitative).

4.3.1 Study setting

Ghana has a multi-layered health care system that embraces both public and private health care. Ghanaians receive health care from the formal health care system, the faith-based health care system and services from the ethnomedical system (Aikins, 2014). This study took place in 12 antenatal clinics, five private hospitals, and seven public hospitals located in the Ashanti and Brong Ahafo Regions. The Ashanti Region is the most populous region, with a projected 5,924,498 million people (Ghana Statistical Service, 2020). The region has culturally diverse and demographic characteristics reflective of national data, making it representative of the country. There are five hundred and thirty (530) health facilities in the region, with Kumasi, the region's capital, having the highest (38%). These facilities include government (170), mission (71), private (281) and quasi-governmental (8). The region has 152 PMTCT and 21 antiretroviral therapy centres (NACP, 2018).

The Brong Ahafo region spans 39,557 km^2 and used to be the second-largest in Ghana. It occupies the country's central part, with an estimated 2.6 million population (Ghana Statistical Service, 2020). The region has 27 districts and municipalities that share one regional hospital, 27 district/municipal hospitals, 35 health centres, 102 CHPS centres and 117 PMTCT centres (Ghana Health Service, 2015). The region's central location makes it an ideal study setting as it combines features of both northern and southern Ghana.

4.3.2 Stakeholder[7] identification, access, and recruitment

A crucial step in this process evaluation was the identification and access to stakeholders. Many stakeholders have an interest in routine opt-out intervention in the antenatal clinic. Identifying and engaging them from the outset ensured their full participation and created a sense of ownership of the study findings. Gaining access to study sites and participants required the careful consideration of ethical issues associated with HIV testing among a vulnerable population such as pregnant women. Three ethical review committees, one in New Zealand (Appendix 1; *pp.*249) and two in Ghana (Appendix 3; *pp*251 and Appendix 4; *pp*252), required written approval from the respective hospitals. Here, I describe how I identified and gained access to these stakeholders.

4.3.3 Selection of clinics

I used criterion-based sampling, a purposive sampling variant, to select the 12 antenatal clinics for this study (LeCompte & Preissle, 1993; Omair, 2014). The approach allowed a priori consideration of clinic features deemed essential in answering the process evaluation questions. The approach ensured a maximum variation of key clinic characteristics such as clinic size, patient-provider ratio and geographical location (Medley & Kennedy, 2010). Clinics were included if they: (1) fully consented in writing for the facility to be used, (2) offered HIV testing as part of routine antenatal care, and (3) were either operated by the government, private entities or religious bodies. The expectation was that these hospitals would be at the forefront of implementing the opt-out HIV testing and were the best place to determine whether or not the policy had been implemented with fidelity. Using a list of all available clinics in the two regions, I purposively selected clinics that met the inclusion criteria. I then sent letters of introduction from Victoria University of Wellington containing to all prospective clinics. The letters contained the study's background, objectives, and measures to ensure ethical integrity. As I was unsure of the hospitals that would grant my request, I oversampled by sending letters to 16 hospitals. In the end, 12 hospitals approved

[7] For the purposes of this report, stakeholders are individuals or organizations who have a personal or professional interest in the topic (O'Haire et al., 2011).

the request. The 12 antenatal clinics represent 19.7% of the 61 clinics in the two regions. Selecting these clinics was also partly informed by my ability (in terms of resources, skill-set and time) to collect data across the 12 clinics within the three months that I was in Ghana. I also considered how close the clinics were to each other to reduce the time needed to travel and ensured that I covered more ground within a short period. A concept referred to as research mobility as had been championed by Spradley (1980: cited Burgess, 1992). The included clinics had HIV testing services that were fully (n=4) or partially integrated (n=5) or standalone clinics (n=3) but within the same building as the antenatal clinic.

Including clinics with various levels of HIV integration helped to understand how adherence varied based on the level of integration and how moderating factors differentially affected adherence. Using the type of governing authority as a selection criterion, I included private and public operated clinics. I defined a private clinic as those owned by individuals and religious bodies. Mission hospitals belong to religious bodies and do not strictly fall under private. However, I avoided using this term or having a separate classification for mission hospitals as they are very few, and anyone familiar with the region could easily guess the hospital in question. The same situation does not apply to private hospitals. For this reason, I put all the clinics together under the umbrella term 'private' and naming them as facility 1 to 12 offered group anonymity (See Appendix 6; *pp.* 254). Including different operating authorities was justified as differences in care quality in the antenatal clinics between these two bodies have been reported (Chen et al., 2013).

4.3.4 Qualitative data collection

4.3.4.1 Documents as data

I reviewed Ghana's HIV policy documents published in 2007 to date, reflecting the year before the UNAIDS/WHO policy document was adopted. Policy statements, clinical guidelines, training manuals and strategies were included if they met the following criteria: (1) nationally relevant (not a clinic or district-specific); (2) contained programmatic or clinical guidance on HIV testing and counselling; and (3) published between 2007 and 2018. I also retrieved HIV testing and counselling guidelines from the WHO website. Documents were

reviewed for evidence that the government of Ghana, working through its agencies (GAC and NACP), has created the necessary policy environment that ensured that implementation of HIV testing policy among pregnant women was protective of the human rights of pregnant women (OHCHR, 2011). A total of 11 individual documents were reviewed (see). Findings of the policy review helped to: (1) supplement untraceable information; (2) track the processes involved in policy adoption and diffusion; (3) inform the design of survey questionnaires and qualitative interviews; and (4) triangulate findings, thus improving the validity of the results.

4.3.4.2 Interviewing

Green and Thorogood (2017) observed that researchers could use interviews to explore stakeholder's perspectives about an issue. I employed semi-structured interviewing techniques to corroborate critical issues raised in survey questionnaires and observation sessions. Interviewing also helped glean valuable evidence from diverse stakeholders on how they perceived the opt-out intervention in terms of challenges, facilitators and future directions. The initial adherence findings informed the design of the semi-structured interview guide used in this study. The interview guides were piloted and modified across the different stakeholders. I conducted all interviews in English.

4.3.4.2.1 Key informants' interviews

Recruitment of key informants: I employed purposive and snowballing sampling approaches (Valerio et al., 2016) to select the 20 key informants (national and regional level officers, antenatal clinic managers). I assumed that they had enough experience and nuanced understanding of the HIV testing policy. When selecting them, I expected them to discuss their experiences with the policy more reflexively (Creswell & Plano, 2011; Palinkas et al., 2015; Setia, 2016). The key informants included four (4) national level officers (from GAC and NACP), four (4) regional level officers and managers of the 12 antenatal clinics. I sent emails requesting interviews to all national-level key informants. These also included the information sheets explaining the study's purpose (Appendix 8*; pp* 256). The national level officers were difficult to reach, and some never responded to my e-mails. I later relied on a former work colleague, a regional HIV coordinator, to facilitate the process. Due to the

challenges with recruitment, the sample size for all the key informants was determined by availability and not theoretical saturation (Bernard, 2012) in deciding this group's size.

Semi-structured interviews for key informants: four (4) national-level officers, four (4) regional level officers and twelve (12) antenatal clinic managers consented and were interviewed. The national level officers represented the national level policy implementation stakeholders, responsible for adopting policies and creating the necessary policy environment for implementation. I considered them to be knowledgeable about the policy. The regional level officers worked closely with the NACP to implement policies deployed by GAC. These key informants provided data on how they had used training, guidelines, supervision, and feedback to facilitate opt-out intervention. The managers in the clinic offered information about operational issues within their respective clinics. I travelled to Accra about 248.3km from this study's site to interview national level officers.

I often had cancellations of my interview appointments, so I ended up spending three days for the scheduled interviews. When I finally had the opportunity to interview any top-level officers, I had to rush through the process due to the limited time. At many points during the interview, I paused the interview as office staff delivered information to the manager. Interviews lasted between 18 and 35 minutes. Though I used an interview guide (Appendix 12; *pp.*260), other issues were probed when there was a chance. One national officer requested a copy of the interview guide before the interview, which I obliged. Only one national officer allowed me to do an audio recording of our interview. For the rest, I requested permission to take notes as they spoke.

I interviewed regional level officers at the venue of their choosing. All four regional level officers had many years of experience in training and disseminating HIV testing protocols and guidelines. They had supervised and been in close dialogue with clinic managers and therefore understood (or were supposed to) the facilitators and barriers of delivering the intervention. Using a modified version of the national level officers' interview guide (Appendix 12; *pp.* 260), I conducted semi-structured interviews lasting between 30 minutes and 1 hour. All discussions were audio-recorded with permission from participants. A similar

pattern of interviewing occurred with clinic managers, though this mainly happened in the clinic.

4.3.4.2.2 Healthcare provider interviews

Recruitment of Healthcare Providers: I included healthcare providers (nurses, midwives, physician assistants, community health nurses, nursing assistants) who worked in the antenatal clinic and were directly involved in testing women for HIV. In each clinic, I contacted the nurse or midwife in charge and explained the study using an information sheet. The information sheet contained the study's purpose, the participant's expected role, the study's potential contribution, and its optional nature. I employed a purposive sampling approach to select health care providers to participate in interviews and focus group discussions. The decision was based on the observations made during the counselling sessions, and the level of interest providers showed in the study. I recruited 12 providers for one-on-one interviews, whereas 28 took part in focus group discussions. I emphasised the study's confidential nature and the fact that I would aggregate all findings, with the hospitals or individuals' names omitted. Each healthcare provider received an information sheet to aid decision-making.

Getting healthcare providers together for the planned FGDs was challenging to achieve in the busy and inadequately staffed clinic. It was incredibly difficult to get the few staff into groups while the clinic was in session, and none of the staff was ready to stay back or come to the clinic on a different day for such a discussion. This delayed the FGDs in all the study sites. While collecting other data types, I realised how easy it was to do individual interviews with providers, even in the consulting rooms. For this reason, I converted the FGD guides into one-on-one provider interviews. This gave me enough time to organise the 5 FGDs reported in this study.

I relied on informed consent forms and verbal explanation to obtain informed consent for both interviews and focus group discussions. Interviewees became aware of the study's voluntary nature and the right not to answer questions they found distressing. I made them aware of their right to withdraw consent at any stage of the interview or even six months

after the interview. The rationale for recording the interviews; for using the transcribed audios in the final thesis report or publications were also explained. I further explained how the final transcription would be aggregated and all identifiers removed. For women who could not read the information sheet, I took some time before the interviews to offer a thorough explanation. I employed the same approach in obtaining informed consent from participants of focus group discussions.

Semi-structured interviews: an interview guide was designed for the semi-structured interviews (Appendix 14; *pp.*262). I used it to ask healthcare providers about their work responsibilities, how they understood and interpreted routine opt-out testing, the notion of informed consent and opting out and operationalisation of these guidelines in practice. I audio-recorded all interviews after obtaining permission. Interviews lasted between 20 and 45 minutes. Interviews were conducted in either English or Twi as the provider preferred.

Focus group discussions: I conducted five focus group discussions with 28 healthcare providers. Group size ranged from 4 to 7 and usually lasted between 30 minutes and 1 hour. The focus group discussions helped tap into the interaction between providers, hoping for comments from members of the group that could 'spark off' others to say things they would not have said when alone with the researcher (Webb & Doman, 2008, p. 54). Each group session began with introductions. I established ground rules about confidentiality, accompanied by signing a confidentiality agreement form to indicate that whatever we discussed would not be shared or repeated to others. I emphasised the need to allow one person to talk at a time and respect each other's views. Even though I had a topic guide (Appendix 11; *pp.* 259) containing a list of issues to be covered, I often realised that this was unnecessary as the discussion flowed without prompting. There were times when intense arguments ensued, with the discussion taking a different direction from that anticipated. Such deviations often resulted in rich, unexpected information. All sessions were audio-recorded with the permission of members.

4.3.4.2.3 Pregnant women interviews

Recruitment of pregnant women: the protocol for this study initially included only surveys with pregnant women. However, observation of clinic practices and initial survey analysis made it apparent that some topics required further exploration, which could not be achieved using the survey alone. For example, the nuances of women's concerns about subtle coercive practices in the clinic could not be captured by the survey. Therefore, the human ethics committee's ethical clearance was amended to reflect the change in the protocol (Appendix 2; *pp.*250). Following this, I purposively selected 21 women from across the 12 clinics to participate in the qualitative interview. Women were eligible if they consented to be interviewed, were healthy and able to respond to questions without any barrier (e.g. language). Clinic staff used an information sheet (Appendix 7) to invite women tested for HIV and completed a survey to participate in the study. The sample size was determined using data saturation.

Semi-structured interview for women: I used an interview guide to explore women's opt-out intervention experiences, the test's voluntary nature, confidentiality, and the testing process (Appendix 10; *pp* 258). All interviews were conducted in Twi (local language), often in an antenatal clinic office with optimum privacy. The interviews lasted between 20 and 60 minutes. I stopped the interviews after the 21st participant as I had reached saturation in themes, and no new information emerged. Interviews were audio-recorded with the permission of pregnant women.

4.3.4.3 Field observation

In the form of field notes, I carried out unstructured observations to provide context for the data already collected. I recorded the antenatal clinics' characteristics, room sizes, rooms' privacy, the interaction between the provider and the pregnant woman, and other issues that needed follow up. Observations took place during group information sessions, HIV testing and post-testing counselling. No observations were undertaken during the post-test

counselling of pregnant women testing positive for HIV because of the discussion's sensitivity and in line with the ethics approval's limits.

4.3.5 Quantitative data collection (Adherence)

The quantitative part of this study involved the intervention's content measured by a brief facility survey with clinic managers, healthcare providers, pregnant women self-reports, and researchers administered direct observation.

4.3.5.1 Brief facility survey and review of antenatal clinic register

The 12 antenatal clinic managers answered a brief facility survey using the antenatal clinic audit tool for this study (Appendix 15; *pp.*263). Questions covered included routine antenatal and HIV testing activities, HIV testing practices, counselling and testing approach, staff strength, and estimated time for delivering clinic activities. A review of the antenatal clinic register complemented this data. The data served as background information for the study's findings.

4.3.5.2 Assessing adherence to core elements

I used structured direct observation and self-reports by the healthcare provider and pregnant women to measure the human rights principle of consent, confidentiality, counselling and connection to care. I used the time providers waited before reading the test kit as a proxy for assessing correct test results. A provider and pregnant women's self-report checklist and a structured observation checklist were developed from the core elements adapted from the 'Guide for Monitoring and Evaluating National HIV Testing and Counselling Programmes' (WHO, 2011b) and a review of Ghana's policy documents. The self-reports and the observation checklist incorporated the same 16 core elements expected to be delivered by nurses and midwives (described in section 4.2.2; *pp.*73). The questionnaire asked providers to indicate whether they implemented the identified components as contained in the testing guidelines. To improve the validity of the content of the survey instrument, I used words that were easy to understand and requested the NACP staff and my supervisors to comment on the final copy. I then adapted the questionnaires to the target groups by pre-testing them on

a sample similar to the target group. The pre-testing was followed by an analysis procedure that led to modifying items deemed ambiguous or confusing.

The same approach used in developing provider self-reports was applied to the pregnant women self-reports. In pregnant women, the self-reports were first developed in English and then translated back to the local language (Twi). This approach ensured that women who could read and write only in Twi had no difficulty answering questions. Responses were closed-ended, and the survey took 15 to 20 minutes to complete.

4.3.5.2.1 Pregnant women self-report survey

When recruiting pregnant women, I instituted measures to ensure an ethical process devoid of coercion. Women were eligible if pregnant, 18 years of age or over, attending their first or second antenatal visit and could give informed consent. I excluded a woman if her test came back positive for HIV on the day. A discussion with the human ethics committees about this population concluded that any woman testing positive would be in shock. It would therefore be inappropriate for her to answer the survey questionnaire. Also, since the study aimed to determine adherence to the guidelines, not HIV positive test result experiences, we considered excluding this group was not a significant problem. I also excluded pregnant women with medical conditions that required further management. Clinic staff became aware of these exclusionary conditions from the women's information sheets, which they relied upon to explain the study during group discussions.

The sample size for the various stratum (health facilities) was estimated using a proportionate stratification formula for estimating sample size for stratified sampling, nh = (Nh / N) * n. Where nh is the sample size for stratum h (in this case, the total annual clinic attendance per facility), Nh is the population size for stratum h, N is the total population size, and n is the total sample size. Based on the average number of pregnant women who had visited each antenatal clinic during the previous ten months, a proportional allocation of each clinic's total sample size was calculated (see Table 7). Based on the recruitment strategy described above, more survey questionnaires were distributed in some clinics than was planned, resulting in 483 total returned questionnaires. A total of 35 questionnaires were

either not answered or incomplete, suggesting women either declined to participate or could not complete them.

Table 7: sample size estimation for pregnant women survey

Facility	Calculated total sample size (N)	Average monthly antenatal attendance (x)	Sub-sample (x/300*N)	Actual sample obtained	Sample after exclusion of incomplete questionnaires
Facility 1	422	110	24	30	27
Facility 2	422	142	31	37	34
Facility 3	422	298	64	68	66
Facility 4	422	276	60	63	61
Facility 5	422	142	31	51	40
Facility 6	422	89	19	24	21
Facility 7	422	87	19	20	19
Facility 8	422	384	83	87	82
Facility 9	422	153	33	35	32
Facility 10	422	97	21	27	26
Facility 11	422	121	26	28	27
Facility 12	422	58	13	13	13
Total	-	**1957**	**422**	**483**	**448**

The survey of pregnant women was anonymous. Women became aware of the measures put in place to protect their identity. Firstly, all survey questionnaires were anonymised entirely. Anonymisation measures included the design of the questionnaire with only checkmarks instead of filling in words. I also offered non-identifiable pens to all pregnant women. Secondly, healthcare providers assisting with the research delivered the survey questionnaires to women in plain envelopes. All eligible participants received the same envelope. The instruction was given to put the completed, partially, or empty survey questionnaire in the envelope provided and then drop them in the box provided. Women were to skip questions not clear to them. The approach ensured that no one became aware of women who declined; neither could one trace the questionnaire women filled (Sutton, Cain, Vallo, & Redman, 2017). The only time the study encountered challenges was when a woman could not read and write neither Twi nor English. In this case, I offered some

assistance. However, having some of the questions in the local language minimised such occurrences.

In most cases, women who could not read English answered the translated questionnaires. Participants became aware that once a questionnaire was answered and submitted, there was no way of identifying the participant who answered it. Therefore, withdrawing consent at that stage was not possible.

4.3.5.2.2 Healthcare provider self-report survey

With permission from those in charge of the clinic, I invited all eligible healthcare providers to participate in the survey and to have their HIV testing consultations observed. Providers became aware of the study after an explanation aided by an information sheet. The staff became aware that I would not measure their professional competence or judge their practice. I emphasised the study's confidential nature and the fact that I would aggregate all findings, with the hospitals and individuals' names omitted. A total of 170 of all the invited healthcare providers agreed to be part of the study. I planned was to include all healthcare providers directly involved in HIV test at the antenatal clinic. However, only 170 became available for the survey. This sample also provided data for the structured observation described below. Healthcare providers consented without signing a consent form, in line with the anonymity measures previously discussed. I delivered questionnaires in envelopes, and providers dropped them in the provided at the end of their shift.

4.3.5.2.3 A researcher administered direct, structured observation

I observed HIV testing and counselling sessions using a checklist developed from the same 16 measures as the provider and women's self-reports (Appendix 16; *pp.* 264). These were pre-tested on five counselling sessions and corrections made to improve clarity. This observation served as a direct measure of adherence to confirm or disconfirm the self-reports (O'Leary, 2005; Stone et al., 2000). Testing and counselling sessions observed were selected purposively, often based on the clinic manager's discretion and the provider and women's willingness for me to be in the consulting room. I offered every healthcare provider an information sheet that provided further information about the study. They became aware

that I would not communicate any observed practice to their supervisors. Healthcare providers who consented signed an informed consent form (sample consent form in Appendix 9; *pp.*257).

Since the observation focused on what the provider was doing and said, I did not obtain separate informed consent from pregnant women. However, before observing any counselling session, the healthcare provider first discussed with the woman whether she would like me to be in the consulting room or not. For hesitant women, I did not observe. If a woman tested positive for HIV, the midwife or nurse had me leave the consulting room as agreed on a priori.

Sessions observed were purposively selected since it was impossible to be in all the consulting rooms. I made a total of 158 observations, with each observation lasting between 10 and 15 minutes. The initial plan was to observe the pre-test information delivery during group education and then observe the midwife's consulting room's rapid test. However, because many of the clinics delivered both the pre-test information and rapid testing in the consulting room, I conducted most of my observations in the consulting room. In a clinic where counselling and testing activities occurred in more than one consulting room, I observed a representative sample of counselling sessions by varying the healthcare provider type and selecting consulting rooms.

During observation sessions, I sat either in the consulting room or the outpatient department and used the checklist to record HIV testing activities. Though I played an outsider role, it was sometimes impossible to stay non-participant, as staff became aware of my background and sometimes sought clarification on specific issues. However, I never forgot my role as a guest researcher in the field. I ensured that my presence in the consulting room did not become obstructive to the client-provider interactions. For this to happen, I kept a reasonable distance or sometimes moved out when the midwife discussed a non-HIV related issue. A summary of qualitative and quantitative data collected is shown in Table 8.

Table 8: Summary of data collection methods, participants and data collected

Data Collection Method and participants		**n**
Qualitative data		
1.	*National level officer interviews*	**4**
2.	*Regional level officer interviews*	**4**
3.	*ANC/ART managers interviews*	**12**
4.	*5 Focus group discussion with healthcare providers*	**28**
5.	*Pregnant women interviews*	**21**
6.	*Healthcare provider interviews*	**12**
7.	*Document review*	**11**
8.	*Unstructured observation of clinic environment*	**N/A**
Quantitative data		
9.	*Pregnant women self-reports*	**448**
10.	*Healthcare self-reports*	**151**
11.	*A researcher administered DO of counselling sessions*	**158**

***n**=number of respondents; **DO** =direct observation; **ANC** = antenatal clinic; ART = antiretroviral therapy*

4.3.6 Mixed-methods data management and analysis

4.3.6.1 Quantitative data analysis

Self-report and structured observation data were entered, cleaned, and validated using Microsoft Excel. The checklist used to observe counselling sessions and self-reports from pregnant women and providers were checked for accuracy and validity immediately after each observed session. Datasets were created and information keyed into excel sheets. Incomplete responses were discarded, and a note made of their unique IDs. After resolving discrepancies, data were exported to SPSS V25 (IBM Corp, 2015) for further analysis. The study used descriptive statistics (frequency, median, ranges, and percentages) to describe the characteristics of the study sample and general clinic characteristics. The analysis of adherence levels followed analytic procedures used by Toomey et al. (2017). The differences in continuous data were assessed using the one-way analysis of variance (ANOVA) and Kruskal-Wallis tests where appropriate. The levels of agreement between methods and inter-

rater reliability of the observed and collected data were assessed using percentage concordance. Overall mean fidelity of content and fidelity scores according to a government authority, level of integration and percentage means adherence scores were obtained by calculating total actual scores as a percentage of the total possible score. High fidelity levels were interpreted as previously reported in the literature, with 80%–100% adherence interpreted as 'high' fidelity, 51%–79% as 'moderate' and 0%–50% as 'low' fidelity (Toomey et al., 2017). Finally, the relationship between fidelity scores and the number of participants present were calculated using Spearman's correlation coefficient. P-values of less than 0.05 were interpreted as statistically significant.

4.3.6.2 Qualitative data analysis

I employed the 'framework' analysis aided by QRS International's NVivo 12 software (QRS, 2018). Framework analysis as a qualitative method is considered suitable for applied policy research with clearly defined questions and sample (Srivastava & Thomson, 2009). This section describes the five stages used to manage the data collected from the 12 antenatal clinics. The stages are familiarisation, framework identification, indexing, charting, mapping, and interpretation (Ritchie & Spencer, 1994).

Familiarisation

I became familiar with the data by first importing it into NVivo and then performing transcription using the software's inbuilt transcription tool. Through this process, I made sense of participants' areas of concern regarding opt-out's implementation. As depicted in Figure 22, NVivo helped assign demographic features to all the imported audio data. Assigning demographic characteristics helped track each participants' responses and enabled descriptive analysis of participant attributes. At the end of the familiarisation phase, I had a list of uncategorised preliminary codes that I used in the subsequent stage, identifying the framework.

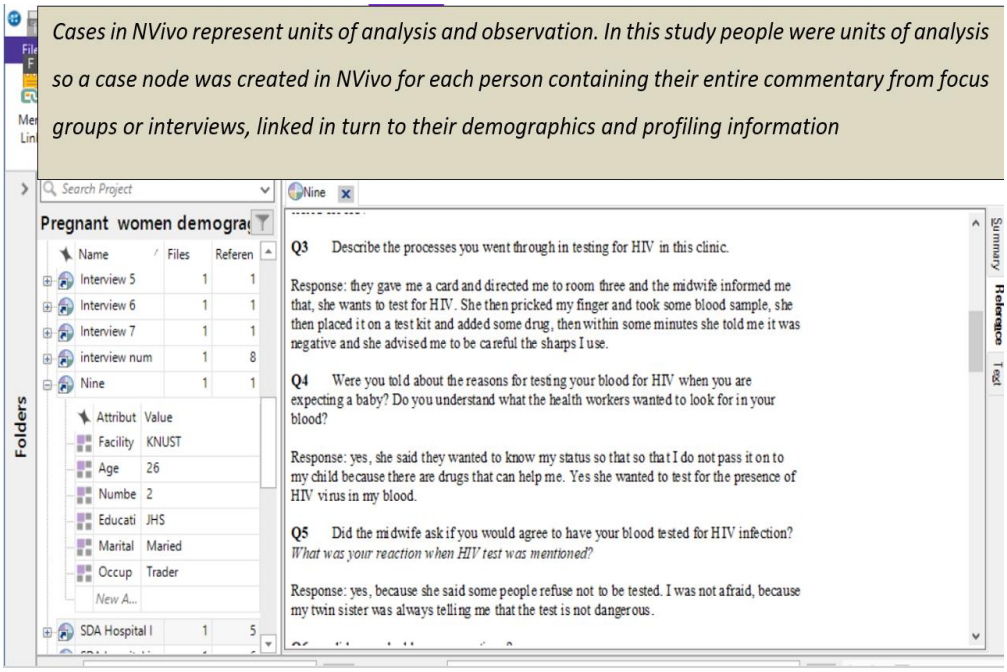


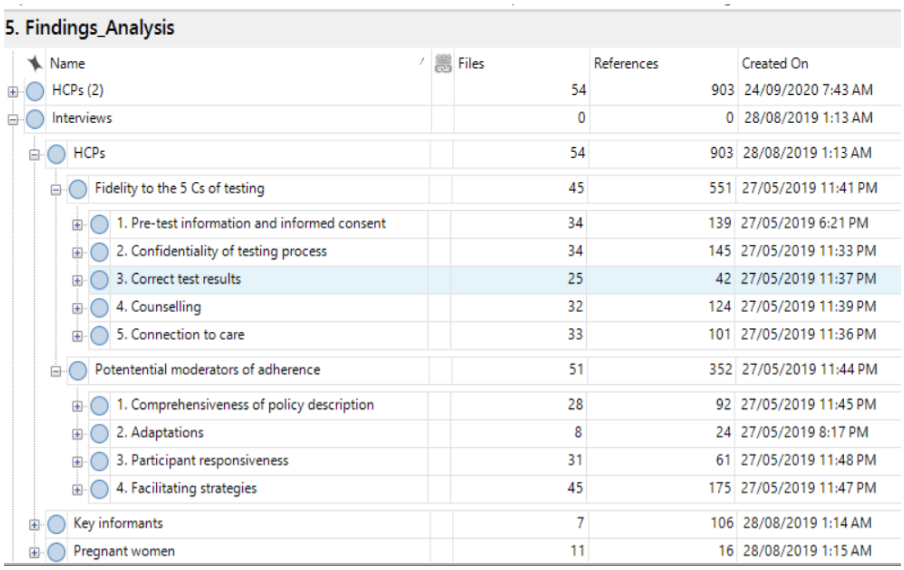
Figure 22: Cases linking participant's words to demographic and profiling information

Identifying a framework

At this stage of the analysis, I organised the freely created codes and free data into a meaningful and manageable form to facilitate subsequent retrieval, exploration and examination (Parkinson, Eatough, Holmes, Stapley, & Midgley, 2016). Since I decided a priori on using Carroll's conceptual framework, I organised the codes around the main concepts as listed below:

1. **Adherence to the 5Cs of testing**
   - Pre-test information and informed consent
   - Confidentiality of the testing process
   - Correct test results
   - Counselling
   - Connection to care
2. **Potential moderators of adherence**
   - The comprehensiveness of policy description
   - Adaptations
   - Participant responsiveness
   - Facilitating strategies
3. **Emerging issues**

As seen in Figure 24, the parent nodes served as 'buckets' where all related quotes were gathered. This allowed subsequent analysis. Clicking on the plus sign would reveal further quotes that emerged from, for example, ' correct test results '.



5. Findings_Analysis

Name	Files	References	Created On
HCPs (2)	54	903	24/09/2020 7:43 AM
Interviews	0	0	28/08/2019 1:13 AM
HCPs	54	903	28/08/2019 1:13 AM
Fidelity to the 5 Cs of testing	45	551	27/05/2019 11:41 PM
1. Pre-test information and informed consent	34	139	27/05/2019 6:21 PM
2. Confidentiality of testing process	34	145	27/05/2019 11:33 PM
3. Correct test results	25	42	27/05/2019 11:37 PM
4. Counselling	32	124	27/05/2019 11:39 PM
5. Connection to care	33	101	27/05/2019 11:36 PM
Potentential moderators of adherence	51	352	27/05/2019 11:44 PM
1. Comprehensiveness of policy description	28	92	27/05/2019 11:45 PM
2. Adaptations	8	24	27/05/2019 8:17 PM
3. Participant responsiveness	31	61	27/05/2019 11:48 PM
4. Facilitating strategies	45	175	27/05/2019 11:47 PM
Key informants	7	106	28/08/2019 1:14 AM
Pregnant women	11	16	28/08/2019 1:15 AM

Figure 23: An example of codes organised under the conceptual framework

Indexing

This stage of data analysis involved reconstructing the data into Carroll's conceptual framework. The data began to make sense in addressing the process evaluation questions of adherence and moderating factors. The process was iterative, sometimes leading to nodes being renamed or merged. I grouped codes that did not fit into any of the above pre-determined categories into new codes. Gradually the codes developed into a more complex hierarchical structure referred to as node trees. With the help of NVivo, I was able to go back and forth between transcripts, audios, and content of nodes, as illustrated in Figure 24.

