UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

A research report submitted to the **Faculty of Health Sciences** in partial fulfilment of the requirement for the award of **Master of Science in Epidemiology** in the **field of Implementation science**

Titled

IMPLEMENTATION FIDELITY OF THE CERVICAL CANCER SCREENING GUIDELINES FOR HIV-INFECTED WOMEN IN EKURHULENI, SOUTH AFRICA.

BY

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August 2020

DECLARATION

I, ***Pureheart Ejovwokeoghene Bazunu***, declare that this research report is my independent work. I am submitting this research work in partial fulfilment of the requirement for the degree of Master of Science (MSc) in Epidemiology (field of Implementation Science) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for examination and the award of any degree at this or any other institution of higher learning.

_____

(Signature of candidate)

Date: Seventh day of August 2020

DEDICATION

To JEHOVAH, THE ALMIGHTY GOD and HIS beloved Son Jesus Christ.

ABSTRACT

Background: The South African national cervical screening guideline contains recommendations to guide the screening of HIV-infected women. However, despite the availability of this evidence-based guideline, the cervical cancer screening coverage remains low amongst HIV-infected women. Whether health workers adhere to this guideline has not been determined. This study, therefore, aims to assess health workers' adherence to the national guideline on cervical cancer screening of HIV-infected women (fidelity of implementation), and evaluate factors associated with fidelity level.

Methods: This was a cross-sectional study with an analytical component. It was conducted in primary healthcare facilities in the Ekurhuleni Metropolitan Municipality in 2019. A survey of 177 primary healthcare providers was conveniently sampled from primary healthcare facilities in Ekurhuleni health sub-districts North (N1) and South (S2). A self-administered questionnaire collected data on four implementation fidelity constructs as well as data on potential determinants of fidelity (provider characteristics, guideline characteristics, system characteristics, and implementation characteristics). Fidelity level was calculated as a score derived by summing the scores from each of the four constructs. The score was converted to a percentage (maximum possible score 100). Exploratory factor analysis was used to categorise the fidelity score into a binary variable (high and low fidelity). Logistic regression was used to analyse for an association between each determinant and the implementation fidelity level, using odds ratios as the measure of association. A generalised structural equation model (GSEM) was used to investigate the indirect relationships between the determinants and implementation fidelity of the cervical screening of HIV-infected women by the healthcare providers. This model adjusted for random effects at the facility level, using a mixed-effects modelling approach.

Results: The median implementation fidelity percentage score was 84.85, with an interquartile range of 75.76 – 87.88. In this study, after categorising fidelity, 62.15% of primary healthcare workers (PHCWs) were seen to have high fidelity, while the remaining 37.85% had low fidelity. The median (IQR) provider characteristics per cent score, guideline characteristics per cent score, system characteristics per cent score and implementation characteristics per cent score were 85.56 (80 – 92.22), 86.15 (76.92 –

92.31), 76.67 (66.67 – 86.67) and 60 (53.33 – 80), respectively. In the logistic regression analysis – unadjusted model, the provider characteristics (OR 1.07; 95% CI 1.04 to 1.11), guideline characteristics (OR 1.05; 95% CI 1.02 to 1.08), and the participants' level of knowledge of the updated guidelines (OR 1.04; 95% CI 1.02 to 1.06) positively influenced implementation fidelity. In the logistic regression analysis – adjusted model, the provider characteristics (OR 1.05; 95% CI 1.01 to 1.10), and the participants' level of knowledge of the updated guidelines (OR 1.02; 95% CI 1.00 to 1.06) were statistically significantly associated with implementation fidelity. From the GSEM path analysis, having the provider characteristic acting as an endogenous (outcome) variable, a significant indirect relationship was found between implementation fidelity and determinants such as; the guideline characteristics (OR 1.03; 95% CI 1.01-1.04), the participant's level of knowledge of the updated guidelines (OR 1.01; 95% CI 1.01-1.02).

Conclusion

This study revealed a high level of primary healthcare workers' fidelity of implementation of the guidelines for the cervical cancer screening of HIV-infected women. Key determinants such as provider characteristics and guideline characteristics were found to be important factors influencing the level of implementation fidelity. These factors should be considered when developing future implementation strategies for improving the level of fidelity.

ACKNOWLEDGEMENT

Firstly, I give special thanks to GOD ALMIGHTY and HIS only begotten son Jesus Christ, for their faithfulness, immense grace, and mercies, which I richly enjoy, and continue to.

Secondly, profound appreciation to my beloved parents; Mr. & Mrs Michael O. Bazunu, my siblings; Mr Michael (Jnr) Bazunu, Dr Gamaliel Bazunu and my sisters-in-law, for their unwavering love and support all through this academic journey.

Special thanks also go to my research supervisors; Professor Eustasius Musenge and Dr Mary Kawonga for their academic guidance through this herculean task of compiling this research report. Appreciation also goes to Mr Baruwa Ololade, Mr Solomon Narh-Bana, Dr Victor Williams, Dr Kenneth Akwue and others too numerous to mention, who gave me various invaluable advice and motivation in completing this research work.

Finally, I extend my heartfelt gratitude to Professor Jonathan Levin for his tutelage and assistance during this research year.

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DEFINITION OF TERMS

Implementation Fidelity – This is the extent to which interventions, guidelines or programmes are implemented as initially designed or intended by the programme developers.

Provider's characteristics - These are the inherent traits of the primary healthcare providers that influence implementation fidelity.

Guideline characteristics – These are the features of the cervical screening guideline, which determines the extent of its use by the healthcare provider's and that ultimately influences implementation fidelity.

Implementation characteristics – These refer to the underlying traits of the instituted implementation strategies in this context, which may affect the fidelity of implementation.

System characteristics – These refer to the health system factors that influence implementation fidelity.

LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti-Retroviral
CAP	Community-Acquired Pneumonia
CDC	Center for Disease Control
CFA	Confirmatory Factor Analysis
EFA	Exploratory Factor Analysis
GDP	Gross Domestic Product
GSEM	Generalised structural equation model
HCT	HIV Counseling and Testing
HIV	Human Immunodeficiency Virus
hrHPV	High-risk Human Papillomavirus
ICC	Invasive cervical cancer
IF	Implementation Fidelity
LMICs	Low- and Middle-Income Countries
NHLS	National Health Laboratory Services
OR	Odds ratio
PHCWs	Primary Health Care Workers
REDCap	Research electronic database
SEM	Structural equation model
STIs	Sexually Transmitted Infections
UTT	Universal Test and Treat
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

Globally, cancer of the cervix is known to be the fourth most common female cancer with new cases estimated at 570 000 in the year 2018, thereby constituting 6.6% of all cancers in women (1). Low- and middle-income countries (LMICs) bear much of this burden, with about 90% of the 311 000 cervical cancer mortalities in 2018 occurring in this region (2). In sub-Saharan Africa, where a vast number of cases exist, cancer of the cervix is the chief cause of mortality among females (3).

In South Africa, cancer of the cervix ranks as the second most common cause of female cancer, and it is also noted as the foremost cause of female cancer-related deaths, in women aged 15 to 44 years, i.e. in the reproductive age group (4, 5). Current evaluations propose that with a population of 20.2 million women aged 15 years and above, who stand a chance of acquiring cancer of the cervix, this cancer is diagnosed annually in 12 983 women with 5 595 recorded deaths as a result of this cancer (5). This figures construe to a crude mortality rate of more than half and is comparable to an age-standardized mortality rate of 19.2 per 100 000 women per year (5, 6). Cancer of the cervix remains one of South Africa's major public health challenge, and it poses a high burden affecting 1 out of 41 South African women (7). Despite it being highly expensive to treat in an already resource-constrained economy, it renders the affected women chronically ill, devastated and economically inactive. This ill-state of these women, in turn, creates emotional trauma and financial burden on their families and communities (8). All these effects put together can further negatively impact the economic status and gross domestic product (GDP) of the country (6, 8).

The huge burden of HIV-infection in sub-Sahara Africa contributes to the elevated rate of cervical cancer in this region. South Africa records the highest number of HIV-infections worldwide, with women having about 60% of the new HIV-infections (4, 9). Human immunodeficiency virus (HIV) is a virus that attacks and suppresses the human immune

system rendering the infected host defenceless against harmful organisms and prone to a wide range of infections and disease conditions. One of such harmful organisms is the Human papillomavirus (HPV) which affects sexually active men and women (10). In comparison with HIV-uninfected women, the HIV-infected women carry a greater risk of contracting a chronic persistent HPV infection (10, 11). This HPV infection is particularly with the high-risk HPV strains (hrHPV 16 & 18), and sometimes with other high-risk genotypes, like the hrHPV 45 which is implicated most importantly within the African population (2, 10, 12). These HPV genotypes are regarded as high-risk because of their carcinogenic potentials, and they are essential aetiological agents of cancer of the cervix, accounting for about 70% of the causes (2). It is for this reason that this group of women, i.e. HIV-infected women, are highly susceptible to developing the pre-invasive cervical disease and faster progression rate to invasive cervical cancer (ICC) (10, 13-16). The knowledge about the varying carcinogenic potentials of these hrHPV strains is important in informing the cervical cancer prevention programmes and in stratifying the risk of HIV-infected women, especially in Africa (12). The average age of diagnosis of cancer of the cervix in South Africa is about 45 years, and it is usually 10 to 15 years younger in women co-infected with HIV (6, 15, 17).

The Centre for Disease Control (CDC) expanded the case-definition for AIDS surveillance in the early ‘90s, by the addition of three new indicator clinical conditions – one of which was invasive cancer of the cervix (18). Progressively, in the early 2000s, the World Health Organization (WHO) grouped cancer of the cervix as stage four Acquired Immune Deficiency Syndrome (AIDS) defining illness (19). With the advent and initiation of ARV treatment, the life expectancy of HIV infected individuals has increased considerably over the years. This increased life expectancy, however, has its drawbacks, as an accompanying rise in the burden of chronic diseases, including cervical cancer, has been noted (20).

A two- to seven-fold increase in the risk of invasive cervical cancer (ICC) has been recorded among these HIV-infected women (21). In 2016, a South African study, estimated the burden of invasive cervical cancer (ICC) in women infected with HIV, to be

between 81 – 247 cases per 100 000 women (15). This figure comes close to be about five times the current national age-standardised incidence of 43.5 per 100,000 (5, 22).

Due to the public health relevance and high figures of cervical cancer incidence in this region and globally, secondary prevention by early detection and diagnosis of this cancer has been propagated to play a key role in drastically reducing its mortality and morbidity (23). Towards achieving this, an actionable, evidence-based screening guideline was developed by the WHO and CDC (24). This guideline dwells on many key areas about cervical cancer, including, the various screening techniques that are available and focused on cervical cancer early detection. These techniques range from; cytology-based method – Papanicolaou smear (Pap smear), human papillomavirus (HPV) DNA testing and visual inspection with acetic acid (VIA) or visual inspection with Lugol's iodine (VILI). These methods are scientifically tested and proven, with different levels of sensitivity (13, 23, 25).

The WHO cervical screening guideline was adopted and modified to fit the South African context (6). This adopted guideline is also readily available and has been subsequently updated to accommodate this high-risk group, i.e. HIV-infected women (6, 26). This updated South African guideline 2017 states that women should commence screening not earlier than 30 years of age, and they should undergo three smears in their lifetime with an interval of ten years in between each smear (6). The guideline requires a different screening approach for HIV-infected women, which is distinct from HIV-uninfected women (6, 26). This approach includes a younger age of screening (less than 30 years), and more frequent screening intervals (three yearly) for HIV-infected women because of their higher cervical cancer risk (26).

However, despite the availability of the evidence-based screening guideline, coverage of cervical screening of HIV-infected women is low (26.7%) (27). This low coverage is seen from the notable disproportion in the NHLS 2015/16 statistics of HIV test done amongst women and the number of pap smear tests that were taken during the same period (27).

In a bid to understand this defect, plausible reasons have been put forward. Some of these reasons include; an uncoordinated and unorganised system for cervical screening amongst HIV-infected women (28), an incredibly slow rate of implementation of the

screening guidelines as well as poor adherence of healthcare providers to this guideline (23, 28, 29). The poor level of adherence of the healthcare provider to evidence-based guidelines has been noted to be a factor contributing to why interventions of known effectiveness do not attain expected effectiveness (29-32). For this reason, it is important to measure and monitor the level of provider adherence (fidelity) to clinical practice guidelines in South Africa (31).

Further bottlenecks to the successful implementation of cervical screening programmes can also be examined from the standpoint of the clients (33, 34). From this perspective, it has been reported that the norms/beliefs of women, the cost and preferences of screening methods (35), clients loss-to-follow-up after initial screen (36, 37), their attitudes and awareness of the cervical screening practices (38), has a compounding effect in negatively influencing the overall success of screening programmes. Unfortunately, in the South African context, these client-based issues are further complicated by differences in race, literacy levels, socio-economic status, and the high burden of HIV-infection – a population which has its accompanying multifaceted competing health and social needs (29).

Given the introduction and implementation of the South African national school-based HPV vaccination programme and the global awareness that HPV-vaccines shows promise as a primary preventive measure against cervical cancer (37, 39, 40), healthcare workers may become laid-back in fully implementing and executing their roles in the performance of cervical screening according to the national guidelines. Ideally, this HPV vaccination should not distract but rather strengthen our focus on other women who are already infected with HPV and will require the early detection of abnormal cervical cells by an already established pap-based screening method and subsequent treatment as required (41).

1.2 LITERATURE REVIEW

1.2.1 Implementation fidelity

Fidelity is defined as “the degree to which programmes or evidence-based interventions or practices are implemented as initially designed or intended by the program developers (42). Implementation fidelity is one amongst other implementation outcomes that are markers of implementation effectiveness or success (42, 43). Implementation effectiveness is an important step on the path to intervention effectiveness (43). Implementation research makes use of theories and frameworks to guide our understanding of implementation outcomes (42, 43). Proctor and colleagues proposed eight conceptually peculiar implementation outcomes. They include fidelity, acceptability, feasibility, appropriateness, adoption, implementation cost, sustainability, and penetration (42). Each of these outcomes can be measured at different stages of intervention implementation; either during the; early, mid or late implementation stages, as the case may be (42). This study concentrates on implementation fidelity.

Implementation fidelity, as is defined above, is an idea that has been in existence and is rather not new. It has been referred to as adherence, the integrity of programme, compliance, quality of programme delivery (42). However, it is more recently that ways in-which fidelity can be measured and operationalised began to spring-up and put forward (44). The concept of implementation fidelity is described using adherence to interventions as essentially its primary measurement (43). Subcategories exist under adherence, which includes frequency, duration, content, and coverage (43). Thus, when the implementation of interventions adheres completely to the design as authorised by the initial developers in terms of content, frequency, duration, and coverage, then fidelity (adherence) can be said to be high (43).

A striking question commonly asked is why fidelity should be considered as important (44). Studies have consistently shown evidence that there are a great impact and a successful outcome when interventions are implemented with fidelity (45-48). Although most of these studies are in the mental and behavioural health field, it contributes to giving an understanding of this rationale. For example, Botvin and colleagues, who conducted

a randomised drug abuse prevention trial, arrived at a key finding (46). They revealed that the intervention group witnessed a drastic decline in drug users relative to controls (46). Within this intervention group, participants in the high fidelity sample (i.e. those who received the relatively complete model of the intervention) portrayed a stronger result (i.e. fewer drug users) and more significant outcomes, as opposed to the others who received the incomplete intervention design (46). Also, Fagan, who experimented with the introduction of a correctional intervention for chronically violent juvenile offenders, made similar conclusions (48). He reported that the study sites with the stronger and well-organized implementation of the programme design portrayed a significant reduction in the frequency and gravity of arrests/re-arrests of the experimental youths as compared to the youths in the control groups (44, 48).

It is also worthy to note that from the frontline implementers' point of view, balancing fidelity and adaptation of interventions to fit their context has been challenging (49). This imbalance has huge implications on healthcare provider's commitment to sustained program implementation and eventually to the overall effectiveness of the intervention (50, 51).

Some studies conducted in South Africa have tried to examine and measure the level of adherence of clinician's to clinical practice guidelines (31, 52-54). One such study conducted in rural district hospitals in the Bojanala district reported an overall adherence level of 51.9% by doctors to the treatment guidelines for hypertension (31). Also, a study done in a tertiary-level hospital in Durban, KwaZulu-Natal, which evaluated the adherence of the healthcare team to the antibiotic treatment guidelines for severe community-acquired pneumonia (CAP), reported a very poor adherence level of 8% (53). Furthermore, a retrospective review study which was done in primary care facilities in Cape Town Metro District, found that the overall guideline adherence of healthcare professionals for the prescribing practice of antibiotics was 45.1% (55). While there is still room for improvement, much more research of this kind should be encouraged, as this will provide more information about the implementation process, in order to benefit maximally from specific clinical interventions (42, 56).

This study adopts and modifies relevant constructs from two implementation research frameworks proposed by Carroll et al. (43) & Gurses et al. (57) to examine the fidelity of implementation of the national guideline of cervical cancer screening. Implementation fidelity can be analysed at the level of the individual providers, during the early to mid-stages of implementation (42).

1.2.2. The South African guideline for cervical cancer screening.

The screening guidelines for cancer of the cervix has evolved in South Africa. Beginning from the year 2000, when the National guideline for the screening of cervical cancer was launched – however, this guideline considered only asymptomatic women and did not account for HIV status (27). In the light of the increased cervical cancer risk in HIV-infected women, the HIV counselling and Testing (HCT) program launched in 2011 included a routine screening of HIV positive women who had a CD4 count ≤250/µl. In 2014, this was reviewed, and the then incumbent Health Minister declared that women with a positive HIV test result and a CD4 count of ≤500/µl qualified for cervical cancer screening (27). In 2016, the Universal test and treat (UTT) strategy, which replaced the HCT program, stated that all women testing positive for HIV should undergo a cervical smear irrespective of CD4 count level (27). This guidance was included in the revised national policy for cervical cancer prevention and control, developed and published by the South African National Department of Health in June 2017.

The South African National policy for cervical cancer prevention and control has guidelines for screening HIV-infected women (6, 26). The guideline recommendations are presented under the headings below:

- Screening technique – The recommended cervical screening technique in South Africa is the cytology-based pap smear test (6). This technique is largely prescribed because it is evidence-based, widely used and entrenched in most public and private health sector (26).
- Age of initiating and exiting screening – Concerning this, the guideline recommendation states that all HIV-infected women should start screening as

soon as diagnosed to be HIV positive. HIV-infected women below 30 years of age can undergo screening. The cervical screening of these women should continue for the rest of their lives (i.e. screening should never end).

- Frequency of screening intervals – Once an initial pap smear test of an HIV-infected woman is carried out, the timing of the subsequent follow-up screen depends on the results of the previous smear test. Those with a negative (normal) first smear test should undergo a follow-up screen after three years, while those with a positive (abnormal) smear result should have a confirmatory diagnosis (colposcopic biopsy) and if precancerous lesions confirmed, should be treated and have a follow-up screen after one year.
- Special considerations – The guideline recommended that all HIV-infected women should undergo cervical screening irrespective of their CD4 count levels, whether they are on ARV treatment or not, and irrespective of pregnancy status (i.e. cervical screening can be done in pregnancy up to 20 weeks gestational age) (6).

1.2.3 Factors that affect the implementation of practice guidelines

Various factors could contribute to the successful implementation of the screening guidelines for cervical cancer in HIV-infected women. According to Gurses et al. (2010) and other past pieces of literature, factors affecting the implementation of practice guidelines are grouped as; Guideline factors, Provider-related factors, and System-level factors, in order to logically elucidate this further (30, 57, 58).

1.2.3.1 Guideline factors

These factors embody what the clinical guideline entails and its features, from the developmental and design phase to its final use. It is viewed in terms of the guideline complexity, ambiguity of wordings and the procedural method suggested, i.e. how easy is it to understand and comprehend the guideline instructions and recommendations by the end-users – healthcare providers (57, 59). It has been suggested that clinical guidelines which actively involves the targeted healthcare professionals during the guidelines design and developmental stages are most likely to be adhered to, easily understood and relatable by the targeted end-users (60).

Other relatable characteristics of clinical guidelines that can affect the successful implementation include; the trialability, and applicability of the guideline, i.e. the ease to which healthcare providers can test or carry out the guideline recommendations (57, 58). Concerning the currently available cervical screening procedural techniques and the comparative differences amongst them, in terms of their relative ease-to-use and its application – from the process of cell/tissue sampling to interpreting the end-results (61), these can influence healthcare provider's choices and ultimately the success of screening programmes. Another feature is the compatibility of the guideline recommendations with the healthcare provider's norms, clinical evidence-based knowledge and the general population perceived specific public health needs (57). Also, the clinical guidelines should specify and state the clinical assessment methods, materials needed, and the healthcare professional's role at each stage of the management protocol (59).

1.2.3.2 Provider related factors

Healthcare professionals play a vital role, been forefront implementers that influence health/screening programmes. Some of the contextual provider-related factors that act as possible barriers that may hinder the proper implementation of cervical screening are highlighted. They include; the age and gender of the healthcare provider (62-64) – younger male patients may feel embarrassed in telling their patients to undress to undergo screening. Patients also, may feel awkward and refuse younger healthcare providers from attending to them (62).

Furthermore, a low recommendation of cervical screening by the service provider to the client (62) and even a lack of physician's referral to the point of testing (65), both play key roles in influencing the successful implementation of screening programmes. This lack of referral is linked to one of the system-level factors which underlie a poor integration of routine cervical cancer screening practices with HIV-care and management clinics (28, 65).

Healthcare provider's knowledge – been unfamiliar with the recommendations and to the key components of the screening guidelines (29, 58), their attitudes – insensitivity of a few healthcare professionals to patient's needs (64, 66) and perceptions to cervical cancer disease (62). These also tend to affect the successful implementation of the

guidelines. Towards understanding the perception of healthcare providers in the South African context, a study done amongst the registered nurses in primary health clinics in KwaZulu-Natal concluded that the nurses exhibited a positive perception as they showed gratitude towards the cervical screening programme and its expected benefits. They also reckoned that sexually active younger women were at higher risk of HIV and STIs, and for this reason agreed that the starting age of screening for this group of women should be reduced (52).

