A Multi-level Analysis on Implementation of Low-Cost IVF in Sub-Saharan Africa: A Case Study of Uganda.

by
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A thesis
presented to the University of Waterloo
in fulfillment of the
thesis requirement for the degree of
Doctor of Philosophy
in
Public Health Sciences

Waterloo, Ontario, Canada, 2023

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Author's Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Introduction: Globally, infertility is a major reproductive disease that affects an estimated 186 million people worldwide. In Sub-Saharan Africa, the burden of infertility is considerably high, affecting one in every four couples of reproductive age. Furthermore, infertility in this context has severe psychosocial, emotional, economic and health consequences. Absence of affordable fertility services in Sub-Saharan Africa has been justified by overpopulation and limited resources, resulting in inequitable access to infertility treatment compared to developed countries. Therefore, low-cost IVF (LCIVF) initiatives have been developed to simplify IVF-related treatment, reduce costs, and improve access to treatment for individuals in low-resource contexts. However, there is a gap between the development of LCIVF initiatives and their implementation in Sub-Saharan Africa. Uganda is the first country in East and Central Africa to undergo implementation of LCIVF initiatives within its public health system at Mulago Women's Hospital.

Methods: This was an exploratory, qualitative, single, case study conducted at Mulago Women's Hospital in Kampala, Uganda. The objective of this study was to explore how LCIVF initiatives have been implemented within the public health system of Uganda at the macro-, meso- and micro-level. Primary qualitative data was collected using semi-structured interviews, hospital observations informal conversations, and document review. Using purposive and snowball sampling, a total of twenty-three key informants were interviewed including government officials, clinicians (doctors, nurses, technicians), hospital management, implementers, patient advocacy representatives, private sector practitioners, international organizational representatives, educational institution, and professional medical associations. Sources of secondary data included government and non-government reports, hospital records, organizational briefs, and press outputs. Using a multi-level data analysis approach, this study undertook a hybrid inductive/deductive thematic analysis, with the deductive analysis guided by the Consolidated Framework for Implementation Research (CFIR).

Findings: Factors facilitating implementation included international recognition of infertility as a reproductive disease, strong political advocacy and oversight, patient needs & advocacy, government funding, inter-organizational collaboration, tension to change, competition in the private sector, intervention adaptability & trialability, relative priority, motivation &advocacy of fertility providers and specialist training. While barriers included scarcity of embryologists, intervention complexity, insufficient knowledge, evidence strength & quality of intervention, inadequate leadership engagement & hospital autonomy, poor public knowledge, limited engagement with traditional, cultural, and religious leaders, lack of salary incentives and concerns of revenue loss associated with low-cost options.

Research contributions: This study contributes to knowledge of factors salient to implementation of LCIVF initiatives in a Sub-Saharan context. Effective implementation of these initiatives requires (1) sustained political support and favourable policy & legislation, (2) public sensitization and engagement of traditional, cultural, and religious leaders (3) strengthening local innovation and capacity building of fertility health workers, in particular embryologists (4) sustained implementor leadership engagement and inter-organizational collaboration and (5) proven clinical evidence and utilization of LCIVF initiatives in innovator countries. It also adds to the literature on the applicability of the CFIR framework in explaining factors that influence successful implementation in developing countries and offer opportunities for comparisons across studies.

Acknowledgements

I acknowledge that the land on which I completed my degree is on the traditional territory of the Attawandaron (Neutral), Anishinaabeg and Haudenosaunee peoples. The University of Waterloo is situated on the Haldimand Tract, the land promised to the Six Nations that includes ten kilometers on each side of the Grand River.

First and foremost, I would like to my supervisor, Professor Craig Janes, for unwavering support, guidance, and mentorship throughout my doctoral studies.

I would also like to acknowledge all the participants and organizations who took part in this study. It is through their participation that this study has been made possible.

Furthermore, I would like to express my sincere gratitude to my family, friends and university community who have been an incredible system of support during this period.

I would like to acknowledge and appreciate my thesis committee members, Dr. Willem Ombelet, Dr. Elena Neiternman, Dr. Katy Fulfer and Dr. Jennifer Liu for their instructive support and feedback throughout this process.

Finally, I am grateful to Dr. and Mrs. Edward Sali of Women's Hospital International & Fertility Centre, Uganda and Mrs. Rita Sembuya of Joyce Fertility Support Centre. It is through our work and passion for helping couples start families that this journey was conceived.

I completed this doctoral training amidst supporting and admirable minds.

Dedication

This PhD thesis is dedicated to my heroes, Dr. John Fredrick Kayongo Mutumba and Mrs. Irene Josephine Mutumba, to my amazing daughter, Nora Godya Kirabo Kironde and husband, Muyise Kijala Kironde, supportive siblings, George Busulwa Mutumba and Samuel Kayongo Mutumba, and beloved sister, Alice Nanteza Ntambi. They are the reason I am and the reason I will be.

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List of Abbreviations

ANARA	The African Network and Registry for Assisted Reproductive Technology
ASRM	American Society of Reproductive Medicine
CBRC	Cross-border Reproductive Care
CFIR	Consolidated Framework for Implementation Research
ESHRE	European Society of Huan Reproduction and Embryology
ET	Embryo transfer
FSH	Follicle Stimulating Hormone
HIV	Human Immunodeficiency Virus
ICMART	International Committee for Monitoring Assisted Reproductive Technologies
ICSI	Intracytoplasmic sperm injection
IFFS	International Federation of Fertility Societies
IS	Implementation Science
IUI	Intra uterine insemination
IVF	Invitro Fertilization
JFSC	Joyce Fertility Support Centre
LCIVF	Low-cost Invitro Fertilization
LMIC	Low-Middle Income Country(s)
MoH	Ministry of Health
MoF	Ministry of Finance

MoP	Ministry of Public Service
MURE	MildMay Uganda Research Ethics Committee
MWH	Mulago Women's Hospital
NMS	National Medical Stores
OHSS	Ovarian hyperstimulation syndrome
ORE	Office of Research Ethics
REC	Research Ethics Committee
SSA	Sub-Saharan Africa
STIs	Sexually Transmitted Infections
TRF	Total fertility rates
UBOS	Uganda Bureau of Statistics
UBTH	University of Benin Teaching Hospital
UDMPA	Uganda Dental and Medical Professional Association
UFC	Uganda Fertility Society
UN	United Nations
UNCST	Uganda National Council for Science and Technology
WHO	World Health Organization

Chapter 1: Introduction

1.1. General Overview

Infertility is a reproductive disease of global public health concern that affects roughly 8% to 12% of reproductive aged couples (Ombelet, 2011; Ombelet et al., 2008; Ombelet and Onofre, 2019; Sciarra, 1994). This translates to an estimated 120 million to 180 million people worldwide experiencing childlessness (Mascarenhas et al., 2012; van der Poel et al., 2012). Globally, factors contributing to infertility are approximately one third male-related, one-third female-related and the rest are either unknown or a combination of both male and female related factors (Serour, 2009). Although not an immediate danger to physical health or threat of life, infertility has been ranked as the fifth highest cause of global disability, due to its significant implications on biopsychosocial wellbeing of individuals (Borumandnia et al., 2022; Cook, Dickens & Fathalla, 2003, p305). Persons experiencing infertility often present with clinically significant symptoms such as anxiety, depression, suicidal thoughts, and severe grief (WHO, 2013). The negative impact of infertility are tied to the fact that that health is not just mere absence of disease, but includes complete emotional, physical, mental and social wellbeing of an individual (WHO, 1948). In Uganda, women experiencing infertility reported it to be a severe social and emotional morbidity, citing that it was worse to experience infertility than to be diagnosed with HIV (Kudesia et al., 2018).

Notably, the highest prevalence of infertility is in low-resource contexts. Sub-Saharan countries experience a significant burden of the condition (up to 30%) due to infection-related tubal blockages (Inhorn, 2003; Nachtigall, 2006; Ombelet & Onofre, 2019). The main factors that contribute to infertility include poor obstetric and postpartum care, untreated sexually transmitted infections (STIs), reproductive tract infections, unsafe abortions, schistosomiasis, and harmful cultural practices (Boivin et al., 2007; King, 2018; Ombelet & Onofre, 2019; Ombelet et al., 2008; Shahara, 1998; WHO, 1987). Furthermore, the impacts of infertility in these fundamentally pronatalist contexts are severe, including polygamy, divorce, intimate partner violence, isolation, increased STD risk, economic instability, and suicide in some cases (Dierickx et al., 2018; Kok, 2013; Pennings, 2012; Ombelet & Onofre, 2019; WHO, 2013). Infertility, thereby, should be considered beyond an individual medical condition and emphasized as a social and public health issue (Ombelet and Onofre, 2019).

Consequently, there is a need to prioritize public education, prevention and access to affordable diagnostic and fertility treatment services (Ombelet and Onofre, 2019). Standard assisted reproductive technologies (ART) provided in fertility clinics to overcome infertility are often costly and reserved for the financially advantaged (Starrs, 2018). The average cost of IVF related treatment varies from $12,000 in the U.S, to $5,000 in China and up to $10,000 in Nigeria (ASRM, 2021; Fadare & Adeniyi, 2015; Qiao & Feng, 2014). Strategies to reduce costs of infertility care have been documented and include simplifying the diagnostic process through minimal investigations, taking accurate medical history, as well as simplified laboratory, and treatment protocols (Agarwal et al., 2018; Blerkom et al., 2014; Ombelet and Campo, 2007; Verberg et al., 2009). Nonetheless, barriers to implementation of these low-cost technologies in developing contexts have been reported, including widespread belief that infertility is of low priority, concern regarding overpopulation, limited availability of resources and lack of ART regulations (Dhont et al., 2011; Ombelet and Onofre, 2019). These arguments obscure the devastating psychosocial, economic, and personal

implications of infertility in these contexts (Chiware et al., 2021; Ombelet, 2011; Ombelet, 2020; Ombelet & Campo, 2007; Ombelet & Onofre, 2019). Furthermore, many developing countries have succeeded in lowering their high birth rates from more than five to just over two, with the expected population growth attributable to improved life expectancy (United Nations, 2007). When it comes to limited resources, low-cost IVF technologies have been developed to address this obstacle (Ombelet & Onofre, 2019). However, Ombelet and Onfre (2019) cite low priority for low-cost IVF programmes in Africa, even from local healthcare practitioners. Furthermore, challenges associated with absence of well-trained fertility specialists, limited access to quality supplies, lack of stable power supply and foreign supplied equipment costs have been cited as obstacles to implementation (Adageba et al., 2015).

This study, therefore, aimed to understand factors that influence implementation of LCIVF initiatives within the public health sector of Uganda at Mulago Women's Specialist (MWH) hospital. Using the Consolidated Framework for Implementation Research (CFIR), this multi-level study examined factors influencing implementation using five main domains of the framework, namely, outer setting, inner setting, intervention characteristics, individual characteristics, and process (Damschroder et al., 2009). New themes were captured as they emerged from the data. Firstly, macro-level factors investigating broader contextual factors i.e., political, economic and social influences surrounding implementation were considered. Next, meso-level factors looking at how the Mulago Specialist Women and Neonatal Hospital organized itself to be able to deliver affordable fertility services were examined. Finally, micro-level elements within the ART department were investigated, taking into account adaptations and prioritization of clinical protocols to deliver affordable fertility care.

1.2. Study Significance

This study was beneficial in providing a practical, holistic picture into the complex nature of implementation of LCIVF in Uganda. The findings revealed opportunities for knowledge transfer to other developing countries or contexts in pursuit of affordable access to fertility treatment. Accomplishments, challenges, and gaps identified in implementation of LCIVF in Uganda could contribute to areas for further research and actionable recommendations to minimize barriers and maximize facilitators. Finally, the study builds on applicability of the CFIR framework in explaining factors that influence successful implementation of novel interventions in developing countries and offer opportunities for comparisons across studies.

Chapter 2: Literature Review

2.1. Infertility: Overview & Terminology

Infertility is an important reproductive disease that impacts individuals' wellbeing and yet has been neglected (Gipson, Bornstein & Hindin, 2020). As many as 180 million couples around the world are estimated to experience the burden of infertility (Vayena et al., 2009). The exact prevalence and incident figures remain unclear as global definitions for *infertility* vary resulting in inconsistencies in measurement. Various definitions of infertility include failure to conceive after twelve or twenty-four months of unprotected sex (*clinical/epidemiological definition*) or based on absence of a live birth in a woman of reproductive age (*demographic definition*) which complicates efforts to summarize current estimates (Gurunath et al., 2011). The most recent international glossary on infertility and fertility care by WHO, defines clinical *infertility* as "a disease of the reproductive system determined by failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse or due to a person's inability to reproduce individually or with a partner" (Zegers-Hochschild et al., 2017). This definition emphasizes the importance of regular intercourse as an essential component in achieving pregnancy and infertility as a disease that leads to impairment of the reproductive system (Zegers-Hochschild et al., 2017). Other definitions include, *epidemiological infertility* is defined as "women of reproductive age at risk of pregnancy, reporting failure to conceive for more than two years" (WHO, 2006) and *subfertility* refers to any form or level of reduced fertility in couples that have failed to achieve conception (Jenkins et al., 2004). However, *subfertility* is often used interchangeably with *infertility* and to promote standardization of terms and prevent confusion; it was declared a redundant term by the WHO (Zegers-Hochschild et al., 2017). *Sterility* is another term, defined as a permanent state of infertility and thus differs from *infertility,* as it is considered over a restricted period (Zegers-Hochschild et al., 2009).

2.1.1. Etiology & Risk factors for Infertility

Infertility is characterized into two categories namely, primary, and secondary infertility. The term "*primary female infertility*" refers to an infertile woman or couple who has never achieved clinical pregnancy and has been diagnosed with infertility (Zegers-Hochschild et al., 2009; Zegers-Hochschild et al., 2017). *Secondary female fertility* refers to an infertile woman who has previously achieved clinical pregnancy but is now unable to establish a pregnancy (Zegers-Hochschild et al., 2009; Zegers-Hochschild et al., 2017). Infertility in men can be categorized similarly, depending on their participation in inception of a pregnancy (Vander Borght & Wyns, 2018). *Primary male infertility* is defined by a man who has never initiated a clinical pregnancy and meets the infertility criteria, while *secondary male infertility* is a man who previously initiated a clinical pregnancy but is now unable to (Zegers-Hochschild et al., 2017). However, it is challenging to accurately determine prevalence of male infertility given its gold standard of measurement is manual sperm assessment (Zegers-Hochschild et al., 2017). Globally, secondary infertility is the most frequent form of female infertility (Borumandnia et al., 2022; Inhorn & Patrizio, 2015; Nachtigall, 2006; Rutstein & Shah, 2004). Although not representative of all regions, male infertility exclusively accounts for approximately 20% - 30% of cases but overall contributes to 50% of cases (Vander Borght & Wyns, 2018).

Causes of infertility are variable depending on the country/region and observed prevalence. Infertility may be caused by anomalies, physiological or genetic factors linked to either male or female reproductive systems or both systems (Benksim et al., 2018). Female infertility might be caused by hormonal disorders, premature ovarian failure, endometriosis, polycystic ovarian syndrome, fallopian tubal blockage, reproductive tract infections, sexually transmitted infections and other complications associated with pre-existing medical conditions such as diabetes, tuberculosis, sickle cells and Cushing's syndrome (Bhattacharya et al., 2010; Cedars and Robert, 2005; Lash et al., 2008, WHO, 2010). Secondary infertility is most common in contexts where rates of unsafe abortions, postpartum infections, sexually transmitted infections and poor maternal healthcare is high (Borumandnia et al., 2022; Inhorn and Patrizio, 2015; Larsen, 2000). In cases of male infertility, causes may include genetic, endocrine, functional or immunological abnormalities of the reproductive system, chronic illness and sexual condition (Dissanayake et al., 2019; Zegers-Hochschild et al., 2017). Furthermore, both sexes can be impacted by lifestyle factors such as diet, age of couple, alcohol consumption, smoking and use of recreational drugs (Cedars & Robert, 2005; Macaluso et al., 2010). Medications to treat other conditions such as anti-cancer drugs, antidepressants, narcotics and tranquilizers may also affect ability to reproduce (Cedars & Robert, 2005). Finally, exposure to environmental factors such as radiation, lead, toxic fumes and pesticides impact fertility (Asemota, & Klatsky, 2015).

2.1.2. Measuring Infertility: Epidemiology and Demographic Impact

Infertility is estimated to affect 15% of couples of reproductive age, worldwide (Dissanayake et al., 2019). However, the exact rates have been difficult to measure and compare due to a lack of uniformity around the definition of infertility (Zegers-Hochschild et al., 2017). Data on infertility from various regions around the world is limited and figures are not accurately representative of the variability in prevalence for some regions. Population surveys estimate the prevalence of infertility in developed countries at 6.9% –9.3% and in developing countries at 3.5–16.7% (Bolvin et al., 2007; Ombelet, 2009). However, some regions of the world have an infertility prevalence as high as 30% such as in Central Asia, Middle East, North Africa, sub-Saharan Africa and Eastern Europe (Inhorn and Patrizio, 2015; Mascarenhas et al., 2012). This data translates to 1 in 7 couples of reproductive age in developed countries and 1 in 4 couples in developing countries experiencing infertility (Vander Borght & Wyns, 2018). Therefore, indicating that developing countries, particularly, Sub-Saharan Africa and Asia, experience the highest rates of infertility.

Demographic studies have also been employed to assess global burden of infertility through measurement of the average number of live births per woman – known as total fertility rates (TFR) as a proxy (Bongaarts, 2015). Based on data from 2010 – 2015, the global average fertility rate is 2.5 live births per woman (United Nations, 2017). Developed countries have seen a decline in TFR to roughly 2 live births or less per woman, resulting in fertility levels falling below replacement and population decline (United Nations, 2013; United Nations, 2017). Fertility levels falling below replacement is defined as the level at which each generation replaces the previous one, resulting in zero or negative population growth as is seen in regions such as Europe (United Nations, 2013). TFR in developing regions such as Africa, also dropped to 4.7 in 2010-2015 from 5.1 live births per woman in 2000 - 2005 (United Nations, 2017). Future projections suggest that even in these regions, fertility rates will drop to about 2.1 live births per woman (United Nations, 2017). The main factors associated with the worldwide drop in TFR include changes in social and economic trends such as women pursuing careers, postponement of marriage and childbearing, and desire for fewer children

(Nachtigall, 2006). However, it is important to note that the same lifestyle factors contribute to an increase in infertility rates.

Recent studies based on data between 1993-2017 indicate that the prevalence of primary infertility in both men and women has declined in high-income countries (Borumandnia et al., 2022). In developing regions like South Asia, Africa and the Middle East, a notable increase in both male and female infertility has been identified due to dietary inadequacies of iodine and toxic environmental exposure (Abebe et al., 2020; Borumandnia et al., 2022). Also, worth noting is an all-round increase in secondary infertility due to male related factors (GBD 2017; Borumandnia et al., 2022). These trends are supposedly due to the lower fertility rates in developed regions such as Europe in comparison to the frequent diagnosis of secondary infertility and higher rates of infectious diseases and fertility treatment centres in developing countries (Borumandnia et al., 2022). Globally, estimates of couples affected by primary and secondary infertility range from 48.5 million (Mascarenhas et al., 2012) to 186 million (Rutstein & Shah, 2004). As men and women marry later or choose to delay having children, there will be an increasing likelihood for seeking infertility-related care (Sneeringer, 2009; Starrs et al., 2018).

2.1.3. Infertility Diagnosis, Management and Treatment

Infertility is normally diagnosed through a detailed medical history of a woman's menstrual cycle, sexually transmitted infections, previous/pre-existing illnesses, medication intake, toxin exposure and surgeries (Cedars & Robert, 2005). A pelvic exam normally follows to examine the reproductive tract (ovaries, uterus and vagina), followed by blood tests to assess hormone levels (Cedars & Robert, 2005). Male infertility is diagnosed through semen analysis and a medical history (Cedars & Robert, 2005). Treatment depends on several variables but may include hormonal medication, surgery, herbal medicine and assisted reproductive technologies such as in vitro fertilization (Cedars & Robert, 2005). Where possible, drugs that induce ovulation can be used to address infertility causes due to ovulation disorders (Starrs et al., 2018). Intrauterine insemination (IUI) can also be used to address unexplained infertility and low sperm count (Starrs et al., 2018). Surgery can be performed to target uterine fibroids, blocked tubes and other reproductive abnormalities (Starrs et al., 2018). Assisted Reproductive Technologies (ART) may also be used to address any of the causes of infertility and are expanded upon in section 2.3.4. However, there is always a proportion of people who face infertility due to unknown factors that cannot be prevented or treated (Cook, Dickens & Fathalla, 2003). Therefore, other options in these cases may include surrogacy and adoption (Starrs et al., 2018).

2.2. Infertility in Sub-Saharan Africa: Neglected Reproductive Disease

Infertility is a particularly neglected area of reproductive disease in countries with low resources and high total fertility rates (Asemota & Klatsky, 2015; Vayena, Peterson, Adamson & Nygren, 2009). In African countries, infertility has been overlooked given the higher fertility rates, yet these same countries also experience the highest infertility rates affecting 1 in every 4 couples of reproductive age (Vander Borght & Wyns, 2018; Chiware et al., 2021; Rutstein et al., 2015). This presents a stark contradiction, a phenomenon characterized as the "barrenness amid plenty" in which infertility is most prevalent in places with the highest fertility rates (Larsen, 2000; van Balen & Gerrits, 2001; WHO, 2010). A 1990 – 2000 demographic survey

by the WHO estimated that 186 million women[1] in developing countries experience infertility (Inhorn & Patrizio, 2015; WHO, 2013; Ombelet and OnOfre, 2019). The "African Infertility Belt" as it has been termed extends from East to West Africa and is said to have the highest infertility rates in both women and men (Inhorn, 2003; WHO, 2010a). This infertility belt includes countries like the United Republic of Tanzania, Uganda, Kenya, Cameroon and Gabon (WHO, 2010a). Infertility is one of the most common reasons women attend gynecology consultants in Kenya, Nigeria, and other African countries (Murage, Muteshi & Githae, 2011; Okonofua, 1996). It is estimated that infertility rates in this "belt" are as high as 32%, considerably higher than the global average of 8–12% (Larsen, 2003; WHO, 2010a).

The main type of infertility experienced in Africa is secondary infertility (Ombelet, 2019). Tubal factor is the most common contributor of secondary infertility in women. This is primarily due to biomedical-related factors including untreated sexually transmitted infections (STIs), reproductive tract infections, unsafe abortions, poor obstetric and postpartum care, exposure to environmental toxins (pesticides, industrial chemicals), schistosomiasis and cultural practices (such as female genital mutilation and early sexual debut) (Boivin et al., 2007; King, 2018; Ombelet et al., 2008; Shahara, 1998; WHO, 1987). Male infertility is also thought to be highest in Africa although under-reporting of the condition makes it difficult to estimate exact figures (Agarwal et al., 2015; Sengupta et al., 2017). Male related cases in infertility are mostly due to poorly treated STIs, excessive consumption of alcohol and tobacco smoking, age, hormonal abnormalities and occupational and environmental exposure to toxic agents like heavy metals and pesticides (Chandra, Goswami & Sengupta, 2012; Krajewska-Kulak & Sengupta, 2013; Kuku and Osegbe, 1989; Sengupta & Banerjee, 2014). Taken together, lifestyle factors such as diet, advanced age at marriage, high levels of smoking, drinking and caffeine intake in developing countries have also been associated with the fertility decline (Curtis, Savitz and Arbuckle, 1997; Inhorn, 2003).

2.2.1. Severe Impact of Infertility in Sub-Saharan Africa

The impact of childlessness in developing countries is often more severe than in developed countries. Families in developing contexts often depend on children for economic survival and societal desirability of continuing lineage (van Balen & Gerrits, 2001). In developed countries, having children is mostly considered a personal choice and therefore, infertility mainly impacts personhood and well-being of affected persons (van Balen & Inhorn, 2002). In Africa, however, infertility has additional profoundly socio-cultural and economic implications for infertile couples (Bahamondes & Makuch, 2014; Dierickx et al., 2018; Dierickx, 2020; Nachtigall, 2006; Serour et al., 2019).

[1] Women used to approximate couples due to lack of male infertility data (WHO, 2013).

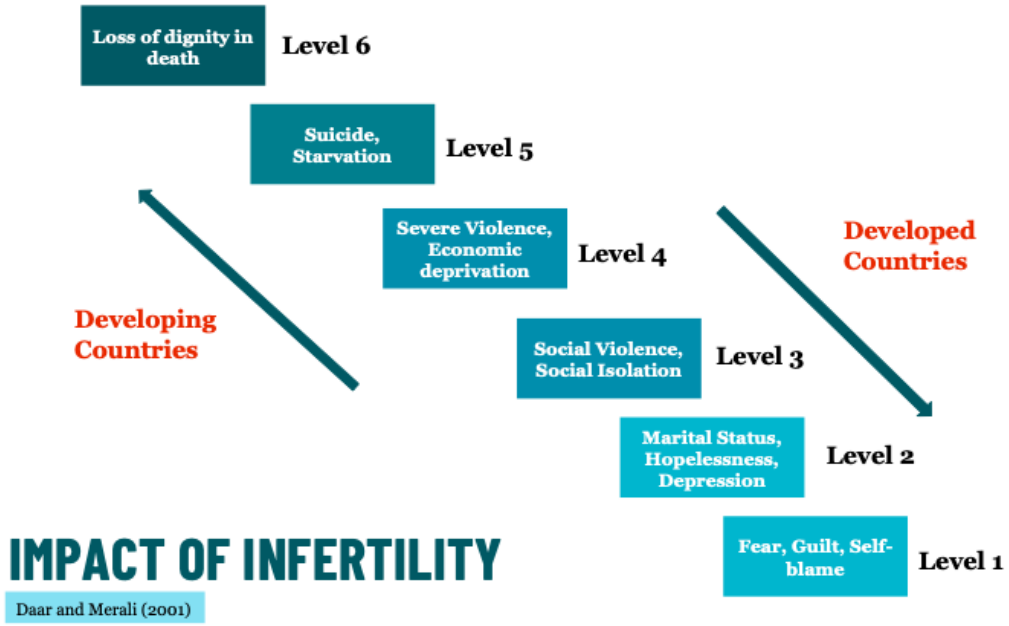

Figure 1: Infertility consequences on a continuum: developed countries rarely see consequences beyond level 2 while developing countries see the full spectrum of consequences. (Daar and Merali, 2002).

Having children in these contexts is a social obligation towards the family (in-laws) and wider community that often results in social pressure (Nguimfack, Newsom, & Nguekeu, 2016; Ofosu-Budu & Hanninen, 2020; Pennings & Mertes, 2012). Women in particular face the greater burden of infertility as motherhood is the only means by which they can gain status with family and society (Balen and Inhorn, 2002; Dierickx et al., 2018; Dierickx et al., 2019; Serour, 2019; Tabong & Adongo, 2013). Those who are not able to produce children are often perceived as inferior and incompetent (Aluko-Arowolo, & Ayodele, 2014; Dierickx et al., 2018). Consequently, on an individual level, infertility leads to anxiety, distress, self-blame, depression, guilt, low self- esteem and reduced sexual interest (Dhont, et al., 2011; Hammarberg & Kirkman, 2013; Stellar et al., 2016; van Balen & Inhorn, 2002). At a societal level, a lack of children can bring about stigma, isolation, ostracization, loss of social status and identity, infidelity, polygamy, increase risk of STI/HIV infection, domestic violence, lack of social security in old age, disinheritance and shameful funeral proceedings (Barden-O'Fallon, 2005; Dhont et al., 2012; Dyer, 2007; Nachtigall, 2006; Ombelet, 2011; Ombelet et al., 2008; Pennings & Mertes, 2012; Serour, 2019; Serour et al., 2017; Stella et al., 2016; WHO, 2013).

In male-related infertility cases, while less is reported on its impact on men; some studies have cited feelings with loss of respect and family pressure to reproduce or take on a second wife (Dierickx et al., 2019; Dyer et al., 2004; Parrott, 2014). In many cases however, women are mistakenly blamed or choose to take on the blame to 'protect' their husbands from shame (Inhorn, 1996). These high social costs of infertility result in early fertility seeking behaviour that often begins as early as six months after unsuccessful fertilization, leading to higher demand for fertility care (Okonofua, 1994). Infertility is often said to lead to a kind of social death for infertile individuals, particularly women urging for the provision of ART in Africa (Bochow, 2012). Therefore, infertility in Sub-Saharan Africa (SSA) should be considered a critical social and public health issue, not simply an individual one (Bahamondes & Makuch, 2014; Ombelet & OnOfre,

2019; van Balen and Gerrits, 2001, 2009). However, availability and access to quality interventions to address infertility remain scarce (Asemota & Klatsky, 2015). Even access to basic interventions such as medical examinations to diagnose infertility, information, counseling, and treatment are limited (Gerrits & Shaw, 2010). Explanations for why this is the case are highlighted in the sections that follow.

2.2.2. Sociocultural and Religious Barriers

The influence of culture and religion on childlessness for both men and women are undeniable in many developing contexts (Gerrit, 2012). Local interpretations of infertility and its causes are often multifaceted and may include biomedical, cultural, naturalistic, and religious concepts (Dyer et al., 2004; Jegede & Fayemiwo, 2010; Kudesia et al., 2018; Ofosu-Budu & Hanninen, 2020). Studies in Ghana, Nigeria, Mozambique, Malawi and Chad have found spiritual causal explanations for infertility to be present i.e. spiritual possession, witchcraft or punishment for improper behavior (Aluko-Arowolo, & Ayodele, 2014; Leonard, 2002; Koster-Oyekan, 1999, Gerrit, 1997; Hemmings, 2007; Tabong & Adongo, 2013). Infertile women are accused of overconsumption of contraceptives, multiple sexual partners and multiple abortions as the reason for their infertility (Dierickx et al., 2018; Tabong, & Adongo, 2013). While infertility in men is wrongly linked to emasculation, leading to loss of respect, pressure to take another wife or a male relative to impregnate the wife (Dierickx et al., 2019; Moyo & Muhwati, 2013; Parrott, 2014).

Furthermore, sociocultural and religious barriers coupled with a lack of knowledge about ART have been reported as barriers to early acceptance and implementation of ART in Africa (Afferri et al., 2022; Bittaye et al., 2023; Gerrits, 2016; Jegede & Fayemiwo, 2010; Serour et al., 2019). For instance, a Nigerian survey of two hundred fifty-seven women on knowledge and awareness of ART revealed that only forty six percent of respondents were aware of ART, a third of women did not believe in ART and said only God gave babies, while quarter thought ART babies were artificial (Olugbenga et al., 2014). Sociocultural concerns regarding third party involvement in ART have also been documented as barriers to acceptability and coverage of fertility services (Gerrits, 2016; Inhorn, Birenbaum-Carmeli, Tremayne & Gürtin, 2017). For example, a study on cultural and ethical challenges of ART among the Yoruba of southwestern Nigeria demonstrated concerns with the legitimacy of children born through third party reproduction and continuity of family lineage (Jegede & Fayemiwo, 2010). Moreover, a general belief that men are not infertile in Africa (due to lack of adequate knowledge on male infertility) presents barriers to health seeking behaviour (Agarwal et al., 2015; Osei, 2016). Furthermore, the study by Jegede & Fayemiwo (2010) revealed that women had no decision-making autonomy over use of ART. Consequently, women primarily carry the financial, emotional and social burden of infertility, often seeking treatment options by themselves (Dierickx et al., 2019; Starrs et al., 2018). To avoid high costs of biomedical fertility treatment, studies have reported on women's choice of traditional healing and mediation as a means of treating infertility (Aluko-Arowolo & Ayodele, 2014; Gerrits, 2016; Nieuwenhuis et al., 2006; Osei, 2016). In certain cases, however, the cultural value placed upon having children has been advantageous in drawing national governments to pay attention to infertility and infertility care such as in Uganda. Therefore, socio-cultural and religious influences play a significant role in acceptability and utilization of infertility services.

2.2.3. Population Control Agenda

Global concern regarding overpopulation has led to a significant focus on population control particularly in regions such as Africa (Asemota & Klatsky, 2015; Ombelet, 2020). This has resulted in de-prioritization

of infertility as an important reproductive health issue and gaps in preventative and treatment measures (Asemota & Klatsky, 2015; Gribble & Bremner, 2012). The world's population is expected to rise to 9.8 billion people by 2050, from 7.6 billion people in 2017 (United Nations, 2017). The economic and social benefits of reducing fertility include infant survival, children's wellbeing, women's economic productivity and greater household savings and income (Canning & Schultz, 2012; Starrs et al., 2018). However, prevailing propaganda on population reduction, family planning and contraception further deepens marginalization of infertile persons and as such as are neglected from healthcare interventions (Chiware et al., 2021; Ombelet, 2011; Ombelet, 2020; Ombelet & Campo, 2007). The need to accelerate economic growth through reduced birth rates and smaller populations has been applied to discount access to infertility care (Gribble & Bremner, 2012). For instance, in Uganda, harnessing the demographic dividend has been the central and rallying message to championing family planning and socio-economic development to fulfill the country's ambition of becoming a high middle-income nation under Vision 2040 (MoH, 2014, 2020). This demographic dividend is defined as "accelerated economic growth that arises when birth rate declines rapidly, and the ratio of working-age adults significantly increases relative to dependents." (Gribble & Bremner 2012). The Ugandan government has posited that a rapid drop in fertility rates is one of the critical paths towards this goal because the dual burden of a high population growth rate and a high child dependency ratio are bottlenecks on the road to socioeconomic transformation (MoH, 2014, 2020). Furthermore, infertility has been referred to as a 'solution to overpopulation' (Inhorn & Patrizio, 2015).

Still, societal benefits of a reduced population should not be met at the expense of infertile individuals' sacrifice (Pennings & Mertes, 2012). The right to reproductive autonomy requires that significant efforts be made to allow all persons to make decisions about how many and when to have children, even in developing countries (Pennings & Mertes, 2012). The United Nations (UN) third Sustainable Development Goal (SDG3) highlights the importance of universal access to sexual and reproductive health care services by 2030, including fertility care (United Nations, 2015). Access to fertility treatment in LMICs would contribute less than 1% of deliveries globally (Ombelet, 2011; Ombelet, 2020). Hence, while one couple may have eight children and have the unmet need for family planning support; the neighboring couple may encounter challenges trying to conceive one child (WHO, 2013). Furthermore, UN data shows that many LMICs have by now succeeded in dropping their global fertility rate (Ombelet, 2020; United Nations, 2019). Egypt is a good example of this, in that while the country is considered overpopulated; it has managed to reduce their population growth rate whilst attending to infertility services that include state subsidization of ART (Inhorn and Gurtin, 2011; WHO, 2010). As a pronatalist country with strong Islamic influence, there is a strong value on parenthood in Egypt that has led to availability and further broadening of access to fertility services (including ARTs) to the resource poor (Inhorn & Gurtin, 2011).

Population growth reduction can also be implemented in much more effective ways by educating women, provision of contraceptives and safer abortions (Pennings & Mertes, 2012). As Frank (1983) highlighted, "women and men will be more inclined to utilize contraceptives if their concerns and fears over infertility are taken seriously." Dr Mahmoud Fathalla, previously of the WHO also states that, "If couples are urged to postpone or widely space pregnancies, it is imperative that they should be helped to achieve pregnancy when they so decide, in the more limited time they will have available" (WHO, 2010). Notably, a lack of population level databases that accurately define and measure the burden of infertility in Africa obscure the real figures and thus need for ART (Serour, 2019). For instance, in a 2016 fertility surveillance report by the International Federation of Fertility Societies (IFFS), data from only six African countries (Senegal, South Africa, Cameron, Kenya, Mali, and Nigeria) could be included in the overall analysis due to a poor

response rate and quality of data reporting (Serour et al., 2019). Therefore, withholding access to ART to persons experiencing infertility is not a legitimate policy solution for population restriction (Ombelet, 2011). This negligence is unjust, unethical and violates human rights and every effort should be made to provide and reduce the costs of ART (Serour et al., 2017; Serour et al., 2019).

2.2.4. Limited Resources

The cost of fertility treatment is one of the biggest barriers to provision of fertility care in SSA. Treatment of infertility using advanced methods such as IVF technologies requires highly skilled labour, expensive equipment and maintenance, which present challenges to treatment access (Nachtigall, 2006; Serour et al., 2019). Arguments for neglect of infertility have pointed to other pressing priorities such as severe or life-threatening conditions (like STIs & HIV/AIDS), limited resources and poor health systems (Gerrit, 2012; Ombelet, 2011, 2012). These urgent needs are likely to take precedence over expensive fertility treatments that cannot be justified in low-resource contexts with competing priorities (Ombelet, 2012). Furthermore, although limited resources ought to be dispersed thoughtfully, donor countries' prioritization of maternal healthcare and family planning further marginalize infertile persons (Asemota & Klatsky, 2015; Hörbst, 2012). The policy making process can be steered by donors through exertion of political influence and social policy (Afferri et al., 2022). However, these priorities fail to recognize the severe psychosocial and economic burden of infertility in developing countries, likely higher than in developed countries (Asemota & Klatsky, 2015).

Globally, the fertility industry is estimated to be worth $25 billion and is predicted to grow to $41 billion by 2026 (Strodel, 2020). The average cost per IVF cycle (USD) is USD $8,500 in Canada, USD $12,513 in the United States, USD $5,244 in the United Kingdom and USD $4,500 in South Africa (Chambers et al., 2009; Huyser and Boyd, 2013; NHS, 2013). A study on the cost of fertility care in Africa revealed approximately USD $4,000–5000 in Nigeria and Mali, and USD$3,500 in Uganda (Hörbst, 2016; Okohue et al., 2010; Platteau et al., 2008). Gerrits and Shaw (2010) reported that the cost of one IVF cycle in Ghana was the equivalent of a nurse's salary over 18 months. These high treatment costs reflect inequitable global distribution of IVF treatment services. An estimated 180 million couples worldwide might be affected by infertility, yet services are mainly available only to the wealthy (Starr et al., 2018). Consequently, infertility has been described as a "rich person's disease" with treatment only accessible to elite or rich couples (Serour et al., 2019; WHO, 2013).

Even with local importance attached to infertility, few resources are made available to advance infertility care in SSA (Asemota & Klatsky, 2015). National governments are unwilling to fund the high cost of ART treatments, generating significant growth of private clinics to address the gap in fertility services, at catastrophically high costs (Jones et al., 2010; WHO, 2013). In many African countries, ART is mainly provided with the private sector or through public-private sector partnerships (Serour et al., 2019). This is mainly due to high investment costs associated with opening these facilities, importing equipment, medicines and extensive, consistent medical training required to provide quality services (Serour et al., 2019). Additionally, private fertility clinics are often clustered in larger cities, presenting travel and accommodation expenses and thereby increasing barriers to access of fertility treatment (Gerrit, 2012). Without public IVF centers and insurance coverage for ART, individuals are restricted to substantial out of pocket payments in the private sector (Kissin et al., 2016; Serour et al., 2019). Moreover, in Africa, this economic burden of infertility and its treatment often rests on women (WHO, 2010; Dyer & Patel, 2012).

Women are at risk of sacrificial expenditure on IVF treatment and impoverishment, oftentimes borrowing money, working more and selling their assets (Dyer et al. 2013). Lack of services due to geographical barriers (Okwelogu, Azuike, Ikechebelu & Nnebu, 2012) or quality treatment also leads persons to travel elsewhere for appropriate care, a phenomenon known as cross border reproductive care (CRBC) (Salam, 2018). Therefore, absence of political concern combined with prohibitive socio-cultural beliefs and high cost of ART has resulted in significant inequities in access to fertility care in SSA.

2.3. The Need to Address Infertility

Globally, the prevalence of infertility continues to increase given postponement of childbearing in developed countries and impact of STIs, unsafe abortions and poor delivery care in developing countries (Inhorn & Patrizio, 2015; Tannus & Dahan, 2019). Yet, infertility care in health systems face considerable gaps in research, communication, surveillance, and policy development (Morshed-Behbahani et al., 2022). Although the devastating consequences of infertility in Africa are well documented and the need for intervention evident; there was limited interest[2] in the prevention and treatment of infertility (Ombelet, 2020; Ombelet and Onofre, 2019). To adequately address infertility in developing countries, a multi sectoral approach will be required. The WHO recommendations for fertility care call for a holistic and comprehensive approach that can be integrated from the community level through awareness to affordable care through the health system (WHO, 2010). This comprehensive package of interventions required to assist men and women in achieving their desires of building a family should consist of fertility awareness, prevention, management and support (Zegers-Hochschild et al., 2017). In their conceptual framework of enablers to fertility care policy making in Africa, Afferri and colleagues (2022), propose four categories to guide policymakers into supporting fertility care in Africa below and expanded upon in the next sections (Afferri et al., 2022).

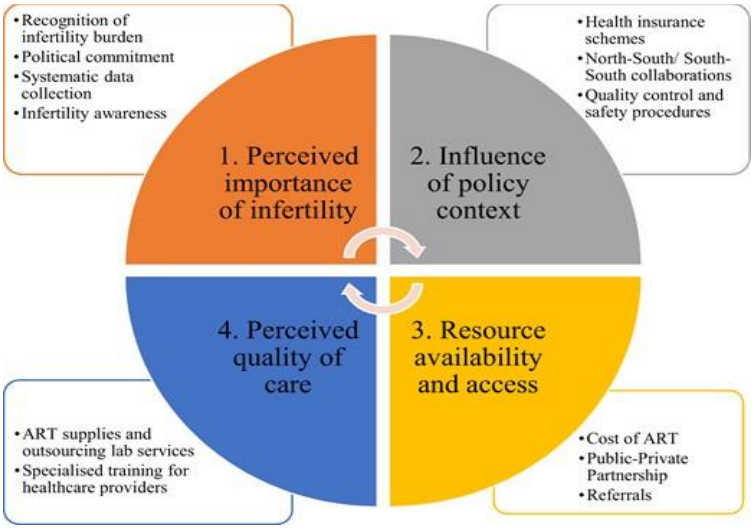

Figure 2: Conceptual framework: enablers to fertility care policy making in Africa (Afferri et al., 2022).

[2] Prior to 2001, with exception of Egypt and South Africa; there was a lack of interest in addressing infertility in Africa (Ombelet & Onofre, 2019)

2.3.1. Global Policy on Infertility Care

Infertility affects millions of people around the world, yet in low-income countries (particularly Sub-Saharan Africa), policy inclusion of fertility care in reproductive health remains fragmented or absent (Afferri et al., 2022). Human rights literature as early as 1948 has highlighted the right to found a family, if and when individuals choose to do so (United Nations, 1948; WHO, 2007). In particular, Article 16:1 of the 1948 Universal Declaration of Human Rights states, "men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and found a family". For this reason, reproductive rights encompass the ability "to decide freely and responsibly the number, spacing, and timing of having children and access to information or means to do so" (Starrs et al., 2018). These rights-based arguments have formed the basis for meeting reproductive needs of populations; however, efforts have been mainly focused on preventing unplanned pregnancies (Gipson, Bornstein, & Hindin, 2020). Until recently, infertility received little to no recognition by policy makers and the public health sector in many developing countries (WHO, 2010; Gerrit, 2012). International emphasis on family planning and population control also undermined infertility as a reproductive health condition in need of intervention (Ombelet, 2011; Pennings & Mertes, 2012). Yet, the human rights of infertile couples to have access to fertility treatments meets the 1948 UN Declaration of human right (Serour, 2019). Additionally, at the 1994 International Conference on Population and Development Programme of Action (ICPD) in Cairo, 179 countries signed towards addressing infertility through prevention and access to appropriate fertility treatment (UNFPA, 2014).