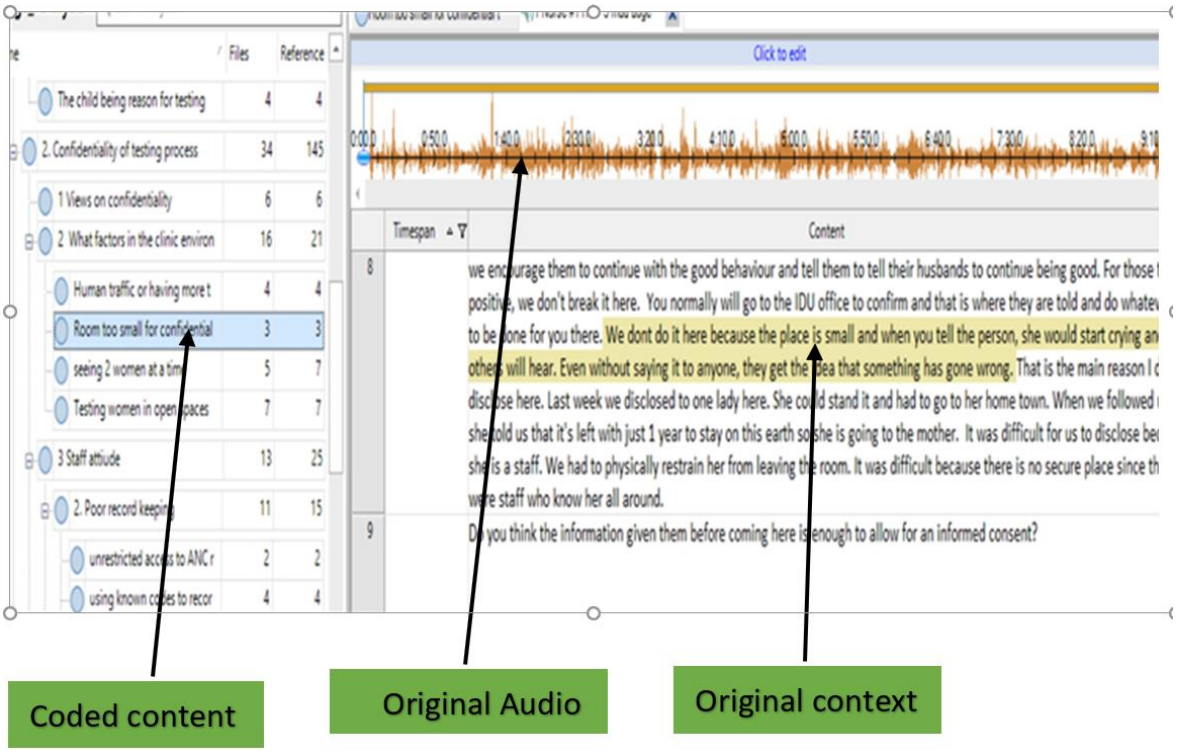
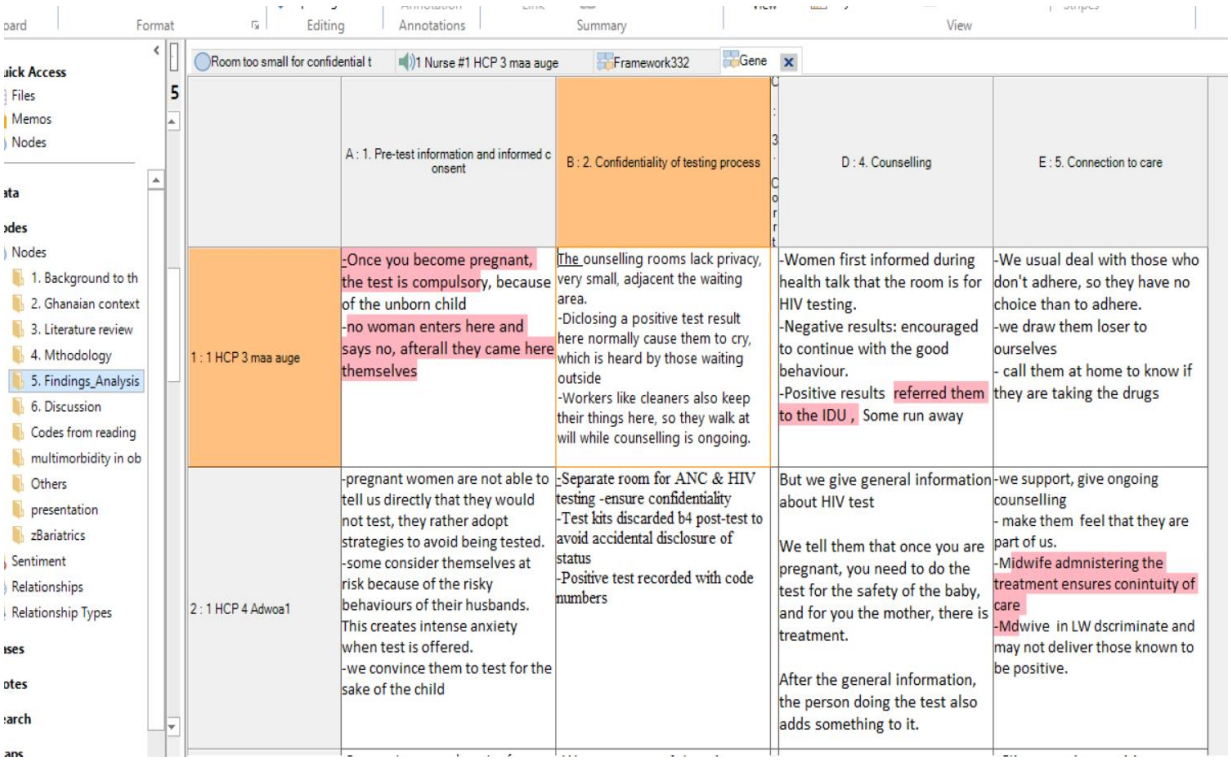


Figure 24: An example of linking and identifying sources in NVivo

Charting

The fourth stage of the analysis involved arranging all the data indexed in the previous stage into charts and themes. The charts consisted of headings and sub-headings from Carroll's conceptual framework (Ritchie & Spencer, 1994). The stage involved placing the indexed, coded data into a grid or matrix. Figure 25 is an example of a 'framework' grid exported from NVivo. At this stage, the data was reduced into manageable in-case and cross-case summaries.



	A : 1. Pre-test information and informed consent	B : 2. Confidentiality of testing process	D : 4. Counselling	E : 5. Connection to care
1 : 1 HCP 3 maa auge	-Once you become pregnant, the test is compulsory, because of the unborn child -no woman enters here and says no, afterall they came here themselves	The counselling rooms lack privacy, very small, adjacent the waiting area. -Diclosing a positive test result here normally cause them to cry, which is heard by those waiting outside -Workers like cleaners also keep their things here, so they walk at will while counselling is ongoing.	-Women first informed during health talk that the room is for HIV testing. -Negative results: encouraged to continue with the good behaviour. -Positive results referred them to the IDU , Some run away	-We usual deal with those who don't adhere, so they have no choice than to adhere. -we draw them loser to ourselves - call them at home to know if they are taking the drugs
2 : 1 HCP 4 Adwoa1	-pregnant women are not able to tell us directly that they would not test, they rather adopt strategies to avoid being tested. -some consider themselves at risk because of the risky behaviours of their husbands. This creates intense anxiety when test is offered. -we convince them to test for the sake of the child	-Separate room for ANC & HIV testing -ensure confidentiality -Test kits discarded b4 post-test to avoid accidental disclosure of status -Positive test recorded with code numbers	But we give general information about HIV test We tell them that once you are pregnant, you need to do the test for the safety of the baby, and for you the mother, there is treatment. After the general information, the person doing the test also adds something to it.	-we support, give ongoing counselling - make them feel that they are part of us. -Midwife admnistering the treatment ensures conintuity of care -Mdwive in LW dscriminate and may not deliver those known to be positive.

Figure 25: Ritchie and Spencer's 'Framework' Grid applied to my data

As seen in Figure 25, the first column represents the case ID, and the subsequent columns are the themes. Thus, reading across each row offered a summarised view of each case or participant, while reading down each column offered a summarised view of each indexed theme. This process moved the analysis beyond the information as contained in the transcripts (factual descriptions) to a nuanced understanding of the discourses (interpretative analysis)(Bonello & Meehan, 2019).

Mapping and interpretation (Ritchie & Spencer, 1994)

At this stage of the analysis, prominent trends emerged from the data, and NVivo allowed for the generation of schematic diagrams, which helped interpret the data in a more nuanced manner. At this stage, I made connections and sought explanations for connections between the data's breadth and depth (Ritchie & Spencer, 1994). Since document analysis occurred in the same NVivo document, I could link aspects of the field data with its contents to explore the connections between the practice as observed and as intended. In all these, I moved back and forth between the synthesised data and the original transcripts to clarify issues and undertake a more in-depth analysis when I found exciting patterns in the data. For example,

in the hierarchy diagram displayed in Figure 26, focus group discussions with midwives where healthcare providers discussed women's ability to decline to test. The diagram shows that decision-making and autonomous decisions are the most coded topic. Offering advice was less mentioned, which meant I did not explore this concept in-depth, suggesting a need for follow-up interviews.

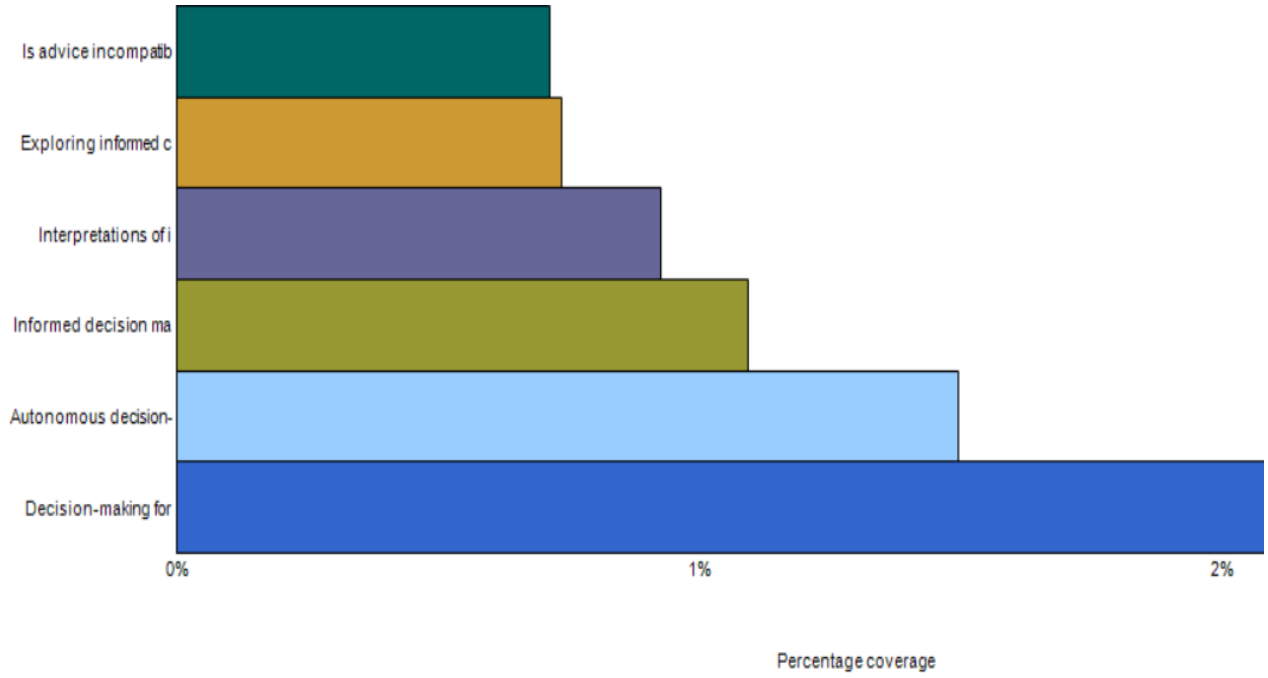


Figure 26: An example of a hierarchy diagram displaying the most issues

4.3.7 The ethical and practical approach

Whatever form research assumes, there is always the potential to infringe on an individual's integrity and autonomy (Bain, 2015). For this reason, the research community designs codes of ethics and institutionalised ethics committee review boards. Even though I described the various steps that would be taken to ensure an ethically sound data collection process in the preceding sections, I consider a separate section that would emphasize how central ethics was to this study.

4.3.7.1 Ethical approval

I gained ethical approval for this study from the Victoria University of Wellington's Human Ethics Committee (HEC) (Appendix 1; *pp.*249), Ghana Health Service Ethical Review Committee (GERC)(Appendix 3; *pp*251) and the Kwame Nkrumah University of Science and Technology School of Medical Sciences and Okomfo Anokye Teaching Hospital Committee on Research, Publication and Ethics (Appendix 4; *pp*252). Meeting the stringent requirements for these three Ethics Review Boards located in two different countries was problematic, as previously reported by Dovey et al. (2011). These ethical review boards operated on the same ethical principles, but there existed no unified communication pathway that avoided duplication of processes that I had to go through. Victoria University of Wellington required that I secure ethical approval from Ghana before granting my ethics application. At the same time, GERC also considered it a pre-requisite that I get approval from my institution before getting the nod from them. After getting ethical clearance from three research ethics committees, I had to go through another long process of signing a data exchange agreement with NACP, the custodians of HIV testing data in the country.

4.3.7.2 The ethical rationale for including vulnerable group (pregnant women)

The first step in ensuring an ethically sound evaluation process was acknowledging the vulnerable nature of pregnant women who took part in this study. In the past, researchers have excluded women from many research work due to fear of unintentional harm (Dickerson, Leeman, Mazure, & O'Malley, 2009). In planning this research, I became aware of the dangers posed to women who had to recall possible traumatic experiences linked to

HIV testing. This reason was not enough to exclude women. The intervention under investigation directly affects women, making their inclusion ethically fair. Including women would ensure that their voices and concerns would be included in the policy changes that may result from this study. Therefore, the study's benefits to women outweighed the possible harms (van der Graaf et al., 2018).

I considered all research participants vulnerable due to 'their universal embodiment and fragility, which makes them at risk for clinical research (van der Zande, van der Graaf, Oudijk, & van Delden, 2017, p. 658). For this reason, while I took extra care to deal with the peculiarities researching pregnant women brought, I also ensured the protection of all other participants by adhering to the ethical review committees' requirements. I understood that pregnant women could be psychologically distressed in recalling aspects of their testing experiences. I minimised this by allowing them to skip or stop answering questions they found distressing. During the study's preparatory stages, I planned to notify a counsellor to be on stand-by to offer counselling services if needed. This arrangement was not necessary later in the data collection process as each clinic had health care providers with the requisite counselling skills.

4.3.7.3 Information and informed consent for surveys

In keeping with the ethical principles of informed consent (Nijhawan et al., 2013, p. 134), I ensured that all study participants providing data in this study became aware of the study's objective, the rationale for information sought, and the voluntary nature of the study (participant information sheets for all data collection methods attached as appendices). Of interest was the refusal by a few healthcare providers and national level key informants to record their interviews. Other healthcare providers declined to sign informed consent, as they considered it time-wasting, while others felt uncomfortable to sign such formal documents. One participant explained that they believe that researchers sometimes 'collect their signatures to claim monies' from donor agencies. I took time to dispel such notions and respected their decision, and relied on the verbal consent provided as reported elsewhere (Lawton et al., 2017).

Even though I obtained informed consent to record interviews, doing so always proved difficult. While health care providers and some key informants were explicit on not being recorded, it was not always clear when pregnant women fully consented to be audio-recorded. The challenge came to the fore when I interviewed one young pregnant woman. She agreed to be interviewed and recorded, but she appeared uncomfortable during the interview and offered what I will describe as closed-ended responses. Sometimes she just nodded her responses. Her demeanour and responses to questions, however, improved after I switched off the recorder. While it was not always clear whether such a participant truly consented, I was guided by Miller and Bell (2012, p. 4), who opined that 'whichever approach is adopted, the motives around why some people become participants, and others resist should concern the researcher and be documented in a research diary'. In keeping to this, I documented all cases where I sensed any form of resistance.

4.3.7.4 Confidentiality and anonymity of the survey questionnaire

Confidentiality and anonymity of research participants, and in some cases, study sites were central to ensuring an ethical evaluation process. In sub-Saharan Africa, society has inextricably linked HIV and AIDs with sexual immorality (Ulasi et al., 2009). This was the great reason that absolute confidentiality was critical. In this process evaluation, I addressed confidentiality at three points during the research process: data collection, data cleaning and (future) dissemination of evaluation reports. The first component was described under the various methods.

Ensuring the confidentiality of data collected was as crucial as the data collection process itself. Collected data was stored and treated per Victoria University of Wellington's Records Management policy. The first thing I did on return from clinic sites was to upload all digital data collected for the day onto Victoria University's OneDrive shared space, using a password-protected laptop. I then deleted the audios from the recorder and the computer. I kept filled survey questionnaires, field notes and structured observation sheets under lock and key.

I also ensured confidentiality during data cleansing by removing names and other identifiers to create a 'clean' data set (Kaiser, 2009). I used pseudonyms to replace the names of participants and the 12 facilities named facility 1, 2, 3…12. Quasi-governmental hospitals, mission and private hospital included have unique combinations of traits that anyone remotely familiar with these settings could use to identify them. For this reason, I grouped all these facilities under the umbrella term 'private' during quantitative sub-group analysis. Kaiser et al. (2010) referred to this approach as the dominant approach to confidentiality. Similar confidentiality concerns applied to prominent individuals recruited from governmental organisations. It was impossible to report their positions in this study as their quotes could easily be traced. To address this, I added their data to other interviews conducted in the same facilities and referred to any participant as a 'national officer' in this study without mentioning their titles or directly quoting their positions.

I signed a data-sharing agreement with the National AIDS Control Programme (NACP) (Appendix 5; *pp.*253) regarding data dissemination. The data-sharing agreement stipulates that NACP had given me access to HIV testing data for the current study. In return, any time I intend to publish the HIV data collected (e.g. number of women testing positive in a month), I will approach NACP, allowing them to know what will become of their data and making them understand how the data and, for that matter, how their work in the field of HIV, would be portrayed in the final publication. This approach will ensure that respondents are offered an opportunity to make the necessary corrections before the study is published. The NACP, having years of experience in keeping HIV testing data, offered enough guidance on how I handled their data. This offered an extra layer of protection.

4.4 Chapter summary

Seeking to answer the process evaluation questions in this study required an approach that generated data reflecting the intervention's actual delivery and receipt. Discussions of right-based HIV testing approaches are complex such that they required a nuanced understanding of global policies, national frameworks, deep socio-cultural norms and gender power relations. In line with the questions asked, I proposed to examine various dimensions of the opt-out HIV testing intervention using Carroll's conceptual framework, and the justification for this was offered in this chapter. The opt-out HIV testing's logic and its intended implementation have been made explicit here. Philosophically, I have argued that focusing on the questions asked instead of methods is the best approach to address a real-world situation; hence, pragmatism is the philosophical reason for selecting mixed-methods. The process evaluation design described in this chapter incorporated the most current and widely used evaluation framework by Carroll (2007), which extends the HIV implementation research literature. The findings of the data collected are presented in the next chapter.

5 CHAPTER FIVE: FINDINGS

5.1 Introduction

This thesis aimed to achieve two objectives; adherence to the opt-out HIV testing's recommendations and the factors that moderated observed adherence levels. This chapter will focus on providing answers based on the analysed responses and observations in this study. This chapter is organized into four sections; sections one and two present the antenatal clinics' present characteristics and summarise how the policy has been described in policy guidelines. Section three describes adherence, and the last section presents findings for moderators of the observed adherence.

5.2 Characteristics of the antenatal clinics and study participants

This section describes the 12 antenatal clinics' distribution, a general description of the clinic layout, integration, patient flow, and structural organisation of care. I then describe the study participants who answered the survey questionnaires.

5.2.1.1 Distribution and profile of antenatal clinics

Table 9 summarises the characteristics of the 12 antenatal clinics. The clinics included were owned by private entities (n=5) or the government (n=7). The two categories of organisational authorities had dissimilar funding models and staff support systems and were likely to adopt and implement the policy differently (Tynkkynen & Vrangbæk, 2018). Privately-owned clinics were more likely to be in semi-urban areas. Clinics also differed according to size. Antenatal clinic's routinely collected data showed that in 2017, three of the clinics saw more than 2000, and these clinics were all government-owned and located in urban[8] settings. Eight of the clinics, distributed equally among private and private hospitals, served 1000 to 2000 pregnant women per year.

[8] Urban population refers to people living in urban areas as defined by national statistical offices. Its highest value over the past 56 years was 54.68 in 2016, while its lowest value was 23.25 in 1960.

Table 9:Profile of clinics included in this study

Clinic variable	Government *(n=7)*	Private *(n=5)*
Location		
Urban, n (%)	5(71.4)	3(60)
Semi-urban, n (%)	2(28.6)	2(40)
Estimated clinic attendance		
>2000/month, n (%)	3(42.9)	0(0.0)
1000-2000/month, n (%)	4(57.1)	4(80)
<1000/month, n (%)	0 (0.0)	1(20)
Antenatal clinic-related services		
Focused ANC, n (%)	7(100)	4(80)
A group health talk, n (%)	7(100)	5(100)
History taking & physical examination, n (%)	7(100)	5(100)
Lab services (e.g. syphilis, malaria, G6PD), n (%)	3(42.9)	3(60)
Time spent in delivering health talk (mins), mean (SD)	19(3.7)	18(2.8)
Size of a group for a health talk, mean (SD)	41(18)	61(11)
HIV-related services		
The opt-out offer of HIV test, n (%)	7(100)	5(100)
HIV service available 5 days/week, n (%)	6(85.7)	2(40)
Rapid HIV testing, n (%)	7(100)	5(100)
Information about HIV testing giving during health talk (Yes), n (%)	7(100)	5(100)
Positive test results confirmed at ANC, n (%)	4(57.1)	1(20)
Initiation of ART for pregnant women testing positive for HIV (Yes), n (%)	4(57.1)	1(20)
HIV testing performed by ANC staff, n (%)	6(85.7)	1(20)
HIV testing performed by dedicated staff outside the ANC, n (%)	2(28.6)	3(60)
Human resource capacity		
Number clinicians (mean, range)	3(0-18)	2(0-4)
Number of nurses (mean, range)	10 (3-30)	9(3-20)
Number of HIV testing pregnant women/week (range)	426.3(260-1153)	392.3(175-459.3)
Number of weekly HIV testing clients/staff (range)	60.7 (32.8-103.3)	33(27-41)

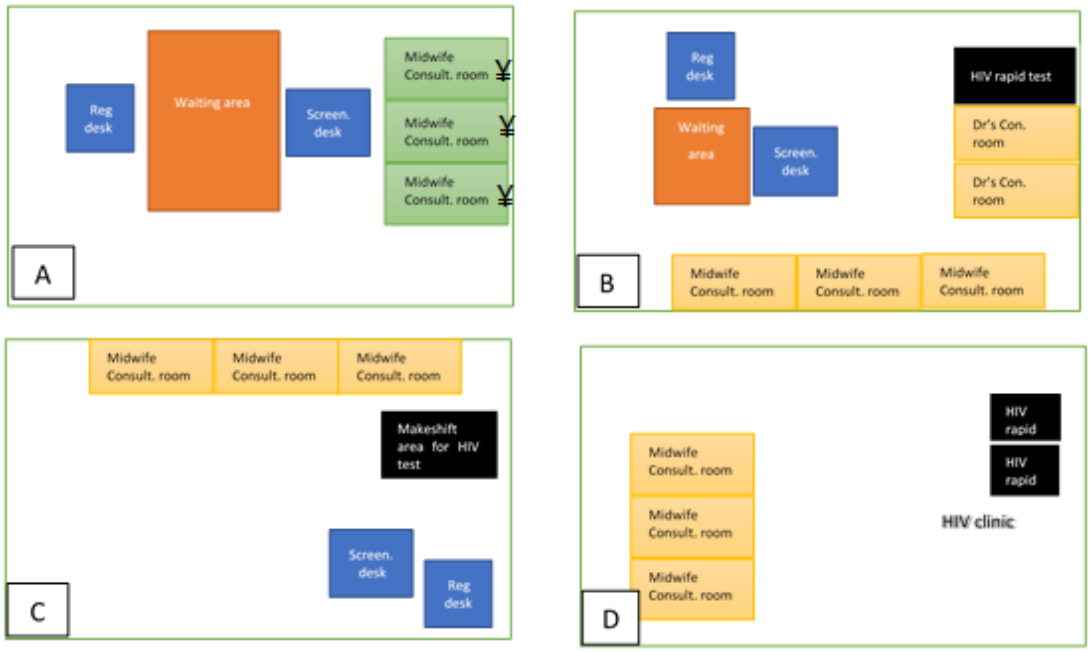
SD=standard deviation; ANC=antenatal clinic; HIV=Human Immunodeficiency virus
Source: ANC register/field notes

A privately-owned clinic located in a semi-urban setting served less than 1000 pregnant women in a year. This suggests that each month in 2017, the number of pregnant women visiting these clinics ranged from 260 to 1153 in public hospitals and 175 to 497 in private hospitals (see *Error! Reference source not found.*). Public hospitals recorded a higher workload per week per clinical staff than their counterpart in private facilities (61 clients per provider in the public clinic versus is 33 clients per provider in private facilities). The mean number of private and public hospitals was similar (10 nurses in public hospitals vs nine nurses in private clinics).

5.2.1.2 The physical layout of the antenatal clinics

All 12 antenatal clinics that served as sites for this study were part of an established hospital setting. Here, I offer a generic description of the clinic layout without specific details that could reveal the clinic's identity. Figure 27 exemplifies four main clinic types found in this study. Together, the layouts constituted a triage or registration desk, a waiting area for women, consulting rooms for midwives and doctors, and dedicated HIV consulting rooms.

Image A in Figure 27 represents a clinic layout with HIV testing services undertaken by midwives in the same consulting room where usual HIV testing activities such as palpation occurred (coloured light green). This setup is described as fully integrated HIV testing in this study. It represents the model of HIV testing in the antenatal clinic that has been recommended by the HIV testing guidelines (GAC, 2008). **Image B** represents a clinic layout in which HIV testing occurred in a separate consulting room different from midwives' consulting rooms used for usual antenatal clinic activities (coloured black). Testing is done by the antenatal clinic staff who were permanently stationed in these rooms or rotated weekly.



¥: depicts where HIV testing occurs together with routing ANC care

Figure 27: Physical layout of antenatal clinics.: Source: Field notes

Image C represents an antenatal clinic where no room is made available for HIV testing. Instead, testing takes place in makeshift spaces created within the waiting areas. These clinics ensured privacy with a screen or had the test done in an open area in the clinic. Here too, the same staff from the antenatal clinic offered the HTC services. In this study, this clinic layout is described as partially integrated. The last antenatal clinic layout is shown in **image D** in Figure 27. Referred to as standalone in this study, this clinic layout has an antenatal clinic separated from the HIV testing unit, but the two are co-located in the same building. Midwives work collaboratively to refer women who need HIV testing to this clinic. The healthcare professionals providing services here are usually specifically trained in providing counselling services for HIV and other chronic disease conditions.

5.2.1.3 Clinic and HIV testing activities

I understood clinic activities through observations during clinic sessions and survey/interviews with clinic managers. Patient flow in this study encompassed all the steps between the patient entering the antenatal clinic, being registered, seen by the midwife, and

then referred to the doctor for further management. All clinics offered the basic package of antenatal clinic services in addition to HIV testing. Such activities included group health education, history taking and physical examination, managing minor conditions and referral of severe medical and gynaecological conditions. Even though almost all clinics indicated operating some form of the focused antenatal clinics (FANC), interviews with clinic managers and observation of clinic activities revealed otherwise. Clinic managers blamed their inability to deliver services by FANC approach on inadequate staffing and insufficient consulting rooms.

Observation data revealed that women's first point of contact in the clinic was the registration desk, where healthcare professionals entered their details. While waiting to be seen, a midwife delivered health education to women (the mean size of a group ranged from 61 women in private hospitals to 41 in public facilities). Healthcare providers self-reported spending a mean time of 19 minutes in public clinics and 18 minutes in private clinics to deliver health education.

Clinic managers mentioned that each month, the health education sessions addressed one prenatal topic considered necessary for preparing women for successful delivery, and this was determined at the beginning of the year. This arrangement made it possible for clinic staff to dedicate one month in the year to educate women on PMTCT and other HIV prevention measures. Besides the monthly education, the clinic offered brief information on the availability of HIV testing in the clinic during each day's health education.

After group education sessions, women proceeded to the registration desk, where clinic staff recorded their details. From here, the paths that women took to get tested differed based on the clinic layout, as shown in Figure 27. In the clinic described in this study as fully integrated (image 1 of Figure 27, pp. 111), women proceeded to the midwife's consulting rooms (coloured light green). Typically, a midwife and two to three assistants managed one consulting room. Physical examination and management of minor ailments were carried out by the experienced midwife, while her assistant performed routine testing such as rapid HIV. If a woman tested negative for HIV, she received brief information about the need to retest

during the pregnancy's 34th week. For positive test results, the experienced midwife often took over the post-test counselling. After extensive post-test counselling, the woman received same-day ART, or the midwife referred her to another unit for the drugs.

Women who attended clinics labelled as 'B' and 'C' (Figure 27, pp. 111) were directed to the dedicated counselling room (coloured black) to be tested for HIV. Here, testing was done by the same antenatal clinic staff whose primary role for the day was to test and counsel women. These healthcare professionals are either permanently stationed in these clinics or are rotated every week. In the labelled layout D, there exists a separate antenatal clinic and HIV clinic, but these are co-located in the same building, and therefore women could move between these two units for services. The clinic is managed by midwives and nurses who have received extra training on HTC and are often permanently stationed there.

5.2.2 Characteristics of study participants

5.2.2.1 Characteristics of pregnant women

Of the 448 pregnant women who answered the exit survey, 326 (71.8%) were from publicly funded hospitals. The entire sample's mean age was 28.3 years (*SD*=5.63; range 16 to 44 years), with the majority (80%) being between 27 and 30 years. Women attending private antenatal clinics had a mean age a year higher than those attending public clinics. Most women were urban dwellers (60%), married (73%), had some form of employment (75%), and had more than one pregnancy (75%). About 11% of pregnant women had no formal education, while 17% had high school education and above. Women attending public clinics differed significantly from private clinics regarding age, residence, and marital status but not in the number of pregnancies and occupation (See Table 10).

Table 10: Socio-demographic characteristics of pregnant women

	Government clinic *n=326(71.8%)*	Private clinic *n=122 (27.2%)*	*p-value*
Mean age in years (SD)	28(6)	29(6)	**0.0231**
Place of residence, n (%)			**0.0025**
Urban	196(60)	77(63)	
Peri-urban	83(26)	42(34)	
Rural	41(13)	(2)	
Marital status, n (%)			**0.0035**
Single	91(28)	16(13)	
Divorced	4(1)	2(2)	
Married	225(69)	104(85)	
Missing	6(2)	0(0)	
Number of pregnancies n(%)			**0.2116**
First pregnancy	80(25)	24(20)	
> 1 pregnancy	240(74)	98(80)	
Missing	6(2)	0(0)	
Occupation, n (%)			**0.3543**
Unemployed	61(19)	19(2)	
Student	19(6)	6(5)	
Employed	249(76)	97(80)	
Missing	6(2)	0(0)	
Educational level, n(%)			**0.1421**
No formal education	40(12)	10(8)	
Completed primary school	26(8)	7(6)	
Completed junior high school	124(38)	40(33)	
Completed senior high school	89(27)	35(29)	
Some diploma	24(5)	16(13)	

5.2.2.2 Characteristics of healthcare providers

Most healthcare providers were from government-operated antenatal clinics, compared to 34% in privately-run clinics. Providers were mostly females (89%) and with a median age of 29 (20-59). A little over half (61%) reported having attained a diploma in nursing education, with more respondents from private-run hospitals acquiring some form of a degree. More than half (68.9%) of the respondents identified themselves as midwives, with less than a quarter (17%) self-identifying as nurses. The rest were nursing assistants (5%), medical officers (2%) and HIV counsellors (5%). Private hospitals reported a higher proportion of midwives than government hospitals (76% versus 67%). Overall, respondents had provided HTC services for a median duration of 2 years (1-14). Privately operated clinics had an older healthcare provider population but had the same years of experience with HIV testing. No

statistically significant difference existed between providers in private and government hospitals regarding sex, age, years of working experience and professional background (see Table 11).

Table 11: Socio-demographic characteristics of providers

	Government *n=100 (66.2%)*	Private *n=51(33.8%)*	*p-value*
Sex, 8 (%)			**0.36112**
Female	87(86.5)	47(91.7)	
Male	13(13.5)	4(8.3)	
Age (median, range)	28(20-48)	30(23-59)	
Yrs. of HIV testing experience (median, range)	2(1-10)	2(1-14)	
Educational background, n (%)			**0.4759**
Senior High School	2(2)	0(0.0)	
Certificate	19(19)	9(18.0)	
Diploma	61 (61)	28(56.0)	
1st degree	17(17)	13(26)	
Professional background, n (%)			**0.5244**
Registered Midwife	67(67)	37(75.5)	
Registered Nurse	18(18)	8(16.3))	
Medical Doctor	3(3.0)	0 (0.0)	
Nursing Assistant	7(7.0)	1(2.0)	
HIV counsellor	4(4.0)	3(6.1)	
Other (field technician)	1(1.0)	0(0.0)	

5.3 The level of adherence to the opt-out intervention

This section addresses the findings of the first objective. First, I describe how the policy has been captured in Ghana's policy documents to offer some context for subsequent interpretation of the adherence findings. I draw attention to gaps in how the documents have conceptualised the human rights issues. In the second part, I present healthcare providers' awareness and use of the 'opt-out' test approach. Finally, adherence to the opt-out test's principle of consent, confidentiality, correct test result, counselling and connection to care is presented.

5.3.1 Ghana's opt-out policy analysis as on paper

A total of 11 documents made up of 'handbook or manual', 'policy documents', 'strategy frameworks', 'reports' and 'guidelines' were retrieved (see Appendix 22). Six (6) of the policy documents were released by the Ghana AIDS Commission, followed by the National AIDS/STI Control Programme (NACP) working under the Ghana Health Service (see). Only three of the policies were specific to pregnant women. One of the three pregnancy-specific documents was a strategic plan for the scale-up of PMTCT services, released two years after the national guidelines were released. I reviewed general HIV testing policies for the remaining documents and determined how it generally applies to pregnant women in the antenatal clinic.