1.2.3.3 System-level factors

In addition to the other two factors discussed above, we have system-level factors that are implicated in affecting the implementation of clinical screening guidelines. Some of these factors include; Periodic paucity of screening materials – screening tools running out-of-stock and a delay in restocking supplies (34), Unavailability of workspace for screening – with the available spaces relatively few and overtly crowded (34). These few workspaces contribute to the flashback effect in having an elongated clinic waiting time, which further hinders the clients from undertaking screening test (34, 66). Lack of resources, shortage of healthcare workers (34) to provide the routine screening of women – which translates to heavy workload (58), has also been noted as a possible barrier (34). In addition to these, lack of staff training on the guidelines recommendation, poor supervision and limited support system (60), are all also implicated system-level factors.

Despite all these barriers, plausible facilitators to a successful implementation of the cervical cancer screening guideline can be hinged on the presence of the HIV illness (63). This line of thought is built on the fact that the epidemic of HIV in South Africa and all the heightened risk of other HIV-accompanying diseases – cervical cancer inclusive, has made it a prime focus in this context, in order to curb this cancer scourge.

It is pertinent to note that these factors listed above, plague the health workforce of most countries, especially the low- and middle-income countries (LMICs) (67). The underlying issues common to these countries are constrained resources – including financial, human and infrastructural. Resources are a prime focus when developing nations decide on what cervical screening technology is appropriate in their settings (68). Given the available screening technologies, low-cost screening VIA techniques have been proven and

recommended as a suitable test for Subsaharan Africa, and having the potential of increasing feasibility of cervical screening implementation (69-71). In South Africa, bearing in mind the inequitable distribution of health resources as well as the pros and cons of each available screening techniques, the national policy still recommends the pap-based screening method for the country (6). However, an allowance is given for the choice of the screening method to be used in each health setting based on their available resources (6, 26). This rationale may act as an added influence on healthcare workers adherence to the screening guidelines, as a result of discretionary judgement. This study will, therefore, help to illuminate these barriers further and examine how they relate with one another to affect the implementation fidelity of healthcare providers.

1.3 PROBLEM STATEMENT

Following the metamorphosis of the National policy for cervical cancer screening in 2011, through 2014 and in 2016, combined with the implementation of the programme, an exponential increase in the cervical smears was expected. However, there has not been a comparable increase in the number of pap smears received at the National Health Laboratory Services (NHLS) with the number of women tested HIV positive as recorded in the NHLS annual statistics for 2015/2016. This statistic revealed that women tested for HIV at the NHLS laboratory were 1 012 053 in 2015/16, while pap smears screened was 900 000 in 2015/2016 – with 26.7% (about 204 300) of these smears from HIV-infected women (27). The 1 012 053 women who were diagnosed with HIV in 2015/16, ought to all have undergone pap smear test as it is being recommended by the screening guideline (27).

A previous study done in South Africa has tried to examine the probable challenges for the lack of full implementation of the screening guideline. They revealed that it was either due to the chronic shortage of healthcare workers, coupled with the high infectious burden in this country and the lack of essential medical equipment (27). Similarly, a study conducted in Cape Town, South Africa, which analysed primary health clinic's data on recently diagnosed HIV-positive women, showed that the percentage of women who had done at least one pap smear was low (13.1%) (28). The possible cause of this was linked

to poor incorporation of the cervical cancer prevention with the care of the HIV-infected as a result of large patients volumes and the highly fragmented service provision witnessed especially in larger primary HIV clinics (28).

According to the screening guideline, every woman should be screened for cervical cancer at the point of being diagnosed with HIV-infection. It has been suggested that poor adherence and non-conformity of frontline healthcare providers with this recommendation could be a contributing factor to the low screening coverage amongst HIV positive women (72-74). However, studies on the fidelity of implementation of the screening guideline have not been conducted to confirm this. Although it was only in 2017 when the cervical cancer prevention and control policy was published and therefore more specific and formal guidelines for screening HIV-infected women were put forward, it is important to understand whether recommendations are adhered to, two years after the existence of the guidelines. There is a paucity of information on health workers' adherence to the 2017 guidelines for screening HIV-infected women, and the determinants affecting adherence. Therefore, this study will analyse the fidelity (adherence) level and its associated factors, in one health district in South Africa.

1.4 JUSTIFICATION

This study will provide data on the fidelity of implementation of the screening guideline focusing particularly on one of the implementation outcomes – fidelity (adherence) and help decipher the factors affecting their adherence to the National guideline for cervical cancer screening of HIV-positive women or high-risk population. Limited research has been carried out to assess the adherence to the cervical cancer screening guideline for HIV-infected women in Ekurhuleni, South Africa, the site for this study. Low implementation fidelity can cause potentially useful intervention guidelines and policies to appear ineffective. The research findings from this study will, therefore, be a valuable step in establishing the extent to which the cervical screening implementation process is executed as prescribed in the guideline, and this will further strengthen our confidence in the effectiveness of this evidence-based screening guideline. Understanding the level of fidelity to the 2017 national guidelines can help in future policy decision-making on

effective planning and implementation strategies. These strategies such as the provision of technical support and adequate training of primary healthcare providers on the current clinical cervical cancer screening practices will help to promote further the cervical cancer prevention and control for HIV-infected women in South Africa.

1.5 CONCEPTUAL FRAMEWORK

Implementation research makes use of theories and frameworks to guide our understanding of implementation outcomes (75). This study which examines fidelity has adopted and modified relevant constructs from two implementation research frameworks to develop the framework that was used for this analysis (Figure 1.1).

Firstly, the implementation fidelity conceptual framework developed by Carroll et al., which measures fidelity traditionally as adherence, and they identified four subcategories of adherence which include; content, frequency, duration, and coverage (43). They described the 'content' as the active-ingredients that the intervention attempts to convey to its receivers. 'Coverage' which is spoken to be synonymous with 'dose', bear slight connections with 'frequency' and 'duration'; which collectively suggests whether an intervention is carried out as often and for as long a time period as initially designed while capturing all intended recipients of such intervention. It was also proposed that the extent or level of adherence to the intervention, is influenced by some other variables which were termed potential moderators (43).

For this study, the 'content and coverage' of the cervical cancer screening guidelines entails that a cervical screen test is done for all HIV-positive women at the point of diagnosis of infection, irrespective of her age, whether on ARV treatment, CD4 levels, and pregnancy status. The 'frequency' of screening will depend on the initial screening results; with future annual screening for an initial positive test after receiving precancer treatment, whereas triennially for a negative first result. The "duration" of this will be all through the woman's life.

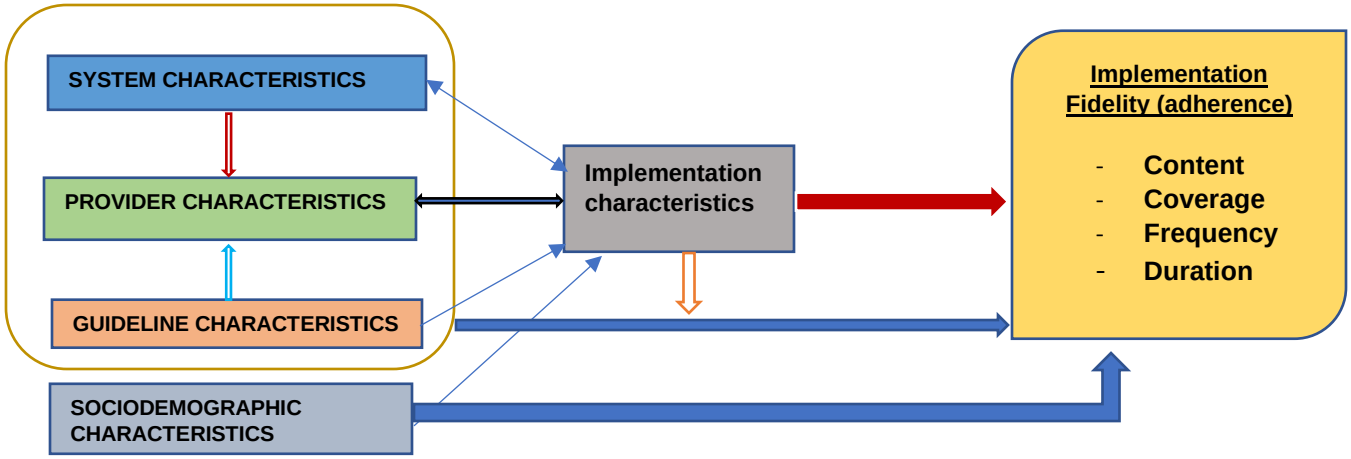


Figure 1.1: A modified conceptual framework for assessing factors associated with the fidelity of implementation of the national guidelines for cervical cancer screening of HIV-infected women in Ekurhuleni, South Africa.

Secondly, the factors affecting implementation fidelity are adopted from a framework of determinants that affects clinician's compliance to evidence-based guidelines which was developed by Gurses et al. 2010 (57). Gurses and colleagues went through several disciplines and specialities to critically examine them, in a bid to expansively describe and identify basic causes of non-compliance to guidelines. They admitted that it was difficult to do so considering the complex nature of each discipline. Notwithstanding, they came up with four broad and well-grouped constructs to help explain these factors and their interrelationship. Relevant broad constructs and subcategories include;

- Provider characteristics – (Awareness, Familiarity, Agreement, Self-efficacy, Subjective norm, Motivation/inertia).
- Guideline characteristics – (Relative advantage, compatibility, complexity, trialability, observability).
- System characteristics – (Workload, task ambiguity, responsibility ambiguity, tools-technologies, expectation ambiguity, method ambiguity, workspace-layout, teamwork).
- Implementation characteristics – (Funding availability, technical support, training, Monitoring and feedback mechanisms) (57).

The background sociodemographic characteristics of providers were treated as a separate factor for this study. This idea was guided by past study findings which have reported that; healthcare provider's age, sex (76) and level of experience, have their contributory influence on guideline implementation (60, 62, 77, 78). The level of knowledge of the screening guideline among healthcare providers is instinctively part of the provider characteristics; however, for analysis purpose and better explanation of this study findings, it was treated as a separate entity.

It is worthy to note that these proposed factors affecting guideline adherence, are dynamic and may change over time (57). Bearing this in mind, it is a possibility that when they do change, the pathway changes in this framework may occur (57). The expected interlink among them is depicted in figure 1.1.

1.6 STUDY AIM AND OBJECTIVES

1.6.1 Aim

To assess the fidelity of implementation of the national guidelines for cervical cancer screening of HIV-infected women by healthcare providers at primary health facilities in Ekurhuleni in 2019 and evaluating the association between fidelity level and its determinants.

1.6.2 Objectives

1) To measure implementation fidelity of the cervical cancer screening of HIV-infected women among primary healthcare workers in 2019.

2) To describe the determinants of implementation fidelity of the cervical cancer screening of HIV-infected women among primary healthcare workers.

3) To determine the relationships between the described determinants and implementation fidelity of the cervical cancer screening of HIV-infected women

CHAPTER TWO

METHODOLOGY

This chapter explains the sampling techniques, data collection and management, as well as the statistical techniques used for analysing the data of this study. This chapter also highlighted and presented some salient results of the factor analysis in a bid to help explain and provide clarity on the methods used.

2.1 STUDY DESIGN

This study used a cross-sectional study design, which was based on primary data. This study design was chosen in order to examine the implementation fidelity of the cervical cancer screening guidelines for HIV-infected women and establish its determinants at a point in time in Ekurhuleni district in 2019 (79).

2.2 STUDY SITE

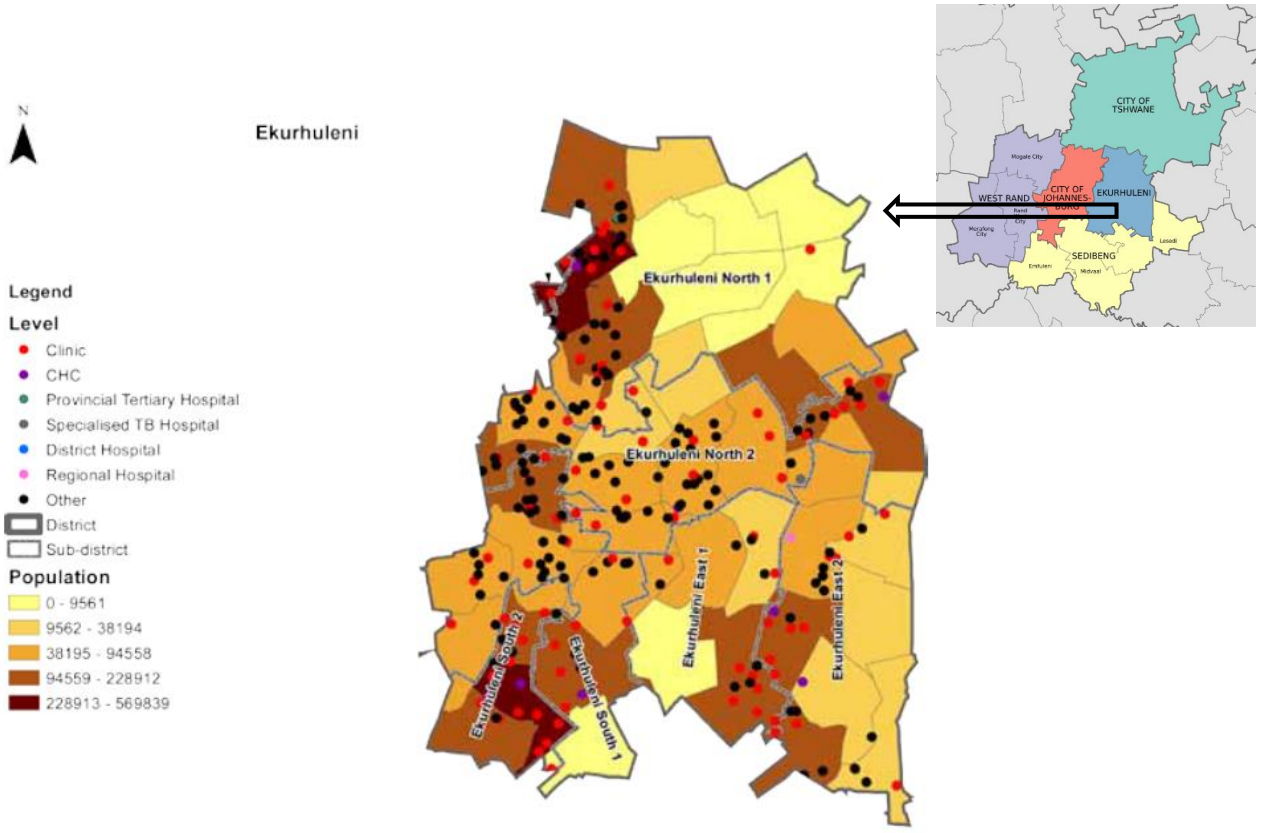
This study was conducted in primary healthcare facilities in the Ekurhuleni Metropolitan Municipality, which is in the eastern part of Gauteng province in South Africa (80).

South Africa is located in the southernmost tip of the continent of Africa (81). It encompasses a land area of 1.22 million km^2, with a population of about 58 million (82). South Africa has nine provinces which are further divided into 52 districts – comprised of 44 district municipalities and eight metropolitan municipalities (83).

Gauteng province is one of the nine provinces in South Africa. It is the smallest province, occupying a land area of more than 17 000 km^2 (80). Gauteng is in North-eastern South Africa, and it has a population of about 13.2 million (82). Gauteng has five regions comprised of three metropolitan municipalities and two district municipalities. Ekurhuleni is one of the three metropolitan municipalities (80).

Ekurhuleni has a population of about 3.3 million, with an estimated medical scheme coverage of 24.3% (84). Ekurhuleni district has been territorially demarcated into six

health sub-districts for planning, monitoring, management, and supervision. The health sub-districts are labelled as – East 1(E1), East 2(E2), North 1(N1), North 2(N2), South 1(S1), South 2(S2). Primary healthcare clinics, community health centres, and hospitals are succinctly grouped, depending on which health sub-district they are embedded (84).



Source: Gauteng province – District Health Barometer 2016/17 report

Figure 2.1: Enlarged regional map of Ekurhuleni showing the health sub-district boundaries

2.2.1 The primary healthcare setting – Ekurhuleni context

Like other districts in South Africa, Ekurhuleni's (the focus area for this study) local health care system is a product of the South African process of decentralisation (85). The primary healthcare clinics and community health centres (CHCs) in Ekurhuleni, South Africa, stands as the point of care for HIV testing, Anti-retroviral (ARV) drug administration and collection of cervical smears for cancer screening (86). They also offer other basic

healthcare services ranging from, but not limited to; management and care of acute and chronic illnesses, maternal and child healthcare (86). These set of prescribed services provided at the primary care level usually falls within the competency base of a professional nurse or midwife, who forms the backbone of primary health care in South Africa (87). These primary healthcare facilities are mostly nurse-led – usually identified as the Facility Manager or Senior manager, nursing or Clinical Heads. These facilities also accommodate weekly visits from a local doctor or specialist. These primary healthcare clinics run out-patient services which operate for 8 hours a day (Mondays to Fridays) excluding weekends, while the community health centres (CHCs) run in addition to the above services, a 24-hour in-patient maternity and casualty care. These facilities provide cervical screening services usually during normal daily working hours – from 8:00 am to 4:30 pm on Mondays through to Fridays (88).

2.3 STUDY POPULATION

The study population is the primary health care workers (PHCWs), who are the nursing staffs of the selected primary health facilities in 2019. They are the frontline implementers of the cervical cancer screening guideline, who are usually involved in, and tasked with conducting daily screening tests for all eligible patients at the primary care level (6, 89).

2.4 PARTICIPANTS INCLUSION, SAMPLING TECHNIQUE AND SAMPLE SIZE

The study population was filtered into this study using the criteria given below.

2.4.1 Inclusion criteria

All primary healthcare workers involved in primary HIV-testing and cervical cancer screening in the selected facilities were eligible for participating in the study. The primary healthcare workers included in this study were those available on the day of the survey, and willing to participate.

2.4.2 Sampling technique

2.4.2.1 Selection of health sub-districts

This study was conducted in two health sub-districts, namely Ekurhuleni North (N1) and South (S2). These two health sub-districts were purposively selected because they had the lowest and highest coverage of cervical cancer screening, respectively, according to 2016/17 health statistics (84).

2.4.2.2 Selection of primary healthcare facilities

All primary healthcare facilities, i.e. clinics and CHCs, in the selected health sub-districts 'North 1' and 'South 2' were included in this study. There were 11 and 17 facilities in each sub-district, respectively, giving a total of twenty-eight (84). The final ethical approval was granted for Twenty-six healthcare facilities, which were all eventually included in the study.

2.4.2.3 Selection of healthcare providers

This selection was made by convenience sampling of all the PHCWs involved in HIV testing and implementation of the national cervical cancer screening guideline in the selected facilities. This non-probability sampling method was applied by recruiting and collecting data from the eligible PHCWs who were available and agreed to participate on the day of the survey (90). The number of participants included in the study was determined per a sample size calculation as described in the sub-section below.

2.4.3 Sample size

A sample size calculation was conducted to determine the minimum number of PHCWs needed for the study. A near-similar study previously done in Morocco gave an understanding of the cervical cancer screening practices and attitudes among Moroccan nurses in a primary healthcare setting. It was deduced that there was mainly non-adherence to screening practices, with an adherence level of about 10% (76). Morocco,

which is analogous to South Africa as one of the middle-income African nations, also has cancer of the cervix ranking as the second most common cancer in their women (91).

This study, therefore, derived the sample size calculation on detecting a 10% level of adherence to cervical cancer screening practices in the primary healthcare settings in South Africa. A minimum sample size of 130 healthcare providers was required in a particular setting to detect this proportion within 8% of the estimated value of 10%. This sample size calculation was done using the *'power oneproportion'* command for 'a one-sample proportion test' on the STATA Statistics/Data Analysis software version 15 (92). This calculation was instructed by using the following parameters – an 80% statistical power at a 5% precision level. An anticipated 74% response rate was put into consideration, having in mind a participant's willingness to partake in the study and their availability. These considerations led to a final sample size estimate of 177. This final sample of 177 was allocated quotas of 6 to 7 healthcare providers, which were taken from each of the health facilities. This allocation was based on the total number of 26 primary healthcare facilities in the selected health sub-districts. (See appendix B for STATA output of the sample size calculation).

2.5 DATA COLLECTION

This section describes the tool used for data collection, as well as the process embarked upon for data collection for this study.

2.5.1 Data Collection tool – study questionnaire

Primary data were collected on implementation fidelity and its determinants using a structured self-administered questionnaire (See appendix A for a detailed copy of the questionnaire). This data collection tool was paper-based and was designed and developed in the English language. The fidelity questions were designed using constructs adopted from the implementation fidelity conceptual framework by Carroll et al., 2007 (43) and the questions exploring determinants were adapted from the framework developed by Gurses et al. 2010 (57). Questions were adapted based on the researcher's logical understanding of the local context. This data collection tool was designed to have four

sections that collected data on participant background characteristics, the fidelity of implementation of the cervical screening guideline, determinants of fidelity, as well as the health care provider's knowledge of the guideline. These sections are described below.