Even so, a 2018 Guttmacher–Lancet commission on sexual and reproductive health rights revealed that infertility had not been prioritized by policy makers in global health and gained far less attention than other rights such as access to contraceptives and care for HIV (Starrs et al., 2018). A strong public health argument for prioritization of infertility in Africa can be made based on its demonstrated impact on individuals through psychological distress (Naab et al., 2019; Nieuwenhuis et al., 2009), marriages through intimate partner violence (Stellar, Garcia-Moreno, Temmerman, & van der Poel, 2016), increased HIV risk (Dhont et al., 2011), divorce, polygamy (Dierickx et al., 2018) and socially through stigma, exclusion and economic difficulties (Dyer & Patel, 2012). The failure to recognize the burden of infertility as a reproductive disease and treatment as a human right leads to barriers in achieving a desired pregnancy through fertility care.

Therefore, policies that recognize infertility as a reproductive disease and reproductive health right are essential to incorporation of fertility care in reproductive health programming (Morshed-Behbahan et al., 2020). Furthermore, policies that are responsive to equity in distribution of financial resources to infertility through appropriate insurance coverage, adequate funding strategies to reduce out of pocket payments are beneficial in contexts with limited resources (Jakovljevic, Groot & Souliotis, 2016). However, several authors revealed a lack of consensus on how inclusion of fertility care should be adapted and implemented in different contexts (Dierickx et al., 2019; Serour et al., 2019). Still, lessons can be taken from countries like Iran for instance; where the MoH introduced pronatalist policies mandating insurance companies to cover costs of infertility therapeutic and diagnostic tests and subsidized the price of drugs for the treatment (Tremayne & Akhondi, 2016). Furthermore, studies have demonstrated that financially stable countries have better policies of fertility services compared to countries with limited resources (Akinloye & Trute, 2011; Ogura & Jakovljevic, 2018).

2.3.2. ART Legislation & Regulation

ART regulation enhances safety and transparency of ART, while restricting various applications of ART that are not contextually fit through licensure, monitoring and accreditation of fertility providers (IFFS, 2016). Yet globally, existence and forms of regulation regarding fertility care are highly variable in terms of *what* to regulate and *how* to regulate it (Jones & Cohen, 2007, IFFS, 2016). As guidelines continue to evolve rapidly, countries generally determine their own applications of ART based on culture and local stakeholders (IFFS, 2016). However, in many African countries where ART exists, there is a complete lack of legislation and regulation of the industry (Chiware et al., 2021; Gerrits & Shaw, 2010). This is partly explained by ART export to Africa in the 1980s, which was not accompanied with establishment of data registries to monitor and report utilization and outcomes (Botha, Shamley & Dyer, 2018). For example, the first ART birth in Nigeria happened over 30 years ago in 1989, enough time to develop appropriate legislation; yet like other African countries, it still struggles to find the appropriate legal framework to provide guidelines for these technologies (Ekechi-Agwu & Nwafor, 2020; Muanya, 2015). Similarly, a study in Mali and Uganda cited that responsibility of how fertility care is practiced is completely dependent on the private clinic professionals (Horbst, 2016). Lack of regulation in these countries presented clinical practice freedom to medical professionals (Horbst, 2016).

Still, regulation of ART is critical to curtailing unethical practices and abuses associated with ART and ensuring quality fertility care (Ekechi-Agwu & Nwafor, 2020). Fertility care needs to be incorporated into national reproductive health policies (WHO, 2010; Ombelet, 2009; van Balen and Gerrits, 2001). Furthermore, variation in or lack of regulation contributes to the rapidly growing cross border reproductive care (CBRC), which poses safety risks in contexts where there are no best practice guidelines (WHO, 2013). In countries like Egypt where legislation exists, it is often shaped by the dominant religious beliefs and local cultural values such as pronatalism, genetic lineage and the view of embryo as a person (WHO, 2010). Some individuals travel to other countries seeking fertility services to overcome legal and ethical prohibitions as well as quality and privacy concerns, and high costs of care in their own countries (Inhorn & Gürtin, 2011; Inhorn & Patrizio, 2015; Salama, 2014; Salama et al., 2018). Hence, formulation of specific fertility care legislation that guides consistent auditing and regulation of accredited, registered facilities is essential in establishing appropriate standards of practice and protections of all involved (Ombelet, 2011; Sharma, Mittal & Aggarwal, 2009). The African Network and Registry for Assisted Reproductive Technology (ANARA) has taken the lead effort in registering all IVF cycles in Africa to support data sharing, transparency and quality standards (Afferi et al., 2022; Dyer et al., 2019; Fauser, 2022; Ombelet & OnOfre, 2019). However, it is important to bear in mind that national regulation of fertility care in some contexts might hinder access to some groups further promoting CBRC as excluded individuals seek these services elsewhere (Gurtin & Inhorn, 2011).

2.3.3. Fertility Education & Preventative Services

Limited knowledge of the burden of infertility on health and quality of life by the public, patients and healthcare providers presents barriers to ART utilization and need (UNFPA, 2017). In developing countries, reproductive education and awareness is significantly low (WHO, 2010). Yet, improvement in reproductive knowledge is a cost-effective solution to preventing secondary infertility, the most common type in these contexts (Botha, Shamley & Dyer, 2018; FIGO, 2012; Starrs et al., 2018). Defined as the inability to get pregnant after an earlier birth, secondary infertility is largely due to preventable and treatable causes,

compared to primary infertility (Mascarenhas et al., 2012). Preventative fertility awareness could improve understanding of reproduction and address both primary and secondary infertility by communicating risk factors associated with the condition e.g., advanced age, irregular menstruation, and timed intercourse (Serour et al., 2019; Starrs et al., 2018; Zegers-Hochschild et al., 2017). Timely, comprehensive education and reproductive counseling on prevention of unwanted pregnancies, diagnosis, treatment and prevention of STIs, as well as safe delivery, postnatal care and abortion services would reduce incidence of infertility (Kudesia, Talib & Pollack, 2017). Furthermore, preventative health education could be directed towards modifiable lifestyle factors such as obesity, smoking, alcohol consumption and environment or occupational exposure to toxins to reduce infertility rates (Collins & Rossi, 2015; Kovac, Khanna & Lipshultz, 2015; Ombelet, 2011; Zegers-Hochschild et al., 2017).

Cultural, religious and traditional beliefs also play a significant role in interpretation of disease, including infertility and access to healthcare services. Persons experiencing infertility often face challenges communicating their feelings to relatives and friends due to beliefs they would not understand their situation or be ridiculed, resulting in isolation and limited support (Dyer, 2007; ESHRE, 2010; Read et al., 2014; Schmidt, 2009). Lack of awareness or misconceptions regarding male infertility pose additional barriers to access to fertility care. Furthermore, complex procedures like third-party reproduction and surrogacy in many contexts are prohibited, which hinders universal access to fertility care (Inhorn, 2003). Therefore, societal, and cultural factors affecting options to meet family building needs should be considered and addressed (Zegers-Hochschild et al., 2017). Traditional and religious leaders need to be educated on ART and brought on board as champions (Ombelet, 2011). Additionally, local health care providers at health centers and in communities can educate the public and address some of the myths and misconceptions regarding infertility and refer affected persons to fertility services (Asemota & Klatsky, 2015).

Better education, particularly for women, has been linked to economic empowerment, reduced fertility rates, and can dispel infertility myths[3] and address social stigma (Serour et al., 2019; WHO, 2013). Infertility prevention is the most efficient solution to addressing infertility in developing countries that would benefit the largest group of people and can be combined with maternal and family planning services (Ombelet, 2011). Therefore, governments can support integration of infertility education into reproductive health programs to improve fertility outcomes (Ombelet, 2011). Still, even with better reproductive education and infertility preventative services as important priorities, these solutions neglect persons that are already infertile or who will become infertile nonetheless (Ombelet, 2011). Therefore, the need for greater public awareness and likewise, demand for affordable ART in SSA continues to be high (Ombelet & OnOfre, 2019; Ndegwa, 2016; Osei, 2016).

2.3.4. Assisted Reproductive Technologies (ART)

Assisted reproductive technologies (ART) have seen significant advancement since their debut more than 30 years ago (Steptoe & Edwards, 1978; Vayena et al., 2009). This technology has offered hope for many struggling to have children as their last chance at conceiving biological children (Inhorn & Patrizio 2015). ART not only provides infertile individuals and couples with a choice, but positively impacts families and societies by offering fulfillment of reproductive choice (Serour and Serour, 2017). ART are defined as "all

[3] A lack of accurate information about infertility has resulted in misconceptions that link the disease to contraceptive use or vaccination (WHO, 2013).

technologies that include the *in vitro* handling of human oocytes and sperm or embryos for the purpose of reproduction, including but not limited to in vitro fertilization (IVF), embryo transfer (ET), semen, oocyte and embryo donation, intracytoplasmic sperm injection (ICSI), preimplantation genetic testing (PGT) etc but excluding artificial insemination" (Zegers-Hochschild et al., 2017). Although success rates vary, infertility can be clinically managed through medication and ART (Bahadur et al., 2020). As of 2018, reports showed that there are more than eight million babies born in the world through ART, 2.5 million IVF cycles conducted annually and 500,000 babies born as a result (ESHRE, 2018; Fauser, 2019).

Despite this massive global expansion of ART services over the past decade (2004-2015), access to ART remains limited in many parts of the world, particularly in SSA, Asia, Latin America and Eastern Europe (Jones et al., 2011; Ory et al., 2014). Furthermore, a recent report from the African ART registry (ANARA) reported that utilization of ART was very low, although data from 13 African countries showed a total of 25,770 initiated ART cycles (Fauser, 2019). Africa represents less than 2% of global ART provision (Adamson et al., 2018; Dyer et al., 2020; Ombelet & Onofre, 2019). Cost is the most cited barrier to provision and access to fertility care in Africa (Botha, Shamley & Dyer, 2018; Dyer et al., 2019; Fauser, 2019; Menuba et al., 2014; Ombelet and Onofre, 2019; Omokanye et al., 2017). Establishment of an ART unit according to international standards costs USD $400,000 to USD $500,000 (Van Zandvoort, de Koenig & Gerrits, 2001). Other barriers include insufficient infrastructure for ART, inadequate specialist knowledge and need for appropriate obstetric and neonatal care (Okonofua, 1996; Inhorn, 2003). Hence, governments are not willing to establish publicly funded ART centers and the majority of services are provided in the private sector at exorbitant costs. Yet the most common cause of infertility in Africa is tubal blockage, a reproductive condition that can most effectively be treated using ART (Bahamondes & Makuch, 2014; Ombelet, 2009; Sharma et al., 2009). Consequently, many infertile couples go untreated or undertreated due to the high cost of infertility treatment (Morshed-Behbahani et al., 2022). Majority of patients pay out of pocket for fertility treatment either due to absence or exclusion of health insurance to cover fertility care (Ethics Committee of the American Society for Reproductive Medicine, 2015; Dyer et al., 2016; Fauser & Serour, 2013). A comparative study on infertility in seven countries, revealed inadequate financial protections in Ghana and the U.S compared to good protections in Australia, United Kingdom and Singapore (Morshed-Behbahani et al., 2020). In Ghana, all IVF clinics were in the private sector and no government services were available for treatment of infertility (Morshed-Behbahani et al., 2020).

Like Ghana, most African countries have no publicly accessible ART and financial protections for fertility care; therefore, couples experiencing will not have access or complete access to ART given the significant financial burden involved (Botha, Shamley & Dyer, 2018; Serour et al., 2017). The cost of ART is estimated to be up to 50% higher than the gross national per capita income in many LMICs (Vayena et al., 2009). For instance, in Nigeria, ART reportedly costs $10,000 yet the national monthly minimum wage is $110 (Fadare & Adeniyi, 2015). Additional barriers to accessibility of fertility clinics may include geographical barriers as the majority of clinics are located in urban areas or out of the country. In Kenya, patient access to ART was limited by few clinics available (Murage et al., 2011) and cross border ART is becoming common in Ghana (Gerrits, 2016). Therefore, the need for fertility care is emerging from all socio-economic classes, in both developed and developing nations but only accessible to the wealthy (Inhorn & Patrizio, 2015). Despite limited resources in Africa, increasing demand and need for ART is indisputable (Botha, Shamley & Dyer, 2018; Murage, Muteshi & Githae, 2011; Serour, 2019). Furthermore, availability and access to ART in Africa has been shown to reduce social stigma attached to the condition (Inhorn & Patrizio, 2015).

Hence, in order to overcome the unjustifiable cost of infertility treatment in developing countries, low-cost ART needs to be considered for more equitable access to fertility care (Murage, Muteshi & Githae, 2011; Ombelet, 2011; Starr et al., 2018).

2.4. Low-cost IVF Initiatives: Overview

Although ART is available globally, it is inaccessible for many in developing countries who demand for good quality fertility services to resolve childlessness for many infertile women (van Balen, 2002). Cost of IVF technologies presents one of the biggest barriers to treatment access. High treatment costs, predominantly provided by the private sector and unavailability of services in the public sector act as barriers to fertility treatment and lead to inequitable access to care (Serour et al., 2019). Furthermore, delays in access to care reduce treatment success rates (van Balen, 2002). To overcome these barriers to infertility, the cost of ART needs to be reduced and requires development of low-cost protocols and techniques (Akande, 2008; Bahamondes & Makuch, 2014; Ombelet, 2014; Serour et al., 2019). International networks such as Friends of LCIVF and the Walking Egg are researching innovative ways to develop low-cost treatment options (Ombelet, 2014).

Low-Cost IVF (LCIVF) initiatives have been introduced as the answer to the reproductive inequalities associated with the high cost of ART by simplifying conventional IVF technologies. (Ombelet, 2011; Ombelet et al., 2008). These initiatives were developed in response to the Universal Declaration of Human Rights Article 16:1 which states, "Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and found a family" (United Nations, 1948). This declaration called for reproductive health programs to include prevention and appropriate treatment of infertility (United Nations, 1995). LCIVF initiatives, therefore, offer IVF at a reduced cost for infertile individuals, in mostly developing countries to improve accessibility (Inhorn & Patrizo, 2015). They represent actions taken to reduce health inequities and promote reproductive autonomy by offering an opportunity for women and men to decide whether to have children, when and how to achieve at least one biological child (United Nations, 1995; Ombelet, 2011).

Other forms of cost reduction may include publicly funded IVF. AlAzhar University, located in the center of Cairo, Egypt, is a good example of a public hospital that has been able to provide subsidized IVF at $600 per cycle to Egyptian infertile couples annually (WHO, 2010). However, while there are limited reports on state-funded ART in Africa, some studies have cited attempts to introduce affordable ART through clinical protocols in Nigeria, Mali and Uganda (Eluga et al., 2010; De Beer et al., 2016; Orhue et al., 2012). In Uganda, the out-of-pocket cost for ART alternatives was $200 per IVF cycle using mild ovarian stimulation (Eluga et al., 2010), compared to $2,700 in Ghana (Gerrits, 2016), $4,500 in Kenya (Ndegwa, 2016) and up to $10,000 in Nigeria (Fadare & Adeniyi, 2015). By supporting low-cost IVF, governments may be more willing to make fertility care more widely available (Ombelet & Campo, 2007; Ombelet et al., 2008). Wider access to fertility treatment would also provide hope for infertile couples by encouraging them to remain together and decreasing social stigma (Inhorn & Patrizo, 2015). Additionally, reduced costs would also encourage patients to seek care in the country of origin and deter them from the risks associated with CBRC (Ombelet, 2014). Therefore, literature on affordable fertility care has highlighted the need for future studies to examine barriers to affordable infertility care and assess provision, access and utilization of LCIVF initiatives in developing contexts (Gerrit, 2012).

2.4.1. Strategies for LCIVF Clinical Protocols

Several alternatives to conventional IVF have been proposed and developed to reduce the cost of fertility treatment are described below.

Simplified diagnostic protocols. Infertility diagnosis can be determined in most cases based on taking a detailed medical history of the couple, use of clinical judgement and light microscopy semen analysis rather than sophisticated laboratory testing and superfluous investigations (Aleyamma et al., 2011). Furthermore, tubal factor blockages can be detected using hystero-salpingo-contrast-sonography and vaginal ultrasound, which are simple and accessible techniques, without significant cost implications (Ombelet & Campo, 2007). Laparoscopic procedures have also been simplified and can be conducted in a one-stop ambulatory approach (Campo et al., 2005). More recently, a smart phone, at home semen analysis technique is being developed (Kobori, 2019).

Minimal ovarian stimulation. This includes use of inexpensive stimulation medication (e.g., clomiphene citrate or letrozole) instead of expensive versions of conventional gonadotropins (e.g. recombinant FSH) for follicular development that increase risk of ovarian hyperstimulation syndrome (OHSS) (Aleyamma et al., 2011; Allersma, Farquhar & Cantineau, 2013; De Beer et al., 2016; Eluga et al., 2010; Ingerslev et al., 2001; Nagulapally et al., 2012; Özörnek et al., 2013; Verberg et al., 2009). A study of minimal ovarian stimulation using Letrozole in Turkey showed similar pregnancy outcomes, fewer side effects and cost effectiveness (Özörnek et al., 2013).

Simplified laboratory procedures. Lab procedures are often expensive due to use of carbon dioxide cylinders to incubate embryos that require a lot of electricity, which is uncertain in many developing countries (Ombelet, 2011). The use of a petri-dish containing embryos in a plastic bag, a procedure that has been successfully implemented for over a decade in veterinary IVF might be employed as a low-cost alternative (Hovatta & Cooke, 2006; Ombelet et al., 2008; Vajta et al., 1997, 2004). Portable digital microscopes could also be used to confirm cell division, as they are cheaper (i.e., USD $7) than expensive ones used in the developed countries (Kobori et al., 2016).

Simplified culture systems. The plastic incubator capsule (INVOcell®) in which fertilized eggs are placed in a capsule and inserted in a woman's vagina for three days to keep them at desired temperature can be used instead of incubators (Frydman & Ranoux, 2008; Lucena et al., 2013; Navarro-Carbonell et al., 2012). A study in Colombia on INVOcell® reported good quality embryos, higher implantation and pregnancy rates obtained using INVOcell® in comparison to conventional IVF/ICSI (Navarro-Carbonell et al., 2012). A feasibility study of the simplified method of culturing called (t)WE lab system, a closed system (worth Euros 200) developed to enable fertilization and embryo development to occur until day three, when uterine transfers are done for fertilization, resulted in comparable outcomes to conventional IVF laboratory systems (Ombelet, 2013; Ombelet et al., 2014; Ombelet et al., 2022*a*, Ombelet et al., 2022*b*).

Early embryo transfer. Transfer of embryos on 1st or 2nd day as opposed to 6th day in standard IVF protocols is more cost effective; while the delay is meant to identify defects and best embryos, it also makes storage expensive (Lee et al., 2017).

***Cheaper incubators*.** Tabletop incubators that use solar power are a better alternative for countries with frequent power cuts compared to standard incubators (Swain, 2014).

Single Embryo Transfer. Another low-cost procedure is the transfer of a single embryo as opposed to multiple embryo transfers to reduce the cost burden of IVF outcomes associated with multiple births and complications (Bahamondes and Makuch, 2014; Kato et al., 2012; Lee et al., 2016; Ma et al., 2022; Monteleone et al., 2019). This protocol is an even more appropriate option for health systems like those in developing countries, as they may not have capacity and resources to handle multiple pregnancies and neonatal cases (Bahamondes & Makuch, 2014).

Intravaginal fertilization and culturing. This innovative procedure has shown relative success and involves oocytes being kept in the vagina held by a diaphragm for 50 hours maximum (Frydman & Ranoux, 2008).

Batching treatment cycles. In Nigeria, batching patients (about thirty) together during treatment cycles has been used to reduce costs, reporting a 30% pregnancy rate per embryo transfer (Orhue et al., 2012).

2.4.2. Implementation of LCIVF Initiatives in Sub-Saharan Africa

Successful implementation is described as the incorporation or routine use of a technology on an ongoing basis in an organization (Yin, 1977; Szulanski, 2000). While there are studies reporting on efficiency, safety and acceptability of LCIVF initiatives, there has been a gap between development of these low-cost protocols and implementation in low-income settings (Chiware et al., 2021). Few initiatives have been geared towards implementation of ART at an affordable or low-cost in low-resource contexts (Bahamondes & Makuch, 2014). Yet, the urgent need for accessible and affordable fertility countries in Africa has been emphasized (Ombelet & Onofre, 2019). Availability of fertility services to the unprivileged is a moral and social responsibility for governments that have committed themselves to improving access and availability of reproductive health services (Nachtigall, 2005). Literature on implementation of LCIVF in developing countries has cited this as a challenging endeavor that will need of involvement from multiple parties to increase investment in healthcare, public education, training and reduce costs of fertility treatment in developing countries (Afferri et al., 2022; Collin, 2002; Cooke et al., 2008; Ombelet & Campo, 2007; Ombelet et al., 2008; Salam, 2008). Key players may include pharmaceutical companies for cheaper drug options, clinicians, researchers and professional organizations in order to provide simpler, cheaper procedures at minimal costs to improve access to and utilization of ART treatment (Ombelet et al., 2008; Pennings & Mertes, 2012).

Previous research has also suggested that multiple key stakeholders will be necessary to provide funding needed to sustain universal accessibility of fertility care (Salam, 2008). Fixed expenses for establishment of new facilities (facility, equipment), medical staff training, running expenses (medication, staff salaries, consumables) and educational/awareness programs need consideration (Sallam, 2008; Ndegwa, 2016). Fertility care, although closely associated with IVF procedures, also includes providing psychological and emotional support to couples, basic diagnostics, timed coitus, simplified ovarian stimulation and reproductive surgery (Ombelet, 2011). Governments in developing countries such as Uganda and international organizations such as the WHO, ESHRE, ICMART (International Society for Monitoring

Assisted Reproductive Technology) and IFFS (International Federation of Fertility Societies) have declared enthusiasm towards universal access to fertility care through low-cost IVF initiatives (Ombelet, 2011). However, according to the 2018 IFFS surveillance report, 45 out of 85 countries (53%) in an IFFS survey said they did not offer any type of financial support (IFFS, 2018). Of the twelve African countries included in the study, 91% either had no financial coverage for fertility care or it was unknown (IFFS, 2018). Only Kenya reported partial coverage for services (IFFS, 2018). Thus, highlighting a gap between appreciation of the burden of infertility versus a country's ability or willingness to fund it. Still, every individual should have the right to basic medical care and therefore, global access to fertility care should be acknowledged as an essential human right (Ombelet, 2011). This can be achieved through implementation of LCIVF initiatives and/or inclusion of state-funded fertility care.

2.4.3. Risks of LCIVF Implementation in Sub-Saharan Africa

Given resource limitations in many Sub-Saharan countries, questions around the selection criteria for patients and prioritization of who should receive low-cost IVF treatment will emerge. Issues regarding whose reproductive treatment requests will be considered over whose will not need attention (Gerrit, 2012). For instance, female age, marital status, sexual orientation of couple or individual have all been cited as determinants for receiving fertility services in different countries (IFFS, 2018). Initial exclusion of patients with secondary infertility has also been highlighted, with priority given to those with primary infertility (Pennings & Mertes, 2012). In addition, some treatment options are more expensive than others. The level of care provided will be context specific, differing from country to country based upon variables such as healthcare infrastructure, economy, level of education and political stability (Ombelet, 2011). Studies have shown that limited availability of resources has also led to creative modes of funding treatments. For example, in Mali and Uganda, fertility doctors offered discounts for multiple treatments and offered patients embryo sharing alternatives as a means to reduce cost treatments (Horbst, 2016).

Furthermore, other risks of implementing ART in low-income contexts include the inability to handle complications associated with fertility treatment (Ombelet, 2011). These might include ovarian hyperstimulation, multiple pregnancies, premature babies, ectopic pregnancies and must be prevented as much as possible (Ombelet, 2011). Another possible risk is the impact of cross border reproductive care; in particular, by persons from developed countries seeking cheaper services and leading to exploitation such as with surrogacy exploitation in India (Vayena et al., 2009). Although concerns of quality have been raised, low-cost treatment does not affect quality of care, many LCIVF initiatives have been tested in a number of studies achieving acceptable pregnancy rates and sometimes similar success to the high-tech alternative (Kawachiya et al., 2006; Teramoto and Kato, 2007; Ombelet et al., 2022; 2023). Nonetheless, attention to biomedical costs of infertility treatment may not alleviate the cultural and societal implications of infertility on childless persons such as stigma (Gerrit, 2012). Therefore, provision with biomedical interventions must be led with interventions to increase awareness and reduce stigma.

In summary, studies focused on implementation, access and affordability of LCIVF services in low-income countries are non-existent (Chiware et al., 2021). Research needs to be conducted on implementation of these low-cost processes, validity of low-cost IVF pregnancy results and the hidden costs (personal and infrastructure) (Johnson, Cohen & Grudzinskas, 2014). Furthermore, clinical practitioners should provide detail on particular components of the treatment that are low cost, their success rates, risks to their patients

and context acceptability (Bahamondes & Makuch, 2014). Therefore, this study aims to address these gaps in knowledge through examining the implementation of LCIVF initiatives in Uganda's public health system.

2.5. Theoretical Framework

Implementation of evidence-based interventions into clinical practice is a challenging task given the interplay between diverse actors, at various organization levels and social, economic, cultural and political contexts in which they are being integrated (Casper & Koeing, 1996; Pantoja et al., 2017). Many implementation efforts of evidence-based innovations fail (Damschroder et al., 2022). Implementation Science (IS) as a discipline that embraces contextual realities at work during implementation and examines the methods by which research, evidence-based practices and interventions are adopted and integrated into routine healthcare practices for improvement (Dopson et al., 2010; Eccles & Mittman, 2006; Nilsen et al., 2020). IS draws upon theory, frameworks and models to examine and predict likelihood of successful, sustainable implementations (Nilsen, 2015). The WHO expanded on the definition of IS as "the process of scientific enquiry by which implementation of interventions or initiatives is examined along with contextual factors that influences these processes" (Peters et al., 2013). This characterization not only considers implementation as a methodology to improve intervention uptake but also underscores contextual factors as a defining component that may favour or disfavor successful evidence-based implementation (Peters et al., 2013). Context is described as a combination of unique attributes surrounding the implementation actions (Damschroder, 2009; Damschroder et al., 2022). In developing countries, context plays a crucial role in implementation of health technologies based on additional considerations including societal norms, healthcare infrastructure, resources, culture, politics and regulatory processes (Yapa & Bärnighausen, 2018). The interaction of these factors may take place at multiple levels, influencing the success or failure of implementation of interventions (Ferlie & Shortell 2001; Grol 1997; Shortell et al. 2000). Therefore, an understanding of factors that hinder or facilitate routine inclusion of quality-improvement interventions is crucial to implementation (Grol & Wensing 2004; van Bokhoven, Kok, & van der Weijden, 2003).

2.5.1. Categories of Implementation Frameworks

Various implementation frameworks have been used to guide program planning, design, implementation and evaluation in several disciplines. These frameworks help researchers bridge findings across a broad range of studies by providing standardized language, terminology, tools for examination and theory development guidance (Damschroder, 2020). While they are valuable in implementation studies due to their flexible application; there are an estimated 60+ frameworks with the most commonly used including Reach Effectiveness Adoption Implementation Maintenance (RE-AIM), Theoretical Domains Frameworks (TDF), the Consolidated Framework for Implementation Research (CFIR) (Birken et al., 2017; Nilsen, 2015; Tabak, Khoong, Chambers & Brownson, 2013). This abundance of frameworks presents challenges resulting from unstandardized or overlapping constructs and heterogeneity in constructs complicating determination of the appropriate framework for a study as well as for comparison across different settings and populations (Cane et al., 2012; Damschroder et al., 2009; Martinez, Lewis &Weiner, 2014; Mitchell et al., 2010).

Theories used in IS can be categorized into three main approaches: process theories, which translate and guide research translation into practice; classic theories, determinant frameworks, and implementation

theories, which assist understanding and explanations of what influences implementation outcomes and evaluation frameworks, which focus on evaluating implementation (Nilsen, 2015). Theories that guide understanding of contextual factors salient to implementation are nested within determinant frameworks. These theories characterize determinants (facilitators and barriers) that influence implementation outcomes (Lewis et al., 2018; Nilsen, 2015; Tabak et al., 2012).

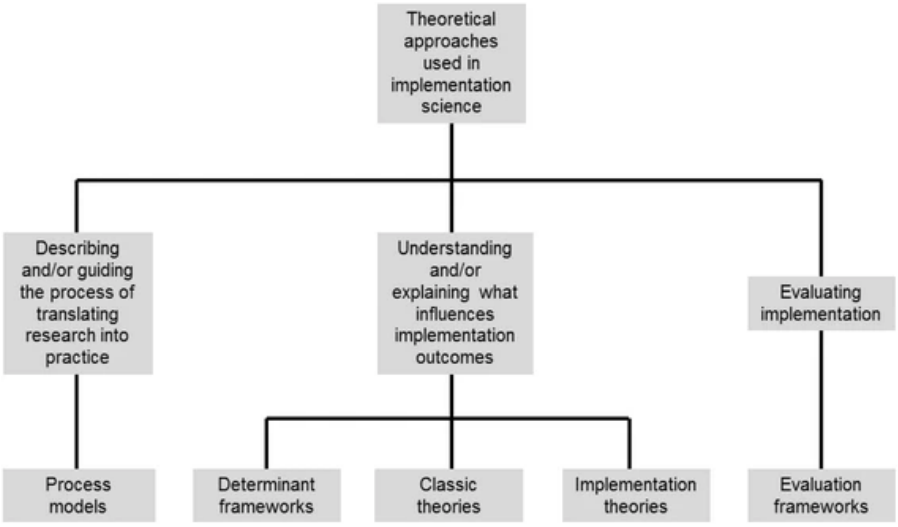

Figure 3: Five categories of theories, models and frameworks in Implementation Science (Nilsen, 2015)

For this study, we considered 1) The EPIS (Exploration, Adoption/Preparation, Implementation, Sustainment) Framework, a process framework developed to articulate variables salient to evidence based practices in publicly funded settings (Aarons et al., 2011; Moullin et al; 2019); 2) The RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) Framework, an evaluation framework developed to guide formation and evaluation of complex interventions to maximize public health impact (Glasgow, Vogt and Boles, 1999; Glasgow et al., 2019); 3) The Consolidated Framework for Implementation Research (CFIR), a deterministic framework developed to consolidate terminology in identifying facilitators and barriers to implementation that can be comparable (Damschroder et al., 2009) 4) The FRAME (Framework for Modification and Adaptations), a coding framework developed to investigate modifications made to interventions to support contextual fit and outcomes (Stirman et al., 2013; Stirman, Baumann and Miller, 2019), and 5) The Stages of Change Model, designed to illustrate barriers and facilitators to clinical guideline implementation in LMICs (Stokes et al., 2016) . The CFIR framework was chosen because of its detailed constructs valuable in exploratory research to identify barriers and facilitators to implementation. As a meta-theoretical framework, CFIR provides a consistent implementation language for researchers that can be used in comparison in other settings conducting similar research (Damschroder et al., 2009). Furthermore, as a deterministic framework, it facilitates exploration and explanation of factors (barriers and facilitators) influencing implementation effectiveness of a novel intervention (Nilsen, 2015).

2.5.2. Consolidated Framework for Implementation Research (CFIR)

This study draws upon the Consolidated Framework for Implementation Research (CFIR), a comprehensive framework designed to consolidate classification of barriers and facilitators to the implementation process across diverse contexts (Damschroder et al., 2009; Damschroder et al., 2022). It builds on more than 500 existing theories of evidence-based interventions, innovation, dissemination, organizational change, knowledge translation and implementation (Damschroder et al., 2009). This 'meta-theoretical' framework offers an extensive range of constructs by which implementation of an intervention may be achieved (Damschroder et al., 2009). This unifying taxonomy of implementation constructs facilitates exploration of factors that influence successful implementation of an intervention (Damschroder et al., 2009; Hill, 2018). It serves researchers as a guide to identify factors most relevant to their implementation context, formulate data collection tools, develop testable theory and provide a macro-level structured appraisal of "what interventions work, where and why", across diverse settings (Damschroder et al., 2009; Nilsen, 2015; Damschroder, 2020; Kirk, 2015). CFIR also gives weight to stakeholders' perspectives of the implementation process as a core measure of evaluation (Damschroder et al., 2009; Warren, 2017). The flexibility of the CFIR has made it popular for utilization in various studies to understand complex multidimensional health systems, with multiple stakeholders across multiple levels (Means et al., 2020; Nnaji et al., 2021). The framework has already been employed in several studies in Africa to assess quality improvement initiatives including Uganda[4], Zambia[5] and Kenya[6].

The CFIR framework is made up of five domains namely, intervention characteristics, outer setting, inner setting, individual characteristics and process by which the intervention is achieved (Damschroder et al., 2009). Each of these domains is further broken down into constructs to delineate factors salient to implementation as shown in Figure 4 below. Intervention characteristics is further divided into intervention source, evidence strength & quality, relative advantage, trialability, adaptability, complexity, design quality and packaging and cost; Outer setting - patient needs and resources, cosmopolitanism, peer pressure and external policies and incentives; Inner Setting - structural characteristics, networks & communications, culture, implementation climate and readiness to implement; Individual Characteristics - knowledge and beliefs about innovation, self-efficacy, individual stages of change, individual identification with organization and other personal attributes; and Process - planning, engaging, executing, reflecting and evaluation. Refer to Appendix B for a detailed description of the domains and constructs.

[4] A mixed methods study that used CFIR to assess facilitators and barriers to national level policy implementation on HIV testing, care and treatment at health facilities (McRobie et al., 2017).

[5] A system review that employed CFIR to identify implementation factors for the SAFE strategy (surgery for trichiasis, antibiotics for active infection, facial cleanliness and environmental improvement) in low-income countries (Maritim et al., 2019).

[6] A qualitative study to evaluate the contextual factors influencing implementation of mHealth intervention to improve medicine and health care adherence (Bardosh et al., 2017).

Domains	Construct
Intervention Characteristics	Intervention Source Evidence Strength and Quality Relative Advantage Adaptability Trialability Complexity
Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policy and Incentives
Inner Setting	Structural Characteristics Networks and Communications Culture Implementation Climate 1) Tension for change 2) Compatibility 3) Relative Priority 4) Organizational incentives and rewards 5) Goals and Feedback 6) Learning Climate Readiness for Implementation 1) Leadership engagement 2) Available resources 3) Access to knowledge and information
Characteristics of Individuals	Knowledge and Beliefs About the Intervention Self-Efficacy Individual Stage of Change Individual Identification with Organization Other Personal Attributes
Process	Planning Engaging 1) Opinion leaders 2) Formally Appointment Internal Implementation Leaders 3) Champions 4) External Change Agents Executing Reflecting and Evaluating

Figure 4: Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009; Khan, 2021)

In this study, the CFIR was employed to support exploratory investigation into the implementation of low-cost IVF in Uganda's public health system. The CFIR framework was used to guide data collection, coding, and analysis of factors, barriers and facilitators to the implementation of LCIVF in Uganda (Damschroder & Lowery, 2013). It facilitates consistent implementation language that can be used for comparison in other settings conducting similar research. However, limitations of the CFIR framework include that it does not examine interactions between constructs. To date, to the knowledge of the author, CFIR has not been used in the study of implementation of affordable fertility services in LMICs and thus adds to the body of knowledge of its applicability. Notably, the most recent updated version of the CFIR framework was not utilized in this study because it was developed in 2022 at the end of the research study.

2.5.3. Application of CFIR Framework

The CFIR framework domains have been defined in the context of the implementation of LCIVF interventions at a national specialist referral hospital (unit of analysis) - Mulago Specialized Women and Neonatal Hospital (hereafter known as Mulago Women's Hospital - MWH) as follows:

Intervention characteristics: The low-cost IVF initiatives, a simplified or cheaper version of ART used in the treatment of infertility. The CFIR posits that an intervention is made up of core components that cannot be changed and adaptable components that can be adjusted to fit the local setting.

Outer setting: This is defined by external factors that influence implementation of the intervention. These factors include political, economic, social and cultural factors within the local context such as policy, competition and the degree to which the setting is networked. For this study, international and national policy, patient needs, collaborations with other organizations and peer pressure from the private sector were included.

Inner setting: The women's specialist national referral hospital, MWH, in Kampala, Uganda. The domain includes the systems, people, infrastructure, communication and resources within the hospital.

Individuals Characteristics: The persons within the inner setting of the MWH.

Process: The active process of change by which LCIVF initiatives have been implemented into the hospital including planning, engaging stakeholders, execution and evaluation of the cycle at the macro, meso and micro levels.

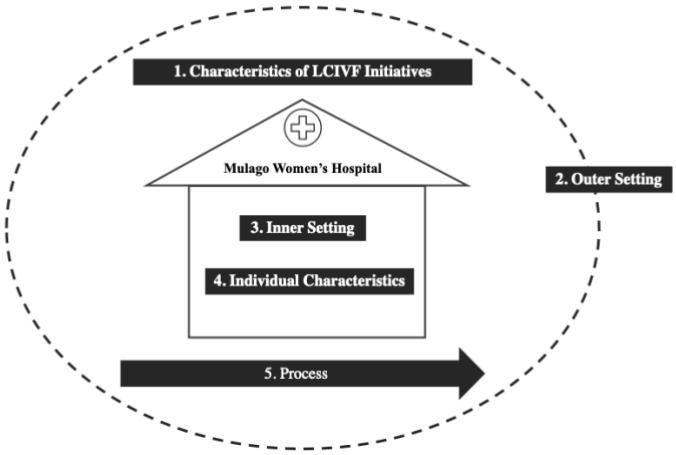

Figure 5: Theoretical framework adapted from Consolidated Framework for Implementation Science (CFIR) domains and constructs (Damschroder et al., 2009).

Chapter 3: Study Rationale

3.1. Justification for study

Infertility is an urgent public health issue globally that poses severe, life threatening consequences in Africa. There is a need for implementation research within developing countries to examine the possibilities of safe, innovative and cost-effective solutions to overcoming infertility and their implementation to improve access to fertility services that include diagnosis, management and treatment (Starrs et al., 2018; WHO, 2019). Understanding of country-specific magnitude of infertility and pre-existing resources is essential to provision of ART in low-resource settings (Bahamondes & Makuch, 2014; Sharma et al., 2009). Low-cost IVF initiatives have been developed as a safe and affordable alternative to the catastrophically expensive ART currently available. Therefore, scholars have called for an in-depth analysis of limitations of implementation and impact of low-cost ART in African settings on access to high-quality fertility care (Afferri et al., 2022). Furthermore, there is limited literature on state-funded ART treatment programs in Africa (Chiware et al., 2021).

The justifications for this study included:

- Generate new knowledge by providing a practical, holistic picture of the complex nature of implementation of LCIVF in a low-resource setting.
- The findings will present an opportunity for learning and knowledge transfer to other low-income countries in pursuit of universal access to fertility treatment.
- Accomplishments, challenges and gaps in the implementation of LCIVF in Uganda may highlight areas for further research and actionable recommendations for minimizing barriers and maximizing facilitators to LCIVF implementation.
- Build upon the usefulness of the CFIR as an implementation framework in health studies and offer opportunities for comparisons across future studies

3.2. Overarching Research Question

The overarching research question of this study, "How have low-cost IVF initiatives/affordable fertility care been implemented in Uganda's public health system?". To guide the overall data collection and analysis process, more specific questions have been employed below:

3.3. Specific Research Questions

i. How did macro-level factors influence implementation of low-cost IVF treatment/affordable fertility care within the public health system of Uganda?
ii. How did the public hospital unit at the meso-level organize itself to facilitate the implementation and provision of low-cost IVF treatment as part of its service delivery?
iii. How were low-cost IVF treatment protocols operationalized at the micro-level within the clinical practice and what were the lessons learned (i.e., facilitating factors) on implementation of LCIVF initiatives in a public health system of a developing country setting?

Chapter 4: Research Methodology

4.1. Introduction

The overall goal of this study was to understand how LCIVF initiatives/affordable fertility care were implemented in Uganda's public health system, particularly focusing on barriers and facilitating factors to the establishment of the ART Department in MWH. To address this objective, particular research methodologies were undertaken. The study design included a mid-implementation, exploratory, single case, qualitative study based on in-depth, semi-structured interviews, participant observations, informal conversations, document reviews, field, and reflective notes. This chapter details the research process and paradigms that shaped the study design. The chapter is divided into six sections; first the study context which geographically and socially sets the scene for the research site; second is the research design and rationale; third is ethical approval; fourth is sampling; fifth is data collection and finally data analysis process.

Complex interventions such as the one in this study require consideration of the multiple, interlinked components at play in designing and delivering LCIVF initiatives within a specific context. The ontological paradigm suited for this study was based on realism (Given, 2008; Pawson, 2008; 2013). This is based on the understanding that 'complex interventions are often introduced into complex social systems' (Pawson, 2013, p33). Realism assumes that there is an external reality independent of human perception. The realist methodological approach takes from this paradigm in assuming that observational data alone cannot predict causal relationships between variables and underlying mechanisms of change brought about by the intervention, its implementation and context should be considered (Dalkin et al., 2015). It assumes that social systems and structures are real, with human actors who respond variously to different interventions, in different contexts (Given, 2008). This philosophical position aims to explore why complex interventions work or not, how, for whom, in what context and to what degree (Pawson, 1997; Greenhalgh et al., 2015). In this approach, the context, and mechanisms at play result in the outcomes observed. *Context* is defined as the political, social and economic environment under which the intervention occurs (Pawson, 2006). *Mechanisms* are understood as the behaviours, emotions, motivational, cognitive, psychosocial behaviours elicited by the context (Pawson, 2006). Both context and mechanisms bring about multi-level, anticipated and unanticipated outcomes (Jagosh, 2019; Yakovchenko et al., 2021). Therefore, the intervention sets into motion different mechanisms, in different contexts to produce varied outcomes (Wong, et al., 2014).