5.3.1.1.1 Terminology

Five different terminologies ('voluntary testing', ' client-initiated ', 'routine offer', 'routine testing', ' provider-initiated ') were used to describe HIV testing among pregnant women in the antenatal clinic. Even though documents described HIV testing using these diverse terms, all policies unanimously described HIV testing as ' provider-initiated '. The retrieved documents used terminologies such as ' human rights ', 'women rights' and 'right to'. The terminology 'human right' was exclusively used in general HIV testing documents, with none found in the three pregnancy-specific documents.

5.3.1.1.2 Consent

Refreshingly, none of the policy documents advocated mandatory testing. The 2013 Ghana National HIV and STI policy put it this way: *'mandatory testing or compulsory testing and treatment are prohibited unless as part of stipulated medical procedure'* (GAC, 2013, p. 6). This compelling statement notwithstanding, I identified five critical issues in the reviewed documents that might have undermined this position. Firstly, the policy documents offered no guidance on when providers should obtain consent for testing, i.e. before or after pre-test information. None of the documents reviewed reported on this. Secondly, and most strikingly, the guidelines gave no guidance on how to obtain consent. Thirdly, only three documents specifically mentioned that consent does not need to be in a written form. However, since none of the remaining studies advocates written consent, one can assume that verbal consent suffices. Fourthly, little attention was paid to the policy documents regarding making women aware of the potential negative consequences or risks of being tested for HIV before consent. Fifthly, most policy documents did not report on the consequences if a pregnant woman refused a test, though it has been stated in three documents that the decision to refuse a test should be respected.

Additionally, the National HTC guideline points out that a woman's decision to refuse a test should not affect the received antenatal care services (GAC, 2008). However, it is provided in the same document that pregnant women should be re-offered the test in a subsequent visit. None of the three documents suggested assessing the rationale for the woman's refusal.

5.3.1.1.3 Confidentiality

Another critical concern identified in the reviewed documents was the protection of pregnant women's confidentiality. Less than half of the documents reviewed addressed confidentiality. Only the National HIV testing guidelines released in 2008 explained what confidentiality entails. It referred to confidentiality as 'the client's right to expect that health care professionals will not disclose personal health information (including HIV serostatus) without the person's consent '(GAC, 2008, p. 20). Confidentiality should be part of all activities of the counselling and testing sites. Five policy documents were explicit on the need

for HIV test results to be shared in certain circumstances or specific individuals. Only one of these documents focused exclusively on pregnant women. The Ghana HIV and STI policy and the Ghana AIDS Commission's ACT summarise the conditions for sharing confidential information. Both mentioned that test results could be shared with a healthcare provider directly involved in providing care to the person or by a court order, where the information contained in the medical file is directly relevant to the proceedings before the court. However, it is not clear from the reviewed documents if confidentiality can be broken if an HIV-positive individual refuses to disclose to the partner.

5.3.1.1.4 Provision of counselling services

Counselling services must be part of the testing process (Kim et al., 2013). The four policy documents that addressed this issue mentioned delivering streamlined and shortened pre-test counselling processes or information. Unanimously, the policies recommended offering adequate information before testing. All pregnancy-specific policies recommended that providers inform pregnant women about the benefits of testing and partner notification. The PMTCT handbook for Healthcare providers further stated that the mother should be given information on PMTCT, HIV testing processes, implications of positive and negative results, the option of informed refusal and the fact that refusal would not affect the provision and quality of other services. Similar information is contained in the general HIV testing policy documents.

Information regarding how Healthcare providers carry out pre-test counselling is provided by three out of the eleven policy documents reviewed. The 2014 National guidelines for PMTCT identifies two HIV testing strategies for PMTCT, client-initiated testing and counselling (CITC) and provider-initiated testing and counselling (PITC). Approaches to delivering pre-test counselling or information in CITC and PITC differ as pointed out by the 2008 National HTC guideline as: '*for client-initiated testing and counselling, the client shall be offered pre-test counselling*', whereas for provider-initiated testing, adequate (pre-test) information should be provided (GAC, 2008, p. 20). The policy requires a pre-test counselling/information session in groups as part of 'general education talks' (GAC, 2008, p. 20). However, the policy

documents were emphatic that under certain situations, individual pre-test counselling should be provided. However, it is advised that employing group pre-test counselling should be an adjunct to the individual/couple pre-test counselling sessions and not a replacement. It is further stated in the guideline that pre-test information sessions are a form of health education and not counselling per se.

All the four policy documents reporting on post-test counselling advocated brief individual post-test counselling for pregnant women testing negative. The 2014 handbook for PMTCT explained that for women testing negative, the healthcare providers should give information on what the negative test result means, prevention of future infections, window period and the retesting in the third trimester. For positive test results, providers must commit much time to counsel women and address any immediate concerns. The primary focus is on informing the woman of essential PMTCT services and ART initiation for the mother and prophylaxis for an infant. In the pregnancy-specific PMTCT handbook, post-test counselling included discussion around infant feeding and disclosure decisions.

5.3.1.1.5 Provision of treatment and care services

I reviewed documents for sections that highlighted the opportunity for women testing positive for HIV to be linked to antiretroviral therapy. Three policy documents referred to Ghana's adherence to WHO standards in PMTCT programmes by the adoption of 2015/2016 WHO guidelines on ART with 'specific strategy to test and treat all HIV positive clients irrespective of CD4 count and WHO clinical stage criteria' (NACP, 2016, p. 3). Only two policy documents, the 2014 handbook for PMTCT and the 2017 Differentiated Service Delivery manual, contain an algorithm to guide the timing of testing and administration of ART for those testing positive. Four policy documents included information on providing prophylaxis for pregnant women who test positive for HIV. Almost all the documents reviewed (9/11) talked about referring individuals who test positive for further treatment. The 2014 PMTCT handbook and the Ghana National HIV Strategic plan require health providers to initiate ART immediately or refer pregnant women for ART provision. The national guideline for preventing mother-to-child transmission of HIV further recommends linking pregnant

women testing positive to other support services for comprehensive medical care and social support.

5.3.1.2 Adherence to the recommendation of test offer

I employed a facility survey with managers and field observation to assess healthcare providers' awareness and use of the 'opt-out' approach when offering HIV tests to pregnant women. The data revealed that providers offered HIV tests to all pregnant women during their first antenatal clinic visits per PMTCT guidelines. However, the approach of the test offer did not always correspond with the guideline's recommendations. As shown in Table 12, just under half (41.7%) of clinics surveyed adhered to the requirement of obtaining informed consent through the opt-out approach, while four clinics (33.3%) employed the opt-in approach. Twenty-five per cent of clinics employed a combination of opt-in and opt-out approaches. Despite the GAC and UNAIDS/WHO recommendations that took away the need for pre-test counselling, this study found that 41.7% of clinics spread across private and public hospitals employed some form of individual pre-test counselling. About half of the clinics adhered to this recommendation by delivering pre-test information in groups before an HIV test. In one clinic, no evidence of pre-test counselling nor information delivery was observed.

Table 12: Healthcare provider adherence to the opt-out approach to test offer

Variable	N(%)
Type of consent procedure	
Opt-in approach only	4(33.3)
Opt-out approach only	5(41.7)
Both opt-in and opt-out	3(25.0)
Approach to informing women about the test	
Pre-test counselling only	5(41.7)
Pre-test information only	6(50)
Both pre-test counselling and information	0(0)
Neither pre-test counselling nor information	1(8.3)

Source: Field notes/survey

Despite varied approaches to test offering, testing coverage was high. Antenatal clinic register analysis revealed that of the 80933 women reported in the eight antenatal clinics that offered this data, 17%, comprising women attending the clinic for the first time and in the 34th week, were offered an HIV test. Of this number, 13505 (98.1%) tested for HIV. A total of 277 HIV positive test results were recorded, representing an HIV prevalence rate of 2.1%. Data on the number of pregnant women testing positive who received ARV prophylaxis and other obstetric interventions was incomplete and was not reported here.

Table 13: Coverage and HIV prevalence of rapid HIV testing (2017) in 8 selected clinics

Facilities	Mothers making first attendance	Number offered test (1st attendance + retesting in 34th week)	Number testing at registration	% testing positive
Facility 1	1169	1884	1884	43
Facility 2	1874	2652	2619	64
Facility 3	1704	1684	1684	42
Facility 4	3,307	3307	3085	33
Facility 5	1064	984	984	29
Facility 6	1453	1453	1453	23
Facility 7	1040	1040	1040	29
Facility 8	774	756	756	14
Totals (%)	***12385(15.3%)***	***13760(17%)***	***13505(98.1)***	***277(2.1%)***

Source: antenatal clinic register (n=8)

5.3.1.3 Adherence to the 5cs of the opt-out intervention

Adherence to consent, confidentiality, counselling and connection to care are presented in this section.

5.3.1.3.1 Agreement between methods

Adherence to the opt-out intervention content was measured by direct observation and self-reports (providers and women). The agreement between direct observation and self-report (women) in measuring low, moderate, and high adherence was 16.3%, 35.5% and 18.8%, respectively. Also, an agreement between direct observation and self-report (provider) in measuring low, moderate, and high adherence was 10.6%, 16.1% and 43.8%, respectively. Overall, the level of agreement between direct observation and self-report (women) in measuring adherence was poor (kappa= -0.082). Similarly, the level of agreement between direct observation and self-report (provider) in measuring adherence was very poor (kappa= -0.034); See Table 14.

Table 14: Measures of agreement between direct observations and self-reports

	Direct observation				
(N=151)	**Low adherence**	**Moderate adherence**	**High adherence**	**Kappa coefficient**	**Kendall's tau-b**
Self-report (women)				-0.082	-0.208
Low adherence	17 (16.3)	7 (22.6)	9 (56.3)		
Moderate adherence	34 (32.7)	11 (35.5)	4 (25.0)		
High adherence	53 (51.0)	13 (41.9)	3 (18.8)		
Self-report (Provider)				-0.034	0.049
Low adherence	11 (10.6)	1 (3.2)	0		
Moderate adherence	29 (27.9)	5 (16.1)	9 (56.3)		
High adherence	64 (61.5)	25 (80.6)	7 (43.8)		

Besides poor agreement between methods, this study also recorded differences in adherence levels based on the assessment method. The study found low adherence levels for direct observation (38.8%, range of 61.1%–95.8%) and pregnant women self-reports (54.0%; range 39.5-67.5%), compared to moderately high adherence levels (78.9%; range 72.9-87.0%) for provider self-reports. Also, adherence scores differed significantly according to the governing authority (private vs government), the level of integration (fully, partial, or standalone) and core component category (the 5Cs). Clinics located in public hospitals displayed higher levels of adherence in both self-report and direct observation. Hospitals with standalone HIV Clinics recorded the highest adherence levels than clinics with partially and fully integrated HIV testing services; See Table 15.

Table 15: Adherence levels based on assessment methods used

	Direct observation % (SD)	**Self-report (Women) % (SD)**	**Self-report (Providers) % (SD)**
Total mean adherence score (SD)	38.8 (22.7)[a]	54.0 (25.2)[b]	78.9 (16.0)[c]
% mean adherence score per governing authority*			
• *Private*	34.1 (19.7)[a]	49.7(23.2)[b]	78.7 (16.4)[c]
• *Public*	43.0 (24.4)[a]	55.6 (25.7)[b]	79.1 (15.8)[c]
% Mean adherence score per level of integration			
• *Standalone*	46.8 (28.1)[a]	67.5 (24.2)[b]	**81.3** (15.0)[c]
• *Partially integrated*	34.2 (18.7)[a]	51.0 (21.0)[b]	79.9 (15.4)[c]
• *Fully integrated*	33.7 (14.0)[a]	42.1 (22.9)[a]	76.0 (17.1)[b]
% mean adherence score by category^			
• *Pre-test information*	40.1 (36.2)[a]	59.8 (34.5)[b]	87.0 (25.4)[c]
• *Informed consent*	56.3 (25.7)[a]	39.5 (39.2%)[b]	72.9 (28.1)[c]
• *Confidentiality*	NA	61.5 (36.6)	**85.4** (23.5)
• *Post-test counselling*	35.5 (19.9)[a]	51.8 (23.1)[b]	73.1 (19.2)[c]

Superscript values denote significant differences between categories according to (a vs b, p-value <0.000), (a vs c, p-value <0.0001), (b vs c, p-value <0.0001).
*Significant differences between per governing authority of according to DO (p-value <0.0001), Self-report (women, p-value <0.0001).
^ Values are compared using the Kruskal Wallis test. N/A- not available (confidentiality had only one item).

5.3.1.3.2 The adherence findings applied to the human rights principles

This section describes the adherence findings aggregated by the 4 of the 5Cs. The frequency distribution of responses to each item on the adherence scale based on methods employed has been summarised in Table 16. Overall, there was a tendency for healthcare providers to self-report that they delivered most of the content as intended. This self-report bias is indicated by a 'yes' response for each item skewing towards the healthcare provider's self-reports. There was a significant bias (p-value <0.0001) for each response based on assessment methods (direct observation and self-report). A consistent response was observed for question 6 (agreed to test) between direct observation and self-report by a healthcare provider but not by pregnant women. Also, consistency in adherence response between direct observation and self-report (women) was observed for item 13 (discussed partner testing) and item 15 (explained support services). I describe a breakdown of these responses in the next section.

Table 16:Frequency of response to each item on adherence scale

Item	Variable	Direct Observation N (%)	Self-report, woman N (%)	Self-report Provider N (%)
A	**Consent**			
1	HIV testing process explained	86 (54.8)	309 (70.1)	131 (89.1) *
2	Mother-to-child transmission explained.	58 (36.7)	297 (67.7)	129 (86.0) *
3	Meaning of positive & negative explained	73 (47.1)	274 (61.4)	132 (88.6) *
4	Mother aware of preventive options for HIV	62 (39.2)	250 (56.9)	131 (90.3) *
5	Mother given opportunity to ask questions	38 (24.1)	207 (47.2)	133 (90.5) *
6	Pregnant woman agreed to test	142 (**91.0**)	212 (48.0)	139 (**93.9**) *
7	Mother informed about her right to decline test	36 (22.9)	141 (31.7)	81 (57.0) *
B	**Confidentiality**			
8	Explained that results would not be shared	31 (19.7)	238 (54.3)	114 (78.1) *
9	Provider & client believed results kept confidential	N/A	312 (69.8)	144 (95.4) *
C	**Counselling**			
10	Meaning of results explained	146 (**95.4**)	389 (**88.4**)	122 (**80.8**) *
11	Give advice on prevention	56 (36.8)	232 (52.8)	114 (76.0) *
12	Partner testing discussed	54 (34.4)	136 (31.0)	67 (46.2) *
13	Window period explained	36 (23.5)	232 (51.9)	115 (79.3) *
D	**Connection to care**			
14	Explain support services	10 (6.5)	26 (5.9)	107 (72.8) *
15	Allow time for questions	19 (12.4)	193 (43.9)	104 (69.8)

**statistically significant*

5.3.1.3.3 Pre-test information to facilitate informed consent

The first thematic area of opt-out's intervention examined in this study was the delivery of pre-test information. The quantitative analysis revealed that women often did not receive the required information to make decisions that would be considered informed, as shown in Figure 28. Offering the right amount of information scored low for direct observation (mean 40%; range: 24.1% to 54.8) and moderate for pregnant women self-reports (mean - 59.8% range: 47.2%-70.1%). Healthcare provider self-reported moderately high adherence levels (mean, 87.0%; a range of 86.0%-90.5%). This suggests that while it was only in 39.2% of sessions that the researcher observed the healthcare provider informing women about the meaning of positive test results, slightly more than half of the women (56.9%) when asked, mentioned that they received this information and 90.3% of providers stated that they delivered this information to pregnant women. The trend was consistent across the remaining thematic areas.

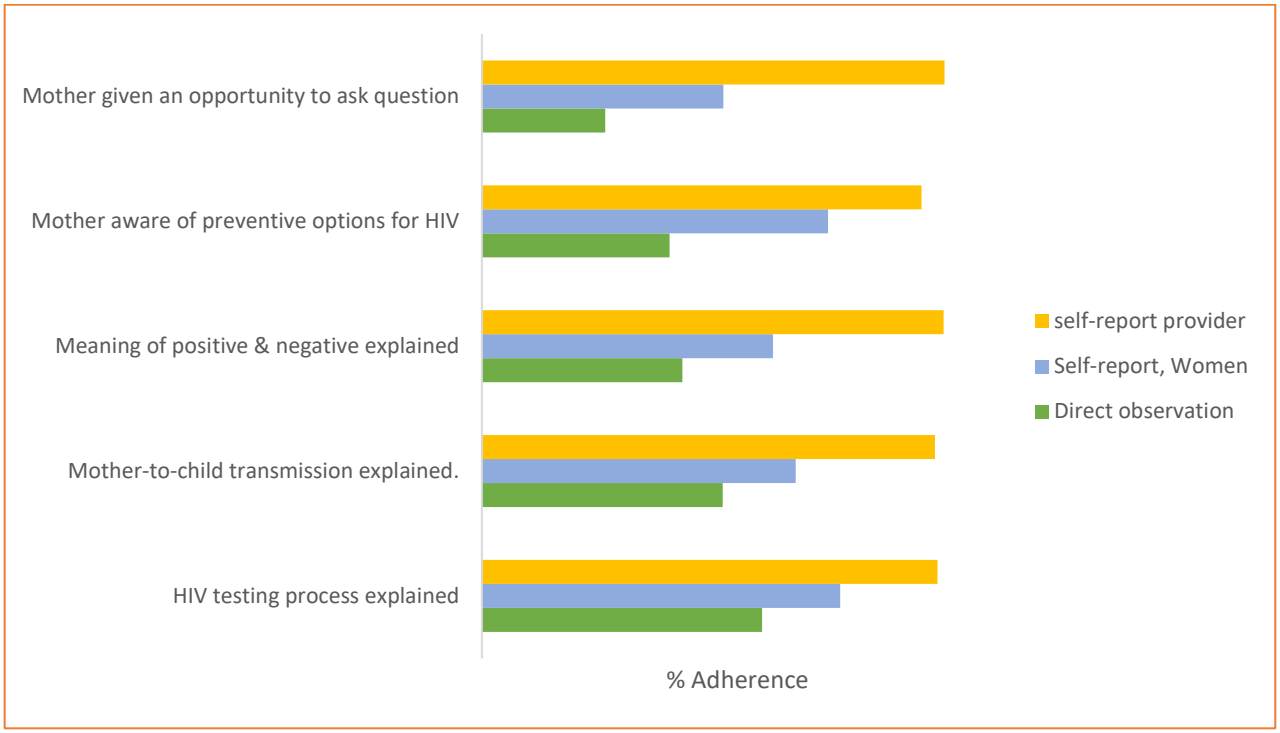


Figure 28: Level of adherence to the content of pre-test information

5.3.1.3.4 Voluntary nature of consent

I assessed the voluntary nature of the test using two indicators: the provider informing women that they could decline the test (optional) and women agreeing to test. Informing women of the test's optional nature appeared to have been neglected, as just over half (57%) of healthcare providers answered 'yes' to this question. About one-third of women recalled being told this, and direct observation revealed an even lower percentage of 22.9%. Even though disclosure of the test's optional nature appeared to be lacking, almost all providers (93.9%) felt women voluntarily agreed to the test, which was corroborated by direct observation (91.0%). Surprisingly, about half (48%) of women mentioned that they agreed to undergo the test. The finding may suggest a situation where women showed their willingness to test when, indeed, they preferred not to undergo any test.

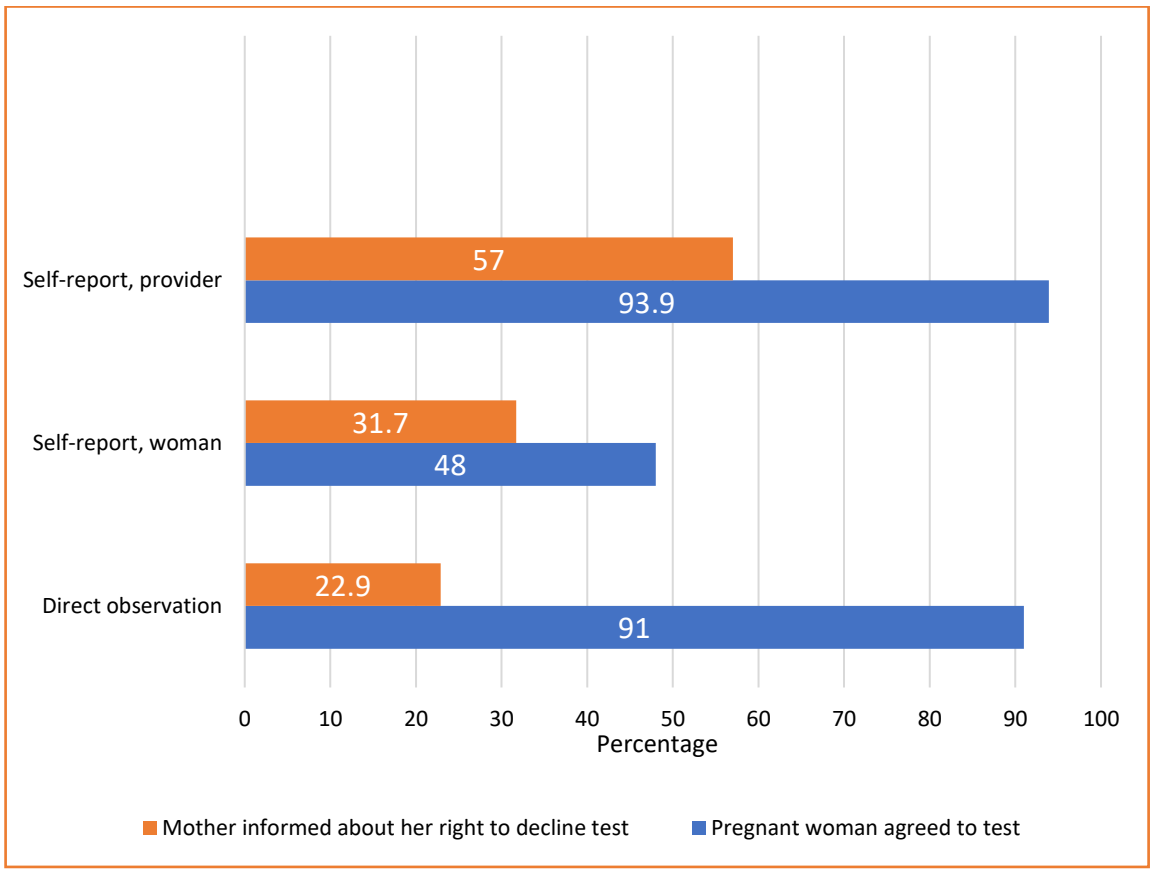


Figure 29:pregnant women right to decline the test

5.3.1.3.5 Confidential nature of the testing process

The third HIV testing human rights principle assessed in this study was the perceived confidential nature of the testing processes. I asked providers whether they had ensured a confidential testing process when testing women in accessing this element. As had been the trend, most healthcare providers felt they instituted adequate measures to ensure a private testing process, as almost all (95.4%) affirmed the confidential nature of the process. More than half (69.8%) of the women corroborated this finding. Similarly, explaining to pregnant women that providers would not share test results without their permission received a moderately high (78.1%) adherence rating by providers, moderate (54.3%) by pregnant women and exceptionally low (19.7%) by direct observation. See Figure 30.

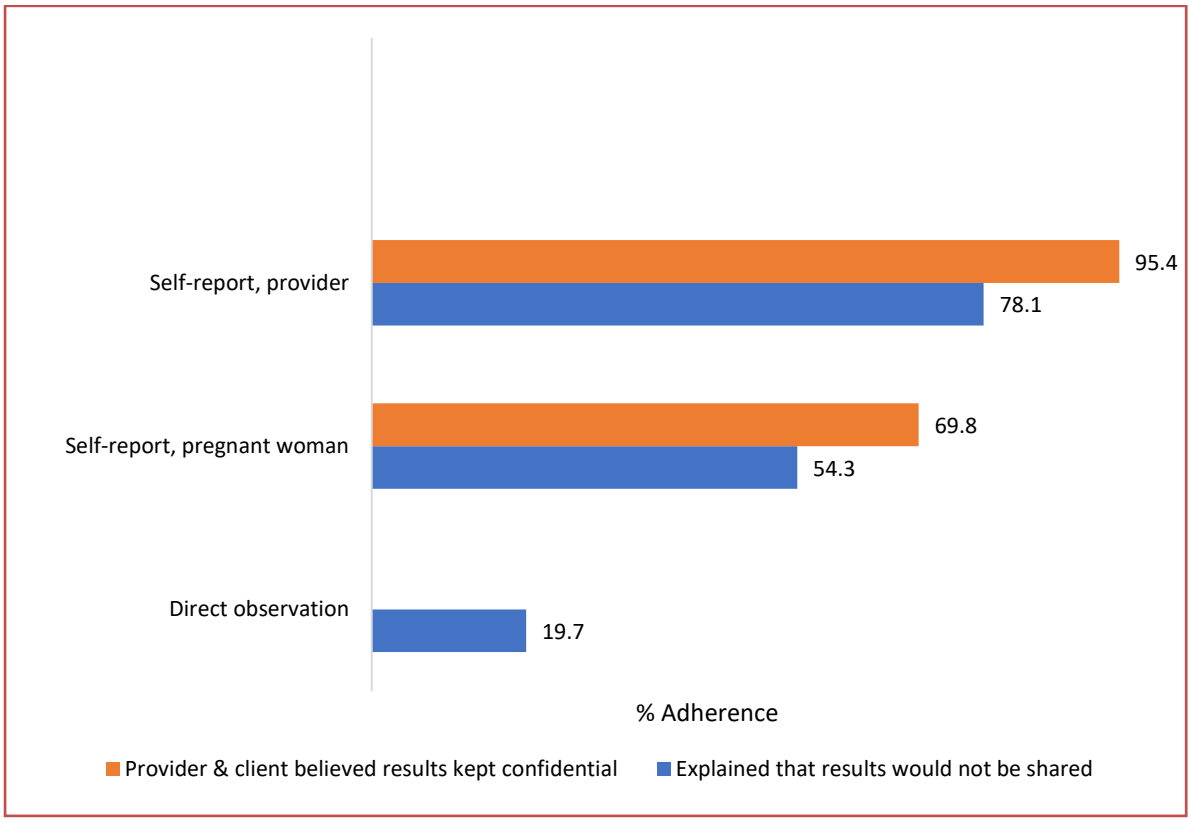


Figure 30: Level of adherence to the content of confidentiality

5.3.1.3.6 Post-test counselling services for women testing negative

This study assessed healthcare providers' adherence to the post-test counselling needs of women testing negative for HIV. Healthcare providers highly adhered to the requirement of making women aware of what a negative test result meant. However, this was not the case in telling women about preventive strategies for HIV after testing negative. Just over half of the women (52.8%) reported receiving this information. Informing women of the need to bring a partner for testing was the least discussed post-test counselling by all the assessment methods, with only 31% of women saying that the healthcare provider offered this advice. The study saw a similar trend in non-adherence to the content of post-test counselling in explaining to women the possibility of a window period and retesting during the 34th week, as well as allowing women to ask questions (see Figure 31).

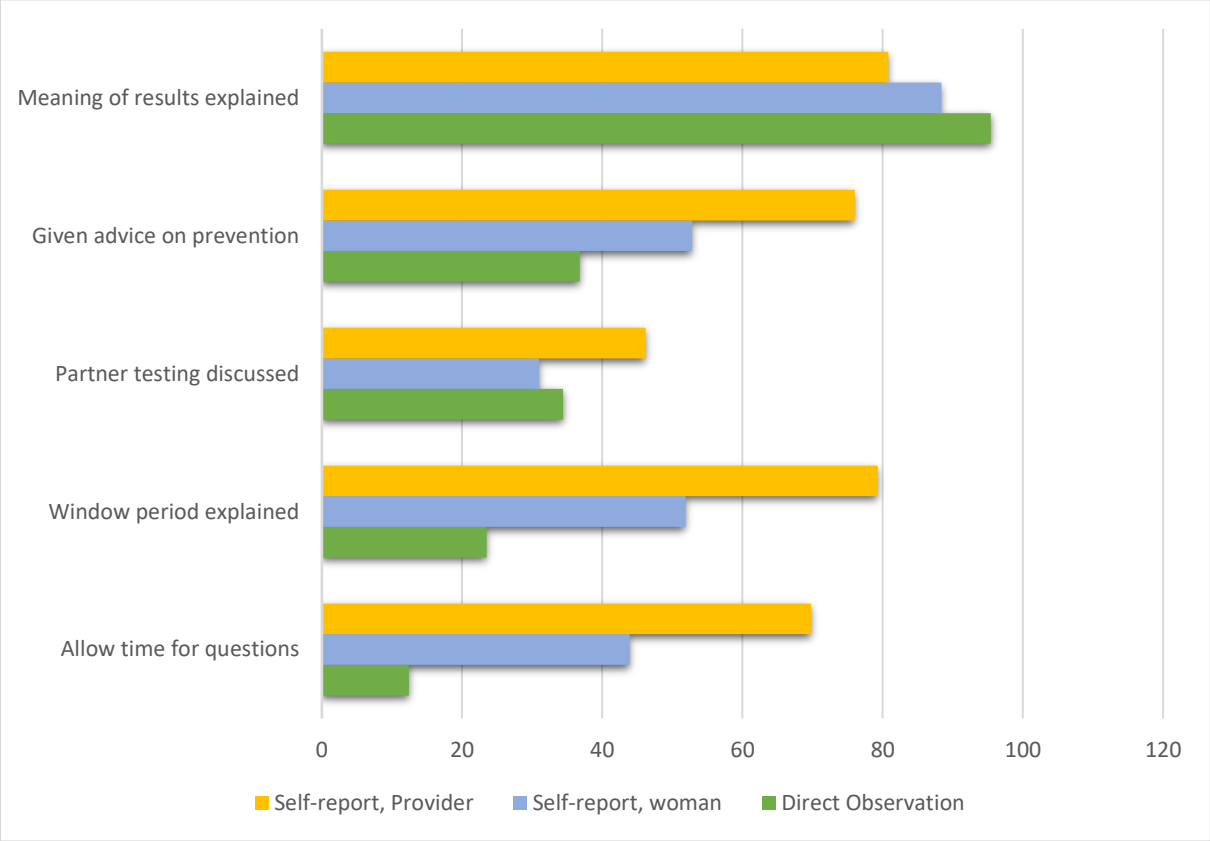


Figure 31:Content of post-test counselling for women testing negative for HIV

5.3.1.3.7 Connecting women to HIV prevention services

Healthcare providers are obliged to help women testing negative for HIV to stay negative by linking them to preventive services (King et al., 2013b). Adherence to this principle was assessed by the two indicators, 'informing women about HIV preventive measures' and 'referring pregnant women to supportive service'. Explaining support services was least adhered to as assessed by direct observation (6.5%) and pregnant women's self-reports (5.9%). More than half of pregnant women (52.8%) mentioned that providers advised them on preventive measures, compared to the observations (36.8%) (Figure 32).