- Section A – This section collected data on the background socio-demographics of participants, such as age, sex, the highest level of education attained and the number of years of professional working experience.
- Section B – This section included questions to ascertain the healthcare provider's level of knowledge of the guideline recommendations for cervical cancer screening of HIV-infected women. Survey responses in this section were obtained on a three-point scale given as *"True, False, and I do not know".*
- Section C – This section contained questions about guideline implementation fidelity. Each provider was asked to rate the extent to which they undertook specific cervical cancer screening tasks as recommended by the National guideline. These set of questions were grouped in subsections according to the four constructs (content and coverage, frequency and duration) that feed into implementation fidelity (43). The 'content and coverage' subsection contained questions on providers performing cervical screening on 'all' HIV-infected women, irrespective of CD4 count, ARV treatment, age of 30 years and older, as well as pregnancy status. 'Frequency and duration' subsection, had questions on the recommended screening intervals with which providers perform a follow-up cervical screen, after an initial pap smear result. Responses to these questions were rated on a four-point scale as *"Never, Rarely, Sometimes, Always".*
- Section D – This section collected data on determinants of implementation fidelity, and it was further subdivided into four parts, namely; provider characteristics, guideline characteristics, system characteristics, and implementation characteristics. Responses to the questions under this section were based on a five-point Likert scale given as *"Strongly disagree, Disagree, Neutral, Agree, Strongly agree".*

  The questions on *provider characteristics* gave information on the extent to which healthcare providers agreed with the components of the recommended cervical

screening guideline, such as; screening technique/method, screening intervals, patient's age of entry and exit of screening. It also had a subsection that displayed statements that were reflections of the provider's skills, self-confidence/efficacy, motivation, workload, team-spirit, and subjective norms/beliefs. These statements were rated on a scale of 1 to 5, with '1' standing for "*very untrue of me*" and '5' which stands for "*very true of me*".

The part on *guideline characteristics* contained questions on the complexity/ease of use of the guideline, its compatibility and applicability to work, as well as whether or not it is in line with existing medical knowledge and public health needs.

The *system characteristics* section had questions about the primary healthcare provider's perceptions of the healthcare system, such as; clarity of roles/responsibility in performing screening, screening room availability/workspace-layout, the sufficiency of screening materials and supplies, as well as where to find these supplies when needed.

The *implementation characteristics* contained questions on routine supervision of the healthcare provider's screening practices, feedback on their screening performance, and availability of workforce in reaching the allocated target number of screen tests.

2.5.2 Pilot testing of the data collection tool

The development and pre-testing of this tool were done via a series of iterative evaluation sessions with this study research supervisors to ensure its appropriateness. It was then piloted in a different healthcare facility not included in this study but bore the similar characteristics and set-up as the clinics included in this study.

This pre-testing was done in order to assess the structure, suitability and appropriateness of questions asked, its format and likewise the clarity of the language used. Further suggestions, comments, and feedback were obtained from the pilot participants, as they were encouraged to do so. Consequently, they all agreed that the questions were simple and unambiguous. This tool was then used for this study without any further change.

2.5.3 Data collection process

Data collection was done by the principal investigator and was conducted between the periods of 11th April 2019 to 29th May 2019. In each selected healthcare facility, access was gained to the study participants through the Clinic heads or their representatives. They mediated the introduction of the principal investigator and explained the purpose of the principal investigator's visit to their healthcare facility.

Survey questionnaires were then distributed to each participant for completion. The principal investigator stayed back in each health facility, to address any queries as well as to retrieve the completed questionnaires on the same day. Few respondents who could not complete the survey on the same day it was distributed, gave future dates for its collection. These dates usually fell within five working days from the day survey questionnaires were distributed. Quality assurance, consistency, and completeness of data were ensured and carried out by the principal investigator on the same day of data collection. At the point of collecting the filled questionnaires from the respondents, each question was scrutinized by the principal investigator for any missing information/responses. If any was found, it was corrected and completed on the spot by the respondents.

2.6 DATA MANAGEMENT

This section describes the online capturing process of the collected data, and the variables used for this study.

2.6.1 Capturing of the collected data

After all the data was collected, it was captured on a password-protected laptop, using REDCap (Research Electronic Data Capture) hosted by the University of the Witwatersrand. REDCap is a secured web application that allows for the online design of questionnaire forms, data entry in real-time, amongst other notable functions (93). All the information on the paper-based questionnaires were transferred to the online questionnaire forms on REDCap. Each of these online REDCap forms was developed to follow a similar structure to the paper-based questionnaires. Specified field types were

adhered to, for example; ‘Numerical fields’ – specified for “*age*”, “*number of professional working experience*” and ‘Radio buttons fields’ – as specified for all items with a Likert scale. These fields were given variable names and field labels as they reflected on the paper-based questionnaire.

Quality assurance was also ensured at this stage of data capturing. It was achieved by introducing strict restrictions when designing the online REDCap forms. During the process of data capturing, these restrictions caused an alert message to pop-up on the laptop screen, each time a missing response is detected. This message hinders the progress of the capturing process until the information is inputted correctly and in the right format (93). The captured data was then transferred to STATA version 15.1 (92) for subsequent data cleaning, coding, and analysis.

2.6.2 Study variables

This subsection explains the variables that were measured in this study and in what format they were used for data analysis. Table 2.1 below is the list of the variables for this study.

Table 2.1: List of study variables

Outcome variable	Type of variable	Coding in analysis
Implementation fidelity	Continuous	Min = 0, Max = 33
	Categorical	1 – “Low”, 2 – “High”
Explanatory variables		
Provider characteristics	Continuous	Min = 18, Max = 90
Guideline characteristics	Continuous	Min = 13, Max = 65
Implementation characteristics	Continuous	Min = 3, Max = 15
System characteristics	Continuous	Min = 6, Max = 30

Sociodemographic/Other determinants		
Age (in years)	Continuous	Min = 24, Max = 63
Sex	Categorical	1 – “Male”, 2 – “Female”
Years of professional working experience	Continuous	Min = 2, Max = 40
Highest educational qualification	Categorical	1 – “Undergraduate degree”, 2 – “Postgraduate degree”
Health sub-districts	Categorical	1 – “North”, 2 – “South”
Training	Categorical	0 – “No”, 1 – “Yes.”
Level of knowledge	Continuous	Min = 0, Max = 10

Min = Minimum possible score, Max = Maximum possible score

2.6.2.1 Scale reliability coefficient

Further tool validity was examined using the scale reliability coefficient – Cronbach’s alpha; for implementation fidelity and its determinants (see table C.1 and C.2 in Appendix C). It was done in order to determine the level of consistency among the items under each construct, as an indication of whether they were a reliable measure of the construct they intended to measure (94). The number of items and Cronbach’s alpha values of each construct is displayed in Table 2.2. A Cronbach’s alpha value of greater and equal to 0.7 is considered to be acceptable for exploratory research (94, 95).

Table 2.2: Cronbach’s alpha for implementation fidelity of cervical cancer screening guidelines for HIV-infected women and its determinants.

Variable	Items	Cronbach’s alpha
Implementation fidelity	11	0.74
Provider characteristics	18	0.82
Guideline characteristics	13	0.84
Implementation characteristics	3	0.76
System characteristics	6	0.77

2.6.2.2 Outcome variable

The outcome variable was implementation fidelity. It was expressed as a continuous variable, as well as a categorical variable. For the first objective, the outcome variable was used both as a continuous and categorical variable, while for the second and third objective, it was used as a categorical variable.

The 11-items under this variable used a 4-point ordinal Likert scale, to obtain the implementation fidelity scores for each respondent. This rating scale was coded ranging from 0 for "*Never"* to 3 for "*Always"*. The composite score of implementation fidelity for each participant was obtained by the summation of their respective responses (*Min = 0, Max = 33*). This score was a continuous variable. This continuous fidelity score was necessary in order to report an overall fidelity score for this study, which can be easily interpreted and understood. This continuous score also gave an understanding of the distribution of fidelity scores between each explanatory variables. It also served the purpose of the outcome variable used in the linear regression analysis. This linear regression analysis acted as a sensitivity analysis to see the difference(s), if any, in the results obtained from the logistic regression analysis used in objective three.

Also, factor scores were obtained for implementation fidelity using the factor analysis techniques – exploratory and confirmatory factor analysis. The goal of this factor analysis was to arrive at an acceptable cut-off point for fidelity level, as there is no general agreement on this issue from existing literature (96).

In bringing these generated fidelity scores together, the Pearson correlation matrix was done. The fidelity composite scores derived through the addition method were correlated with the factor scores obtained from the exploratory and confirmatory factor analysis, respectively (see matrix table C.3 in Appendix C). This correlation was necessary to assess the strength and direction of the association between the composite fidelity score and the fidelity factor scores.

The categories of implementation fidelity for this study was achieved using the factor scores derived from exploratory factor analysis because it had a stronger correlation with the scores derived via summation. The factor scores obtained from this exploratory factor

analysis technique reflected both negative and positive signs. Based on the sign of these scores, implementation fidelity was then categorised into high and low. Negative factor scores, i.e. below zero (<0) representing low fidelity, while positive factor scores, i.e. zero and above (≥0) representing high fidelity. The categorised (binary) fidelity score was the outcome variable used for the logistic regression and GSEM analysis in objective three.

2.6.2.3 Explanatory variables

These are the determinants of implementation fidelity of the cervical cancer screening guidelines for HIV-infected women. The '*key determinants'* were adapted from the Gurses et al. determinants framework for clinician's compliance (57). They include; provider characteristics, guideline characteristics, implementation characteristics, and system characteristics. They had eighteen (18), thirteen (13), three (3) and six (6) items, respectively. These items had their responses based on a 5-point Likert scale, which were rated and coded ranging from 1 for "*strongly disagree"* to 5 for "*strongly agree".*

Corresponding scores for each key determinant above were obtained by summing the points obtained from responses to their respective items; provider characteristics score (*Min = 18, Max = 90*), guideline characteristics score (*Min = 13, Max = 65*), implementation characteristics score (*Min = 3, Max = 15*) and system characteristics score (*Min = 6, Max = 30*). All these variables were continuous.

Training of healthcare providers on the updated guideline recommendations was used for analysis as collected. The level of knowledge was assessed using ten (10) item questions. Each item had their responses awarded score-points of one (1) for correct answers, while zero-point (0) for incorrect/" I don't know" type of responses. The knowledge score was then derived by adding up all acquired score-points (*Min = 0, Max = 10*).

Sociodemographic characteristics, such as; age (in years), sex, years of professional working experience, were used for analysis as collected. As a result of the small sample sizes in the categories, the highest educational qualification attained was further recategorised into two groups (undergraduate and postgraduate degree). Participants with a bachelor and/or undergraduate diploma were grouped as an undergraduate

degree, while those with a postgraduate diploma and/or masters were grouped as a postgraduate degree. The health facility regions were also categorised into two – North and South, for regression analysis purpose.

2.7 STATISTICAL ANALYSIS

This section discussed and explained the statistical analysis of this study data, following the already laid-out research objectives, in sequential order. Firstly, the implementation fidelity score was derived for the cervical cancer screening of HIV-infected, and it was categorised. Secondly, establishing and description of the determinants affecting implementation fidelity of the cervical cancer guidelines for HIV-infected women among PHCWs in Ekurhuleni. Lastly, the direct and indirect associations between these determinants and implementation fidelity were examined.

2.7.1 Objective 1 – Measuring implementation fidelity of cervical cancer screening of HIV-infected women among primary healthcare workers

This objective was achieved in two-phases. These phases are further discussed in detail below.

- Phase 1 – Composite score method

In the first phase, the composite scoring method was used to obtain the overall implementation fidelity score for the study population. These scores were further expressed as percentages for better interpretation.

This method was done by the summation of all responses to each 11-item questions and getting an overall composite score of all the observed variables under implementation fidelity. The measure of internal consistency and scale reliability of these items was assessed using Cronbach's alpha, before summation, as described in subsection 2.6.2.1 (94).

The implementation fidelity scores obtained for each study participants were computed (see Table C.4 in Appendix C) and expressed as percentages of the maximum score.

The composite fidelity score distribution was displayed using a histogram (See figure 3.1). The derived implementation fidelity scores were observed from the normality distribution curve to be non-normally distributed and negatively skewed. Therefore, the median and interquartile range were reported and used in interpretation.

- Phase 2 – Factor analysis

The second phase made use of the factor analysis technique – exploratory and confirmatory. Regarding the adherence to the clinical practice guidelines, healthcare providers are often caught in a cross-road in finding a balance between adaptation (fitting implementation to their specific contexts) and fidelity, thus whether there is fidelity often cannot simply be a yes/no assessment (50, 97). Thus, a straight forward and fixed approach is not always possible in medical reality as many variables need to be considered when measuring the level of fidelity. This rationale creates a dilemma when looking for a specific cut-off point in grouping fidelity into high and low, as there is no widespread agreement on this issue.

For this reason, the factor analysis technique was used in this study, to help guide the decision for an agreeable cut-off point for the categorisation of fidelity into high and low. Also, factor analysis was used for data reduction purpose and arriving at those observed variables that measured similar subcategories of implementation fidelity, conceptually (98). This phase is described in details below.

- *Exploratory factor analysis* – Prior to commencing this analysis, the correlation between the 11-item questions under implementation fidelity and its sampling adequacy was checked. It was done using the polychoric correlation matrix (99) and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy (see table C.5, appendix C). A KMO value of 0.69 was obtained, and KMO values of greater than 0.5 are considered satisfactory (99). Factor analysis was then performed, and the factors with eigenvalues greater than one (>1) were retained – these were factors 1 to 4 (98). It was further visualised using the scree plot (see graph below).

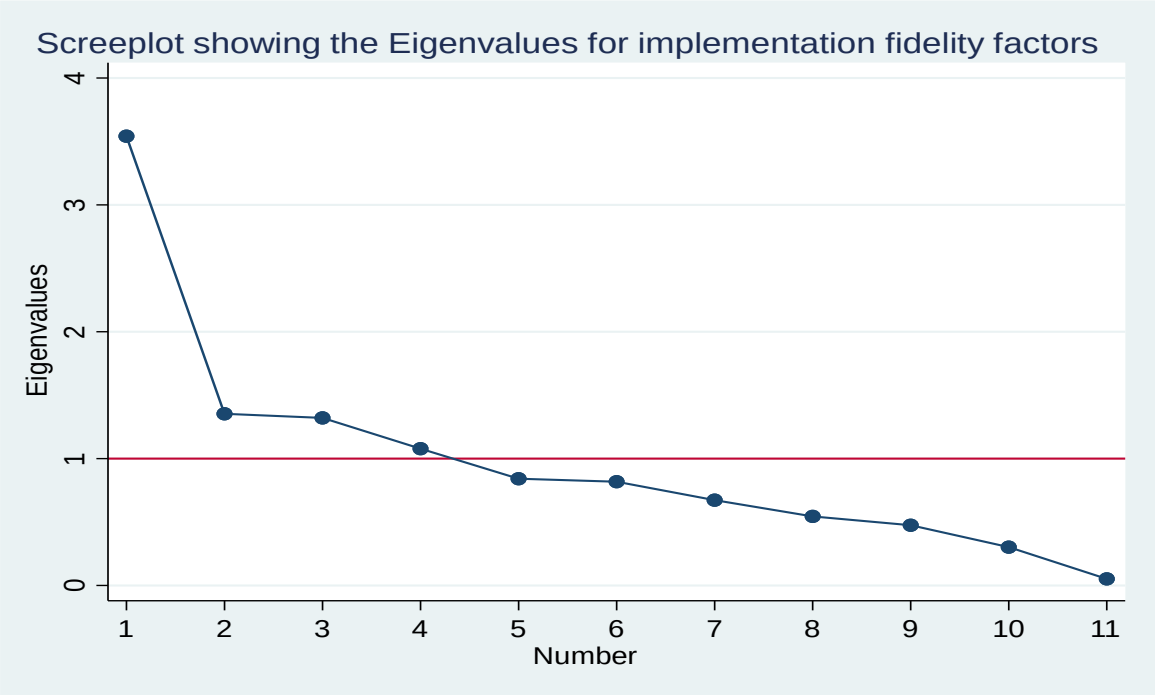


Figure 2.2: Scree plot showing the eigenvalues for implementation fidelity factors

Furthermore, the Kaiser's rule was used to inform the decision to retain factor loadings greater than 0.4 (100). These retained factor loadings were then rotated using the varimax orthogonal rotation (i.e. default setting) which produced uncorrelated factors. Factors 1 to 4 cumulatively explained a large proportion (about 66.31%) of the total variance observed, and each factor was defined mainly by key aspects of the cervical screening guidelines, as shown by the pattern matrix table (table 2.3) below.

Names were assigned to each of these four factors (i.e. factor 1 to 4). The names were allocated based on which of the 11-item variables that had the strongest association to the underlying factors, i.e. by looking at those variables which loaded highly onto these factors. Factors one and four had the variables "*Greater CD4*", "*Lesser CD4*" [*screening HIV-infected women with CD4 > or <500/ul*] and "*Younger than 30*" [*screening HIV-infected women younger than 30*] loading highly respectively, thus were both named as 'content fidelity'. Factor two had the variable "*Point of diagnosis*" [*screening all HIV-infected women at the point of diagnosis*]

loading highly, therefore, was termed ‘coverage fidelity’. Factor three had the variable “*Repeat screen after one year*” loading highly, thus was named ‘frequency fidelity’.

Table 2.3: Pattern of rotated factor loading matrix and uniqueness variance

Variable	Content fidelity	Coverage fidelity	Frequency fidelity	Content fidelity	Uniqueness
Point of diagnosis		0.6914	0.3075		0.5006
Younger than 30				0.7679	0.3176
Pregnant women		-0.7090			0.4128
ARV	0.6904	0.3428			0.3753
No ARV	0.7382	0.3023			0.3463
Greater CD4	0.9247				0.1189
Lesser CD4	0.9091				0.1408
Smear date			0.6565	0.3389	0.3660
Refer for colposcopy				0.7598	0.3446
Repeat screen after 3 years	0.4266	0.4316			0.5929
Repeat screen after one year			0.8946		0.1905

(blanks represent abs(loading) <.3)

The scores for each of these factors (i.e. factor 1 to 4) were predicted from factor loadings under them, respectively. (See table C.6 in Appendix C for the exploratory factor analysis output). The final scores for implementation fidelity were obtained by taking an average of the scores predicted from the four factors. This final simple average technique recognizes that each component of the cervical screening guideline is essential, i.e. are prerequisite in order to attain a reduction in cervical cancer incidence (6, 24). Thus, the final average fidelity scores were calculated with the assumption that each of the four subcategories of adherence (fidelity) has equal contribution and importance in the measurement of adherence. Therefore, fidelity to the whole guideline intervention is needed (43).

- *Confirmatory factor analysis* – This was done using the graphical user interface (structural equation model builder) on the STATA 15.1 statistical package (92). For this study, this technique was explored to give an idea as to how the various observed 11-item variables under fidelity, are conceptually set-up/linked to create implementation fidelity. In order to build the structural equation model accurately, dummy variables with two levels were generated from responses to these observed variable items. These dummy variables were then used for the confirmatory factor analysis. The paths – direct and indirect links, between the latent variable "Implementation fidelity" and its observed variables, were displayed (see figure 3.2). Decisions for the indirect links in the CFA model was driven by logical reasoning. For instance, it was noted that prior to clients keeping appointments to undergo future cervical screening (either annually or triennially), they would have to be informed of the next screen dates by their healthcare providers. Statistical significant links/paths were reported. A detailed breakdown of the standardised coefficients, p-values, confidence intervals and goodness-of-fit statistics are shown in Table C.7 (Appendix C). Factor scores for implementation fidelity were also predicted from this model.

2.7.1.2 Creating the implementation fidelity categories

The strength of association between the fidelity scores obtained through the composite scoring (addition) method and factor analysis (exploratory and confirmatory) was investigated using a correlation matrix (see matrix table C.3 in Appendix C). The fidelity factor scores derived from exploratory factor analysis had a stronger association with the scores derived through addition (i.e. it had a correlation of 0.93 with the addition method).

For this reason, the scores obtained via exploratory factor analysis was used in categorising implementation fidelity (outcome variable). The factor scores obtained from exploratory factor analysis reflected both negative and positive signs. The sign of the fidelity factor scores stood as the reference point for its grouping, and this was consistent with the composite score as low scores also were classified as negative and vice versa. Based on the sign of the scores, implementation fidelity was then categorised as high and low, as explained in subsection 2.6.2.2. The number of observations for each fidelity category was reported.

2.7.1.3 Examining the correspondence of high and low implementation fidelity to the obtained percentage implementation fidelity scores

High and low implementation fidelity categories were matched with its corresponding overall fidelity percentage scores obtained through the addition method. The descriptive statistics of the percentage implementation fidelity score by these two categories were used to show that lower values of the percentage fidelity score corresponded to the derived category for low implementation fidelity, while higher values of fidelity percentage score corresponded to the derived category for high implementation fidelity. These descriptive statistics (median, interquartile range, frequency) were reported in a table.

2.7.2 Objective 2 – Describing the determinants of implementation fidelity of the cervical cancer screening of HIV-infected women among primary healthcare workers

For this objective, the descriptive features of the determinants of fidelity were reported, as well as their distribution between each implementation fidelity category (high and low fidelity). This section is further explained in the sub-sections below.

2.7.2.1 Description of the key determinants

The rationale for this description was to allow a simpler interpretation and meaningful presentation of the determinants. The four main groups of determinants of implementation fidelity, as presented in chapter one, are; Provider characteristics, Implementation characteristics, System characteristics, and Guideline characteristics. Cronbach's alpha values of each of these determinants were obtained and are shown in Table 2.2. The scores for the four main determinants – Provider characteristics, Guideline characteristics, Implementation characteristics, and System characteristics; were calculated and computed, as explained in subsection 2.6.2.3. These scores were expressed in percentages for better interpretation. The descriptive features for each main determinant were displayed using tables. Also, the distribution of the percentage scores for the four main determinants between the implementation fidelity categories (high and low), was described and displayed using a table. The overall score for these four main

determinants followed a skewed distribution; thus, the median and interquartile range were interpreted and reported.

2.7.2.2 Description of other determinants and relevant sociodemographic characteristics

Sociodemographic characteristics and other explanatory variables were also described using the mean, standard deviation, median and interquartile range. Categorical variables such as; sex, training, highest educational qualification, and health sub-districts; had their frequencies/percentages calculated and summarised. Their distribution was further described between the low and high-fidelity categories. The distribution of the composite fidelity percentage score was also described between all the categorical explanatory variables. Descriptive statistics results were shown in a table.