Regarding epistemological considerations of this study, a social constructivism paradigm was undertaken given that the effectiveness of implementation is influenced by stakeholder perceptions in the receiving organization, which may be different, socially constructed in the local setting (Crotty, 1998; Damschroder et al., 2009; Thomas et al., 2014). Social constructivism is a sociological theory of knowledge which aims to examine how individuals come to construct and apply knowledge in socially mediated environments (Hutchinson & Huberman, 1993). Literature on healthcare posits that clinicians act upon new knowledge by reconstructing information based on pre-existing experiences and understandings, relating it to existing knowledge, imposing meaning to it and not simply receiving it as passively participants (Hutchinson & Huberman, 1998; Thomas et al., 2014). This study explores the complex mechanisms at work that influenced implementation of affordable IVF initiatives in Uganda's public health system. Therefore, a

social constructivism approach was appropriate in understanding the decision-making processes as to how and why participants in this study were able to (or not) implement LCIVF initiatives within MWH.

Tools used for data collection included informed consent forms (in English), semi-structured interviews, observational sheets, and field diary entries. Purposive and snowball sampling was utilized to identify the target audience including government officials, non-government representatives, practitioners, professional medical organizations, patient groups and construction companies. Additional data sources included relevant documents to support triangulation of data sources and respondent validation. The data analysis involved a detailed case history, thematic analysis as an inductive approach and deductively in relation to CFIR (Braun and Clarke, 2006; Damschroder et al., 2009). The combination of inductive and deductive approaches was used to remain open to emerging concepts as well as the CFIR constructs respectively (Bradley, Curry and Devers, 2007; Gale et al., 2013).

4.2. Study Context

Figure 6: Map of Uganda (National Geographical Society, 2022; Uganda Investment Authority, 2022)

Uganda is a low-middle income country situated in East Africa, right on the Equator. With a land area of 241,038 km^2, Uganda has a population of about 48.5 million people, with an annual population growth rate of 3.3% (UNFPA, 2022). The country's population is relatively young, with more than half (54%) of the population under 18 years of age and only 4% aged over 65 years (UBOS, 2020). The overall life expectancy has risen from 46 years in 2000 to 63 years in 2020 attributable to improved national health indicators (UBOS, 2020; World Bank, 2022). A majority of Uganda's population lives in rural areas (73%) compared to urban dwellers (26.6%) and the former experience the highest rates of poverty (UNHS, 2020). According to the most recent Uganda National Household Survey (UNHS) in 2019/2020, the median monthly household income is USD $53, with national variances indicating the highest monthly median of USD $180 in the capital city of Kampala. The two main sources of household income are subsistence agriculture (39%) and non-subsistence sources including wage employment in manufacturing and service

sector (61%) (UBOS, 2020). However, 20% of the population are considered poor, living under the poverty line of USD$ 1.77 per person per day, of which nearly 85% reside in rural areas (UNHS, 2020). The country has a 70% literacy rate for individuals over the age of 10 years, with 91% of the population having had at least primary school level education (UBOS, 2020).

The health system in Uganda is characterised by both public and private health sector (MOH, 2016). The public health sector consists of a decentralized system, subdivided into three levels of care: primary level care (health center levels - I, II, III, IV), secondary level care (district & rural hospitals) and tertiary level care (national & regional referral hospitals) (MOH, 2016). The Ministry of Health (MoH) is responsible for policy formulation & implementation, coordinating all health sector activities, setting standards of practice, clinical & public health programs, resource allocation countrywide, quality assurance and engagement of all stakeholders to deliver quality healthcare in Uganda (MOH, 2021). Government expenditure on healthcare is 7.2% of the country's total budget, contributing USD $16 per capita healthcare expenditure (MoH-AHSPR, 2020; UBOS, 2021). For a developing country, this falls short of WHO's recommended USD $83 per capita per year allocation to health and leads to high out-pocket payments by individuals (MoH-AHSPR 2020; UBOS, 2021). Uganda is also heavily dependent on donor funding for healthcare financing, contributing to more than half the budget towards drugs and services (MOH, 2021). Health insurance coverage is low with only 4% of the population above aged 10 years covered (UNHS, 2020). Additionally, the three leading causes of death are attributed to malaria, pneumonia, and injuries in descending order (MOH-AHPR, 2020). Due to various efforts, maternal mortality in Uganda has dropped to 92 deaths per 100,000 live births in 2018/19 compared to 168 deaths per 100,000 live births in 2012/13 (MOH-AHPR, 2020). The main factors that influence health in Uganda include access to sanitation and safe drinking water, education, income level, living conditions, cultural beliefs, social mannerisms and access to quality health care (MOH-AHPR, 2020).

Uganda's fertility rate has been on the decline, from 7.1 children per woman in 1980 to 4.7 children per woman in 2022 (World Bank, 2022). However, there are in-country variations, for instance, women in rural areas on average had 5.9 children compared to 4.9 children in urban areas (MOH, 2020). The main factors associated with this fertility decline include delayed entry into marriage, urbanization, level of education, working status and exposure to knowledge of family planning (Ariho, Kabagenyi & Nzabona, 2018; MOH, 2020). Nonetheless, compared to the global average fertility rate at 2.9 births per woman, Uganda's average fertility rate is considered high (World Bank, 2022). Paradoxically, Uganda also has one of the highest infertility rates recognized amongst countries within the "African infertility belt", in which as many as 30% of couples suffer with this reproductive condition (Larsen, 2003; WHO, 2010). Secondary infertility is the most common type of infertility mainly caused by tubal infections (Kudesia et al., 2018). In Uganda, ART is a fast-growing industry (Kaye et al., 2014). Until 2018, fertility treatment had been provided exclusively through the private sector. The country's first private fertility clinic was opened in 2004 with the help of international experts and more facilities have been opened since (Platteau et al., 2008; Onyango, 2017; Wandawa and Nabatanzi, 2018). Throughout this period, there has been a lack of legislation on the practice of ART, and fertility clinics have operated without much oversight and quality assurance (Sajjabi et al., 2008). Consequently, the average cost of fertility treatment in Uganda is about $4,000 per cycle, which, compared against a national average household income of $58.75, is considerably high (UBOS, 2018; UNHS, 2021).

The Ministry of Health (MoH), in collaboration with the MERCK foundation, began an infertility campaign primarily to enable infertile women by increasing awareness and changing societal attitudes (Independent, 2018). The government further committed to prioritize accessibility and affordability of ART through LCIVF and development of policy & ethical guidelines addressing moral and religious issues (Sajjabi et al., 2008). Therefore, through the MoH and Ministry of Finance, Planning and Economic Development (MoF), the government financed the construction and equipment of MWH through a loan amount of $ 34.1 million, of which $ 30.28 million came from the Islamic Development Bank as loans and US$ 0.44 million as grants from the Islamic Development Bank grant and US$ 3.42 million as the Government contribution (Mulago Specialist Government Policy, 2012). Construction of the hospital began back in April 2013 and was concluded in July 2018 (Nabatanzi, 2018).

As a result, Uganda led the way as the first country in the East African region to implement a public fertility treatment unit for the provision of safe, affordable and accessible fertility care (Oketch, 2017). It offers a tertiary level of care as part of the national referral hospital and is situated in the capital city of Uganda, Kampala and governed by the MoH (MOH, 2016a; Wandawa & Nabatanzi, 2018). The overarching goal for developing this specialized unit was to improve access to specialised maternal and neonatal healthcare services; offer better quality of services; and support to project management (Mulago Specialist Government Policy, 2012). MWH intends to serve Sub-Saharan countries including Uganda, Kenya, Rwanda, Tanzania, Zambia, Sierra Leone, Liberia, Gambia, Ghana, Ethiopia and Cote d'Ivoire (Oketch, 2017). The new specialist facility offers services for High-Risk Antenatal Care, Delivery and Postnatal Services, Gynecology Uro-gynaecology, Assisted Reproductive Health Technologies, Pharmacy, Blood Bank, Labour Suites, Intensive Care Unit and Operation Theatres (MOH, 2016*b*). LCIVF services have been implemented in this specialist hospital as part of the reproductive medical care services to the public (MOH, 2016*b;* Wandawa and Nabatanzi, 2018).

4.3. Qualitative Case Study Design Rationale

The study employed a qualitative, single case study approach. Implementation is often a complex, multi-faceted set of social processes intended to integrate an intervention into organizational practice (Damschroder et al., 2009; Davidoff et al., 2008). Qualitative case studies are suitable for this type of study because they allow for rich, in-depth exploration and nuanced understanding of complex phenomena in its context, using multiple sources of data (Baxter & Jack, 2008; Punch, 1998, p.150; Yin, 2003, p.8). In this case, deeper understanding of the phenomenon is more important than generalizability of results as seen in quantitative studies. In IS, qualitative inquiry is the most preferred research design given its capability to illuminate perspectives of key stakeholders within the implementation process and improve understanding of contextual influences (Nnaji et al., 2021). Indeed, qualitative methods enable exploration of how people, actions and contexts influence processes, success, or failure of implementation (Creswell, 2003; NIH, 2015). Case studies ensure initial understanding of a phenomenon is not addressed through one perspective, but through diverse perspectives to showcase diverse aspects of the phenomenon (Caronna, 2010; Stake, 1995). They aid holistic examination of complex social phenomena of implementation, especially where there is a lack of clear boundaries between the phenomena and its context (Yin, 2003). Case studies are similarly useful in addressing what and how questions to analyse how interactions are organized (Silverman, 2013, p.192). Based on Robert Stake (1995: p.3) case study types, this is an *instrumental* case

study based on the study's intention to generate insights into the implementation of low-cost IVF in a poor resource context and its impact on access and affordability of infertility treatment.

The case unit for this study was the hospital - Specialized Maternal and Neonatal Health Care unit at Mulago National Referral Hospital in Kampala, Uganda. This case was chosen to examine factors salient to the implementation process of low-cost/affordable IVF in a low-income setting. The study examined how a network of systems, organizations, communities and individuals interact with one another to operationalize LCIVF within a public health facility and the consequences thereafter. A multi-level analysis was conducted to characterize the processes and underscore the heterogeneous factors influencing implementation of low-cost IVF in Uganda (Caronna, 2010).

4.4. Ethics Approval

This study involved human participants requiring ethics approval prior to data collection. The research sought and was granted ethics approval by The University of Waterloo's Office of Research Ethics (ORE) on Sep 1, 2020 (#ORE 42165). An amendment was added to the ethics application in Feb 05, 2021 to fulfill the COVID-19 research protocol by The University of Waterloo. In Uganda, the ethics application process is two tiered; with the first review conducted by one of many designated local Research Ethics Committees (RECs) and followed by final review and decision from the Uganda National Council for Science and Technology (UNCST). The student researcher requested for written consent to conduct the study at MWH from the hospital director's office. This request was granted in writing on 15th February 2021 ((#ADMN/2021/02/D6975) and served as a prerequisite for ethics approval applications to the local REC. An ethics application was submitted to MildMay Uganda Research Ethics Committee (MUREC), a designated REC and was approved on 20th January 2022 (# REC REF 1009-2020). The final application for ethics was submitted to the UNCST and approval was received on 12th March 2021 (#HS1214ES).

Prior to conducting interviews, all participants were provided with consent forms covering the nature of the study, its purpose, procedures, outcomes, risks and anticipated benefits. Upon agreement, participants were then required to give consent by signing the study consent forms. The consent covered permission to conduct and audio record interviews, take field notes, conduct hospital observations, take visual data and use of non-identifiable direct quotations in future reports. Furthermore, the voluntary nature of the study was emphasized to participants, who were at liberty to decline the interview or any questions they were not comfortable responding to without consequence. The anonymity and privacy of the respondents was indicated as well. The researcher asked for permission to audio record interviews and take field notes to accurately capture the dialogue for each interview. After the interviews, participants received remuneration along with a "Letter of Appreciation" for taking part in the study.

On completion of the data collection process, signed consent forms, documentation, field notes, and transcripts were stored in a locked cabinet. Identifying information was removed from all participants and identity codes were assigned to maintain their privacy. All the study records were stored on a password protected computer, with an encrypted password that was only accessible by the researcher and supervisor.

4.5. Sampling

4.5.1. Selection Criteria

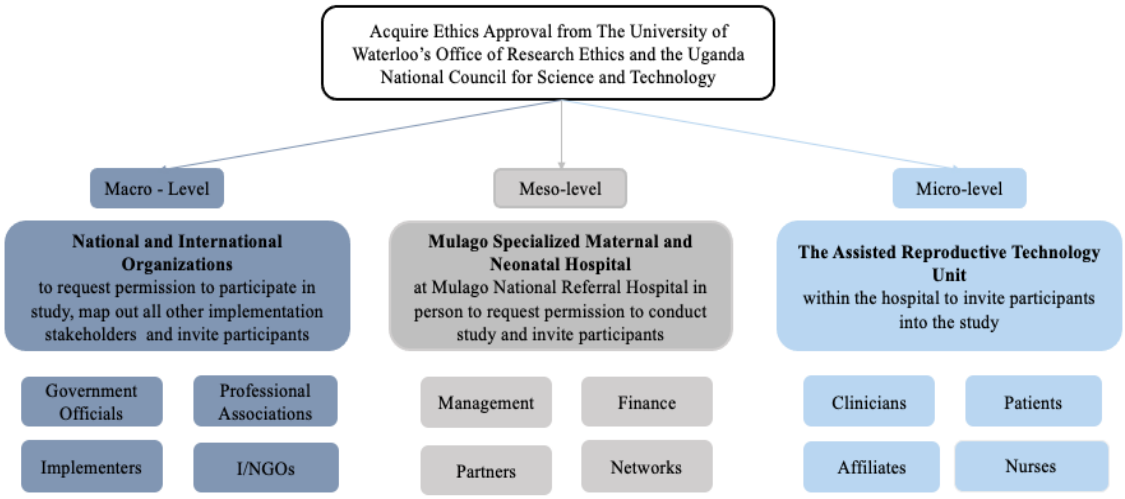

Figure 7: Sampling strategy for study participants

The criteria for sampling in IS is often based on the level of involvement in the implementation process and duty to maximize multiple viewpoints (Colon-Emeric et al., 2016). To understand factors influencing implementation of LCIVF services in Uganda, this study undertook purposive and snowball sampling of study participants based on their institutional positions and roles during implementation of LCIVF at MWH. All identified key stakeholders were above the age of 18 years and were either involved or impacted by implementation of the intervention. Sampled individuals and organizations resulted in a total of 21 study participants to ensure heterogeneous representation of stakeholders and a range of perspectives including government officials, non-government representatives, international representatives, implementers, organizational partners, practitioners, hospital administrators, professional associations and patient representatives. Two participants were interviewed twice bringing the total number of interviews to 23.

In particular, the study included government officials from the MoH and professional associations representatives from Uganda Dental and Medical Professional Association (UDMPA) and Uganda Fertility Society, technocrats from institutes affiliated with Mulago Women's Hospital that were actively involved in planning and implementation of the ART department (e.g., Makerere University School of Medicine, World Health Organization), non-government organizations (e.g. Joyce Fertility Support Center and private sector practitioners.

4.5.2. COVID-19 Protocols

The study endeavoured to conduct interviews virtually or through phone calls as much as possible to limit in-person contact with participants due to the COVID-19 pandemic. In cases where this was not possible, in-person interviews were conducted in accordance with COVID-19 guidelines in Canada and Uganda to protect participants. Participants scheduled for in-person interviews were provided with an information letter describing the risk of COVID-19 prior to the study to go over.

4.5.3. Sample Recruitment

Figure 8: Image of Mulago Specialist Women and Neonatal Hospital (Makula, 2020)

Mulago Specialised Women and Neonatal Hospital, also known as Mulago Women's Hospital (MSW) was the main site for this study. Therefore, endorsement and approval of this study was sought as a prerequisite for local ethical approval and a starting point for mapping out the implementation process and key stakeholders. The researcher submitted a formal application and informational package (including introductory/recruitment letter, thesis proposal, study information and participant consent forms) to the hospital director's administrative assistant for partner approval. The administrative assistant then forwarded the documentation to the Director and the Head of Department - Reproductive Medicine for review. After a detailed discussion on the study expectations between the researcher and Head of Department, the Director granted written consent to the researcher to conduct the study at MWH. This administrative consent covered permission to conduct interviews, hospital observations, take field notes and use of non-identifiable direct quotations in research reporting.

Furthermore, as a gatekeeper, MWH provided contact information and facilitated introductions to relevant study participants. Participants were then approached in person, via email or phone depending on the availability of contact information and mode of introduction. The researcher developed a telephone script to recruit participants as an initial contact point in order to obtain verbal consent to share the information package (Refer to Appendix G). All participants were provided with an information package and remuneration in the amount of UGX 20,000 (USD $8) after the interview was conducted. Notably, some prospective participants refused to receive this compensation and, in some instances, asking whether it was a bribe. Therefore, some simply refused to take the money while another participant asked for it to be given to their secretary.

4.6. Data Collection, Management and Analysis

Case studies in IS allow for use of multiple sources of data to reveal diverse facets of the phenomena and increase confidence in findings through triangulation (NIH, 2015; Stake, 1995, Yin, 2003). The most common data sources in case studies include interviews, direct observations and documentation (Devers, 1999; Yin, 2003). This study employed face to face, or virtual, semi-structured in-depth interviews, hospital observations, informal conversations, document review, field notes and reflexivity as a means of data collection to address the research objectives. This data was stored in the qualitative computer program NVivo Version 12 (QSR International, Doncaster, Victoria, Australia). A multi-level[7] data collection and analysis approach was employed to improve the understanding of the factors that influence the implementation of low-cost IVF treatment (Caronna, 2012).

Data Source	**Study Group**
Semi- structured Interviews (*n*=23)	● Government officials (*n*=1) ● Clinicians (doctors, nurses, technicians) (*n*=7) ● Hospital management (*n*=3) ● Implementers (clinicians, contractors) (*n* = 5) ● Patient Advocacy representatives (*n*=1) ● Private Sector (doctors) (n=3) ● International representatives (n=3) ● Educational Institutions (*n*=1) ● Professional Associations (Medical/Fertility) (*n*=2)
Observations (3 weeks)	Mulago Women's Hospital Operations
International Documentation (n=9)	● United Nations Secretary General's Global Strategy on Reproductive ● Maternal, Newborn, Children's and Adolescents' Health ("Global Strategy") provides a roadmap to advancing the health of women, children and adolescents. ● Reproductive Health Commodity Security Strategic Plan ● IFFS First International Workshop On Assisted Conception, Eko Hotel, Victoria Island, Lagos - Nigeria on 7th November to 9 th November 2005. ● Surrogacy Legislation, and Kenya's ART Bill 2016: Reproductive Uhuru (Freedom) a Myth or a Reality for Infertile Citizens! ● Fertility Under Treatment for Universal Reproductive Enhancement (FUTURE) Proposal ● Hope Fertility Support Center, Kenya Presenation ● How to proceed after Arusha (held in Dec, 2007)? Roadmap to implementation of LCIVF in Africa

[7] Multiple levels of analysis in research include: micro (individual), meso (organizational), and macro (environmental) (Caronna, 2012).

	● Briefing Note by Islamic Solidarity Fund for Development (ISFD) Islamic Development Bank Group. Thoul Ki'dah 25, 1433H / October 10, 2012G)
National documentation (n=22)	● Ministry of Health Strategic Plan 2020-25 ● National Family Planning Advocacy Strategy & Costed Implementation Plan 2020/21 – 2024/25 ● International Human Right agreements such as International Declaration for Human Rights, Convention on the Elimination of All Forms of Discrimination against Women, Child Rights Convention, the International Conference on Population and Development programme of action and the Beijing Declaration and Platform of Action. ● The National Policy Guidelines and Service Standards for Sexual and Reproductive Health and Rights (2006 - infertility management guidelines) ● Specialized Maternal & Neonatal Health Care Unit in Mulago Hospital Project Brief Report ● Semi-Annual Budget Monitoring Report Financial Year 2019/20 ● Report of the Auditor General on the Financial Statements of Support to the Development of a Specialized Maternal & Neonatal Health Care Unit in Mulago National Referral Hospital (Mulago III), 30th June 2015 ● Health Sector Annual Budget Monitoring Report Financial Year 2018/19 ● Motion Seeking Leave of Parliament to Introduce a Private Member's Bill Entitled 'The Surrogacy and Assisted Reproductive Technology Bill'. ● Uganda Health Accounts, National Health expenditure FY 2016/17 and 2017/18 ● Ministry of Health National Health Accounts 2016-2019 ● Semi-Annual Budget Monitoring Report Financial Year 2019/20 ● Parliamentary Committee Minutes, 26 July 2012. ● The Uganda Assisted Reproductive Technology Regulation (ARTR) draft ● IFFS International Symposium, 28 February – 2 March 2018, Kampala Serena Hotel, Kampala, Uganda ● Infertility in Developing Countries: The Call for Low cost Assisted Reproductive Technology in Uganda ● Why Mulago Women's Hospital will do very little to address Maternal and Child mortality in Uganda by Initiative for Social and Economic Rights ● Joyce Fertility Support Center - Uganda, June 2004 - 2004 Report ● Infertility Working Group in Department of Reproductive Health, Ministry of Health Kenya, 16th March 2004

	• Motion Seeking Leave of Parliament to Introduce A Private Members Bill entitled, The Surrogacy and Assisted Reproductive Technology Act, 2021 • Workshop Aimed at Introducing Low-cost Reproductive Treatments in Uganda • A proposal for development of a low-cost IVF unit at Mulago Hospital.
Hospital Documentation (n=2)	• Proposed specialized maternity and neonatal unit (Women's Hospital) presentation. • Operationalizing the IVF facility in a Mulago Women's and Neonatal Hospital
Media Output (n=3)	• African Newsroom: "Merck More than a Mother" addresses Infertility Challenges and Solutions in Africa in partnership with International Federation Fertility Societies (IFFS) • Monitor Uganda: Govt sued over Mulago's specialised women wing August 12, 2019 — updated on September 15, 2020. • ChimpReports: Full List: Government Reveals Fees Structure for New Mulago Women's Hospital, Says It's 60% Cheaper. Sam Waswa, September 19, 2018

Table 1: Summary of study data sources

4.6.1. Semi-structured interviews

In-depth, semi-structured interviews with key informants were used in this study, in addition to informal conversations to facilitate detailed examination of factors influencing implementation of LCIVF in MWH. Interviews are an important aspect of case studies because they allow a researcher to investigate details about the study topic as well as gain the participants opinions about the issue (Yin, 2003, p.90). They offer an opportunity for snow-ball sampling as the participants may recommend other persons to interview (Yin, 2003). The semi-structured interviews were informed by a publicly accessible CFIR Interview Guide Tool on http://cfirguide.org/. This tool guides researchers on interview themes but was tailored to facilitate exploratory questioning on factors influencing LCIVF implementation in MWH (Damschroder et al. 2009). Damschroder and colleagues advise researchers to determine in advance which constructs may be relevant to the study and then document decisions and rationale for what level a construct should be examined (Damschroder et al. 2009). The interviews were tailored to two different stakeholder groups i.e., professional and patients, to reflect their association with the intervention. The interview guide included questions complementary to five domains of CFIR relevant to this study as shown in Appendix B. Operationalization of the CFIR domains for this study included:

1. Intervention characteristics: Assisted Reproductive Technologies/Low-cost IVF initiatives.

2. Inner setting: Assisted Reproductive Technology Unit unit in Mulago Women's Hospital
3. Outer setting: the patients, policy makers and practitioners that influenced or impacted the implementation of LCIVF
4. Characteristics of individuals involved: the physicians, nurses, administrative and clinical support staff who participated in the implementation of LCIVF
5. Process: the process of implementing LCIVF

The student researcher conducted all 23 (including two participants interviewed twice) one-on-one, semi-structured, individual interviews, in English, in-person (n=19) or remotely (n=4) (Skype, Zoom, WhatsApp) with adult participants from December 2020 to May 2021. In person interviews (COVID restrictions allowing) took place in a mutually agreed upon location that is appropriate for conversation and privacy. The interviews lasted from 15 minutes to 90 minutes, were audio-recorded with permission and transcribed verbatim for analysis; except for one interview in which notes were taken by the student researcher at the request of the interviewee. Prior to starting the interviews, formal consent was given, and participants were encouraged to be open in their responses, with the freedom to decline to answer. Emphasis was made regarding the interview's focus on understanding their experiences with the implementation of LCIVF. The formal interviews were supplemented with casual conversations at MWH, with other stakeholders. All audio-recordings were securely stored by student researcher. Additionally, the researcher asked for permission from the participants to take field notes during and immediately following the interviews and to use non-attributed quotations in future reports.

4.6.2. Observations

Observation as a data collection method is recommended in exploratory research where a basic understanding of the phenomenon is being established (Silverman, 2013, p191). It is particularly useful in documenting complex contexts as it enables a researcher to experience first-hand processes in action, behavioral patterns, interactions and highlights the informal aspects of decision making that take place (Nilsson et al., 2018; MacPherson and McKie, 2010). The CFIR observation template was used to guide observations related to the implementation of LCIVF services in MWH (https://cfirguide.org/wp-content/uploads/2019/08/cfirobservationtemplate10-27-2014.xlsx).

Direct observation of hospital flow and administrative processes within MWH (COVID restrictions allowing) took place from January 2021 to April 2021. The goal was to get a sense of activities, processes in action, interactions and highlight informal aspects of the practice that took place. Primarily, the researcher observed hospital flow, clinical environment (public spaces such as waiting rooms), consultation rooms, administrative meetings, patient flow & interactions and clinical team engagement for about 2-3 weeks and field notes were taken during this time.

4.6.3. Documentary Analysis

The review of documents was used to investigate policy, guidelines and internal context that contributed towards implementation of ART services at MWH. Documentation is often used in case studies to authenticate evidence from other sources of information (Yin, 2003, p.87). Such documents may include annual reports, project reports, letters, meeting minutes, organizational records, newspaper articles, press reports and policy documentation (Yin, 2003; Sheaff et al., 2003). In this study, documents analysed included policy documents, internal documents, presentations and published literature, researcher field and reflective notes.

Inclusion criteria

The selection of documentation was guided by documents provided or referred to by participants during the interviews. Additionally, international and national level documentation focusing on implementation of LCIVF services were incorporated to illuminate the research objectives. A majority of documents (international and national level papers) were publicly accessible through a web search as listed in Table 1, while others were shared by participants during data collection.

4.6.4. Field and Reflexive Notes

The researcher used field notes to document observations, key concepts, interpretations, thoughts and body language during observation in the hospital and during interviews with participants to enhance understanding of factors influencing implementation of LCIVF services. Participants were asked for permission to take these notes during and immediately after the interview prior to the interview beginning. The researcher collected detailed field notes capturing observations of staff interactions, patient flow, physical layout of the hospital including the size, distances between the offices, and spaces available for clinicians to examine patients. Reflexive notes were taken to capture ideas, feelings, impressions, challenges and prejudices throughout the research process. In qualitative research, researchers often practise reflexivity to ensure rigour by reflecting, identifying and examining personal assumptions throughout the research process (Alvesson and Sköldberg. 2009; Hesse-Biber, 2016; Hibbert, Coupland and Macintosh, 2010). Some of the reflections included: How did my background, age, gender and professional background shape the interactions with the research participants? How am I feeling during the interview process? Are the interviews going well or not? How can they be improved? Are there ways to reduce response bias in the way questions are posed? How comfortable are participants with the interview questions? Which ones are they choosing to answer or not answer? What was my thought process during the interviews and observations? For instance, after a few interviews in which hospital staff were hesitant to participate in the study (some asking if I was a spy or a journalist). This may have been due to a few negative articles published about the hospital. Consequently, I decided to begin each introduction by sharing the written approval to conduct the study by the hospital director. Additionally, introductions by hospital staff to study participants legitimized my research and made the encounters more pleasant. However, some prospective participants declined to comment altogether or visibly showed disinterest offering short or one answer responses.

4.6.5. Positionality

As a student researcher, I understood the implications of my identity on the research process and centered equity by addressing my personhood in relation to this study on implementation of low-cost IVF in SSA and its outcomes (Lett et al., 2022; Gergen & Gergen, 2000). I am a 35-year-old year old, black, heterosexual, Ugandan woman, born to middle-upper income parents. My professional inclination towards Public Health and Implementation Science was developed at a young age observing my physician father coordinating child health programs in Uganda. Furthermore, I was raised in an Anglican home, cultivating strong Christian beliefs with a desire for community service. These early encounters within Public Health pointed me towards pursuing a career in this field. I pursued my higher education in Pharmacology and Public Health in the United Kingdom strengthening my knowledge in this area. After which, I was able to work in the field of maternal, sexual and reproductive health and more recently in the past decade in the field of infertility in Uganda, Zambia, Tanzania and Rwanda. Through my role as a general manager, I was able to hear first-hand the joy and sorrows (primarily from women) of the infertility experience. These encounters deeply impacted me and compelled me to explore infertility further with a doctoral program at the University of Waterloo in Canada. As a mother, I could appreciate the deep desire for parenthood expressed by the infertile couples I spoke with.

With regards to the research methodology, I am inclined towards quantitative methods and positivist approaches. However, the novelty of the research question and interest in in-depth understanding implementation of affordable fertility services, coupled with my subsequent training in qualitative methods enabled me to develop a suitably qualitative approach for this study. Altogether, the knowledge I have acquired has influenced my focus towards a public health, system-level perspective on affordable fertility treatment in Uganda's public health sector. When engaging with my participants; I considered my status as an "insider" based on race, citizenship, heterosexuality, cisgender, socialization, knowledge of local language and professional experience in fertility care in Uganda. However, my overseas education and global exposure have influenced my personality, mannerisms and accent which made me an "outsider". In some instances, during interviews, participants with university aged children would ask me how they can apply to universities in Canada, which types of programs are available and information on scholarships; information which I was more than happy to share.

It is my belief that exposure to multiple cultures and ways of life have made me a more open-minded, assertive, and driven individual. On the other hand, being away from "home" as a foreigner and my role as a mother has deepened my desire to tell the "African story" as an African myself. Within academia, particularly in the topic of infertility, much of the research on Sub-Saharan Africa is penned by individuals outside the research context, and this is where I see myself adding value. As Foley (2002) put it, "I wish to come down from Mount Academe and bridge the significant cultural and linguistic gap that separates academics from layman" by producing accessible writings that honour my research participants and study context.

While conducting this research, I was keenly aware of the sensitive nature of the topic of infertility and politics involved within the implementation process. The study participants included physicians, government officials, patient groups and other stakeholders; most of whom were considered "elite". I was able to use snowballing system to gain introductions that were beneficial in building trust with the

participants. However, some did refuse to participate citing it as a political landmine and asking why I wanted to research such a sensitive issue. Many of my participants were older men in influential positions; while I thought they would perceive my positionality as a young, educated woman and impact the researcher-participant power dynamic, it was beneficial because they seemed to freely share their real thoughts with me, were very open in talking about the sensitive matters that emerged from the implementation process. I assume they regarded me as harmless. I was asked a few times to stop audio recording so that they could honestly say what was happening and I appreciated their genuineness. I found the research process to be highly enriching, pulling out valuable insights that will benefit the field.

4.7. Data Analysis

In this study, data analysis was carried out alongside data collection using CFIR as an analytical framework through which this complex, multi-level implementation process could be described. All audio recorded interviews were transcribed verbatim and coded along with documentation and field observations, using a combined inductive and deductive approach to thematic analysis. This approach was deemed appropriate for this study owing to its theoretical flexibility, ability to capture complex accounts of data and different perspectives of research participants (Braun and Clarke, 2006; Nowell, Norris, White and Moules, 2017). Deductive coding was guided by the CFIR implementation framework using the publicly accessible codebook to facilitate identification of factors salient to the implementation of LCIVF in Uganda (Braun and Clarke, 2006; Damschroder et al., 2009) (Link to codebook). Two constructs did not match the implementation factors (Design Quality and Packaging Cost and Other Personal Attributes) which were excluded from this study. Inductive thematic analysis was also undertaken to remain open to novel themes that could emerge from the data; especially since the CFIR framework has mainly been applied to established interventions rather than novel innovations (Braun and Clarke, 2006; Braun and Clarke, 2012; Hill et al., 2018). Thematic analysis as represented below is linear; however, it was an iterative process, moving back and forth throughout the data set (Creswell, 2007).

The data analysis process included:

1. All interviews but one were audio recorded with consent from participants and transcribed verbatim for analysis.
2. Transcripts, electronic documentation and field notes were organized and stored in NVivo (N12) qualitative analysis software (QSR International, Doncaster, Victoria, Australia). Coding of paper-based documents was manually done.
3. Initially, the researcher familiarized herself with the data set by thoroughly reading and comprehension to generate initial ideas (Braun & Clarke, 2006).
4. In the first phase of analysis, the data was coded deductively based on the CFIR framework domains and constructs provided by the CFIR NVivo project pre-populated with the CFIR codes (https://cfirguide.org/tools/tools-and-templates/).
5. The codes and sub-codes were refined further to label facilitators or barriers to implementation of LCIVF in Uganda.
6. In the second phase, inductive coding was used to capture themes that were not represented in CFIR to ensure coding was reflective of the data, especially given that CFIR had mainly been used to assess discrete interventions rather than larger scoping programmatic evaluations. Emergent

themes not represented in the CFIR constructs were determined using Microsoft Excel (Ose, 2016). Only one new code emerged.

7. The third phase involved iteratively re-organizing inductive codes into the CFIR framework domains and carefully considering inductively derived constructs to be added into the analysis report.
8. Finally, to support interpretation of the study findings, typical quotations were added. To uphold the confidentiality of the participant, a study identification number was provided without any identifiable information.

QSR NVivo 12 and Microsoft Excel were the software tools used to conduct thematic analysis of the data. The student investigator was the only coder. Finally, the facilitators and barriers to implementation of LCIVF initiatives as per the CFIR constructs, were identified as described in chapter 5.

4.8. Rigour in Qualitative Research

The credibility of this study was addressed through maintaining an audit trail and triangulation of data (Bekelman et al., 2016; Martinez et al., 2016; Lincoln and Guba, 1985). All decisions made throughout the study and their rationale were continuously documented including methodological decisions, interpretations and findings (Koch, 1994). Furthermore, a reflexive journal was kept ensuring a self-critical examination throughout the research process (Lincoln and Guba, 1985). Finally, the presentation of study findings includes quotations directly from the transcripts to increase interpretation transparency (Varsi et al., 2015).

Chapter 5: Findings

5.1. Introduction

The findings of this study are presented in five main sections that correspond with the CFIR domains and constructs regarded as facilitators and barriers to implementation of LCIVF initiatives at Mulago Women's Hospital. To determine which constructs to include in the report, deductive and inductive coding was performed, shared with the key hospital management, analyzed along with the field notes and documents reviewed. There were twelve constructs of which evidence was mixed and two that had no supposed influence on implementation. In this section, we begin by describing the case, then detail the deductive implementation themes in correspondence with the CFIR domains, conclude with the inductive theme and a summary of findings.

5.2. Description of the Case

This section focuses on the components and attributes of MWH, its departments and activities by providing historical context of its genesis. I provide a comprehensive description of the formation of the fertility clinic in the old Mulago hospital and how it culminated into implementation of a fully-fledged specialized department.

This study is centered on a single case as described in the methodology section, exploring the implementation of LCIVF services in MWH. This was the first publicly funded ART department in a national referral hospital throughout East and Southern Africa. The MWH is a specialized component of Mulago's National Referral Hospital, the country's only national-level referral hospital. This is a highly specialized, 6 storey, 450-bed hospital constructed over a 20,520 square meter area on Mulago Hill, in the capital city of Kampala. It was officially launched in October 2018 by H.E The President of Uganda. The specialized services offered focus on high risk antenatal and postnatal services, Gynaecological Oncology, Urogynecology (mainly obstetric fistula), and Intro Vitro Fertilization (IVF) or Assisted Reproductive technology.

Figure 9: Collage of different areas at MWH

On arrival, you are met with a big blue sign written Mulago Specialised Women & Neonatal Hospital. There is tight security at the entry and exit gate where persons wishing to enter are checked and asked who they are going to see or what services they are seeking. In response, you are directed to the main reception on the ground floor. It is an expansive open space with a semi-circular reception desk. The ground floor is where triage takes place and individuals are guided to the right persons or locations. The ART department is on the second floor under the Reproductive Medicine department.

Level	**Department**	**Services**
Ground	Outpatient Services 1 (Silver)	Antenatal clinic, Benign Gynecology, Uro-gynaecology, Gyn-oncology, R.E.I clinic, Emergency Services, Physiotherapy, Banking Hall, ATMs, Radiology (Fluoroscopy, Mammography, Ultrasound)
1st floor	Outpatient Services 2 (Gold & Platinum)	Antenatal clinic, Benign Gynecology, Uro-gynaecology, Gyn-oncology, R.E.I clinic, Laboratory, Pharmacy, Laundry, Kitchen
	Outpatient Services 3 (Gold & Platinum)	Family planning, Kangaroo Follow-up clinic, Immunization, Cervical Cancer screening, Postnatal clinic
2nd floor	Administration & Training	Administration offices, Board room, Main conference room, Video conference rooms, Skills Laboratory, Library (Research office & Archive), Reproductive Medicine, Benign Gynaecology
3rd floor	Critical Care Unit	Neonatal Intensive Care unit, Kangaroo Mother Care, Operation Theatres, Intensive Care Unit, High Dependence Unit
4th floor	Maternal Fetal Medicine (MFM)	MFM Suite 1 (Antenatal), MFM Suite 2 (Postnatal), Labour suites, Operation Theatres
5th floor	Other Services	Urogynecology, MFM Suite 3, Gyn-oncology, Cafeteria
6th floor	Gold Suites	Suites 1 - 53, Visitors' Lounge
7th floor	Platinum (VIP Suites)	Presidential Suite, Platinum Suites 1-5, Labour Suites, Operation Theatres, VIP Open Terrace

Table 2: Mulago Women's Hospital Floor Plan

Rank	Department	Number of beds
1	Assisted Reproductive technology	25
2	Gynaecological Oncology	45
3	Urogynecology	60
4	High Risk Obstetrics	130
5	Multi-purpose	60
	TOTAL	450

Table 3: Bed Distribution at Mulago Women's Hospital (Nakibuuka, 2018)

5.3. Participant Demographics

Purposive and snowball sampling was applied in this study to identify participants suitable in addressing the research questions. A total of 21 participants were interviewed for this study that were either involved, impacted or interested in low-cost IVF services at Mulago Women's Hospital. These comprised of Clinicians (7), Educational Institution (1), Hospital Administration (3), ART Nurses (2), Laboratory Technician (1), Professional Regulatory Officials (2), Government Officials (1), International Fertility Specialists (1), Patient Advocacy Organization (1) and Construction Company (2). The participants were predominantly male (n=16/76%) and females (n=5/23%). Clinicians offered specialist fertility care and the non-clinicians were either involved or impacted by the implementation of ART at MWH. There were 3 individuals that declined participating in the study, 2 of whom citing the politically sensitive nature of the study topic, while 1 had left their role and did not wish to discuss the implementation process. The eligibility criteria for this study included any key actor or organization that was involved or impacted by implementation of LCIVF in Uganda including but not limited to implementers, government officials, policy makers, funders, clinicians, international organizations, local organizations, professional organizations, hospital management & administrators, clinical directors, clinical staff, patients.

5.4. Relevant CFIR Domains & Constructs

5.4.1. Intervention Characteristics Domain

Intervention characteristics are "features of the intervention that influence its implementation by the selected organization" and can be categorized into core components that cannot be changed and adaptable components that can be changed to appropriately fit context (Damschroder et al., 2009; Lukas et al., 2008). This domain comprises eight constructs that can be found in Table 1. In this study, analysis of the data revealed that constructs most relevant to implementation included: *intervention source*, *evidence strength & quality*, *relative advantage*, *trialability*, *adaptability*, *complexity* and *cost*. The *design quality and packaging* construct was deemed not relevant to the study as it did not come up during the research process.

Source of LCIVF initiatives

The "*intervention source"* refers to key stakeholders' perceptions relative to whether the intervention is internally or externally developed (Damschroder et al., 2009; Greenhalgh et al; 2004). During the interviews, respondents exhibited multiple interpretations of what constituted LCIVF or alternative initiatives that influenced perceived source of the intervention and its acceptability. Two main interpretations emerged from the data: i) treatment cost subsidized by government and ii) clinical cost reduction via modified clinical processes, simplification of equipment or protocols used and adoption of newer cost-effective innovations.

Government Subsidized Treatment (Internally Developed). Some participants understood LCIVF initiatives as a governmental initiative to reduce overall cost of fertility treatment through subsidization. The intervention was, therefore, referred to as internally developed and participants looked favourably upon it and supported the initiative. Some participants described it as a governmental endeavour to reduce costs by financing infrastructure development of the hospital, purchase of equipment, coverage of utility costs and staff salaries that would otherwise be passed on to patients. Five out of twenty-one respondents held this perspective and regarded it to be a positive step in helping the country. One administrator reflecting on this initiative stated:

> *So, we felt as a country, as a government, we needed to help the community by putting up a service which would grossly be subsidized and able to help the community in terms of offering this [LCIVF] service. In a nutshell that is the background of how the ART services came to be at the specialized women's hospital (Hospital_Admin 2_135)*

This position was also echoed by clinical participant who conveyed government's efforts in providing the necessary infrastructure to offer LCIVF services to patients:

> *So the low cost comes in that aspect, that the government has basically done the infrastructural set up but also when it comes to the utilities, what we need, the drugs, the sanitary [products], everything that will be needed, we are hoping is going to be a government [funded]....therefore, the patient is expected to contribute quite a little to their own success story (Clinical_ Staff 1_125)*

Clinical Intervention (Externally Developed). Participants that regarded LCIVF initiatives as externally developed, clinical protocols conveyed mixed reactions towards the intervention, with some voicing concern. Nine of the twenty-one respondents mentioned micro-level, clinical applications of LCIVF initiatives, citing them as externally developed. Three of the nine respondents cited literature from the WHO on development of low-cost IVF initiatives.

> *Somewhere along the way…. something called low-cost IVF from WHO…they were saying that these procedures could be assisted between USD 1000-3000. That is still low cost because you know it currently costs about 20M Uganda Shillings [USD$ 5,400] that is much more (Hospital _Doctor 4_224)*

Another clinical participant cited specific individuals as the originators of the LCIVF idea:

> *…Integration of fertility care into primary healthcare services, the issue of cost always came up. So, this concept was then developed, I think, by Professor Sharpe from Sheffield, Professor Willem from Belgium (PA_Doctor 1_8)*

Some participants also referred to literature on examples from other African countries like Nigeria where experiences of offering LCIVF in the public sector was said to be challenged by power cuts and commitment of staff. A majority of the respondents reported having been introduced to the intervention during the first *Low-Cost IVF Conference* held in Kampala, Uganda. The two-day conference titled, "*Infertility in Developing Countries: The Call for Low Cost Assisted Reproductive Technology in Uganda.*" was held on 26th January 2010 in Kampala and led by the Joyce Fertility Support Center (JFSC) - a patient advocacy group, a team of local fertility specialists, WHO and IFFS representatives. The conference covered topics on infertility in Uganda, introduction of new technologies in low cost assisted reproductive technologies and patients' needs on fertility management (Conference Communica, N.A). On the one hand, the merits of the initiative were demonstrated during the conference, however, LCIVF technologies also drew criticism as described by one participant:

> *So in 2007/2008….we had some discussions about low cost IVF. There is a gentleman called Professor Cooke from the UK, who came in and he was really interested in starting IVF in Mulago and was talking about low-cost IVF. (Clinical_ Staff 5_276)*

He continues:

> *Of course, the opponents of [low cost] IVF said that why do you talk about low-cost IVF in Africa when you don't do it in your countries. Because why do you want it low cost here and not low cost there? (Clinical_ Staff 5_297)*

These sentiments created some resistance and gave rise to recommendations outlined in the *knowledge and beliefs* construct.