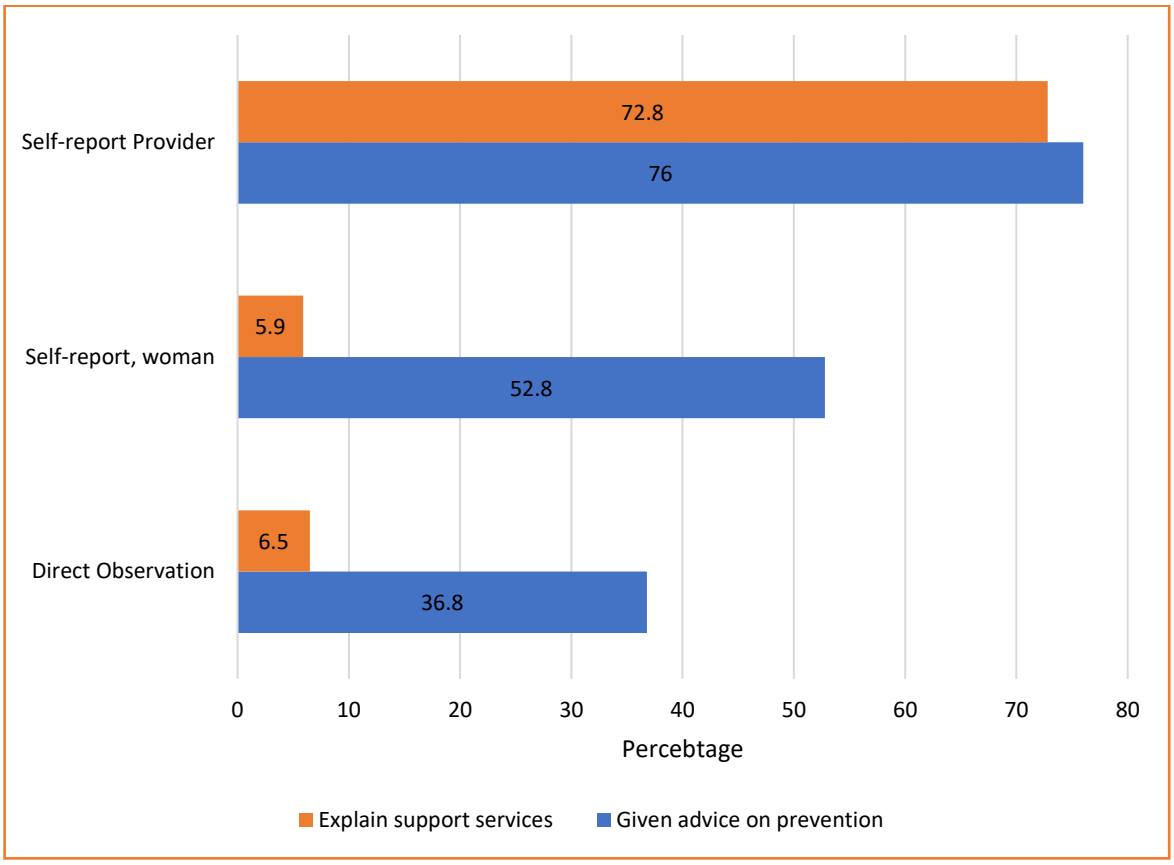
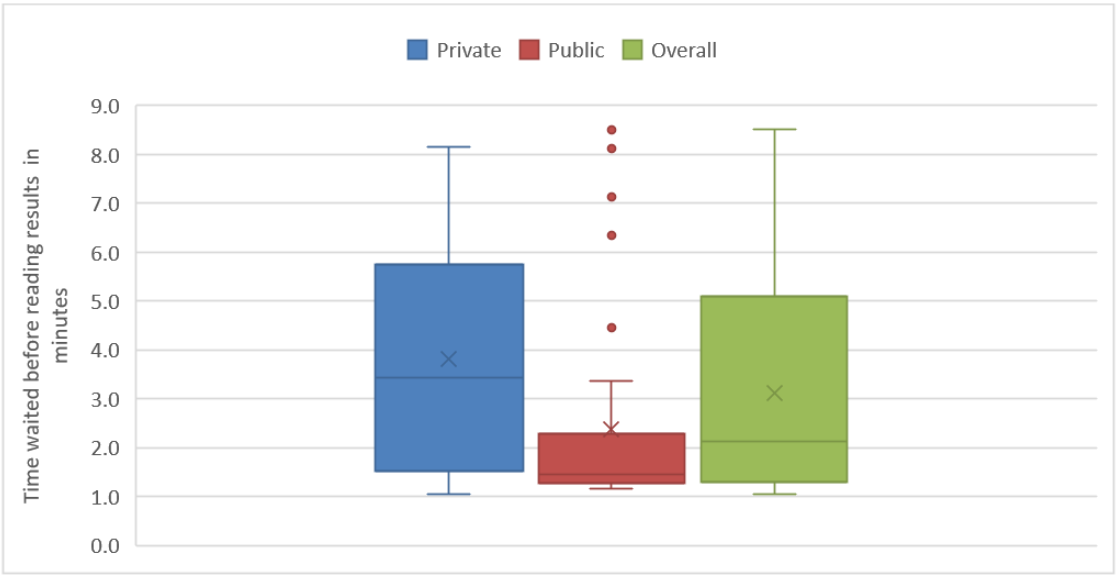


Figure 32: Connecting women testing negative to care

5.3.1.3.8 The right to correct test results (duration)

The fifth 'C' was assessed by how long providers waited to read the test after applying the buffer. Correct timing of HIV testing was an issue in this study. As shown Figure 33, the average time for reading test results was 3.1 minutes, 12 minutes earlier than recommended (Boadu, Darko, Nortey, Akweongo, & Sarfo, 2016; Wolpaw et al., 2010). Even though not statistically significant (p= 0.22), providers in private hospitals were more likely to wait longer (median time waited 3.4 minutes; IQR: 1.5-5.8 minutes) before reading test results, compared to public hospitals (median 1.5; IQR 2.31-1.27 minutes). WHO recommends waiting 15 minutes for rapid testing (WHO, 2016). Failure to follow this standard may lead to providers giving false negative and positive results to women.



Box represents minimum, first quartile, median, third quartile and maximum for private and government hospitals.

Figure 33: Box plot showing the median time providers waited before reading results.

This section has so far focused on describing the antenatal clinic context, the opt-out policy as on paper and healthcare providers' adherence to the policy in terms of approach to test offer and the underlying core principles. In the next section, findings on the factors believed to moderate the observed adherence levels will be presented

5.4 Factors that moderated the observed adherence levels

This last section of the chapter addresses the second objective (moderators) of the process evaluation by answering the questions; is the policy adequately explained in programme guidelines? What is the level of support in terms of guidelines, training, supervision, and feedback? How do Healthcare providers and pregnant women perceive and experience the opt-out HIV testing in the clinic? And what contextual factors influence the delivery of the opt-out intervention? I addressed these questions mainly through qualitative data. Question one was partly answered under sub-section 5.3.1 (policy analysis finding).

5.4.1 Context of the antenatal clinic as moderator of adherence

Analysis of qualitative interviews of pregnant women, providers, and key stakeholders revealed several factors that moderated the antenatal clinics' observed adherence levels. I describe these factors under two broad headings: antenatal clinic design and the communication style.

5.4.1.1 Structural organisation of antenatal clinic and adherence to testing principles.

This study found that adherence levels in clinics classified as fully integrated recorded the lowest adherence levels (across all three assessment methods) compared with partially integrated and standalone clinics (see Table 15). The study also found the structural organisation and these clinics' unique spaces as moderators of low adherence. The study found fully integrated consulting rooms to be small, overcrowded and poorly ventilated. Many providers felt the limited working spaces negatively impacted their ability to ensure auditory and visual privacy: '*the room is too small, and the patients are many. So how do we follow the many things contained in the guidelines?* (**Focus group participant 5; Public hospital**). An HIV counsellor in a private hospital narrated how she had to leave the doors open to minimise the heat:

> *'This room can become so hot on sunny days, and the fan up there just circulates the hot air around. The only option available to me is to leave the door open. See how close*

the queue is to this room. The women in the queue can see and hear all that is going on with the door open' (**Nurse counsellor #1; Private hospital**)

For clinics with HIV testing services and routine antenatal clinic consultation organised in the same room, two pregnant women being seen simultaneously in the same consulting rooms by two midwives and their assistants was common. The midwives attributed the practice to the considerable number of clients, which did not correspond with the number of consulting rooms: *'because of inadequate space and many patients, we have one midwife doing palpation while the other will be consulting with a second patient. If we do not employ this strategy, some women will sleep here'* (Nurse #2, Public Hospital). While the approach reduced the turn-around time for the numerous women waiting to see the midwife, it took away the needed privacy and confidentiality of the testing process. Many women interviewed were uncomfortable about the practice. A 29-year-old pregnant woman expressed how unsettled she felt when, in addition to one other woman in the consulting room, she also had to deal with more than two student midwives:

*'The test should be between the nurse and me, just like the two of us talking here. The nurse who tested me put a drop of my blood on the test kit and then displayed it on the table. While I was anxious to know whether one or two lines would appear (*negative or positive respectively*), the other side of me was concerned about the two other nurses and the pregnant woman sitting across the table. Can you imagine what those who stay in my vicinity would tell our neighbours if I tested positive?'* (**Pregnant woman #1; private hospital**).

Testing positive in the presence of other women may lead to dire consequences. Unfortunately, ensuring that the process was private had not been possible. One midwife revealed that many women testing positive cry inconsolably, which inevitably draws attention to themselves. Since every woman in the clinic was aware of the ongoing HIV test, most assume the results by observing the woman's facial expression or demeanour. In such a situation, the healthcare professional must develop strategies to minimise this

unintentional status disclosure. One such strategy is the creation of private space by sending other women from the consulting room:

> *'When the test is positive, we ask the other woman to go out so that we talk to the client alone. Even the students here must leave. Sometimes sending them out does not even help the situation, as most of them have been in this room and have received their negative test results in front of other women, so why is the midwife sending us out now. They then wait outside for the woman to come out'* (**Focus Group participant #4; Public hospital**).

If a woman tests positive in such a consulting room, asking other women to leave the room would not solve the problem if the woman cannot assume a cheerful facial expression as she exits the room. Some midwives mentioned that they often kept the woman in the consulting room for an unusually long time. The long wait in the room often created more suspicion.

The situation was not different in clinics that tested women in makeshift spaces carved out of the waiting area. A woman sitting behind the screen could often be heard or even seen. In one of the clinics, the makeshift space was at the back of the clinic, where staff usually had their lunch. While women testing negative found no problem with the setup, it becomes very problematic for the midwife when a woman tests positive for HIV:

> *'Some may cry, but we make sure they do not get out of the corner* (the makeshift space created)*; otherwise, the others would know that something had gone wrong. We usually talk to them until they assume a relaxed facial expression '* (**Nurse-Midwife #1; Public hospital**).

The midwife must keep her voice low when talking to the woman. Providing extra attention combined with uncontrollable grief in a clinic setting may indirectly reveal the client's undisclosed HIV status. In such a situation, the pregnant woman leaves the clinic, knowing that her test result has become public knowledge.

Finding it difficult to ensure the confidentiality of the testing process caused many women interviewed to express a desire to have their HIV testing separated from the regular services:

> *'If I had gone specifically for the HIV test, then I would expect it to be private. The midwife would not have allowed another woman to be in the same consulting room. However, this place is not an HIV testing centre; it is meant for routine antenatal clinic checks, then for some reason, they have added HIV to it. What do you expect the midwives to do?'* (**Pregnant woman #20; Public hospital**).

The many women in a group also posed some challenges. Therefore, group size moderated information delivery: *'we used to discuss the test when the groups were small. Today the group you saw, do you think we can discuss HIV testing there?'* (**Focus group participant #7; Public hospital**).

The challenge encountered in delivering information in large groups resulted in some partially integrated clinics delivering individual pre-test counselling. In one standalone clinic, observation data showed that all women viewed a short video on HIV tests to address the information gap. In many fully integrated clinics, information about HIV was delivered mainly by a nurse or midwife in the consulting room. Therefore, the antenatal clinic setup and many women influenced the healthcare providers' ability to deliver the required amount of information needed to empower women to make an informed decision about their test.

Even if a midwife attempted to deliver some HIV related information, the sensitive nature of the HIV information coupled with the total lack of privacy made it impossible. Such a situation might make it difficult for a woman to say 'no'. This is how a woman narrated her encounter: *'When I entered the room, I wondered, will the midwife discuss all my problems in front of these students?' (***Pregnant woman #15; Public hospital***)*. A nurse working in a public hospital explained that she was sometimes unable to discuss everything about the test when other women or even students were around:

> *'Apart from the two pregnant women, there are also students sitting here to learn, sometimes even where the staff will sit becomes a problem. When it happens that way,*

we are unable to discuss very personal and sensitive issues. I usually stop talking when I see the woman looking over my shoulders to see those at the far end' (**Nurse #2; Public hospital**).

Structural organisation and acuity of the clinics also affected measures taken to ensure the quality of the test result. Many healthcare professionals identified HIV testing as an additional responsibility that was outside their core mandate. For this reason, some midwives often assign HIV testing to the student or newly trained midwife while they concentrated on palpitation and other activities considered more technical. A midwife explained how getting help from the students helped her focus on the more essential needs of the women:

'Most of my students are incredibly good at pricking and applying the buffer. Rapid testing does not need any technical expertise. They will let me know if they have problems. If a woman tests positive, they know what to do. They will usually discard that test kit and then refer the woman to me. I will do the test again and then disclose it. Disclosing test results is beyond them' (**Midwife #6, Private hospital**).

In one clinic that had a separate consulting room for HIV testing, the entire testing procedure was handled by students who were on clinical placement, as seen below:

'The midwife showed me all the consulting rooms designated as midwife and doctor's consulting rooms. The last consulting room adjacent to the dispensary labelled 'counselling room', was dedicated to HIV testing. On entering, I saw four students, nurses and a pregnant woman undergoing an HIV test. The midwife later explained that the testing is often undertaken by staff in the clinic, but when they were busy, they allowed the students to carry out the test' (**Field notes, 24th March 2017**)

The observation pointed to how simple, rapid HIV testing was considered in this clinic. Other clinics handled the increased client numbers by reorganising services so that healthcare professionals could see women making their first visit and therefore requiring HIV testing on specific days of the week.

In two antenatal clinics that operated partially and standalone testing systems, providers handled the large client numbers by practising what they referred to as 'rapid group testing'. With this approach, healthcare providers called all the women queuing for an HIV test into the counselling room at one time. They then pricked each of them and put the sample on the test kit, and labelled them. The health professional then called the women one after the other and delivered the results to them. Testing women this way might have shortened the time women had to wait but could potentially lead to incorrect results being delivered to women. A nurse reported instances where she mistakenly gave the wrong test results to another woman:

> *'We write the full name on the test kit because sometimes, with the first name, we get about four pregnant women with the same first name. We once had a case where there were three individuals with the same surname. One was positive. When we called the first name, we realised that the positive individual was still sitting there'* (**Focus group participant #6; Private hospital**).

Besides giving the wrong results, there is a risk of recording false-positive results due to reading the results too early or too late. The narratives and observation data presented here show that the antenatal clinic context and the structural organisation of care may have moderated the observed adherence levels in this study.

5.4.1.2 Communication strategies and power relations

An essential finding of this study is that many women felt that their decision to test for HIV was neither voluntary nor informed. This study's findings pointed to unique subcultures in the antenatal clinics that directly or indirectly influenced women's decision to test. The first is the unequal and often hierarchical relationship that favoured the healthcare provider. Observation of interactions during counselling sessions and interviews with women and providers showed that knowingly or unknowingly, midwives and other healthcare professionals took advantage of this unbalanced relationship to control the amount of HIV-related information delivered before an HIV test, and even the level of interaction women could have with them. For example, a healthcare provider's narration of strategies she often

used to limit women's ability to ask her questions: *'I am careful not to give the women lot of information or even ask them whether they have questions, especially the educated ones. We must not act weak; otherwise, they will have the opportunity to say 'no''* (**Focus group participant #3; Private hospital**).

Health professionals offered highly scripted, procedural, and often closed-ended information that gave women no chance to decide what would be considered a voluntary and informed decision to limit communication and interaction further. A nurse working in a public hospital narrated how brief the information she offered was: *'mostly we told them the things we do here and asked them whether they wanted to test or not. We do not go into details'* (**Nurse # 10; Public hospital**). A pregnant woman considered the healthcare provider's approach to the test offer rather directive: *'She* (the midwife) *told me to sit down. She said, "Can you give me your hand"? I need some blood to do something'* (**Pregnant woman #3; Public hospital**). Offering a test this way compromised the 'informed and voluntary nature ' of the test.

The study also found that providers' communication approach appeared not to meet most women's information needs. Most women I interviewed were aware of an HIV positive diagnosis' gravity and expected more information than they received. In some cases, women complained that healthcare professionals tested them without their knowledge. A woman who went through the testing process in a public hospital expressed her frustration this way: *'I expected the midwife to at least tell me that she was about to test me for HIV and to say sorry because the needle prick is a bit painful. The midwives and nurses treat us as though we know everything'* (**Pregnant woman #10; Public hospital**). While the above narration may suggest that women felt they required extra information, none of the women interviewed appeared to have requested it. For some women, undergoing HIV testing without prior notice; *'was a rule in the clinic'* (**Pregnant women #16; Public hospital**). These women have understood that asking questions in the clinic amounted to disobeying instructions from the provider; *'what the midwives say is what holds'. They* (the healthcare providers) *would not be happy if one keeps asking about their activities'* (**Pregnant woman #2; Private hospital**). Seen this way, many women tested without adequate information or an opportunity to clarify issues they did not understand.

Interviews with healthcare providers and pregnant women further showed that providers relied on the 'sake of the child' message when presenting HIV test to pregnant women. The midwives knew the value Ghanaian women place on delivering a healthy baby and therefore exploited it in influencing their decision to test: *'once I mention the unborn child, no woman will allow her child to be infected, and therefore agrees to test'* (**Midwife #6; Private hospital**). The approach used in presenting the test indeed reflected women's narratives. When asked about the test's benefits, most women could only mention how the test may protect the unborn child. A woman attending an antenatal clinic in a private facility narrated her experience with an offer of an HIV test: *'the midwife explained that she was doing the test because it will help the child in my womb. Even if I have the virus, she said they have medicine to prevent the child from getting the disease'* (**Pregnant woman #1; Private hospital**). The above narrative suggests that the discussions around HIV testing focused on the child, with little said about how the test may impact the woman. Therefore, a woman tests for HIV without what it means to test positive, negative or to be on a lifelong ART. Therefore, coming to terms with a positive diagnosis and adhering to lifelong treatment becomes challenging after the child is delivered.

Besides apparent neglect of the woman's needs for information regarding the test, using the unborn child as the reason for testing introduced an element of moral discourse that constrained voluntary decision making. Implicitly, a woman who decides not to test for HIV becomes wicked and unwilling to have a 'normal baby'. Such a notion made it unsurprising when most women mentioned 'protecting the unborn child ' as the reason for testing. For women, becoming pregnant meant losing control over one's body: '*when you become pregnant, you do not have your will. All the laboratory test become compulsory for you* (**Pregnant woman #17; Public hospital**). Considering their bodies are a reservoir for HIV, these women considered it their responsibility to get tested: '*I know my child uses my the blood, so if I test positive for HIV and do not get treatment, it is the innocent child who will suffer* **(Pregnant woman #19; public hospital**). The woman's body, therefore, becomes a tool for HIV prevention.

Aspects of providers' narratives regarding their role in protecting the unborn child and ensuring a healthier life for the mother portrayed paternalism. The interview data revealed that healthcare providers often blamed a pregnant woman who had tested positive for HIV and her partner for engaging in sexual activities outside marriage. The consequence of such a mistake, according to some midwives, must not be borne by the 'innocent child'. For this reason, the midwife considered it a professional responsibility to protect the vulnerable child: *'most of these women had the disease through having multiple sexual partners. As a midwife, I could not look on while the poor child becomes infected. Therefore, protecting the child is my professional responsibility '* (**Midwife # 9; Public hospital**).

Besides relying on the unborn child as a reason to test, this study found that providers often presented the test as 'an offer women cannot refuse'. Many providers mentioned that the test is an 'order from the doctor' or 'a government policy'. A midwife would usually employ this strategy when she suspected that a woman might decline the test: *'Ideally, HIV testing should not be compulsory. However, it is now a policy and part of the focused antenatal clinic, and whether the woman likes it or not, the midwife would test her* (**Focus group participant #7; public hospital**). A pregnant woman who desires further services from a midwife would be willing to sacrifice her autonomy and test to keep the midwife away from trouble: *'The midwife said the test is government's initiative, so every pregnant woman must be tested, maybe that is why she did not ask whether I will do it or not*. *She must do it to not get into trouble'* (**Pregnant woman #6; Public hospital**).

Considering the test as a government policy that the midwife must deliver caused some women and even some healthcare providers to regard it as a pre-requisite for receiving subsequent care in the clinic. For example, women expressed concerns that without the test, the medical team would have no guidance regarding the treatment to give them: '*The midwife and doctor base their decision on the test results to treat us. If I refuse to test, they may prescribe the wrong medication for me*' (**Pregnant woman #5; Public hospital**). For others, refusing a test offered by a midwife might affect their subsequent relationship with providers, reduce the quality of service they received, and may not have midwives to assist them when in labour: '*I think the midwife can decide not to care for me because I refused an*

important test. I even heard they look at the test results before admitting you into the delivery room' (**Pregnant woman #8; Public hospital**). These experiences might have covertly nudged women to test for HIV, even if they did not want to test.

A clinic put in a measure to ensure that any woman who refused to test did not progress through subsequent stages of antenatal care. They achieved this by stamping the back of antenatal clinic folders of any woman they tested. If a woman entered a consulting room without the stamp, the doctor would send her back. Women were aware of this practice in the clinic: *'the midwives will write in our antenatal clinic book that we refused the test. This will cause them to deny us care during delivery'* (**Pregnant woman #9; public hospital**). A nurse in a public hospital described the practice as a local policy put in place to reduce the chances of women refusing the test:

> *"Putting a stamp at the back of the folder is our policy. If you do not have the stamp, those in the doctor's consulting room will send you back. A lady once refused the test. I just asked her to go. The doctor turned her back because she did not have the stamp. Trust me, if we do not do that, most of them will not do the test, and you know they must do it*' (**Nurse #4; Public hospital**).

A midwife in a private hospital narrated a similar practice. She said if a woman refused a test, she often referred her to the doctor. According to her, they do this with the knowledge that no woman would like to disobey a doctor: *'we do not force women who refuse to test. We refer them to see the doctor. They usually will agree to test once they hear the doctor's name'* (**Nurse #9; Private hospital**). These private and public clinics' narratives depict how healthcare providers use institutional powers to coerce women to test.

5.4.2 Complexity – provider awareness and understanding of the policy

In terms of its description in national policy documents, the opt-out intervention's complexity was presented in sub-section 5.3.1; *pp.*116). Healthcare providers' nonadherence to the opt-out test approach and general nonadherence to the human rights principles was also noted. Of interest was a trend where healthcare providers consistently had higher adherence scores that did not agree with other assessment methods. Further interviews with providers and reviews of HIV policy documents' content revealed that providers were either unaware of the intervention's expectations or had never heard of the intervention; *'I know testing is routine, which means we should test all women coming to the clinic. For the opt-out, I have not heard about that.'* (Midwife #2 public). The few providers who reported being aware of the opt-out's approach found the difference between eliciting consent by opt-out and opt-in difficult. Data from field notes revealed that many providers asked women: '*Do you agree for me to test you for HIV?* (i.e. opt-in approach)' instead of informing the clients that *you will be tested for HIV as part of your blood works, however, you have an option to decline if you do not want to'* (opt-out approach). Such misinterpretation of the policy was apparent in the narratives of many providers who repeatedly mentioned that they were supposed to '*initiate*' testing without necessarily obtaining informed consent.

Even some national level officers displayed a limited understanding of the policy, despite having a clear mandate to determine what was in it. For example, an officer could not tell the difference between 'routine testing' with 'routine offer of testing' (contrary meanings) (**Field notes, 19th March 2017**). The observed misunderstanding of the policy indicates the challenges local actors face in translating underlying testing principles developed in a context with different beliefs and practices.

Without any structured training, these providers found even the act of pricking a woman and applying the right amount of buffer solution difficult: '*even how to prick the women was difficult. Sometimes out of fear I pricked lightly, and no blood would come, and even how to draw the blood and put it on the test strip, most of us do not know how to do it'* (**Community Health Nurse #1, Private**). Even more challenging is when the woman tests positive. Without

accurate test information offered to the woman, a midwife with little experience with HIV testing found it challenging to disclose a positive test result or offer post-test counselling:

> *'For women testing negative, it was easy to disclose. However, if a woman tested positive, it became problematic. How do I look at a healthy-looking professional and tell her that she is positive for HIV? I once had a positive test result. She became very aggressive and started pacing around. Since then, I have always called someone senior to disclose the result'* (**Midwife #10, public**).

The difficulty in disclosing was often due to inadequate counselling skills and not adhering to the pre-test information and the opt-out approach. There was always the chance that a woman would refuse the test; some may become aggressive, as narrated above.

Pregnant women data showed that even though women readily agreed to test, they usually did not trust the outcome, mainly when it was positive. For one woman, even the simplicity of the rapid test made it hard for her to believe that it is the approach used to diagnose such a dreadful disease:

> *'The test is too simple. It would be best if the blood passed through machines rather than putting a few drops on a test kit and reading the result after about three minutes. What if the woman has HIV and the test kit results showed positive? It would be good to take a sample to the laboratory for proper screening'* (**Woman #3; private hospital**)

These complexities occur daily, requiring healthcare providers to be knowledgeable and skilful in every aspect of the HIV testing continuum: *'with little knowledge about this disease, how do I disclose to a healthy-looking woman that she is positive?'* (**Focus group participant #7, Public Hospital**). The complex nature of eliciting informed consent through opt-out and the challenges that follow when a woman tests positive makes the observed task-oriented and transactional relationship between providers and women during HIV testing not worthwhile.

5.4.3 Level of facilitation as a moderator of adherence

The opt-out testing intervention was, in general, unfamiliar and complex to the healthcare professionals as described above. For midwives to deliver such an intervention with fidelity, there needed to be some facilitation, as Carroll et al. (2007) suggested. Carroll described such strategies as the provision of clear guidelines, training, supervision and feedback. In the next section, I present findings relating to these key facilitating factors.

5.4.3.1 Availability of clear guidelines

I reviewed a total of 11 Ghana's HIV policy documents made up of 'handbooks or manuals', 'policy documents' and 'strategic frameworks' to inform this study. Findings have been summarised in Section 5.3.1 (pp. 116). These guidelines exist at the offices and websites of GAC and NACP; I found none in all the 12 clinics. The lack of these facilitating materials sharply contradicted national-level officers' narratives that they had distributed the guidelines and manuals to all antenatal clinics. Antenatal clinic managers revealed that national level officers give out the guidelines to staff who attend a workshop. Most of the staff consider these to be personal property and therefore take them home; *'workshop organisers give the guidelines to those nominated to attend workshops. These staff assumed ownership of the guidelines and took them home instead of presenting them to the clinic for us all to use'* (**ANC manager #4, private hospital**). The absence of guidelines meant that providers had nothing to look at when delivering pre-test information or other related activities. During a focus group discussion in one public hospital, a nurse described the challenges she went through any time she was called upon to deliver group information:

> *'There is nothing to guide what exactly to tell the patients. In the morning, the in-charge issues instruction on who is to deliver health talks to women. The person delivering the talk must decide what to include in the talk. Therefore, we communicate different things to pregnant women' (***FGD participant #1, Public hospital**).

This study found that the principles of offering testing in an opt-out manner is not a norm and is unfamiliar to healthcare providers. Without guidelines as described, training of healthcare professionals becomes essential. Interview data revealed that national level

officers addressed this training need only when introducing the intervention in 2008. The training was intensive and focused mainly on equipping midwives with the skills needed to handle difficult counselling situations. Interview data suggest that follow-up training after this initial training had been infrequent; '…*the training was many years ago when the organisers showed us the new ways of testing women. Since then, I have not had the opportunity to receive further training. I am not sure if our new midwives are trained* (Midwife #5, Public Hospital). For many of the midwives with less than five years' experience, there had been no opportunity for them to learn the opt-out intervention in a structured manner. They learned how to test and counsel by observing what their senior colleagues did:

> '*I looked at how others were doing it. This approach to learning has not been perfect. I have been testing for some time after watching a colleague, but I never knew that sometimes when the drop of buffer solution is thick, just a drop or two is enough. I recall squeezing all the drops on the test kit. I still think about the result I gave that woman'* (**Focus group participant #3, private hospital**).

The above narration reflects the concerns shared by many healthcare providers in this study. While they expressed the desire to test women, most felt inadequately prepared to undertake the intervention's technical aspect.

Lack of supervision and prompt feedback was another facilitation issue this study found. Even when supervision occurred at the clinic level, the clinic managers often focused on routine antenatal testing activities. The act of obtaining informed consent and correctly applying buffer to test kits appear to receive no supervision. Healthcare provider interviews showed that on the few occasions that regional HIV testing officers visited, they focused on how they (providers) ensured accurate data entry and not how they went about testing:

> *'They usually check to see whether we are doing the entries well or not. They collect our register and check entries to see if they match what they came with from the region. They never enter the testing room to see what is going on there'* (**Healthcare provider # 6; Private hospital**).

The difficulty in supervising HIV testing activities appears to have been caused by a lack of adequate regional level supervisors for the increased HIV testing centres. The study revealed that the regional monitoring team could often conduct a twice-yearly targeted external quality assessment (EQA) even within this limited human resource capacity. According to the regional HIV coordinator, part of EQA involved doing proficiency testing for staff engaged in rapid testing: *'…we issue simulated specimen to clinics and performance is assessed by comparing reported results with the expected results* (**Regional HIV testing officer- Key informant**). The key informant explained that they often compared the result they received from the various clinics with a standardised test result. If the staff of a particular hospital recorded false results, it alerted them that the hospital staff required training and target supervision.

Facilitation, in terms of logistics, was not a problem in many of the clinics. Providers directly involved in testing reported that the test kits needed to screen women (1st response) were in abundance. The only challenge providers encountered had to do with testing kits needed to confirm a positive test, also referred to as OraQuick: *'the OraQuick is scarce in this hospital, so the ART coordinator usually gives us about 10, which last for about a month depending on the number of positive results we get'* (**Nurse manager #3; private hospital**). Shortage of test kits resulted from poor documentation of test kits used in the various consulting rooms, which usually affected forecasting. In the absence of confirmatory test kits, providers referred women who tested positive to other departments or even other hospitals for confirmation.

5.4.4 Participants' perception of the intervention - responsiveness

Responsiveness is the last moderating factor addressed in this study. I was interested in finding out how various stakeholders viewed the intervention. Carroll et al. (2007) indicate that stakeholders' beliefs, enthusiasm, and attitudes about an intervention directly influence adherence. National level officers in GAC and NACP responsible for policy formulation and implementation, respectively, differed in their views regarding the required level of adherence to the intervention's core components. GAC officials considered themselves

adopters of the policy and therefore emphasised strict adherence. Officers of NACP, responsible for translating the policy into practice, advocated flexibility in implementing the policy. The NACP officials noted that the practice environments differ, which meant that careful adaptation and streamlining would improve individual clinic needs.

Frontline staff were optimistic about their role in testing. Some did not view HIV testing as a separate function but rather as one of the many activities that midwives undertake to ensure a safe pregnancy and birth. These midwives argued that detecting women living with HIV and offering them medication was an essential professional responsibility to their clients. A key informant at the regional level, who previously worked in the antenatal clinic, compared testing women in the clinic to a syphilis test this way:

> *'We test the women here for syphilis, and the women are okay with it. HIV is not different from it; it is part of what we went to school to learn. However, the employer must add HIV testing to our job description to help our salary negotiation'* (**Key informant #2: Regional HIV facilitator**).

Providers who viewed HIV testing as part of their role held the view that the 'ritual' of client autonomy and informed consent practices if emphasised, may come in the way of delivering their professional mandate. A provider narrated: *'I know HIV has a stigma to it, but once the woman comes for antenatal clinic services, they consent to all procedures in the clinic. Do I have to get permission before undertaking all the activities on them?* (**Focus group participant #9; public hospital**). For a midwife who sees HIV testing as an integral part of her role, the very act of seeking informed consent appeared paradoxical, especially when the test is free. For many of these midwives, coming to the clinic for services means the woman has implicitly consented.

Other frontline staff viewed testing women for HIV as a tool to protect both the unborn child and the midwife delivering the woman. Expectedly, these healthcare providers felt no need to keep the test results of women confidential from their other colleagues who may be caring for the woman who has tested positive. Aspects of the national guidelines seem to give

credence to this notion, albeit subtly: '*… test results may be shared with other counsellors and other members of staff who may be involved in the client's care within the facility to ensure the continuity of care'* (GAC, 2008, p. 19). Therefore, it was a standard practice for providers both within and without the antenatal clinic to show interest in test results, especially those they know. Some healthcare providers returned to the clinic after everyone had left to comb through the register for the HIV status of women they might know. Some midwives considered this unprofessional, and therefore devised strategies to curb it:

> *'After the woman tests positive, it is written on the antenatal clinic card, which passes through many hands '.* (Midwife # 12, Private Hospital). '*For those testing positive, I do not give the card to those making the entries at the front desk...they often get to know the status of the woman but cannot keep their mouths shut.'* (**Midwife #6; public hospital**).

Few women considered it useful for the midwife to direct them on what to do in the clinic. They mentioned that the midwife offers advice on what food to eat, hygienic practices, and preparation for delivery throughout the pregnancy. For this reason, they have come to rely on the midwife for advice. Therefore, it would be difficult for them to make an independent decision as to whether to test or not.

> *I came to the hospital because I needed help from the midwife. So she needs to advise me on whether to take the test or not. There are things I can decide for myself, but not health and hospital issues. Yes, she must give me a choice to decide, but I would like to rely on the advice she gives.* (**pregnant woman #4, private**).