The distribution of other continuous explanatory variables, such as; age, level of knowledge and years of professional working experience, were described individually, as well as between both implementation fidelity categories. The distribution of age followed a normality curve; hence the mean and standard deviation were reported. Other continuous explanatory variables had their median, and interquartile range reported. Tables were also used to display results.

2.7.3 Objective 3 – Determining the direct and indirect relationships between determinant variables and implementation fidelity

The relationship between each determinant variable and implementation fidelity was examined using the logistic regression analysis (unadjusted model and adjusted model; which included all determinants in the model) and the generalised structural equation model (GSEM) – for determining the direct and indirect effects. The GSEM path analysis method was used for further analysis because it could produce more robust findings – which is a step further than the multivariable logistic regression analysis – by providing clarity on the pathways through which the various determinant factors influence the fidelity of implementation of the cervical screening guideline by PHCWs. This GSEM path analysis further offered a guide as to how these determinant factors are interlinked and related in their influence on fidelity and illuminated which factors influence fidelity directly

and those that influence it indirectly. For this study, the direct effects or paths were those links between the factors that impact fidelity (outcome variable) directly without any mediator. Indirect effects or paths were the links formed between the determinant factors themselves, thereby producing an effect on fidelity (outcome variable) through other factors acting as mediators

2.7.3.1 Logistic regression – Univariate model

The logistics regression analysis was used to determine the association between the determinants and fidelity of implementation of the national guideline on cervical cancer screening for HIV-infected women. This technique was adopted because of the outcome variable (implementation fidelity) used was categorical (binary). For the univariate model, regression was done between each of the explanatory variables and the outcome variable. The crude or unadjusted odds ratio was computed at a 95% confidence interval, and Pseudo R^2 of each model was reported. Statistical significance was at a p-value of < 0.05.

2.7.3.2 Logistic regression – Multivariable model

All determinant variables (explanatory variables) were fitted in this model. Multicollinearity of explanatory variables was seen to be absent, and this was detected using the *'collin'* function in STATA (see Table C.8 in Appendix C) (92). The adjusted odds ratio, p-values, 95% confidence interval, and pseudo R^2 were estimated and reported.

2.7.3.3 Generalised structural equation model (GSEM)

The goal of using the generalised structural equation model (GSEM) was to determine, explore and graphically display the path analysis for the direct (unmediated) and indirect (mediated) relationship between the determinants and providers' level of fidelity to the guideline on cervical cancer screening of HIV-infected women. This model was built using the graphical user interface (structural equation model builder) on the STATA 15.1 statistical package (92). The explanatory and outcome variables used were the same as with the multivariable logistic regression model. The direct GSEM model was explored first followed by the indirect model.

The initial step was to turn-on the GSEM feature on the SEM builder in STATA (92). The outcome variable (fidelity) was specified as a Bernoulli logit variable. Health facilities were also specified as the cluster variable to adjust for facility-level random effects. The direct effect model was then fitted first, by drawing paths (arrows) directly from each of the explanatory variables to the outcome variable. Afterwards, the indirect model was fitted by drawing paths between the explanatory variables. The main idea of using the GSEM was to create a significant replication of the conceptual framework in figure 1.1 with the direct and indirect pathways.

The final estimates obtained are the beta-coefficients which were exponentiated to give the odds ratio for the direct, indirect and total relationships. These odds ratios were reported for the model. The indirect relationship was calculated by the product of the coefficients along related pathways, pointing to the outcome variable using the '*nlcom*' function in STATA (92). The total relationship was arrived at by the sum of the direct and indirect coefficients. The p-values and 95% confidence intervals were also reported for the direct and indirect relationships. The Stata syntax employed for the GSEM indirect and total effects is presented in Appendix D of this research report.

2.7.3.4 Sensitivity analysis

The goal for this sensitivity analysis was to see the difference(s), if any, in the results obtained from the logistic regression analysis used in objective three. For the sensitivity analysis, a linear regression model was fitted using the outcome variable (implementation fidelity) as a continuous variable. The explanatory variables used were the same as with the multivariable logistic regression model. Statistical significance was at a p-value of < 0.05. (see Table C.9 in Appendix C).

2.7.4 Assessing model goodness-of-fit

The goodness-of-fit test for the models in this study was assessed and interpreted using the parameters below.

- CFA model – using the *'estat gof'* function in STATA, the "coefficient of determination" (CD) was estimated, and its interpretation was reported (see Table C.7 in Appendix C).
- Logistic regression model – For this model, using the *'lfit'* function in STATA, the Hosmer and Lemeshow's goodness-of-fit test was estimated (see Table C.10 in Appendix C). The p-values were reported, and findings interpreted.
- GSEM model – the "Akaike information criterion" (AIC) and "Bayesian information criterion" (BIC) was estimated using the *'estat ic'* function in STATA, (see Table C.11 in Appendix C). Their values and its interpretation were reported.

2.8 ETHICAL CONSIDERATIONS

This research protocol was be submitted to WITS "Human Research Ethics Committee (HREC – medical), and the Provincial Health Research Committee - Ekurhuleni District (EHDRC), via their National Health Research Database (NHRD) website portal, for subsequent ethical approval. The Ekurhuleni Health District Research Committee (EHDRC) reviewed and gave this research study its approval on the 14th February 2019, with NHRD number; GP_201901_021 (see attached as appendix E). Consequently, the WITS Health Research Ethics Committee (HREC – medical) issued this study an unconditional approval on the 14th March 2019, with clearance certificate number M181154 (see attached as appendix F).

2.8.1 Study authorisation and support visits

Prior to commencing data collection, pre-information was given, and verbal permission obtained from the Regional Manager Health Service, Manager Nursing Services and Chief Professional Nurses who were in charge of the primary healthcare facilities that are under the local government authority, distinct from the provincial government authority. This process was carried-out either through face-to-face meetings, e-mail or via telephone calls. They were briefed on the research project and of its aims, objectives and proposed methods.

Study participants were well-informed, and a clear explanation was conveyed to them, about what the study research entails (see information sheet as appendix G). They were also made to understand their rights to participate or withdraw at any given time freely – as study participation was voluntary, without any form of punitive measures. All respondents signed informed consent (see attached as Appendix H) prior to partaking in this study, and they were reassured of utmost confidentiality. This study posed no form of risk to the study participants. The research questionnaires were completely anonymous as participants did not fill their names or any identifying information. All given information was stored safely in a locked cabinet and captured on a secured database on a password-protected laptop, which was strictly accessible to the primary investigator and both research supervisors only. Also, all Healthcare facilities included in this study were de-identified and assigned a code to maintain their anonymity. All obtained information was used for the purposes indicated for this study alone.

2.9 Dissemination of research findings

These study findings were compiled as a research report and submitted to the University of the Witwatersrand, Johannesburg library for public access and use. These findings from this research will also be communicated to the primary healthcare workers (PHCWs), cervical cancer screening programme implementers, researchers and other relevant stakeholders via seminars, conference presentations, and research symposiums.

CHAPTER THREE

RESEARCH RESULTS

In this section, the result outputs of the statistical analysis of data collected from the one hundred and seventy-seven (177) primary healthcare providers, are reported. The obtained results are produced and illustrated using tables and graphs, following the three already laid-out research objectives.

3.1 MEASURING THE FIDELITY OF IMPLEMENTATION FOR THE CERVICAL SCREENING OF HIV-INFECTED WOMEN AMONG PRIMARY HEALTHCARE WORKERS.

In measuring the level of fidelity of implementation of the cervical screening of HIV-infected women among primary healthcare workers, the techniques used, are explained in subsection 2.7.1 in chapter two. Deriving the fidelity scores was necessary, as explained in subsection 2.6.2.2 in chapter two. In addition, the fidelity composite scores were computed for each respondent in order to see the aspects of the screening guideline were PHCWs had a good/or poor performance.

3.1.1 Determining the composite fidelity score

The Cronbach's alpha for the 11-item was 0.74, which indicated that the fidelity scale was reliable. A composite fidelity score was derived by summing up the 11-item scale. The histogram shows the distribution of implementation fidelity scores within the study population (see Figure 3.1 below). The histogram shows that the distribution of the scores is negatively skewed, i.e. to the left.

The median percentage implementation fidelity score for all PHCWs was 84.85, with an interquartile range between 75.76 and 87.88. Also, the minimum percentage implementation fidelity score was 27.27, while the maximum percentage fidelity score was 100. When visualizing these composite fidelity scores, it was observed that PHCWs having low fidelity scores, had this poor performance in the aspect of the screening

guideline that fell under the coverage and frequency fidelity. PHCWs, who scored higher, performed better in fidelity to the content of the guideline. (see Table C.4 in Appendix C).

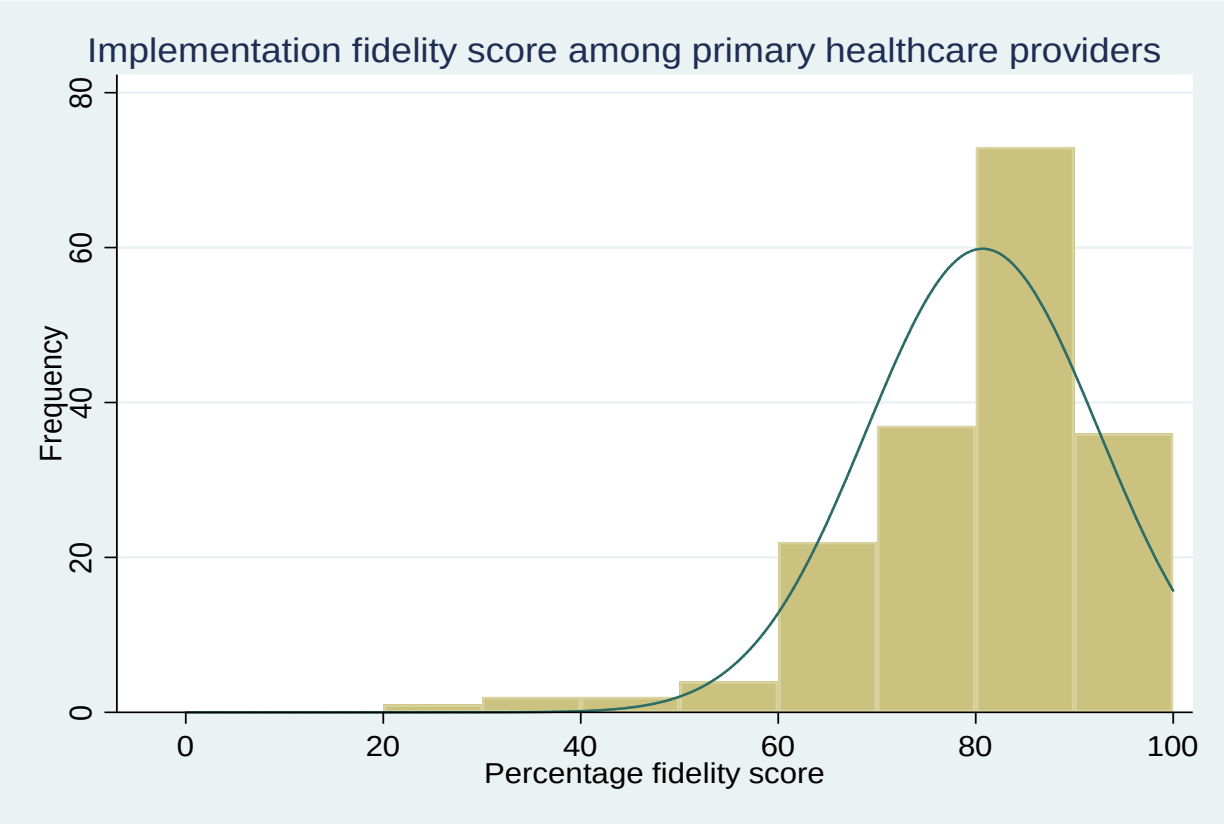


***Figure 3.1: Histogram showing the distribution of the implementation fidelity score per cent*.**

3.1.2 Exploratory factor analysis to determine implementation fidelity category

The skewed distribution of the fidelity scores suggests that it cannot be operationalised as a linear variable (101). Thus, the categorisation of implementation fidelity into two, namely; High and Low, was done using exploratory factor analysis, as explained in subsection 2.7.1.2 in chapter two.

As seen in Table 3.1 below, 37.85% of the study participants had low fidelity, with a median fidelity score of 72.73% (IQR%: 66.67 – 75.76). The remaining 62.15% of participants had high fidelity with a median fidelity score of 87.88% (IQR%: 84.85 – 90.91).

Table 3.1 Descriptive statistics of the Implementation fidelity percentage score by implementation fidelity categories – low and high

Implementation fidelity category	Number of observations N (%)	Mean (SD)	Median	IQR
Low	67 (37.85)	69.61 (11.25)	72.73	66.67 – 75.76
High	110 (62.15)	87.47 (5.12)	87.88	84.85 – 90.91
Overall score	**177 (100)**	**80.71 (11.80)**	**84.85**	**75.76 – 87.88**

IQR = Inter Quartile Range, SD = Standard Deviation

3.1.3 Confirmatory factor analysis

As seen in figure 3.2, all the dummy variables created from the 11-items used by this study to get the measure of fidelity were observed to have a direct link/path to implementation fidelity. Statistically significant (p-value < 0.05) direct paths to implementation fidelity was noted among some of the observed variables, such as; “SD” *[inform clients of next screen date*], “ASC” *[refer clients with abnormal smears for colposcopy].* Direct paths with an overwhelming statistical significance (p-value < 0.001) was noted in variables such as; “ARV” *[cervical screening of HIV-infected women on ARV]*, “nARV" [*cervical screening of HIV-infected women not on ARV]*, “GCD” [*cervical screening of HIV-infected women with a CD4 count of > 500/ul*], “LCD” [*cervical screening of HIV-infected women with a CD4 count of < 500/ul*].

For the indirect links, two variable items, namely; “*RST*” [*repeating follow-up cervical screen after three years]* and “RSA” [*repeating follow-up cervical screen after one year*], were both observed to assess implementation fidelity indirectly through the endogenous (mediating) variable; *“SD” [inform clients of next screen date*]. The indirect link between variables “SD” and “RSA” showed statistical significance (p-value <0.05).

Also, several other statistically significant (p-value < 0.05) correlations between the error terms of the observed variable items were noted. It includes correlations between “ARV” and “LCD4”, “nARV” and “GCD4” variables.

3.1.3.1 Assessing the CFA model Goodness-of-fit

The goodness-of-fit test for the final CFA model showed that it was a good fit (see Table C.7 in Appendix C). The parameter test – “size of residuals”, reported the coefficient of determination for the whole model to be 0.968. This value is close to 1, which indicates a good fit (102).

3.1.4 Correlating fidelity scores

The rationale for fitting this correlation matrix between the fidelity scores is explained in subsection 2.7.1.2 in chapter two. The correlation between the composite fidelity scores and the fidelity factor scores derived from exploratory factor analysis revealed a strong direct association with a coefficient of 0.93. This relationship was statistically significant (p-value <0.01).

Also, the correlation coefficient between the composite fidelity scores and the fidelity factor scores obtained from the confirmatory factor analysis was -0.81, which indicates a fairly strong inverse relationship between them. This relationship was also statistically significant (p-value <0.01).

Likewise, the correlation between the fidelity factor scores from exploratory and confirmatory factor analysis was -0.63 (p-value <0.01), which indicates a moderate inverse relationship. (see matrix table C.3 in Appendix C).

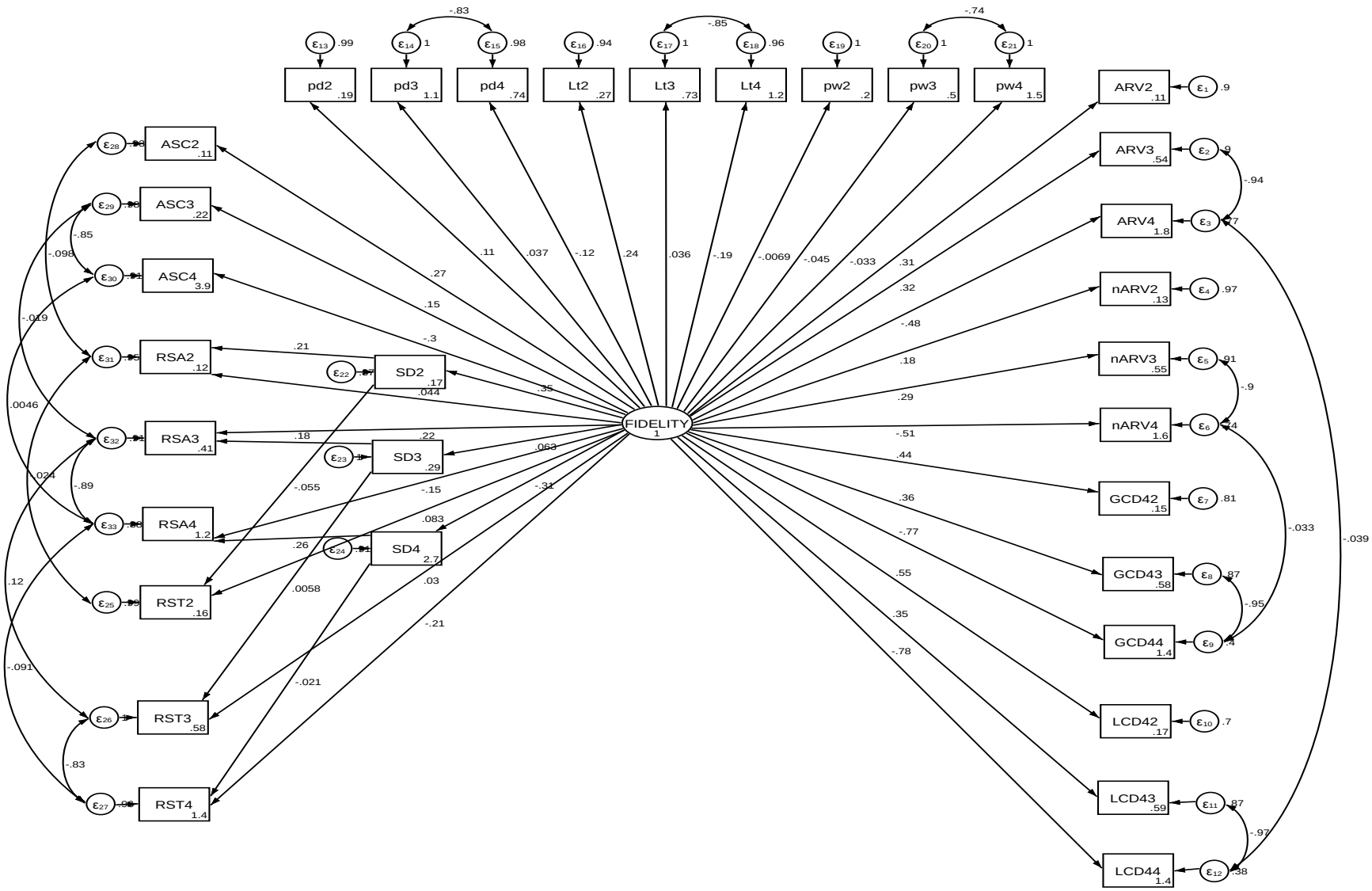


Figure 3.2: Confirmatory factor analysis using the structural equation model (SEM)

3.2 DESCRIBING THE DETERMINANTS OF IMPLEMENTATION FIDELITY OF THE CERVICAL CANCER SCREENING OF HIV-INFECTED WOMEN AMONG PRIMARY HEALTHCARE WORKERS

The descriptive features of the determinants of fidelity are reported, as well as their distribution between each implementation fidelity category (high and low fidelity).

3.2.1. Description of the main determinants of implementation fidelity among PHCWs.

The descriptive features of the four main groups of determinants of implementation fidelity – provider characteristics, implementation characteristics, system characteristics, and guideline characteristics, are displayed in Table 3.2 and 3.3 below. The score for the main determinants followed a skewed distribution; thus, the median was used in interpretation.

The overall median percentage score for the provider characteristics was seen to be 85.56, with an interquartile range of 80 – 92.22. The median percentage score of provider characteristics among primary healthcare workers with low implementation fidelity was 82.22 with an interquartile range of 76.67 – 87.78. Those with high implementation fidelity had a median score of 87.78, with an interquartile range between 82.22 and 94.44.

For the guideline characteristics, the overall median percentage score was 86.15 (IQR; 76.92 – 92.31). Those PHCWs with low implementation fidelity had a median guideline characteristic score per cent of 81.54 (IQR; 72.31 – 89.23), while those with high implementation fidelity had a median score of 89.23 with an interquartile range between 80 and 93.85.

Table 3.2 Descriptive statistics of the main determinants affecting the implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa.

Determinants	Number of observations	Range	Mean (SD)	Median (IQR)
Provider characteristics (%)	177	51.11 - 100	84.98 (10.10)	85.56 (80-92.22)
Guideline characteristics (%)	177	53.85 – 100	83.79 (11.36)	86.15 (76.92-92.31)
System characteristics (%)	177	36.67 – 100	75.80 (14.25)	76.67 (66.67-86.67)
Implementation characteristics (%)	177	20 - 100	64.78 (18.99)	60 (53.33-80)

SD = Standard deviation, IQR = Inter Quartile Range

Table 3.3: Descriptive statistics of the main determinants by the Implementation fidelity category.

Determinants	Low Fidelity (N = 67) Median (IQR)	High Fidelity (N = 110) Median (IQR)	p-value
Provider characteristics (%)	82.22 (76.67-87.78)	87.78 (82.22-94.44)	0.01***
Guideline characteristics (%)	81.54 (72.31-89.23)	89.23 (80-93.85)	0.01***
Implementation characteristics (%)	60 (53.33-80)	63.33 (53.33-80)	0.75
System characteristics (%)	76.67 (63.33-83.33)	76.67 (66.67-86.67)	0.34

*IQR = Inter Quartile Range, IF = Implementation fidelity, significant at *p <0.10; **p <0.05; ***p <0.01*

The median implementation characteristics score per cent was 60, with an interquartile range of 53.33 – 80. Primary healthcare workers belonging to the low implementation fidelity category had a median implementation characteristic score of 60 (IQR; 53.33 – 80), while those with high implementation fidelity had a median implementation characteristic score of 63.33, with an interquartile range between 53.33 and 80.