Taken together, when LCIVF initiatives were perceived as internally developed, it was seen as favourable. However, when viewed as externally developed, the intervention brought about mixed reactions and, in

some cases, deemed unfavorable. The main criticism being the lack of application and use in the originators' contexts prior to *introduction* to Africa.

Evidence Strength & Quality

The s*trength of evidence and quality of the intervention* is defined by stakeholders' perception on whether available evidence and quality of the intervention will support the intended outcomes (Damschroder et al., 2009). Participants discussed evidence strength and quality of low-cost in two ways: as governmental subsidized care and clinical protocols.

Subsidized Standard Care. Participants who regarded low-cost initiatives as government led, emphasized that *'low'* in low-cost would not be reflected in the standard of care but more so in how much the patient paid for the service. The quality of the service and treatment protocol standards would remain unchanged as stated by one participant:

> *So that is what we think should be low cost, the low cost is on the patient; not the overall cost of the service provided. It is not going to change much because it is sort of a set standard for us to be able to achieve what we want but the low cost is on the patient, the beneficiary at the end of the day (Clinical_ Staff 1_134-9)*

Insufficient Clinical Evidence from Intervention Developers. Some participants were skeptical about the quality of LCIVF initiatives and contested limited availability of clinical evidence from the countries in which these protocols were developed. As stated by one participant, lack of quality evidence on the myriad of ever evolving low-cost IVF clinical initiatives within the developers' countries had brought about opposition to the interventions.

> *My understanding at that time of low cost IVF was that you use less medication for stimulation…but then along the way there have been other concepts that have come up about low cost IVF….I don't know how far that has gone. (Clinical_ Staff 5_298)*

Some themes in this construct overlapped with the *source of intervention* construct in that, the perceptions of intervention source influenced evidence strength and quality. When the intervention was perceived as a governmental cost-cutting intervention, the standard of care would remain the same and therefore was deemed as advantageous. In contrast, the perceived ambiguity of clinical evidence from "developer" countries generated doubts regarding the evidence base and quality of the intervention.

Relative Advantage

The perception of whether an intervention should be implemented in comparison to different intervention is defined as the *relative advantage* (Gustafson et al., 2003).

Standard Treatment Too Expensive for Ordinary Citizens. Participants voiced the importance of implementing LCIVF initiatives within the public health system as part of reproductive health services;

given significant demand for these services, the right to parenthood and the awfully high costs of treatment in the private sector. Prior to implementation of LCIVF initiatives at MWH, no public hospital in Uganda offered IVF services. This was perceived as a major limitation towards the fulfillment of fertility treatment, to which patients were often referred to expensive private clinics. The value of LCIVF initiatives within the public health system was seen as beneficial to reproductive health with a governmental participant asserting:

> *First and foremost, every person that desires to have a child should be assisted and I would want to see the public sector government taking up this line; the same way they provide services for other [areas]. If you talk about reproductive health, we should have this service incorporated in there. You don't just talk about family planning, what about those who cannot [have children]. It is my wish to see reproductive health, issues of fertility are taken care of and I would even appreciate if this was a free service given to the people by Government or were that is not possible given at some minimum cost because right now it is too expensive for the ordinary person to afford (Govt_Official 1_217-9)*

Furthermore, a patient representative of a fertility advocacy group regarded implementation of low-cost initiatives in the public facility as advantageous for ordinary citizens.

> *Low-cost IVF is the way to go for the ordinary family. There are so many people who are suffering who would like to have children, but they cannot afford. So low cost is the way to go, and we are looking at the public hospital (NGO_Patient 1_417)*

The participant goes on to highlight the benefits of LCIVF initiatives over standard treatment approaches.

> *It [LCIVF] was initiated by Professor William Ombelet in his over 20 years of working with infertility in Africa. He sees that the problem is so big, it is not being given priority and comes up with the idea of how infertility can be managed at low cost…which he thinks can work for Africa because this treatment is highly expensive everywhere all over the world. (NGO_Patient 1_284)*

Beyond Diagnostic Services. Prior to LCIVF implementation, MWH only provided diagnostic fertility services and a few surgical procedures to address blocked tubes. The department was not able to offer IVF-related services, compelling the need to extend fertility services beyond what was currently available.

> *The provider [public hospital] saw the need to move from just providing a diagnosis and telling you your tubes are blocked, nothing can be done except IVF and so the patient will say where can I go for IVF, then you have to provide solutions and options that are available (Clinical_ Staff 5_224)*

Hindrance to Revenue Generation. However, for some, implementing LCIVF initiatives was seen as a hindrance to those interested in revenue generating opportunities of offering conventional IVF treatment. As one external participant expressed:

> *Often one of the problems with low-cost IVF was that everyone was interested but nobody wanted to do anything…because in many of the countries, there was already some private IVF and they*

could see this is a way of making large amounts of money and people were not interested in doing something that was not going to bring in a lot of money. (Int.Org_Doctor 1_23)

LCIVF was perceived by some as unprofitable, threatening income generating opportunities for providers.

Adaptability

Adaptability is the degree to which an intervention can be altered or amended to fit into its local context (Damschroder et al., 2009). The adaptability of an invention is informed by which components are considered core and cannot be changed versus the adaptable elements that can be modified (Fixen et al., 2005; Greenhalgh et al., 2004).

Plethora of Initiatives. The breadth of IVF initiatives considered to be low-cost favored implementation as the intervention could be adapted to fit the organization's needs. Participants described flexibility over choice in equipment, medications, consumables, treatment protocols, based on patient related factors and clinical judgement. As revealed by a clinical participant, simpler procedures could be adapted based on specific cases:

For example, we have things like intrauterine insemination that is not typical IVF. But there are scenarios or cases where someone can benefit from that and it is really very low cost because it may not necessarily involve things like ovulation (Clinical_ Staff 1_82)

In this construct, *adaptability* was perceived to be a positive attribute favouring implementation of LCIVF initiatives. It is also worth noting that participants did not explicitly define what they considered to be core vs adaptable elements of the technology.

Trialability

Trialability is the ability to test or reverse an intervention on a modest scale prior to its implementation (Klein, Conn and Sorra, 2001; Greenhalgh et al., 2004). The potential to carry out initial trials with a few patients favoured implementation, especially, since MWH as a public national referral hospital had the capacity to do so for free.

Step by Step. Clinical participants reported the importance of not overextending themselves and starting slowly by providing uncomplicated procedures and then working their way up to more complicated ones that included IVF and third-party reproductive services.

We don't want to bite what we cannot swallow. We were initially looking at taking it slow starting from the basics, simple patient cases that don't require in-vitro fertilization like we have always done…. like IUIs, we want to start there and then do actual IVF…We want to go step by step (Clinical_ Staff 1_424)

Trial & Publish. The department discussed opportunities to provide free treatment trials to a few patients as was custom within the national referral hospital for any new service. One participant described the benefits of this approach in allowing the department to test and publish first, without the financial burden to patients.

> *Just like any other service we have done in this facility…for the first month, we were offering free service...so have a few people, we go through it together…we get our babies, through that we publish....That was the intention, than have people come and pay their money…So our bosses were suggesting that we start with a few like 8, 10, 12 patients for free…but when COVID-19 came, things stopped (Clinical_Staff 8_342)*

This trialability facilitated the implementation of LCIVF initiatives as participants felt they had the leeway to proceed cautiously and test with a few patients at no cost.

Complexity

The *complexity of the intervention* is defined by perceived difficulty of implementation based on its scope; number of steps or intricacy (Greenhalgh et al; 2004). For a public health facility, the complexity of LCIVF initiatives was considered a barrier to implementation owing to the level of specialized expertise required (e.g., fertility specialists, embryologists, ART counsellors), resources involved, varied patient related factors and the number of procedures undertaken.

Highly Specialized Requirements. The implementation of LCIVF requires highly specialized infrastructure, equipment, and a dedicated, multi-disciplinary team. Participants emphasized the need for a committed specialist team with a keen attention to detail to facilitate a well-functioning department. One participant discussed the importance of specificity on implementing the intervention:

> *You need the facility itself to be a very specific and highly specialized facility…For example the Lab, the IVF Lab has particular specifications for success of what we are dealing with (Clinical_ Staff 1_98)*

Scope Complexity. Participants narrated several models they considered to be LCIVF initiatives that originated from diverse innovators; some of which were not well understood. The vast scope of these initiatives, along with how quickly they evolved over time contributed to difficulties in remaining abreast which added to its complexity. One clinical participant described various elements within the scope of LCIVF:

> *I believe that many other people are working on the other elements of low cost because they are elements, whether it is price, reducing the medical processes or concentrating on the core, third party reproduction, diagnosis, storage for gametes and embryos; those are all elements considered within the cost in the context of low cost (PA_Doctor 1_31)*

Another clinical participant tried to recall some of the LCIVF initiatives he was aware of but revealed that he was not sure how far some had gone.

> *My understanding at that time of low-cost IVF was that you use less medication for stimulation… add on some medications like clomiphene, like letrozole and give a little bit of gonadotropins and then go through the process of IVF. That was initially that point but then along the way there have been other concepts that have come up about low cost IVF….I don't know how far that has gone…you reduce the cost of culture, you reduce the cost of stimulation, that way it becomes low cost. (Clinical_ Staff 5_298)*

Process Complexity. Complexity is defined by length and breadth of processes (Kochevar & Yano, 2006). There are different levels and lengths for LCIVF treatment protocols that could be considered based on several factors. For example, participants reported protocols as simple as hormone imbalance where balancing medicine can rectify the issue. But also highlighted that it could be as complicated as inability to carry a pregnancy to term requiring IVF, third party donation or surrogacy. Participants expressed concern over complicated cases dictated by patient related factors that would necessitate third parties, several treatment courses and introduce ethical dilemmas for providers and patients alike. One participant describes this complexity in providing care:

> *Sometimes you may need to use donor gametes, either from the male or from the female, when we cannot achieve what we want from the primary people. We are getting into a stage where we must involve surrogates, where the patients can provide the gametes but cannot sustain pregnancies, but we know that they can get babies. All those become very complicated issues…when you talk about someone carrying someone else's baby, it also becomes another issue, especially at birth. These are all issues…which are all emotionally draining (Clinical_ Staff 1_239).*

Risk of Clinical Error. LCIVF treatment requires a team of highly competent clinicians to work collaboratively as each member's actions influences those of others and impacts treatment outcomes. This was considered to be a barrier in MWH as public hospitals were said to often have larger teams that rotate periodically and have varied levels of expertise that limited control and accountability of the process, impacting quality of care. One participant cited these characteristics as detrimental, creating a higher risk for clinical error within a public facility stating:

> *People can mix up embryos, sperm, eggs and can do all sorts of things…You have heard of third-party reproduction, surrogates, egg donors, sperm donors and all that so at the end of the day, you are likely to mess-up some things. So, you need to be able to control the process from the word go, you know who is responsible for what and they do their work and if they don't do their work then there must be a punishment for that (Clinical_ Staff 5_395)*

There were linkages between the *complexity* of the intervention and its *compatibility* within the public hospital. The complex nature of the intervention was disadvantageous given the level of expertise required, difficulty in staying up to date on various LCIVF initiatives and greater likelihood of clinical error within a public facility. Furthermore, LCIVF presents a multitude of treatment options, dependent on a variety of patient factors and clinician's dexterity; all of which influence decision making.

Cost

The *cost of the intervention* refers to expenses associated with the intervention itself and its implementation e.g., opportunity cost, investment and supply (Damschroder et al., 2009).

Implementation Costs. Initial investment for setting up an IVF department with MWH was considerably high attributable to infrastructure development, procurement of equipment and drugs. This was not a barrier as it was a government funded initiative as one participant describes:

> *But also, even if you went to actual IVF, there is quite a cost when it comes to drugs and equipment involved because people invest in that…it requires a lot of input in terms of cost. The initial investment is high and therefore this sort of turns back to the patient, when they start offering the service. The difference here is that it is government that has funded (Clinical_ Staff 1_100)*

Furthermore, the total hospital project cost USD $ 33 Million dollars and the IVF department reportedly took a significant portion (USD $8 million) of the budget. An administrative participant described the process:

> *So, we set up a unit, procured the necessary high-end equipment to ensure that we are able to do all these services like in vitro fertilization, things like embryo transfer…we even put things like a sperm bank, so the facility was well designed to cater for all that. It took us a significant chunk of the budget because that was among the primary focus under reproductive medicine (Hospital_Admin 2_114-7)*

High Operational Costs. Clinical participants expressed concern over the high cost of maintaining IVF related equipment and ensuring adequate supply of quality drugs. They reported that most of the IVF specialized equipment and supplies were not locally available or accessible, often imported, with high import duty taxes which significantly contributed to the elevated costs of treatment. Equipment was said to be "locked" by overseas manufacturers, making price negotiations challenging and procurements and regular maintenance costly and logistically burdensome. As a clinical participant asserted, "*And the maintenance of those supplies also needs to be considered (Clinical_Staff 7_55)".* According to the "how to run an IVF" document, IVF remains a costly treatment modality for Sub-Saharan Africa. While there is an overwhelming demand for fertility services, it was considered costly to start and maintain it. Furthermore, the report noted that there was endemic poverty that continued to frustrate patients from accessing IVF while practitioners struggled with high operational costs, terming it as "The paradox of the typical IVF practitioner in Africa".

IVF Pricing Debate. There was considerable debate regarding whether the services should be free or subsidized and applicable to all fertility patients. Some clinical participants highlighted that provision of LCIVF services attracted considerable clinical maintenance costs associated with drugs/consumables and equipment. In this scenario, the government was expected to fund these costs that would otherwise be covered by patients. As on clinical describes the government's role in subsiding cost:

Government is planning to subsidize a number of costs that would otherwise have been passed on to the patient. For example, they provide the facility, maintenance of the equipment, electricity, water, and salaries for the people who are working there (Clinical_ Staff 5_329)

However, pricing the service itself proved to be contentious as reported by some participants. A portion (mostly administrative, governmental officials and the public) insisted that the service be offered freely. One administrative participant contended that the service should be offered for free as its set up was funded by taxpayers' money stating:

This hospital is built by the African Development Bank loan, a loan which everybody pays into. So, you cannot say to a patient, you are going to pay and then prevent the people who are jointly contributing…They are the owners of the facility…they are the taxpayers…so you cannot push them away…because it is not only the rich people who are affected by this bareness. Get the rich people to subsidize for the poor. If we had national insurance, most of those things would have been sorted. You can never get 100% equity but there should be a percentage known. (PA_Doctor 2_194)

Other participants (mainly clinicians) contended that a free model would not be sustainable and would collapse the system. One clinical participant reflected on the rationale for charging patients a subsidized fee saying:

Costing. How do you price? Pricing in a public sector, you would want to price like NGOs, it's not for profit but must be able to run…it is difficult to expect that the government is going to continue funding given competing priorities…and if they don't fund, it will collapse.…Our opinion was that maybe the cost at about 2/3 of market price could work. (Clinical_ Staff 3_244)

Furthermore, some participants reported that the concept of MWH was never to offer services for free and was in fact targeting individuals who travel abroad for specialized treatment through medical tourism. One clinical participant affirmed that the rationale behind pricing IVF services:

Because they said that the new hospital would be a paying hospital but probably subsidized by the government. So, if IVF costs like USD 5000 elsewhere [private sector], maybe people might have to pay something like USD 2000 or USD 2500 or USD 3000 for the service...That was the idea, it wasn't meant to be free, but it was going to be something of subsidy from the Government (Clinical_ Staff 5_77)

Tiered Treatment Plan. The hospital published their service prices to the public offering a tiered package for fertility treatment. The plan consisted of three tiers, with the most basic package as 'silver', followed by 'gold' and at the top-end 'platinum'. A majority (60%) of patients came to MWH through referrals and were automatically seen under the silver package and the rest Gold (40%) and Platinum (20%). The main difference between the packages was assumed to be the quality of accommodation one received as an administrator shared:

"*The charge for IVF 13 million [USD $3,500] for Silver…Gold is 16.25 million [USD$4,500] and then Platinum is 19.5 million [USD$5,200]…this difference is based on accommodation type but maybe medical care is the same because these people are seen by the same consultants and specialists. You either have a room, with a TV or a bed in a curtain or a room with a sitting room" (Hospital_Admin 1_67)*

However, prior to being admitted on the ward, a patient was expected to pay for consultation and investigative fees. The majority of patients reportedly paid out of pocket because most insurance companies did not cover fertility services. This raised uncertainty regarding the feasibility of the treatment plan. Given that IVF services had not yet been offered, this payment process had not yet been tested. Furthermore, the delayed start of the IVF department (4 years and counting) meant that prices would need to be revised to reflect current (increased) market rates.

Treatment Waivers. The cost of treatment through the tiered plans was considered to be high and resulted in public outrage once published. However, an administrative participant revealed that while the initial goal of the hospital was to target paying customers, patients received at MWH through the referral system would be considered for treatment waivers:

> *"One, the facility at inception was targeting clients who are able to pay and it was even looking at these people travel abroad for medication [medical tourism]….In circumstances where a patient is referred, they come directly through silver…if they don't have money…we have the waiver committee, they will assess the patient and waive off the bill. In fact, we have quite a lot of money in waive off "(Hospital_Admin 1_137)*

The initial investment cost for implementation of LCIVF initiatives was high, however, this was not a barrier considering the government was able to finance it through a loan. Still, there were conflicting perspectives regarding how the service should be priced, which resulted in discrepancies between the government, hospital, clinical and public expectations. This in part may be attributable to different *knowledge and beliefs* about the intervention and thus, interconnects with the respective construct.

In summary, results in the interventional characteristics domain identified two main constructs that facilitated implementation (adaptability and trialability of LCIVF initiatives), three constructs with mixed evidence (source of the intervention, relative advantage and cost) and two constructs that posed considerable barriers to implementation (evidence strength and quality of intervention and complexity of intervention). The design quality and package construct was not relevant to this study.

5.4.2. Outer Setting Domain

The *outer setting* is characterized by external factors that can influence implementation of an intervention including cultural, political, social and economic context within which an intervention is implemented (Mendel et al., 2008). Analysis of the data revealed all four constructs in this domain were relevant in influencing implementation namely *patient needs and resources*, *cosmopolitanism*, *peer pressure* and *external policies and incentives*.

Patient needs and resources

The *patient needs and sources* construct considers an organization's awareness of the needs of its patients, barriers and facilitators to meeting their needs and its capacity to prioritize meeting them (Damschroder et al., 2009). For instance, some patients may be aware that a service exists, but fear judgement from others

when accessing it, such as HIV services. Understanding of patients' needs was evident throughout the interviews from the severe impacts of infertility, vocal presence of patient-led advocacy groups to the high demand for affordable fertility services at the public facility. These factors favored implementation of LCIVF initiatives at MWH. Participants emphasized the significant burden of infertility on individuals, visible demand for fertility services, financial support to overcome barriers to access, public sensitization to address social stigma, health seeking behaviours and their obligation as a public facility to meet these needs.

Limited Public Sensitization. Many participants highlighted the considerable impact of infertility and the importance of breaking silence within public discourse to address misconceptions, myths and stigma faced by childless individuals (mainly women). One clinical participant reflected on the amount of stigmatization she had observed including societal inferior treatment of women who have no children, particularly in rural communities and their designation as second-class citizens. In some scenarios, blame of infertility was placed on childless women through accusations of partaking practices that could have been preventable and calling for greater public awareness to combat these assumptions and improve health seeking behaviours.

> *…like in the villages, women who have no children are stigmatized ….A woman who doesn't have children is second class…People thought you get infertile because you have done something crazy like taking out a lot of pregnancies, getting sepsis, STIs, tubes gone, all sorts of things, some of which seem like you could control and prevent. So, [they say] she exposed herself, it was her fault…I think people need to know a lot more about infertility. People think it is witchcraft [bamuloga], genetic, of course in some cases it is genetic, but you know, there are all sorts of beliefs out there (Clinical_ Staff 2_295)*

Furthermore, addressing infertility misconceptions was emphasized given the obscurity and marginalization of persons experiencing infertility, particularly amidst public discourse on the country's high fertility rate. As a clinical participant stated:

> *But the burden is big, so it is a misconception when you talk about the high birth rate. That has always been the misconception that we are fertile, we seem to put what we may consider as the minority on the side. We don't look at infertility as a disease, but infertility is one of the most painful things to deal with. Both for the practitioner but more importantly for the couple that is going through it (Clinical_ Staff 1_189-191)*

There was government concern over the impact of infertility on individuals in the community as well. As detailed by a political advocate, infertility had severe implications on women's marriages and economic wellbeing in that they were silenced in communities, many of them divorced and sent back to their homes by their spouses without any land ownership or economic security. Furthermore, this need for public education was echoed at the highest level of office, by the President of the Republic of Uganda: HE Yoweri Museveni. The President expressed concern through public address on several occasions, acknowledging the causes and consequences of infertility and the desire for these issues to be addressed. One participant recalls the President's appeal to his constituents during a cabinet meeting saying:

Slowly when we spoke, people started understanding [the burden of infertility] even those who were opposed and His Excellency the President in one of the cabinet meetings when we were discussing, he said you people you don't know what people are going through (Govt_Official 1_79)

Therefore, there was a keen awareness for the need for public awareness and education to address patient barriers and improve access to fertility care.

Demand for Fertility Treatment. A need for offering fertility services within the public health system to address growing fertility challenges was apparent. Prior to the new facility, the clinical team recognized existing demand for comprehensive fertility services based on patients reviewed during a weekly fertility clinic held to offer basic diagnostic and treatment services. Furthermore, as general obstetrics and gynecological physicians, participants felt incompetent to provide expert guidance and treatment options to patients. This demand for comprehensive ART services was evident by the masses of patients who flocked into the hospital within its opening week as described by an administrative participant:

But again, we noticed that in the community at that time, we had a high number of people who needed assisted reproductive technologies. Actually, I remember when we had just opened, in the first week we registered nearly 600 mothers or clients who expressed interest in having this assisted reproductive technology. (Hospital_Admin 2_109)

Interestingly, another participant was made aware of the significant burden of disease and need for fertility services during a trip to India.

For example, when I went to India, people were telling us that your people have infertility. They [Indian clinicians] had diagnosed patients who have infertility, cancer, patients who have AID (Hospital _Doctor 4_456)

Therefore, this knowledge of patient needs favored implementation of LCIVF initiatives.

Call for Affordable Fertility Treatment. Many participants pointed out the financial burden associated with accessing fertility treatment. At the time, fertility services were offered exclusively through private sector hospitals at remarkably higher costs to patients. Financial barriers favoured implementation of lower cost treatment options within the public facility. An administrative participant described research done to validate the need for affordable services at the hospital:

One, we did research and most patients dealing with infertility don't have money, they are able to manage the cost. They have the problem but the cost of treatment and material for getting the baby, if it is successful, it's quite expensive. So it should be addressed, if there is any way they can subsidize costs for these people, the better (Hospital_Admin 1_8-14)

Furthermore, it was noted that in most cases, women bore the financial costs of fertility treatment as another clinical participant noted.

Some of patients were asked to come with their husbands but were unable to and came alone. We conducted research asking infertile women how their relationship is in terms of support, financially, morally and they were transparent. We discovered that most of them struggle alone financially (Clinical_Staff 6_59)

Privacy in Accessing and Utilizing Care. The need for patient privacy while receiving fertility care deserved attention given the stigmatizing nature of the condition. Considerations about spacing, partitioning, ambiance and seclusion were reported. A clinical participant described the importance of privacy in the way the department is designed and structured stating:

> *Even the facility itself should have enough space. Space also matters because they [the hospital] keep on partitioning but these patients need privacy…the laboratory, the whole structural set up…. should be conducive and attractive…Privacy is very important as it creates a good level of comfort for the patient. I even think it promotes faster healing…. So for me, this is important work. I would prefer that they look at the structure to make patients comfortable in rooms for privacy purposes (Clinical_Staff 6_275)*

Knowledge Gap. Participants disclosed that patients often had a little knowledge of how IVF technology is carried out, unclear expectations throughout the treatment process, were unaware of success rates and complications that may arise. Consequently, as described by one clinical participant, there is a fundamental requirement to meet these gaps through the counseling:

> *They go through a lot of counseling to be able to give the couple the whole picture up to the end. It is not a matter of picking gametes and that is it. They must be taken through the whole picture, what we are going to do, why we are going to do it, what may be expected, the bad and good, and the positive and negative including that sometimes things may fail, even after we have done all we have done. So, there is a very big component of counseling (Clinical_ Staff 1_343-5)*

Patient Vulnerability and Exploitation. Some participants emphasized a need for rigorous regulation of fertility practitioners to safeguard fertility patients who were often vulnerable given the novelty of the intervention. Patients were reportedly unaware of IVF technologies and willing to do anything to achieve pregnancy, while some practitioners took advantage of this desperation when offering services by conducting unnecessary investigations, providing substandard treatment protocols and charging higher fees. A clinical participant revealed this abuse saying:

> *There is a lot of abuse from doctors…and of course that is possible because it [IVF] was relatively a new aspect, no one really knew much about it…But also the fact that the group we are dealing with is vulnerable…because they are really desperate, they want something out of this, they could have been taken advantage of in some respects (Clinical_ Staff 1_286)*

Patient Satisfaction. Furthermore, there was recognition of the sensitive nature of infertility and the need to exercise empathy and compassion when handling patients during counseling to satisfy their needs. One participant pointed out the importance of answering all the patients' questions to satisfaction as essential to their needs.

> *Client satisfaction is very important…The doctors here are committed to their work, to the clients, even when the doctors are talking to patients, they give them sufficient time and share their telephone numbers to answer their questions. (Clinical_Staff 6_224)*

The keen awareness of patients' needs within this construct facilitated the implementation of a LCIVF services and influenced departmental operations within the reproductive medicine department. This awareness was also linked to the *cosmopolitan* construct, in which collaboration with external organizations revealed and aided patients' needs. MWH had the capacity to receive, diagnose, counsel and provide limited corrective surgeries to patients but not IVF related treatment. However, the department's inability to fully respond to the needs of their patients was related to *availability of resources* construct, in that the hospital had not successfully identified an embryologist for IVF procedures.

Cosmopolitanism

The connections an organization has with external entities illustrates how *cosmopolitan* it is (Damschroder et al., 2009). These webs of networks and relationships often facilitate agile implementation within organizations leveraged through social capital (Brehem & Rahn, 1998). Collaboration with external organizations played a vital role in establishing MWH and facilitated implementation of a reproductive medicine department to provide affordable fertility services. These network relations included a range of players, national and international, that were advantageous to implementing LCIVF initiatives including UMDPC, MERCK Foundation, Joyce Fertility Support Center, Makerere University, John Hopkins, WHO, IFFS, ESHRE, Islamic Development Bank, Ministry of Health, Ministry of Finance, Uganda Fertility Society, Women's Medical Doctors Association, Obstetrics & Gynecological Association, Private Fertility Sector, ASRM, Low-cost Foundation and the Walking Egg.

Partnerships with Local Organizations. Local entities played a significant role, facilitating implementation of LCIVF at MWH by providing staff training opportunities, research, manpower, technical guidance, community sensitization, quality management, lobbying and regulatory support. One of the hospital administrators emphasized the importance of partnerships for a project of this magnitude. The first local partner was Makerere University, the largest national higher educational institution, in supporting staff training and Makerere University John Hopkins University (MUJHU) partnership in conducting research.

> *Of course, you know a project of this magnitude, there are many partners that work together and take part. One of the key partners was Makerere University, coming in strongly in terms of training, research and as I said since we don't have all the manpower that we require, Makerere is focusing on how best they can have them trained. We worked with other partners like MUJHU- Makerere University John Hopkins University…many other partners, I may not be able to cite all of them, but we have always worked with partners (Hospital_Admin 2_308-12)*

Furthermore, at the regulatory level, the clinical team from MWH collaborated with the UMDPC, UFS and Makerere Medical school to draft the first Assisted Reproductive Technology bill for parliamentary review.

> *The initiator [of the ART bill] was Uganda Medical and Dental Practitioner Council, the main interested party was Uganda Fertility Society and its members and then of course the medical school at the society at large (Clinical_ Staff 3_311)*

The Uganda Fertility Society (UFS), a consortium of local fertility specialists, alongside UMDPC also provided quality assurance support through certification of fertility specialists, continuous education, lobbying for fertility services and regulation of reproductive medicine in the absence of national laws and community sensitization.

Collaboration with International Organizations. There were several international organizations that provided early technical support on implementation of LCIVF initiatives. Representatives from WHO, IFFS, ESHRE and ASRM worked alongside clinicians, patient groups and government officials to provide recommendations, conduct site visits, benchmarking, training workshops, conferences and draft proposals on LCIVF implementation. Many of the initial engagements were established by Joyce Fertility Support Center (JFSC), a patient advocacy group, in partnership with local fertility doctors. A participant representing JFSC described interactions leading up to the first LCIVF conference in Uganda and visit to Mulago stating:

> *Together with the doctors, we invited Professor Willem Ombelet, who visited this hospital with the intention of considering a public hospital for treatment of reproductive diseases, specifically infertility…through our interactions...Professor Ian Cooke, who headed the IFFS at that time under ESHRE… came here in 2010… And through our participation we worked with the doctors to convene the first low-cost IVF workshop in Uganda (NGO_Patient 1_46)*

ASRM, in particular, initiated and supported discussion on development of the ART bill. Another international organization that played a significant role was the MERCK foundation, particularly at the ministerial and community level. The foundation's CEO, Rasha Kelej, in partnership with the then Minister of Health placed a national spotlight on the issue of infertility through countrywide "More than a mother" campaigns and was credited for converting the minister into a political champion for infertility. MERCK foundation provided a visible platform that gave voice to women experiencing infertility who had been previously silenced and offered economic empowerment initiatives to many of them. The foundation also offered technical IVF related training to clinical staff, expert guidance during construction of the IVF department and technical support (embryologists) to kick start IVF services at the hospital, while the local team built their own capacity. However, the offer of technical support from embryologists was not taken up. A government participant spoke on MERCK foundation's involvement in illuminating the burden of infertility and supporting implementation phase:

> *So Dr Rasha told me, you don't know the magnitude of the problem…when a Kenyan member of parliament who had gone through all this stigma got up to speak….I now started appreciating the problem…I tried to sell the idea to my technical people in the ministry…working with MERCK, she [CEO] identified an Indian company that would help us come run the facility, meanwhile passing on the skill to our staff at the women's hospital. (Govt_Official 1_93)*

The role of MERCK was echoed further by clinical participant:

> *So there was quite a lot of support. There was also another company called MERCK which was very supportive trying to help in issues of training, short term trainings for people if we had started and I think it also had interests in helping some patients to be able to get this service if we start, probably partially pay part of their bills (Clinical_ Staff 5_435)*

However, a major drawback to the international collaborations was the nature of their connections to the local context. Most of them were said to be founded on personal rather than institutional relationships, posing sustainability challenges to implementation process.

But I don't know how it will go because most of those collaborations are not institutional, they are individual. If someone who is so passionate goes away, then they probably go away with a passion that the other person had for helping out. (Clinical_ Staff 5_439)

Engagement with Patient Groups. The clinical and administrative staff of MWH reportedly interacted with patients and patient groups on numerous occasions, facilitating successful lobbying efforts in the implementation of LCIVF initiatives. JFSC, in particular, as the first and longest running patient-led fertility support group in Uganda played a significant role in building and leading grassroots advocacy for access to affordable fertility treatment in Uganda. As one clinical participant highlighted, the organization "gave a face to the condition and humanized the experiences of individuals suffering with infertility beyond statistical figures". JFSC engaged international stakeholders from the WHO, ESHRE, IFFS in discussions on implementing affordable fertility treatment and convened the 1st LCIVF workshop in Uganda in January 2006. The conference successfully brought together local and international key stakeholders including fertility clinicians, patients and government officials to spark dialogue around addressing needs of persons with infertility. The Executive Director of JFSC spoke about the work performed by the organization to achieve its goals for LCIVF saying:

When we came up with this idea, we spoke to Professor Ian Cooke, Willem Ombelet, and several different doctors as I used to present patient's perspectives at ESHRE. And it was in those interactions there that we talked of Uganda….and the goal to see if these doctors internationally can help the doctors in Uganda to establish a low-cost IVF in Uganda. (NGO_Patient 1_131)

The role of JFSC in lobbying for the implementation of LCIVF initiatives was crucial, as a clinical participant highlights, in presenting a strong case in its favour and initiating the formation of the Uganda Fertility Society.

…for us in the hospital, we were seeing a few people but…she [JFSC Director] even had examples of people who had gone through this [infertility], who were suffering from domestic violence at home. Later on, she had wanted us to form a society to support women with infertility, develop IVF units but the clinicians were not comfortable forming it…saying it should only be for fertility doctors (Hospital _Doctor 4_218)

Unfortunately, JFSC was excluded from participating in the Uganda Fertility Society (UFS) despite having initiated the idea of the society and expressing interest in managing it. The doctors reportedly justified this action citing that a fertility society was for doctors only and not social scientists or patients. While the organization stated its intentions to work collaboratively, as the executive director said, they eventually went quiet and focused on patient-facing efforts.

Knowledge Exchange with the Private Sector. Some private fertility hospitals were interested in supporting establishment of the first publicly run IVF department and offered practical training in ART to medical students and embryologists. One of clinical participants described their partnership saying:

Yes, we do have doctors, post graduate doctors, who come in and rotate in private facilities to have a feel. In class it is just theory but here, they have a [practical] feel of what it means to do assisted

reproduction. How the patients are stimulated, the collection is done, what are the parameters for monitoring, how the person is responding, transfers, what is done in the lab, embryology, intracytoplasmic sperm injection, if you are doing aspiration of sperms, basically they get a feel of it (Clinical_ Staff 5_96)

Political Allyships. The clinical team of MWH, along with Women's Medical Doctors Association and the Obstetrics & Gynecological Association worked closely with women politicians to lobby approval of funds to facilitate construction of the women's specialist hospital and thus, implementation of LCIVF initiatives. The close ties between clinicians and political officials spanned over years, involving multiple discussions that built momentum to successfully secure funds for implementation. One participant described it as "micro advocacy" going on in between these spaces. Another clinical participant recalled the role women parliamentarians and importance of giving women a voice concerning issues of their gender:

…they [women parliamentarians] pushed back in the parliament for ultimately getting the whole idea of having a women's hospital to be created…. They galvanized their male colleagues and others so that they get convinced when the issue is mentioned in parliament, they have a critical mass to support it…So the parliamentarians, especially women parliamentarians, were pushing at that level of government to have the women's hospital, so we now had partners in parliament (Clinical_ Staff 3_63)

This sub-construct highlights the extensive collaborative endeavours between local and international players that facilitated implementation of LCIVF initiatives. There are notable intersections with the *patient needs and resources* and *external policy and incentives* sub-constructs.

Peer Pressure

Peer pressure considers the likelihood that an organization implements an intervention due to competition from other organizations that have been able to implement it (Damschroder et al., 2009).

Competition in the Private Sector. There were a growing number of fertility hospitals in the private sector providing fertility services and generating considerable revenues attributable to the high treatment fees. This demand for services observed within the private sector favoured implementation of LCIVF in the public sector. At the time of the study, there were over 8 private hospitals providing fertility care and were said to charge on average $6,000 per IVF cycle with none in the public sector. Furthermore, these hospitals reportedly had high failure rates. Consequently, there was public outcry for affordable services to counter high treatment costs and quality uncertainty in the private sector. An administrative participant described the need to counter exorbitant prices in private clinics within the public sector:

So, we needed to provide a service that other facilities were not offering and of course the other driver to this was that many people were going to the private sector, and it wasn't possible for them to receive treatment because of the high charges. And the failure rates were also very high. Failure rates being that once the treatment costs are high, then the response becomes a challenge (Hospital_Admin 2_126-30)

He states further:

> *Others would drop off; others would fail to show up at the time when they are supposed to and so on. So, we felt as a country, as a government we needed to help the community by putting up a service which would grossly be subsidized and help the community in terms of offering this service. So really in a nutshell that is the background of how the ART services came to be at the specialized women's hospital (Hospital_Admin 2_136)*

The evident boom of fertility hospitals in the private sector charging high prices facilitated the implementation of IVF services in the public sector. This construct corresponds with the *relative priority* and *external policies and incentives*.

External Policy and Incentives

This expansive construct represents any strategies external to the organization that influence implementation of an intervention including mandates, policy and regulation, recommendations and guidelines, benchmark reporting and incentives (Mendel et al., 2008).

Favourable International Policy of Infertility. Changes in international discourse and policy on infertility played an instrumental role in justifying implementation of affordable fertility services in Uganda. Participants specifically referred to the 2009 WHO declaration on infertility as a global reproductive disease and the UN Universal Declaration for Human Rights Declaration (Article 16) as validation for implementation of affordable fertility services. A clinical participant regarded the acceptability of infertility as a reproductive condition as a pivotal moment:

> *Assisted Reproductive Technology has been running for quite some time. The concept of low-cost IVF was already in plain view with several protagonists from various perspectives. The key development was first, fertility being accepted as part of reproductive health, whereas previously the argument revolved around an already high enough fertility. (PA_Doctor 1_1-3)*

He continued by referring to the UN Human Rights Declaration citing:

> *So the concept is reproduction, it is called Human Rights and if you check on the Universal Declaration of Human Rights that anybody who is 18 years and above can have a family; the timing, number is their choice, not attached to marriage and it doesn't matter how you achieve your children, come whether into marriage or a one night stand [laughs](PA_Doctor 1_139-42)*

Therefore, recognition of international agencies on importance and impact of infertility facilitates local implementation efforts for LCVIF initiatives at MWH.

National Legislation on Infertility. However, participants expressed the need for legitimizing infertility as a reproductive disease at the national policy level as well to ensure resources were made available to address its consequences. During interviews, some participants discussed the role of the government in designating infertility as a reproductive health condition to facilitate implementation of LCIVF initiatives:

> *If you talk about reproductive health, we should have this service incorporated in there. You don't just talk about family planning, what about those who cannot [have a family]. So, it is my wish to*

see reproductive health, issues of fertility are taken care of, and I would even appreciate if this was a free service given to the people by government or were that is not possible given at some minimum cost (Govt_Official 1_213)

ART Bill Development. An ART bill was drafted expeditiously by the clinical team in collaboration with the professional medical association (UMDPC) for submission and review by parliamentarians. The speedy development of this document for parliamentary review aided early discourse concerning how LCIVF services would be administered within the public hospitals. It drew upon interpretations of the Uganda Constitution, Universal Declaration of Human Rights and European Convention for Human Rights for guidance. A clinical participant provided an overview of the essence of the bill stating:

So we have worked on the draft registration for ART registration…I have looked at the draft in detail. It is a good draft looking at the interest of the unborn child, of the parents, whether it just ordinary IVF, looking at the interest of third party because they're going to be the surrogates, all those people who donate genetic materials, what are their rights and obligations? What are the rights and obligations to the child? A majority of children want to know who their biological father is. There has been an attempt to look at all those issues, what happens? (Clinical_ Staff 3_326)

In the bill, ART was defined as "a range of techniques that attempt to obtain a pregnancy by using the sperm or/and egg (oocyte) outside the body, dissecting, washing or storing, or taking biopsy and transferring the gamete (sperm or/and egg) or embryo into the woman". Furthermore, fertility services were described as "any medical, surgical, gynaecological or obstetric services provided for the purpose of assisting women to carry children." Components of the bill covered conditions for ART licensure (grant/suspend/revoke), information disclosure, application of the law, the authorizing professional body and its scope of jurisdiction (i.e., inspection and licensing). Notably, the bill assumed heterosexual relations and was non-discriminatory towards marital status (married, unmarried, single, separated, divorced) of individuals undergoing treatment. It permitted storage and use of donor gametes with consent. It was also flexible concerning donor anonymity, whereby the gamete provider may or may not be known to the gamete recipient and on compensation, whereby the gamete provider may or not be compensated by the intended recipient. Interestingly, a gamete provider undergoing fertility treatment could offset the cost of treatment by offering their excess gametes to an intended recipient via egg or sperm sharing. Furthermore, individuals were permitted to advertise their need for gamete donors/surrogates through any media outlet. Under contractual agreement, donors/surrogates were required to relinquish all rights of gametes or child once birthed to the recipient. Service providers could also advertise factual information. The bill, however, did prohibit embryo preference based on sex, physical or mental abnormality. Remarkably, posthumous insemination in an event that the husband/partner died after written consent to use of his sperm or that of a donor was permitted. Lastly, the ART bill mandated services to be offered only under circumstances where the intended parents had received comprehensive counseling and information on parenting.

Unfortunately, during parliamentary review, there was resistance and misunderstanding of the ART bill by some constituents. As reported by a government official, several politicians and religious authorities protested the bill. They recalled pro-supporters receiving accusations of wanting to distort families by going against the natural order of reproduction. Furthermore, the ART bill was combined with the Organ Donor

bill which led to the confusion and misinterpretation of IVF technologies. Together, these factors led to opposition, slowing approval of the bill. At the time of the study, the ART bill had not yet been revisited and practitioners reported reverting to self-policing until approval. A clinical participant revealed the unfolding of events that led to halting of the bill saying:

> *It was unfortunate that something called an organ donation, you know how you would donate a kidney, donate something…so [IVF] gametes were also being looked at as part of the organ donation bill, but our argument was no, it is totally a different scenario. So, we hit a sort of snag at that time, we needed to convince the policy makers, especially the politicians, that these are two different things, and they must be handled in a different manner. (Clinical_ Staff 1_261-5)*

Participants revealed that the policy confusion was further confounded by a lack of sensitization of government officials that resulted in hesitancy. One participant indicated varied degrees of knowledge, citing that some politicians did not even appreciate the gravity of infertility given the ease with which they, themselves were able to have children. Therefore, the majority of study participants recommended substantial sensitization of policy makers to facilitate consistency in understanding of ART and its prioritization. As documented by the 2020 MoH Strategic Planning report, the ART bill was yet to be passed by Cabinet under the MoH's mandate to strengthen its governance and stewardship responsibilities in the health sector. Therefore, drafting of the bill was a positive step but was misunderstood by the parliamentary constituents halting progress on regulatory guidelines.