5.5 Chapter summary

This chapter reported the findings of the opt-out intervention as implemented in the 12 antenatal clinics. HIV testing was widely available in all the clinics, as pregnant women reporting to the clinic were routinely tested. Healthcare providers did not adhere to the requirement of offering HIV testing using the opt-out approach. Many were unaware of the opt-out approach but still offered HIV tests, with the approach being a mixture of the opt-out and opt-in and some mandatory practices. Clinics still performed individual pre-test counselling instead of pre-test group education. Adherence to the intervention's core components of consent, confidentiality, correct test results, counselling and connection to care was low for direct observation, moderate for pregnant women self-reports and moderately high for healthcare providers. Healthcare providers consistently self-reported high adherence, which was not corroborated by direct observation or women's self-reports. There were differences in adherence rates based on the nature of the clinic layout and the level of integration of the intervention. Standalone clinics exhibited the highest adherence rates, with fully integrated clinics recording the lowest adherence in all the thematic areas. The low to moderate adherence means that the decision to test may not be informed, and the test's voluntary nature remains questionable. The antenatal clinic context potentially moderated the observed adherence levels, which did not support a rights-based test. The intervention was unfamiliar with lack of facilitation in terms of guidelines, training, and supervision. Nurses and midwives perceived their role as helping the woman know her status, while many women felt midwives must advise them regarding the HIV tests. In the next chapter, I will rely on Carroll's implementation fidelity framework to discuss these findings.

6 CHAPTER SIX: DISCUSSION

6.1 Introduction

This process evaluation evaluated healthcare providers' adherence to the opt-out HIV testing intervention and explored factors that moderated observed adherence levels. I have interpreted the findings considering the adapted Carroll's framework (see Figure 19). The study found low adherence to the opt-out's recommendations. It also identified the complex and unfamiliar nature of the opt-out intervention; lack of facilitation through clear guidelines, training, and supervision; poor practice environment in private and integrated clinics as potential moderators of opt-out intervention's recommendation. The outcome of observed non-adherence to the intervention was: inadequate information for women to make an informed choice; women not empowered enough to make an autonomous decision; non-confidentiality and incorrect testing practices; and failure to link women to preventive services. The results showed a great need to improve women's testing experience by improving the identified potential moderators.

6.2 Discussion of key findings

6.2.1 Adherence: Low adherence to opt-out's recommendations

The study found that the opt-out intervention's overall fidelity was low, with variation between facility types and HIV testing service integration levels. The finding suggests that the delivery of the routine opt-out testing across the twelve clinics did not correspond with existing guidelines by the WHO/UNAIDS (2017) and GAC (2013). After more than ten years of implementation, providers were expected to have internalised the opt-out approaches and routinely applied them in practice. At all times, providers reported high adherence, consistent with previous studies that recorded adherence through provider-self-reports (Amboko & Brysiewicz, 2015; Toomey et al., 2017). Amboko and Brysiewicz (2015), for instance, reported provider self-reported adherence of 74% in Kinshasa. Generally, adherence levels have been lower for more objective data collection methods (Amoakoh-Coleman et al., 2016; Krüger, Heinzel-Gutenbrunner, & Ali, 2017). Overestimation of self-

reported adherence is common, warranting the use of more than one method to measure adherence.

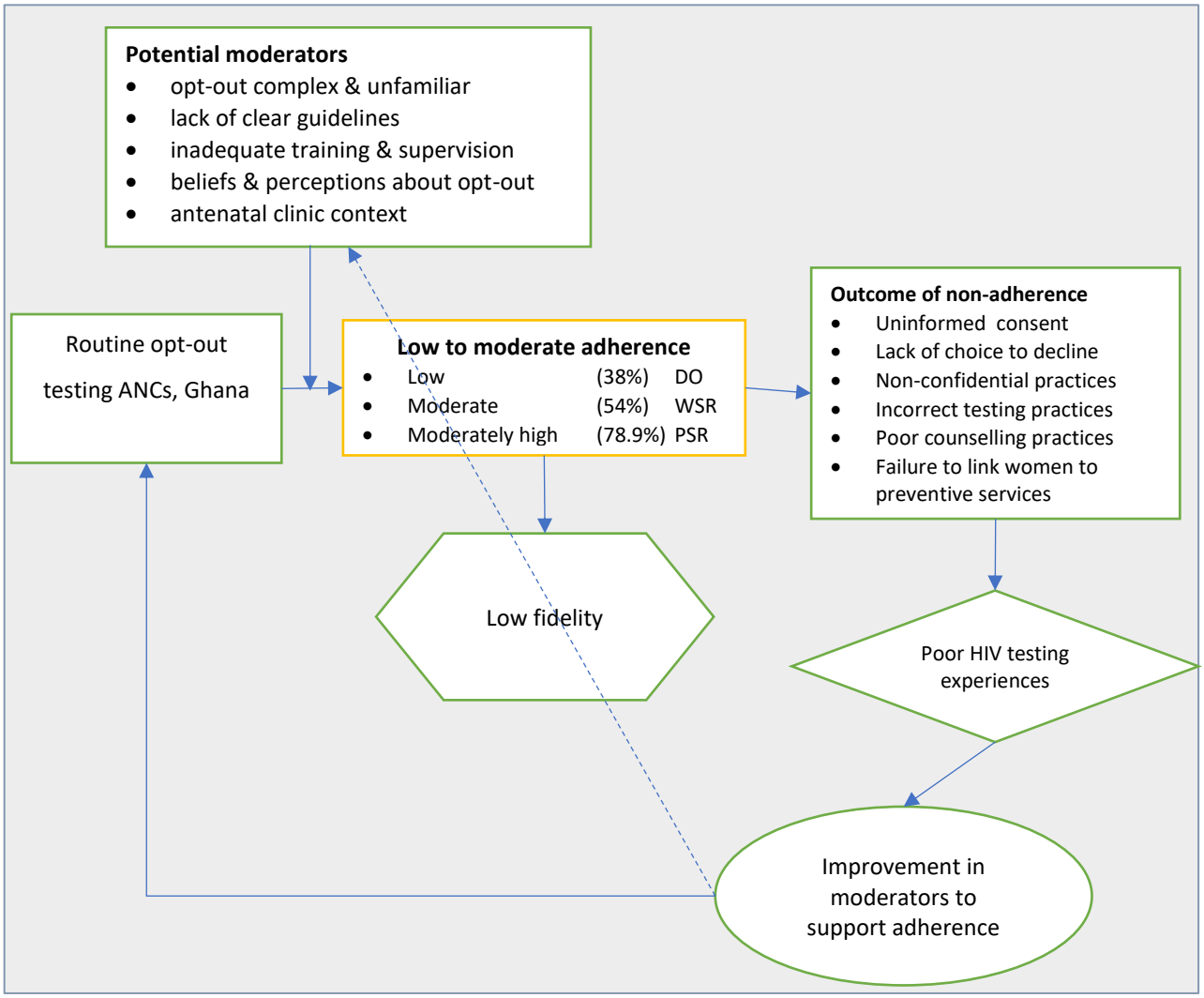


Figure 34: Implementation fidelity of routine opt-out HIV testing in 12 selected clinics

ANC - antenatal clinic; **DO** - Direct observation **WSR** – women self-reports; **PSR** – provider self-reports

Achieving 100% adherence or implementation fidelity was not possible in this study, which was expected (Carvalho et al., 2013). It has been suggested that an evidence-based intervention constantly undergo some modifications when transferred to a new context (Søvik, Larsen, Tjomsland, & Samdal, 2016). The prominent discourse had been that it may not always be possible, practical or even desirable to model the implementation of an HIV intervention as precisely as the original trial (Durlak & DuPre, 2008; Neumann & Sogolow,

2000). What is not clear is the extent to which frontline staff can modify a programme without deleting essential content (Durlak & DuPre, 2008; Welch, Riley, Montgomery, von Tettenborn, & Mansi, 2006). In Malawi, Angotti (2010) demonstrated how counsellors transformed guidelines because they found them difficult to execute due to socio-cultural differences between the Western countries where the policy originated and the Malawian context. Like this study, counsellors, in her study, found strict fidelity to the 3Cs recommendations of the PITC policy challenging (Angotti, 2010).

In Ghana (Amoakoh-Coleman et al., 2016) and other parts of LMICs (Baker et al., 2012) (Boudreau, McNally, Rensing, & Campbell, 2004; Ndirangu, 2016), following guidelines are often not an overriding consideration for providers. Noncompliance to healthcare standards, therefore, remains a common challenge in most developing countries, including Ghana. While nonadherence and modifications of programmes may be unavoidable, the adaptation process would require technical guidance and continuous feedback to policymakers to avoid compromising the core components needed to produce outcomes. Even though adaptation as a concept was not assessed in this study, it does appear that there was no such professional advice or guidance.

6.2.2 Potential moderators of adherence to the opt-out intervention

Moderators are factors that influence the degree to which frontline staff implement an intervention (Carroll et al., 2007). Carroll's framework emphasized the following moderators: participant responsiveness, comprehensiveness of a policy or complexity, facilitators and quality of delivery. Hasson added recruitment and context. The current study assessed complexity, facilitation, responsiveness and context.

6.2.2.1 COMPLEXITY: Opt-out test unfamiliar and poorly described

An intervention should be specific and straightforward to improve adherence (Carroll et al., 2007). More complex programmes may be more challenging to learn and implement with fidelity (Durlak & DuPre, 2008). This study found the terminologies such as 'opt-in', 'opt-out', 'provider-initiated and 'routine testing' used inconsistently to describe the intervention. Many healthcare providers found the intervention and its intended delivery unfamiliar and

complicated. Ahmed et al. (2016) reported similar findings when they reviewed the implementation of PITC in Malawi. The study found that even though providers widely reported employing a routine opt-out approach, most practised symptom-based PITC[9]. The authors observed that by wrongly interpreting the policy to target clients with advanced disease, the testing modality failed to achieve its intended outcome. This finding echoes the results of this study.

The opt-out intervention is an example of default, and the difficulty of its deployment in clinical practice has been reported (Francis-Graham et al., 2019). Such complexity gained attention when decision-makers started thinking of scaling up the intervention to the antenatal clinic setting (Campbell et al., 2000; Phillips, Bayer, & Chen, 2003). Poorly described intervention and the inconsistent use of terminologies, as seen in this study, hinder the intervention's delivery (Branson et al., 2006).

It was very confusing for some healthcare providers to understand that women had a choice when offered a test considered ' provider-initiated ' or 'routine' in the clinic. This study's finding echoes the initial challenges raised by critics who expressed the need for caution in scaling up such a policy with so many ambiguous notions and a lack of clarity of terminologies (Tarantola & Gruskin, 2007). For example, it was of concern to add HIV tests to usual routine tests in the clinic and expect the midwife to initiate the test unless the woman opted out by saying 'no'. The challenge here is that the policy, in its strictest sense, does not require the midwife to prompt women to consent. In other words, once the woman becomes aware of the tests, the midwife goes ahead to test unless the woman refuses (Branson et al., 2006). Many found this confusing (Tarantola & Gruskin, 2007).

Though Tarantola and Gruskin (2007) explained in their commentary to 'The Lancet' that there was an indication that WHO/UNAIDS would avoid liberal use of these terminologies in

[9] PITC has two implementation modalities: the universal or routine testing approach and the targeted testing approach or symptom-based testing. While the universal testing approach recommends HIV testing for all clients visiting a health facility for any reason, the symptom-based model promotes HIV testing in individual with clinical features that suggest that they might be infected with HIV(Yumo et al., 2019)

its final guidelines, this was not to be, as the final guidelines contained these terminologies. In adopting the country's guidelines, all LMICs, including Ghana, did not modify these terminologies (Baggaley et al., 2012a). As seen in this study, the inconsistent use of these terminologies has created (deliberately or not) a broad avenue for healthcare providers to test women for HIV with or without expressed consent. The policy has been in place for more than a decade now, and the emerging evidence suggests more attention from decision-makers and an improvement in the clarity of terms used in offering the test. Such terminologies must reflect the public health interest, medical ethics and human rights (Tarantola & Gruskin, 2007). The finding directly calls on policy adopters and decision-makers to consider altering complex recommendations to make them more straightforward and implementable in different settings. Achieving this may involve ensuring consistency of the policy's content with local norms and core values of care providers (Lugtenberg, Burgers, & Westert, 2009) and making sure that the new guidelines do not demand too many changes in existing routines (Camerer, Issacharoff, Loewenstein, O'Donoghue, & Rabin, 2003; Grol et al., 1998; Halpern et al., 2007; Kastner et al., 2015).

6.2.2.2 Facilitation: lack of clear guidelines, supervision, and training

None of the antenatal clinics had an HIV testing guideline, although copies existed at the national level. Data from interviews suggest that the lack of a clear strategy for guideline distribution was the primary cause of these shortages. This finding is hardly distinguishable from Mwangome et al. (2017), who reported that none of the facilities included in their study carried out in Tanzania's south-eastern districts had any version of the HIV testing national guidelines for HIV testing. Non-availability of guidelines in many LMICs, including Ghana, has been traced to distribution challenges (Baker et al., 2012; English, Wamae, Nyamai, Bevins, & Irimu, 2011; Stanback, Griffey, Lynam, Ruto, & Cummings, 2007). Therefore, putting structures in place to facilitate dissemination is imperative (Shayo, Våga, Moland, Kamuzora, & Blystad, 2014). LMICs can learn from high-income countries that rely on information and communication technologies (ICT) to disseminate some of these guidelines (De Angelis et al., 2016). Ghana and other LMICs must consider digitalising guidelines and distributing them to frontline staff. The approach would be efficient, cheap, and fast. The frontline staff could

conveniently assess them on their smartphones, and the content could be reviewed and updated as new evidence emerged (Mwangome et al., 2017; Neuhaus et al., 2015).

The lack of training identified in this study is concerning, as many providers had challenges with testing. Traditionally, highly trained technicians performed these HIV tests in the laboratory using sophisticated technology. Clinic manager interviews showed that the test was considered easy; hence there was a lack of attention paid to training staff. Interview data further revealed that many of the providers had never received training on HIV testing. Regardless of the setting, healthcare providers must receive training and retraining. The training offered must not be generic but instead modified to suit the setting and context. Such training must also go beyond the basics of HIV to address ethical and legal issues and help providers become more aware of the power imbalance in the clinic and how this affects women's decision-making. Content of HIV training must also consider helping nurses and midwives become more aware and reflective about the effects of unbalanced power relations in the clinic. This study recommends exploring the possibility of using E-learning and online teaching resources.

6.2.2.3 Context: Private and fully integrated clinics reported low adherence

This study found that the antenatal clinic environment, characterised by overcrowding, staff shortages, lack of space, and high workloads, did not encourage adherence to the opt-out's recommendations. Clinic observation and other data sources revealed that these infrastructure and other operational challenges were more prevalent in private hospitals' antenatal clinics. For example, the facility survey showed that the number of women doing group pre-test education sessions at private hospitals was more (n=61) than in public hospitals (n=41). As expected, adherence levels were lower in private hospitals. Evidence exists in Ghana to suggest that women attending private health facilities may not have better antenatal care (Tenkorang, 2016) and that there are widespread violations of medical practice standards and poorer patient outcomes in many private antenatal clinics found in LMICs (Basu, Andrews, Kishore, Panjabi, & Stuckler, 2012). Quality standards in private antenatal clinic settings require further exploration.

Increased workload, limited space, and overcrowded consulting rooms in fully integrated clinics often constrain providers' adherence to the recommended guidelines. Studies have previously identified these factors as barriers to effective implementation of routine HIV testing (Evans & Ndirangu, 2009; Pope et al., 2010; Roura, Watson-Jones, Kahawita, Ferguson, & Ross, 2013). Lack of suitable rooms caused healthcare providers to use examination rooms for testing and counselling in Uganda (Medley & Kennedy, 2010). The low adherence reported in fully integrated clinics is problematic, as Ghana has so far integrated HIV testing services in most antenatal clinics (Dudley & Garner, 2011; Pfeiffer et al., 2010). Although studies have recorded some positive effects, such as women receiving all services from one provider (Killam et al., 2010; Vo et al., 2012; Winestone et al., 2012; Young et al., 2019), the shift from vertical to integrated care appears to challenge the already overstretched antenatal clinics (Ahumuza et al., 2016; Mutemwa et al., 2013; van der Merwe et al., 2006). The identified challenges in the integrated clinics appear to affect the quality of HIV testing services. This study has made an initial step in estimating the time providers use to deliver various intervention components. In Kenya, Liambila et al. (2009) reported that routine HIV testing services added seven minutes to a median consultation time of ten minutes. In Zambia, the time for provider-patient contact more than doubled when the routine offer of HIV was introduced (Topp et al., 2010). In the current study, providers addressed this extra task by delegating HIV testing to the lower cadre of healthcare professionals. Together, these findings have led me to conclude, unsurprisingly, that fully integrated HIV testing and privately operated clinics require more support around infrastructure and resources.

6.2.2.4 Responsiveness: differences in stakeholder perceptions of guideline adherence

National level officers, midwives and nurses interviewed in this study were very enthusiastic about their roles in HIV testing. Many national-level officers felt obliged that the testing guidelines' content had to reflect WHO/UNAIDS' guidelines' content. They insisted on strict adherence to the testing guidelines at the facility levels. As Sheikh and Porter (2010) reported earlier, the national level officers encouraged strict adherence to international guidelines. At the local level, interview data showed that midwives and nurses did not emphasise women's

rights in the guidelines but rather stressed their moral obligation to protect the unborn child. They fulfilled this obligation by ignoring the strict guidelines 'imposed' on them and operated using their own rules. For many midwives interviewed, seeking informed consent from women before testing hindered the provision of reasonable care.

This study's observation corroborates findings from Angotti (2010) that HIV counsellors in rural Malawi were cognisant of the harms that strict adherence to the guidelines might bring to the women. Therefore, they modified the guidelines to balance adherence to the guidelines' perceived aims while still fulfilling their professional mandate to the patients. This finding echoes with narratives of midwives interviewed in this study. Many midwives perceived that employing coercive practices to get women tested was a tremendous professional mandate that also met the public health aim of preventing the child from getting HIV. The current study's finding builds on the existing evidence by showing that different stakeholders at various levels of implementation interpreted the HIV testing guidelines differently and justified their actions based on their assumed professional mandate.

6.2.3 Effects of non-adherence on rights-based testing

This study identified several issues of concern regarding various stakeholders' obligation to ensure rights-based HIV testing. It is relevant to highlight and discuss these gaps and offer forward-looking recommendations to ensure that women's rights are protected in the context of HIV testing in the antenatal clinic (King et al., 2013b).

6.2.3.1 Inadequate information for informed decision

To make an informed choice, women need to deliberate about HIV-related information and evaluate all the risks and benefits involved (Abhyankar et al., 2014; Ahmed, Bryant, & Cole, 2013). Healthcare providers are responsible for offering information that allows women to make informed decisions (Deans & Newson, 2011; Gunderson, Mayo, & S. Rhame, 1996). However, this study's findings suggest that this is not happening as many women tested without knowing the testing process, its optional nature and what it means for the test to emerge as positive or negative. Notably, women had no opportunity to ask questions when the healthcare provider offered them the test. This study does not corroborate previous

findings that have reported the adequacy of information received by women during HIV testing (Delva et al., 2006; Groves et al., 2010; Ismail & Ali, 2009; Ujiji et al., 2011b).

In this study, many women had become aware of HIV through the media and social networks such as friends and close family members. None of the women mentioned the healthcare provider as a source of information. The challenge with these informal sources for HIV-related knowledge acquisition is that they may be incapable of providing comprehensive information about HIV, leading to recycling inaccurate information about HIV (Gombachika, Chirwa, Malata, & Maluwa, 2013). A study conducted in Ghana reported that women attending antenatal clinics considered HIV life-threatening (Addo, 2005). More than a decade after Addo's study, Asiedu, Agyemang, and Agyei (2019), in their descriptive survey of 158 expectant mothers in Ghana, concluded that women held the same fearful belief about HIV, leading them to decline the test. Without formal or educated information sources, misinterpretation of HIV biomedical messages will continue to hinder the uptake of HIV testing.

The HIV testing guidelines recommend offering information about the HIV test during group education sessions (GAC, 2013). The antenatal group education might have offered an ideal forum for women to share knowledge, engage with the midwife and other women to learn about HIV testing and make informed decisions about the test (Benediktsson et al., 2013; Klima, Norr, Vonderheid, & Handler, 2009; Nolan, 2009; Teate, Leap, & Homer, 2013). However, the circumstances under which healthcare providers conducted group education presented some challenges in ways previously undocumented. The study observed scheduled monthly clinic education topics across clinics, leading to the healthcare provider discussing HIV testing and PMTCT in the particular month assigned to the topic. The finding suggests that women who did not attend group sessions during this month would not hear about HIV testing during their pregnancy. Pre-test information delivered in groups had to be available to all women testing for HIV and not restricted to a particular month.

Other challenges that hindered women's access to HIV-related information were large group sizes, the didactic approach to information delivery, and information overload as reported in

China (Ho & Loke, 2003), Gambia (Anya, Hydara, & Jaiteh, 2008) and Rwanda (Lundeen et al., 2019). The average size of a group in this study was 41 in public hospitals and 61 in private hospitals. Interviews with both providers and women produced a consensus that such a group size does not foster learning. Women find such large groups unsatisfactory (Lee & Holroyd, 2009). A small informal class that employs role-play, problem-solving activities and experience-sharing, promotes group interaction (Grol et al., 1998). Similarly, women found the practice of receiving a considerable amount of information about pregnancy, birth and postnatal care during the first antenatal visit counterproductive for informed consent about the HIV test. As suggested by Ahmed, Bryant, Tizro, and Shickle (2012), women may find it difficult to digest all the information within such a limited time.

6.2.3.2 Women not empowered to make autonomous decisions

Integration of survey and qualitative data showed that the test's optional nature remained obscure for many women because the provider failed to make this explicit. The survey data showed that two out of three women were never made aware of the optional nature of the HIV test. Further exploration of women's interview data revealed that many women considered the test compulsory due to direct and indirect coercive practices. In South Africa, women attending antenatal clinics reported that the option to decline was less clear (Groves et al., 2010). In Zambia, 77.3% of the 366 women perceived the test as compulsory (Kapembwa & Mubita-Ngoma, 2018). Several other studies have recorded similar findings across the LMIC sub-regions (Angotti, Dionne, & Gaydosh, 2011; Groves & Eyakuze, 2010; Kapembwa & Mubita-Ngoma, 2018; Kedote et al., 2011; Mugore et al., 2008b; Obermeyer, 2014; Ujiji et al., 2011c; Veloso et al., 2008). This finding underscores the importance for healthcare professionals to present HIV testing as an explicit choice in addition to any other tests in the clinic. Presenting a test as a choice would cause women to learn more about the test details and decide.

Subtle coercive practices observed in this study included the power imbalance, which made refusal difficult, the belief that testing was a pre-requisite for subsequent care, and presenting HIV as a risk to the mother and an opportunity to save the unborn child. Many women considered it morally imperative to accept the test because the midwife presented

the HIV test as 'the best thing she (the woman) could do for the unborn child'. In a context where HIV infection and sexual immorality are intrinsically linked (Dapaah & Senah, 2016), the healthcare provider's offer of an HIV test became easily misunderstood by women as an accusation of sexual infidelity. In Cote d'Ivoire, 10% of women declined to test for HIV because they felt that offering such a test meant the healthcare provider considered them prostitutes (Kedote et al., 2011). The findings suggest that facilitating informed decision-making in this environment can be challenging. Antenatal clinics can improve women's understanding of the test's optional nature by offering additional options for information provision, such as written materials to allow women to review further and consider the information offered.

In this study, test refusal was not an option for pregnant women because they needed to do it for the child's sake and prove their trust in the midwife. Information is never value-free or ethically neutral (Bahm, 1971), and in this case, women came to accept the test as a moral responsibility to protect their unborn babies (Groves et al., 2010; Malaju & Alene, 2012; Nyuzaghl et al., 2011; Ujiji et al., 2011c). The concern here is that using 'sake of the child', although valid, undermines any concern for the woman independent of her pregnancy and makes it impossible for her to make a genuine consent. For many women in this study, making such a decision becomes more challenging due to the clinic's fast-paced nature, the immediacy of care, and the presence of a person with power and authority (healthcare provider). As reported in Uganda (Homsy et al., 2007) and Malawi (Mtumbuka et al., 2012), the evidence points to the need for healthcare professionals to offer balanced information and to facilitate women's decision making about accepting the test through support, while making time to discuss women's concerns.

For many women in this study, the fast-paced clinic setting, immediacy of care, and the presence of a person with power and authority (healthcare provider) made such a decision difficult. As reported in Uganda (Homsy et al., 2007) and Malawi (Mtumbuka et al., 2012), the evidence found in this study points to the need for women to have support and time when making this ethically challenging decision. Healthcare providers need to be aware of the complexity of the information required to make these decisions (Abhyankar et al., 2014).

Doing this within a limited time erodes the woman's ability to make an autonomous decision. I recommended that midwives use innovative ways to empower women in this decision-make process.

The HIV test's routine nature caused many women to assume that having the test was the clinic's expected behaviour. In other words, routinisation made testing for HIV in the clinic self-evident, causing women to feel pressured to accept testing even if they had a reason not to do so. For many women in this study, the test constituted part of standard care. This was also the case in rural Malawi, where women understood the refusal of HIV testing as an indirect refusal of antenatal care (Angotti et al., 2011). In this study, one clinic stamped the back of a woman's antenatal card to indicate that a woman had tested. Midwives then prevented women without a stamp from seeing the doctor and taking part in any antenatal activity. Denying women who refuse testing access to care represents a direct coercive practice. The practice is ethically unacceptable as it violates internationally recognised human rights and medical professionals' duties (Bi & Klusty, 2015).

Providers considered the act of seeking informed consent for a life-saving test from the woman was somewhat paradoxical. In this study, all women included in the survey tested for HIV, but when later asked if they agreed to test voluntarily, 48% said no. The finding suggests that these women acquiesced to testing instead of actively consenting after a conscious reflection (Draper & Frith, 2004). Interviews with healthcare providers indicate that they often do not make women aware of the test's optional nature nor ask them whether they want to test. Few women, however, shared this view.

Making an independent decision about antenatal HIV testing can be very difficult for some women, hence needing support from nurses and midwives (Ahmed et al., 2012). A small number of women interviewed in this study expressed such a need by stating that they would require directive advice from the healthcare provider. The finding fits and confirms previous findings from other LMICs (Ahmed et al., 2019; Ahmed et al., 2018; Chen et al., 2018; Ezeome & Marshall, 2009; Zhong et al., 2018). Policy and practice in many countries emphasize self-determination, self-sufficiency, and independence, and therefore expects women to make

their own decisions when having a screening test in the clinic (Ahmed et al., 2013). In other settings (e.g. China, Hongkong), women have consistently expected their healthcare providers to act as experts on the topic and involve their husbands in decision-making (Lau, Yi, & Ahmed, 2016). A Q-methodology study conducted among 137 participants (women, men and healthcare providers) in Pakistan also found that in this context, making an autonomous decision required directive advice from doctors (Ahmed et al., 2019). This finding represents an excellent initial step towards re-conceptualising the role of nurses and midwives who facilitate patient and client decision-making in Ghana and other LIMCs.

This finding also suggests that individuals are socially embedded and that their relationship with the healthcare provider and significant others shapes their decisions (Mackenzie & Stolijar, 2000). In describing how traditional structures of childbirth in Ghana influenced women's decisions not to use supervised deliveries, Jansen (2006) used ethnographic techniques to demonstrate how the older female relatives mainly influenced women's decisions. In Nepal, Thapa and Niehof (2013) reported that husbands offer advice regarding women's maternal health activities, with women with more economic autonomy less likely to seek such advice. Several other studies in LMICs have emphasized the role families play in women's decision-making process (Ahmed et al., 2019; Ahmed et al., 2018; Loll et al., 2020; Tsara, Zvinavashe, Kasu, & Gundani, 2011). The finding in this study suggests that pregnant women look to the healthcare provider for advice when making antenatal screening decisions. Most women in this study had high school qualifications or higher but still felt they needed directive advice. Ghana's adult female literacy rate in 2018 was 74.47% (Central Intelligence Agency, 2020), indicating that many women expect to seek directive care.

The limited autonomy seen in this study calls for further examination of autonomy as the dominant principle that underlines informed consent for the opt-out intervention. Autonomy in antenatal testing requires individualistic principles to protect patients from healthcare professionals' paternalistic influences and pressure from others (Mackenzie & Stolijar, 2000). The individualistic approach, emerging mainly from Western societies' ideologies, does not consider that individuals from more collective cultures such as Ghana may view themselves as dependent on others in decision-making. For this reason, studies have called for

alternative forms of autonomy (Ahmed et al., 2012; Ahmed et al., 2018; Osamor & Grady, 2016). The widespread implementation of rapid opt-out testing in many LMICs makes it imperative to understand the nature of autonomy and informed choice in these cultures. In these cultures, individuals are socially embedded, and social relationships shape one's identity and decisions. Relational autonomy may be beneficial for decision-making in the antenatal clinic. It stresses 'interdependence' instead of 'independence', where the woman's social environment and personal relationships influence her ability to make an autonomous decision. The findings of women's capacity to consent and reliance on the provider for directive advice leads to the conclusion that Western approaches to promoting women's autonomy for routine antenatal opt-out testing are unlikely to suit Ghana.

6.2.3.3 Non-confidential testing process

The stigma accompanying HIV diagnosis and status disclosure mean that a woman testing for HIV must trust the healthcare provider (Dapaah & Senah, 2016; Worthington & Myers, 2003; Young, Monin, & Owens, 2009). Therefore, it is worrying that 30% of women in this study felt they could not trust that a healthcare provider would keep their test results confidential. The finding is not consistent with studies in other parts of Ghana (Kwapong et al., 2014) and Ukraine (Tripathi et al., 2013), which reported that almost 100% of women expressing trust in the provider. Women in these studies trusted the medical rules that governed privacy in the facilities where they received care. These studies have mainly relied on women's self-reports to report on trust, with not much information on whether, in practice, women enjoy a private testing process. The current study provides an understanding of the situation and connects women's pronouncement of trust to the clinic's actual privacy situations.

This study found that clinic layout and structural organisation of care influenced privacy, with the tendency for fully integrated care to have more concerns about lack of privacy and confidentiality. Standalone clinics in this study operated within the same antenatal clinic building, and therefore women did not have to leave the antenatal building to get tested. The HIV testing literature has not examined the antenatal clinic's structural organisation and how it impinges on the testing process's privacy

Malcolm (2016) explored former patients' perceptions of privacy in shared hospital rooms in inpatient settings. Although not directly comparable, the study found a conditional acceptance of privacy loss in an environment dictated by an architectural structure and fiscal constraints, with many patients expressing distress about others overhearing their health issues. Mlinek and Pierce (1997) reported that privacy breach frequency depended on room location and design. Considering the pervasive stigma and the call for rights-based HIV testing, hospitals must address the antenatal clinic's structure to make it more HIV testing friendly. Healthcare institutions built antenatal clinics before HIV testing became routine in the clinic, and therefore, might not have critically considered privacy. The lack of privacy has implications for protecting the confidentiality of women who test positive in the clinic.

The study also identified unprofessional staff attitudes, such as disclosing positive test results in a manner that infringes on the policy and requirements of privacy and confidentiality (GOG, 2016). Confidentiality is about trust (Dapaah & Senah, 2016) and leads to dignity and individual autonomy (Mlinek & Pierce, 1997). As seen in this study, the practice of ensuring confidential and private testing processes lacked in the antenatal clinic. In Ghana, Kwapong et al. (2014) have reported that privacy and confidentiality concerns influenced women's decision to test. In the same setting, Dapaah and Senah (2016) found that the health facility itself, because of confidentiality and privacy breaches, causes women to be stigmatised. Other studies in other LMICs have recorded similar confidentiality challenges (Angotti et al., 2011; Bell, Mthembu, O'Sullivan, & Moody, 2007; Hardon et al., 2012; Tripathi et al., 2013). This finding implies that nurses and midwives must become more aware of their professional responsibilities of keeping patient information confidential.

In Ghana, pregnancy and childbirth are considered private by many (Ganle, Parker, Fitzpatrick, & Otupiri, 2014). Ensuring private and confidential testing processes, therefore, assumes both symbolic and practical significance. The country has specific laws and policies regarding maintaining the privacy and confidentiality of HIV status (Health Policy Plus, 2017). The Ghana AIDS Commission Act (2016) establishes the right to privacy for all individuals living with HIV, noting that 'every person shall enjoy a right to privacy and confidentiality as regards the HIV status of that person' and protects against unwanted disclosure of HIV status

(GOG, 2016, p. 14). The 2013 National HIV and AIDS, STI policy and the Ghana AIDS Commission Act further clarify the conditions under which a provider may disclose a woman's HIV status without permission(Health Policy Plus, 2017). These policies apply to the general public and fail to address key confidentiality challenges peculiar to the antenatal clinic. More specificity is therefore required.