For the system characteristics, the overall median percentage score and the median system characteristics score of PHCWs belonging to the low and high implementation fidelity categories are presented in tables 3.2 and 3.3 above.

3.2.2 Description of other determinants and relevant sociodemographic characteristics affecting implementation fidelity among PHCWs

Other relevant determinants described include; background sociodemographic characteristics, training, and level of provider's knowledge. As presented in table 3.4 below; of the 177 study participants, 38.98% were from the Northern health sub-district. Among these study participants in the Northern sub-district, 33.33% and 66.67% had low and high implementation fidelity, respectively. Participants in the Southern health sub-district constituted 61.02%, with 40.74% of them having low implementation fidelity and 59.26% with high implementation fidelity.

The level of knowledge obtained among study participants ranged between 30% and 100% with an overall median knowledge score of 80% (IQR; 70 - 90). Primary healthcare providers, belonging to the low and high implementation fidelity categories, had a median knowledge score of 70% (IQR% 60 – 80) and 80% (IQR% 70 – 90), respectively.

Furthermore, only 24.86% of study participants had training on the updated National guidelines for cervical cancer screening, while 75.14% had no training on the updated National guidelines. Among the primary healthcare providers who have had no training, 41.35% had low implementation fidelity, while 58.65% had high implementation fidelity. For those with training, 27.27% and 72.73% had low and high implementation fidelity, respectively.

The distribution of age followed a normality curve (see figure 3.2 below), with the mean age of study participants observed to be 41.49, and a standard deviation of 8.45. The mean age of participants with low fidelity was 42.45 (SD; 9.93), while the mean age for those with high fidelity was 40.91 with a standard deviation of 7.40.

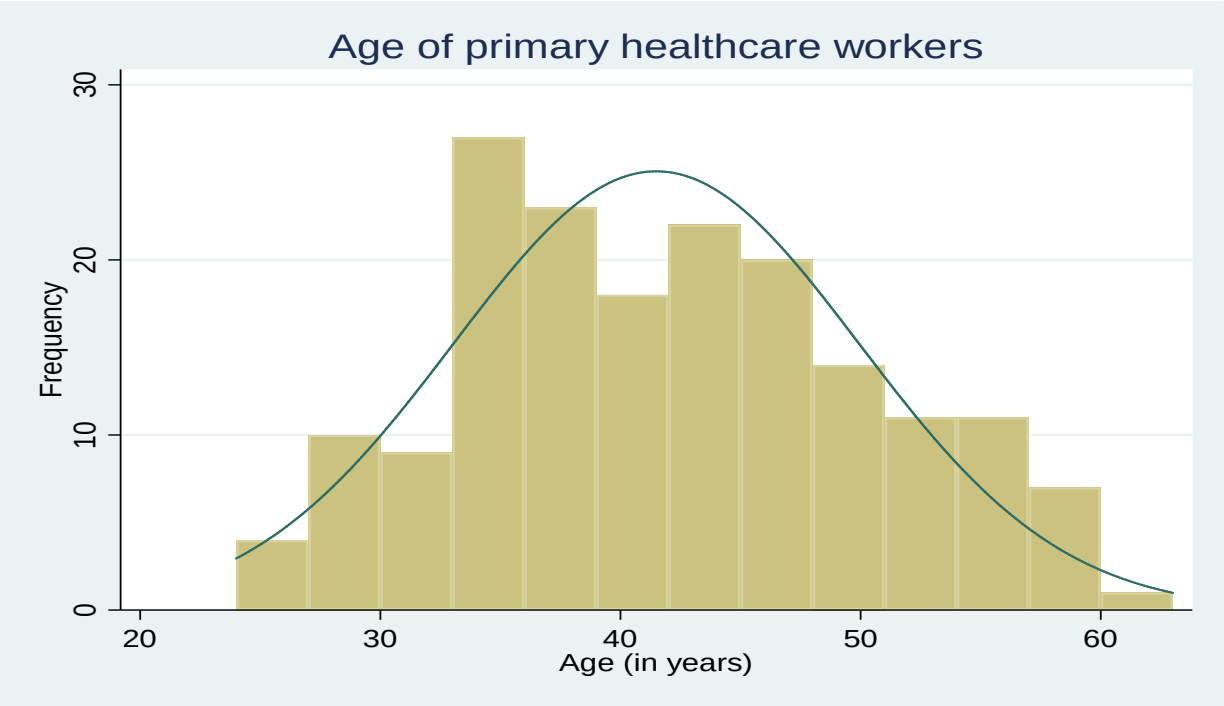


Figure 3.3: Histogram showing the distribution of age of study participants

Table 3.4: Descriptive statistics of sociodemographic characteristics and other determinants affecting the fidelity of implementation for the cervical screening of HIV-infected women.

Determinants	Number of participants (N=177)	IF% composite score Median (IQR)	Low Fidelity (N = 67)	High Fidelity (N = 110)	p-value
Sociodemographics					
Age (in years)					
Range	24-63		25-63	24-57	
Mean (SD)	41.49(8.45)		42.45(9.93)	40.91(7.40)	0.24
Median (IQR)			42(34-51)	39.5(35-46)	
Sex					
Male n(%)	11(6.21)	81.82 (69.70-87.88)	7(63.64)	4(36.36)	0.07*
Female n(%)	166(93.79)	84.85 (74.24-87.88)	60(36.14)	106(63.86)	
Highest level of education attained					
Undergraduate degree n(%)	94(53.11)	81.82 (72.73–87.88)	39(41.49)	55(58.51)	0.29
Postgraduate degree n(%)	83(46.89)	84.85 (75.76-90.91)	28(33.73)	55(66.27)	
Professional working experience (in years)					
Range	2-40		2-40	2-33	0.85
Mean (SD)			14.84(9.68)	14.40(7.72)	
Median (IQR)	12(8-22)		12(7-22)	13(8-22)	
Other determinants					
Knowledge (%)					
Range	30-100		30-100	40-100	0.01**
Mean (SD)			71.04(15.58)	80.18(13.55)	
Median (IQR)	80(70-90)		70(60-80)	80(70-90)	
Training					
Yes n(%)	44(24.86)	84.85 (78.79-90.91)	12(27.27)	32(72.73)	0.10
No n(%)	133(75.14)	84.85 (72.73-87.88)	55(41.35)	78(58.65)	
Health sub-district					
North n(%)	69(38.98)	81.82 (75.76-90.91)	23(33.33)	46(66.67)	0.32
South n(%)	108(61.02)	84.85 (75.76-87.88)	44(40.74)	64(59.26)	

*IF = Implementation fidelity, SD = Standard deviation, IQR = Interquartile range; significant at *p <0.10; **p <0.05; ***p <0.01*

Males made up 6.21% of the study participants, while the other 93.79% were females. Among primary healthcare providers who are females, 36.14% had low implementation fidelity, while 63.86% had high fidelity. For the male participants, 63.64% and 36.36% were observed to have low and high fidelity, respectively.

PHCWs whose highest level of educational qualification attained was an undergraduate degree accounted for 53.11%, while those with a postgraduate degree was 46.89%. Amongst those with an undergraduate degree, 41.49% had low fidelity while 58.51% had high fidelity. More so, those with a postgraduate degree, 33.73%, and 66.27% had a low and high implementation fidelity, respectively.

3.3 DETERMINING THE DIRECT AND INDIRECT RELATIONSHIPS BETWEEN THE ESTABLISHED DETERMINANTS AND IMPLEMENTATION FIDELITY OF THE CERVICAL CANCER SCREENING OF HIV-INFECTED WOMEN AMONG PRIMARY HEALTHCARE WORKERS, ADJUSTING FOR FACILITY LEVEL RANDOM EFFECTS

The relationship between each recognised determinant and implementation fidelity was examined using the logistic regression analysis (unadjusted model and adjusted model; which included all determinants in the model) and the generalised structural equation model (GSEM) – for determining the direct and indirect effects.

3.3.1 Univariate model

In the unadjusted analysis, two out of the four main determinants showed significant associations with implementation fidelity of the cervical cancer screening guidelines, at a p-value less than 0.05, at a 95% confidence interval. They include; Provider characteristics and guideline characteristics. Detailed results of this are presented in Table 3.5.

For the provider characteristics, an overwhelming significance (p-value < 0.001) was observed, and this showed that for every 1% increase in provider characteristics score, the odds of fidelity moving from low to high, increases by 1.07 times (OR=1.07, 95%CI: 1.04 – 1.11).

Similarly, for guideline characteristics, for every 1% increase in guideline characteristics score, the odds of a high implementation fidelity were 1.05 times greater than low fidelity (OR=1.05, 95%CI: 1.02 – 1.08).

Furthermore, in the unadjusted analysis for other determinants (explanatory variables), overwhelming statistically significant associations ($p < 0.001$) were observed between the level of knowledge and implementation fidelity. Training on the updated screening guidelines and the participant's sex only showed a marginal statistically significant ($p<0.1$) association with implementation fidelity.

This study participant's level of knowledge showed that for every 1% increase in knowledge score, the odds of a high implementation fidelity (IF) were 1.04 times greater than a low IF (OR=1.04, 95%CI: 1.02 – 1.06).

In study participants who were females, the odds of a high implementation fidelity versus a low implementation fidelity was 3.09 times, higher than for those who were males (OR=3.09, 95%CI; 0.87 – 10.99). Study participants who had training on the updated screening guidelines, the odds of a high implementation fidelity versus a low implementation fidelity were 1.88 times, greater than those without training (OR=1.88, 95%CI; 0.89 – 3.97).

Similar results of the univariate analysis were obtained by a sensitivity analysis using linear regression. Determinants such as Provider characteristics, Guideline characteristics, and level of knowledge; all showed statistically significant (p-value <0.05) relationships with implementation fidelity. (see Table C.9 Appendix section)

3.3.2 Multivariable model

All variables were fitted in this model. There was no multicollinearity among the explanatory variables, as estimated by a variance inflation factor (VIF) value of 1.75 (VIF values close to 1 indicates no multicollinearity) (103). The adjusted odds ratios are displayed in Table 3.5 below. As shown from this table, three determinants; Provider characteristics, participant's level of knowledge and training on the updated screening guidelines, were significantly associated with high implementation fidelity, holding other

explanatory variables constant. The variable; highest level of education attained showed marginal significance (p-value <0.1) with implementation fidelity.

3.3.2.1 Assessing the multivariable model goodness-of-fit

The goodness of fit statistics for the final multivariable logistic regression model showed that it was a good fit (see Table C.10 in Appendix C). The Hosmer and Lemeshow's goodness-of-fit test reported the p-value for the whole model to be 0.718. This large p-value indicates a good fit (104).

Table 3.5: Crude and adjusted odds ratio of determinants associated with implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa

Variable	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Main determinants				
Provider characteristics	1.07 (1.04 – 1.11)	0.01**	1.05 (1.01 – 1.10)	0.02*
Guideline characteristics	1.05 (1.02 – 1.08)	0.01**	1.02 (0.98 – 1.05)	0.39
Implementation characteristics	1.00 (0.99 – 1.02)	0.82	1.00 (0.98 –1.02)	0.93
System characteristics	1.01 (0.99 – 1.03)	0.30	1.00 (0.97 – 1.04)	0.83
Other determinants				
Training				
No	Ref		Ref	
Yes	1.88 (0.89 – 3.97)	0.09	2.33 (0.99 – 5.52)	0.05*
Level of Knowledge	1.04 (1.02 – 1.06)	0.01**	1.02 (1.00 – 1.06)	0.03*
Facility region				
North	Ref		Ref	
South	0.73 (0.39 – 1.37)	0.32	0.79 (0.38 – 1.64)	0.53

Variable	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Sociodemographic characteristics				
Age (years)	0.98 (0.94–1.02)	0.24	0.95 (0.83 – 1.04)	0.26
Sex				
Male	Ref		Ref	
Female	3.09 (0.87–10.99)	0.08	1.61 (0.39 – 6.58)	0.51
Years of professional work experience	0.99 (0.95 –1.03)	0.74	1.01 (0.94 – 1.10)	0.74
Highest level of education attained				
Undergraduate degree	Ref		Ref	
Postgraduate degree	1.39 (0.75 – 2.57)	0.29	2.03 (0.90 – 4.57)	0.09

Pseudo R-squared (adjusted)=15.49%; Ref=reference category; OR=Odds ratio; CI=95% confidence interval; *significant at p ≤ 0.05; **significant at p < 0.0001

3.3.3 Path analysis from the Generalized structural equation model (GSEM)

3.3.3.1 Direct Effect

The Average Direct Effect (ADE) of the explanatory variables on implementation fidelity was estimated by holding constant all intermediate variables and adjusting for facility-level random effect (see Figure 3.4). The output results show the direct (unmediated) effect, adjusting for the facility-level random effect. It produces almost similar results as the logistic regression adjusted odds ratio reported in Table 3.5. The output of the direct effect odds ratio is reported in Table 3.6. Also, the Stata syntax employed for the GSEM is presented in Appendix D of this research report.

Table 3.6: GSEM output of the direct odds ratio of the determinants of implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa.

Variable	Adjusted OR (95% CI)	p-value
Main determinants		
Provider characteristics	1.05 (1.00 – 1.10)	0.04*
Guideline characteristics	1.01 (0.98 – 1.05)	0.49
Implementation characteristics	1.00 (0.98 –1.03)	0.92
System characteristics	1.01 (0.97 – 1.04)	0.72
Other determinants		
Training		
No	Ref	
Yes	2.22 (0.91 – 5.45)	0.08
Level of Knowledge	1.03 (1.00 – 1.06)	0.02*
Sociodemographic characteristics		
Age (years)	0.95 (0.87 – 1.03)	0.21
Sex		
Male	Ref	
Female	1.85 (0.42 – 8.00)	0.41
Years of professional work experience	1.02 (0.94 – 1.10)	0.69
Highest level of education attained		
Undergraduate degree	Ref	
Postgraduate degree	1.98 (0.85 – 4.61)	0.11

Ref=reference category; OR=Odds ratio; CI=95% confidence interval; *significant at p ≤ 0.05; **significant at p < 0.0001

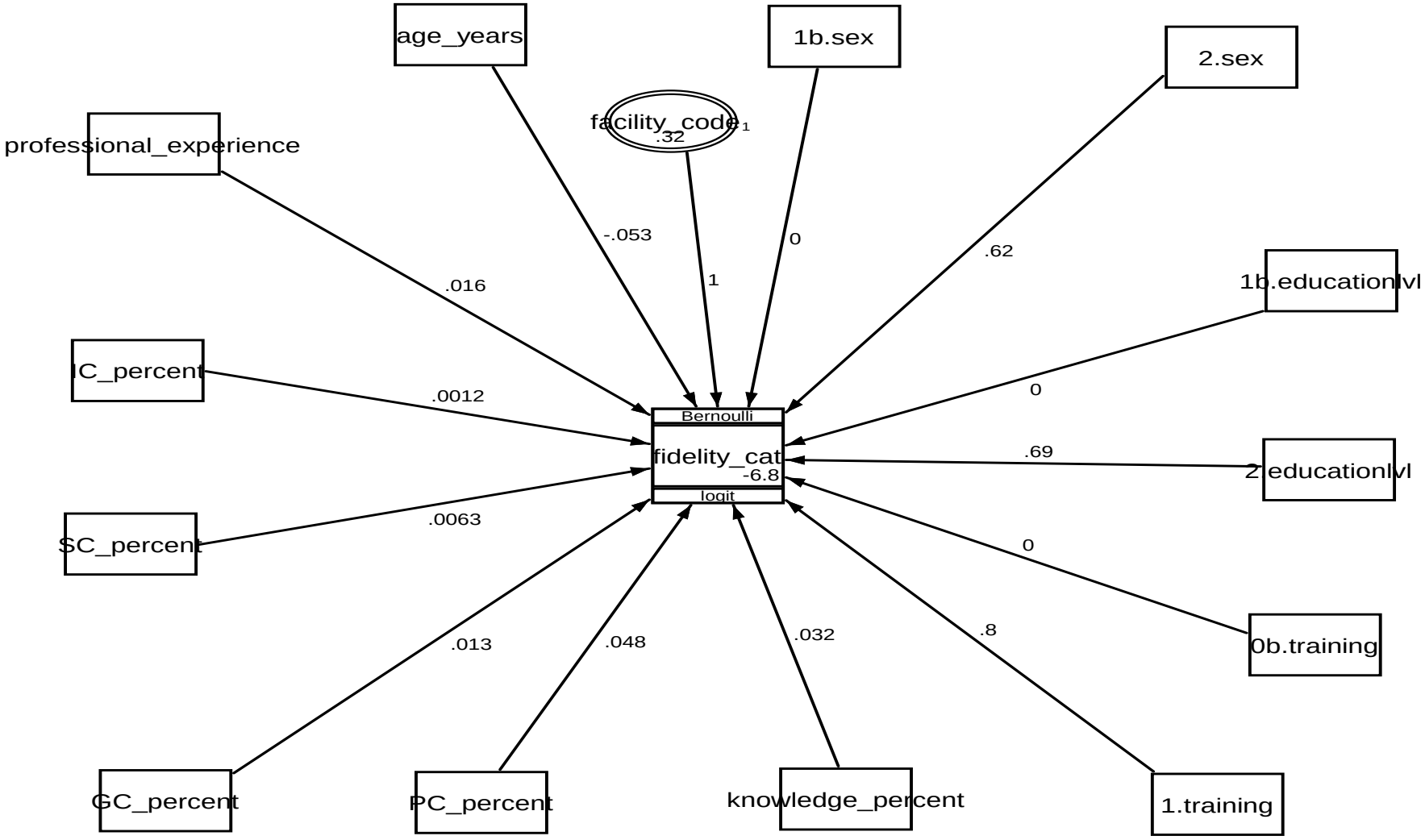


Figure 3.4: Pathway modelling showing direct effects of the determinants of implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa 2019.

3.3.3.2 Indirect Effect

The pathway analysis demonstrates the direct (see Figure 3.4) and indirect (see Figure 3.5) interactions route among determinant variables that predict implementation fidelity. In Table 3.7, there is the display summary of the computed results output of the direct (unmediated), indirect (mediated) and total effects for the predictors of implementation fidelity, adjusting for the facility-level random effect.

In this analysis, participants' age, years of professional work experience, training on the update National cervical screening guidelines, participant's level of knowledge and guideline characteristics, all indirectly impacted on implementation fidelity through provider characteristics.

Further observation of figure 3.5 and Table 3.7, reveals that provider characteristics had a statistically significant ($p<0.05$) direct positive predictive effect on implementation fidelity, i.e. for every 1% increase in provider characteristics score, the odds of fidelity moving from low to high increases by 1.07 times, holding all other variables constant.

However, with provider characteristics '*PC_percent*' as an endogenous (outcome) variable, the following statistically significant ($p<0.05$) variables that indirectly impacted on implementation fidelity includes; the guideline characteristics and the participant's level of knowledge of the updated guidelines. These variables displayed a positive predictive effect on implementation fidelity, with an odds ratio of 1.19 and 1.48, respectively, holding all other variables constant. The greatest indirect impact on implementation fidelity is the guideline characteristics, with an odds ratio of 1.03, i.e. for every 1% increase in guideline characteristics score, the odds of fidelity moving from low to high increases by 1.03 times, holding all other variables constant.

3.3.3.2.1 Assessing the GSEM Goodness-of-fit

The goodness of fit statistics for the final GSEM model showed that it was a good fit (see Table C.11 in Appendix C). The Akaike information criterion (AIC) and Bayesian information criterion (BIC) estimated values for the model to be 221 and 260, respectively. These small values indicated a good fit (105).

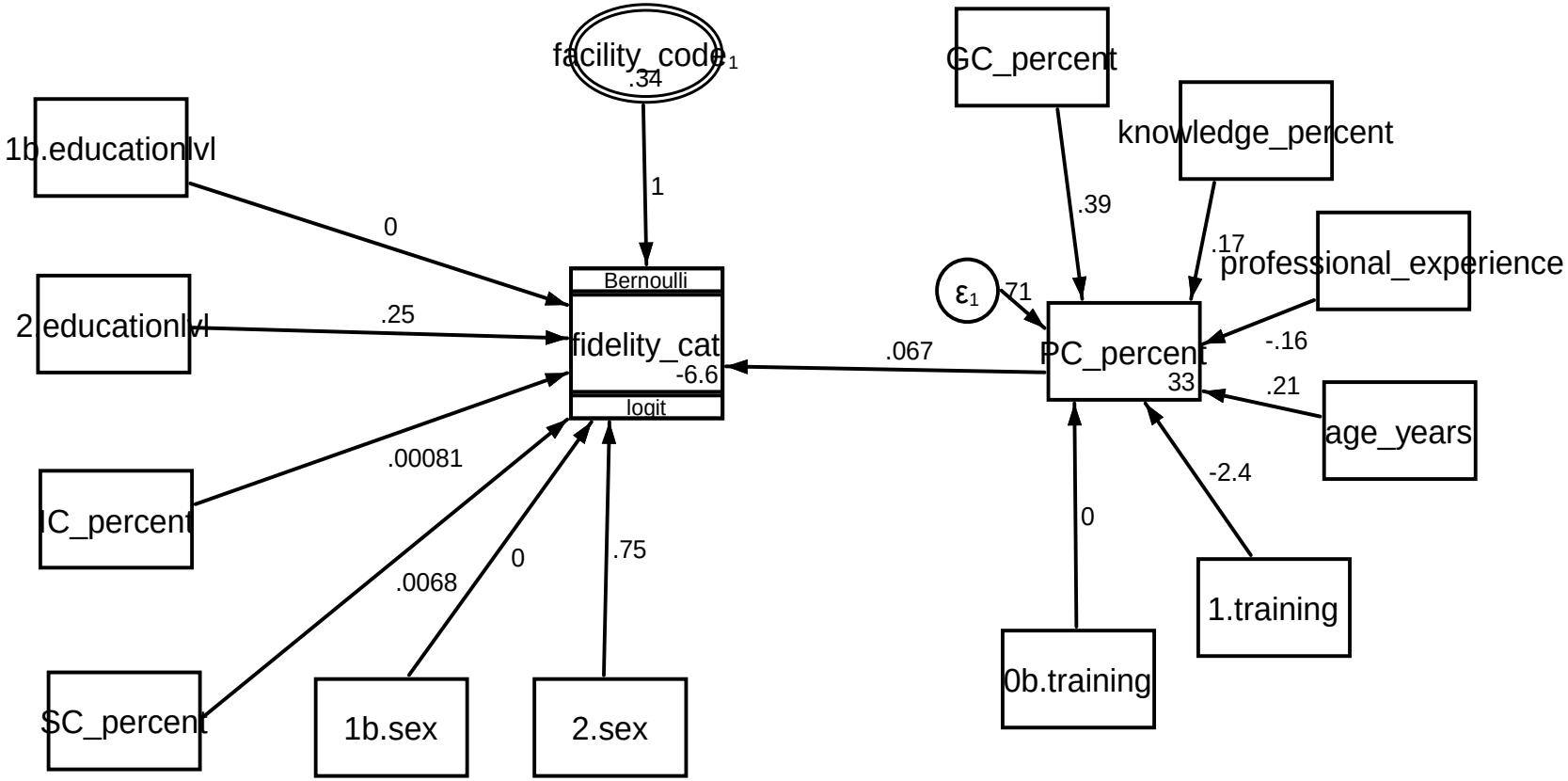


Figure 3.5: Pathway modelling showing indirect effects of the determinants of implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa 2019. Key for variables names: Implementation fidelity category (**fidelity_cat**), Percentage score for provider characteristics (**PC_percent**), Percentage score for guideline characteristics (**GC_percent**), Percentage score for system characteristics (**SC_percent**), Percentage score for implementation characteristics (**IC_percent**), Percentage score for knowledge (**knowledge_percent**), Years of professional working experience (**professional_experience**), Highest level of educational qualification attained (**educationlvl**), Individual primary healthcare facility (**facility_code**), Age of participants (**age_years**), Sex (**sex**), Training on the updated National cervical screening guidelines (**training**). Other: the arrows pointing from the exogenous (explanatory) to endogenous (dependent) variables and the error terms (ε) placed on the endogenous variables are guided from theory and the modified conceptual framework of implementation framework (see figure 1.1)

Table 3.7: Direct, indirect and total effects of the determinants of implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa, 2019.