Benchmarking. Clinical participants reported various opportunities to benchmark women's hospitals and IVF departments. Some were able to travel to various countries like Ethiopia, South Africa, Egypt, India, and Canada for placement visits and attend IVF conferences as well. One of the pioneers for the MWH vision revealed how a visit to a women's hospital in Ethiopia made an impression on her. She noted that while the hospital standards were not ideal, everything in it focused on women; from the supplies to the services provided, which was not the case in Uganda. This experience inspired her to advocate for a specialist hospital for women. Another clinical colleague described the benefit of benchmarking visits explaining that:

> *We spent about a month in India benchmarking with one of the IVF facilities there. Some of the nurses went and a few of the doctors also went so benchmark…We were benchmarking in other areas to see how women's hospitals were basically running. We had several elective placements in places like McMaster University in Hamilton, Ontario…we felt that we had a lot of things that we could do. We also had benchmarking in Liverpool hospital; it was a women's hospital and so we felt that was the way to go. (Clinical_ Staff 5_30-33)*

Further, clinical participants reported on observations regarding standards of care citing a global trend towards specialized care and the need to follow suit. One clinical participant noted that the obstetrics and gynecology department held multiple discussions reflecting on these trends as the basis for building a women's hospital with diverse specialities. This was echoed by another clinical participant who detailed the departmental dialogue and enthusiasm for specialization saying:

We had quite several discussions before as a department about the trends that were happening worldwide on sub-specialization. And we basically felt that being a general obstetrics and gynecology person, we were not being utilized fully because we knew a lot of all things in obstetrics and gynecology but probably a few of the specifics. So a number of doctors went into sub specialization….and there was enthusiasm that people had that people went into sub specialization. (Clinical_ Staff 5_27)

Government Funding Support. The provision of funding by the government to finance construction, equipping and training within the new specialist hospital was a strong facilitator for implementation. The GoU, through The MoH and MoF, received a USD 30.72 million loan from the Islamic Development Bank to finance development of a Specialized Maternal and Neonatal Health care Unit (MWH) in Mulago National Referral Hospital (Mulago III) project. Funding from the MoH and MOF in collaboration with the Islamic Development Bank and African Development Bank (ADB) kick-started implementation. A hospital administrator confirmed the funding process stating:

It was started by the African Development Bank, but they contacted Islamic Development Bank to fund the construction of a specialized Maternal and Neonatal hospital. That was supposed to be a wing of the hospital (Hospital_Admin 2_51)

Parliamentary meeting documentation described the government's partnership with the Islamic Development Bank to construct and equip MWH. In the description of project objectives, the loan would forward the GoU's efforts towards enhancing its public health system and infrastructure in Kampala. In particular, decongesting and improving the quality of clinical care at Mulago National Referral Hospital, as the designated national centre of excellence for health. The total cost of the project stood at US$ 34.1 million, of which US$ 30.28 million came from the Islamic Development Bank as loans and US$ 0.44 million as a grant, plus a government contribution of US$ 3.42 million (Parliamentary Committee Minutes, 2012).

Centralized Remuneration System. Some clinical participants expressed concern regarding insufficient financial incentives in the public system and cautioned that would drive specialist clinicians to the private sector. This was in light of perceived higher fees fertility patients would pay compared to other services in the public hospital and quality of care needed for successful treatment. The absence of a surplus income for salaried clinical staff was unfavourable as described by one clinical participant citing:

On the other side, there is the human resource issue. How do you motivate human resource to keep them there so that they don't run to some other places? But how can you motivate them if you have no control? If you collect fees and then they are banked on the consolidated fund and you have these staff here who are committed and sometimes if the injection needs to be given at midnight, the person must be there to give the injection at midnight so that the egg collection takes place at the right time (Clinical_ Staff 3_192)

There is a connection between *external incentives and rewards* and *organizational incentives* given that in the public hospital system, staff are paid directly by the government and the hospital has no control on the matter.

This domain presented mixed influencing factors facilitating and impeding implementation of LCIVF initiatives. Constructs that facilitated implementation included patients' needs and resources, cosmopolitanism and peer pressure. While mixed findings were seen in external policy and incentives construct; favourable international policies, benchmarking visits, government funding and development of an ART bill facilitated implementation efforts, while misinterpretation of the ART bill, limited engagement with traditional, cultural and religious leaders and lack of salary incentives led to delays and unfavourable sentiments respectively. There are links between this construct with the *cosmopolitan, available resources* and *organizational incentives* constructs.

5.4.3. Inner Setting Domain

The "Inner Setting" refers to internal characteristics of the organization that can influence implementation of an intervention (Damschroder et al., 2009). This domain consists of five constructs namely, *structural characteristics, networks & communications, culture, implementation climate* and *readiness to implement*. All constructs were relevant to the study.

Structural Characteristics

This construct represents the size, maturity, age and social architecture of an organization (Damschroder et al., 2009). Social architecture considers how people in large organizations arrange themselves to form smaller groups working together to produce the whole product or service (Thompson, Scott & Zald, 2003). The variability in teams or departments represents knowledge diversity and team stability is associated with successful implementation efforts (Edmondson, Bohmer & Pisana, 2001). Participants in this study reported structurally related facilitators including the longevity of the hospital and preexistent sub-specialities, while the noted barriers were staff instability, limited autonomy and centralized processes.

Longevity of Hospital. Mulago Hospital is the largest public hospital in Uganda, established in 1913 with a 1,790-bed capacity. Its newest addition, MWH was built in 2018 with a 450-bed capacity. Through the years, Mulago has undergone multiple renovations and iterations to improve capacity and quality of care. The hospital reinvented itself through the political instability of the 70s and 80s, and as quoted on its history web page[8], describes itself as a centre of excellence for patient care and training. The hospital expanded from a single hospital to a multi-complex, including Old Mulago Hospital, Mulago Women's Referral Hospital, Mulago National Specialized Hospital, Uganda Cancer Institute, Infectious Diseases Institute and Uganda Heart Institute (MOH, 2022). Participants discussed this history within the organization and their experience through many of the iterations of the hospital:

> *I had been part of the obstetrics and gynecology department in the old Mulago before it was also specialized and then we were divided…From there we went to Kawempe, which is now a national referral because then it was specifically for obstetrics. At that point about 2014-2016 it was basically obstetrics, so we shifted from there as a department (Clinical_ Staff 1_38)*

[8] https://mulagohospital.go.ug/Our_History

Having undergone multiple renovations, Mulago Hospital was no stranger to reinventing itself, favouring the development of a new women's specialized hospital and implementation of the ART department. However, the complexity of the organization also led to communication challenges highlighted in the *networks and communications* construct.

Referral System. MWH operated through two systems, mainly through a hospital referral system and a self-referred system. Participants reported that patients were able to access services via referral through the public health system from regional and health center level facilities, private hospitals or through walk-ins. An administrative participant described the focus of the referral system:

> *The referral to the specialized women's hospital would be mainly from the national referral hospitals…Our focus was that referrals can be from any of those regional referrals…Basically because the regional hospitals have some specialists as well but what they are lacking is the equipment. So, they can do the preliminary assessment and then referral to us. But, also, we can get referrals from private hospitals, private not for profit that are at a level of tertiary care (Hospital_Admin 2_199)*

This system was beneficial in ensuring that patients from around the country could be guided in accessing services at MWH without discrimination.

Staff Transfers. The practice of transferring staff within public hospitals in Uganda between departments, hospitals and geographical locations created team instability that affects continuity of care, retention of specialized knowledge and overall quality of care. Shifting was most commonly seen with non-physician clinicians (nurses and laboratory staff) and participants perceived this practice as unfavourable towards retention of specialist knowledge, and therefore disadvantageous to implementation of LCIVF initiatives. It was reported that previously trained staff were lost to different departments and this was exacerbated by a delayed start of IVF services, creating staffing disparities. While this is further elaborated upon in the *available resources* construct, one clinical participant revealed how routine staff reassignment in the public sector and delayed start of the IVF unit led to losses of trained talent over time:

> *…. I have experienced this in the nursing area, you identify somebody, she goes for training, has interest in that area and with experience and skills, then you find again someone has been changed to another unit, with different things all together...In other words, you are creating another team and you begin afresh. So continuity is very important to continue updating the same people. You know when something takes so long people start getting diverted. (Clinical_Staff 6_279)*

Limited Autonomy. The inability to make decisions as a department as quickly as possible was cited as a concern for participants. Under the immediate management of Mulago Hospital and more broadly, the MoH, participants reported decision making limitations and delays as an obstacle to successful implementation of affordable fertility services. The department had no authority to control resources based on the demand, which hampered implementation efforts. For instance, absence of control halted the hospital's ability to set prices for services, make hiring decisions, procure equipment and adequately remunerate staff. A clinical participant reflected on the impact of lack of autonomy on the department's procurement processes and staff remuneration:

What didn't work well, initially, was this women's hospital was going to be administratively part of the Mulago Hospital…These are either autonomous or semi-autonomous; they ultimately became autonomous of Mulago. So, a place like the reproductive medicine needs to be autonomous or semi- autonomous from even the women's hospital so that the decisions are made there and then and it is given a lee way on government procedures of procurement……Because the culture media is [finished], you have collected more eggs than you had anticipated, you need culture media now and it cannot wait. (Clinical_ Staff 3_181)

He further highlights similar difficulties observed in public organizations:

…we have other examples like the Cancer institute and the Heart institute…They were also having challenges on how you control the resources to be able to renumerate the staff that are there. You want to set the fees for ART but then parliament says no, this is a government institution…without really knowing what goes in and what you are getting. (Clinical_ Staff 3_210)

The impact on staff remuneration is described in greater detail in the discussion of the *organizational incentives* construct. Furthermore, procurement of medical supplies through the central entity namely, National Medical Stores (NMS) presented additional bottlenecks. This obstacle is elaborated upon in the *compatibility* construct. Overall, this construct revealed variability of factors facilitating and hindering implementation of LCIVF initiatives. Connections existed between the organization's *structural characteristics* and *compatibility, available resources, individual identification with organization* and *organizational incentives* constructs as presented respectively.

Networks and Communications

The *Network and Communications* construct considers the nature and quality of formal and informal communications within an organization on implementation efforts (Damschroder et al., 2009). The quality of relationships, internal bonding, shared vision and information describes the organization's social capital and influences implementation outcomes (Damschroder et al., 2009; Greenhalgh et al., 2004; Safran, Miller and Beckman, 2006).

Monthly Departmental Meetings. Clinical participants reflected fondly on their bond as a department that often-facilitated speedy actions during implementation. The clinical team met on a monthly basis to discuss matters pertaining to the department as a whole. The goals of the meetings were to go over any challenges and offer recommendations. One participant described the inclusivity in the meetings in facilitating team cohesion and accountability to top management:

We do it on a monthly basis, not just centered on the IVF but on the other activities within the department and we remind ourselves that we will keep pressurizing the authorities [to see that we start IVF]....The whole team right up to the nurses everyone is brought on board because we must move together and then we give reports to the authorities, to the administrator that this is what we discussed , this is where we are, this is what we are still wondering about (Clinical_ Staff 1_522)

Communication with Top Management. Participants exercised caution in their correspondences with top management (hospital & government) and reported experiencing instances of powerlessness, ultimately hindering implementation efforts to provide LCIVF services at the clinical level. The department had not yet started offering IVF services at the time of the interviews and a few clinicians reported multiple attempts to remind or provide information to management on how to move forward but with no success. Some participants revealed instances in which top management did not listen to the team:

> *I wrote and I told those people …at the end of the day it looks like what I wrote remained on their emails...No one responded to me about the things that I clearly pointed out (Clinical_ Staff 5_193)*

In another instance, the clinical team's recommendations to undergo training locally were rejected by decision makers. One participant recalled these discussions saying:

> *We wonder because they had suggested a certain facility, the one we could go to because there are a number of these gynecologists who are doing IVF practice in Uganda, they had suggested some facilities because for them they went there, they trained and they were practicing but the people who were organizing this refused, they said they had got the better one in Fortis so they took us there (Clinical_Staff 8_108)*

Communication with Building Contractor. Poor communication and misunderstandings with management and the building contractors also led to construction errors. Participants shared the recommendations to undergo a turnkey IVF process to overcome construction challenges that were rejected by management. Furthermore, management engaged an external consultant during construction of the IVF department who was perceived to not be competent enough by the department. To engage the construction team, there were reports that the contractor listened primarily to the project lead or director and as a department, they were not able to have their voices heard. One participant echoed these communication difficulties during construction stating:

> *They [contractors] heard a lab and we were telling them, no, this is a whole complex, an IVF Lab is a different thing, we have an IVF theatre, this is a different thing and we had to go back with the architect, with the consultant and there are some of the problems that persisted in the hospital lab. Sometimes they show you that they understand it, this is their job but they may not actually understand and it is so difficult to change it anything now, it has a lot of implications (Clinical_ Staff 3_88)*

The implications for training outcomes will be further discussed in the *available resources* construct.

Interorganizational Discord. The implementation process involved multiple agencies that brought together diverse expertise that facilitated the implementation process as outlined in the *cosmopolitanism* construct. By and large, participants reported positive engagement with the various organizations in the early stages of implementation. However, further along in the process, institutional boundaries and power dynamics increasingly affected the level of engagement and slowed down the implementation process. In particular, blurred lines between staff associated with the teaching institution (Makerere University) and those who practised at the government hospital (MWH) became more evident:

Yes, at the beginning, it [the partnership] worked very well because all these people had been involved but when this confusion started, saying you are Makerere, you are a different institution, people lost morale…for some time, for a whole year, while other sections were opening, the IVF section was not running, so people got scattered (Clinical _Staff 4_437)

Another participant similarly cited emergence of internal disputes that led to them to step away:

Anyway, to cut the long story short, at the end of the day our suggestions were ignored. Things that happen in these types of facilities, people start saying that maybe this person doesn't have to be there...they are from Makerere University, they started fighting…because I know a lot of problems are going to come out of that (Clinical_ Staff 5_110)

The *networks and communications* construct presented mixed evidence of factors influencing the implementation process and outcomes.

Culture

The *culture* of an organization can affect staff working conditions, which in turn impacts quality of care (Gershon, Stone, Bakken & Larson, 2004). By definition, culture comprises the values, norms and underlying presumptions inherent in an organization; factors that are often intangible and best measured through qualitative inquiry (Hemmelgarn, Glisson & Dukes, 2001; Schein, 1992). When speaking about the way "things work", participants talked about a bureaucratic culture and "a not caring attitude" within the public hospitals and health system as impediments to implementation of LCIVF initiatives.

Bureaucracy. Participants reported on the bureaucratic nature of the public system as a limiting factor where decisions needed to be made quickly. The consensus was that "things of government take forever". In particular, challenges associated with who makes decisions, lack of clarity on the long chain of command and multiple interests led to delays, frustration or a complete halt of the implementation process. One participant highlighted the influence of bureaucracy on implementation saying:

The bureaucracies you can't believe...Because you know sometimes, I am a practical person, I don't want to waste time so if I know you are the head of the department, I want to deal directly with you to move. So when I deal with the Head of the department then [laughs] may be another [leader] begins saying, why don't you pass through me? But why should I pass through you? So let me just say the bureaucracies slowed down the process (Govt_Official 1_105)

Poor Work Culture. Likewise, participants described a culture of lateness in the public health sector. A participant highlighted the impact of this on the IVF treatment:

…but now they are comfortable, they do what they do, of course late coming is a chronic issue here…and so on happens when we start talking about the IVF or fertility where certain things are timed that can be a very detrimental (Clinical_ Staff 2_267)

Some participants also cited poor culture of work in public hospitals as a potential barrier to implementation considering the time-sensitive nature of LCIVF treatment and efficiency of care. One participant expressed concerns over mentalities in the public sector that hindered provision of quality fertility services:

> *I have seen the way we work; I mean you have to push some people sometimes which does not work in IVF. Yes, and certain people are used to certain mode of work, they know that even if I have not gone to work, my salary will come but then you have a mother whom you have started [cycle] (Clinical_Staff 8_217)*

Therefore, the culture of MWH was considered to be a barrier to implementation of LCIVF initiatives. There were connections between this construct and *networks and communications* construct.

Implementation Climate

Implementation Climate refers to an organization's permeability towards change, mutual interest of individuals involved towards the innovation (Greenhalgh et al; 2004), and the degree to which it is promoted and rewarded by the organization (Klein & Sorra, 1996). All the major sub-themes of this domain influenced the implementation climate namely, *tension for change*, *compatibility*, *relative priority, goals and feedback* and *learning climate*.

Tension for change

Tension to change is the extent to which stakeholders regard the current situation as unbearable or in need of change (Greenhalgh et al; 2004). It also suggests that the level of satisfaction experienced by individuals involved is likely to positively influence implementation (Gustafson et al., 2003)

Hospital Decongestion. Paradoxically, the impetus of MWH was in response to high patient volumes and deliveries in the maternity ward at Mulago (the old hospital). The facility experienced gross overcrowding and unbearable patient conditions that compelled actions to alleviate them. The volumes seen at the hospital were described by an administrative participant saying:

> *What I need to mention is that before construction of this hospital, Mulago was seeing the highest number of deliveries in the world. At about 40,000 deliveries and plus per annum, that is phenomenal. There was no other single hospital delivering as many as we were doing. So inevitably this of course had brought us a lot of challenges of overcrowding, issues of unhygienic environment because of the crowds, missed opportunities because of numbers, delays in service delivery because of numbers and all these were packaged to say we need to improve the service (Hospital_Admin 2_75)*

He continues to outline the Ministry of Health rationale for implementation:

> *The general framework mission was decongesting Mulago National Hospital because previously in the year 2010, Mulago had been grossly, grossly overcrowded. And the Ministry of Health came up with a project to decongest Mulago National referral Hospital. (Hospital_Admin 2_30)*

Participants reported poor patient conditions that included a lack of space, mothers delivering on the floor as only one floor was assigned to the maternity ward. Thus, there was a need for a fully-fledged hospital to support demands for space. Furthermore, parliamentarians (particularly female ministers) visited the hospital and were able to see the dire hospital conditions as described by a clinical participant:

> *And we got a visit from members of parliament, especially female members of parliament, and they saw our pain and saw the pain of mothers of the nation on the floor and they went back, pushed in the parliament for ultimately getting the whole idea of having a women's hospital to be created. (Clinical_ Staff 3_64)*

Stark Statistics on Infertility. The statistics on infertility rates played a vital role in convincing stakeholders on the gravity of the issue. One participant revealed how statistical figures on infertility that shocked management into action:

> *You know all these things are about leadership and advocacy…we presented to the hospital management [infertility] figures…when we showed them, they said goodness, these are mind boggling figures! Then, the whole thing started, the director took it up, senior management started talking about it so infertility…you know how big the problem is (Hospital _Doctor 4_343)*

Furthermore, another participant highlighted the misleading nature of fertility statistics in concealing infertility rates:

> *….As a national referral, you have a hospital grappling with numbers and deliveries so the question then would be how do you justify [fertility services]?...when we calculate the TFR [total fertility rate], we take the average number, including those that have been unfortunate to have children. So why should they be part of the statistics when they don't even have a child? We felt that we could have a duo approach looking at mothers….we assist those who are unable to have children to at least have a child or two but can we also look at the other side…to intensify our effort in family planning so that we also cut numbers. (Hospital_Admin 2_214)*

Prioritization of Fertility Patients. Correspondingly, high delivery volumes in the reproductive ward brought about neglect of persons seeking fertility services. The reproductive department was overwhelmed by deliveries obscuring needs of those who could not conceive in the first place. Therefore, a separate ART department would alleviate this barrier. One participant reported on implications of shared spaces in the general maternity ward on fertility care:

> *If you were to go for your IVF procedure and then the theatre is occupied, and you have hours which are being calculated, then that [IVF] cycle is lost and then a cycle costs so much to restart (Clinical_ Staff 2_270)*

This construct facilitated implementation of LCIVF initiatives with linkages to the *access to knowledge* and *patient needs and resources.*

<u>Compatibility</u>

The "compatibility" of the intervention is the degree to which it fits into existing processes and systems, individuals' norms and values (Greenhalgh et al., 2004; Klein and Sorra, 1996).

Speciality Subdivisions. Prior to implementation of LCIVF initiatives, the Obstetrics and Gynecology department (as it was known then) had already reorganized itself into specialized teams namely, reproductive medicine & family planning, gynecological oncology, urogynecology, maternal & fetal medicine and community reproductive health. The vision behind this move was to become a "Center of Reproductive Health Excellence in Africa". The pre-existing specialist departments reportedly aided compatibility into specialties at the newly constructed MWH facilitating implementation. A clinical participant highlights this process saying:

> *And about 15 or so years ago with Prof. Florence Mirembe and others we started saying we needed to develop the department and have the subspecialties, gynecologic oncology, reproductive medicine, infertility, urogynecology and fetal maternal medicine…So about 4 years and so before breaking ground for the women's hospital, we had already re- arranged our department into subdivisions. Even in the old space, we had already made 5 subdivisions [sub-specialities] (Clinical_ Staff 3_26)*

Centralized Procurement Processes. The existing centralized process of procurement was noted by participants as a hindrance to implementation. Current procurement processes are done by the National Medical Stores (NMS), a government entity that supplies all public hospitals. However, this centralized process reportedly caused equipment delays for about two years. Furthermore, the NMS primarily provided supplies based on an "essential medicines" list. IVF related drugs were not on this list posing potential barriers to procurement. One administrative participant revealed challenges with NMS ability to provide ART related supplies:

> *Yes, especially in relation to our own procurement system because the government prefers that all supplies, medicines, and pharmaceuticals are procured from National Medical Stores (NMS). Now NMS has an essential list, they mainly procure drugs that are part of the essential services, basic supplies. So, when you talk about supplies for reproductive technology, then it becomes a challenge. They don't have them on their supply list. (Hospital_Admin 2_292)*

Furthermore, while participants appreciated the centralized system for the procurement in enforcing accountability; it presented delays to quick decision making due to the notable bureaucracy. This was perceived to be a major limitation for time-sensitive IVF treatments that may require emergency procurements. The history of NMS also fed into concerns over the department's ability to manage sensitive procurements in IVF treatment. One participant expressed his lack of confidence in the procurement entity to manage IVF supplies:

> *Given the history of [NMS] and the challenges we have been going through, simple things as simple as this, procuring IVF media that has a short shelf life and you may need that constant supply; I doubt whether NMS can manage. This cycle they can give you and next cycle, they don't. And you can't ask because there is politics. So, the issue of supplies is very tricky. We have always talked about it in meetings (Clinical_Staff 8_248)*

In proposing a solution for this limitation, participants recommended a separate procurement account for the IVF department under hospital management. This would facilitate a greater level of autonomy to make quick decisions that aid service provision.

Non-Interoperability of IVF Equipment. Participants identified a broader challenge of few suppliers of IVF equipment globally and its impact on compatibility with the hospital's existing equipment. Furthermore, a lack of supplier options resulted in an inability to negotiate and source affordably. One participant highlighted how this barrier affected the procurement and operations processes:

> *And the source of these items is also limited, there are issues of compatibility with the equipment that is already installed. You want to procure from this point, but they are not compatible with the equipment because there are still very few manufacturers in the world because of the numbers, there is a limitation in terms of the usage of many consumables. (Hospital_Admin 2_294)*

Centralized Recruitment System. Government hospitals employed staff centrally through the Ministry of Public Service (MoPS). However, the role of an embryologist was non-exist in the staffing structure prior to implementation which presented hiring challenges. One participant revealed limitations experienced bringing an embryologist into the clinical team saying:

> *But this is a position that never was, there was never a position in the structure…Because there was never any reproductive medicine…But the embryologist was never there, so you have to have a decision made at the highest [office] to be able to create positions, to be able to recruit for those positions and it is not something that is going to be managed at the hospital level. It is going to be managed at the level of public service, finance, and the Ministry of health. So, we have had challenges of having an embryologist or two on the staff and that is absolutely a limiting factor (Clinical_ Staff 3_143)*

Furthermore, participants called for the need for autonomy to expeditiously hire dedicated staff who were competent and fire those who did not meet IVF standards of practice. The quality of the team was said to be a mediating factor in successful implementation of LCIVF initiatives, therefore this factor caused bottlenecks as described by a clinical participant:

> *Being a government facility, it doesn't belong to anyone and these are the bottlenecks…you might not be able to choose the team you are going to work with. You have to work with who is given to you…If you are stuck with someone who is not doing the right thing and you have to follow through the process of getting that person out you are doomed. Someone blunders, for example, the consent processes of a patient, you are in trouble. No consent has been done patient has gone through probably positive or negative outcome. This is a very sensitive area and so you have to have a very dedicated team. (Clinical_ Staff 5_392)*

Centralized Reimbursement. Furthermore, the MoF was in charge of payment of public servants' salaries including MWH staff. Participants revealed this centralized process as disadvantageous to incentivizing and motivating staff in their work, which is of much importance when offering IVF services. One clinical participant speaks to this dilemma saying:

> *But how can you motivate them if you have no control? If you collect fees and then they are banked on the consolidated fund and you have these staff here who are committed and sometimes, if the injection need to be given at midnight, the person must be there to give the injection at midnight so that the egg collection takes place at the right time…And they were also having challenges on how you control resources to be able to remunerate the staff that are there (Clinical_ Staff 3_191)*

This hindrance is covered in more detail in the *organizational incentives* construct.

Staff Rotations. The rotation of clinical staff on duty within the department was also perceived as a hindrance to workflow, accountability and quality of work given varied levels of expertise. A participant shares the implications of this practice on IVF outcomes:

> *It is a public facility, whoever is on duty that day will do the transfer. And we have different dexterity in whatever we do. I might get very good oocytes; someone comes to do the transfer and messes it up. The whole catheter comes with blood that is a negative. I am under no obligation to do everything for you, it is a public facility, so I don't have to follow you through your tune. So, you come and ask me, doctor what happened? When I am now the one who is giving you the tests, I say I don't [what happened] (Clinical_ Staff 5_256)*

Furthermore, the participant drew upon comparisons from South Africa to highlight the impact of staff changes on quality of fertility services in the public hospitals.

> *So, it [low-cost IVF] is going to be a very big challenge. South Africa I know has tried it in a public facility, still the same things, very cheaper than the private one but they have lower pregnancy rate because of the same thing, different people [involved] (Clinical_ Staff 5_273)*

There was a combination of facilitators and barriers to implementation in this construct.

<u>Relative Priority</u>

The *relative priority* is described as the shared perception by individuals of how important the intervention and its implementation within the organization (Feldstein & Glasgow, 2008; Klein, 1996; Klein & Sorra, 2001). A majority of the participants spoke on the urgency for fertility services in the public hospital citing high demand, private sector costs and the role of government in improving access to affordable reproductive services.

Global Trend towards Specialization. Participants reported on the impact of global trends towards specialization of health facilitating implementation of LCIVF initiatives. One participant described the rationale behind the department's reorganization:

> *So, it was running every Friday, we saw infertility patients just as general doctors, general obstetricians and gynecologists but over time about 2009/2010 discussions really started to form a sub-specialization. Because a lot of people got a number of skill sets for particular areas for example urogynecology…in fistula management and then oncology…And so we thought that it*

would be important that we follow the trends which were happening worldwide to go into sub specializations (Clinical_ Staff 5_24)

Government Social Contract. Participants emphasized the importance of the government in providing all services including ART. An administrative participant echoed the role of the GoU in providing citizens affordable healthcare options including IVF, albeit resource limitations that exist.

We were looking at what we can provide in terms of a social contract agreed with the citizenry to provide. Now these reproductive services are not part of the basic healthcare but that is not to say government does not recognize the need for the service because of the limitations of funding (Hospital_Admin 2_229)

Patient Demographics. Participants often reported that type of patients that normally came to their hospitals were of low economic status who expected more affordable options, facilitating implementation of LCIVF services. One participant described patients who typically come to public hospitals as those generally seeking more affordable options saying:

You see most of the patients that come here for fertility issues, they are running away from high charges from the private sector (Hospital_Admin 1_154)

Participants therefore made the argument that there were many people seeking services in the private sector who could not afford, and it was the role of government facilities to meet this need.

Pool of Specialists. Participants recognized the advantageous position of the government hospital with its access to a pool of physician specialists as an implementation facilitator. One participant reported benefits of implementation in MWH:

Mulago is very well placed to provide a very good service. It has a very big basket to pick from on a number of specialists who are knowledgeable about obstetrics and gynecology as well as assisted reproduction. They have a facility for high-risk maternity services which are likely to come from the people who are having ART. So, there was quite a lot of support. (Clinical_ Staff 5_348)

Model Service. One clinical participant articulated the importance of implementation of LCIVF services at the national referral hospital as a model to the government for regional facilities.

….We want to use this as sort of a model. We want to show, not prove to the government, but just show that this can work and therefore if we can use this as a training ground for the government to be convinced that at least regional hospitals, the ones at regional level can be able to offer this specialized service. Maybe not highly specialized but at least there are some basics that can be done at regional level before someone is sent to this as a national referral. (Clinical_ Staff 1_173)

This construct determinately facilitated implementation of LCIVF initiatives and presented connections to understanding of *patient needs and resources* and *available resources*.

Organizational Incentives and Rewards

This construct represents external incentives that influence organizational members' inclination to implement an innovation, and include factors such as goal setting, performance reviews, salary raise, praise and promotions (Klein and Sorra, 2001; Helfrich, Weiner, McKinney & Miasian, 2007).

Career Enhancement. Participants purported opportunities for further training and career development as incentives for implementation of LCIVF initiatives. Clinicians were keen on advancing their knowledge and specializing. An administrative participant shared appeal of the public sector for career benefits and development opportunities:

> *So, the public [sector] attracts the most skilled manpower and there are many reasons, the pay, other opportunities for example, opportunities to teach, enhance your career, get government benefits like leave and so on. So, you will find that public facilities on one hand will have that advantage over the private. As as a matter of fact, you will find that even in private, when you look at numbers [infertile patients], eventually you can't cope with the numbers in government because the cost is high (Hospital_Admin 2_264)*

However, non-physician participants emphasized the need for documented evidence of specialization (i.e. certification) over and above acquiring skills, particularly for nurses and allied health workers. One participant voiced the importance of training certification as proof of career progression and specialization:

> *I looked at the Heart Institute, they identified colleagues…they took them for training for more than the period we went for…then they qualified to be given a certificate that one called a speciality…like an incentive for the team.*

This respondent further emphasized:

> *It is very important because without a paper [certificate] you will be asked…now, this hospital is specialized, what have you specialized in? Someone can ask if you have a paper for proof as a specialist? Apart from the knowledge and the skills you have acquired of course and [if you don't have certification] that can put you off. (Clinical_Staff 6_294)*

Nonexistent Salary Incentives. Participants revealed an absence of financial incentives as a limitation towards staff morale, retention and quality of care in the public sector. One participant reported observations concerning lack of incentives with the organization:

> *Currently, there is no incentive that is going on rather than making sure the facility is there and a few people have been identified to run the facility but for now as far as I know I don't see any incentive to work there (Clinical_ Staff 5_382)*

The discussion of incentivization considering higher treatment costs associated with fertility services compared to other services. One participant narrates negative implications of knowledge on how much patients pay for treatment affected salary expectations and motivation:

One of the challenges we have met, personally I see much as I come to work every day, is motivation of staff. It is tricky because IVF is very expensive; people are coming and they have now worked on this person who paid this much….but they only get on their account or see their normal salary what they used to get even before going into [IVF] …motivation is important because I have already seen it happening patients are paying here….staff always ask me; I see mothers consultations 50,000 [shillings] pay day, I see 10, tomorrow I see 20 but on my account, I don't see anything [more] apart from my salary. (Clinical_Staff 8_223)

Goals and Feedback

The *goals and feedback* construct examines the degree to which goals are clearly communicated and feedback is provided to staff in alignment with the stated goals (Kochevar & Yano, 2006).

Performance Reviews. Monitoring of the implementation process was conducted through multiple mechanisms including financial audits, monitoring reports and board updates. The project management unit underwent auditing and monitoring as per the Ministry of Health project accounting guidelines and the Islamic Development Bank terms and conditions for funding (Office of Auditor General Report, 2015). Audit findings were made publicly available and reported project background, progress and recommendations for actions. In a 2015 audit report, the main findings highlighted delays in civil works including procurement activities. Additional detail on implementation findings were provided in the *execution* construct. Regular annual and bi-annual monitoring reports were conducted internally by the MoH outlining performance measurements against hospital objectives. Furthermore, hospital management reported to the Board of Directors on performance and on-going challenges faced.

Learning Climate

This construct describes the ability of organizational leaders to recognize their own deficiencies and readily engage team members for input (Kochevar & Yano, 2006). Furthermore, team members feel mentally safe and valued in their contributions to be able to contribute freely (Nembhard & Edmonson, 2006). The degree to which participants felt comfortable in sharing their opinions varied depending on their status relative to the leaders.

Shifting Learning Climate. Earlier in the implementation process, participants reported a positive learning climate, feeling valuable and psychologically safe to make contributions attributable to the strong political leadership support and advocacy from the then MoH - Dr Sarah Opendi. One participant described her leadership through the willingness to listen:

We had a State Minister of Health, unfortunately she was transferred to another ministry but while she was a minister, she wanted this to start. Unfortunately, we did not start but she was on it…because she could listen to what we said and I mean she wanted this to start. (Clinical_Staff 8_320)

These sentiments were echoed by another participant:

I will really point out there was one [individual], she was changed from the Ministry of Health, the former Minister of State, Hon Opendi…she was a very key advocate, she understood us, she understood our background, she understood where we were coming, she was very very pushy. And we actually lost out that is the truth, so she is one of the biggest tools that we had. (Clinical_ Staff 1_568)

In absence of Dr Opendi, participants reported instances in which their feedback was solicited but ignored or rejected. One participant, in particular, pointed out that individuals whose opinions went against "the institution" run the risk of being branded as anti-government:

Because I gave them my suggestions, they ignored them…If you suggest something contrary to what the establishment thinks then you are anti-government. You see that type of thing, so people start looking at you [as someone who is anti-government] (Clinical_ Staff 5_170)

This construct draws connections from the *leadership engagement*, *structural characteristics*, *culture* and *network and communications* constructs, highlighting both facilitating and impeding factors to successful implementation.

Readiness to Implement

Leadership Engagement

This construct is defined by commitment, engagement and answerability leaders and managerial staff within the organization to implement an innovation (Klein, Conn & Sorra, 2001; Lukas et al., 2007). Lucas and colleagues (2007) posit that top leadership commitment is vital to organizational change but should comprise of all levels.

Fluctuation in Political Engagement. MWH had strong leadership support for the implementation of fertility services from the top by then, the MoH, Project Implementation Committee, Head of Obstetrics and Gynecology department and frontline clinicians. A majority of the participants described the critical role played by The Minister of Health then, who acted as a champion for the initiative. During her time as Minister, Dr Opendi showed unwavering commitment to the successful implementation, pushing the team as one participant affirms:

So at the time, having the Minister Opendi,..gave a very significant push… She was fighting to make sure that the facility starts saying "I want you guys to start next month". And that is what we have always wanted, someone to push and let's start. I will shoulder you; I will deal with any repercussions that come. You need to have some political backing from someone who says you know what, the back will rest on me...Anything that happens, you guys do and I will answer. You need that type of person to stand in for you and she was a person who could do that. Who could tell you guys do this, I will have you back (Clinical_ Staff 5_449)

However, the reassignment of Dr. Opendi midway through implementation presented challenges. Participants reported a lack of political engagement in the later stages of implementation which affected progress. A clinical participant reported on the new leadership's disinterested in IVF:

> *I don't think IVF is receiving a lot of attention even now from the ministers. I interact with them a lot, I have meetings and I have not heard anyone talking about infertility. Dr. Opendi who would have been talking about it, they transferred her from Ministry of Health…The new one, that one has totally different priorities (laughs) (Clinical _Staff 4_324)*

Therefore, this loss of political championship towards the end, impeded implementation efforts.

Departmental Engagement. Participants within the department spoke positively regarding on-going support and engagement from their departmental heads. The first female Head of the Obstetric and Gynecological department, Professor Florence Mirembe, avidly led efforts that garnered enough support from political leadership and clinicians alike to set up the first hospital in the country dedicated to women. Her leadership played an unquestionable role in the successful funding of this new project and establishment of the ART unit.

> *Eventually they got the money, I think they got a grant or loan and when they took it up in parliament it went through and of course immediately they are calling me, Florence we have won you have won what? You know our hospital [laughs] and I was happy (Clinical_ Staff 2_142)*

Furthermore, the head of department's successors were also praised for their leadership and willingness to support the clinical team through knowledge sharing, training and proper communication. One participant shares an experience working with the departmental leads:

> *I have observed our departmental heads as champions…because based on how they have worked with us, how we have shared the knowledge, even looking for funds for our training, even communicating with outside people about our accommodation. They have been supportive (Clinical_Staff 6_421)*

The leadership was said to not only be committed to the department's team but also to the patients.

> *..like the team of doctors we are working with; I have seen them also committed to their work, to the clients even when they are talking to them, they give them time, even allow them to share their telephone numbers to answer their questions. (Clinical_Staff 6_228)*

This construct highlights a significant influence of political and hospital leadership engagement early on in facilitating implementation progress. While departmental engagement continued to be strong, diminished leadership engagement at the political level stifled progress.

Available resources

This sub-construct comprises the extent to which resources are made available for implementation including but not limited to funds, physical space, time, training and education (Lukas et al., 2007).

Financial Resource Availability. The GoU committed USD 34.14 million towards development of MWH to diversify and improve quality of services via specialized maternal and neonatal healthcare services (Health Sector Semi-Annual Report YR, 2019-20). According the Mulago Specialist Policy Brief (2012), these funds were to be allocated to three components: i) improvement of access to specialized healthcare (civil works, provision of medical equipment and furniture, non-medical furniture and support for Hospital Health Management Information Systems [HHMIS]); ii) improvement of quality of services (specialized training and revision of hospital clinical management protocols); and iii) support to project management (consultancy services, project management unit and project audit financing). Availability of these resources was a major driving force behind the implementation of LCIVF services given the high investment costs.

Physical Space. The hospital was built with 6 floors and dedicated a floor to the Reproductive Medicine department housing IVF related services:

> *So, I then said the women's hospital is being constructed, this is a specialized service, can we have this service [IVF] at the women's hospital. So, we dedicated a floor for that [IVF]. (Govt_Official 1_67)*

However, a clinical participant revealed the original hospital was meant to have 12 floors but was unsure what happened. Additionally, according to the MWH project brief, 25 beds were to be allocated solely for ART services (Mulago Project Brief, 2014).

Specialist Equipment. The clinical team worked alongside management and external consultants to procure high end equipment to provide fertility services. A clinical participant recalled the cost of the procurement process stating:

> *I remember, we put equipment of about USD 8M to equip that hospital but some of it probably, it was reproductive health and reproductive medicine (Clinical _Staff 4_163)*

Another administrative participant detailed the procurement process:

> *We set up a unit, we procured the necessary high end equipment to ensure that we are able to do all these services like in vitro fertilization, things like embryo transfer…we even put things like a sperm bank so the facility was well designed to cater for all that…It actually took us a significant chunk of the budget because that was among the primary focus under reproductive medicine (Hospital_Admin 2_116)*

Specialist Training. Funds were also allocated towards specialist training to acquire knowledge in providing IVF services. The fertility team (physicians, nurses, laboratory technician) was sent to India for

a month of training. Some participants reported receiving a wide range of training and expressed satisfaction with the program. A physician participant described his training experience:

> *Yes we went to train in IVF, what for about 4 weeks….for purposes of developing assisted reproductive technology in Uganda and that was around 2016…we even went to the laboratories' like the Ultra labs…embryology labs like head collection we even went to theatre…We did all those laparoscopies….it was very very beneficial. (Clinical _Staff 4_177)*

However, other participants expressed dissatisfaction with the duration and quality of training. Based on their evaluation of training requirements according to the project, the duration was deemed to be too short and the quality generic. As a super-specialized hospital, the core team that had gone for training was expected to receive enough expertise to function as nucleus from which the department would grow by training others. However, the training in India was not sufficient to meet these expectations. Non-physician participants appreciated the training but also echoed the subpar quality of training, mainly conducted by observation rather than hands-on training as was expected. One of the non-physician participant described the training's inability to meet previously understood expectations saying:

> *We were taken to some facility in India called Fortis Memorial. Yes, that training was supposed to be hands-on training. That was in the paperwork, we were told it is going to be hands-on [training] but the only disappointing thing when we reached there was the reverse; it was observations, theory in class, that was it, you don't touch. It was one month….At least if there are simulators, you would first try there then later you [touch]. But that was not the case. (Clinical_Staff 8_104)*

He goes on to note how the context chosen for training (India) was a culturally poor fit, describing how racism and the unpreparedness of the trainers impacted the quality of their training:

> *And then also the country they took us (laughs), it is a bit tricky because you cannot touch an Indian, this color of ours [black] you can't…Yes, you observe even the theory that we got somebody would come and say that now I am going to teach embryology and you see someone just gambling. Yes, somebody gambles, you even wonder, is this why I took the plane to India? Those Indians, they cheated us, there was no value for money at all (Clinical_Staff 8_157)*

Another participant echoed their disappointment in the quality and relevance of ART counseling information provided based on the local context:

> *The goal of the training in India was to see how those people handle patients for infertility…and it was mainly observation…there were very few sessions that we were given….not to practically counsel…they gave us some lectures…but I think we needed more time to get more in detail because it was all superficial….They told us that mainly they use yoga…but I have not been doing those yogas, I wasn't trained (Clinical_Staff 7_39)*

Lack of Embryologists. The clinical team did not have an embryologist on staff and was not able to start offering fertility services as a result. An embryologist was reported to be one of the most critical roles in the IVF process, making it a major deterrent as described by one participant:

> *First and foremost, one of the biggest bottlenecks currently is that the hospital does not have an embryologist…An embryologist is the person who is going to be the lead in the IVF lab and so look after the equipment to make sure that it's cleaned well. So they don't have that. Unfortunately, in the public service structure, there is no embryologist level. So that is the major issue that is still the biggest hindrance. If we get an embryologist, then we can start. (Clinical_ Staff 5_241)*

Participants also highlighted that there were no group of embryologists available locally to tap into like the fertility specialists. A clinical participant noted that the department had already identified and recommended an embryologist to management:

> *That has been our challenge. But we know the embryologist, we have said what needs to be done and we have told the people who can make that decision what needs to be done and how to get the embryologist on board. We hope that can be worked upon, but it raises issues of the personnel and the human resource (Clinical_ Staff 3_152)*

Access to information and knowledge

This construct is defined by how easy it is to access comprehensible information and knowledge about the intervention and integrate it into one's workflow (Greenhalgh et al., 2004).