Midwives need to become aware of the potential impacts of privacy breaches on a pregnant woman who tests positive in the clinic. A positive test comes with lots of complexities, requiring the woman to have ample time to consider the pros and cons of disclosure (Poku et al., 2017), the possibility of stigma (Mkwanazi, Rochat, & Bland, 2015), abandonment, rejection, and violence (Greeff et al., 2010; Rujumba et al., 2012). Instead of disclosing against women's knowledge, midwives must create a supportive environment for disclosure. Preserving women's privacy and confidentiality are longstanding professional obligations rooted in ethics, religion, tradition, and law. Fulfilling these obligations constitutes recognising the dignity and worth of women as individuals and the inherent rights of human beings to control their issues (Loll et al., 2020).

6.2.3.4 Failure to link women testing negative for HIV to preventive services

Many women in this study narrated that the main benefit of testing in the clinic is the public health interest; preventing the 'innocent' child from HIV infection. The woman also benefits from taking the medication and reducing her infectiousness. One of this study's central findings is that many women became aware of their test results but not the preventive measures for HIV. About half of them (51.9%) recalled healthcare providers telling them about the window period and retesting during the 34th week. In effect, close to half of the women left the clinic without knowing they could become positive in the gestation period or after. Not informing women about preventive measures has implications for women in the window period, serodiscordant couples and those with risky sexual behaviours.

The finding makes an essential contribution to the literature on the association between opt-out HIV testing and preventive care. While there is evidence that individuals who test positive for HIV adopt less risky sexual behaviours, there remains uncertainty about the effect on

women who learn they are HIV-negative, especially among the pregnant population (Norris, Jackson, & Khoshnood, 2012). For instance, in Kenya, Tanzania and Trinidad, a randomised controlled trial found that HIV-negative women reported safer sexual practices more than a year after becoming aware of their HIV status, compared to individuals who did not receive HIV testing (Wanyenze et al., 2013). Other researchers have reported that those who tested negative for HIV failed to adopt or sustain risk-reduction behaviours, sometimes taking up riskier behaviours, as though the negative test results offered 'proof' that their previous actions were safe (Ryder et al., 2005). Research indicates that the chances of having unprotected sex and therefore being at risk for HIV increase during pregnancy due to the possibility of seroconversion and discordant test results (Brenner et al., 2007). So, for women testing negative, adopting appropriate preventive behaviours become paramount. Midwives need to spend time to help women understand the window period, the possibility of false-negative and serodiscordant results. I agree with Ezeanolue et al. (2017) and (Doll et al., 2018) that actively improving efforts to link women to preventive services remain critical in testing women in the clinic.

6.2.3.5 Incorrect testing process

This study found that healthcare providers did not always adhere to recommended quality standards for routine opt-out testing. Observed practices that predisposed women to false-positive and false-negative test results included declaring a woman positive for HIV without a confirmation test, not reading test results within the recommended timeframe, and difficulty pricking and applying the right amount of buffer solution. The observed practices could potentially lead to misdiagnosis. Whether false-negative or false-positive, an incorrect test result has deleterious public health and personal consequences (WHO, 2015c). Studies that have looked at misdiagnosis in HIV testing have mainly been in the medical setting, with little known about its magnitude among women attending antenatal clinics. The rapid expansion of HIV testing in the antenatal clinic and the observed non-adherence makes it imperative to institute correct testing processes.

An audit of HIV testing practices by Shanks, Klarkowski, and O'Brien (2013) in the Democratic Republic of Congo (DRC), Burundi and Ethiopia identified 44 patients who received false-

positive test results and then received antiretroviral drugs. In Malawi, 4.6% of individuals referred for antiretroviral therapy in 2015 were later HIV negative after retesting them (Eaton, Johnson, & Gregson, 2017). In Zimbabwe, 77 (3.8%) of 2033 HIV positive women enrolled in the PMTCT programme were HIV negative when a laboratory test was conducted in 2012 (Gonese et al., 2016). Delivering a false-negative test result to a woman and subsequent late diagnosis may result in a 20% to 40% chance of the woman transmitting the disease to the unborn child, and also herself progressing to having AIDS (Christopoulos et al., 2011). The evidence points to the challenges non-laboratory staff have in performing rapid testing in ways that enhance quality (Granade, Parekh, Phillips, & McDougal, 2004; Johnson et al., 2017). Quality concerns identified in this study, therefore, require further examination.

In adopting the opt-out HIV testing programme, the Ghanaian society is encouraging otherwise healthy women to go through a process that they would not have undergone but for the sake of the unborn child and society. This step taken by the woman is not neutral, as any medical test carries a risk of harm (Deyo, 2002). In their ethical analysis of cancer screening and practices, Parker, Carter, Williams, Pickles, and Barratt (2017) identified non-maleficence as a neglected value in screening policy. A systematic review of the HIV ethics literature had concluded that the opt-out approach is 'ethically justified due to its potential benefits to the foetus, mother and society' (Bain et al., 2015, p. 1). Such enthusiasm for beneficence (preventing HIV transmission) may inadvertently lead to neglect of non-maleficence (adverse harms of opt-out testing).

No HIV test result is perfect. False-negative and false-positive results will persist in clinical practice (Johnson et al., 2017). Since HIV misdiagnosis can be far-reaching, providers are encouraged to ensure very low incidence (Johnson et al., 2017).

6.3 Methodological discussion

6.3.1 Personal choices: mixed methods approach to process evaluation

The research journey has involved making several methodological choices. The principal among such decisions was using a pragmatic, mixed-methods approach situated within Carroll's implementation framework. Mixed methods offered richer and more comprehensive insights into pregnant women's HIV testing, previously unknown. While surveys and structured observations quantified adherence levels, qualitative interviews afforded an in-depth understanding of HIV testing complexities. Direct observation of testing and counselling services further improved the reliability of findings and minimised biases inherent in self-reports (Perepletchikova, Treat, & Kazdin, 2007). Such validation of provider-client interactions would have been difficult to attain with just self-reports and interviews. More importantly, triangulation, which was a vital component of the mixed-method research, enhanced the validity and reliability of outcomes (Creswell, 2014; Palinkas et al., 2011), offered a broader picture of fidelity levels (Ivankova, Creswell, & Stick, 2006; Wisdom & Creswell, 2013), and revealed convergences, divergence and power relations inherent in the clinic environment (Aarons et al., 2014; Johnson, Onwuegbuzie, & Turner, 2007; Oakley, Strange, Bonell, Allen, & Stephenson, 2006).

A strength of this process evaluation is that it offers insight into the HIV testing intervention delivery. This study is the first to assess the context-specific implementation process of opt-out HIV testing among pregnant women, particularly in Ghana's context, where very few primary studies have determined pregnant women's intervention experiences (Kwapong et al., 2014; Nyuzaghl et al., 2011; Osei et al., 2016). This study provides a valuable insight to facilitate further development and the scaling up of the HIV testing programme within antenatal clinics and other departments. This study's adapted framework usefully guided the systematic evaluation of the intervention's implementation fidelity and moderating factors.

6.3.1.1 Threats to the quality of the process evaluation (study limitations)

The approach used to collect data has its merits and demerits (Ihantola & Kihn, 2011). In selecting methods to measure the implementation's fidelity, I strived to use methods with fewer disadvantages or weaknesses. However, the aim to develop new skills, coupled with financial and time constraints, made this impossible. An approach that proved helpful was compensating for weakness in one method by combining several other methods to answer a research question. This approach is the overall idea behind methodological triangulation (Creswell, 2009). In this study, triangulation involved self-reports (interviews, questionnaires), structured and unstructured observation, and document analysis. These methods have their inherent weaknesses that must be identified and addressed at every stage of the research process (Bryman, 2006; Creswell & Clark, 2007; Ihantola & Kihn, 2011; Morse, 2009). Andrew and Halcomb (2009) described the use of mixed methods in an academic piece of work as unnecessarily burdensome. A lone researcher interviewing, administering questionnaires, observing, and reviewing clinic data threatens the study's validity and reliability. In the following sub-sections, I synthesise the threat to the quantitative study's internal and external validity and reliability and analogously on contextual validity and transferability for qualitative work (Ryan, Scapens, & Theobald, 2002).

6.3.1.2 The threat to internal and contextual validity

I adapted the provider and pregnant women self-reports checklist and structured observation checklist from WHO's evaluation tools (WHO, 2011a). The tools underwent substantial reconstruction to fit the implementation fidelity and contents of Ghana's policy documents. Even though the tools had been validated and used on other HIV research projects (Osei-Ofei, 2015), the substantial modifications threatened its content validity. I applied several content validity minimisation principles to minimise this threat, such as getting national and regional level officers involved in the policy adoption to verify the content. For this study, supervisors who had experience developing process evaluation instruments further examined the instruments. The process resulted in an improved version that I tested among healthcare providers and pregnant women (five each). After the pre-testing, a further review of the instruments helped improve feasibility and acceptability

(Almanasreh, Moles, & Chen, 2019; De Silva, 2011). Undertaking these activities minimised the threat to internal validity.

Another threat to this study's internal validity was the self-reporting bias; in the form of social desirability and recall bias (Adams, Soumerai, Lomas, & Ross-Degnan, 1999; Latkin, Edwards, Davey-Rothwell, & Tobin, 2017). This exhibited itself in providers consistently overreporting adherence levels compared to structured observation and pregnant women self-reporting. These differences were statistically significant. Minimisation of this threat occurred through the reliance on direct observation of the conduct of HIV testing in the clinic. Using more than one data collection approach to collect data from more than one category of informants on the same phenomenon minimised self-reporting bias and ensured a broader and in-depth understanding of the phenomenon (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014). Also, this study included between 4 to 7 participants in focus group discussions, with group sessions lasting between 30 minutes to 1 hour. The small numbers meant that the group was not interactive enough, the scope of discussion was narrow, so issues were not exhaustively discussed.

Further, this study required pregnant women to recall and comment on receipt of HIV testing. The fact that the intervention is routine in a busy environment makes recall bias a potential threat to internal validity (Althubaiti, 2016). To minimise this, I employed exit surveys immediately after the pregnant woman finished the clinic activities. Using exit surveys was a challenge because there were never adequate numbers of women making their first visit and testing for HIV. Recall bias caused by psychological suppression of pain and trauma associated with a positive diagnosis was addressed by excluding all women who tested positive for HIV. I acknowledge that excluding this category of women was not always possible, as a positive status was always confidential. In estimating high, moderate and low adherence levels, I relied on adherence categories previously used in the evaluation literature (e.g. Borrelli et al., 2005; Nurjono et al., 2019; Toomey, Matthews, & Hurley, 2017). I recognise that these references have been used as a convention without any validated basis for such categorisation. Also, threats to qualitative studies' contextual validity in this study included insufficient or biased knowledge of qualitative studies (Ihantola & Kihn, 2011, p. 42)

and researcher bias. Steeped in the quantitative research approach, I identified the need to understand qualitative research methods. I enrolled in advanced qualitative methods to understand the practical details of the qualitative research approach. I also took short NVivo and qualitative data analysis courses to improve my data analysis and integration skills. Most importantly, I received immense guidance from two supervisors with qualitative and quantitative research and process evaluation expertise.

6.3.1.3 Reflexivity and the role of the researcher

My motivation for conducting this study was to research human rights issues among pregnant women and gain more insight into implementation fidelity and process evaluation. My prior research experience with non-adherence (Amankwaa, Boateng, Quansah, Akuoko, & Evans, 2018) nurtured this motivation. I was aware that implementation research and qualitative research approaches were unfamiliar territories. I was also aware of identifying as male and how it might affect various stages of the study. When discussing the research ideas, colleagues often asked whether I had what it took to conduct meaningful and credible research with women. There were, for example, some concerns about my ability to understand and represent women's experiences. To some extent, these questions assumed that being a male inherently challenged the credibility of my work with women.

I became genuinely concerned about how my gender would affect the research process. After extensive reading on the role of gender in research, I came across this submission by Loizos (1992, p. 173) that 'it is not whether the fieldworker is male or female…which is likely to be decisive, but gender, age, marital status and topic or research interest'. Galam (2015, p. 7) argues that how successful a male negotiates the research process within the women's world depends on the 'character participants see the researcher possess or demonstrate'. I had no time cultivating a reputation based on study participants' interaction in the fast-paced antenatal environment. Such a reputation was only vouched for by nurse managers who introduced me to them. Subsequent interactions helped build on this reputation. Nurse managers introduced me to the participants as a nurse who is researching women's health. Despite the explanation, pregnant women consistently referred to me as a medical 'doctor'. This was not strange to me as any male working in a hospital is considered a doctor in Ghana.

As a ‘doctor’, a researcher and an educated expert who will determine the research results, I became aware of the inherent participant/researcher power differentials (Dodgson, 2019). I was aware of the influence of power imbalance, especially during qualitative interviews, and therefore instituted measures to minimise them.

Nurse managers introduced me to healthcare providers as a senior nurse and a researcher pursuing a PhD at a foreign university. Reflecting on her PhD data collection experience, Rook (2017) reported that her position as a researcher from a local university and having many years of experience in the nearby Intensive Care Unit elicited unrealistic expectation from the nursing team. Like her experience, providers in this study often identified me as a senior colleague and a nursing lecturer. In some instances, some of them were once my students at the undergraduate level. Therefore, it was common for them to approach me for advice or intervene in some challenging situations. For example, a nurse approached me while I was getting ready to observe counselling sessions to talk to a pharmacist who had refused to issue HIV test strips. The pharmacist acted on the hospital’s policy to present a sheet detailing all pregnant women whom providers were testing with the testing kits. As Rook's (2017) study, I adopted a nurse 'who was new' to the antenatal clinic area and often referred nurses and midwives to speak to their managers when an issue like this came up. Such a stance helped maintain a detached observer role (Rook, 2017).

Admittedly, gender shaped the qualitative data collection in two ways. First, gender influenced the broader environment within which I conducted interviews. Interviewing women in a ‘neutral’ place or even in their homes would have eliminated social desirability bias often associated with interviewing women in the clinic environment (this was, in fact, the purpose of the qualitative interviews with women). Women were, however, reluctant with the arrangement to see them at any other place besides the clinic. Reflecting on this experience, I concluded that the initial intention, even though germane, was ethically and methodologically flawed (Galam, 2015). In the Ghanaian context, a married woman seen together with a middle-aged man could spin rumours that may affect the individual’s marriage. Therefore, it was understandable that pregnant women, especially the younger ones, did not agree to this arrangement. Even though not made explicit, other women were

concerned about a male 'health worker' interviewing them in their house on the topic of HIV. Such an interview could have wreaked havoc for such a woman who lived in compound houses with shared facilities that did not allow for a private interview.

Second, gender influenced the type of questions asked and the extent of probing. During interviews, I was conscious of the inherent power differences and how they affected the woman's ability to decide which questions to answer and not to answer. I was also not oblivious that HIV and AIDS and sexual immorality are intrinsically linked in Ghanaian society. Juxtaposed with my male gender, I decided to limit my interview to questions linked directly to women's experiences around human rights.

The study was conducted in Brong Ahafo and Ashanti Regions, where my primary and secondary education occurred. My adult life had all been spent in the latter region. Speaking the local language (Twi) offered a cultural connection with interviewees and minimised known inconveniences associated with interviews, such as loss of meaning after translation. I discerned crucial messages, verbal and nonverbal, that a non-native speaker might have overlooked. I also paid attention to my general conduct during interview sessions. I ensured modest dressing to allow clinic staff and patients to approach me more easily.

Quite challenging was the expectation among clinic staff to be reimbursed for taking part in the study. Such an expectation was occasioned by a commonly held belief that activities related to HIV testing received sizeable financial support from foreign organisations. Not allowing responses to be influenced by such expectations, I was explicit about my role as a student researcher and emphasised that the research had no direct input from any HIV organisation. After the interviews, I offered some gifts to study participants who travelled or had to wait for some time.

Before undertaking this study, I had become aware of various implementation challenges and successes along the way. During data collection, I was cognizant of my prior working relationship with some nurses implementing the testing intervention and how this influenced my observations. Such an insight enlightened me to the barriers in implementing the policy.

Such insight, however, had the potential to bias observations made. The potential bias was addressed by keeping a journal of all observations and reflecting on how prior personal experiences might influence their interpretation. Regular debriefing with supervisors also ensured transparency and a neutral perspective to counterbalance personal judgements.

The last aspect of the research process worth reflecting on is how data was analysed. I approached the data analysis process being aware of my existing preconceptions and expectations. For example, I expected most government-operated hospitals and experienced healthcare providers to implement the policy with high fidelity since they are well-resourced and had received extensive training. I also held a preconception that informed consent, confidentiality, quality health care, and linking women to necessary care was part of the nurses' and midwives' roles. Thus, I expected midwives to be applying these human rights principles in their practices even in the absence of testing guidelines and protocols. My experience of the nursing sub-culture of the hierarchical power structure within nursing made me doubt the feasibility of an informed consent process.

Even though I harboured these preconceptions, I aimed to conduct an analysis grounded in the subjective experiences of study participants. I achieved this by using the NVivo 12 data management tool, which helped keep an accurate and verifiable coding process (Bonell, Oakley, Hargreaves, Strange, & Rees, 2006). NVivo also allowed for a verifiable audit trail that allowed supervisors to comment on the codes before applying them consistently according to the adapted fidelity framework. Qualitative analysis can be improved using member checking. It involves testing findings with key stakeholders from whom the data was initially collected (Lewis, 2009). I could not carry out this activity as contained in the study proposal due to limited time and the distance from the research site (Ghana) and my institution (New Zealand). However, I intend this aspect of the evaluation process to happen soon to disseminate the study findings. Other measures to minimise researcher bias include providing a detailed and transparent account of the procedures for collecting data in the Methods section and checking transcripts against recordings to minimise transcription errors.

6.3.1.4 External validity (transferability and generalisability)

External validity relates to the generalisation and transferability of study findings (Ihantola & Kihn, 2011). In quantitative research, external validity determines whether general conclusions can be drawn based on the model employed and data collected and whether findings may be generalised to other samples, time and settings (Ryan et al., 2002). This study focused on the Ghanaian context; therefore, I recognise the limited ability to generalise the results to other settings. It is also important to note that the 12 clinics included in this study were selected conveniently because of financial and time constraints. Most of the clinics were in the urban city of Kumasi, where the researcher resided during the data collection process. I acknowledge that hospitals in an urban setting could differ from their counterparts in rural settings. In effect, this study's results may not reflect the situation in clinics located in rural areas.

Healthcare providers and pregnant women interviewed in this study may not represent all healthcare providers and pregnant women in the country. However, providers who had previously worked in clinics located in rural areas offered some exciting and cross-cutting perspectives. Also, the non-inclusion of pregnant women who tested positive for HIV would mean that pregnant women's narratives may negatively reflect those testing negative. There may also be bias introduced by these respondents' willingness to participate in this study, primarily those who felt particularly strong about HIV testing or the research process agreed to participate. However, the range of viewpoints put forward by participants makes it unlikely that such bias has influenced the findings. Qualitative and quantitative approaches could increase the study's external validity and make broader generalisations when drawing conclusions and making recommendations. While the quantitative approaches provided generalisable and systematic evidence, the qualitative strand offered grounded and interpretative evidence unique to each participant.

6.3.2 Utility of Carroll's Conceptual Framework for this process evaluation

This study's adapted framework had a significant effect on this doctoral thesis's process, structure, and presentation. The utility of Carroll's conceptual framework as applied to this study has been summarised in Figure 35.

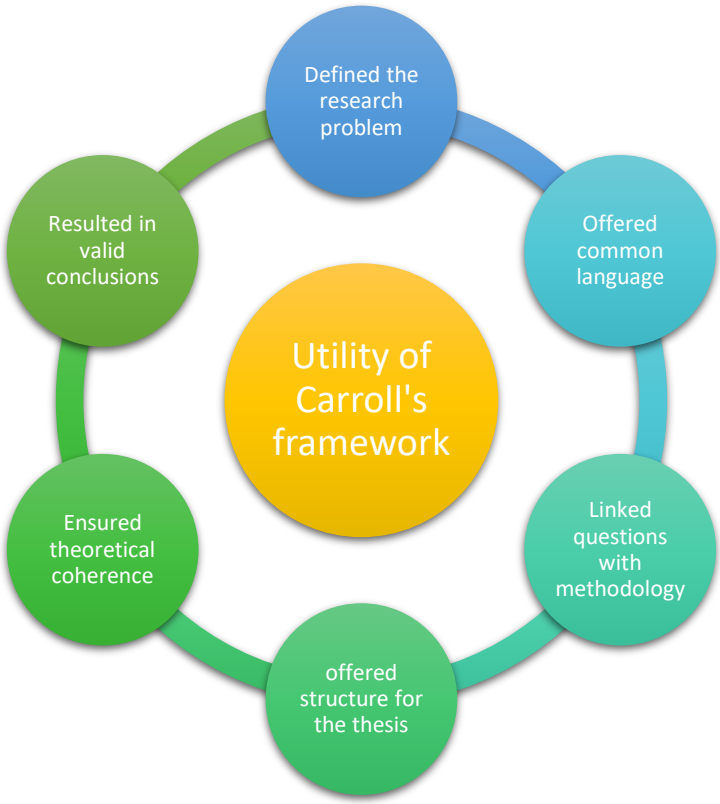


Figure 35:Criteria for considering the utility of conceptual frameworks

Source: Adapted from Berman and Smyth (2015, p. 3)

Right from the first chapter, the framework acted as a scaffold for the remaining thesis. Firstly, this helped define the evaluation problem and provided a common language for communicating the research ideas. Adherence and moderators became the two keywords used to describe the study's aim. These terminologies offered clear objectives and improved how I communicated these objectives with others.

Secondly, the framework supported the generation of appropriate methodology to address the questions. The framework generated two objectives that led to the formulation of five

process evaluation questions. This placed the questions (and not the methods) at the centre of inquiry. This aligns with pragmatism. With pragmatism as the philosophical foundation, the mixed-methods approach became the natural choice for this study. Thirdly, the framework helped establish the theoretical coherence of the entire thesis. Coherency in this thesis' use of theories became relevant because of the multiplicity of theories that underpin opt-out HIV testing intervention (e.g. behavioural economics, the health belief models and normalisation process theory) (Leidel, Leslie, Boldy, & Girdler, 2017). Similarly, several human rights frameworks (e.g. the 5Cs) have been used to explain how the test must be undertaken. Carroll's framework brought together these multiple perspectives.

Fourthly, the framework provided the structure of the written dissertation. The many months of writing and data collection generated a large amount of information that needed to be presented succinctly without sacrificing detail. I found the framework helpful in achieving this. Except for chapters two and three, all the remaining chapters were organised around the framework. In chapter four, the framework resulted in creating an evaluation plan to guide the study. During analysis, the framework's concepts helped organised the parent nodes using QRS International's NVivo 12 software (QRS, 2018). The ability to organise the collected data using NVivo software complemented the chosen methodology with the added assurance of a comprehensive data collection and analysis process (Smyth, 2004). I summarised the findings using the framework, as shown in Figure 35 (*pp.*150). The findings and discussion chapter followed the same framework format. In the concluding chapter, I modified the framework into a proposed human rights framework (Figure 36 *pp.*183) to create a coherent structure to link the study and the conceptual frame of valid conclusions (Leshem, 2007). This was made easier by using Carroll's conceptual framework, which became the source of all policy, research and policy recommendations.

The use of the framework was not without problems. My naïve understanding of frameworks and their application made things difficult at the beginning. The situation was made more challenging by the lack of standardised guidance on implementing fidelity for HIV testing to serve as reference material. There were some dimensions of the framework that were difficult to assess in practice. For example, it became challenging to operationalise 'quality of

delivery' and 'adaptation' as moderators of adherence. In the case of adaptations made to the programme, I realised that measuring it was not feasible since the intervention had become wholly embedded in practice for some years now. The framework is beneficial but requires more guidance notes to aid its application in practice.

6.4 Chapter summary

Ghana has implemented the opt-out HIV testing policy for more than a decade now. However, many healthcare providers interviewed were unaware of the policy and failed to adhere to its principles. Such a knowledge gap suggests that the high testing uptake previously attributed to opt-out effects may be inaccurate. Paying more attention to the process of intervention delivery may prevent this situation in future. I have also explored how women's rights to self-determination and autonomous decision are affected by inadequate information and coercive practices in the clinic. The link between the structural organisation of care, unprofessional practices, and undermined confidential testing process has also been explored. Dwelling on providers' failure to follow recommended testing algorithms, the challenge in performing the rapid testing and the lack of support, I have explored the possible occurrence of misdiagnosis and how this may undermine a crucial human right principle, non-maleficence. The magnitude of emotional consequences that follow non-adherence to these principles have been discussed, and implications stressed. The limitations that threaten the validity of the conclusions drawn here have also been demonstrated in this chapter. The extensive discussion of threats offered here would guide how readers of this work would interpret the findings.

7 CHAPTER SEVEN: CONCLUSION

7.1 Introduction

This thesis aimed to achieve two objectives: (i) assess the adherence to the recommendations of the opt-out HIV testing's process and (ii) assess the factors that moderated observed adherence. To achieve these objectives, I first reviewed the ethics literature, which pointed to several potential human rights concerns linked with the antenatal clinic's opt-out test approach. However, the reviewed empirical data indicated that past efforts at researching the opt-out testing in the antenatal clinic had focused mainly on outcome variables. This finding gave validity to the study's focus on the process itself and shaped the methodological decisions and methods employed in the study. The findings of the study were revealing, as discussed in the previous chapter. As a prelude to making recommendations for the opt-out intervention, I revisit the main objectives to reiterate what I found.

7.1.1 Adherence to the opt-out intervention

Overall, this study indicates that provider-initiated HIV testing was widely available in the 12 antenatal clinics and that HIV testing among pregnant women was high (98.1% women testing). However, the study found a considerable gap between the opt-out policy on paper and the observed practice. Health practitioners seldom offered the test using the opt-out approach. Against the policy's recommendations, a few clinics still practised one-on-one pre-test counselling. Adherence to the human rights principles was generally low, with healthcare providers' tendency to over report the delivery of parts of the intervention.

7.1.2 Moderators of observed adherence

The evidence from this study suggests that observed adherence levels were potentially moderated by the complexity of the opt-out approach and the lack of facilitation in terms of guidelines, training, and supervision. Also, healthcare provider and pregnant women's understanding and beliefs about the intervention and the antenatal sites' physical and cultural contexts did not suit rights-based HIV testing. The finding would suggest that health practitioners' lack of adherence to the policy's recommendations may not be deliberate but

was a way of adapting a foreign and possibly culturally inappropriate intervention to suit the local context's demands.

7.2 Contribution to knowledge and theory

In addition to providing policy and research directions, the study makes four original contributions to the HIV testing literature:

- The study illuminates our understanding of how researchers and programme implementers can use fidelity data to interpret observed outcomes in practice. Until this study, the HIV testing literature discourse was that opt-out HIV testing had resulted in an increased HIV testing uptake in antenatal clinics. This study has improved our understanding that within the 12 antenatal clinics in Ghana (and possibly other LMICs), HIV testing activities do not align with what policymakers planned and that the core principles intended for pregnant women were never conveyed. The finding suggests that the opt-out HIV testing as a programme may not be credited with the increased testing uptake, neither can it be blamed for the lack of impact. This information would improve how policymakers decide about adopted policies and minimise the potential of wrongfully concluding and terminating a programme for being ineffective. The findings also suggest that decision-makers must be guided by the question ‘are pregnant women receiving the planned opt-out test’s content? Answering this question may help clarify why so many women test positive for HIV but fail to enter care and why there are varying effect sizes and uptake across settings.
- The finding that healthcare providers have substantially drifted from the planned intervention delivery (without even knowing) has improved our understanding of how policies ‘transplanted’ to other settings without any form of facilitation, supervision, and feedbacks may not follow intended implementation. The findings further make us aware that for a programme to thrive in a new context, policymakers need to engage frontline staff, offer supportive supervision, and equip them with the relevant skills and knowledge needed to deliver the intervention's core components.

- The study also contributes to our understanding of the role of a particular context in delivering evidence-based interventions. We are now aware that the antenatal clinic environment is uniquely unsuited for deploying many ambitious human rights principles in WHO/UNAIDS guidelines. We have also been enlightened about the need for adopted policies to be responsive to local norms, sub-cultures, and practices. The opt-out policy is based on principles of independence, autonomy, and the pregnant woman's individuality. It disregards the needs of individuals with collective cultures.
- The HIV testing literature has mainly focused on women who test positive and the challenges they go through. Little was about the experiences of those testing negative for HIV. The study makes an original contribution by revealing that these women go through similar challenges previously reported among women who test positive. However, women testing negative leave the antenatal clinic without any information about the possibility of false-negative results, the window period for HIV infection and the need for retesting during the 34th week of pregnancy. Achieving the 2030 targets of zero HIV would mean paying attention to this finding.

7.3 Contribution to methodology

This study's findings contribute immensely to the overall science of fidelity as it fills the limited current evidence for applying fidelity assessment methods within HIV testing interventions. The use of mixed-methods, coupled with Carroll's framework of implementation fidelity, offers the following key contributions:

- This thesis' essential strength is using a mixed-methods approach to assess adherence and moderating factors. The study offers a detailed description of how the methods unfolded during fieldwork. It offers new insights on using multiple methods to assess the fidelity of complex evidence-based intervention delivery. The methodology described in this thesis would offer guidance on the complexity of real-world evaluation. I have demonstrated practical ways researchers can use QRS International's NVivo 12 software (QRS, 2018) to pull all these data sources together, offering a transparent and credible analysis process. This study's evidence emerged

from multiple stakeholders and used different data collection methods, leading to better inferences, confirmation, and sometimes contradiction. All this has enriched the findings. This has improved the reliability and validity of the conclusions drawn about the opt-out intervention and its implementation than would have been achievable using other approaches.

- Carroll's Conceptual Framework of Implementation Fidelity proved useful in raising consciousness about how several factors moderate and shape intervention outcomes. For example, it raised awareness of the opt-out intervention's complexity and how policy documents have inconsistently captured its terminologies. The framework ensured that I was systematic and consistent when analysing adherence and moderators of implementation fidelity. Based on this framework, this study has proposed a human rights framework to guide future evaluation and implementation of rights-based health interventions such as the opt-out HIV testing among pregnant women in the antenatal clinic (Figure 36). The utility of the proposed framework's utility (see section 6.3.2; *pp.*175) which formed the basis of all recommendations made in this study, may enable researchers to look beyond the narrow delivery of proposed interventions to consider multiple moderating factors that impinge on successful programme delivery.

7.4 A framework for moving towards rights-based HIV testing

If increasing the number of women who have become aware of their HIV status in the short term was the only target for routine opt-out intervention, then its merit was achieved per the findings of this study and others in the HIV literature. However, since opt-out also aimed at ensuring a rights-based testing experience for women, its inclusion in the clinics seems imperfect at best and counterproductive at worst. Twenty years after its introduction, many providers were still using an opt-in approach, which was not surprising. Switching to the opt-out approach involves changing attitude, knowledge and behaviour, and assumptions about the individual's role in consent and decision-making (Shayo et al., 2014). Even though the UNAIDS/WHO proposed the 5Cs to serve as the guiding principles for rights-based HIV testing, the framework fails to capture the intervention's context. As seen in this study, a more useful framework must reflect several moderating factors. The proposed framework, which will guide the recommendations made for this study, stipulates two key things that the midwife must deliver with fidelity: (1) the opt-out approach of test offer and (2) the 5Cs of opt-out HIV testing. From the framework I used and in line with Carroll's original framework, policymakers need to consider five main moderating factors. For example, if policymakers fail to address local norms and customs and women's preferences, adherence or fidelity cannot be achieved.

I relied on the adapted Carroll's conceptual framework of implementation fidelity to outline the conceptual conclusions presented here (Leshem & Trafford, 2007). I propose a final version of the framework to guide generalizable recommendations that would enhance rights-based testing. In the next section, I will rely on this framework to make several generalizable recommendations for decision-makers, mainly around policy adoption, adaptation, and facilitation.