	Direct effects on IF as shown in Figure 3.5 conceptual framework		Indirect effects on IF	Total effects on IF
	OR (95% CI)		OR (95% CI)	OR (95% CI)
Factor	Provider characteristics	Implementation fidelity category (Low vs High)		
Age_years	1.25 (0.95-1.61)		1.01 (0.99-1.03) [I]	1.01 (0.99-1.03)
Male vs Female		2.12 (0.51-8.82)		2.12 (0.51-8.82)
Professional_experience	0.86 (0.66-1.11)		0.98 (0.97-1.00)	0.98 (0.97-1.00)
Undergraduate degree vs Postgraduate degree		1.29 (0.64-2.59)		1.29 (0.64-2.59)
No training vs Training	0.09 (0.01-1.55)		0.85 (0.67-1.03)	0.85 (0.67-1.03)
Knowledge_percent	1.19 (1.09-1.30) ***		1.01 (1.01-1.02) ***	1.01 (1.01-1.02) ***
System characteristics		1.00 (0.97-1.04)		1.00 (0.97-1.04)
Guideline characteristics	1.48 (1.32-1.66) ***		1.03 (1.01-1.04) ***	1.03 (1.01-1.04) ***
Implementation characteristics		1.00 (0.98-1.02)		1.00 (0.98-1.02)
Provider characteristics		1.07 (1.02-1.11) ***		1.07 (1.02-1.11) ***
Intercept	2.16×10^{14} (1.08×10^{8}-3.64×10^{20}) ***	1.42×10^{-3} (3.21×10^{-5}-6.28×10^{-2}) ***		

p <0.10; **p <0.05; ***p <0.01; OR: Odds ratio; CI: Confidence interval; IF: Implementation fidelity; I: indirect effects computed as the product of coefficients along the related pathways, i.e. 0.211 x 0.067 ≈ e^(0.014137) i.e. [Odds Ratio of 1.01]

CHAPTER FOUR

DISCUSSION

4.1 INTRODUCTION

This study aimed at assessing whether the cervical screening of HIV-infected women by primary healthcare workers in Ekurhuleni, South Africa, was done as set by the National policy on cervical cancer prevention and control. Also, the determinant factors associated with implementation fidelity (adherence) to the cervical cancer screening guideline for HIV-infected women, were evaluated.

This chapter discusses and interprets the results presented in the previous chapter, as well as the study strengths, limitations, conclusions, and research recommendations. Discussion of key findings will follow the already laid-out research objectives in sequential order.

4.2 MEASURING IMPLEMENTATION FIDELITY

Although, when objectively heeding to the definition of implementation fidelity established by Carroll et al., it implies that fidelity (adherence) ought to be full or complete, i.e. 100% (43). However, in considering the scientific and medical reality, complete adherence to clinical practice guidelines is quite ambitious as there are too numerous variables involved, and none of which can be adequately covered by any summary report (106). Therefore, in this study, it was found out that, in measuring the fidelity (adherence) to the cervical screening of HIV-infected women as prescribed by the guideline, the overall implementation fidelity score was high. This median score was 84.85% of the maximum obtainable score.

In this study, the healthcare providers who exhibited high fidelity reported a good performance in adherence to the content (one of the fidelity constructs) of the guideline. This fidelity to the content of the guideline refers to the extent to which they adhered to conducting cervical screening in-keeping with recommendations, i.e., screening of HIV-

infected women for cervical cancer irrespective of the age of start screen (i.e. sexually active girls <30 years), CD4 count levels, and whether or not on antiretroviral treatment (6, 24). This finding was not surprising in the South African context, as this attribute could be linked partly to the positive beliefs and perceptions of primary healthcare providers about the reduction of the starting age of screening for sexually active women (52).

Many health professionals feel that due to the rise in the incidence of HIV/AIDS, younger women are at risk of cervical cancer (107). A study done in Cape Town revealed similar findings, with a little above half of the nurses who participated sharing a similar opinion – that cervical screening should be done for girls at the start of sexual activity (108). These shared sentiments among health professionals concerning the rate of HIV/AIDS and STIs in South Africa and its strong association with cervical cancer could explain this study finding – i.e. high fidelity.

Notwithstanding, this study findings also revealed that some healthcare providers exhibited low fidelity to the screening guidelines. In particular, this portion of healthcare providers had a poor performance in adherence to coverage and frequency (two of the fidelity constructs), i.e. the extent to which they adhered to the cervical screening of all their clients at the point of diagnosis of HIV-seropositivity, and conducting other follow-ups cervical screening, was suboptimal (26). These aspects significantly contributed to their low scores.

It was found that many providers rarely conducted cervical screening of their clients at the point of diagnosis of HIV-seropositivity. This finding is in contrasts with what is prescribed by the screening guideline, which recommended initiating cervical screening for all HIV-infected women at the time of HIV diagnosis (26). This scenario may be attributed to the lack of an integrated healthcare service delivery to patients who are diagnosed and managed for HIV-infection (65). This attribute has been demonstrated in the South African context, as a phenomenon which mainly occurs in high volume healthcare facilities that displayed low coverage for the cervical screening of HIV-infected women (28).

The national guidelines for cervical screening of HIV-infected women also gave clear recommendations on the frequency and timing of screening intervals and the follow-up screening after treatment. It states that HIV-positive women should undergo cervical screening three-yearly for those with a normal Pap smear test. Those with an initial abnormal Pap smear test should undergo follow-up cervical screening every year after their treatment until the smear test becomes normal (26).

Despite these clear proposals, many providers reported to only occasionally adhering to this aspect of the guideline concerning screening intervals and follow-up screening. This scenario could be attributed to an inadequate mechanism of record-keeping, as demonstrated with findings from a study done in KwaZulu-Natal, South Africa, which assessed the implementation of the provincial cervical screening programme (73). The above-stated reason, i.e. poor incorporation of the wholistic care of the HIV-infected women (65), as well as poor retention of these women in care (36), could also explain this low adherence level to cervical screening timing/intervals.

4.3 FACTORS ASSOCIATED WITH IMPLEMENTATION FIDELITY

This study focused its second and third objective on establishing the determinants of the fidelity of implementation of the guideline for the cervical screening of HIV-infected women, as well as evaluating the association between these determinants and fidelity. This study found out that the implementation fidelity of cervical screening was influenced by a combination of factors either directly or indirectly. The provider's characteristics directly influenced implementation fidelity. Healthcare providers' knowledge of screening guideline, and the guideline characteristics, on the other hand, indirectly impacted fidelity, with the provider characteristics acting as the mediating variable. This relationship implies that fidelity increased with increasing knowledge of the guideline. Of all these, the characteristics of the guideline had the greatest indirect impact in predicting implementation fidelity.

4.3.1 Main determinants

4.3.1.1 Provider characteristics – This determinant had a strong direct positive association with the implementation fidelity of the cervical screening of HIV-infected women. For this study, provider characteristics looked at; providers' self-efficacy, confidence, communication skills, motivation, subjective norms/attitudes/beliefs, as well as the extent to which they agreed with the various components of the recommended cervical screening guideline. These features can be viewed as inherent traits of the healthcare providers, that may hinder them from providing effective cervical screen services. This finding was however not surprising as it was consistent with evidence from previous studies that had reported similar findings regarding the provider-level barriers and motivation to cervical cancer screening (34, 58, 109, 110).

A study done in Western Cape province of South Africa, revealed amongst other things, that the cervical screening programmes are usually unsuccessful due to the lack of understanding of the health professionals on the rationale of the screening policy (72). Also, findings from an Iranian study revealed that the healthcare practitioners work commitment as well as clear communication in informing their clients of cervical screening, are essential factors that affect their adherence to screening practices and ultimately the quality of patients' care (110).

Considering that this field of research is new and emerging, especially in Africa, caution should be applied in interpreting and comparing these study findings with those from high-income countries. Having this in mind, similar findings from a study done in El Paso, Texas revealed that positive attitudes and support gotten from the healthcare providers go a long way in facilitating cervical screening practices (64). Another study done in the United States, which examined provider's attitudes and screening practices, reported that a reason for primary care provider's noncompliance with the guideline was their disagreement with the amended screening guidelines (111).

4.3.1.2 Guideline characteristics – In this study, implementation fidelity was indirectly influenced positively by this predictor. This study examined guideline characteristics in terms of; its complexity, applicability, ease of use and its conformity with the general

population perceived specific public health needs. This effect was mediated through provider characteristics. This finding was synonymous with those reported in previous studies which demonstrated that guideline features as well as how it is being used by the healthcare providers, determines the extent to which they adhere to the guideline (57, 58, 60).

4.3.2 Other determinants

4.3.2.1 Knowledge of the cervical screening guideline – The level of the healthcare provider's knowledge, had an indirect positive effect on implementation fidelity. The provider's characteristics mediated this effect. The level of knowledge determines the healthcare provider's self-efficacy and confidence which are important for attaining a high-level fidelity (112). This finding agreed with previous studies which had portrayed that familiarity with, and knowledge of the contents of a guideline is beneficial for a higher chance of its implementation (58, 60, 109). The insufficient knowledge of the healthcare provider's about the cervical screening guideline and practices also translates to whether or not women get adequate information on cervical cancer, that they require (72). This trend can affect implementation fidelity and also affect ultimately, the intervention outcome, i.e. a reduction in cervical cancer (113).

4.4 Relevance of study findings

These study findings give the understanding that to improve the fidelity of implementation of cervical screening, nurturing a positive attitude, motivation and improving the knowledge of the healthcare providers (i.e. frontline implementers) is essential. Combined with other characteristics of the healthcare providers (modifiable and non-modifiable – age, sex, & other sociodemographic features), they stand as a strategic mediatory point through which other determinant factors (the guideline characteristics) can positively impact the fidelity of implementation of the cervical screening of HIV-infected women.

The findings of this study are beneficial to South African cervical cancer control programme developers and frontline implementers as it reveals the points of focus that

implementation strategies could be tailored to in order to improve the fidelity of implementation of the cervical screening guideline.

4.5 STRENGTH AND LIMITATIONS OF THE STUDY

The strength and limitations of this study are explained in three categories: the outcome variable – design/classification; research results relevance – locally and globally; and statistical analysis approach. These are discussed sequentially below.

4.5.1 Design of the outcome variable

The main strength of this study in our outcome variable is that it incorporated all key components of the cervical screening guideline, in deriving the adherence rate for each healthcare provider. This study also made use of the factor analysis technique in guiding our decision for a specific cut-off point for classifying our outcome variable (fidelity). It is unlike other studies which depicted adherence level by just asking a simple single question on 'whether providers adhere to cervical screening guidelines', with a 'yes or no' type of response (76), and assuming an arbitrary cut-off for high and low fidelity. This approach adopted in this study provided a more comprehensive method for assessing fidelity of implementation of the cervical screening of HIV-infected women. This method of measuring implementation fidelity (adherence) can be applied to other clinical guideline interventions. Nevertheless, since our outcome variable was based on self-reported implementation fidelity, which may contain some element of bias such as social desirability, extremity, and acquiescence (96). Although, reassuring respondents of utmost confidentiality instituted precautions against this.

4.5.2 Generalisability – local and global relevance

A limitation of this study is based on the fact that this study focused on one district (Ekurhuleni) only, and it is the first study to measure implementation fidelity in this setting. As a result of this, there is limited evidence that these results about the implementation fidelity of cervical cancer screening of HIV-infected women, can be generalised to the entire Gauteng province. However, this study which established the determinants of the

fidelity of implementation of the cervical screening guideline had findings that reflect similar patterns in other primary healthcare settings at least in Northern Africa (76) and other parts of Africa (34). It is also worthy to note that contextual factors, such as the healthcare system organisation, as well as the national or organisational policies, largely affect result outcomes. Likewise, validation of this research data collection tool is advised, before it can be adopted and applied in a different study context.

Another limitation of this study is premised on the use of convenience sampling technique, which has its shortcomings including its attendant possibility of under- or over-representing the study population.

4.5.3 Statistical analysis approach

Also, as one of the strengths of this study, in dealing with confounding variables, multiple regression was used, and added the facility-level random effects in modelling and also performed pathway analysis. The GSEM method, which was used to examine the mediatory effect – direct and indirect pathway analysis of the determinant factors, added methodological value to this study. Also, the GSEM analysis contributed empirical evidence in testing the implementation fidelity framework as proposed by Carroll et al. (43).

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

In conclusion, this study has found that there is a high level of fidelity of implementation of the guideline for the cervical screening of HIV-infected women, by primary healthcare providers in Ekurhuleni, South Africa, in 2019. This study was also relevant in establishing the factors which affect this implementation fidelity, as well as how they are interlinked. Worthy of interest is the provider's characteristics and guideline characteristics, which could serve as a key-points of focus for future implementation strategies.

From the perspective of implementation research, it is imperative to examine the implementation process to ensure that programmes are executed as prescribed in the original design (fidelity). This step must be established before an intervention can be said to have led to a programme outcome (114). Therefore, this current research adds a vital input to this field.

5.2 RECOMMENDATIONS

Several evidence-based clinical practice guidelines are developed to improve health outcomes. Regretfully, the development and availability of guideline recommendations, on its own, does not automatically translate to its use. Therefore, a structured implementation is needed to improve adherence to guidelines (115)

The Expert recommendation for implementing change (ERIC) project has put forward some evidence-based implementation strategy recommendations from which we can draw an understanding (116). These strategies could be applied in a multi-level approach as this study has provided findings to back the mediatory effects of some of the determinant factors of the fidelity of implementation for the cervical screening of HIV-infected women in South Africa. These recommendations are highlighted below.

The study findings indicate it is needful to enhance the skills, proficiency, competence and knowledge of the PHCWs on the updated cervical screening practices in South Africa. This goal can be done through implementation strategies such as continuous medical education (CME), seminars, training workshops and such-like, in order to improve guideline adherence and patient's clinical outcome, ultimately. Training also may not always be sufficient, so a mentoring, audit of practice with continuous feedback are evidence-based strategies that could be implemented (116).

Local consensus meetings and discussions (116) should be conducted, whereby the relevant local stakeholders – including the PHCWs – are involved in addressing their perceptions on whether the clinical screening guidelines are appropriate for addressing cervical cancer in their local context and find ways to deal with perceptions that may hinder screening.

Also, the South African national, provincial, district and or facility level-programmes should consider collecting information on implementation fidelity (adherence) level of healthcare providers as one of the routine data described in their annual summary reports. This data can help; improve screening/prevention policy, provide valuable information on how cervical screening is being conducted and also help identify the barriers to successful implementation, for which strategies tailored to a specific setting and target groups can be developed.

Furthermore, to permit robust findings, future large-scale research that ensures adequate power through an increased sample size should be conducted to measure fidelity objectively. Other measuring techniques such as; observation, use of checklist/or records review (42) should be considered, as well as the use of qualitative research design to synthesise better, the contextual predictors of the healthcare provider's fidelity of implementation of the cervical screening of HIV-infected women.

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APPENDICES

APPENDIX A – Questionnaire

Section A: Sociodemographics

1. Age (In years) ……..
2. Sex: Male ☐ Female☐
3. Occupation cadre: Medical doctor☐ Professional Nurse☐
   Others(please specify) ……..
4. Educational qualification (highest level attained): Undergraduate diploma☐ Bachelor☐ Postgraduate diploma☐ Master's ☐ Others (please specify) …….
5. The number of professional working experience **(in years)** ……..
6. Length of time working in this health facility **(in days, months, or years)** …….

Section B: Knowledge of healthcare provider

The National cervical cancer prevention and control policy have guidelines on screening of HIV-infected women. According to the guidelines, which of the following statements are TRUE or FALSE? Tick (✓) any of the three available options.

7. Pap smear cytology-based screening is the recommended screening method in South Africa.
   True☐ False☐ I don't know☐
8. All HIV positive women should be screened for cervical cancer at the point of diagnosis of HIV-infection.
   True☐ False☐ I don't know☐
9. HIV-positive women on ARV treatment should start cervical screening at the age of 30 years.
   True☐ False☐ I don't know☐
10. Only HIV-positive women NOT on ARV treatment should start screening before the age of 30 years.
    True☐ False☐ I don't know☐
11. Only HIV-positive women with a CD4 count of less than 500/ul should be screened before the age of 30 years.
    True☐ False☐ I don't know☐
12. Asymptomatic women who are HIV-infected and under the age of 30 years, should NOT be screened for cervical cancer.
    True☐ False☐ I don't know☐
13. All HIV-infected women with an initial POSITIVE smear test should undergo follow-up cervical cancer screening every three years.
    True☐ False☐ I don't know☐

14. All HIV-infected women with an initial NEGATIVE pap smear test should undergo follow-up cervical cancer screening ANNUALLY.
    True☐ False☐ I don't know☐
15. HIV-infected pregnant women who are 20 weeks gestational age or less, can NOT undergo cervical cancer screening.
    True☐ False☐ I don't know☐
16. All HIV-infected women should have cervical cancer screening for the REST OF THEIR LIVES.
    True☐ False☐ I don't know☐

Section C: Implementation fidelity

Content and coverage

For the next few questions, we have provided a statement on various activities. For each statement, please indicate (✓) whether you perform this activity "always, sometimes, rarely or never". There is NO RIGHT or WRONG answer; please indicate (✓) which refers to you.

17. I perform a cervical cancer screening test for HIV-positive women at the point of diagnosis of HIV-infection.
    Never☐ Rarely☐ Sometimes☐ Always☐
18. I perform cervical cancer screening on HIV-infected women younger than 30 years.
    Never☐ Rarely☐ Sometimes☐ Always☐
19. I perform cervical cancer screening on HIV-infected pregnant women with 20 weeks gestational age or less.
    Never☐ Rarely☐ Sometimes☐ Always☐
20. I perform cervical cancer screening on HIV-infected women receiving ARV treatment.
    Never☐ Rarely☐ Sometimes☐ Always☐
21. I perform cervical cancer screening on HIV-infected women NOT receiving ARV treatment.
    Never☐ Rarely☐ Sometimes☐ Always☐
22. I perform cervical cancer screening on HIV-infected women with a CD4 count of ≥ 500/µl.
    Never☐ Rarely☐ Sometimes☐ Always☐
23. I perform cervical cancer screening on HIV-infected women with a CD4 count of ≤ 500/µl
    Never☐ Rarely☐ Sometimes☐ Always☐
24. I inform all HIV+ clients that I screened for their next screening date.
    Never☐ Rarely☐ Sometimes☐ Always☐
25. I refer all HIV+ clients with an abnormal cervical screening test for a colposcopy examination.
    Never☐ Rarely☐ Sometimes☐ Always☐

Frequency and duration

26. If my HIV+ client has an initial normal pap smear test, I repeat the follow-up screening test after three years.
    Never ☐ Rarely ☐ Sometimes ☐ Always ☐
27. If my HIV+ client has an initial abnormal pap smear test, I repeat the follow-up screening test after one year.
    Never ☐ Rarely ☐ Sometimes ☐ Always ☐

Section D: Determinants of fidelity

The National policy for cervical cancer prevention and control has guidelines for screening HIV-infected women. This guideline states that:

- **The recommended primary method for screening is the Pap smear cytology.**
- **All HIV-infected women should start screening as soon as diagnosed to be HIV+**
- **HIV+ women below 30 years, can be screened for cervical cancer.**
- **All HIV+ women should be screened irrespective of their CD4 count levels.**
- **All HIV+ women should be screened, whether they are on ARV treatment or not.**
- **HIV+ women who are pregnant can undergo screening up to 20 weeks gestational age.**
- **If the initial test is positive (i.e. an abnormal smear), a follow-up screen should be done after one year.**
- **If the initial test is negative (i.e. a normal smear), a follow-up screen should be done after three years.**
- **All HIV-infected women should be screened for the rest of their lives (i.e. no cut-off age).**

Provider's characteristics

We have provided several statements below. For each statement, please indicate (✓) whether you strongly agree, agree, disagree, strongly disagree or neither agree nor disagree. There is no right or wrong answer, please indicate how you feel.