Local Expertise. The clinical team had access to local, experienced fertility specialists for further training and expert guidance. This local knowledge was valuable during construction of the IVF lab and more so, in light of the limited training received prior in 2016. As one participant noted:

> *We were lucky that in the group, we already had some people practicing IVF. Gynecologists had gotten interested and they were already practicing IVF in the private sector so we could tap the knowledge from that particular aspect. (Clinical_ Staff 3_93)*

Proposal for LCIVF program in Uganda. An International Federation of Fertility Societies (IFFS) representative (Ian Cooke) put together a concept note for development of a Low-Cost IVF Unit at Mulago Hospital as a phased approach of the national programme. Components of the proposal included the need for a suitable referral system, establishment of a specialist training program at Mulago, development and staffing of an IVF laboratory (include trained clinicians, nurses, semenology and embryology technicians and counsellors), a national educational programme for the general population about relevant aspects of fertility to reduce infertility prevalence and acquaint the population with the facilities available and the routes of referral for diagnosis and treatment, and the role of government in discussing and formulating a regulatory framework suitable for Uganda. Other notable details included the invitation to WHO from the outset to aid designing of a referral system within the national health system and development of an intracytoplasmic sperm injection (ICSI) training to treat men with low sperm counts.

How-to-do IVF Guide. The senior clinical team also put together a document titled, "How to successfully run an IVF facility in a Mulago National Referral Hospital" to provide guidance on clinical protocols for submission to hospital management:

We provided a document on how we think we are going to run this facility which document we have provided to the director (Clinical_ Staff 1_272)

The document was first written in 2016 and then redrafted in 2019. Within it, the team provided background on WHO's declaration of infertility as a reproductive disease, the statistics on infertility, the role of MWH as a tertiary level hospital and university teaching hospital in provision of ART, need for internal quality control and external quality assurance programs in monitoring performance, importance of strict adherence to standard operating procedures, possible challenges and emphasized on the fact that poor quality can lead to enormous legal challenges for the hospital. The report provided a basic description of IVF processes, underscoring the importance of a strictly controlled laboratory environment. It also highlighted possible challenges for consideration including power outage and fluctuations, absence of training programs in Uganda and unreliable quality drug supply. Lastly, the report emphasized that IVF remains a costly treatment modality, despite the overwhelming need: IVF services are very costly to start and maintain and amid rampant poverty, makes it unsustainable. This challenge was termed, "…. the paradox of the typical IVF practitioner in Africa".

Equipment Usage. While high end equipment had been procured and installed, some participants expressed need for training in utilizing the new specialist equipment. Most of the equipment was supplied by third parties who themselves had limited knowledge of their use. This was further confounded by the COVID-19 pandemic that restricted travel of the manufacturers to offer training to the clinical team. A participant described the challenges with utilization of the equipment:

Before the corona pandemic, we had our equipment…but we should be trained on the equipment that was provided…But the way that I see things and the people who provided the equipment were just middlemen basically bringing in equipment. They didn't even have any idea about how to use them except us who are using them in other places (Clinical_ Staff 5_131)

This construct was a facilitator for implementation of LCIVF initiatives.

To summarize, the *inner settings* domain presented mixed evidence on factors influencing facilitating and impeding implementation of LCIVF initiatives. Constructs that facilitated implementation included a positive implementation climate, high relative priority, clear goals and feedback, access to knowledge and information. Mixed findings were seen in the structural constructs of networks and communications, available resources, compatibility, organizational incentives and readiness to implement construct. Constructs that impeded implementation included culture and learning climate.

5.4.4. Characteristics of Individuals Domain

Change at the organizational level is initiated by change at the individual level, which can influence the success of an intervention as individuals exercise their power and influence (Damschroder et al., 2009; White, 2019). This domain considers the individuals within the implementing organization; examining knowledge and beliefs on the innovation, their ability to make changes, stages of change, relation to the organization and any other personal attributes (Damschroder et al., 2009; Lukas et al., 2008). In this study,

a majority of the constructs, namely, *knowledge and beliefs* about innovation, *self-efficacy*, *individual stages of change* and *individual identification with organization* emerged from the data as influencing implementation of LCIVF initiatives.

Knowledge and Beliefs About Intervention

This construct considers the stance and value individuals place on the intervention including validity, facts, truths and principles about the intervention (Damschroder et al., 2009). In an effort to not replicate the *knowledge* of the intervention described in the *intervention characteristics* domain described earlier, I focus on the *beliefs* about the intervention.

Moral Lenses. Majority of the participants expressed strong morally driven belief in favour of the intervention and its implementation. Accordingly, provision of these services in an affordable way was cited to be important as participants presented compelling arguments based on foundations of human rights, spirituality and morality. One participant posited that the desire to have children as a God-given right, calling for provision LCIVF initiatives:

> *…..but also reproduction, the desire to achieve a pregnancy is a God given right it is not a privilege. Everyone is entitled to that, it is just that some people would say are not fortunate as many of us and therefore if there is an opportunity to assist that, to achieve that I think that would be a worthwhile cause (Clinical_ Staff 1_163)*

Cultural Belief. Culture was also used as justification for implementation of LCIVF initiatives. A clinical participant framed the value of IVF through a cultural lens:

> *But all in all, the IVF brings new quality of life and also stabilization of families. People are looking for many children, those who don't have children at all, we are talking about the inheritances in the African sense. So, it is a useful thing but those stakeholders [cultural & religious leaders] need to be engaged so that they understand the benefits (PA_Doctor 2_239)*

National Symbolism. One participant described incorporation of LCIVF services in an African hospital as symbolic. It was perceived as an opportunity to be exemplary:

> *So the hospital within Africa is probably the only one which has been built to incorporate ART within the public system…so the symbol is therefore very strong. May be many other doctors are probably saying, "don't you see in Uganda" (PA_Doctor 1_222)*

Personal Interest. Participants emphasized the importance of building IVF clinical teams based on interest in the success of the project. A keen interest in specializing on fertility care was perceived to be a strong prerequisite for employability of an individual into the team. Many of the staff recommended to the IVF department had already shown interest in this area. Interest was also considered a facilitator to retention within the department as staff turnover was a major concern in public facilities. A participant discussed the importance of hiring staff based on interest as a priority:

The service providers need to take time to identify people who are interested. Among us, the service providers….a prerequisite to giving quality services is this interest, it is very important. If it is not done this way, someone will just be there [working] for the sake…Some people even put money first saying how much will they pay me? I have heard those things and I have seen a number of them and they end up not giving quality services (Clinical_Staff 6_220)

LCIVF is not universal. Some participants also noted that LCIVF clinical protocols would not be applicable to all patient cases. As described by a clinical participant, patient factors were the main determinant in cost of care:

Almost about 70% of the cost for IVF is on medication for stimulation…So it [LCIVF] has to be very individualized, you cannot say we are going to start low cost for this place because there are people who because of their nature, age, AMH levels have to use very high levels of gonadotropins and so you don't talk about low cost for them (Clinical_ Staff 5_314)

Emotional Tax. One clinical participant noted the emotional burden of fertility as a speciality on clinicians when providing the service, particularly when one considers the high cost of treatment. When treatment was unsuccessful, patients often attributed its failure to the practitioner's skills, rather than the treatment response.

It is a very burdensome specialty… mentally taxing….it is a lot of psychology a lot of emotions in there. And so, you try to put yourself in the patient's shoes, to see what you can do...So it is emotionally draining especially when you come to aspects where you keep trying...And remember it is a very costly [service] so if you have done it and there is no success the couple says all this money [wasted]

He goes on to highlight how failure brings into question the clinicians' skill:

…it's like you are the problem…it still comes back to your skill ability being put into question (Clinical_ Staff 1_214)

Serendipity. Some participants suggested that implementation of LCIVF in MWH was to some extent happenstance. The construction of a new specialist women's hospital was said to present a timely opportunity to include the IVF services. When asked if the ART department would have been added had it not been for the construction of MWH; one participant responded by saying probably not revealing the coincidences that facilitated implementation:

No possibly not, because you see it was not receiving a lot of attention. They would not have put it up, so it was a coincidence…We were lucky that we were building the women's hospital and then women were arranged in a specialized way and for us we were ready...Yes, the Director would say concept and I would send it in about one hour…it was a good coincidence…There would be no developing an IVF department alone, no way (Hospital _Doctor 4_366)

Family Planning as a cause of Infertility. It was interesting to note that one of the administrative participants perceived causes of infertility to be associated with contraceptive use justifying the need for LCIVF initiatives.

> *Either as a result of family planning and it is not an intention that let me do family planning such that I don't get a kid, but these are effects of which we cannot prove now. So, the fact that a Ugandan or your person has fallen a victim of those effects, a discount can be offered (Hospital_Admin 1_125)*

Patient-Cost Related Response. Majority of the participants considered the anticipated reduction in treatment costs associated with implementing LCIVF initiatives of greater advantage to high cost of implementation. One participant added to this, indicating that while the cost of implementation was high, failure treatment rates were associated with the impact of high treatment costs on patients in the private sector.

> *We needed to provide something that other facilities were not offering and of course the other driver to this was that many people were going to the private sector, and it wasn't possible for them because of the high charges. And the failure rates were also very high. Failure rates being that once the [treatment] rates are high then the response becomes a challenge (Hospital_Admin 2_127-8)*

He adds:

> *Others would drop off, others will fail at the time when they are supposed to appear and so on. So, we felt as a country, as a government, we needed to help the community by putting up a service which would grossly be subsidized and then be able to help the community in terms of offering this service. So really in a nutshell that is the background of how the ART services came to be at the specialized women's hospital (Hospital_Admin 2_135)*

Self-Efficacy

Self-efficacy is described as confidence in one's own ability to accomplish the tasks needed to achieve implementation. (Bandura, 1977). The greater an individual's belief in the ability to perform actions towards successful implementation, the higher their self-efficacy (Damschroder et al., 2009).

Modest Self-efficacy. Participants reported low self-efficacy attributable to limited practical training they had received, delayed start of the IVF department and absence of an embryologist:

> *From the time we went to India [for training] in 2016, just because the service has dragged too much. Even us who went [for training], when we are to begin, we must go through training again…So I see that we are not ready (Clinical_Staff 6_486)*

Another clinical participant validated the need for updating clinical skills:

And then of course we have been looking at the human resource that is on there and enthusiastic you look across who needs further training. The clinicians who need further polishing of their skills in laparoscopy, hysteroscopy, and of course the embryo transfer, egg collection to have the skills to do that. (Clinical_ Staff 3_154)

Individual Stages of Change

Personal Initiative. Many of the clinical participants regarded themselves to be passionate, self-motivated practitioners and took personal initiative in pursuing opportunities for further training independent of any institutional support to improve their specialist skills. Almost all had expressed interest in specializing early on, prior to implementation and had either taken on further training or considered it. One participant describes his experience:

Most of this training that I got, was basically due to self-drive on my part, because one of the things is that I had a lot of affection for and passion for and so I said this is what I want to do. Unfortunately, in this part of the world, people don't believe that infertility is a problem at all. And so, when they see you are thinking about even assisting reproduction in Africa, people think well what is this person talking about? (Clinical_ Staff 5_101)

Loss of Enthusiasm. However, over time, some participants revealed that the delayed start of the IVF department demoralized staff, some of whom had moved on to other departments.

You know when something takes so long to start, people start getting diverted. So, for me I these are challenges contributing to not being ready to open (Clinical_Staff 6_503)

Identification with the Organization

This construct describes in a broad sense, an individual's perception of the organization, their relationship with it and the amount of commitment to it (Damschroder et al., 2009). Individual identification with the hospital revealed complexities as described by participants. While LCIVF initiatives were being implemented at a hospital level, the project included multiple players under the umbrella of the MoH forging diverse organizational dynamics.

Strong Service Commitment. A majority of the clinical and administrative participants had worked with the national hospital for over a decade and spoke earnestly about their service contributions. The longest serving participant had been part of the department for 41 years had since retired. Participants highlighted their working history, contributions and relationships over the years. There was a strong sense of cohesion within the clinical team that they credited for their ability to work quickly towards the implementation of LCIVF initiatives. One participant shared their service history stating:

I have worked in Mulago Hospital now this is the 19th year [laughs]...But I began from wards where this infertility was not involved…I was even at old Mulago and later alone in lower

Mulago….then I started being involved in infertility clinic….The team dynamics, I have loved it well, especially with those doctors. (Clinical_Staff 6_197)

Diminished Institutional Identity. Clinical participants spoke confidently about their role within their respective departments but were cautious of their perceived capacity at the ministerial level. Participants used terms like "a nobody" and "a small fish" when describing their positioning with the government. One participant highlights this shift saying:

My vision was to actually have a hospital, by the way, not the type we are having [paid service]…I thought we would have a hospital which would cater for all…who have difficulties to access special services….But I think nobody has your vision. When you are a small person, nobody would love your vision. Now, it is a government project [laughs] (Clinical_ Staff 2_198)

Another participant also shared his experience engaging at the government level:

Well, they involve you but you are like a small fish. If you suggest something contrary to what the establishment thinks, then you are anti-government. (Clinical_ Staff 5_144)

The characteristics of individuals construct presented mixed and inhibitory findings. Knowledge and beliefs about intervention, identification with organization and stage of change constructs revealed mixed evidence, while low levels of self-efficacy were an impediment to implementation.

5.4.5. Process Domain

The "process" domain considers how implementation takes place within an organization; either formally or informally, functioning interchangeably and categorized into four stages; *planning, engaging, executing, reflecting and evaluation* (Damschroder et al., 2009).

Planning

This is the extent to which mechanisms are developed in advance to support implementation of the intervention and their quality (Damschroder et al., 2009).

Project Implementation Plan. The GoU provided formal guidance on development of the 320-bed Specialist Women's Hospital as outlined within the Parliamentary Committee Report dated Thursday, 26 July 2012. The report detailed the overarching objectives of the project, its timeline (48-months), implementation team, training requirements, funding, project risks, oversight plans and recommendations. The major driver for this project was decongesting and improving the quality of clinical care at Mulago National Referral Hospital through access to specialised maternal and neonatal health care services, which included assisted reproductive technologies/services. According to the Health Sector Semi-Annual report FY 2019/20, the strategic objective was to increase the range and quality of super-specialized maternal and neonatal healthcare services thereby reducing referrals abroad. These activities were determined to be in alignment with the government's aspirations to develop the health sector and attain the Millennium Development Goals (MDG 5), which is to improve maternal health by the year 2015 for its citizenry. As one of the participants stated:

The general framework mission was decongesting Mulago National Hospital because previously in the year 2010, Mulago had been grossly overcrowded. And the Ministry of Health came up with a project to decongest Mulago National referral Hospital. Among the components of this project which was funded by ADB…

He breaks down the components of the project:

One was the civil works…the construction of the entire hospital mainly focusing on the specialized Maternal and Neonatal hospital…Number two was equipping it, number three was training of the specialized specialists because it was very important and number four was working and revising the clinical protocols so that we work towards getting the facility getting accredited with different organizations like ISO, JCI and others. So, our focus was to start with world class specialized wing of the hospital that would decongest Mulago (Hospital_Admin 2_62)

Formally Appointed Implementation Team. The development of a specialist women's hospital project at its conception detailed requirements of the implementation team to be established under the supervision of the Permanent Secretary of the Ministry of Health (Parliamentary Committee Report, 26 July 2012). The team would be composed of a 1) Project Coordinator, who managed the day-to-day implementation and functions of the project; 2) Project Architect; 3) Project Quantity Surveyor; 4) Project Engineer; 5) Project Accountant and 6) Procurement Specialist. Furthermore, The MoH Project Steering Committee, chaired by the Permanent Secretary of the Ministry of Health served to provide overall guidance and oversight to the project. Planned support staff included accounts assistant, senior secretary, office receptionist, security guard, office attendant and two drivers. A clinical participant described the positive engagement between the planning committee and clinical team during the implementation process:

In the planning, they really involved us a lot and it was like the department had a building construction committee so that we sit and think if you are developing a hospital, how would patients flow or where do you put theatre, where do you put what. So, people really worked hard…sat the whole weekend and do the planning for this floor, we put this, we want this, all sorts of things which used to come into our heads (Clinical_ Staff 2_153)

She further states how pleased the team was with the level of engagement:

Everybody was happy about the hospital, everybody participated. We never had issues when somebody walk up with some vision of something, they would write it and bring it up so that it is not lost we can think about it (Clinical_ Staff 2_170)

Planning Committees. One participant described discussions that took place on the many planning committees that took place involving design and procurement plans.

We sat on several committees that were necessary for the planning as well as for the procurement of the equipment. (Clinical_ Staff 5_47)

Internal Rearrangement in Sub-Specialities. The reproductive health department had already moved from general obstetrics and gynecology into sub-specialities ahead of the construction of MWH. This proactive action guided the planning process in terms of determining which specialities to include in the new facility:

> *We thought we would have some specialties. So, in 2008, that is when we started this. We had reproductive medicine and family planning, maternal fetal medicine, gynecological oncology, urogynecology, the fistula and all those prolapsed and so on, cancers (Hospital _Doctor 4_75)*

He adds:

> *So it is from this basis that we used to build that women's hospital based on this. It has got reproductive medicine section, maternal and fetal medicine, and different floors and so on (Hospital _Doctor 4_90)*

Benchmarking IVF units. When it came to planning for the IVF department specifically, the clinical team planned the layout and type of equipment based on benchmarking that had been done. One participant explained the actions taken:

> *And so, they started construction of the women's hospital. We started planning how the IVF unit is going to look like….we had benchmarked in Liverpool, seen how their IVF facility was…we stayed there for sometime about 3 months or so…So we made the plans for the ground layout of the facility, we also did all the procurements that were necessary for the equipment. (Clinical_ Staff 5_46)*

Specialist Concept. Furthermore, the clinical team developed a concept paper for the IVF department as requested by the hospital's director:

> *They [management] asked us to write a concept. We wrote a concept according to those sub specialties and I remember at that time, we were having more than 490 mothers presented with infertility in and out (Hospital _Doctor 4_103)*

Incremental Service Provision. When it came to providing IVF services, the team planned to offer services incrementally, starting with the simplest procedures and advancing into the more complicated cases. As a clinical participant quoted:

> *We were initially looking at taking it slow, starting from the basics, the simple ones that don't require in-vitro fertilization like we have always done. We are not going to discard but simple things like IUIs we want to start there and then do the actual IVF…..We want to go step by step (Clinical_ Staff 1_413-425)*

<u>Engaging</u>

The involvement of the right individuals, teams and key stakeholders throughout the implementation process is an important consideration to its success (Pronovost, Berenholtz, & Needham, 2008).

Engagement of Internal Implementation Team. The formally appointed internal implementation leaders are individuals that have been officially selected for the responsibility of implementing the intervention as part of their job (Damschroder et al., 2009).

The project implementation team was highly engaged in the planning process providing concepts and visions of what they would want to see in the newly constructed MWH. Participants perceived their role on the team as providing expertise and knowledge as salaried government employees. They provided technical guidance on concept, structural designs, fittings, procurement of equipment, development of clinical protocols and training. Participants detailed how the teams were engaged and capacity they brought to the implementation process. One participant broke down the stages of engagement:

> *It engaged Mulago hospital. So, once you engage Mulago hospital, now you go to the next level of engagement you engage the department of Obstetrics and Gynecology, then the recent reproductive medicine unit the level of engagement that side, later when we started procurement (Clinical_ Staff 3_262)*

Key Stakeholder Engagement. Participants noted that a variety of stakeholders were consulted throughout the process for feedback and recommendations. A clinical participant outlined the various stakeholders that were engaged through the implementation process:

> *Yes, this process was all engaging not only at the initial stage but even during the process especially through maternal patient organizations, lobbyists and many of these lobbyists were considered and consulted and the process continues because stakeholder consultations never ends (Hospital_Admin 2_302)*

Furthermore, consultants were engaged to provide technical knowledge during the procurement process as one participant highlighted:

> *So, we somehow started making an IVF lab and so we did some consultations here and there I spearheaded the purchase, the design and most of the things for the IVF lab (Clinical_ Staff 5_54)*

Engagement with Contractor. Arab Contractors was the civil works company that collaborated with the implementation team to construct MWH. This favourable working relationship facilitated implementation of LCIVF initiatives by accelerating construction efforts to complete within the agreed upon time and to the specifications. The company reportedly had a positive working history with the MoH, having built multiple projects including hospitals and other structures. A representative participant from the company described their engagement:

> *This was very good because our relation[ship] was very good. The cooperation was very good to achieve our mission and this is exactly what the President said, " I see that the relationship was very good and that you cooperated to achieve the work on time, the consultant, client and contractors"....Because this is very important, if you don't have a problem with me, we discuss and the work can be done well without any problems or challenges. Sure, we had problems, but we would sit together and look for the suitable solutions (Contractor_ Staff 1_42-8)*

Press Engagement. The value in engaging press/media was also highlighted given that as journalists had previously written poorly researched articles on infertility. One participant shared his efforts in intentionally engaging the media to guide them in communicating accurate facts regarding infertility and influence public education, policy and advocacy efforts:

> *We were active trying to influence policy and advocacy, whether through the media because I also formed the journalist fertility group because there is no way in which you can be able to influence articles in the media without having a specialist group dealing with fertility…So some of their articles were really very poorly researched, very poorly informed….So for me it is good…to interest the political masters in the ministry and integrate fertility care as part of reproductive care (PA_Doctor 1_199)*

Opinion Leaders. Individuals who have the ability to formally or informally shape the perceptions, beliefs and actions of others concerning implementation of an intervention are defined as *opinion leaders* (Greenhalgh, 2004). Greenhalgh and colleagues (2004) classify opinion leaders into two categories: expert opinion leaders who leverage their status and power; and peer opinion leaders who exercise their influence through representativeness and credibility. Some opinion leaders in this study also served as champions and are discussed further in the respective sub-construct. In this construct, we focus on the opinion leaders that were not sufficiently considered to the detriment of implementation efforts.

Cultural, Traditional & Religious Leaders. Participants revealed that limited engagement with cultural, religious and traditional leaders as social influencers hindered implementation efforts. These community leaders were deliberately excluded early in the implementation efforts due to the assumption that they would block progress. One clinical participant describes the rationale for not engaging these leaders in much depth during the implementation process:

> *No, of course the religious leaders, especially the Catholic Church, they say children should come normally. When you tell them that in the harvesting, you can harvest 10 eggs and use three; they say what happened to the seven? Those are lives thrown. And then, they also see that you might as well do abortions on those which you don't want. So those are their concerns but what we had decided was to first put everything in place. We consulted them earlier, but we wanted to have the bill reach a certain stage so that we can engage them on something which is much [serious]. Otherwise, they can block it in the infancy because all those MPs they go to those churches (PA_Doctor 2_231)*

As noted in the quote, many decision makers ascribed to beliefs shaped by these opinion leaders influencing their own perceptions on IVF initiatives. This lack of engagement with traditional, cultural and religious led to backlash when the ART bill was put forward in government. A government participant describes the protests that arose:

> *So we moved on with this bill amidst protests from some [people] Father [_], some ministers, politicians were saying we want to distort families because now we are saying if are unable may*

be [you can try IVF], but my message was those who had passed menopause and can't give birth, you can still get a donor with your partner and you still have a baby (Govt_Official 1_73)

She explains further:

So it was like I was distorting the family but how was I distorting [the family] because I am married to X already and the man is the head of the family. So we were into those things and we didn't progress with the Bill, but I left it there (Govt_Official 1_75)

Additionally, a patient group representative expressed concern over the absence of statements from the church concerning IVF citing that the church had not said anything regarding the right of a child born out of egg donation for instance. Therefore, the opinions of cultural, traditional and religious were purported to be vital in moving implementation efforts forward.

Champions. Individuals who devote themselves to promoting, advocating and marketing the implementation and overcome resistance are considered champions (Greenhalgh, 2004). Furthermore, a key characteristic of champions is their willingness to put their informal status and reputation on the line as because of their strong belief in the intervention (Maidique, 1980). Significant support for affordable fertility services in Uganda's national referral hospital was driven by a multiplicity of champions from the national level (government officials), grassroots (patient advocacy group), and internally (within the hospital).

Political Champions. The MoH engagement with infertility included support from the President which facilitated implementation of LCIVF initiatives at MWH. One of the most notable champions for infertility identified by the majority of participants, and as noted above, was the former MoH; Dr. Sara Opendi. As an infertility advocate, Dr. Opendi campaigned for women who experienced infertility at legislative level, in the communities and within the hospital in which implementation was to occur. Dr. Opendi rallied throughout the country talking to communities experiencing infertility women and expedited the implementation process as she shares:

So when I tried to sell the idea to my technical people in the ministry,...they didn't buy into the idea…So we agreed to start the talking [about infertility]...then I said no I think we are underestimating the problem. So…it was February 2016 when we officially launched this campaign against infertility trying to remove the stigma around infertility but also educating the people about the causes of infertility and you can't believe the responses we got thereafter. (Govt_Official 1_46)

She further adds:

So, I then said now the women's hospital is being constructed, this is a specialized service, can we have this service at the women's hospital? So, we dedicated a floor for that (Govt_Official 1_76)

Clinical participants also echoed the influence of the then MoH, Dr Opendi:

We had probably nationally; the Ministry was giving us very good support for that. We had a very good minister at that time called Opendi who was very passionate about fertility. Unfortunately, she was moved to another docket (Clinical_ Staff 5_432)

Another participant also affirmed her influence:

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I will really point out there was one…she was changed from ministry of health, the former minister of state Dr Opendi…She was a very key advocate, she understood us, she understood our background, she understood where we are coming, she was very very pushy…And we actually lost out that is the truth so she is one of the biggest tools that we had (Clinical_ Staff 1_568)

Therefore, the influence of a political champion significantly facilitated the implementation of LCIVF initiatives at MWH.

Technical champions. Within the clinical team and hospital, there were several internal advocacy efforts taking place that facilitated implementation of MWH and provision of affordable fertility services. Many of the clinical leaders championed implementation including the head of the obstetrics and gynecological department at the time (Prof. Florence Mirembe), who avidly advocated for a women's only hospital and the fertility specialist team, who provided the evidence base for the need of affordable fertility services. One clinical participant details the conception of the MWH:

And about 15 or so years ago Prof. Florence Mirembe and others started saying we needed to develop the department and have the subspecialties…So along the same time, we were pushing for the idea of a women's hospital. The women's hospital is as old as about 15 years ago, the idea (Clinical_ Staff 3_53)

Participants also praised the fertility specialists who led implementation efforts saying:

For me the time I have observed everything the champion has been Dr Mark Muyingo together with Dr Busingye…because based on how they have worked with us, how we have shared the knowledge. (Clinical_Staff 6_421)

Grassroots Champions. As noted, Joyce Fertility and Support Center (JFSC) played an important role in championing implementation of LCIVF initiatives, as a grassroot patient-led organization. JSFC rallied international support from fertility experts through its strong advocacy work with the WHO, IFFS, ESHRE and other organizations. As a result, JFSC organized the first low-cost IVF workshop in Uganda and facilitated collaboration with local practitioners to make it a reality. Furthermore, the organization was said to have brought the invisible stories of those experiencing infertility to light. One clinical participant describes the significance of JFSC:

But for her [Joyce Fertility Support Center] she even had examples of people who had gone through this who were suffering, you know the domestic violence at home and so on …So she had wanted us to form a society which later alone the idea the clinicians were not comfortable forming it (Hospital _Doctor 4_216)

Another international participant highlighted the role played by JFSC in advocating for patients' needs stating:

> *In Kampala, the real driver was the Joyce Clinic because Rita already had desks in the hospital where she would identify the patients and give them advice, but you can have professional drive as well she can't do it by herself. And I said to them that they needed to link to link strongly with her and mobilize the patient voice for popular support (Int.Org_Doctor 1_118)*

However, while organization played an intricate role during the conception of LCIVF initiatives; it was excluded from further engagement when implementation efforts launched.

Therefore, as *champions* and *innovation participants*, in that they were the beneficiaries of the intervention, JFSC was not engaged during the implementation process.

External Change Agents. These are individuals identified as external to the organization, affiliated with an outside entity who formally influence or aid intervention decisions in the preferable direction usually with technical expertise (Damschroder et al., 2009). Participants discussed four main *external change agents* namely: MERCK Foundation, World Health Organization (WHO), International Federation of Fertility Societies (IFFS) and The European Society of Human Reproduction and Embryology (ESHRE).

MERCK foundation worked alongside the MoH to bring public awareness to infertility, providing training opportunities and technical expertise during construction of MWH. The foundations' CEO, Dr Rasha Kelej, introduced the then Minister of Health to the burden of infertility in Africa, an issue she was previously unaware of. As the former MoH describes, her appointment as a Fertility Global Ambassadors for MERCK Foundation's "More than A Mother" campaign and hearing others speak of the gravity of the infertility inspired her:

> *Our focus then was really on cancer and diabetes…along the way, Dr. Rasha Kelej, who is actually the CEO MERK, told me about this challenge of infertility and her thoughts about it. I did not think of that as a problem, and I told her let me think about it but she still pushed me. She said you don't know the magnitude of the problem.*

She continues to explain:

> *I tried to consult within my ministry, but the information was scanty [laughs], nobody knew about infertility as a problem…I think the first launch in Africa was in Kenya when the member of parliament one of them who had gone through all this stigma got up to speak and then I now started appreciating the problem (Govt_Official 1_38)*

Representatives from the WHO, IFFS and ESHRE also played a major role through providing technical support from LCIVF initiatives. Professor Ian Cooke, who was a former President of the British Fertility Society and Director of Education for the IFFS worked with JFSC to facilitate a workshop of LCIVF initiatives in Africa as well as drafting a document called "The Way Forward" on how to implement LCIVF

in the public sector. One of the clinical participants spoke on the role of Prof. Cooke in introducing the concept of LCIVF:

> *So, in 2007/2008 around there…we had some discussions about low-cost IVF. There is a gentleman who I think is still alive called Professor Cooke from the UK who came in and he was really interested in starting IVF in Mulago and was talking about low-cost IVF. (Clinical_ Staff 5_279)*

However, due to slow engagement from the MoH, he lost touch with the doctors, but the idea was planted. Participants also reported another key external change agent, Dr Williem Ombelet, a fertility specialist from Belgium who advocated for LCIVF in Sub-Saharan Africa. As one participant recalls his involvement:

> *Then there was an embryologist called Willem Ombelet from Genk in Belgium and he was patiently interested in this…And he created a meeting in Arusha in Tanzania to talk about developing low cost IVF in the developing world in 2007. (Int.Org_Doctor 1_36)*

External consultants from the US and India were also brought on board to provide expert guidance on the construction of the department and provision of services.

This construct showcases the multiple players whose efforts combined, significantly facilitated the implementation of LCIVF initiatives at MWH. However, lack of engagement from cultural, traditional and opinion leaders deterred the progress of the intervention.

Execution

The *execution domain* examines the implementation of an innovation according to its predetermined plan and the implications it may have on the intended outcomes (Carroll et al., 2007; Damschroder et al., 2009). The assessment of implementation fidelity is important in discerning whether performance is a result of intervention itself or how it has been implemented (Dobson and Cook, 1980).

Civil Works Progression. Construction works were undertaken by Arab Contractors with an anticipated timeline of 48 months. The project was delivered on time, having commenced in February 2014 and officially delivered to the GoU in October 2017, altogether 44 months (MoF, 2019). While the majority of construction work for MWH carried on smoothly, there were considerable mishaps and delays in the completion of the IVF lab and department. Participants reported barriers in communication and understanding which led to further delays. In particular, the type of floors and positioning of the doorways was not done to user specifications and had to be changed. A clinical participant details the challenges during the construction of the IVF lab:

> *The construction of the women's hospital started and we had already given these ideas but we were not all exactly on the same page. When we said an IVF Lab, they heard a lab…and we said no, this is a whole complex…the IVF Lab is a different thing…we have an IVF theatre, this is a different thing and we had to go back with the architects, with the consultant and there are some of the problems that persisted they happened in the hospital Lab (Clinical_ Staff 3_83)*

Indeed, when inquiring with the contractor on whether there was a difference between an IVF lab and a conventional lab, they stated that they were the same. The contractor did emphasize the need for clear plans and designs (including bills of quantities and specifications) at conception, team corporation, quality of work, delivery window and availability of funds. Nonetheless, participants reported persistent structural challenges:

> *One of them was we could not have any drainage system above the IVF lab but above the IVF lab was the ICU, which needed many water points for washing and this was a problem they were unable to solve, they saved us of the drainage systems over the IVF labs but caused a problem in the HTU and ICU and their water points were not adequate like hand washing, they had to do some adjustments (Clinical_ Staff 3_85)*

To rectify these errors, there were fierce discussions with the contractor as a clinical participant reported, stating that, "*we were almost losing our minds but for the purpose of [respect] we decided to let it go".* However, they expressed concern over the impact of these errors on the quality of treatment and outcomes. Fortunately, as this participant described, there were some doctors already providing IVF services that were able to offer their expertise from practising in the private sector and this minimized the construction challenges experienced.

Slow Fund Release. There were budgetary increases (roughly USD $ 1 million increase) and delays in release of funds as reported by The Health Sector, Annual Budget Monitoring Report Financial Year 2018/19. One participant also noted the impact of unsteady release of funds for equipment on the department's timeline:

> *Yes, we did our part …but the funds are released in batches, in small batches…We realized that we can't do it [in bits]. We cannot do it as quickly as we want to like from the private sector (Clinical_ Staff 1_444)*

The report offered recommendations to The MoH and MFPED to prioritize payment of outstanding obligations to the contractor to avoid cost overruns and ensure that works in the IVF section are completed, equipment installed and tested in a timely manner (MoF, 2019).

Equipment Procurement. While participants were pleased with the quality of equipment procured for the IVF lab, a few participants noted considerable delays in the delivery attributable to slow release of funds, procurement processes and limited manufacturer. A clinical participant discussed the delay associated with funding delays:

> *Yes, we did our part through the procurement process of what is needed but the funds are released in small batches so we keep getting what we can get and keep them where we can keep them eventually when we have everything together, we will put ourselves together. We realized that we can't do it[in bits](Clinical_ Staff 1_440)*

The Health Sector Annual Budget Monitoring Report Financial Year 2018/19 also reported "delays in start-up of IVF procedures due late delivery and installation of some equipment". Particularly, delivery, testing and installation of equipment such as theatre tables was expected to end by September 2018, however by June 2019 supplies by Achellis and Microhem Scientific and installations were not completed (MoF, 2019).

Reflection & Evaluation

Either quantitative or qualitative feedback from stakeholders on the experience, progress and quality of implementation is captured through "*reflection and evaluation*" (Damschroder et al., 2009; Edmondson, Bohmer & Pisano, 2001). Reflections and evaluation of the implementation process was documentation through government project monitoring reports and personal reflections from interviews.

Greater Public Sensitization. A majority of the participants underscored the importance of public awareness and education to overcome the stigma associated with infertility and improve health seeking behaviour. One of the participants reports on the

> *I think people need to know a lot more about infertility. People think it is witchcraft, it is genetic, of course in some cases it is genetic, you know, there are all sorts of beliefs out there (Clinical_ Staff 2_295)*

Sustained User Engagement. Participants shared the importance of sustained engagement of end users (clinicians & patients) throughout the implementation process to achieve expectations. The omission of the fertility team during the design of IVF lab early on, led to costly mistakes that had to be changed. Department leads needed to be involved at the design stage to provide input into functional use of space, equipment, furniture and flow of traffic. Furthermore, this continued engagement was perceived to encourage teams to take ownership of their departments, feel valued as contributors and exercise their influence over the project. Participants who were disregarded midway through the implementation process expressed sadness and either distanced or detached from the process altogether.

> *Of course, I think at the beginning it would be good to involve all stakeholders. But when you have involved them then don't drop, them like fertility centre was almost dropping them (Hospital _Doctor 4_447)*

Political Champions. Many of the participants voiced the significance of political champions in the successful implementation of LCIVF initiatives in the public health sector. Throughout the implementation process, political support was perceived as essential to avoid loss of momentum and facilitate difficult discussions that would arise beyond the capacity of clinicals and hospital management at the national level. A government participant spoke to this need saying:

> *We need the government to move that process, we need somebody to take it up like I had taken it up. It was something that I wanted to see up and fully and it is one of the specialized services that is really lacking in public sector (Govt_Official 1_139)*

Engagement of Traditional, Cultural and Religious Leaders. Participants acknowledged that traditional, cultural and religious opinion leaders needed further engagement. A clinical participant indicates why would be important:

But we think we still believe that one of the biggest opinion leaders or society leaders that we still need to reach out to or we need to get to are the religious leaders and the cultural institutions, especially the culture institutions because it is the cultural institutions both the religious and cultural institutions it is still a big taboo (Clinical_ Staff 1_570)

Project Monitoring Reports. The implementation process was formally monitored and evaluated through bi-annual audit reports and recommendations documented to address challenges reported. For example, the Health Sector, Semi-Annual Budget Monitoring 2019/2020 reported implementation challenges associated with lack of comprehensive policy on fertility treatment in Uganda, limited staffing by way of the lack of an embryologist to perform IVF procedures, lack of specialized medicines and late delivery of some equipment (MoF, 2020). Therefore, recommendations provided included development of policy and guidelines on IVF and fertilization treatment to ensure effective use of the facility. The report also advised the hospital to speed up efforts to collaborate with international experts to undertake 'Training of Trainers' to enable sustainable use of the facility. Identified stakeholders were provided that needed to be engaged to support staffing gaps of critical staff to enhance performance of the hospital. And finally, the report suggested that MWH and NMS should ensure specialist medicines are balanced in both requisitions and deliveries. (MoF, 2020).

Turnkey IVF. Clinical participants reflected on their recommendation towards management in constructing the IVF department as a turnkey operation. Turnkey project is a type of venture in which the builder sells the product to the buyer as a completed and ready to use with minimal installation and setup (Turnkey, n.d.). One participant described how this model would have averted the civil works challenges encountered during implementation:

We did not manage to sell the idea of the Turnkey because it did not fall into the contractor's obligation to have a turn-key. Somebody who would do the floor for IVF, do the wall for IVF, put the equipment, set the equipment, and take you for training and come and start working. That is what we wanted but we didn't get the Turnkey type of project. It would have served us much better. (Clinical_ Staff 3_109)

Contractor Demands. Upon reflection, the building contractor appreciated the positive collaborative relationship with the implementing team. He went ahead to advise on the specific fundamentals needed to avoid construction challenges including establishing clear building designs from the start to ensure desired outcomes for all stakeholders. The contractor participant describes these basic requirements during implementation:

My process is first of all, they have to be sure they have the funds for this project because we don't want to delay waiting for the money. Second, the drawings, BOQ and all the specifications should be clear from day one because I have to price the BOQ…If the design was wrong from the beginning and…they change something without informing us before building, I don't like it…These are the items for the contractor, money and the drawings (Contractor_ Staff 1_150)

Hospital Staffing. Regarding the operations at the hospital, an evaluation by one of the clinical participant revealed that the hospital did not do well in planning for the appropriate volume of staff needed to support operations of the new facility saying:

And those problems are still there cutting across…that the human resource for this hospital as a stand-alone was not looked into…If you have a hospital of 400 beds and you move in, you need physicians…you need a psychiatrist, you need a surgeon…you need a whole fully fledged department of radiology, laboratory medicine etc. So, these were not handled, and those problems are still there (Clinical_ Staff 3_277)

Embryologist Recruitment. Furthermore**,** lack of an embryologist on the fertility team presented a major barrier to offering IVF services. Upon reflection, some participants proposed alternative ideas including outsourcing experts, contracts with external embryology groups or private-public partnerships with local private fertility clinics to loan their embryologists. One participant shared recommendations passed on to management:

So no embryologist is the major issue that is still the biggest hindrance. If we get an embryologist, then we can start. Because we had told them the other thing that we can do, they can hire someone on contract if the structure is not yet there, so that we don't have to waste time and we do a trial run to see where the problems might be and those can be rectified (Clinical_ Staff 5_249)

However, another clinical participant expressed concern regarding outsourcing services to external entities citing that the hospital may encounter risky contracts:

And these people want their numbers you must produce. They come in expecting minimum numbers. We also had discussion with some people, some Indians the same thing they expect some numbers, and you get in a very dangerous contract of their numbers and you don't fulfill the quarter, you have no contract with the people that they are going to get the money and come into the system (Clinical_ Staff 3_204)

Local Capacity. Clinical participants emphasized the importance of garnering local interest in IVF technologies through teaching it in medical schools and providing on-going practical training that is locally accessible. Specific recommendations included the introduction of IVF technologies to students early on in undergraduate medical and applied health classes as part of Reproductive Medicine. Building local capacity was seen as a viable solution to the limited expertise that often led to higher treatment fees. Furthermore, local trainers were preferred over outsourced expertise. Participants perceived training locally as more sustainable and cost-effective. They reported that continuous training would maintain quality of care relevance to local context and reduce training costs associated with travel and time spent away. One participant expressed thoughts on strengthening local capacity:

I think we have to first identify local people who are doing this work first and probably where possible, bring them on board…Much as of course there would be some conflict where some are saying I am training these people they are going to take my customers but people are many…But I see it as a simpler way to save money...less than taking a flight, air ticket, accommodation, per diem it is very costly (Clinical_Staff 8_189)

Supplementary Training. Given the delayed start of the IVF department, the team called for additional, on-going training to remain knowledgeable in this ever-evolving sector. There was a strong preference for local trainers to avoid lengthy staff absences and risk of brain drain as described by one participant:

> *The need for training is there. On the embryologist side, training is critical and then they need to have the nurses. We have already identified each of the people that we have and their training needs. This type of training is not easy, the cost, where this training takes place, how long does the training last. Does a short training really make sense?*

He continues by recommending:

> *Can we have a trainer come in and we are having training ongoing? So if one has one or two core training already, then the rest of the training can occur in-house…because we cannot have all the human resource going for a two year training process and they may not turn up again…The usual brain drain may still occur (Clinical_ Staff 3_166)*

Quality Equipment. Participants reflected positively on the quality of equipment that was procured for the department. A clinical participant described it as the best in Uganda saying:

> *We used the best companies that supply some of this equipment in the world…Mulago probably has the best equipment in Uganda currently. The process went well and most of the equipment was delivered as we had requested for. (Clinical_ Staff 5_405)*

Operational Considerations. The clinical participants through their report on 'how to successfully run an IVF department' recommended the setup of a comprehensive and reliable power back-up system including powerful UPS systems and generators.

Quality Control. Furthermore, quality management was emphasized through document control, competence testing, quality control records, equipment maintenance, inter-laboratory benchmarking, audits and accreditation.

Tax Breaks. Clinical participants acknowledged that the main expense associated with fertility treatment was the often-imported drugs and supplies that attracted high income taxes. They, therefore, called for the government to offer tax waivers as echoed by a clinical participant:

> *So, the patient's cost will be majorly on things like the drugs. The drugs of course they buy in bulk and the regulators can be able to negotiate very easily on the cost. They can do the tax waivers for example for the person bringing in drugs for Mulago so government can do quite a lot to minimize the cost for the people in Mulago (Clinical_ Staff 5_340)*

Financial Incentives. Participants emphasized the importance of ruminating highly sought-after clinical staff to support retention in the public sector and preventing outflow into the private sector. This was further justified with the understanding that IVF required more commitment in comparison to other obstetric and

gynecological specialities and staff needed to be paid well in order to do so and develop the IVF department. As a clinical recommends:

> *I have voiced some concerns about the issues of emoluments for the people who are going to work there. A bit more pay for the additional extra work they have to put into this facility. The Doctors, the nurses, the cleaners all of them have to be [incentivized] (Clinical_ Staff 5_384).*

Departmental Autonomy. There was emphasis on the importance of autonomy of the hospital and department from national level systems to address hiring, remuneration, pricing and procurement activities.