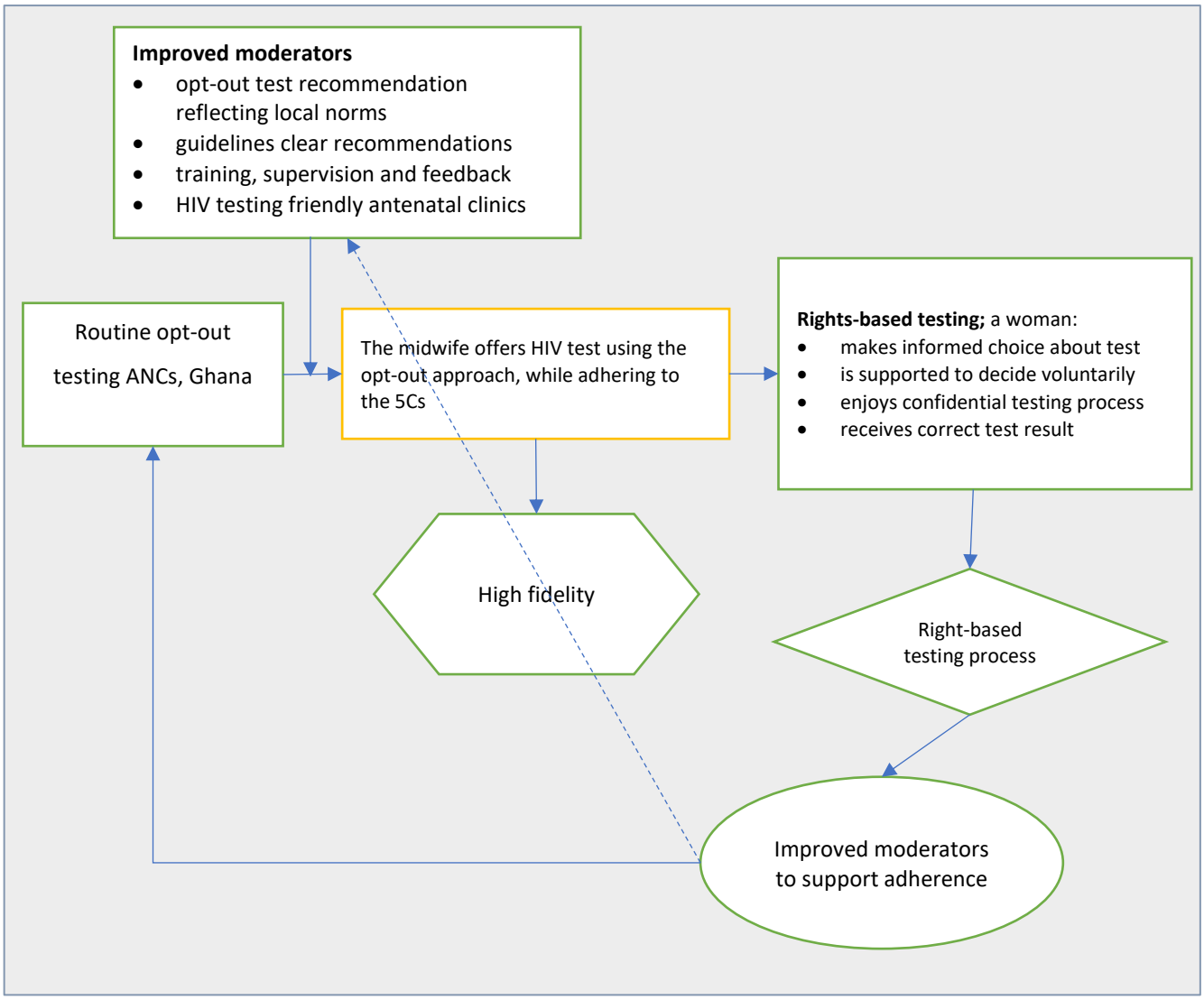


Figure 36: Proposed framework for ensuring rights-based HIV testing in antenatal clinics

7.5 Policy considerations

7.5.1.1 Align informed decision principles with local norms and values

The study's findings suggest that the opt-out test's consent principles that emphasise individuality, self-determination, and autonomy are incongruous with most women's cultural values and expectations. Women would prefer to maintain the status quo of receiving directive advice from the midwife or nurse, who is considered knowledgeable about health issues. In recognition of the socially embedded nature of both women and midwives, this study recommends that the GAC and MoH must:

- Review the current HIV testing guidelines with both women and midwives' input to ensure fit with Ghana's particular social relations and power dynamics;
- Consider adopting a relational autonomy framework that emphasises 'interdependence' instead of independence. The framework has gained popularity in many LMICs that have collective cultures like Ghana;
- 'Think global and act local' by developing policies locally to reflect local norms and values of healthcare providers (Kasoka, 2020);
- If de novo development of policies is not possible, then the process leading to adopting WHO's generic policies must include voices from the field.

7.5.1.2 Clarify the use of 'opt-out', 'provider-initiated' and 'routine' in policy documents

Healthcare providers used opt-out and opt-in interchangeably and sometimes found the two terms unfamiliar. Many providers understood 'routine' testing as a test for all women coming to the clinic and provider-initiated as the midwife having the mandate to initiate tests for all women she cares for in the clinic. The concern is that small changes to how we ask patients about their preferences can significantly affect their preferences (Montoy et al., 2016b). If policymakers do not address this issue, patients' decision-making choices may be compromised because the test was presented to them using the wrong term, or the midwife did not understand her real mandate in offering HIV test. Given this, the GAC, NACP and MoH should consider reviewing the existing HIV testing guidelines to reflect the following recommendations:

- HIV testing guidelines must contain detailed and precise recommendations regarding the expected delivery of the intervention. E.g. sample statement of what providers must say when offering HIV test by opt-out can improve clarity;
- The terminology 'routine testing' should be changed to 'routine offer' to reflect the test's voluntary nature. Similarly, 'provider-initiated' should be changed to 'provider-recommended.'
- GAC and NACP need to obtain frontline staff feedback regarding clarity, format and applicability of terminologies before rolling such guidelines out.

7.5.1.3 Facilitation of practice with guidelines, training, and supervision

No clinic had a testing guideline in this study, and part of the reasons was that no dissemination plan existed. The GAC, NACP and MoH should consider the following recommendations:

- Have a robust dissemination strategy for all policy guidelines;
- Frequent monitoring of clinics to ensure availability and use;
- If possible, digitalise all guidelines and disseminate them through the existing information communication technology (ICT) platforms. This is efficient and cheaper and would ensure easier updating of the guidelines' content.

7.5.1.4 Continual monitoring of adherence and adaptation

While I support local clinics' adaptation of the opt-out intervention to suit their contextual needs and empower localised decisions, such adaptation must receive technical support and guidance to ensure that frontline staff do not neglect essential intervention components. Fidelity would also improve with ongoing monitoring of delivery at the clinic level. None of the clinics included in this study had mechanisms to monitor providers' implementation of the intervention. For a manualised opt-out programme, providers need support to understand and to ensure fidelity. The GAC, NACP and MoH can achieve this through:

1. Establishing a two-way communication process to obtain information from frontline staff on the challenges they have encountered in the course of implementation;
2. Determining changes made in the programme, incorporating useful ones and working towards eliminating barriers;
3. Establishing realistic expectations regarding what constitutes 'success' in adhering to the policy's recommendations recognises that 100% fidelity cannot be achieved.

7.6 Practice and training considerations

7.6.1.1 Becoming aware of legislative rights

The issue of routine opt-out HIV testing of pregnant women in the antenatal clinic lies at the nexus of the public health goal of preventing the spread of HIV and protecting women's human rights (UNAIDS, 2020). Ghana is supported by various international and national human rights conventions (GOG, 2016; Health Policy Plus, 2017). Additionally, the Nursing and Midwifery Council of Ghana and the Ghana Health Service have codes of conduct combined with these conventions to determine acceptable professional conduct. Midwives and nurses have a professional responsibility to become informed about the underlying human rights principles explored in this study and ensure that their HIV testing practices align with them. Such a mandate includes ensuring informed consent before performing any intervention on a patient and protecting the confidentiality of information gathered about a patient during care provision. Even without access to the testing guidelines, a nurse or a midwife must recognise the dire consequences for the woman who gets her HIV status disclosed against her will. This study's findings regarding nurses' and midwives' adherence practices could be incorporated into local guidelines.

7.6.1.2 Ensuring a rights-based approach to HIV testing

This study revealed how women tested for HIV in the antenatal clinic felt the test was compulsory and could not trust the provider or the system to keep testing confidential and private. The study identified low-quality testing practices and failure to link women testing

negative for HIV to preventive services. These practices persist amidst the growing recognition that protecting human rights is key to safeguarding human dignity. The question then is, what would be the human rights approach to safeguarding the dignity of women attending antenatal clinics? I offer specific practice recommendations in light of the discussed findings and its resultant proposed framework (see Figure 37; pp.184).

The right to informed and voluntary consent

Nurses and midwives must become aware of how to offer the test correctly to make it easier for women to decline if they wish to do so. The offer of the test must emphasise benefits to both the mother and child. This study also suggests that many women may not make independent decisions and require directive advice and support. To ensure this in practice, the provider must create safe spaces for women to contemplate and enact their decisions (Loll et al., 2020). There should be enough room for social support from the provider and partner. In recognition of many women in the clinic whose presence can make achieving this difficult, I recommend that providers deliver pre-test information in small informal groups. During the education session, the provider must avoid assuming the expert role as observed during information delivery. Instead, the provider should rely on problem-solving strategies to elicit women's prior knowledge about the issues and address identified misconceptions. I make this recommendation because many women already have some idea about HIV testing in the clinic (Asiedu et al., 2019). The provider must also be cognizant of her position as a knowledgeable professional, a situation that makes test refusal difficult. Being reflexive about this can minimise the impact.

Ensuring a confidential testing process

Nurses and midwives must know that women might not openly complain about the perceived and actual confidentiality issues identified in this study due to the unequal power balance. However, the provider must be concerned that a woman who harbours such mistrust towards her healthcare provider may withhold any information they consider private. The provider must have an awareness of these issues, together with relevant legislation that protects client confidentiality. The provider must be aware of the adverse social implications of disclosing a woman's HIV status against her will. When there is an

indication that a woman might not disclose to a partner, the provider must understand her reasons and offer support rather than disclosing against the woman's consent. The provider must be sensitive to respect a woman's rights to privacy by limiting the number of providers in the consulting room, speaking quietly or providing a more private setting for discussion (Malcolm, 2016). Midwives and nurses must be aware of their professional mandate of building a trusting relationship.

Ensuring correct testing process

To ensure that women receive a correct diagnosis, all healthcare providers must become aware of the recommended testing algorithm and keep abreast of any updates. Healthcare providers need to consider a woman as positive for HIV only after a confirmatory test. The healthcare provider performing the test must ensure that she has received the required training and is confident in doing the test. At all times, providers should use the correct reagent when performing rapid HIV testing. When unsure of test results, a second provider must be asked to cross-check. Internal and external quality assurance audits must pay attention to the test delivery process. Antenatal clinic managers must reduce the test kit and buffer shortages by better forecasting and prioritising resources. Provider challenges in pricking, dropping the right amount of buffer, and reading results can be addressed through training, mentorship, and supportive supervision.

Connecting women testing negative to preventive services

Providers need to inform women of the negative test results and what they mean. The woman must understand that testing negative does not mean that one cannot be positive at the next antenatal clinic visit. Such information would pave the way to explain the window period, serodiscordance, partner testing and retesting during the third trimester. This study's finding that the clinic is often busy may inform the need to deliver this information during the pre-test information session or distribution of leaflets if there is the capacity to do so. Delivering the information in small groups would lead to few women requiring detailed, one-on-one counselling. The midwife can then spend more time with these women.

Building provider capacity

Delivery of the intervention can be improved by strengthening providers' counselling skills. These skills are vital to improving their capacity to obtain informed consent, protect confidentiality, and communicate therapeutically with women. Hospital management should offer providers the opportunity to access professional development courses. Pre-registration nursing and midwifery educators must emphasise the value of evidence-based HIV testing guidelines on informed consent practices, confidentiality, respectful maternity care, and other quality assurance measures. In-service training and pre-registration training must also incorporate counselling and communication skills with women receiving antenatal clinic services. Lack of supervision, feedback and incentives emerged strongly in provider interviews. This study recommends an organisational leadership with a robust monitoring system to drive local-level implementation to ensure timely flagging of challenges and timely institution of corrective measures.

Ensuring HIV testing friendly antenatal clinic setting

Privacy and confidentiality challenges identified in this study were mostly due to the nature of the antenatal clinic that was unsuitable for ensuring confidentiality, plus the unprofessional attitudes of healthcare providers. Hospital management and administrators must be aware of these constraints and consider retrofitting existing structures to provide private rooms, exit gates for women testing positive, and patient flow improvement in general.

7.7 Conduct further process-related research

This study intended to determine the level of adherence to the opt-out intervention. The study has offered an initial step towards addressing the paucity of research on antenatal clinic-based HIV testing and counselling. This study has revealed several new issues and nuances embedded in the antenatal clinic that warrant further exploration.

1. Although the healthcare providers' adherence to opt-out tests was low, almost 100% of women agreed to the test. While conclusions have been drawn about observed coercive practices and their impact on the high test uptake, it will

remain speculative until a study establishing causality had been undertaken. An adequately powered study that establishes the relationship between nonadherence and outcomes is urgently required. A longitudinal cohort study could examine the observed non-adherence and possible attrition from HIV testing services prospectively.

2. This study's findings suggest that delivering pre-test information in the antenatal clinic is very challenging. Future studies must explore practical ways to overcome this challenge. Studies must explore the feasibility of delivering this information through an audio-visual medium or offering leaflets that contain the information women need to make an informed decision.
3. The proposed conceptual framework needs validating through more rigorous research. Studies may examine how the identified moderating factors can improve testing outcomes in ways that will produce impact. For example, studies may examine how improving the identified moderating factor would impact the overall adherence and women's satisfaction with care.
4. Based on the finding that women would prefer directive advice, this study recommends further research involving women to determine how the healthcare provider can facilitate decision-making among this population.
5. Many healthcare providers self-rated their adherence levels highly, which did not correspond with direct observation findings. It would be interesting to explore this issue further using qualitative approaches.
6. The study identified several modifications and adaptations of the opt-out testing intervention in the various clinics. There is a need to examine the type and nature of adaptations made, whether the components changed or deleted are core to the intervention's success. The study may identify beneficial changes that can be incorporated into the programme as evidence.
7. Closely related to the above, future research must take a historical perspective and ask if the intervention has significantly changed since its adoption in 2008, and document which component(s) have/has been changed most, and how this

affects outcomes. Such findings will help educational content developers know where to focus their training attention.

8. Healthcare providers' role in facilitating women's decisions requires attention, given this study's finding that women prefer directive advice. A parallel study exploring women's decision-making, understanding and preferred method of test offer and consent approaches can also be undertaken. These studies can rely on theories of social and behavioural sciences such as diffusion of innovation.
9. The antenatal clinic environment emerged strongly as a moderator of women's enjoyment of women's right. More research efforts must focus on this issue. Research will benefit from examining the differential effects of fully integrated, partially integrated and standalone clinics on adherence and patient testing outcomes.

7.8 Conclusion

Staff: *Have you been tested for HIV in this pregnancy? (She asked while standing in front of Ruth, and looking down at her)*
Ruth: *'No'*
Staff: *'As part of the government's policy to prevent the baby from getting HIV, we will test you for HIV unless you refuse. In case you have the disease, you will also be put on treatment today.*
Ruth was too scared to say no, although she did not adequately understand what the midwife said. Moreover, she did not consider herself at risk for HIV. Fifteen minutes later, the midwife informed Ruth that she was HIV positive. The midwife offered instructions on what she must do, including antiretroviral drugs the same day. She then asked whether Ruth had any questions. Ruth was still in shock and trying to process what the midwife had told her. She sat there, reflecting on how the other women waiting in the queue would not be aware of her new HIV positive status and worried about informing her husband without getting divorced.

Ruth was aware that the clinics tested women routinely for HIV, but she never considered herself at risk for HIV infection. Instead of 'good news' about her child, Ruth left the clinic with various life-changing decisions to make. How would she disclose this 'deadly' diagnosis to her husband without any trouble or even a divorce? She kept staring at the carefully wrapped antiretroviral drugs that the midwife gave her. Did she hear the midwife right that these medications were to be taken for life? Soon, her thinking shifted to the unborn child.

Did the midwife say taking the medication would prevent the child from getting the disease? In the days that followed, Ruth deliberated on these issues. While she was unsure about many things, she became certain that informing her husband was not an option. Ruth continued taking the antiretroviral therapy but did not go back to the clinic after her last pill. She felt that many women and clinic staff might have become aware of her diagnosis and therefore continued her care in another clinic. She had a difficult few years living with an incurable and complex medical condition that attracts so much stigma.

Ruth's story is just one of the many narratives of women who test for HIV in the antenatal clinic. I was very much aware of these stories before I commenced this PhD study. However, examining the process itself has offered me several learning points. I would never have imagined that many healthcare providers have not heard about the opt-out approach and the human rights principles that come with it. It appears that many of the healthcare providers now know that women must be tested for HIV but have never given a thought about the consequences that follow the test.

At its core, opt-out's underlying principles appear incongruous with the studied community's cultural values and expectations. It seemed like a bad fit, even without the lack of time and resources. Twenty years after its introduction, many providers are still using an opt-in approach. Ruth required adequate information about the test before testing. She needed to know what it would mean to test positive. She needed private testing space and support for disclosure. However, as reported by this research, this was not available, and the test itself did not appear genuinely voluntary.

I know well that the practice of rights-based HIV testing has not been widely acknowledged. I hope that the recommendations made in this study will be considered carefully and changes made to support healthcare professionals testing women for HIV. Ruth will be pleased to know that the experience she shared with me became part of the reason for this comprehensive process evaluation and the clear recommendations to support future improvements in the testing of women in the clinic.

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APPENDICES

Appendix 1 ETHICS APPROVAL – VICTORIA UNIVERSITY OF WELLINGTON

VICTORIA UNIVERSITY OF WELLINGTON
TE HERENGA WAKA

Phone 0-4-463 6028
Email judith.loveridge@vuw.ac.nz

TO	Isaac Amankwaa
FROM	Associate Professor Judith Loveridge, Convenor, Human Ethics Committee
DATE	14 November 2017
PAGES	1
SUBJECT	**Ethics Approval** **Number:** 25399 **Title:** Routine (Opt-out) Antenatal HIV Screening in Ghana: A Process Evaluation

Thank you for your application for ethical approval, which has now been considered by the Human Ethics Committee.

Your application has been approved from the above date and this approval is valid for three years. If your data collection is not completed by this date you should apply to the Human Ethics Committee for an extension to this approval.

Best wishes with the research.

Kind regards,

Convenor, Victoria University of Wellington Human Ethics Committee

Appendix 2 ETHICS APPROVAL (AMENDED) – VICTORIA UNIVERSITY OF WELLINGTON

VICTORIA UNIVERSITY OF WELLINGTON
TE HERENGA WAKA

Phone 0-4-463 6028
Email judith.loveridge@vuw.ac.nz

TO	Isaac Amankwaa
FROM	Associate Professor Judith Loveridge, Convenor, Human Ethics Committee
DATE	21 March 2018
PAGES	1
SUBJECT	**Ethics Approval** **Number:** 25399(V1) **Title:** Routine (Opt-out) Antenatal HIV Screening in Ghana: A Process Evaluation

Thank you for your application to amend/extend your ethics approval. This has now been considered and the request granted.

In the case of an amendment, this approval is valid until the end date of your original ethics approval; in the case of an extension, this approval applies until the new end date that you have nominated. If your data collection is not completed by this date you should apply to the Human Ethics Committee for an extension to this approval.

Best wishes with the research.

Kind regards,

Judith Loveridge

Convenor, Victoria University of Wellington Human Ethics Committee

Appendix 3 ETHICAL APPROVAL FROM GHSERC[10]

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: ghserc@gmail.com
30th November, 2017

MyRef. GHS/RDD/ERC/Admin/App |865
Your Ref. No.

Isaac Amankwaa
Victoria University of Wellington
New Zealand

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 009/11/17**
Project Title	Routine (Opt-Out) Antenatal HIV Screening in Ghana: A Process Evaluation
Approval Date	29th November, 2017
Expiry Date	28th November, 2018
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

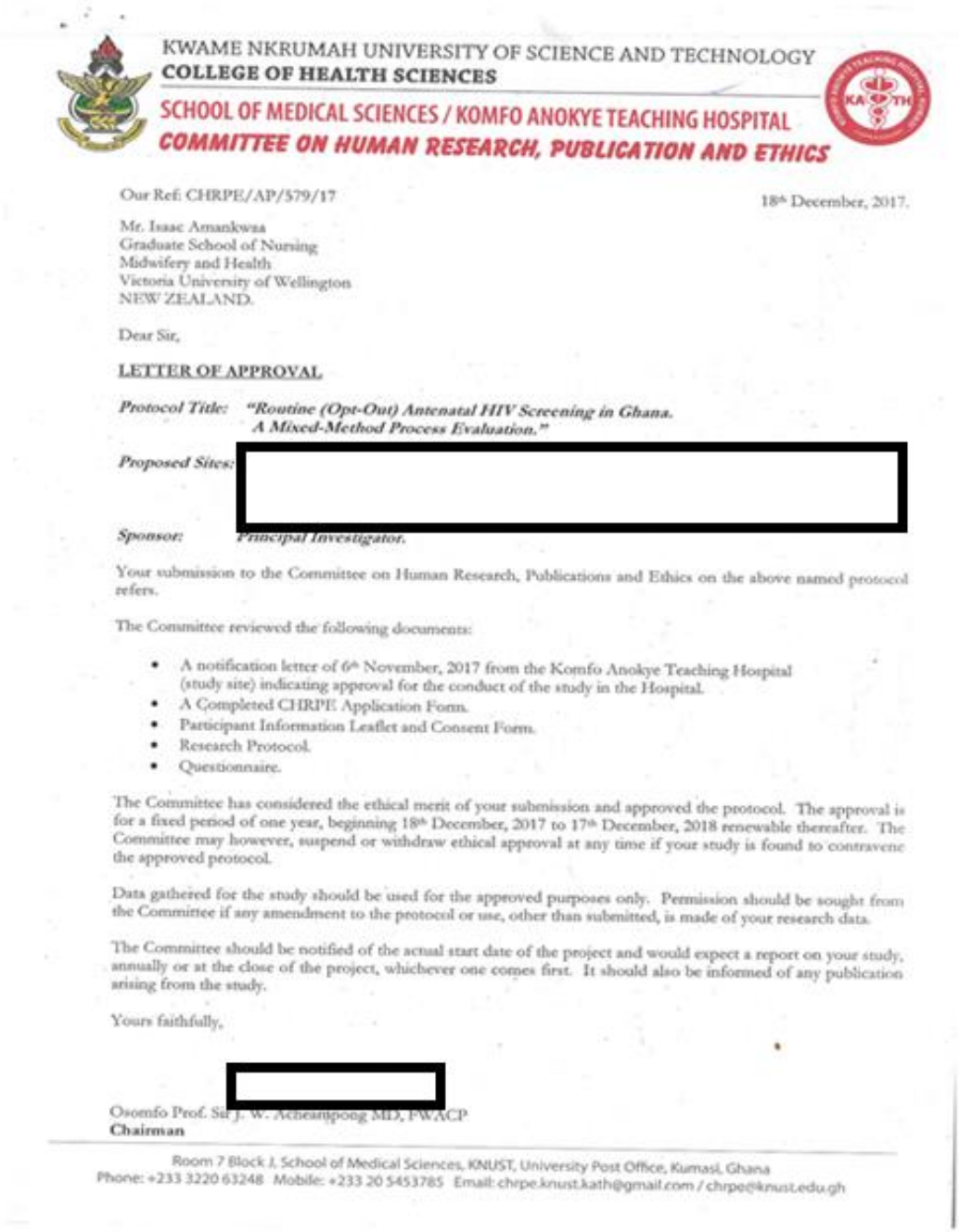
Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....[redacted].....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

[10] Ghana Health Service Ethical Review Committee

Appendix 4 ETHICS APPROVAL SCHOOL OF CHRPE[11]



KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS

Our Ref: CHRPE/AP/579/17

18th December, 2017.

Mr. Isaac Amankwaa
Graduate School of Nursing
Midwifery and Health
Victoria University of Wellington
NEW ZEALAND.

Dear Sir,

LETTER OF APPROVAL

Protocol Title: *"Routine (Opt-Out) Antenatal HIV Screening in Ghana. A Mixed-Method Process Evaluation."*

Proposed Sites: [redacted]

Sponsor: *Principal Investigator.*

Your submission to the Committee on Human Research, Publications and Ethics on the above named protocol refers.

The Committee reviewed the following documents:

- A notification letter of 6th November, 2017 from the Komfo Anokye Teaching Hospital (study site) indicating approval for the conduct of the study in the Hospital.
- A Completed CHRPE Application Form.
- Participant Information Leaflet and Consent Form.
- Research Protocol.
- Questionnaire.

The Committee has considered the ethical merit of your submission and approved the protocol. The approval is for a fixed period of one year, beginning 18th December, 2017 to 17th December, 2018 renewable thereafter. The Committee may however, suspend or withdraw ethical approval at any time if your study is found to contravene the approved protocol.

Data gathered for the study should be used for the approved purposes only. Permission should be sought from the Committee if any amendment to the protocol or use, other than submitted, is made of your research data.

The Committee should be notified of the actual start date of the project and would expect a report on your study, annually or at the close of the project, whichever one comes first. It should also be informed of any publication arising from the study.

Yours faithfully,

[redacted]

Osomfo Prof. Sir J. W. Acheampong MD, FWACP
Chairman

Room 7 Block J, School of Medical Sciences, KNUST, University Post Office, Kumasi, Ghana
Phone: +233 3220 63248 Mobile: +233 20 5453785 Email: chrpe.knust.kath@gmail.com / chrpe@knust.edu.gh

[11] CHRPE -Committee on Human Research, Publication and Ethics

Appendix 5 DATA SHARING AGREEMENT WITH NACP

NATIONAL AIDS/STI CONTROL PROGRAMME
(NACP)

In case of reply the number and date of this letter should be quoted

My Ref: nacp/gen/vol.16

Your Ref. No.....

GHANA HEALTH SERVICE
Your Health - Our Concern

P. O. Box KB 547
Korle-Bu, Accra
Tel. (233-302) 67 84 57 - 9
Fax: (233-302) 66 26 91
Email: info@nacp.org.gh

17th April, 2018

RE: SUPPORT OF DATA SHARING AGREEMENT: ISAAC AMANKWAA

We wish to state that the National AIDS/STI Control Programme (NACP) has signed a data sharing contract with **Mr. Isaac Amankwaa of the Victoria University of Wellington, New Zealand (a PhD Candidate)** to enable him acquire data for his research activities using HIV data at the **under-listed hospitals in the Ashanti and Brong Ahafo Regions.**

In line with the above, please be informed that the NACP has agreed to allow Mr. Isaac Amankwaa the right of limited access to the datasets for the research activities using HIV data at the under-listed hospitals in your Region.

He may therefore go ahead with the said research taking into consideration the conditions in the agreement.

We count on your cooperation.

[redacted]

DR. STEPHEN AYISI ADDO
PROGRAMME MANAGER

Distribution:

- **Ashanti Region**

1. The Director, Obstetr
   Teaching Hospital, K
2. The Medical Director
3. The Medical Director
4. The Medical Director
5. The Medical Director
6. The Medical Director
7. The Medical Director
8. The Medical Director
9. The Medical Director
10. The Medical Director

[redacted]

Appendix 6 SAMPLE FACILITY LEVEL APPROVAL LETTER

In case of the reply the number

and the date of this letter

should be quoted

My Ref. No: SH

Your Ref. No:
Tel number: + 233-322022253

GHANA HEALTH SERVICE
[redacted] HOSPITAL
P.O.BOX 14775
KUMASI-ASHANTI

24TH NOVEMBER, 2017

Mr. Isaac Amankwaa,
Graduate School of Nursing, Midwifery &Healt
Faculty of health
Victoria University of Wellington,
P.O.Box 7625,
Newton, Wellington 6242
New Zealand.

Dear Mr. Isaac Amankwaa,

RE: Routine Antenatal HIV Screening in Ghana: A process of Evaluation.

The hospital management has studied your protocol for the study, **"Routine Antenatal HIV Screening in Ghana: A process of Evaluation"** and finds it suitable for the discourse of HIV/AIDS treatment, care and support at the hospital.

Permission is hereby granted to undertake the study at the Infectious Disease Unit of the [redacted] Hospital, Kumasi.

All staff concerned have been duly informed to offer the needed support.
It is the requirement that the hospital be acknowledged in the final reports and publication related to the study.

Since[redacted]

[redacted] BSc, MBChB, MPhil, DipGUM, MSc.PH, Ph.D.
Head of Infectious Disease Unit/ Clinical Care Coordinator

Appendix 7 INFORMATION SHEET FOCUS GROUPS - PROVIDERS

Routine (Opt-Out) Antenatal HIV Screening in Ghana (working title)

You are invited to take part in this research. Please read this information before deciding whether to take part. If you decide to participate, thank you. If you decide not to participate, thank you for considering this request.

Who am I?

My name is Isaac Amankwaa, and I am a Doctoral student in Nursing at Victoria University of Wellington. This research project is to work towards my thesis.

What is the aim of the project?

The purpose of the study is to contribute to the quality of HIV testing experience and pregnancy outcomes for pregnant women who are routinely tested for HIV during the antenatal visit, through a process evaluation of the HIV testing policy.

How can you help?

You have been invited to participate because you are directly involved in providing HIV testing and counselling services to pregnant women in an antenatal clinic. If you agree to take part, you will be part of a focus group discussion held in this hospital. I will ask you and other participants questions that relate to your understanding of routine opt-out testing, how you go about the test and information given, perceived barriers and facilitators; adaptations you make during delivery of service and suggestions for improvement in the programme's implementation. The focus group will take between 30 minutes to 1 hour. I will audio record the focus group with your permission and write it up later. The information shared during the focus group is confidential. That means that after the focus group, you may not communicate to anyone, including family members and close friends, any details about the focus group. You can withdraw from the focus group at any time before the focus group begins. You can also withdraw while the focus group it is in progress. However, it will not be possible to withdraw the information you have provided up to that point as it will be part of a discussion with other participants

What will happen to the information you give?

This research is confidential. This means that the researchers named below will be aware of your identity, but the research data will be combined, and your identity will not be revealed in any reports, presentations, or public documentation. Only my supervisors and I will read the notes or transcript of the focus group. The focus group transcripts, summaries and any recordings will be kept securely and destroyed on 28TH December 2019.

What will the project produce?

The information from my research will be used in my PhD dissertation, report to the Ghana AIDS Commission, academic publications and conferences

If you accept this invitation, what are your rights as a research participant?

You do not have to accept this invitation if you do not want to. If you do decide to participate, you have the right to:

- choose not to answer any question;
- ask for the recorder to be turned off at any time during the focus group;
- withdraw from the focus group while it is taking part however it will not be possible to withdraw the information you have provided up to that point;
- ask any questions about the study at any time;
- read over and comment on a written summary of the focus group;
- be able to read any reports of this research by emailing the researcher to request a copy.

If you have any questions or problems, who can you contact?

If you have any questions, either now or in the future, please feel free to contact either:

Student:
Name: Isaac Amankwaa
University email address: Deleted
Phone: Deleted

Supervisor:
Name: Joan Skinner
Role: Senior Lecturer
School: Nursing, Midwifery and Health
Email: Joan. deleted

Human Ethics Committee information

If you have any concerns about the research's ethical conduct, you may contact the Victoria University HEC Convenor: Deleted

Appendix 8 INFORMATION SHEET; KEY INFORMANTS INTERVIEWS

Information Sheet for National, Regional Level Officers and Facility Managers (Interviews)

You are invited to take part in this research. Please read this information before deciding whether to take part. If you decide to participate, thank you. If you decide not to participate, thank you for considering this request.

Who am I?

My name is Isaac Amankwaa, and I am a doctoral student in Nursing at Victoria University of Wellington. This research project is to work towards my thesis.

What is the aim of the project?

The purpose of the study is to contribute to the quality of HIV testing experience and pregnancy outcomes for pregnant women who are routinely tested for HIV during an antenatal visit, through a process evaluation of the HIV testing policy.

How can you help?

You have been invited to participate because you are a key stakeholder and know how the testing policy was adopted and implemented in Ghana. If you agree to take part, I will interview you in your office, or a place was chosen by you that may be convenient and safe for an interview. I will ask you questions about the policy and its implementation. The interview will take 20 minutes. I will audio record the interview with your permission and write it up later. You can choose not to answer any question or stop the interview at any time, without giving a reason. You can withdraw from the study by contacting me at any time before 30th June 2018. If you withdraw, the information you provided will be destroyed or returned to you.

What will happen to the information you give?