28. To what extent do you agree or disagree with the components of the recommended National guideline for cervical cancer screening of HIV-infected women?

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Use of pap smear cytology as the recommended cervical cancer screening method	☐	☐	☐	☐	☐
Conducting follow-up screening annually, if the initial smear test is abnormal.	☐	☐	☐	☐	☐
Conducting follow-up screening triennially, if the initial smear test is normal.	☐	☐	☐	☐	☐
Starting screening before the age of 30 in HIV-infected women	☐	☐	☐	☐	☐
Screening HIV-infected women for the rest of their life (no age cut-off).	☐	☐	☐	☐	☐
Screening of HIV-infected women irrespective of pregnancy status.	☐	☐	☐	☐	☐
Screening of HIV-infected women irrespective of CD4 count levels.	☐	☐	☐	☐	☐
Screening of HIV-infected women whether they are on ARV treatment or not.	☐	☐	☐	☐	☐

29. To what extent are the following statements a true reflection of you, as a healthcare provider?
(Rating scale is from 1 to 5, with "1" standing for "very UNTRUE of me" and "5" stands for "very TRUE of me")

	1	2	3	4	5
I possess the necessary skills to perform the guidelines on screening of HIV-infected women	☐	☐	☐	☐	☐
I am self-confident in implementing the guideline's recommendations	☐	☐	☐	☐	☐
I possess good communication and collaboration with my colleagues	☐	☐	☐	☐	☐
I perform screening mostly because it is expected from me by my supervisors	☐	☐	☐	☐	☐
I perform screening because my patients request for it	☐	☐	☐	☐	☐
I perform screening because its of low financial cost to my patients	☐	☐	☐	☐	☐
I perform screening mostly because my patients show symptoms	☐	☐	☐	☐	☐
I do not perform screening because I feel embarrassed in telling my patients to undress	☐	☐	☐	☐	☐
I perform screening because I have less workload	☐	☐	☐	☐	☐
I perform screening because I have a strong belief it will help reduce the rate of cervical cancer in the community	☐	☐	☐	☐	☐

Guideline characteristics

30. Concerning the screening guidelines, to what extent do you AGREE with the following statements?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The guidelines conflict with my existing medical knowledge	☐	☐	☐	☐	☐
The guidelines do not clarify the healthcare provider's role	☐	☐	☐	☐	☐
The guidelines give concise instructions on which screening tests to use	☐	☐	☐	☐	☐
The guideline's recommendations are too complex to follow.	☐	☐	☐	☐	☐
The guidelines ignore the individualisation of patient care	☐	☐	☐	☐	☐
It is time-consuming to apply the guidelines in practice	☐	☐	☐	☐	☐
The guideline ignores the thought process involved in making a clinical judgement	☐	☐	☐	☐	☐
It is inconsistent with the public health needs because cervical cancer poses a minimal threat to HIV-infected women as opposed to uninfected females	☐	☐	☐	☐	☐
The guidelines are inconsistent with public health needs because HIV-infected women need to be screened for TB and other opportunistic infections rather than cervical cancer	☐	☐	☐	☐	☐

It makes patient care more efficient	☐	☐	☐	☐	☐
It provides citable evidence for litigation	☐	☐	☐	☐	☐
It provides an authority that reassures you about the appropriateness of screening practices	☐	☐	☐	☐	☐
It provides uniformity and consistency in patients care	☐	☐	☐	☐	☐

System characteristics

31. Concerning your health care facility, to what extent do you AGREE with the following statements?

In my health facility:	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
It is clear whose responsibility it is to perform pap smears	☐	☐	☐	☐	☐
The guidelines for cervical screening of HIV-infected women are provided to health workers	☐	☐	☐	☐	☐
It is clear where to find necessary supplies needed to perform a cervical cancer screening test.	☐	☐	☐	☐	☐
There are always sufficient screening tools and materials available	☐	☐	☐	☐	☐
There is an available workspace /rooms for screening	☐	☐	☐	☐	☐

There is a referral system in place for referring clients with an abnormal pap smear result to the next level of healthcare	☐	☐	☐	☐	☐

Implementation characteristics

32. Concerning your health care facility, to what extent do you AGREE with the following statements?

In my health facility:	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
There is enough staff available to perform the target number of screening tests.	☐	☐	☐	☐	☐
Health workers receive supervision on screening practices	☐	☐	☐	☐	☐
Health workers receive feedback on their screening performance	☐	☐	☐	☐	☐

33. Have you been trained on the updated recommended national guidelines for cervical cancer screening of HIV-infected women?
    Yes ☐ No ☐

34. If Yes, when was your last training session?
    _____
    (In days, weeks, months or years)

APPENDIX B – Sample size calculation (STATA output)

power oneproportion 0.1 0.18

Estimated sample size for a one-sample proportion test

Score z test

Ho: p = p0 versus Ha: p != p0

Study parameters:

alpha = 0.0500

power = 0.8000

delta = 0.0800

p0 = 0.1000

pa = 0.1800

Estimated sample size:

N = 130

display 130/0.74

175.67568

APPENDIX C – Cronbach's alpha

Table C.1: Cronbach's alpha of each of the 11-items for assessing implementation fidelity

Items	Obs	Sign	Item-test correlation	Item-rest correlation	Average inter-item covariance	Alpha
I perform a cervical cancer screening test for HIV-positive women at the point of diagnosis of HIV-infection.	177	+	0.41	0.25	0.22	0.74
I perform cervical cancer screening on HIV-infected women younger than 30 years	177	+	0.49	0.34	0.21	0.73
I perform cervical cancer screening on HIV-infected pregnant women with 20 weeks gestational age or less.	177	-	0.16	-0.01	0.25	0.78
I perform cervical cancer screening on HIV-infected women receiving ARV treatment.	177	+	0.68	0.57	0.19	0.69
I perform cervical cancer screening on HIV-infected women NOT receiving ARV treatment.	177	+	0.67	0.56	0.19	0.69
I perform cervical cancer screening on HIV-infected women with a CD4 count of ≥ 500/µl.	177	+	0.78	0.69	0.17	0,68
I perform cervical cancer screening on HIV-infected women with a CD4 count of ≤ 500/µl	177	+	0.75	0.66	0.18	0.68
I inform all HIV+ clients that I screened of their next screening date.	177	+	0.56	0.43	0.19	0.71
I refer all HIV+ clients with an abnormal cervical screening test for a colposcopy examination.	177	+	0.43	0.28	0.22	0.74
If my HIV+ client has an initial normal pap smear test, I repeat the follow-up screening test after three years.	177	+	0.45	0.29	0.21	0.73
If my HIV+ client has an initial abnormal pap smear test, I repeat the follow-up screening test after one year.	177	+	0.41	0.25	0.22	0.74
					0.20	0.74

Table C.2: Cronbach's alpha for each item of the four main determinants.

Provider characteristics

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem correlation	alpha
screen_met~d	177	+	0.6841	0.6178	0.1936	0.8032
scre~_normal	177	+	0.7816	0.7322	0.1871	0.7965
scre~bnormal	177	+	0.6035	0.5254	0.1989	0.8085
start_of_s~n	177	+	0.7144	0.6530	0.1916	0.8011
stop_of_sc~n	177	+	0.6763	0.6087	0.1941	0.8037
pregn_scre~e	177	+	0.3517	0.2489	0.2156	0.8237
cd4_screen~r	177	+	0.7513	0.6963	0.1891	0.7986
arv_screen~g	177	+	0.7706	0.7191	0.1878	0.7972
skills_ref	177	+	0.5106	0.4214	0.2051	0.8143
self_con_ref	177	+	0.5116	0.4224	0.2050	0.8142
comm_ref	177	+	0.5920	0.5124	0.1997	0.8092
belief_ref	177	+	0.4299	0.3329	0.2104	0.8192
superv_ref	177	+	-0.0623	-0.1712	0.2430	0.8451
px_ref	177	-	0.2037	0.0942	0.2254	0.8318
cost_ref	177	-	0.2975	0.1915	0.2192	0.8267
symp_ref	177	-	0.2540	0.1461	0.2220	0.8291
embarrass_~f	177	-	0.5289	0.4416	0.2038	0.8132
workload_ref	177	-	0.3985	0.2990	0.2125	0.8210
Test scale					0.2058	0.8234

Guidelines characteristics

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem correlation	alpha
concise_in~t	177	+	0.4333	0.3177	0.3059	0.8410
efficient_gl	177	+	0.5597	0.4592	0.2913	0.8315
evidence_gl	177	+	0.2943	0.1681	0.3220	0.8507
authority_gl	177	+	0.6572	0.5722	0.2801	0.8236
uniform_gl	177	+	0.6618	0.5776	0.2796	0.8232
new_confli~s	177	+	0.6102	0.5173	0.2855	0.8274
new_role	177	+	0.6639	0.5801	0.2793	0.8230
new_worded	177	+	0.6274	0.5373	0.2835	0.8260
new_indivi~x	177	+	0.6830	0.6027	0.2771	0.8214
new_time	177	+	0.6181	0.5264	0.2846	0.8268
new_iterat~e	177	+	0.5648	0.4651	0.2907	0.8311
new_incons~t	177	+	0.6399	0.5519	0.2821	0.8250
new_incons~n	177	+	0.6009	0.5066	0.2866	0.8282
Test scale					0.2883	0.8404

System characteristics

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem correlation	alpha
reponsible~s	177	+	0.7255	0.5726	0.3380	0.7185
gl_sys	177	+	0.6685	0.4951	0.3613	0.7388
where_supp~s	177	+	0.8089	0.6923	0.3040	0.6859
tools_sys	177	+	0.7107	0.5521	0.3441	0.7240
space_sys	177	+	0.6673	0.4934	0.3618	0.7392
referral_sys	177	+	0.5041	0.2876	0.4284	0.7894
Test scale					0.3562	0.7685

Implementation characteristics

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem correlation	alpha
staffing_i~l	177	+	0.7643	0.4872	0.6666	0.7999
superv_impl	177	+	0.8703	0.6872	0.4044	0.5759
feedback_i~l	177	+	0.8377	0.6214	0.4851	0.6533
Test scale					0.5187	0.7638

Table C.3: Correlation matrix between the overall percentage implementation fidelity score, implementation fidelity score derived via exploratory factor analysis and confirmatory factor analysis fidelity

```
pwcorr fidelity_score_percent fidelityEFA_score fidelityCFA_score, sig
```

	fideli~t	f~EFA_~e	f~CFA_~e
fidelity_s~t	1.0000		
fidelityEF~e	0.9303	1.0000	
	0.0000		
fidelityCF~e	-0.8048	-0.6324	1.0000
	0.0000	0.0000	

Table C.4: Computations for respondent's fidelity scores

RESPONDENT ID (N=177)	CONTENT SCORE (N=18)	COVERAGE SCORE (N=9)	FREQUENCY/DURATION SCORE (N=6)	OVERALL FIDELITY SCORE (N=33)
1.	18	6	4	28
2.	18	5	6	29
3.	18	4	4	26
4.	14	4	4	22
5.	18	4	4	26
6.	17	6	4	27
7.	18	5	3	26
8.	14	4	5	23
9.	17	4	4	25
10.	14	3	3	20
11.	14	4	6	24
12.	18	6	6	30
13.	13	4	4	21
14.	9	3	4	16
15.	18	5	6	29
16.	12	5	4	21
17.	16	7	6	29
18.	18	6	6	30
19.	18	9	6	33
20.	13	3	4	20
21.	16	4	6	26
22.	13	4	6	23
23.	15	4	3	22
24.	18	9	6	33
25.	6	2	4	12
26.	18	6	3	27
27.	17	6	6	29
28.	6	2	1	9
29.	18	5	6	29
30.	18	4	6	28
31.	18	4	6	28
32.	14	2	4	20
33.	17	6	6	29
34.	18	3	6	27
35.	18	4	6	28
36.	16	9	4	29
37.	17	3	6	26
38.	18	3	3	24
39.	7	3	6	16
40.	14	4	3	21
41.	17	6	6	29
42.	10	4	6	20
43.	18	6	5	29
44.	13	5	6	24
45.	14	2	3	19
46.	18	6	6	30
47.	18	5	6	29
48.	18	4	6	28
49.	18	2	6	26
50.	14	5	3	22
51.	18	6	3	27
52.	18	9	3	30
53.	11	4	3	18
54.	16	3	6	25
55.	18	5	6	29
56.	12	5	5	22
57.	12	9	5	26

58.	12	9	6	27
59.	18	9	5	32
60.	18	9	5	32
61.	11	6	6	23
62.	12	9	5	26
63.	18	6	6	30
64.	18	5	5	28
65.	18	3	4	25
66.	18	5	4	27
67.	6	4	3	13
68.	18	8	6	32
69.	9	7	3	19
70.	12	4	6	22
71.	18	6	4	28
72.	14	4	5	23
73.	18	5	6	29
74.	18	1	6	25
75.	9	5	4	18
76.	18	6	6	30
77.	16	6	5	27
78.	18	5	6	29
79.	16	3	6	25
80.	17	4	4	25
81.	18	6	6	30
82.	17	6	5	28
83.	18	5	6	29
84.	14	6	3	23
85.	18	4	4	26
86.	18	4	6	28
87.	18	4	4	26
88.	17	5	6	28
89.	18	6	6	30
90.	15	5	5	25
91.	16	4	4	24
92.	14	5	4	23
93.	18	6	4	28
94.	18	7	6	31
95.	16	5	6	27
96.	15	5	4	24
97.	17	5	5	27
98.	18	7	6	31
99.	17	6	4	27
100.	18	5	5	28
101.	18	5	5	28
102.	16	5	6	27
103.	18	6	5	29
104.	14	5	4	23
105.	18	6	6	30
106.	16	5	6	27
107.	18	5	6	29
108.	18	6	5	29
109.	14	6	6	26
110.	16	5	6	27
111.	14	6	4	24
112.	18	6	6	30
113.	14	4	4	22
114.	18	6	6	30
115.	18	7	5	30
116.	14	5	6	25
117.	18	5	5	28
118.	18	5	6	29
119.	18	5	6	29

120.	18	8	5	31
121.	18	6	6	30
122.	18	5	6	29
123.	14	5	6	25
124.	18	7	6	31
125.	16	5	5	26
126.	18	6	6	30
127.	14	6	6	26
128.	18	7	6	31
129.	14	4	5	23
130.	18	4	5	27
131.	18	4	6	28
132.	18	6	5	29
133.	14	6	6	26
134.	18	4	6	28
135.	18	6	5	29
136.	18	4	6	28
137.	18	5	6	29
138.	18	5	6	29
139.	18	6	6	30
140.	18	5	5	28
141.	18	8	6	32
142.	17	7	6	30
143.	18	6	6	30
144.	12	6	6	24
145.	18	5	6	29
146.	14	5	6	25
147.	18	5	6	29
148.	18	5	6	29
149.	17	5	6	28
150.	18	5	6	29
151.	18	4	6	28
152.	18	4	6	28
153.	17	6	6	29
154.	18	6	6	30
155.	17	5	5	27
156.	18	4	6	28
157.	18	7	6	31
158.	14	5	6	25
159.	18	5	6	29
160.	14	4	6	24
161.	18	6	6	30
162.	18	5	6	29
163.	18	7	6	31
164.	14	5	5	24
165.	18	4	6	28
166.	17	7	6	30
167.	17	6	6	29
168.	14	4	5	23
169.	18	6	6	30
170.	18	5	6	29
171.	18	4	6	28
172.	18	4	6	28
173.	14	4	6	24
174.	18	6	6	30
175.	14	5	6	25
176.	18	7	6	31
177.	14	5	5	24

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Table C.5: Bartlett test and KMO Measure of sampling adequacy of the 11-items

Bartlett test of sphericity	
Chi-square	746.46
Degrees of freedom	55
p-value H0: Variables are not intercorrelated	0.00
Kaiser-Meyer-Olkin Measure of Sampling Adequacy	
KMO	0.693

Table C.6: Unrotated factor score

Factor	Eigenvalue	Difference	Proportion	Cumulative
Factor 1	3.54	2.19	0.32	0.32
Factor 2	1.35	0.03	0.12	0.45
Factor 3	1.32	0.24	0.12	0.57
Factor 4	1.08	0.24	0.09	0.66
Factor 5	0.84	0.02	0.08	0.74
Factor 6	0.82	0.15	0.07	0.81
Factor 7	0.67	0.13	0.06	0.88
Factor 8	0.55	0.07	0.05	0.93
Factor 9	0.48	0.17	0.04	0.97
Factor 10	0.30	0.25	0.03	0.99
Factor 11	0.05	.	0.01	1.00

Chi2 (55) = 750.81 Prob>chi2 = 0.0000

Factor rotation matrix

	Factor 1	Factor 2	Factor 3	Factor 4
Factor 1	0.8773	0.2440	0.2822	0.3019
Factor 2	-0.4729	0.5847	0.4626	0.4695
Factor 3	-0.0783	-0.7640	0.5460	0.3347
Factor 4	0.0219	0.1218	0.6390	-0.7592

Table C.7: Confirmatory factor analysis

Standardized	OIM Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Structural						
SD2						
FIDELITY	.3547265	.0679438	5.22	0.000	.2215591	.4878939
_cons	.1704987	.0757089	2.25	0.024	.022112	.3188854
SD3						
FIDELITY	.0627719	.0764983	0.82	0.412	-.0871619	.2127058
_cons	.2930692	.0767616	3.82	0.000	.1426193	.4435192
SD4						
FIDELITY	-.3064271	.0699611	-4.38	0.000	-.4435484	-.1693058
_cons	2.654329	.1598503	16.61	0.000	2.341028	2.96763
RST2						
SD2	-.0552924	.0806771	-0.69	0.493	-.2134167	.1028318
FIDELITY	.0827868	.0845852	0.98	0.328	-.0829973	.2485708
_cons	.1614845	.0767924	2.10	0.035	.0109741	.3119948
RST3						
SD3	.0057549	.0563175	0.10	0.919	-.1046254	.1161351
FIDELITY	.0297222	.0774182	0.38	0.701	-.1220147	.1814592
_cons	.5821689	.0828398	7.03	0.000	.4198059	.744532
RST4						
SD4	-.021454	.0577007	-0.37	0.710	-.1345454	.0916374
FIDELITY	-.2116997	.0767534	-2.76	0.006	-.3621336	-.0612657
_cons	1.439613	.1886974	7.63	0.000	1.069773	1.809453
RSA2						
SD2	.2077811	.0784153	2.65	0.008	.0540899	.3614723
FIDELITY	.0438694	.080554	0.54	0.586	-.1140136	.2017524
_cons	.1159672	.0751474	1.54	0.123	-.031319	.2632534
RSA3						
SD3	.177046	.0467195	3.79	0.000	.0854774	.2686147
FIDELITY	.2247423	.0715014	3.14	0.002	.0846021	.3648825
_cons	.4138941	.0789964	5.24	0.000	.259064	.5687241
RSA4						
SD4	.2640633	.0483086	5.47	0.000	.1693803	.3587464
FIDELITY	-.1483373	.0724006	-2.05	0.040	-.2902399	-.0064347
_cons	1.163471	.1720456	6.76	0.000	.8262681	1.500674
Measurement						
ARV2						
FIDELITY	.308997	.0715549	4.32	0.000	.1687519	.4492421
_cons	.1069044	.075379	1.42	0.156	-.0408358	.2546446
ARV3						
FIDELITY	.3159745	.082002	3.85	0.000	.1552535	.4766955
_cons	.5403435	.0804642	6.72	0.000	.3826365	.6980505
ARV4						
FIDELITY	-.4802809	.0723804	-6.64	0.000	-.6221438	-.338418
_cons	1.761238	.1197981	14.70	0.000	1.526438	1.996038
nARV2						
FIDELITY	.1808957	.0745869	2.43	0.015	.034708	.3270833
_cons	.1313065	.0754879	1.74	0.082	-.0166471	.27926

nARV3						
FIDELITY	.2920879	.083944	3.48	0.001	.1275606	.4566152
_cons	.5490636	.0806308	6.81	0.000	.3910301	.7070971
nARV4						
FIDELITY	-.506716	.0712693	-7.11	0.000	-.6464012	-.3670307
_cons	1.612936	.1139551	14.15	0.000	1.389588	1.836284
GCD42						
FIDELITY	.4387116	.0641462	6.84	0.000	.3129874	.5644359
_cons	.1520573	.0755978	2.01	0.044	.0038883	.3002264
GCD43						
FIDELITY	.3556857	.0870523	4.09	0.000	.1850663	.5263051
_cons	.5838746	.0813187	7.18	0.000	.4244928	.7432564
GCD44						
FIDELITY	-.7720949	.0474781	-16.26	0.000	-.8651503	-.6790395
_cons	1.426348	.1067794	13.36	0.000	1.217064	1.635632
LCD42						
FIDELITY	.5453689	.0582039	9.37	0.000	.4312915	.6594464
_cons	.1704988	.0757089	2.25	0.024	.0221122	.3188855
LCD43						
FIDELITY	.3539427	.0870664	4.07	0.000	.1832958	.5245896
_cons	.5925753	.0814963	7.27	0.000	.4328454	.7523052
LCD44						
FIDELITY	-.7845232	.0451226	-17.39	0.000	-.8729619	-.6960845
_cons	1.415337	.1062798	13.32	0.000	1.207033	1.623642
pd2						
FIDELITY	-.0069209	.0767063	-0.09	0.928	-.1572625	.1434207
_cons	.2029199	.0759344	2.67	0.008	.0540911	.3517486
pd3						
FIDELITY	-.045015	.0763102	-0.59	0.555	-.1945802	.1045501
_cons	.4964664	.0796617	6.23	0.000	.3403323	.6526004
pd4						
FIDELITY	-.0329956	.0765855	-0.43	0.667	-.1831004	.1171091
_cons	1.489356	.1091594	13.64	0.000	1.275408	1.703305
Lt2						
FIDELITY	.1118799	.0756269	1.48	0.139	-.0363461	.260106
_cons	.1873172	.0758211	2.47	0.013	.0387106	.3359237
Lt3						
FIDELITY	.0374181	.079057	0.47	0.636	-.1175308	.192367
_cons	1.11378	.0956764	11.64	0.000	.9262579	1.301302
Lt4						
FIDELITY	-.1238795	.0778992	-1.59	0.112	-.2765591	.0288001
_cons	.743392	.0849166	8.75	0.000	.5769586	.9098254
pw2						
FIDELITY	.2393323	.0726235	3.30	0.001	.096993	.3816717
_cons	.26968	.076519	3.52	0.000	.1197055	.4196546
pw3						
FIDELITY	.0363778	.0790541	0.46	0.645	-.1185654	.1913209
_cons	.7251635	.0844701	8.58	0.000	.5596051	.8907219
pw4						