> *So that degree of managing finances needs a degree of autonomy even from the very institution that houses facilities should be able to have the staff, motivate them over and above the salaries they may be getting. So that is about the staff, training, retention and the last one is pricing. (Clinical_ Staff 3_216)*

Greater autonomy was also discussed in the relation to being able to compensate donors and surrogates from within the department. As noted, the nature of ART practice demands prompt decisions and actions with minimal bureaucratic red tape as these delays can mean failure of an entire treatment cycle.

Academic Institutions. One participant proposed that academic institutions would be better suited for implementation of LCIVF initiatives compared to public hospitals given their ability to offer alternative incentives to financial ones:

> *Actually, for me by the way when I analyzed...I think it [fertility services] can do well in an academic institution other than just a service delivery. In academia for example, many people would be trained and some of them are interested in developing careers…as they are specializing in assisted reproductive technology. It is much easier….they can be writing, doing research, publishing while developing the unit (Hospital _Doctor 4_519)*

Individuallized LCIVF Services. There was skepticism about the practicality of offering LCIVF universally in a public health system. A clinical participant put forward recommendations for an individualized approach to LCIVF stating:

> *So it [LCIVF treatment] has to be very individualized, you cannot say we are going to start low cost for this place because there are people who because of their nature, age, AMH levels have to use very high levels of gonadotropins and so you don't talk about low cost for them, you use clomid for them; they are just chicken feed you are just wasting their time (Clinical_ Staff 5_314)*

Sustainability of LCIVF services. There were also questions regarding the government's capacity to continuously fund IVF services. Participants highlighted the changing priorities of governments and the importance of considering longer term strategies that support self-reliance. In particular, some participants proposed batching of patients or a mixed model where individuals who can afford to pay, subsidize those who cannot pay for these services.

It is difficult to expect that the government is going to fund that. There are so many competing priorities the children with diarrhea are vomiting and then you have this one (Clinical_ Staff 3_221)

Another participant described the option of batching treatment cycles:

To again lower the costs we do it as a batch…We get may be 10 or so women they are done as a batch, you stimulate at the same time, you introduce the gametes at the same time so you have successes and you have failures (Clinical_ Staff 1_230)

Clinical practitioners from similar establishments in Nigeria echoed similar concerns and provided recommendation on alternative funding models:

But over the years, the challenge has been sustainability, sunken costs. Sustainability in terms of finance, because resources from the government have been dwindling, and you know, has not been so much with subsequent management. So, the IVF unit has had to adjust and develop what we call a revolving fund system, because we can't depend on the dwindling risks of financial resources, material resources from the government or from the main hospital. We have what we call a revolving funding which they are the general owning by (PBH_Doctor 1_32)

However, for some, the opportunity to run the ART unit with the proposed fees of USD $3,518 for government entities and USD $4,500 for the public (compared to the current average of USD $5,000) would generate considerable profit for MWH and support other services in the hospital.

COVID-19 Impact. The pandemic presented additional challenges as the government redirected its efforts hindering implementation of LCIVF services at the clinical level. Participants reported that the hospital was focused on COVID-related efforts including vaccination and treatment. Therefore, participants did not think it to be appropriate to revive discussions around hiring embryologists and launching fertility services. As a clinical participant highlighted, the ministry had more pressing priorities:

…the ministry has other priorities, currently the Covid 19 vaccination is the thing in the priority. So going to talk to them about starting an IVF now might not be probably one of the priority areas that they have on their schedule (Clinical_ Staff 5_264)

Another clinical colleague affirmed the impact of COVID on service provision and training:

It has really impacted IVF services because with Covid now, you cannot ask for certain things…. Until a certain number of individuals have been vaccinated, that is when we shall start again pushing because all money is being channeled to vaccines. And then also these people who provided us with the equipment they were supposed to start user training that very time when they closed the airport and said no travels (Clinical_Staff 8_323)

Disappointment. Nonetheless, participants expressed sadness and disappointment at the fact that IVF services were not offered at the hospital yet. Some even reported feeling frustration and shame that the hospital was not offering IVF services, let alone LCIVF services since its official launch in 2018. One clinical participant describes the disposition of the clinical team:

We are unhappy that we have not done even the first cycle. The first cycle needs to have the embryologist on ground, nobody should dare to do any procedure without an embryologist and a few other things (Clinical_ Staff 3_296)

Another participant was similarly disconcerted attributing the delay to multiple interests:

Yah, up to now it is not yet operational because there is a bit of a pity after like three years…So it is not easy to have it to run in these public facilities because of the different interests…(Hospital _Doctor 4_208)

A patient participant also described the lack of services as a shame:

Because it is a shame for a whole chair of the hospital to report to the parliament that we do not even have an embryologist when you started something of that nature (NGO_Patient 1_363)

Vision Evaluation. In spite of this, there was pride in the successful achievement of the vision to develop a specialist hospital focused on women and led by a woman. One participant highlighted what went well:

…but I think the vision was good at the time and we have seen how long it has taken to actually have the process up to the end…I think it is some 20 years to get the hospital running….But I think a lot of things have been done and I am happy that they are happening and secondary that is headed by a lady (Clinical_ Staff 2_331)

To conclude, the process domain presented mixed evidence regarding factors that facilitated and impeded implementation efforts. Constructs that facilitated implementation included planning, engaging formally appointed internal implementation leaders, champions and external change agents. Execution had mixed evidence. While lack of engagement of opinion leaders (traditional, religious and cultural leaders) hindered implementation of LCIVF initiatives.

5.5. Inductive Themes

Implementer Reputation. Reputation in its definition has taken on multiple interpretations. In this theme, reputation is described as the collective representations shared in the conscience of the public about an organization (Grunig and Hung, 2002), department, or individual over time. Some participants described the public reputation of Mulago as poor, with the public perceiving its services to be substandard. This undesirable reputation was considered a potential barrier to access. One participant described this obstacle citing that it could be overcome easily:

I think the perception of people…people think public things are not of quality...But over time we have been able to change that because they have seen us do certain things in this facility which initially we were not doing, so…at least for publicity that can build confidence in the public (Clinical_Staff 8_237)

Summary of Results

The results in this study were organized into deductive themes and inductive themes. The Consolidated Framework for Implementation Research guided the presentation of deductive findings into five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process. These domains were then sub-divided into thirty six out of thirty-eight themes relevant to implementation of LCIVF initiatives at MWH. The constructs that facilitated implementation efforts included *intervention adaptability* (plethora of initiatives to choose from), *trialability* (ability to pilot and publish), *cosmopolitanism* (multi-sectoral collaborations), *patient needs and resources* (demand and advocacy), *peer pressure* (increased private sector providers), *relative priority* (global trends towards specialization, government social contract, patient SES, pool of specialists available and opportunity to model service), *tension to change* (hospital decongestion, infertility statistics, patient needs prioritization), *goals and feedback* (formal performance reviews), and *planning* (project implementation plan, planning committees, benchmarking).

Constructs that revealed mixed evidence consisted of *intervention source* (internally vs externally developed), *relative advantage* (high treatment cost in private sector and limited diagnostic services versus hindrance to revenue generation associated with LCIVF), *cost* (high investment and operational costs covered by the government, free vs subsidized treatment costs, tiered treatment plans), *external policies & incentives* (international recognition of infertility as a disease, development ART bill, benchmarking, government funding versus lack of national legislation, centralized remuneration system), *structural characteristics* (longevity of organization and sufficient referral system versus staff transfer practices and limited autonomy), *networks & communications* (good departmental communication versus poor communication with top management and interorganizational discord), *compatibility* (pre-existent specialist units versus centralized procurement & employment systems, staff rotations, interoperability of equipment), *leadership engagement* (fluctuations in strong leadership), *available resources* (government funding, physical space, specialist training and procurement of equipment versus a need for embryologists), *access to knowledge & information* (availability of local expertise, how to IVF guide versus lack of technical knowledge of equipment use), *organizational incentives & rewards* (career enhancement versus lack of financial incentives), *knowledge and beliefs about intervention* (supportive moral and cultural beliefs, national symbolism, happenstance, personal interest versus LCIVF not universal and emotionally taxing), *individual stages of change* (personal initiative versus loss of enthusiasm due to delayed start), *individual identification with organization* (strong departmental commitment versus diminished institutional identity), *engaging* (formally appointed internal implementation leaders, champions, the press, patients and external change agents versus limited engagement with opinion leaders and public sensitization), *executing* and *reflection & evaluation*.

Barriers to implementation constructs included *evidence strength & quality of intervention* (limited clinical evidence), *complexity* (highly specialized requirements, rapidly evolving LCIVF initiatives, elevated risk of clinical error), *organizational culture* (bureaucracy, absenteeism, and lateness), *learning climate* (fluctuations in leadership support) and low levels of *self-efficacy*. *Design quality & package* and *other personal attributes* constructs did not reveal any findings.

An inductive theme that emerged from the data was *implementer reputation*, which was a barrier to implementation. A summary of main categories, themes, and factors found to foster and hinder implementation have been presented in Appendix S.

Chapter 6: Discussion, Conclusion and Recommendations

6.1. Introduction

This study took a multi-level analytical approach to describe and understand factors that facilitated and impeded the implementation of LCIVF initiatives within Uganda's public health system. This section of the thesis provides a more in depth understanding of the factors salient to implementation of affordable fertility treatment initiatives, summarizing the key findings in relation to existing literature. To my knowledge, this is the first study focused on implementation of affordable fertility initiatives including LCIVF in Uganda and in Sub-Saharan Africa within a public health system.

The CFIR framework provided a useful conceptual lens that guided exploration of the implementation process and organizing data for analysis. Not all thirty-eight constructs were utilized, as some of them (design quality & packaging and other personal attributes) were found not to be contextually relevant or useful. Furthermore, the framework as highlighted by the authors, was limited in its ability to draw connections arising from a complex, multifaceted intervention (Damschroder et al., 2009). Therefore, the discussion is structured in a way that responds to the research aims, considering the complexity of implementation and how these factors can be linked at multiple levels.

There is limited literature in Implementation Science on the implementation of, or access to fertility care. Prior research has emphasized the impact of infertility in SSA, the need for low-cost/affordable fertility services and offered suggestions on how these initiatives can be implemented (Afferri et al., 2022; Gerrits, 2012; Ombelet, 2014; Sallam, 2008). However, understanding of the process by which low-cost IVF initiatives have been integrated into reproductive health services in the public health system of a low-resource context have not been well researched. This research, thus, contributes to the body of knowledge by providing a holistic picture on implementation of affordable fertility services, examining the multi-level factors working together or in contradiction to influence successful implementation of LCIVF initiatives.

This chapter is structured according to the research aims outlined in the rationale namely: 1) How did macro-level factors influence implementation of low-cost IVF treatment within the public health system. 2) How did the public hospital unit at the meso-level organize itself to facilitate implementation and provision of low-cost IVF treatment as part of its service delivery? 3) How can low-cost IVF treatment protocols be operationalized at the micro-level within the clinical practice? What are the concerns and lessons learned (i.e., facilitating, and inhibiting factors) for a public health system on implementation of LCIVF initiatives in a developing country setting? The CFIR framework closely guided findings that informed the three research aims based on the level at which analysis was undertaken. Notable findings are discussed in relation to these objectives and existing literature are highlighted below.

6.2. Objective 1: Understand the macro-level factors that influenced the implementation of LCIVF within the public health system.

A primary aim for this study was to understand broader level factors that facilitated and impeded implementation of affordable fertility services including LCIVF initiatives at MWH. This section focuses on contextual factors surrounding implementation: political, economic and sociocultural climate and the key actors influencing the process. Macro-level analysis of data revealed several factors that influenced the implementation of LCIVF initiatives at MWH related to favourable international policy on infertility, absence of national ART legislation, strong political support & advocacy, available government funding, inter-organizational collaboration, peer pressure from the private sector, patient needs & advocacy, limited public sensitization and need for engagement of opinion leaders.

6.2.1. Global Policies on Infertility

The findings revealed that acceptance of infertility as a reproductive disease in international policy (*external policy and incentives* construct) played a crucial role in favoring implementation of LCIVF initiatives within Uganda's public health sector. Participants often noted that the 'disease status' of infertility, as recognized by the WHO and the UN Universal Declaration of Human Rights - Article 16 on right to marriage and found a family (United Nations, 1948) provided the MoH with the evidence base needed to undertake implementation efforts. Some participants highlighted this as a 'key development' for infertility to be accepted as part of reproductive health. These findings were consistent in the literature that posits recognition of infertility as a disease by policymakers as a key facilitator for its inclusion in reproductive health policies (Afferri et al., 2022; Serour et al., 2019). Studies in countries such as the UK, indicated policy makers' perception of infertility as a disease complemented provision of state-funded treatment through the National Health Service (NHS) (Maung, 2019). Maung (2019) advanced that, "infertility as a bonafide disease can be taken to provide a *prima facie* justification for its claim to medical treatment". Policies that target sexual and reproductive health rights are crucial to incorporation of infertility programs in health systems (Morshed-Behbahan et al., 2020).

The application of the disease label is not without controversy. Some scholars argue that infertility has been incorrectly labeled as a medical condition and regard it instead, as a socially constructed condition based on societal norms of childbearing (Becker & Nachtigall, 1992; Greil, McQuillan & Slauson-Blevins, 2011). However, in this study, defining infertility as a disease was considered to be of great significance amidst prevailing dialogue on overpopulation and the country's high fertility rates; sentiments which could also be regarded as socially constructed. One participant asserted that this reasoning had been used to justify neglect of fertility treatment and focus national health prioritization on increased uptake of family planning. These arguments have been cited in literature on infertility in SSA revealing oversight of infertility as a global health issue in high fertility-settings such as Sub-Saharan Africa, despite a higher infertility prevalence of one in four couples (Chiware et al., 2021; Inhorn & Patrizio, 2015; Ombelet & Onofre, 2019; Teoh & Maheshwari, 2014). Furthermore, being a non-life-threatening condition, infertility was reportedly viewed as nature's solution to population control and a low priority for policymakers (Inhorn & Patrizio, 2015; Makuch, Petta, Osis & Bahamondes, 2010). The findings described in this project suggest that the designation of infertility as a reproductive disease by reputable international agencies was a significant

determining factor and in similar contexts can serve as the basis for which public health systems can advocate for integration of fertility services into their national reproductive health offerings.

6.2.2. ART Regulation & Policy Makers Proficiency

Participants called for the incorporation of infertility as a reproductive disease in national policy and its operationalization as part of everyday reproductive health care. Attempts were made to do so through the drafting of an ART bill (*external policy and incentives construct*) to address objectives to strengthen governance and stewardship of ART within the MoH. Participants stated that ART legislation was required to guide practice of fertility treatment in the public sector and ensure quality control. In particular, they looked to the law for protections in addressing anticipated concerns associated with complex ART procedures such as surrogacy, third party donation and consequences for clinical non-adherence (including loss of licensure and criminal charges). These findings aligned with studies that suggest ART regulations promote quality assurance and penalties (e.g., fines or loss of medical licensure) when not adhered to (Adamson, 2009; Adageba et al., 2015; Ekechi-Agwu & Nwafor, 2020; Starrs et al., 2018). For instance, in cases of surrogacy or third-party donation which have complex legal and ethical ramifications, laws and regulations are required to protect the rights and health of the individuals involved (Starrs et al., 2018).

Development of a regulatory instrument by the medical professional association (UMDPC) and local fertility specialists (*cosmopolitan construct*) facilitated initial discussions at the parliamentary level, considering the interests of the unborn child, intending parents and third parties, their rights and obligations to ensure safety of all involved (*patient needs & resources construct*). The bill was considerably flexible with respect to donor anonymity, cost sharing practices and surrogacy compensation but only considered single or heterosexual relations. Previous studies have cited flexibility of ART regulations as instrumental given that various regulations and guidelines have a major impact on access to ART services (Jones & Cohen, 2007). For instance, donor anonymity or lack thereof in countries like Australia poses considerable recruitment challenges (Adamson, 2009). Likewise, lack of compensation for surrogates in contexts like Canada limits availability (Adamson, 2009).

While drafting the ART bill was beneficial in addressing legislative concerns, lack of sufficient policymaker understanding regarding certain aspects of fertility treatment and care (e.g., gamete donation) presented barriers and resistance to approval. Although the bill had strong support from the then Minister of Health (*champion*), some politicians and religious opinion leaders did not appreciate the magnitude of the issue [infertility] and reportedly accused advocates of ART for wanting to distort families by using science to disrupt natural reproductive processes. Furthermore, cultural, religious and traditional leaders were not extensively engaged as stakeholders during this drafting process as one participant described, to avoid them blocking the bill at its infancy (*engaging*). These findings echo similar challenges in Brazil, where a study of ART regulation revealed that the catholic caucus along with members of Congress lobbied against highly complex ART procedures, as they were associated with abortion, which was a sensitive topic for the religious groups (Garcia & Bellamy, 2015). To further complicate matters, use of gametes from third parties was misunderstood to be similar to organ donation in its handling of human tissues, resulting in the combination of both the Organ Donation bill and ART bill. Thus, participants called for sensitization of policy makers on the workings of IVF technologies, differences between the two bills and the value of third-party interventions in overcoming infertility.

These results echo a systematic review on factors influencing inclusion of fertility care in reproductive health policies in Africa, which cited limited political commitment and under-recognition of the burden of infertility as barriers to incorporation (Afferri et al., 2022). The urgent need for sensitization of policy makers and international stakeholders on infertility has been emphasized by Afferri and colleagues (2022). Furthermore, lack of regulation in other African countries has been documented with increasing calls for a regulatory framework on ARTs (Egbokhare, & Akintola, 2020; Hörbst, 2016; Hörbst & Gerrits, 2015; Moll, Trudie, Hammarberg, Mandersonae & Whittakere, 2022; Morshed-Behbahani et al., 2020; Nampewo, 2021). In Nigeria, a study on rethinking parenthood within ART called for a particular focus on including definitions for parenthood achieved through these technologies (Egbokhare, & Akintola, 2020). This recommendation was echoed by WHO's report titled "Medical, Ethical and Social Aspects of Assisted Reproduction" that called for management of infertility to be integrated into national reproductive health policy, education programs and services (WHO, 2001). Furthermore, the WHO's recent infertility fact sheet recognized the importance of access to high quality care for infertility and the need to support policy makers and stakeholders in developing guidelines for prevention, management and treatment of the condition (WHO, 2020). Nonetheless, countries like Nigeria have continued to offer IVF services in the public sector, for years, without national ART specific regulations in place (Ekechi-Agwu & Nwafor, 2020).

Though the ART bill is yet to be enacted in Uganda, participants insisted on its importance, especially in curtailing unethical clinical practices and exploitation within an already vulnerable patient population. Concerns of patient exploitation and abuse has been echoed by a recent study of ART in Uganda which found that individuals were desperate to have children and were often tempted to do anything to conceive, making them highly vulnerable and easily manipulated/ exploited by practitioners, because IVF in Uganda was largely unregulated (Nampewo, 2021). Furthermore, studies have reported on the coercion and exploitation of surrogate mothers for financial gain, at the risk of their own health through multiple pregnancies and physiological effects of postpartum child separation (Söderström-Anttila et al., 2016). Indeed, some clinical participants' interest in the bill was for purposes of protecting their own reputation as practitioners, to prevent lawsuits, misunderstandings, sabotage, and accusations of abuse seen in fertility practices (*knowledge and beliefs*). One participant emphasized that the success of fertility doctors depended on patient success stories and a doctor's [good] name was as important as a brand. Not to mention, without regulations or guidelines, countries are unable to grasp and measure ART activity beneficial to improvements (Adamson, Lancaster, de Mouzon, Nygren & Zegers-Hochschild, 2001). Participants also acknowledged that for many African countries, IVF technologies were advancing at a much faster pace than the regulatory bodies could adapt, creating additional legislative challenges. These findings suggest that adoption of national legislation, in combination with policymaker sensitization and consultation with key opinion leaders, can facilitate ART quality assurance by upholding patient well-being and professional standards of care, while building confidence in implementation of LCIVF initiatives.

6.2.3. Political Advocacy, Support & Funding

One of the major driving factors towards LCIVF implementation was strong political support & advocacy and availability of funding from the GoU through the MoH and MoF (*available resources*). The opportunity to secure over USD $30 million in loan financing through the Islamic Bank & African Development Bank was made possible through parliamentary approval to develop a women's specialist hospital. Through this funding, MWH was able to earmark funds for establishment of an IVF department. Parliamentary approval of the budget was said to be a result of efforts from political allies (*cosmopolitan*), many of whom were women, galvanizing their peers and male parliamentarians to support it. This win was seen to be a result of women empowerment as one of the hospital pioneers stated, "*It is important when women are given a voice to make decisions, particularly decisions pertaining to themselves because the men wouldn't know the things that happen in women*". Furthermore, the President of Uganda empathized with the plight of those experiencing infertility and the then Minister of Health, was a strong driver for provision of IVF services in the public sector engaging in infertility campaigns, legislation, and implementation efforts (*political champions*). These findings are in tandem with research revealing the importance of sustained political support in including fertility care in reproductive health policy (Afferri et al., 2022; Ombelet et al., 2008; Serour et al., 2019). Ombelet and colleagues (2008) reported that implementation and sustenance of infertility care in developing countries would only be possible if supported by local policy makers and the international community. Furthermore, increased representation of women in diverse leadership roles has shown positive outcomes on healthcare indices (Dhatt et al., 2017; UN-Women, 2019). For example, Rwanda, where 60% of parliamentarians were women, observed a decline in maternal mortality (Ministry of Health Rwanda, 2015). Another study in India, showed that elected women officials were catalysts for improving public health outcomes associated with women's health and wellbeing (Downs et al., 2014). Therefore, these findings underscore the important role of women empowerment and political leadership in championing and positively influencing decision-making that impact women's health outcomes and facilitate implementation of fertility services.

Participants determined availability of financial resources from the government as central to realizing the vision of a specialized women's unit and incentivized establishment of an IVF department. Interestingly, some believed that without this funding, there would be no IVF department; stipulating that the establishment of a women's hospital is what gave way for implementation of the IVF department, which would have otherwise not been possible (*knowledge and beliefs*). Funding availability facilitated construction of a women's hospital, purchase of equipment, professional training and establishment of a hospital information system (*available resources*). It goes without saying, establishing a tertiary level ART department capable of offering complex IVF related services was a costly endeavor, requiring significant upfront investment. More so, in a context with limited resources and competing healthcare priorities. As reported by administrative participants, the IVF department took up a significant chunk of the budget (*cost*). Therefore, echoing similar studies that have reported on the high costs of setting up an IVF laboratory estimated to be between €1.5–€3.0 million (Klerckx, 2013), while a low-cost IVF laboratory has been said to cost €300,000 (Teoh & Maheshwari, 2014). These findings suggest that as a novel multi-level intervention, availability of substantial funding and hospital restructuring facilitate implementation and incorporation of IVF services in a public hospital.

6.2.4. Inter-Organizational Collaboration

As a multifaceted intervention, implementation of LCIVF saw considerable engagement from various stakeholders that supported implementation efforts (*cosmopolitan*). The diversity of organizations included Makerere University, a government higher educational institution that offered training and research support; the Uganda Fertility Society (UFS) along with the Uganda Medical Dental Practitioners Council (UMDPC) provided support drafting ART bill and oversight for fertility practitioners in lieu of legislative approval. International organizations such as MERCK foundation supported public awareness, offered expert guidance during construction and short-term training for staff. International organizations i.e., WHO, IFFS, ESHRE, ASRM provided expert guidance and knowledge transfer through professional training, IVF conferences/workshops and supported drafting of the ART bill (*external change agents*). External consultants were engaged to offer expertise on construction of the IVF department and delivery of services. Private fertility hospitals offered local practical training opportunities to medical students (*access to information & knowledge*). The Ugandan patient advocacy organization, Joyce Fertility Support Centre (JSFC) played a major role in building momentum for implementation of LCIVF in the public sector by engaging international experts, press media, the public and organizing the first LCIVF workshop with multiple stakeholders (*grassroots champions*). Media houses also worked with practitioners to provide accurate public education on infertility.

These findings are consistent with previous literature on the importance of interorganizational networks in influencing an organization's decision to adopt innovations (Greenhalgh, 2004). Beyond establishing an IVF lab, provision of fertility services in developing countries also includes equipping of clinics, training staff, offering public education and managing operational costs (e.g., salaries, maintenance & consumables) (Sallam, 2008). To this end, a multi-sectoral assistance model is recommended to set up IVF services in developing countries that includes international donors, scientific bodies, private actors and NGO partnerships (Afferri et al., 2022; Sallam, 2008). This approach has been documented in a study on the origins of ART in Ghana, which reported transnational networks as a core contributor to implementation of IVF centres (Gerrit, 2018). Another study in Mali reported the role played by international donor funding in influencing infertility policy and governance (Hörbst, 2012). However, participants in this study reported that a major drawback of some institutional partnerships was that they were based on personal rather than institutional relationships and thus deteriorated once relevant parties moved away. For instance, reshuffling of the then Minister of Health, who had strong ties with MERCK foundation reportedly slowed implementation progress and stakeholder engagement (*leadership engagement*). These findings are in tandem with studies that have emphasized the importance of sustained international partnerships and collaborations in incorporation of fertility care (Gerrits, 2012; Ombelet, 2014; van Balen and Gerrits, 2001). Therefore, implementation of LCIVF services in the public sector would be better strengthened through continuous engagement with multi-sectoral, local and international partnerships and engagement to achieve and sustain its goals. Notably, partnerships should be developed at the institutional rather than personal level to sustain collaborations and avoid diminished engagement in absence of relevant actors.

6.2.5. Government Oversight & Stakeholder Engagement

Upon government approval of the women's specialist hospital, formal planning by the GoU commenced with establishment of a project implementation plan, a team led by the MoH permanent secretary and steering committee to provide project oversight (*planning*). The project implementation plans outlined objectives of the project (i.e. increase range and quality of super-specialized maternal and neonatal healthcare services), its timeline (48 months), the selected implementation team, funding, training requirements and oversight plans. A hospital administrator reported that the project plan included 4 main components: i) civil works, ii) equipping of hospital, iii) staff training and iv) clinical protocol revision for accreditation. The project team included several stakeholders that would support implementation efforts including a project coordinator for day-to-day activities, who was part of the hospital staff. These findings illustrate the central role played by the government in establishing and overseeing implementation of LCIVF initiatives at MWH to improve service delivery. Thus, corresponding with research on the essential role of governments in improvement of health systems (WHO, 2002). Governments have a role to play through stewardship, leadership, and governance of health interventions via oversight of operations and leadership on intersectoral efforts to facilitate responsive and quality health care (WHO, 2000; 2007). Stewardship refers to the broader strategic management of health systems and environments under which interventions operate including financing, resource generation and service provision (WHO, 2002).

Poor leadership management has been identified as one of leading challenges in the healthcare sector in Africa (Fadlallah et al., 2018; Petersen et al., 2017; Oleribe et al., 2019). Previous research on weak public health leadership and governance cited inefficient resource allocation, weak inter-sectional action, inadequate health-related legislation and its enforcement, and limited management and monitoring of health services (Kirigia, & Barry, 2008). An example of this, is a study in Malawi in which participants reportedly viewed poor governance as a significant barrier to effective and equitable healthcare access by way of accountability, health resource management and influence in decision-making (Masefield, Msosa, & Grugel, 2020). These findings, therefore, suggest that successful implementation of LCIVF initiatives in the public sector lies in strong governance and oversight by governments.

With respect to stakeholder engagement in the public sector, governments also have a role to play in ensuring the MoH and other key stakeholders assume their roles (WHO, 2000). The government co-led, planning phase encompassed multi-level stakeholder engagement and detailed planning to ensure active participation in the decision-making process, which facilitated implementation. This was an active form of innovation dissemination, described as formal planning by a central entity that utilizes vertical hierarchies to lead the implementation process (Greenhalgh, et al., 2004). A planning committee was established, including ministers, clinical and administrative staff to guide the ground layout of the facility, offer technical expertise and procure appropriate equipment (*planning*). An internally formed implementation team composed of hospital staff was also established, reporting satisfaction with the level of government engagement during the planning phase, describing it as highly engaging, all-inclusive and open to suggestions (*engaging*). Participants reported consultations with a variety of stakeholders including patient groups and lobbyists during the planning process (*engaging*). Furthermore, the civil works contractor, brought on by the government, reflected fondly on the civil works process; citing good working relationships and cooperation within the project team in discussing any challenges and ensuring the project was delivered on time (*execution*).

Research indicates that centrally developed innovations are more likely to be broadly spread and successful when the developers (GoU) are linked to the potential users (hospital staff & patients) in the development stage to capture and take into consideration their ideas (Greenhalgh et al., 2004). These findings are line with these assumptions and a dearth of literature that recognizes the importance of early multi-level stakeholder identification and engagement in facilitating buy-in, ownership and sustainability of interventions (Akwanalo et al., 2019; Concannon et al., 2019; Holcomb et al., 2022; Majid et al., 2018; Murphy et al., 2021). Stakeholder engagement is defined by the bidirectional partnership by which an organization engages relevant stakeholders (Concannon et al., 2019). Furthermore, in clinical settings, early stakeholder engagement can support organizational specific adaptations to evidence-based interventions to ensure adequate adoption and implementation sustainability (Holcomb et al., 2022). For instance, a Kenyan study on strategies to improve referral systems for hypertension revealed early key stakeholder identification and engagement as a significant contributor to success; owing to consensus building and shaping of the intervention to improve the referral process (Akwanalo et al., 2019). This, therefore, suggests that government co-led planning that includes early recognition and involvement of multi-level stakeholders is advantageous to the implementation of LCIVF initiatives.

6.2.6. Patient Needs & Advocacy

The advocacy efforts and needs of patients seeking fertility services in the public health sector was a strong driver towards implementation of LCIVF services within the public sector (*patient needs and resources*). Clinical participants were keenly aware of the demand for more comprehensive fertility services, having run a half-day infertility clinic at the national hospital since 1991. The part-time clinic only offered diagnostic and minor surgical procedures, which were deemed to be insufficient to meet growing demand (*tension to change*). More than the requirement for fertility services, participants and patients expressed deep concern regarding the financial burden of fertility treatment in the private sector and its impact on women in particular (*relative advantage*). At the time, there was a surge in fertility hospitals in the private sector (over 8 clinics in 10 years) said to charge exorbitant fees, as high as USD $6,000 per IVF cycle (*peer pressure*). One participant described this treatment as too expensive for ordinary citizens. In many cases, women were left to struggle alone financially and emotionally when accessing treatment. Furthermore, these financial barriers were pronounced within the patient demographic (lower SES) that often-sought treatment from public sector hospitals and compelled the sector to consider providing more affordable solutions through LCIVF implementation. These findings agree with studies around the world that have reported on the high cost of fertility treatment as a leading barrier to access of fertility care, prohibiting many from benefiting from the technology to conceive (Afferri et al., 2022; Dadiya, 2022; Klitzman, 2018; Teoh & Maheshwari, 2014; Ombelet and Onfre, 2019). Policy development is beneficial in advancing incorporation of fertility care into reproductive health programs and establishment of financial protections to safeguard individuals against the high cost of treatment (Morshed-Behbahani et al., 2020).

The bid for affordable treatment was also championed by the vocal presence of a local patient-led group (JSFC) that advocated both locally and internationally (through the WHO), engaged the media and international fertility experts, and organized educational workshops for patients, experts and local fertility providers (*cosmopolitan*). The group's visibility was said to be critical to putting a face on an issue that had historically been invisible to non-sufferers and discussed largely as a statistic. Research has shown that

patient advocacy groups can serve as valuable partners to expediting implementation processes (such as lobbying, fundraising, public awareness) as they illustrate the value of practical knowledge (Dang et al., 2016). Founded in 2008, the Joyce Fertility Support Centre Uganda aimed to advance the idea of providing a holistic approach to the problem of infertility and broke with tradition by openly talking about infertility, its causes, and its treatments (Ombelet et al., 2008). Furthermore, during the opening week of MWH, over 600 patients attended the facility seeking affordable fertility services, demonstrating eagerness in accessing them. On the other hand, engagement of JSFC's was not sustained beyond the pre-implementation stage (*engaging*), which resulted in their disenchantment with the implementation process and may have slowed down its momentum. These findings suggest that thoughtful, continuous engagement of patients as partners (Cavaller-Bellaubi et al., 2021; Perfetto et al., 2015) along with practitioners' perspectives can serve as a catalyst for implementation of LCIVF initiatives in the public health sector.

6.2.6. Public Perception, Education & Involvement

Addressing infertility did not end at offering affordable treatment options; participants emphasized a need for greater public sensitization regarding severe implications of infertility on individuals. Many voiced the burden of societal stigma on women mainly, their perception as inferior citizens and the importance of breaking the silence and stigma through public discourse (*patient needs & resources*). Infertile women were reportedly accused of witchcraft, contracting STIs and carrying out multiple abortions. Therefore, public education was deemed vital in overcoming this blame, negative rhetoric and misconceptions about infertility to reduce stigma and improve health seeking behaviour at fertility clinics. These findings reflect research that has shown public education to be an important part of fertility care in developing contexts (Serour et al., 2019). Furthermore, fertility education can be used to disseminate prevention and treatment options available to individuals (Serour et al., 2019). One participant reiterated the significance of public discourse on infertility in view of prevailing agendas on curbing the nation's high fertility rates that obscured and marginalized persons experiencing infertility. This account corresponds with reports in many developing countries whose concern with their high population growth rates led to a single focus on family planning and neglect of infertility challenges (Teoh & Maheshwari, 2014). Furthermore, lack of infertility knowledge in this study aligned with a survey of 100 Ugandan women which revealed basic knowledge of infertility was extremely low (Kudesia et al., 2018). Infertile women in Uganda reported severe social and emotional morbidity, citing that it was worse to experience infertility than to be diagnosed with HIV (Kudesia et al., 2018). Prioritizing public and health provider education on ART and implications of age, lifestyle, delayed childbirth and sexual behavior on fertility can reduce stigma and the need ART services, while increasing acceptability and access to these technologies (Dierickx et al., 2019; Serour et al., 2019). Additionally, empowerment of women is vital for protection of themselves from unsafe abortion, STI/HIV infection, postpartum and post abortive infections; given that its women who carry the medical, social or economic burdens of infertility (Serour et al., 2019).

Furthermore, lack of engagement with key community leaders i.e., religious, cultural and traditional leaders (*opinion leaders*) as partners in creating awareness, disseminating accurate information and becoming champions led to misinterpretation and opposition to ART; in some cases, their silence about these technologies hindered public support for ART. These findings contribute to literature that has emphasized the importance of engaging and educating key opinion leaders including cultural, religious and traditional leaders on ART and onboarding them as champions (IFFS, 2016; Ombelet, 2011). Variability in ART

acceptability and use depends on country specific culture and influence of local stakeholders (IFFS, 2016). Local stakeholders may include patient advocacy groups, local healthcare providers, local and national government agencies, professional organizations, insurance and other organizations responsible for payment, legislative bodies, and religious organizations (IFFS, 2016). Community leaders are known to be held in high regard and play a significant role in many cultures influencing health behaviour of followers, not only at the individual but also political, socio-cultural, and environmental levels (Dennis-Antwi et al., 2018; Heward-Mills et al., 2018). One patient participant pointed out that the absence of statements from the church on issues like egg donation was particularly troubling. Therefore, there was consensus on the need to engage religious leaders and cultural institutions as one of the biggest opinion leaders on this taboo topic to improve public awareness (*reflection & evaluation*).

These findings echo several studies in Africa that have reported on the influence of sociocultural and religious beliefs on interpretations and misconceptions of infertility and acceptability of ART (Dhont et al., 2011; Dierickx, 2020; Chiware et al., 2021; Gerrits, 2016; Nguimfack, Newsom & Nguekeu, 2016; Pedro & Faroa, 2017). IVF technologies, in particular, have received a lot of controversy over the years, more so from cultural and religious groups (Chiware et al., 2021; Sallam & Sallam, 2016). For instance, a study on perceptions of infertility and IVF technologies among married couples in Nigeria, reported that infertility was perceived as destiny or a result of supernatural powers and ART was seen as abnormal, unnatural and not cultural (Okafor, Ngozi & Ikechebelu, 2017). Likewise, third-party ART was strongly condemned by the Executive Council of the Church of Pentecost in Ghana stating that ‘‘The Church believes that physical intimacy between a husband and wife remains the biblical means of producing children’ (Executive Council of the Church of Pentecost, 2012). However, religion has also been reported as an enabler. A study in Ghana revealed that religion assisted participants with a lens through which to cope with the physiological and psychological effects of IVF treatment processes and outcomes (Hiadzi, Boafo & Tetteh, 2021). Other studies have shown that cultural traditions also influenced perceptions of infertility citing spiritual attacks, superstition and evil exacting spiritual cleansing to overcome them (Aluko-Arowolo, & Ayodele, 2014; Dierickx et al., 2018; Dierickx et al., 2019; Moyo & Muhwati, 2013; Nieuwenhuis et al., 2009; Parrott, 2014). These findings suggest the role of traditional, religious and cultural leaders should not be overlooked or delayed, given their influence of sociocultural and religious norms. Their role in information-sharing and decision-making regarding infertility and ART could impact public perception and implementation of LCIVF initiatives in similar settings.

Last but not least, participants reported that public perception of government hospitals was poor (*implementer reputation*) when it came to providing quality services. There was a need to overhaul its modest reputation through public campaigns to increase confidence in the facility and promote access to its fertility services. As one participant revealed; “*People think public things are not of quality*”. Studies in African contexts have similarly revealed the influence of public perception of hospitals on patients’ willingness to utilize services (Cavaller-Bellaubi et al., 2021; Lendado et al., 2022; Onyeneho et al., 2016). Previous studies examining patient perceptions on Mulago hospital reported perceptions of poor quality and continuity of care (Kabatooro et al., 2016; Kaye et al., 2015; Nabbuye-Sekandi, 2011). Likewise, a study on public hospitals in Cameroon reported that public hospitals built negative reputations due to overcrowding, lack of surgical services and poor quality of care (Jaffré & Guindo, 2013). These factors suggest that provision of LCIVF services ought to be accompanied with enhancement of public awareness

on quality of services in the implementing organization to promote prevention, reduce stigma and enhance access to fertility services.

In summary, macro-level factors that significantly facilitated implementation of LCIVF at MWH consisted of favourable international policy on infertility, political support and oversight, appreciation of patient needs and patient advocacy and multi-sectoral collaboration. Other moderately facilitating factors included development of an ART bill, peer pressure from the private sector and early stakeholder engagement. Factors that significantly impeded implementation of LCIVF initiatives included limited engagement of cultural, religious and traditional leaders. Moderate impeding factors included poor perception of public hospitals, limited public knowledge of infertility, sociocultural and religious barriers on this knowledge and acceptance of ART technologies.

6.3. Objective 2: Examine the means by which the public hospital (MWH) at the meso-level organized itself to facilitate the implementation and provision of LCIVF as part of its service delivery?

This chapter of the thesis focuses on meso-level (hospital) factors that facilitated and impeded the implementation of LCIVF initiatives at MWH. This level of analysis considered the organizational attributes of MWH that influenced the implementation process including its structural characteristics of the organization, leadership engagement, networks and communications, implementation climate, compatibility with the innovation with existing infrastructure and resources available to do so. Findings revealed the main facilitators to be tension for change, relative priority, goals and feedback, available resources (including finances, physical space and specialist training) and access to local fertility expertise. Factors that revealed mixed evidence included compatibility with existing structures, centralized processes, organizational incentives and rewards. Barriers to implementation consisted of diminished leadership engagement, insufficient specialist training, impact of COVID-19, and inability to hire an embryologist.

6.3.1. A Woman's Vision for a Women's Hospital

Uganda's largest national referral hospital was established in 1913 and MWH stood as one of its newest additions to a multi-complex of hospitals under the management of Mulago. It formed the women's specialist unit of the national referral hospital, launched in 2018, with the aim of improving capacity and quality care to citizens of Uganda. More specifically, this women's focused facility aimed to address deterioration of the pre-existing maternity unit and adopt international standards of care. Participants spoke of poor hospital conditions under which women gave birth, regarding them as unhygienic, overcrowded, and insufficient to meet the country's high birth rate (*tension to change*). According to a hospital administrator, Mulago had the highest number of births in the world at 40,000 births per annum. A 2019 hospital-based surveillance system report indicated that Mulago contributed 60% of the annual birth rate, approximated at 50,000 births (Mumpe-Mwanja et al., 2019). However, the inferior conditions under which some of these births took place contributed to missed opportunities, delays in service delivery and poor maternal health outcomes, which were considered as unacceptable (*tension to change*). Press reports cited Uganda's biggest hospital, Mulago, as plagued by overcrowding and shortages, with women left on mats, floors, under beds of others and in entryways outside (York, 2011). These infrastructural challenges reportedly brought about considerable barriers to healthcare access; aligning with studies that have shown

poor infrastructure and lack of a conducive environment to deliver as barriers to healthcare uptake and outcomes (Dahab & Sakellariou, 2020; Medhanyie et al., 2018; Wilunda et al., 2016).

To address these challenges, the then head of department conducted benchmarking visits to a women's hospital in Ethiopia, which sparked the idea of a women's focused hospital in Uganda (*external policy & incentives*). Furthermore, her clinical colleagues visited various women's hospitals around the world, generating momentum for a focused approach to women's health care. With her leadership, the departmental head garnered political support from parliamentarians and peer support from clinical colleagues to champion the idea of a women's hospital (*leadership engagement*). Members of parliament also had an opportunity to witness first-hand the substandard conditions at the hospital as narrated by the then department head: "*members of parliament, especially female members, saw our pain and the pain of the mothers of the nation on the floor, compelling them to act.*". Therefore, the plight of women seeking maternal care at Mulago propelled ministers to push back in parliament, ultimately solidifying the idea of building a women's specialist hospital (*political champions*). These findings align with studies highlighting underdeveloped infrastructure as a key barrier to provision of fertility care, in addition to and lack of appropriate drugs and equipment (Afferri et al., 2022; Chiware et al., 2021). Multi-integrated health interventions that include refurbishment of existing health infrastructure have been shown to improve healthcare conditions, positively impacting maternal care quality and outcomes (Kapologwe et al., 2020; Kruk et al., 2018). Strengthening of health infrastructure can improve service delivery and present opportunities for implementing new initiatives such as LCIVF/affordable fertility services. African governments, in particular, have been called upon to improve infrastructure to facilitate provision of ART services (Adageba, Maya, Annan, & Damalie, 2015; Chiware et al., 2022). Mulago, having undergone multiple renovations in the past, was no stranger to reinventing itself to improve service quality. However, there has been considerable debate in the literature as to whether new hospital infrastructure is the appropriate course of action to improve service quality. Building new hospitals is costly, and alleged to be a politically attractive, highly visible action for national governments and funders alike to symbolize progress, better services and nation building (Chabrol, Albert & Ridde, 2019). Integration of these new facilities into national health systems can be challenging, bringing along operational and maintenance costs that may not be sustainable; in addition to debt accumulation that puts governments at risk (Chabrol, Albert & Ridde, 2019). These findings suggest that improving health facility infrastructure through restructuring or construction of a new healthcare facility presents opportunities for implementation and incorporation of LCIVF initiatives into service delivery.