This research is confidential. This means that the researchers named below will be aware of your identity, but the research data will be combined, and your identity will not be revealed in any reports, presentations, or public documentation. However, you should be aware that in small projects, your identity might be obvious to others in the HIV prevention community. Only my supervisors and I will read the notes or transcript of the interview. The interview transcripts, summaries and any recordings will be kept securely and destroyed on 28th December 2019.

What will the project produce?

The information from my research will be used in my PhD dissertation, report to the Ghana AIDS Commission, academic publications and conferences.

If you accept this invitation, what are your rights as a research participant?

You do not have to accept this invitation if you don't want to. If you do decide to participate, you have the right to:

- choose not to answer any question;
- ask for the recorder to be turned off at any time during the interview;
- withdraw from the study before 30th June 2018;
- ask any questions about the study at any time;
- read over and comment on a written summary of your interview
- be able to read any reports of this research by emailing the researcher to request a copy.

If you have any questions or problems, who can you contact?

If you have any questions, either now or in the future, please feel free to contact either:

Student:
Name: Isaac Amankwaa
University email address: deleted
Phone: deleted

Supervisor:
Name: Joan Skinner
Role: Senior Lecturer
School: Nursing, Midwifery and Health
Email: deleted

Human Ethics Committee information

If you have any concerns about the ethical conduct of the research, you may contact the Victoria University HEC Convenor: Associate Professor Susan Corbett. Email deleted

Appendix 9 SAMPLE CONSENT FOR INTERVIEW

This consent form will be held for three (3) years.

Researcher: Isaac Amankwaa, Victoria University of Wellington.

- I have read the Information Sheet, and the project has been explained to me. My questions have been answered to my satisfaction. I understand that I can ask further questions at any time.
- I agree to take part in an audio-recorded interview.

I understand that:

I may withdraw from this study at any point before 30th June 2018, and any information that I have provided will be returned to me or destroyed.
The identifiable information recorded will be destroyed on 28th December 2019
Interview records will be kept confidential
I understand that the results will be used for PhD dissertation, report to the Ghana AIDS Commission, academic publications and conferences.
My name will not be used in reports, nor will any information that would identify me.

I will like a summary of my interview
I would like to receive a copy of the final report and have added my email address below. Yes ☐ No ☐

Yes ☐ No ☐

Signature/thump print of participant: _____
Name of participant: _____
Date: _____
Contact details: _____

Researcher (Witness)
I certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.
Signature …….

Date……

Appendix 10 INTERVIEW GUIDE: PREGNANT WOMEN

Date of interview: ---------- Time of the interview: Start---------- End------

Interviewee number_____

Place of interview_____

Name of facility/organisation- ----------

1. General introduction
2. Prenatal blood work - was HIV testing mentioned
   - *Let's talk about any blood tests that you may have had in this pregnancy.*
3. Reactions to mention of the HIV test
   - *How did you respond when HIV testing was mentioned to you?*
   - *How did you feel about what you were being told? (Elicit perception of personal HIV risk.)*
4. HIV pre-test counselling
   - *What were you told about being tested for HIV in pregnancy? (Elicit perception of mother to child transmission risk; pros and cons of test for mother and baby; use of positive results - reporting; testing options; anything else).*
5. Voluntary nature of the HIV test
   - *What was your impression of what your (midwife/nurse) wanted you to do? (Elicit understanding of voluntary consent and was this requested and given.)*
6. Consent

   Did you feel you could have said "No"? (Elicit power imbalance between provider and pregnant women
7. Responding to the HIV test

   So you decided to go ahead and have an HIV test. Let us talk a little about that. What helped you decide on testing?
8. Waiting for test results

   How was it waiting for the results? (Elicit disclosure of self-identified risk.)
9. Post-test counselling

   Let's talk about how you got your results. (Elicit content of post-test counselling.)
10. Best practices in prenatal HIV counselling and testing
    - *If you were asked to suggest to midwives and other health care providers what they should be telling women about HIV in pregnancy - what would you suggest?*
    - *If you were asked to suggest to midwives and other health care providers how they should be testing pregnant women for HIV in their pregnancy - what would you suggest? (Elicit attitudes towards selective, opt-in, opt-out, mandatory)*

If you were asked to suggest to midwives and other health care providers how they should be talking to pregnant women about their HIV test results, what would you suggest?

Appendix 11 INTERVIEW GUIDE: FOCUS GROUP DISCUSSION

Main questions

1. Can you please give a brief introduction (age, educational level and role in ANC)
2. Can you tell me what you know about the routine antenatal HIV screening policy? (explore their adherence to the policy)
3. Are you aware of any national policies on HIV testing of pregnant women? If yes, does your service here at the ANC adhere to the policy? (explore views about routinely offering HIV testing)
4. What do you consider to be good about testing pregnant women routinely at the ANC?
5. What do you consider as some of the challenges in testing and counselling pregnant women during routine antenatal care sessions?
6. Do you think you are adequately supported in your role (probe training, supervision, psychological support and motivation in the role)
7. Do you think pregnant women are generally aware that they were tested for HIV? (probe how pregnant women get to know this, how they obtain informed consent)
8. Can you tell me about the training and supervision you receive from your superiors regarding routine HIV testing and counselling (probe areas where they require further training)?
9. Can you tell me about how you perform rapid HIV testing (probe incidence of false negatives, positives, stock-outs, quality control measures)
10. Have there been occasions when pregnant women have been given a false-negative or false-positive HIV test results? (if yes, explore how it happened and what was done about it)
11. Is there any other thing you would like to tell me about the routine testing of pregnant women in the clinic?

Appendix 12 INTERVIEW GUIDE; NATIONAL AND REGIONAL LEVEL OFFICERS

Section 1: General Information

Date of interview: ---------- Time of the interview: Start---------- End------
Interviewee number_____
Place of interview_____
Rank/Position of the interviewee----------
Name of facility/organisation- ----------
How many years have you been practising in this position? ----------

Section 2: Main Questions

1. What are your views on the policy that requires pregnant women to be routinely tested for HIV at antenatal clinics?
2. How were you or your office involved in the adoption and implementation of this policy?
3. Do you think implementing the testing policy has been in line with HIV testing and international counselling guidelines? (Probe for areas of adaptation if not in line with international guidelines).
4. How well do you think the routine testing programme has been facilitated? (Probe level of facilitation).
5. What measures have been put in place to ensure that testing and counselling respect pregnant women's human rights visiting the antenatal clinics? (Probe for the existence of national policies and legal frameworks that protect the rights of women testing for HIV at the antenatal clinic)
6. How have you been monitoring the implementation of the policy (Probe if not done).
7. What are the minimum guidelines that should be followed by facilities that offer HIV testing and counselling of pregnant women?
8. What are the effects of not following the HCT policy guidelines on pregnant women?
9. Who has the mandate to monitor and evaluate the HCT policy?
10. Have you received any complaints regarding the quality of delivery of the intervention in the various institutions?
11. What are government's plans to review the HCT policy (probe the adoption of the 5Cs).

Appendix 13 INTERVIEW GUIDE FOR FACILITY MANAGERS

Section 1: General Information

Date of interview: ---------- Time of the interview: Start---------- End------
Interviewee number_____
Place of interview_____
Rank/Position of the interviewee----------
Name of facility/organisation- ----------
How many years have you been practising in this position? ----------

Section 2: Main questions

1. Please describe the antenatal clinic daily operations in terms of how busy or not it is.
2. Are you aware of any national policies on HIV testing of pregnant women? If yes, does your service here at the ANC adhere to the policy? (explore views about routinely offering HIV testing)
3. Tell me about how staff are trained, supervised and motivated to deliver HIV testing and counselling services;
4. Do pregnant women receive the required information to decide voluntarily as to whether to test or not to test for HIV? (explore provider-patient power differences);
5. Have there been occasions when pregnant women have been given a false-negative or false-positive HIV test results? (if yes, explore how it happened and what was done about it)
6. Do you provider post-test counselling services to pregnant women who test positive or negative for HIV? (if not for any of them, probe to find out why)
7. How do you help pregnant women testing positive for HIV in the disclosure process? (probe instances of partner violence, self-harm);
8. Have you ever received complaints about the quality of HIV care services provided in this facility?
9. Can you tell me some of the challenges you encounter in testing and counselling pregnant women during routine antenatal care?

Appendix 14 INTERVIEW GUIDE FOR HEALTHCARE PROVIDER INTERVIEWS

Main questions

1. Please describe the antenatal clinic daily operations in terms of how busy or not it is.
2. Can you tell me what you know about routine antenatal HIV screening policy? (explore their adherence to the policy)
3. What do you consider to be good about testing pregnant women routinely at the ANC?
4. What do you consider as some of the challenges in testing and counselling pregnant women during routine antenatal care sessions
5. Do you think you are adequately supported in your role (probe training, supervision, psychological support and motivation in the role)
6. Do you think pregnant women are generally aware that they were tested for HIV? (probe how pregnant women get to know this, how they obtain informed consent)
7. Can you tell me about the training and supervision you receive from your superiors regarding routine HIV testing and counselling (probe areas where they require further training)?
8. Can you tell me how you perform rapid HIV testing (probe incidence of false negatives, positives, stock-outs, quality control measures)?
9. Are you aware of any national policies on HIV testing of pregnant women? If yes, does your service here at the ANC adhere to the policy? (explore views about routinely offering HIV testing)
10. Have there been occasions when pregnant women have been given a false-negative or false-positive HIV test results? (if yes, explore how it happened and what was done about it)
11. Is there any other thing you would like to tell me about the routine testing of pregnant women in the clinic?

Appendix 15 ANTENATAL CLINIC FACILITY AUDIT TOOL[12]

No.	Questions	Response –codes	Remarks
	First, I would like to ask you some general questions about ANC operating hours, coverage and services		
A	Operating hours and organisation		
1.	What is the average number of ANC visits made per pregnant woman?		
2.	What are the ANCs hours of operation?	a) Opening time _____am/pm b) Closing time _____ am/pm	
3.	How many days per week are ANC services offered?		
4.	How are 'new' and follow-up ANC visits organised?	All visits are together 1 Provided on same days but at different hours 2 Offered on a separate days of the week 3	
5.	On a normal day ANC clinic day, how many women are seen?	Number of first visits_____ Number of follow-up visits_____	
6.	Describe the variations in the volume of visits. For example, do number of visits vary by day? Are there any seasonal variations in the numbers of ANC visits?		
7.	On the average, how much time does a woman spend at the ANC?	Number of first visits_____ Number of follow-up visits_____	
B	**Leadership and supervision**	Response codes	Remark
8.	Is there a formal system in place to provide supervision for providers in VCT/MTCT programme?	Yes……1 No……2	
9.	If yes, please describe this system		

10.	Is there a designated HIV testing and counselling supervisor to provide support and technical back up?	Yes……1 No……2	
11.	If yes, who provides?	Support_____ Supervision_____	
12.	Is there a counsellor support group?	Yes……1 No……2	
13.	Are meetings between supervisors and counsellors held?	Yes……1 No……2	
14.	If yes, how often?	Weekly……1 Every other week……2 Once a month……3 Once every few months……4	
15.	Is there a trained laboratory supervisor who supervises systems of testing?	Yes……1 No……2	
C	**Human Resource and capacity**		
16.	How many midwives/nurses are usually assigned to the ANC on a given day?		
17.	Total number of providers providing ANC/MCH services by provider types	Midwives #_____ Nurses #_____ Doctors #_____ Laboratory staff #_____ Counsellors #_____ Other _____ #_____	

[12] Selected pages

Appendix 16 CHECKLIST FOR STRUCTURED OBSERVATION

Facility code_____ Date_____

Name of observer_____ Testing #_____

Essential component	Implementation	Comments
Pre-test information		
The testing process explained to clients?	Yes No	
Was the woman told about mother to child transmission?	Yes No	
Meaning of positive & negative explained to the woman?	Yes No	
Was the mother made aware of preventive options for HIV?	Yes No	
Was Mother allowed to ask questions?	Yes No	
Obtaining informed consent		
The pregnant woman agreed to test?	Yes No	
Did mother inform about her right to decline test?	Yes No	
Confidentiality		
Woman told that results would not be shared?	Yes No	
Post-test counselling (negative clients)		
Meaning of results explained?	Yes No	
Given advice on HIV prevention?	Yes No	
Partner testing discussed?	Yes No	
Window period explained?	Yes No	
Does the provider explain support services?	Yes No	
Allow time for questions?	Yes No	

Other note

Appendix 17 ADHERENCE QUESTIONNAIRE FOR PROVIDER

Questionnaire ID Number_____

Facility code_____

Instructions

You have been invited to participate because you are directly involved in providing HIV testing and counselling services to pregnant women in an antenatal clinic. If you agree to take part, you will complete a survey. I will like to know what you think about implementing routine HIV testing of pregnant women in this clinic to help us understand whether we are meeting their needs and help us improve on these services. This survey is completely anonymous (your name will not be used), and participation is voluntary. You can skip questions that you do not want to answer. The survey will take you about 15-20 minutes to complete.

SECTION A: SOCIODEMOGRAGRAPHIC CHARACTERISTICS

1. **Sex: [**] Female [ ]Male
2. How old are you? In years _____
3. What was your last level of schooling completed?
   [ ] Senior High
   [ ] Certificate
   [ ] Diploma
   [ ] 1st degree
   [ ] 2nd degree
   [ ] other, please specify……
4. What is your primary profession or role (Check one response)
   [ ] HIV counsellor
   [ ] Nursing assistant
   [ ] Registered nurse
   [ ] Registered Midwife
   [ ] Physician Assistant
   [ ] Medical doctor
   [ ] other, please specify_____

5. Do you provide any of the under-listed routine HIV testing and counselling-related services personally?

		Yes	No
a.	Pre-test counselling/information given	[ ]	[ ]
b.	HIV testing	[ ]	[ ]
c.	Post-test Counselling	[ ]	[ ]
d.	ARV for mother	[ ]	[ ]
e.	ARV for infants	[ ]	[ ]
f.	Referral of HIV positive mothers	[ ]	[ ]

g. Providing psychological support [ ] [ ]
h. Supervision of staff conducting routine HIV testing [ ] [ ]

6. For how long you have been providing HIV testing and counselling services? *in years and months*
   a. ……. Year(s)
   b. ……. month(s)

Item	Essential elements	Code
A	**Pre-test information**	
	I explain the HIV testing process to clients	**Yes/No**
	I explain Mother-to-child transmission	**Yes/No**
	Meaning of positive & negative explained	**Yes/No**
	Mother aware of preventive options for HIV	**Yes/No**
	Mother given opportunity to ask question	**Yes/No**
	Opportunities to improve the use of research were identified	**Yes/No**
B	**Consent**	
	The pregnant woman agreed to test	**Yes/No**
	Mother informed about her right to decline the test	**Yes/No**
C	Confidentiality	
	Explained that results would not be shared	**Yes/No**
	Provider & client believed results kept confidential	**Yes/No**
D	**Post-test counselling for clients testing negative**	
	Meaning of results explained	**Yes/No**
	Advise on prevention	**Yes/No**
	Partner testing discussed	**Yes/No**
	Window period explained	**Yes/No**
	Explain support services	**Yes/No**
	Allow time for questions	**Yes/No**

Appendix 18 ADHERENCE SELF-REPORT FOR PREGNANT WOMEN

Questionnaire ID Number_____

Facility code_____

This survey is completely anonymous (your name will not be used), and your participation is voluntary. You do not have to answer any question that you do not want to answer and can skip these questions. The survey will take you about 15-20 minutes to complete. Thank you for your time.

SECTION A

1. Were you aware that HIV testing is done routinely in this clinic?
   a. [ ]Yes
   b. [ ]No
2. Were you tested for HIV today?
   a. [ ] Yes
   b. [ ] No
   c. [ ] Not sure *if NO, skip to Q6*
3. If YES to question 2 above, did you receive your test results?
   a. [ ] Yes
   b. [ ] No

SECTION B: PRE-TEST INFORMATION/COUNSELLING

4. Before your blood/oral sample was taken for testing, did your health care provider or counsellor do any of the following:

		Yes	No
a.	explained testing process and how the test works?	[ ]	[ ]
b.	explained how to prevent transmitting HIV to your child?	[ ]	[ ]
c.	explained n what it means to test positive/negative?	[ ]	[ ]
d.	offered advice on how to prevent spread of HIV?	[ ]	[ ]
e.	mentioned that results would not be shared with	[ ]	[ ]
f.	anyone except clinic staff who care for you?	[ ]	[ ]
g.	do you believe your result was kept confidential?	[ ]	[ ]
h.	allow time for you to ask questions?	[ ]	[ ]

SECTION C: CONSENT PROCESS

5. Did your provider tell you that you have the choice to decline test?
   [ ] yes
   [ ] no
6. Did a health worker ask you whether you agreed to be tested for HIV before your HIV test was done?
   [ ] yes
   [ ] no
7. Did you agree to be tested?
   [ ] yes
   [ ] no
8. Did you feel that you could have said no?
   [ ] yes
   [ ] no
9. Was anyone else involved in getting your agreement to be tested?
   [ ] Yes
   [ ] No
10. Who? _____

SECTION D: CONFIDENTIALITY OF TESTING PROCESS

11. How important is it to you that your health workers keep your HIV results confidential and do not reveal them to anyone else without your permission?
    [ ]Very important

[ ]Somewhat important
[ ]Not important

12. Did your provider explain that results would not be shared?
[ ]Yes
[ ]No

13. Do you think that these health workers have kept your test results confidential?
[ ]Yes, protected confidentiality
[ ]No, did not protect the confidentiality

SECTION E: POST-TEST SERVICES FOR CLIENT TESTING NEGATIVE

14. After giving your test results, did a health care provider do any of the following

	Yes	Nc
a. explain the meaning of the test result?	[ ]	[ ]
b. offered advice on preventive measures?	[ ]	[ ]
c. suggested that your sexual partner(s) be tested for HIV?	[ ]	[ ]
d. Discuss window period with you?	[ ]	[ ]
e. Discuss support services with you?	[ ]	[ ]
f. Allowed time for you to ask questions?	[ ]	

SECTION E: DEMOGRAPHICS

Now I would like to ask you some things that will help me know more about you.

15. What is your age?.....
16. Place of resident
    a. [ ] Urban
    b. [ ] Peri-urban
    c. [ ]Rural
17. Marital status
    a. [ ] Single,
    b. [ ] Divorced,
    c. [ ] Separated
    d. [ ] Married,
    e. [ ] Cohabitating
18. Number of pregnancies
    a. [ ] First pregnancy
    b. [ ] more than 1 pregnancy
19. Occupation
    a. [ ] Unemployed
    b. [ ] Student
    c. [ ] Employed
20. What is the highest education level you/your partner have completed?

	You	Your partner
No formal education	[ ]	[ ]
a. Completed primary school	[ ]	[ ]
b. Completed junior high school	[ ]	[ ]
c. Completed senior high school	[ ]	[ ]
d. Some diploma	[ ]	[ ]
e. College degree or higher	[ ]	[ ]
f. Don't know	[ ]	[ ]

Appendix 19 ADHERENCE SELF-REPORT FOR PROVIDER

Questionnaire ID Number_____

Facility code_____

Instructions

You have been invited to participate because you are directly involved in providing HIV testing and counselling services to pregnant women in an antenatal clinic. If you agree to take part, you will complete a survey. I will like to know what you think about implementing routine HIV testing of pregnant women in this clinic to help us understand whether we are meeting their needs and help us improve on these services. This survey is completely anonymous (your name will not be used), and participation is voluntary. You can skip questions that you do not want to answer. The survey will take you about 15-20 minutes to complete.

SECTION A: SOCIODEMOGRAGRAPHIC CHARACTERISTICS

Sex: [ ] Female [ ]Male
How old are you? In years _____

1. **What was your last level of schooling completed?**
   [ ] Senior High
   [ ] Certificate
   [ ] Diploma
   [ ] 1st degree
   [ ] 2nd degree
   [ ] other, please specify……

2. **What is your primary profession or role (Check one response)?**
   [ ] HIV counsellor
   [ ] Nursing assistant
   [ ] Registered nurse
   [ ] Registered Midwife
   [ ] Physician Assistant
   [ ] Medical doctor
   [ ] other, please specify_____

3. **Do you provide any of the under-listed routine HIV testing and counselling-related services personally?**

		Yes	**No**
a.	Pre-test counselling/information given	[ ]	[ ]
b.	HIV testing	[ ]	[ ]
c.	Post-test Counselling	[ ]	[ ]
d.	ARV for mother	[ ]	[ ]
e.	ARV for infants	[ ]	[ ]
f.	Referral of HIV positive mothers	[ ]	[ ]
g.	Providing psychological support	[ ]	[ ]
h.	Supervision of staff conducting routine HIV testing	[ ]	[ ]

4. **For how long you have been providing HIV testing and counselling services?** ***in years and months***
   ……Year(s)
   ……..month(s)

SECTION B: PRE-TEST INFORMATION/COUNSELLING

5. Before your blood/oral sample was taken for testing, did you tell the woman any of the following:

		Yes	No
a.	testing process and how the test works?	[ ]	[ ]
b.	mother to child transmission of HIV?	[ ]	[ ]
c.	what it means to test positive/negative?	[ ]	[ ]
d.	offered advice on how to prevent spread of HIV?	[ ]	[ ]
e.	mentioned that results would not be shared with		
f.	anyone except clinic staff who care for you?	[ ]	[ ]
g.	do you believe you kept result confidential?	[ ]	[ ]
h.	allowed time for you to ask questions?	[ ]	[ ]

SECTION C: CONSENT PROCESS

6. Do you tell women that they have the choice to decline test?
[ ] yes
[ ] no

7. Do you ask whether they agree to be tested for HIV before proceeding to do test?
[ ] yes
[ ] no

8. Do they agree to be tested before testing?
[ ] yes
[ ] no

SECTION D: CONFIDENTIALITY OF TESTING PROCESS

9. How important is keeping the client's HIV test results confidential to you?
[ ] Very important
[ ] Somewhat important
[ ] Not important

10. Do you explain to clients that results would not be shared?
[ ] Yes
[ ] No

11. Do you think that you can keep client test results confidential?
[ ] Yes, protected confidentiality
[ ] No, did not protect the confidentiality

SECTION E: POST-TEST SERVICES FOR CLIENT TESTING NEGATIVE

12. After giving negative test results to clients, did you do any of the following?

		Yes	No
a.	explained the meaning of the test result	[ ]	[ ]
b.	offered advice on preventive measures?	[ ]	[ ]
c.	suggested that their sexual partner(s) be tested for HIV?	[ ]	[ ]
d.	discussed window period with them?	[ ]	[ ]
e.	discussed support services with them?	[ ]	[ ]
f.	Allowed time for them to ask questions?	[ ]	[ ]

Appendix 20 SAMPLE SEARCH STRATEGY (MEDLINE)

Set#	Searched for	Database	Results
S1	mesh(hiv) AND human(yes)	MEDLINE®	21934
S2	mesh(HIV infections) AND human(yes)	MEDLINE®	163669
S3	mesh(AIDS serodiagnosis) AND human(yes)	MEDLINE®	6249°
S4	mesh(prenatal diagnosis) AND human(yes)	MEDLINE®	42791
S5	mesh(pregnancy) AND human(yes)	MEDLINE®	649167°
S6	mesh(mass screening) AND human(yes)	MEDLINE	90158
S7	(mesh(hiv) AND human(yes)) OR (mesh(HIV infections) AND human(yes)) OR (mesh(AIDS serodiagnosis) AND human(yes))	MEDLINE®,	220930°
S8	(mesh(prenatal diagnosis) AND human(yes)) OR (mesh(pregnancy) AND human(yes))	MEDLINE®,	654540°
S9	((mesh(hiv) AND human(yes)) OR (mesh(HIV infections) AND human(yes)) OR (mesh(AIDS serodiagnosis) AND human(yes))) AND ((mesh(prenatal diagnosis) AND human(yes)) OR (mesh(pregnancy) AND human(yes)))	MEDLINE®,	12503°
S10	(mesh(mass screening) AND human(yes)) AND (((mesh(hiv) AND human(yes)) OR (mesh(HIV infections) AND human(yes)) OR (mesh(AIDS serodiagnosis) AND human(yes))) AND ((mesh(prenatal diagnosis) AND human(yes)) OR (mesh(pregnancy) AND human(yes))))	MEDLINE®,	737°
S11	(mesh(evaluation studies) OR mesh(program evaluation) OR mesh(process evaluation)) AND human(yes)	MEDLINE	163164
S12	mesh(monitoring) AND human(yes)	MEDLINE	140838
S13	((mesh(evaluation studies) OR mesh(program evaluation) OR mesh(process evaluation)) AND human(yes)) OR (mesh(monitoring) AND human(yes))	MEDLINE	301718°
S14	((mesh(mass screening) AND human(yes)) AND (((mesh(hiv) AND human(yes)) OR (mesh(HIV infections) AND human(yes)) OR (mesh(AIDS serodiagnosis) AND human(yes))) AND ((mesh(prenatal diagnosis) AND human(yes)) OR (mesh(pregnancy) AND human(yes))))) AND (((mesh(evaluation studies) OR mesh(program evaluation) OR mesh(process evaluation)) AND human(yes)) OR (mesh(monitoring) AND human(yes)))	MEDLINE®, .	28°

Appendix 21 CHARACTERISTICS OF SYSTEMATIC REVIEWS

First author	Date published	No. of articles	A study conducted before or after WHO revised guideline (2007)	No of subjects	Quality of studies	Countries
(Ibekwe et al., 2017a)	2017	**18;** Prospective (9), Retrospective (7), randomised (2)	Before- 14 After - 4	942863	Not reported	Africa (8), USA (5), Europe (3), Australia (1), Asia (1)
(Ibekwe et al., 2017b) Economic impact	2017	10 Economic evaluation studies	Before – 9 After - 1	NR	90% rated medium to high quality	Asia (3), Australia (2), Europe (4), USA (1**) no article in sSA**.
(Wettstein et al., 2012)	2012	44	Before 19 After 25	75172	NR	All from 15 sSA countries
Hensen (2012)	2012	10 NRS-9 RCT-1	Before 7 After 3	784469	weak n = 2, moderate n = 7 and strong n = 1	Africa 7, Europe (2) USA (1)
Ferguson 2012(Ferguson et al., 2012)	2012	20 Non RCTs	All published after guideline release	27001 HIV positive women	NR	16 sSA,
Tudor(Tudor Car et al., 2013)	2011	1 Cluster RCT	After	7664 women	Low risk of bias	Zambia
(Pai, Tulsky, Cohan, Colford Jr, & Reingold, 2007)	2007	17 studies Cross-section 13 Surveys 4	Before	106-4849	Potential for selection bias,	USA -4 Africa 6 Latin America -3 Asia 2 Jamaica
ECDC European Center for Disease Prevention and control (ECDC, 2017)	2017	3 economic studies 8 effectiveness, non-randomised studies	3 before, 5 after	NR	Three studies on cost-effectiveness adjudged high quality, even though did not contain comparator	Only EU countries
Blackstone (Blackstone et al., 2017)	2017	27 All non RCT Observation quantitative Qualitative mixed	Before 5 After 22	37581 181-14235	NR	11 African countries
Bain (Bain, 2016)	2015	21 Policy analysis documents (9) Systematic reviews (1) Empirical studies (11)	Before 2	NR	NR	Worldwide

Appendix 22 CHARACTERISTICS OF REVIEWED POLICY DOCUMENTS

Document Title	Authored by	Year released	Document type	Target
1. Differentiated Service Delivery for HIV in Ghana	GHS	2017	Handbook	Gen population
2. Ghana AIDS Commission ACT	GAC	2016	Act	Gen. population
3. Locate, Test, Treat and Retain Ghana Campaign	GHS/NACP	2016	Strategic	Gen. population
4. Ghana National HIV and AIDS Strategic Plan (2016-2020)	GAC	2016	Strategic	Gen. population
5. Country AIDS response Progress Report 2013-2014	GAC	2015	Report	Gen. population
6. National Guidelines for PMTCT	MoH	2014	Guideline	Pregnant women
7. Status Report	GHS/NACP	2014	Report	Gen. population
8. PMTCT handbook for healthcare providers in Ghana	GHS/NACP	2014	Handbook	Pregnant women
9. Ghana National HIV and AIDS STI Policy	GAC	2013	Policy	Gen. population
10. Prevention of mother-to-child transmission in Ghana, scale-up plan 2011-2015	GAC	2010	Strategic	Pregnant women
11. National guidelines for the implementation of HCT	GAC	2008	Guideline	Gen population

Appendix 23 SUMMARY OF SYSTEMATIC REVIEW FINDINGS

Reference	Review aim/main outcome	Main findings
(Ibekwe et al., 2017a)	Evaluated the clinical outcome of routine screening of human immunodeficiency virus in antenatal clinic settings	• **Testing rates: (1)** Routine testing -(68–99.9%; median 88%). **(2)** Comparison (22– 93.5%; median 59%) • **Maternal HIV case detection rates (1)** Nearly doubled following the adoption of routine testing at 99 and 45% values during opt-in. • **Linkage to care (reported on six studies):** ranged between 12.9– 77.2%.
(Ibekwe et al., 2017b)	The economic impact of routine testing of HIV in antenatal (ANC) settings	• programmes found to be cost-effective and cost-saving; showing cost savings between $5,761.20 and $3.69 million per case of previously undiagnosed maternal HIV-positive infection prevented. • *Routine HIV testing is both cost-effective and cost-saving compared to the alternatives.*
(Wettstein et al., 2012)	To determine the magnitude and reasons for loss to programme and poor antiretroviral prophylaxis coverage in the prevention of mother-to-child transmission (PMTCT) programmes in sub-Saharan Africa.	• Provider-initiated opt-out testing resulted in much higher coverage than patient-initiated (opt-in) testing, with an estimated 94% of women being tested with the first approach compared to 58% with the second. • The uptake of ART prophylaxis for mothers was unsatisfactory, and the percentage of cART eligible patients who received the recommended treatment low. • Overall, 70% of women received some form of ERV prophylaxis, 64% of HIV exposed infants accessed early infant diagnosis by PCR around 6 weeks postpartum and 55% were tested between 12 and 18 months
Hensen (2012)	1. Assessed contribution of PITC to achieving universal testing of pregnant women 2. Assessed whether PITC adoption adheres to pre-test information, post-test counselling procedures and linkage to treatment	**Uptake:** Pre-intervention testing uptake ranged from 5.5% to 78.7%. **;** Following PITC introduction, testing uptake increased by a range of 9.9% to 65.6%, with testing uptake ‡85% in eight studies. **Adherence;** pre-test information was provided between 91.5% and 100% and post-test counselling between 82% and 99.8% of pregnant women. Linkage to ARVs for prevention of mother to child transmission (PMTCT) was reported in five studies and ranged from 53.7% to 77.2%. PITC was considered acceptable by ANC attendees..
(Tudor Car et al., 2011)	to assess the effect of integration of perinatal PMTCT interventions with other health care services on the proportion of pregnant women, mothers and infants receiving PMTCT interventions	• There is almost no evidence from reliable, experimental design studies on the effect of integrating PMTCT interventions with other health services on intervention coverage, service uptake, quality of care and health outcomes.
(Pai, Tulsky, Cohan, Colford, & Reingold, 2007)	summarize the overall diagnostic accuracy of rapid HIV tests in pregnancy, and outcomes such as acceptability, patient preference, feasibility and impact of rapid testing.	The overall sensitivity and specificity of blood-based rapid tests were high compared with rapid oral tests. A two-step testing strategy, mainly parallel testing, was superior to single-test strategy in labour and delivery settings. Overall, rapid HIV testing was highly accurate compared with conventional tests and offered a clear advantage of enabling the implementation of timely interventions to reduce MTCT of HIV.
(Blackstone et al., 2017)	explored the barriers and facilitators to routine antenatal HIV testing from the perspective of pregnant women in sub-Saharan Africa during the implementation period of the Millennium Development Goals	The most common barriers identified include communication with male partners, patient convenience and accessibility, health system and health-care provider issues, fear of disclosure, HIV-related stigma, the burden of other responsibilities at home, and the perception of antenatal care as a ‘‘woman’s job.’’ Routine testing among pregnant women is crucial for the eradication of infant and child HIV infections.
(Tudor Car et al., 2013)	to assess the uptake of WHO-recommended integrated perinatal prevention of mother-to-child transmission (PMTCT) of HIV interventions in low- and middle-income countries	The proportion of women attending ANC who were counselled and who were tested was high; 96% (range 30–100%) and 81% (range 26–100%), respectively. However, the overall median proportion of HIV positive women provided with antiretroviral prophylaxis in antenatal care and attending labour ward was 55% (range 22–99%) and 60% (range 19–100%), respectively. However, the overall median proportion of HIV positive women provided with antiretroviral prophylaxis in antenatal care and attending labor ward was 55% (range 22–99%) and 60% (range 19–100%), respectively.