FIDELITY	-.1906641	.0758139	-2.51	0.012	-.3392566	-.0420715
_cons	1.166191	.0974245	11.97	0.000	.9752422	1.357139
ASC2						
FIDELITY	.2652966	.0719098	3.69	0.000	.124356	.4062371
_cons	.1069045	.0753791	1.42	0.156	-.0408357	.2546448
ASC3						
FIDELITY	.1457187	.074962	1.94	0.052	-.0012041	.2926414
_cons	.2173776	.0760489	2.86	0.004	.0683245	.3664306
ASC4						
FIDELITY	-.2977268	.0702005	-4.24	0.000	-.4353172	-.1601365
_cons	3.886663	.220037	17.66	0.000	3.455398	4.317927
var(e.ARV2)	.9045209	.0442205			.8218731	.9954797
var(e.ARV3)	.9001601	.0518211			.8041131	1.007679
var(e.ARV4)	.7693303	.0695258			.6444484	.9184119
var(e.nARV2)	.9672768	.0269849			.9158073	1.021639
var(e.nARV3)	.9146847	.0490381			.8234491	1.016029
var(e.nARV4)	.7432389	.0722266			.6143421	.89918
var(e.GCD42)	.8075321	.0562834			.7044217	.9257354
var(e.GCD43)	.8734877	.0619265			.7601692	1.003699
var(e.GCD44)	.4038694	.0733152			.2829571	.5764496
var(e.LCD42)	.7025727	.0634851			.5885399	.8387001
var(e.LCD43)	.8747246	.061633			.7618961	1.004262
var(e.LCD44)	.3845233	.0707995			.2680385	.5516304
var(e.pd2)	.9999521	.0010617			.9978733	1.002035
var(e.pd3)	.9979736	.0068702			.9845987	1.01153
var(e.pd4)	.9989113	.005054			.9890546	1.008866
var(e.Lt2)	.9874829	.0169223			.9548666	1.021213
var(e.Lt3)	.9985999	.0059163			.9870712	1.010263
var(e.Lt4)	.9846539	.0193002			.9475435	1.023218
var(e.pw2)	.94272	.0347623			.876991	1.013375
var(e.pw3)	.9986767	.0057516			.9874671	1.010013
var(e.pw4)	.9636472	.02891			.9086184	1.022009
var(e.SD2)	.8741691	.0482029			.7846193	.9739394
var(e.SD3)	.9960597	.0096039			.9774132	1.015062
var(e.SD4)	.9061024	.042876			.8258462	.994158
var(e.RST2)	.9933366	.0128308			.9685043	1.018806
var(e.RST3)	.999062	.0046921			.9899078	1.008301
var(e.RST4)	.9575064	.0306027			.8993662	1.019405
var(e.ASC2)	.9296177	.0381548			.8577645	1.00749
var(e.ASC3)	.9787661	.0218467			.9368704	1.022535
var(e.ASC4)	.9113587	.0418011			.8330047	.9970829
var(e.RSA2)	.9484357	.0328067			.886267	1.014965
var(e.RSA3)	.9131502	.0367081			.8439651	.988007
var(e.RSA4)	.8842608	.0384569			.8120098	.9629406
var(FIDELITY)	1	.			.	.
cov(e.ARV3,e.ARV4)	-.9431706	.0092392	-102.08	0.000	-.9612791	-.9250621
cov(e.ARV4,e.LCD44)	-.0393936	.0133172	-2.96	0.003	-.0654947	-.0132924
cov(e.nARV3,e.nARV4)	-.8976472	.0155932	-57.57	0.000	-.9282093	-.867085
cov(e.nARV4,e.GCD44)	-.0328333	.0135017	-2.43	0.015	-.0592962	-.0063704
cov(e.GCD43,e.GCD44)	-.950742	.012991	-73.18	0.000	-.9762039	-.9252801
cov(e.LCD43,e.LCD44)	-.9652027	.0128806	-74.93	0.000	-.9904482	-.9399571
cov(e.pd3,e.pd4)	-.7420565	.0337862	-21.96	0.000	-.8082763	-.6758366
cov(e.Lt3,e.Lt4)	-.8303126	.0233648	-35.54	0.000	-.8761067	-.7845184
cov(e.pw3,e.pw4)	-.8549827	.0202973	-42.12	0.000	-.8947647	-.8152007
cov(e.RST2,e.RSA2)	-.0243734	.0747989	-0.33	0.745	-.1709765	.1222297
cov(e.RST3,e.RST4)	-.8283636	.0231141	-35.84	0.000	-.8736665	-.7830607
cov(e.RST3,e.RSA3)	.1219066	.0302455	4.03	0.000	.0626265	.1811866
cov(e.RST4,e.RSA4)	-.0912031	.0302643	-3.01	0.003	-.1505201	-.0318861
cov(e.ASC2,e.RSA2)	-.0975309	.0766185	-1.27	0.203	-.2477005	.0526387
cov(e.ASC3,e.ASC4)	-.8490391	.0210169	-40.40	0.000	-.8902314	-.8078468
cov(e.ASC3,e.RSA3)	-.0190796	.027691	-0.69	0.491	-.073353	.0351938

```
  cov(e.ASC4,e.RSA4)|   .0045567   .0282332     0.16   0.872    -.0507794    .0598927
  cov(e.RSA3,e.RSA4)|  -.8855451   .0159613   -55.48   0.000    -.9168287   -.8542616
------------------------------------------------------------------------------
LR test of model vs. saturated: chi2(471) =   3958.27, Prob > chi2 = 0.0000
```

estat gof, stats(all)

```
------------------------------------------------------------------------------
Fit statistic        |      Value   Description
---------------------+--------------------------------------------------------
Likelihood ratio     |
        chi2_ms(471) |   3958.266   model vs. saturated
            p > chi2 |      0.000
        chi2_bs(528) |   7057.348   baseline vs. saturated
            p > chi2 |      0.000
---------------------+--------------------------------------------------------
Population error     |
               RMSEA |      0.205   Root mean squared error of approximation
 90% CI, lower bound |      0.199
         upper bound |      0.210
              pclose |      0.000   Probability RMSEA <= 0.05
---------------------+--------------------------------------------------------
Information criteria |
                 AIC |   -634.762   Akaike's information criterion
                 BIC |   -244.095   Bayesian information criterion
---------------------+--------------------------------------------------------
Baseline comparison  |
                 CFI |      0.466   Comparative fit index
                 TLI |      0.401   Tucker-Lewis index
---------------------+--------------------------------------------------------
Size of residuals    |
                SRMR |      0.158   Standardized root mean squared residual
                  CD |      0.968   Coefficient of determination
------------------------------------------------------------------------------
```

Table C.8: Checking for Multicollinearity of the explanatory variables

collin IC_percent SC_percent GC_percent PC_percent educationlvl age_years sex professional_experience training facility_region knowledge_percent
(obs=177)

Collinearity Diagnostics

Variable	VIF	SQRT VIF	Tolerance	R-Squared
IC_percent	1.62	1.27	0.6186	0.3814
SC_percent	1.69	1.30	0.5922	0.4078
GC_percent	1.39	1.18	0.7210	0.2790
PC_percent	1.51	1.23	0.6629	0.3371
educationlvl	1.35	1.16	0.7389	0.2611
age_years	3.66	1.91	0.2734	0.7266
sex	1.13	1.07	0.8814	0.1186
professional_experience	3.56	1.89	0.2812	0.7188
training	1.05	1.02	0.9530	0.0470
facility_region	1.08	1.04	0.9240	0.0760
knowledge_percent	1.21	1.10	0.8272	0.1728

Mean VIF 1.75

Table C.9: Sensitivity analysis using the linear regression model

Variable	Unadjusted coefficient (95% CI)	p-value	Adjusted coefficient (95% CI)	p-value
Main determinants				
Provider characteristics	0.48 (0.32 – 0.64)	0.01**	0.35 (0.16 – 0.54)	0.00*
Guideline characteristics	0.37 (0.23 – 0.52)	0.01**	0.15 (-0.01 – 0.31)	0.07
Implementation characteristics	0.05 (-0.05 – 0.13)	0.32	0.02 (-0.08 –0.12)	0.68
System characteristics	0.11 (0.00 – 0.23)	0.05*	0.04 (-0.10 – 0.18)	0.55
Other determinants				
Training				
No	Ref		Ref	
Yes	2.58 (-1.46 – 6.62)	0.21	2.64 (-0.95 – 6.24)	0.15
Level of Knowledge	0.26 (0.14 – 0.36)	0.01**	0.13 (0.02 – 0.24)	0.03*
Facility region				
North	Ref		Ref	
South	-1.82 (-5.41 – 1.76)	0.32	-1.07 (-4.31 – 2.16)	0.51

Variable	Unadjusted coefficient (95% CI)	p-value	Adjusted coefficient (95% CI)	p-value
Sociodemographic characteristics				
Age (years)	-0.11(-0.32–0.10)	0.31	-0.49 (-0.84 – -0.15)	0.01*
Sex				
Male	Ref		Ref	
Female	2.05(-5.22 –9.31)	0.58	-4.67 (-11.36–2.03)	0.17
Years of professional work experience	0.06(-0.14 –0.27)	0.55	0.39 (0.05 – 0.73)	0.03*
Highest level of education attained				
Undergraduate degree	Ref		Ref	
Postgraduate degree	2.23 (-1.27-5.73)	0.21	3.09 (-0.45 – 6.62)	0.08

Adjusted R-squared=24.90%; Ref=reference category; CI=95% confidence interval; *significant at p ≤ 0.05; **significant at p < 0.0001

Table C.10: Hosmer and Lemeshow's Goodness-of-fit test for Logistic regression model

lfit, group(10) table

Logistic model for fidelity_cat, goodness-of-fit test

(Table collapsed on quantiles of estimated probabilities)

Group	Prob	Obs_1	Exp_1	Obs_0	Exp_0	Total
1	0.3006	4	3.6	14	14.4	18
2	0.4072	5	6.6	13	11.4	18
3	0.5086	8	8.6	10	9.4	18
4	0.5856	11	9.3	6	7.7	17
5	0.6834	13	11.7	5	6.3	18
6	0.7197	13	12.7	5	5.3	18
7	0.7718	10	12.8	7	4.2	17
8	0.8164	16	14.3	2	3.7	18
9	0.8647	15	15.1	3	2.9	18
10	0.9433	15	15.3	2	1.7	17

number of observations = 177
number of groups = 10
Hosmer-Lemeshow chi2(8) = 5.36
Prob > chi2 = 0.7184

Table C.11: Goodness-of-fit test for comparing the GSEM direct and indirect models

estat ic

Akaike's information criterion and Bayesian information criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	177	.	-98.94604	12	221.8921	260.0059

APPENDIX D – STATA syntax for the Generalized structural equation model (GSEM)

****Performing the direct effect****

```
gsem (professional_experience -> fidelity_cat, family(bernoulli) link(logit)) (age_years -> fidelity_cat, family(bernoulli) link(logit)) (1b.sex -> fidelity_cat, family(bernoulli) link(logit)) (2.sex -> fidelity_cat, family(bernoulli) link(logit)) (1b.educationlvl -> fidelity_cat, family(bernoulli) link(logit)) (2.educationlvl -> fidelity_cat, family(bernoulli) link(logit)) (0b.training -> fidelity_cat, family(bernoulli) link(logit)) (1.training -> fidelity_cat, family(bernoulli) link(logit)) (knowledge_percent -> fidelity_cat, family(bernoulli) link(logit)) (PC_percent -> fidelity_cat, family(bernoulli) link(logit)) (GC_percent -> fidelity_cat, family(bernoulli) link(logit)) (SC_percent -> fidelity_cat, family(bernoulli) link(logit)) (IC_percent -> fidelity_cat, family(bernoulli) link(logit)) (M1[facility_code] -> fidelity_cat, family(bernoulli) link(logit)), covstruct(_lexogenous, diagonal) latent(M1 ) nocapslatent

estat eform
```

****Indirect effects****

```
gsem (professional_experience -> PC_percent, ) (age_years -> PC_percent, ) (1b.sex -> fidelity_cat, family(bernoulli) link(logit)) (2.sex -> fidelity_cat, family(bernoulli) link(logit)) (1b.educationlvl -> fidelity_cat, family(bernoulli) link(logit)) (2.educationlvl -> fidelity_cat, family(bernoulli) link(logit)) (0b.training -> PC_percent, ) (1.training -> PC_percent, ) (knowledge_percent -> PC_percent, ) (PC_percent -> fidelity_cat, family(bernoulli) link(logit)) (GC_percent -> PC_percent, ) (SC_percent -> fidelity_cat, family(bernoulli) link(logit)) (IC_percent -> fidelity_cat, family(bernoulli) link(logit)) (M1[facility_code] -> fidelity_cat, family(bernoulli) link(logit)), covstruct(_lexogenous, diagonal) latent(M1 ) nocapslatent

gsem, coeflegend

nlcom _b[PC_percent:professional_experience]

nlcom exp(_b[PC_percent:professional_experience])

nlcom _b[fidelity_cat:PC_percent]*_b[PC_percent:professional_experience]

nlcom exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:professional_experience])


nlcom _b[PC_percent:age_years]

nlcom exp(_b[PC_percent:age_years])

nlcom _b[fidelity_cat:PC_percent]*_b[PC_percent:age_years]

nlcom exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:age_years])


nlcom _b[PC_percent:1.training]

nlcom exp(_b[PC_percent:1.training])

nlcom _b[fidelity_cat:PC_percent]*_b[PC_percent:1.training]

nlcom exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:1.training])


nlcom _b[PC_percent:knowledge_percent]

nlcom exp(_b[PC_percent:knowledge_percent])
```

nlcom _b[fidelity_cat:PC_percent]*_b[PC_percent:knowledge_percent]

nlcom exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:knowledge_percent])

nlcom _b[PC_percent:GC_percent]

nlcom exp(_b[PC_percent:GC_percent])

nlcom _b[fidelity_cat:PC_percent]*_b[PC_percent:GC_percent]

nlcom exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:GC_percent])

nlcom _b[PC_percent:_cons]

nlcom exp(_b[PC_percent:_cons])

nlcom _b[fidelity_cat:_cons]

nlcom exp(_b[fidelity_cat:_cons])

****Total effects****

nlcom _b[fidelity_cat:SC_percent]

nlcom exp(_b[fidelity_cat:SC_percent])

nlcom _b[fidelity_cat:IC_percent]

nlcom exp(_b[fidelity_cat:IC_percent])

nlcom _b[fidelity_cat:2.educationlvl]

nlcom exp(_b[fidelity_cat:2.educationlvl])

nlcom _b[fidelity_cat:2.sex]

nlcom exp(_b[fidelity_cat:2.sex])

nlcom _b[fidelity_cat:PC_percent]

nlcom exp(_b[fidelity_cat:PC_percent])

nlcomexp(_b[fidelity_cat:SC_percent])+exp(_b[fidelity_cat:IC_percent])+exp(_b[fidelity_cat:2.educationlvl])+exp(_b[fidelity_cat:2.sex])+exp(_b[fidelity_cat:PC_percent])*_b[PC_percent:professional_experience])+exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:age_years])+exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:1.training])+exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:knowledge_percent])+exp(_b[fidelity_cat:PC_percent]*_b[PC_percent:GC_percent])

APPENDIX E – Ekurhuleni Health District Research Permission

City of Ekurhuleni

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

EKURHULENI HEALTH DISTRICT RESEARCH PERMISSION

Research Project Title: Implementation Fidelity of the Cervical Cancer Screening guidelines for HIV-Infected women in Ekurhuleni, South Africa.

NHRD No: GP_201901_021

Research Project Number: 14/02/2019-01

Name of Researcher(s): Dr Pureheart Bazunu

Division/Institution/Company: University of the Witwatersrand

Date of review by the EHDRC: 14 February 2019

DECISION TAKEN BY THE EKURHULENI HEALTH DISTRICT RESEARCH COMMITTEE (EHDRC)

- This document certifies that the above research project has been reviewed by the EHDRC and permission is granted for the researcher(s) to commence with the intended research project.

  Facilities approved for the research: Birchleigh , Birchleigh North, Bonaero Park Dresser, Eden Park, Erin, Ethafeni, Goba, Katlehong North, Kempton Park Civic Centre, Khumalo, Leondale, Magagula, Moleleki, Motsamai, Olifantsfontein, Palmridge, Phenduka, Tamaho, Tembisa Main, Tswelopele, Vosloorus Ext 28, Vosloorus Ext 9, Winnie Mandela, Zonkizizwe 1 and Zonkizizwe 2 Clinics.

  - study period and when disseminating the findings.

- No resources (financial, material and human resources) from the health facilities will be used for the study. Neither the district nor the health facilities will incur any additional cost for the study.

- The study will comply with Publicly Financed Research and Development Act 2008 (Act 51 of 2008) and its related regulations.

Title: Implementation Fidelity of the Cervical Cancer Screening guidelines for HIV-Infected women in Ekurhuleni, South Africa

- The EHDRC must be informed in writing before publication or presentation of research findings and a copy of the report/publications/presentation must be submitted to the EHDRC
- The district must be acknowledged in all the reports/publications generated from the research.
- The researcher will be expected to provide the EHDRC with
  - Six monthly progress updates including any adverse events
  - The final study report in electronic format
  - Present the final research findings at the annual Ekurhuleni research conference if possible.
- The EDHRC reserves the right to withdraw the approval, if any of the conditions mentioned above have being breached
- The research committee wishes the researcher(s) the best of success.

DR. J. SEPHYA

DEPUTY CHAIRPERSON: CITY OF EKURHULENI

Dated: 14/02/2019

Dr R. Kellerman

CHAIRPERSON: GAUTENG DEPARTMENT OF HEALTH (EKURHULENI HEALTH DISTRICT)

Dated: 14/02/2019

APPENDIX F – Ethics clearance certificate from WITS HREC (medical)

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr P Bazunu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M181154

NAME: (Principal Investigator)	Dr P Bazunu
DEPARTMENT:	School of Public Health Medical School University
PROJECT TITLE:	Implementation fidelity of the cervical cancer screening guidelines for HIV-infected women in Ekurhuleni, South Africa
DATE CONSIDERED:	30/11/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor E Musenge and Dr M Kawonga
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	14/03/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date of the meeting when the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore reports and re-certification will be due early in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

01-04-2019
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX G – Study Information Sheet

Study title: IMPLEMENTATION FIDELITY OF THE CERVICAL CANCER SCREENING GUIDELINES FOR HIV-INFECTED WOMEN IN EKURHULENI, SOUTH AFRICA.

Good day,

My name is Dr Pureheart E. Bazunu, and I am an MSc student of Epidemiology, the field of Implementation Science, School of Public Health, University of the Witwatersrand, Johannesburg, South Africa. As part of my studies I have to undertake a research project, the purpose of this research is to know how cervical cancer screening guidelines for HIV-infected women are being implemented in primary health care clinics, in Ekurhuleni, South Africa.

As part of this project, I would like to invite you to take part in answering an interviewer-administered questionnaire. This activity will be brief and will take around twenty minutes.

You will not receive any direct benefits from participating in this study, and there are no disadvantages or penalties for not participating. You may withdraw at any time or not answer any question if you do not want to. The questionnaire will be completely confidential and anonymous as you will not be filling your name or any identifying information, and the information you provided will be stored safely on a secure database on a password-protected laptop which is strictly accessible to the principal investigator and both project supervisors only. If you experience any distress or discomfort, we will stop the questionnaire or resume another time.

If you have any questions afterwards about this research, feel free to contact me on the details listed below. This study will be written up as a research report which will be available online through the university library website. If you wish to receive a summary of this report, I will be happy to send it to you upon request. If you have any queries, concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the University Human Research Ethics Committee (medical), telephone +27(0)11 717 2301, email Clement.Penny@wits.ac.za. The committee secretariat can

also be contacted on, telephone 011 717 2700/1234 and email Rhulani.Mkansi@wits.ac.za or HREC-Medical.ResearchOffice@wits.ac.za

Thank you for reading this study information sheet.

Yours sincerely

Dr Pureheart E. Bazunu, purebaz4real@gmail.com (+27) 604263532
Professor Eustasius Musenge, eustasius.musenge@wits.ac.za
Dr Mary Kawonga, mary.Kawonga@wits.ac.za

APPENDIX H – Informed Consent Form

IMPLEMENTATION FIDELITY OF THE CERVICAL CANCER SCREENING GUIDELINES FOR HIV-INFECTED WOMEN IN EKURHULENI, SOUTH AFRICA.

PUREHEART E. BAZUNU

I …….. agree to participate in this research project. The research has been explained to me, and I understand what my participation will involve.

I agree that my participation in this research is voluntary YES NO (please circle)

I agree that my participation will remain anonymous YES NO

I agree that information from this research may be used for a thesis report, publications or presentations YES NO

…… (signature)

…… (name of participant)

…… (date)

APPENDIX I – Plagiarism Declaration Form

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I, Dr Pureheart E. Bazunu_____ (Student number: 1895139_) am a student registered for the degree of Master of Science in Epidemiology (Field of Implementation science) in the academic year _2018_.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: _____ Date: _____7TH August 2020_