Furthermore, the role played by the then departmental head and female politicians in advancing the women's hospital underscores the significance of networks and influence of women leaders on women's health. Research shows that the adoption of innovations is strongly influenced by the quality of networks and structures (Greenhalgh et al., 2004). Doctors are said to operate more under informal, horizontal networks to spread peer influence, in contrast to vertical networks where authoritative decision making occurs (Greenhalgh et al., 2004). However, in this study, the then department head acted as a boundary spanner; this is an individual with considerable ties both in and outside an organization that is willing to connect the organization to the outside world regarding the innovation (Greenhalgh et al., 2004). In her role as departmental head, she was able to garner support from clinical peers (horizontal) and politicians (vertical) to drive the innovative idea of a women's specialist hospital. This gives prominence to the power of networks and usefulness in leveraging both horizontal and vertical networks to drive implementation of

LCIVF initiatives. Regarding the collaborative role of the female politicians with clinicians, there is compelling evidence to demonstrate a direct causal relationship between female empowerment in politics and accelerated decline in maternal mortality (Bhalotra, Clarke & Gomes, 2019). Bhalotra and Gomes (2019) in their analysis of maternal mortality and women's political participation found that women prioritize policies aimed at improving conditions of females including child marriages, education and maternal mortality. These findings suggest that women clinical leaders, in collaboration with women politicians can play an important role in championing initiatives that support women's health (including access to fertility services) and is advantageous to implementation of LCIVF in the public health sector.

6.3.2. Global Trends Towards Super-Specialized Services

Beyond development of satisfactory hospital infrastructure for service delivery, clinical participants regarded MWH as an opportunity to move towards global trends of specialized care. Within the existing infrastructure, the obstetrics and gynecological clinical teams had by now gained interest in specializing further, moving away from general practice. Together, they held a vision to become a "Centre of Reproductive Health Excellence in Africa", proactively restructuring their department into 5 specialities including: reproductive medicine & family planning, gynecological oncology, urogynecology, maternal & fetal medicine and community reproductive health (*planning*). Physicians took personal initiative (*individual stages of change*) to pursue opportunities for specialist training overseas, which guided restructuring and implementation planning (*compatibility)*. These results contribute to studies that have reported an increase in medical specialization in LMIC countries, citing a growing proportion of doctors arranging their careers around specialist training (Sriram & Bennett, 2020). This has been explained in part, by international networks of physicians advocating for specialization, national and global markets, growing burden of non-communicable & chronic diseases and scientific and technological advances in the field of medicine (Hsia et al., 2012; Shawar, Shiffman, & Spiegel, 2015; Sriram, Baru & Bennett, 2018).

However, the movement towards specialization has been contested in the literature. Research conducted in Mexico and India for instance, found that specialization of medical care was driven by a combination of factors including diffusion of ideas from the elite, potential for job opportunities in high income countries and a continued primacy of 'western' biomedical knowledge (Nigenda & Muños, 2015; Sriram, George, Baru & Bennett, 2018). Furthermore, gaining new specialities or expanding on existing ones, may not always translate into healthcare access and improved service delivery, particularly for low-income individuals (Sriram & Bennett, 2020). A study in Nigeria on specialist care raised concerns regarding the financial accessibility of specialist healthcare treatment to their whole population (Chabrol, Albert, & Ridde, 2019). Tertiary or specialist hospitals were seen as profitable investments, providing favorable market opportunities by charging high fees, to the benefit of wealthier citizens, while exaggerating inequitable access to care (Chabrol, Albert, & Ridde, 2019; Marriott & Hamer 2016). These findings suggest that the increase in medical specialization and clinical inspirations to specialize can facilitate implementation of LCIVF initiatives. However, availability of specialist services does not automatically translate to increased accessibility to specialized services and runs the risk of creating greater equities to healthcare access.

6.3.3. Justification for IVF in a public hospital

During the pre-implementation phase, fertility doctors within the hospital took advantage of the momentum for a women's specialist hospital to rally attention towards incorporating specialist fertility care in the new facility. The team of doctors was able to demonstrate the growing burden of infertility to hospital management, by presenting shocking statistical figures which persuaded the director to take up their cause (*tension to change*). A study of infertility in Uganda at the time found that an estimated 5 million people were facing infertility, mainly handled by private fertility centers in urban areas (Sajjabi, 2008). Furthermore, doctors argued that the high delivery rates at the hospital brought about neglect of patients in need of fertility services, as the deliveries overwhelmed all the staff and resources in the obstetrics and gynecology department (*patient needs and resources*). In this way, they were able to advocate for a separate IVF department at MWH to prioritize the needs of fertility patients (*technical champions*). Furthermore, participants expressed several moral, cultural and ethical justifications for incorporating IVF services in the public health sector. From an ethical perspective, participants described the important role of the government in offering affordable healthcare options to its citizens through its social contract, including fertility care (*relative priority*). In particular, they spoke of a balanced/dual approach to reproductive health by offering both family planning to curb high birth rates and fertility treatment to assist those who cannot have even one child. Furthermore, some participants believed that by offering IVF services at a national referral level, MWH would act as a model to the government for incorporation of simpler IVF services in the regional referral hospitals (*relative priority*). Participants also saw this as an opportunity to show African countries that LCIVF/affordable fertility services were possible in the public sector (*knowledge and beliefs*). One participant shared however, that some actors saw the IVF department as a cash cow for MWH and were interested in generating significant revenues, having seen lucrative earnings in the private facilities (*peer pressure*).

These findings illustrate the role of clinicians as technical champions for implementation of LCIVF initiatives and perceived advantages of incorporating them in a public hospital in comparison to private. Concerning the persuasive function of physicians during implementation, the results of this study closely align with research on the essential role of clinicians as leaders and advocates for their patients, individually and collectively (Earnest, Wong, Federico, 2010; Kuehne et al., 2022; Luft, 2017; Siddiq & Rosenberg, 2021). Clinical teams are uniquely positioned with direct patient contact and an in-depth knowledge of patients' needs, along with the ability to influence changes in health systems delivery and policy to meet those needs (Kuehne et al., 2022; Luft, 2017). They have the power to give voice to patients and communities (Kuwahara, 2021). Through their affiliations with professional associations and as clinical researchers, clinicians have opportunities to increase awareness by providing decision makers with evidence-based information and recommendations, as it was in this study (Earnest, Wong, Federico, 2010; Kuehne et al., 2022). On the other hand, there may be limitations to clinical advocacy associated with time constraints, hesitancy of political action and perceived implications on reputation (Logan, 2019). Nonetheless with sufficient evidence and leadership support, these findings suggest that the engagement of knowledgeable clinician advocates can positively influence policy and implementation of LCIVF into public health systems.

Furthermore, when it comes to justifications for IVF in public hospitals, in developed countries, IVF services are widely available in both the public and private sector (ESHRE Task Force on Ethics and Law,

2008). Whereas in African countries, the rationale for not offering IVF in the public health sector has been justified by poor infrastructure and scarcity of resources better used for prevention rather than treatment (Okonofua, 1996). However, these assumptions have been disputed by countries like Nigeria, where the University of Benin Teaching Hospital (UBTH) for instance, was able to show the feasibility of a successful assisted reproduction program at a public health facility as a low-resource country (Orhue et al, 2012). These success stories, much like the participants reported, are a positive example for other low-resource contexts that IVF in the public sector is possible. Furthermore, participants' expectations aligned with the role of governments in protecting citizen's health with social protections against catastrophic costs of treatment and access to quality healthcare (WHO, 2007). Adoption of fertility care at tertiary level care has been cited by the WHO as a key policy measure to address the burden of infertility (van der Poel, 2012). However, research has shown that most tertiary hospitals in Africa continue to charge user fees as part of cost recovery and thus, are often unable to guarantee access to all citizens (Chabrol, Albert & Ridde, 2019). Hence, implementation of LCIVF initiatives in the public health sector is beneficial to increasing equitable access of fertility treatment to all citizens but cautionary measures should be taken to ensure cost of this specialist treatment does not become a barrier for the least privileged.

In terms of service quality, hospital leadership saw MWH as the ideal site to offer LCIVF services given its advantageous position as a government entity and its ability to attract the "most skilled manpower" in the country (*relative priority*). MWH was said to have a big basket of knowledgeable specialists to choose from including obstetrics and gynecology and fertility specialists. This appeal of the public sector was linked to its career enhancement opportunities including salary, training, teaching, leave and publications (*organizational incentives and rewards*). Similar studies have highlighted the correlation between career development and health workers' intention to stay in public hospitals (Ankomah, Kumah & Karikari, 2016; Ndikumana, Kwonyike & Tubey, 2018). A study of health worker motivations and non-financial incentives in Ghana found working environment, training and career development, recognition and growth as important non-financial motivators (Ankomah, Kumah & Karikari, 2016). Thus, suggesting that offering IVF in public hospitals is advantageous to clinicians interested in advancing their specialist careers in fertility treatment and can improve access to care in this way.

6.3.4. Centralized Processes, Decision Making & Autonomy

The status of MWH as a public health facility (*structural characteristics*) within a broader public health sector ecosystem made it particularly sensitive to system-level factors that influenced decision making. As the new hospital began its operations, participants criticized its reliance on ministerial level authorization to implement various procedural functions. Firstly, participants reported challenges associated with centralized recruitment of staff (*structural characteristics*). As highlighted at the macro-level, recruitment of hospital staff as public servants was done at the ministerial level, by the MoP. This process reportedly made it difficult for MWH to recruit efficiently to fulfil staffing needs and establish good quality teams. Furthermore, new roles such as that of an embryologist which had never been part of the existing human resource infrastructure, created hiring challenges for the IVF department and understaffing of the facility. Participants, therefore, called for autonomy of MWH to independently recruit and dismiss staff, retain competent teams and eliminate non-performing members, who were said to demoralize others (*compatibility*).

Furthermore, MWH's dependence on a centralized reimbursement system impeded its ability to incentivize staff appropriately (*compatibility*). MWH did not have the authority and ability to incentivize staff through salary increments (*organizational incentives and rewards*). This was attributed to how funds in the public sector were centrally collected and banked (in a consolidated fund), prior to redistribution by the MoF. Participants expressed dissatisfaction with MWH's limited control over financial incentives to motivate staff and cited it as a significant drawback to implementation efforts. ART staff were deterred, more so, in view of the higher treatment fees paid for IVF and its demand on staff (*organizational incentives and rewards*). A few participants emphasized the significance of salary incentives to retain quality staff and prevent movement into the private sector for better pay. Furthermore, questions were raised on how donors and surrogates would be compensated under such centralized structures. Therefore, calling for hospital autonomy to implement additional salary increments to compensate staff for perceived extra work required in offering IVF services (*reflection and evaluation*).

These study findings reflect previous literature on granting autonomy in African hospitals which cited increased budgetary discretion, remuneration and recruitment of staff without prior Ministry approval as major motivators (McPake, 1995). Studies have highlighted the mismatch of recruitment and distribution of health workers through centralized government authorities (Munga et al., 2009). Furthermore, the inability of facility (hospital-level) managers to hire, fire and remunerate staff presents significant constraints to performance and service delivery (Bossert, Mitchell, & Janjua, 2015; Chen et al., 2021). Uganda's human resource system is centralized, along with its health information management system, governance, pharmaceuticals, vaccines and equipment logistics (Baine & Kasangaki, 2014). Increased flexibility on human resource functions could address workplace performance by enabling productivity, quality incentives and recruitment to increase efficiency and quality of care (Bossert, 1998).

Decentralization policy reforms around the world were introduced to improve performance and counter constraints associated with centralized processes (WHO, 1995; Sreeramareddy & Sathyanarayana, 2019) including in Uganda (Jeppsson, 2004). however, in practice these reforms have not been successful. A case study on autonomy of 11 public hospitals in developing countries revealed mixed success on performance measures (De Geyndt, 2017). In Uganda, greater motivation for autonomy was associated with the ability to recover costs and manage staff more efficiently (De Geyndt, 2017). But, delegating authority over human resources and finances proved to be challenging (De Geyndt, 2017). The author reported that while governing entities (e.g. Boards & Committees) were created to provide managerial oversight of hospitals; the MoF often maintained authority over revenues and expenditures, the MoP upheld its role to hire, promote, transfer and dismiss government employees and the MoH attempted to maintain ownership over appointment of hospital staff, procurement of medical supplies and equipment. Similarly, a Ghanian study of human resource management in the health system and decentralization found that management authority to recruit and remunerate staff was in practice centralized, rather than transferred to subnational units as intended (Sumah & Baatiema, 2019). Furthermore, when it comes to dismissals, a study in Uganda found that health managers could initiate staff dismissals but the authority to fire lay at a higher (ministerial) level (Mansour et al., 2022). The process was reportedly lengthy and bureaucratic; including politics of who can be 'touched' versus the 'untouchables' (Mansour et al., 2022). Likewise, when it came to setting salaries and benefits, the same study showed that financing was set centrally by the MoP (Mansour et al., 2022). Therefore, these results suggest that centrally controlled recruitment and remuneration of staff may be beneficial to equitable distributions within the workforce, but greater autonomy and flexibility is needed to

facilitate efficient recruitment, incentivization and retention of quality staff within public hospitals to increase efficiency and quality of LCIVF services.

Participants also reported centralized procurement processes as another barrier to implementation. Procurement of equipment and supplies was done centrally through National Medical Stores (NMS) to ensure accountability and oversight. It was mentioned that the government preferred all supplies, medicines and pharmaceuticals to be delivered by the NMS. However, the focus of the NMS was to supply from 'the essential drug list', which did not include a number of specialist drugs and essentials (*compatibility*). Furthermore, the NMS was deemed to be highly bureaucratic with poor operational history (*culture*). During implementation, participants cited delays in equipment delivery due to the lengthy bidding processes that did not facilitate quick decision making. Participants, therefore, predicted that implementation efforts would be impaired by its systematic delays, limited supply and incapability to secure emergency purchases commonplace during IVF cycles, despite treatment being time-sensitive (*compatibility*). Not to mention, that sourcing of IVF equipment and supplies was limited to a few international manufacturers necessitating importation. One participant went on to assert that these procurement challenges would not exist in a private hospital setting. In response, participants called for greater autonomy of MWH to independently procure essential fertility related supplies for successful implementation of LCIVF initiatives.

These findings are in tandem with research on the decision-making process of Uganda's public health sector, which reported NMS as the government's central medical supplies distributor to public hospitals (Chen et al., 2021; Lugada et al., 2022). The role of the NMS was introduced to change Uganda's medical supply system from a 'pull system' in which facilities had charge of measuring their drug needs; to a hybrid 'push and pull' system where either facilities manage their supplies or delegated them to a centralized system (Ministry of Health, 2011). However, a study on the hybrid system on distributing medicines in Uganda found that some personnel expressed dissatisfaction with the failure of the NMS to take into account unique needs of their facilities that resulted in stockouts of some essential drugs and excesses of others (Bukuluki et al., 2013). Therefore, the findings suggest that centralized procurement systems need to consider the unique needs of ART specialist departments and timely delivery of the necessary medical essentials to facilitate implementation efforts and improve service delivery. Furthermore, granting facility-level autonomy provides flexibility that enables specialist departments to determine their own needs and efficiently manage procurement processes. Detailed implications of the procurement process on the IVF department are discussed further at the micro-level.

6.3.5. Financial Resource Availability

A major facilitator of implementation of LCIVF initiatives at MWH was availability of government funding. Financial resources aided construction of the new hospital building for greater delivery of specialist services including LCIVF. The hospital layout consisted of designated floors and partitions for distinct specialities. Altogether, six floors were built to accommodate outpatient services, an administrative and training wing, maternal fetal medicine, urogynecology, gyn-oncology, cervical cancer screening, neonatal intensive care unit, operational theatres and a whole floor dedicated to reproductive medicine (i.e. ART services) (*available resources*). Additionally, the new facility was furnished with computers, a health information system and relevant furniture for service provision. Medical equipment was purchased from

far and wide to meet the clinical teams' requirements. One participant reported the estimated cost of the predominantly imported, reproductive medicine equipment at USD $8M, which took up a significant portion of the budget; while another cited that the hospital procured the necessary high-end equipment to ensure all IVF related services would be provided including a sperm bank. However, participants also reported delays in the government's release of funds that interrupted and delayed equipment procurement and installation *(execution*). Furthermore, participants recommended tax breaks for imported IVF equipment and consumables to reduce costs of procurement and maintenance. While funding from the GoU made it possible to equip the IVF department at MWH, some participants raised concern as to whether financing would extend to on-going patient-related costs, how so and to what extent (*reflection and evaluation*) covered at the micro-level.

The results of this study contribute to literature highlighting the significant role of funding in increasing chances for successful implementation of an intervention (Rogers, 1995; WHO, 2007). The WHO 2007 framework posits mobilization and allocation of finances as a key building block to health systems strengthening and improvement of health outcomes (WHO, 2007). More specifically, Greenhalgh and colleagues (2004) assert that dedicated and continuous funding for implementation increases its likelihood and routinization. In healthcare, funding strategies can facilitate or hinder the uptake of evidence-based healthcare delivery (Ivers, Dhalla, & Brown, 2018). Government health financing, in particular, is fundamental to the functionality of all publicly funded health facilities in achieving healthcare delivery (Federspiel, Borghi, & Martinez-Alvarez, 2022). Calls for public financing of IVF services in Africa have been documented (Adageba, Maya, Annan, & Damalie, 2015). However, in LMIC, healthcare financing is a notable challenge for public hospitals, reportedly enduring material and financial resource constraints (Chabrol, Albert, & Ridde, 2019; Oleribe et al., 2019).

In this study, the government was able to secure external funding to equip the hospital through a USD $30 million loan from the Islamic Development Bank and the African Development Bank, and contribute USD $3.24 million, part of which was earmarked for the IVF department at MWH. This was a considerably unique undertaking for a low resource context, given the presence of other health priorities and limitations of the government's budgets. ART procedures typically require sophisticated laboratories with expensive equipment such as incubators and consumables, highly trained personnel, drugs, consumables and uninterrupted power supply (Afferri et al., 2022; van Blerkom et al., 2014; Serour et al., 2019). The estimated cost of setting up an IVF laboratory is significant, between €1.5–€3.0 million (Klerckx et al., 2013). In Nigeria, the cost of implementing a new IVF-programme in a teaching hospital was estimated at USD $2 million, more than half of the hospital's total resources (Okonofua, 1996). Likewise, in South Africa, setting up an IVF laboratory was a major cost driver, exacerbated by importation taxes incurred in procuring equipment overseas (Huyser & Boyd, 2013). However, successful pronatalist policies that reduce cost of drugs, diagnosis and treatment in public hospitals have been reported in Iran, for instance (Tremayne & Akhondi, 2016). Similarly, Hörbst (2012) suggests that reduction of fertility costs could be achieved by using an outsourced laboratory for treatment as it does not require purchasing of equipment or maintaining experienced staff. Therefore, these findings suggest that successful implementation of LCIVF initiatives in the public hospital still requires significant financial commitment from government entities that can be achieved through loans and tax waivers to minimize importation costs.

6.3.6. Specialist Training Abroad

Government funding made it possible for MWH to offer specialist training for the various specialist clinical teams abroad due to limited availability of local training opportunities. Participants reported that clinicians who had previously shown or expressed interest in the relevant specialities were chosen for training (*individual stages of change*). Clinicians interested in IVF techniques (physicians, nurses and laboratory technicians) were able to receive training in India, over a duration of one month. Participants reported mixed reactions regarding their training experiences. Physician participants reflected positively on their hands-on training that included endoscopic and surgical procedures. Non-physician participants, while appreciative of the training, criticized its short duration. Furthermore, it was described as superficial (observational and not practical), with unknowledgeable trainers in some cases and a poor cultural fit. One participant pointed out experiences of racial bias stating: "*It's a bit tricky, because you cannot touch an Indian, not this color [black] of ours*", concluding that the training was a waste of money. Another participant expressed disappointment with the culturally unrelated IVF counseling content citing guidance practices such as offering yoga to help patients, as unsuitable for the Ugandan context. Non-physician participants also reported dissatisfaction with the lack of documented certification for their training, as there was no record or evidence of their specialist knowledge (*organizational incentives and rewards*). On the other hand, physician participants were able to compensate for the limited training, through their own initiative and take additional time off to receive specialist training elsewhere. Physicians visited various IVF facilities in Canada, U.K and South Africa (*available resources*). A non-physician participant endeavoured to obtain training from local, private fertility clinics but was unsuccessful. Furthermore, with a delayed start to the IVF department, along with further advancements in the field; most participants felt insufficiently ready to start offering IVF services at MWH (*self-efficacy*). Fortunately, the team was able to draw from the knowledge of local fertility specialists to guide implementation (*access to information and knowledge*). However, the most significant barrier to service delivery was absence of trained embryologists on the clinical team; this human resource gap paralysed service delivery completely. Consequently, participants in this study called for provision of locally accessible, on-going training of clinical teams to ensure sufficient human resource, supervision and appropriate contextual guidance in providing IVF services, at least in the early stages (*reflection and evaluation*).

These results reflect the importance of building local capacity to provide fertility services through locally accessible, hands-on specialist training for successful implementation of LCIVF initiatives. Studies have shown similar findings on the benefits of specialist training on infertility for healthcare providers in Africa as beneficial to improving and maintaining technical skills of healthcare providers and quality of fertility care (Afferri et al., 2022; Hörbst, 2012; Ombelet, 2014). The quality and success of IVF treatment relies heavily on the dexterity of the clinical team (Meldrum, 2020). Therefore, poor or lack of opportunities to gain quality training has a detrimental impact on access to quality fertility care. Furthermore, lack of locally accessible training as highlighted in this study has been echoed in other research studies (Hammarberg & Kirkman, 2013). Literature has reported on limited training programs on ART in Africa and difficulty in identifying well trained fertility doctors, embryologists and nurses as barriers to fertility care (Adageba, Maya, Annan, & Damalie, 2015; Gerrits, 2016; Serour et al., 2019; Ombelet & Onofre, 2019). This scarcity of well-trained staff has a negative impact on the affordability of ART services as well. In Ghana, for instance, a study looking at making ART more affordable found a lack of local clinical and embryology training as a significant barrier (Gerrit, 2016). Moreover, in a review of setting up an IVF program in Africa,

Adageba and colleagues (2015) found that trained obstetricians and gynecologists often turned to short-term, costly, training courses in India or elsewhere, but were not sufficient to master the speciality before setting up an IVF center (Adageba, Maya, Annan, & Damalie, 2015). These findings call into question the appropriateness and adequacy of overseas training on improving specialist knowledge and skills for African specialist practitioners.

While press outputs reported on the benefits of IVF training in India for African doctors (Mendonsa, 2014), there have been reports of racism. Racism in healthcare is a well reported phenomenon in many parts of the world (Argueza, Saenz, & McBride, 2021; Mahabir et al., 2021; Hamed et al., 2022). India is reportedly one of the least racially tolerant countries in the world according to the World Population Review, with reports on Africans' poor treatment (Camera, 2020; Prabhu, 2017). Racially related experiences have not been as commonly reported in African healthcare contexts and thus, racism while training abroad could significantly hamper experiences of African practitioners. Furthermore, these findings suggest more attention needs to be paid to the quality and content of training for non-physician staff and ought to be adopted to align with the context under which these clinical teams practice (specially in ART counseling). Lastly, participants' call for locally available, practical training corresponds with research by Adageba and colleagues (2015), who proposed that IVF centers in Africa should seek accreditation and begin training programs for all the categories of staff required to provide this highly specialist service. Egypt and South Africa are the only countries that are known to have IVF training programs (Ombelet, & Onofre, 2019). The authors suggest that African universities should consider provision of subspeciality training on infertility and collaborate with local IVF centers and foreign universities for practical training on ART services (Adageba, Maya, Annan, & Damalie, 2015). Hörbst (2012) also recommended countries seek collaboration with international academic clinical specialists, more so with embryologists and andrologists for local capacity development opportunities, especially with the turn to digital learning brought on by the COVID-19 pandemic (Afferri et al., 2022). These initiatives could strengthen local interest and capacity for knowledge building that is contextually relevant and generate sufficient human resources to meet local demands for affordable fertility services in a public health facility.

6.3.7. Networks and Communication (Internal & External)

As the implementation process progressed, participants cited challenges attributable to gaps in communication related to organizational culture & structure. For one, there did not seem to be clear lines of communication i.e., accountability mechanisms and role clarity (*networks and communications*). Participants voiced high levels of bureaucracy when engaging management that led to delays in decision making (*culture*). For instance, one participant disclosed instances where quick decisions needed to be made; by speaking directly to the hospital director the participant was chastised for not going through the ministerial implementation lead. This pronounced bureaucracy as a core reason for delays during the implementation process. As a public sector project, participants purported long chains of command that required approvals from multiple individuals with varied interests than was considered ideal (*structural characteristics*). For instance, this suboptimal communication led to significant construction errors within the IVF department that took time to rectify and posed major delays (*execution*). Clinical participants requested management for a turnkey IVF construction strategy to overcome these anticipated challenges, but this recommendation was rejected (*reflection and evaluation*). Furthermore, it was reported that the original plan was to have twelve floors as opposed to six and this change was unexplained.

When it came to interorganizational collaboration, participants reported confusion regarding levels of decision-making authority of participants from partner institutions. The teaching institution and teaching hospital worked closely during the initial phases of implementation but distinctions between the two became obvious when some participants' recommendations were disregarded based on their affiliation, which led to "*a loss of morale and scattering of people*" as one participant described. Participants also reported internal power struggles that led to discounting of opinions and fighting. To the extent that individuals who had a different opinion from the government, reported a fear of being labeled as 'anti-government' (*learning climate*). Consequently, participants displayed a crisis of identification with the hospital versus the GoU/MoH (*identification with organization*). For many clinical participants, there was a strong sense of service and commitment to their work; with the majority having worked at the hospital for over a decade. However, when it came to matters that required top or ministerial level engagement, participants shrank back and exercised caution in fear of retribution on their reputation and careers. Some participants cited instances in which they would offer their suggestions to top management and would either be ignored or not receive feedback (*leadership engagement*). In one instance, a participant reported their disappointment over the poor specialist training received overseas but was mandated to stay for the complete duration or refund the training costs. Some participants reported feeling sad, devalued and detached; having to step back or be removed from their roles within the implementation process. Accordingly, participants highlighted the importance of not only continual engagement of key stakeholders, but also empowerment of implementers throughout the implementation process to maintain morale and momentum.

The findings illustrate the implications of bureaucracy and fragmented communication as significant bottlenecks to implementation progression. On the one hand, bureaucratic accountability is beneficial as it aids institutional oversight of the public sector to increase transparency, answerability and performance (Hill & Hupe, 2009; Nxumalo et al., 2018; WHO, 2010). This accountability is vital amidst growing demand for health systems to ensure value for money and high-quality services (Nxumalo et al., 2018). However, it also stifles innovation, responsiveness and threatens rapid/quality service delivery in health systems (Cleary et al., 2013; de Sardan, 2014; Kuye & Akinwale, 2021). The challenges in this study are consistent with research that draw attention to the negative implications of bureaucracy on social institutions such as in healthcare (Kleinman, 2010). In African countries, public health services are hierarchical and top-down organizations (Azevedo, 2017; Kawonga, Blaauw & Fonn, 2016). These administrative systems are a consequence of an inherited European colonial administration to maximize authority (Tumusiime et al., 2019). However, bureaucratic systems can undermine authority and decision-making powers of healthcare managers; promoting 'internal' accountability higher up to the central authority compared to 'external' accountability to peers, patients and external parties or citizens (Cleary et al., 2013). A study of decision-making in healthcare in South Africa, similarly, found that primary healthcare managers reported limited decision-making authority as a barrier to taking contextually appropriate and responsive action in their districts (Scott & Gilson, 2017).

Furthermore, the findings reveal contention between hospital leadership's accountability to the MoH as a central authority and the inability to adequately support participants to express their preferences freely, without fear of being reprimanded. Thus, creating a poor learning climate in which participants do not feel valued and psychologically safe enough to contribute to the implementation process. These responses

corroborate research on organizational silence that accorded perceived threat or risk as a key determinant of an employee's unwillingness to speak up (Morrison & Milliken, 2000; Henriksen, & Dayton, 2006). Organizational silence is characterized as a collective-level phenomenon saying or doing the bare minimum in response to critical organizational problems (Morrison & Milliken, 2000; Vakola & Bouradas, 2005). Public hospitals are embedded in governmental systems and are therefore inherently political, impacting employee willingness to openly communicate. This organizational silence phenomenon was found in a study in 5 public hospitals in Istanbul where physicians and nurses notably remained silent on administrative and organizational topics (e.g., institutional policies and decisions they did not agree with) for fear of their jobs (Harmanci-Seren et al., 2018). Consequently, theories on organizational behaviour and healthcare management emphasize leadership inclusiveness and psychological safety to enable innovation, problem solving and implementation to improve service delivery (Brown & McCormack, 2016; Nembhard & Edmondson, 2006). Additionally, when it comes to multi-sector collaboration, the quality of relationships is a strong success indicator whereby feelings of reciprocity and positive relationships increase collaboration and compromise; while poor partnership structures defined by differential power dynamics counter collaboration (Alhassan et al., 2021). There is a need to strike a balance between achieving upward accountability and enabling local level innovation (Cleary, Molyneux, & Gilson, 2013). Therefore, these findings suggest that implementation leadership support that prioritizes on-going, open engagement with implementation stakeholders and quality interorganizational relationships, that values actors' input and does not threaten wellbeing is a facilitator of LCIVF implementation efforts, particularly for a novel intervention.

6.3.8. Access and Quality of Care

On completion of construction works, MWH was officially commissioned in October 2018 by the MoH and the President of the Republic of Uganda. The hospital began operations to provide quality service delivery within the different specialities. The systems of operation were beneficial in some ways but restrictive in others. While implementation of LCIVF services in the public sector was advantageous in some aspects as highlighted above, it also brought about operational challenges from a structural and equity perspective. A clinical participant raised the issue of privacy of patients while accessing fertility services due to the hospital's layout. The tiered service approach at MWH meant that only patients who paid for the Gold or Platinum hospital plans were afforded private suites as they underwent treatment. However, patients who received treatment under the lowest (Silver) payment package were placed on the general ward with curtains for partitioning while accessing care, which minimized privacy (*compatibility*). Stigma was still an issue and there was a call for privacy to be accorded to all patients regardless of care plan (*reflection and evaluation*). As one clinician put it; "*privacy is important. It creates comfortability and promotes fast healing of the patient*" (*patient needs and resources*).

Privacy concerns in this study complement literature that have underscored the vital role of privacy and confidentiality in patient well-being, regardless of financial status (Beltran-Aroca et al., 2016; Dancet et al., 2010; Dancet et al., 2011; Hartigan et al., 2018; Serour, 2006; Webair et al., 2021). The Uganda Medical and Dental Practitioners Act, 9, chapter 272, states that amongst other rights, patients ought to have the right to respect, dignity and privacy when seeking healthcare (Medical and Dental Practitioners, 1998). However, some studies have reported Uganda's public health system as unable to promote and protect the rights of patients (Kaye et al., 2015; Twinomugisha, 2007; UNHCO, 2003). On the other hand, a study on

patients' rights at Mulago found confidentiality and privacy, and a healthy and safe environment were the most practised rights (Kagoya et al., 2013). These findings have considerable implications in the context of accessing fertility service, which carries with it societal stigma. Research aiming to understand European patients' interpretation of 'patient-centered infertility care' reported patient privacy as one of the main factors that would improve their treatment experience, especially during sensitive periods like semen analysis and preferred a limited number of clinicians during a consultation (Dancet et al., 2011). Similarly, in Saudi Arabia, Arab women seeking fertility care reported privacy as an important component to improving quality of care (Webair et al., 2021). The findings, therefore, suggest that ample consideration should be made in offering privacy to all patients, regardless of financial status, when accessing fertility care in public hospitals.

A considerable barrier to continuity of care was the practice of staff transfers within the public sector. Participants reported that transfer of staff from one location/department to another led to loss of specialist knowledge, team instability and a burden of retraining new staff (*compatibility*). This was a significant hindrance given that specialist training had been done overseas and was costly. Furthermore, upon review, another participant concluded the new hospital was understaffed and did not plan for the appropriate volumes to support operations (*reflections and evaluations*). Clinical teams from the Mulago complex of hospitals were being reassigned within the various units, yet the need for more clinicians was evident. The phenomenon of posting and transferring health workers between public facilities or geographical transfers in LMICs has been posited as a main barrier to effective workforce (Abimbola et al., 2017; Heerdegen et al., 2019; Kwamie et al., 2017; McPake & Koblinsky, 2009; Schaaf & Freedman, 2013). Similar to this study, these processes have reportedly been conducted in ways that undermine health system function as they do not maximize outcomes and consistency (McPake & Koblinsky, 2009). The outcomes for poorly managed postings and transfers are inequitable distributions, absenteeism and low morale (Kwamie et al., 2017). In Ghana, a study on health worker transfer processes within the public health sector revealed that transfer procedures lacked transparency, performed at the discretion of decision makers, without involvement of health workers (Heerdegen et al., 2019). In the context of specialist care, for which demand for technical knowledge is heightened; the practice of staff transfers could severely destabilize departments and quality of care. Therefore, stable specialist teams should be prioritized as a core prerequisite for successful implementation of IVF initiatives in a public hospital.

Participants also purported poor work attitudes in public hospitals are commonplace and a barrier to implementation of quality IVF services. A few participants described a poor workplace mentality that included rampant inefficiencies, late coming and absenteeism, that would be detrimental to time-sensitive fertility services (*culture*). This culture impacted continuity and quality of care within clinical teams. Similar reports on poor attitudes and absenteeism of healthcare workers in public hospitals have been documented in many African countries (Brighton, D'Arcy, Kirtley & Kennedy, 2013; Mannava et al., 2015; Tantchou, 2018; Zitti, Gautier, Coulibaly, & Ridde, 2019). Similarly, poor work attitudes of health workers have been identified as a barrier to quality services in Uganda (Kiguli et al., 2009; Tweheyo et al., 2017). In a study on perceptions of health worker attitudes in Uganda, participants reported negative attitudes that included rudeness, yelling, ignoring and dismissal of patients (Kiguli et al., 2009). Furthermore, Tweheyo and colleagues (2017) reported that Uganda had the highest workforce absenteeism in Africa. However, there have been varied explanations for absenteeism including low staffing, inadequate salary, salary delays, poor attendance monitoring and high workload to name a few (Belita, Mbindyo. & English, 2013;

Lutwama, Roos, & Dolamo, 2012; Ramadhan & Santoso, 2015). A survey on satisfaction and intent to stay among health workers in Uganda found that salary satisfaction, job matching and stimulation, job security, active involvement in the facility, a manageable workload, supportive supervision, and workplace flexibility were facilitating factors (MoH, 2007). To compensate for low salaries in the public sector, studies have reported the common phenomenon of health workforce dual practice, where health workers hold concurrent jobs affecting attendance (Ferrinho et al., 2004; Kiwanuka et al., 2011; Paina et al., 2014). Therefore, these findings suggest that facility level autonomy to provide sufficient incentives for staff retention of specialist knowledge in the public sector and adequate monitoring systems will be beneficial to improving service quality. Implications of poor attitudes in ART departments are expanded upon at the micro-level.

To conclude this section, meso-level factors that significantly facilitated implementation of LCIVF at MWH included availability of financial resources, tension to change by decongesting Mulago and building new hospital infrastructure which presented as an opportunity to incorporate IVF services into its service offerings. Strong departmental leadership support, coupled with political allyship and clinicians' interest in specialization and advocacy efforts advanced implementation efforts at MWH. Additionally, availability of specialist training abroad improved staff knowledge in IVF service delivery. Other moderately facilitating factors included global trends towards specialized care, benchmarking other women's hospitals, importance of government hospitals in offering affordable fertility services. Factors that significantly impeded implementation of LCIVF initiatives included bureaucratic structures, fragmented communication and centralized human resource and procurement systems that hindered staff incentivization and timely procurement of IVF related resources. Moderate impeding factors included lack of locally available and culturally relevant specialist training, especially for non-physician staff, poor hospital culture and learning climate, staff rotation practices and absence of privacy in general wards for fertility patients.

6.4. Objective 3: Consider interpretation of LCIVF initiatives at the micro-level within the clinical practice. Examine how the reproductive medicine department organized itself to offer this service and sustainability of LCIVF services in the public health system.

This section of the paper takes a deeper drive into the considerations taken in providing fertility services at MWH, how LCIVF initiatives were interpreted and adapted to prepare for service delivery. It also looks at how the department has organized itself, current operations, and reflections of the implementation process thus far.

6.4.1. Conceptualizing LCIVF Services

The clinical team at MWH consisted of obstetrician gynecologists, nurses and laboratory technicians that received specialist fertility training overseas in India to deliver fertility care. Prior to this training, the team had been running half-day weekly clinics offering basic diagnostic and surgical procedures to fertility patients. These services included hormone assays, diagnostic laparoscopies, medical prescriptions (mostly for infections), hydrotubation for fallopian tube damage but did not offer any IVF related treatment. Consequently, the clinical participants felt dissatisfied with the basic, non-specialized level of care and limited specialist knowledge, advancing discussions on fertility specialization (*relative advantage*). As one clinical participant worded it, "*we saw infertility patients just as general doctors, general obstetricians and*

gynecologists but over time…discussions started for sub-specialization". Some practitioners took personal initiative to obtain specialist training abroad, with limited support from the hospital aside from approved time off (*individual stage of change*).

These results highlight themes of tension to change and individual stages of change in facilitating implementation of LCIVF initiatives (Greenhalgh, 2004). The team perceived their current situation (absence of IVF knowledge and care) as intolerable, which favoured implementation efforts. The findings resemble prior research on predictions of organizational change which found staff's dissatisfaction with the current status as a key indicator for successful change (Gustafson et al., 2003). Studies show that creating this tension for change where none exists can be challenging but is possible through effective communication to reduce friction (Greenhalgh, 2004; Gustafson et al., 2003). Additionally, the team's intentionality to acquire specialist knowledge to solve patients' fertility related problems aligns with previous research in theories on motivation to learn and change (Grol et al., 2007). These theories suggest that for adult learners, problem-based learning, a principle by which individuals learn better and are more motivated based on real problems they have encountered (in contrast to being pressured), facilitates self-directed learning and can be utilized to implement innovations in healthcare (Jamshidi, Hemmati Maslakpak & Parizad, 2021; Merriam, 1996). For instance, a multi-country study of educational needs of fertility healthcare providers revealed that case-based education and interprofessional training of ART procedures improved quality of patient care (Péloquin et al., 2021). However, Norman (2002) posited that not all health providers have proficiency or motivation for self-directed learning. Furthermore, Grol and colleagues (2007) cited that clinicians with no experience of the problem were least likely to adopt new initiatives. The authors also reported that there may be other motivations for self-directed learning including increased professional status, external expectations and financial status (Grol et al., 2007). In this study, global trends towards specialization (as highlighted at the meso-level) among practitioners may have influenced participants' motivations towards IVF specialist training, since their colleagues were pursuing similar goals. Theories of individual stages of change also contribute to the findings as they assume that an individual's actions are determined in part by perceived attitudes and perceived social norms towards that behaviour (Ajzen, 1991). Therefore, these findings suggest that health care providers with personal experience of the burden of infertility on patients, barriers to access and interest in professional specialization have greater motivation to change the status quo; favouring implementation of LCIVF initiatives.

6.4.2. Benchmarking IVF Services

Participants also described conducting benchmarking visits to other IVF facilities abroad, taking elective placements, attending IVF conferences, reviewing literature and exchanges with colleagues around the world (*external policy and incentives*). By benchmarking other IVF departments and attending IVF conferences, the team was able to grasp best practices and costs for implementing IVF service delivery. These results emulated studies on the practice of benchmarking to improve service quality in healthcare (Chakrabarti & Verguet, 2022; Gyedu et al., 2020; Reponen et al., 2021; von Eiff, 2015; Willmington et al., 2022). As described by the European Benchmarking Code of Conduct (2009), benchmarking is a process of identifying and learning good practices in other organizations. For instance, a study on IVF practices in Ghana and Uganda revealed that practitioners regularly participated in international gynecology conferences, including attending several ESHRE conferences to network, gain consultations and knowledge

exchange in ART services (Hörbst & Gerrits, 2016). Furthermore, a systematic review on benchmarking in healthcare cited the importance of continuous, information seeking and sharing to adopt best practices and modify performance (Ettorchi-Tardy, Levif, & Michel, 2012). Benchmarking ART procedures is especially critical, given increased use and rapid evolution around the world (Zegers-Hochschild et al., 2009). Thus, suggesting opportunities for fertility practitioners to access knowledge and networks through benchmarking and conferences is a facilitator implementation of LCIVF initiatives.

6.4.3. Inter-organizational Knowledge Exchange on LCIVF initiatives

The majority of the physician practitioners specified that their introduction to the concept of LCIVF initiatives was the result of their participation in the first ever LCIVF conference held in Kampala, convened by patient advocacy group - JSFC and WHO/IFFS representatives in January 2006. Through this workshop, attendees were introduced to the impact of infertility in Uganda and newly developed low-cost ART initiatives to counter barriers to access (*source of intervention*). Furthermore, respondents referenced WHO publications on LCIVF initiatives, and the 2007 Arusha conference held by Dr. Willeim Ombelet of the Walking Egg, an organization that championed and innovated some of the new LCIVF initiatives. These results echo literature on interorganizational studies that underline the influence of opinion-leading organizations on other organizations to implement innovations (Greenhalgh, 2007). Literature on the impetus of LCIVF, report that the idea came through discussions at the 2001 WHO (*an opinion-leading organization*) meeting titled "Medical, Ethical and Social Aspects of Assisted Reproduction", which urged for the recognition of infertility as a reproductive disease, even in developing countries (WHO, 2002; Ombelet, 2014). Shortly after this meeting, the Walking Egg was founded as a not-for-profit organization to establish affordable subfertility services in developing countries (Teoh & Maheshwari, 2014). Along with ESHRE and the WHO, the Walking Egg started a global initiative to lower costs of IVF by increasing diagnostic and therapeutic options, hosting an expert meeting on "Developing countries and infertility" in Arusha, Tanzania, in December 2007 that included world experts and attendance from a government representative from Uganda (Ombelet, 2013; Ombelet, 2014; Ombelet & Goossens, 2016).

Furthermore, these findings highlight the importance of access to digestible knowledge of the innovation's use that can be transferred between contexts and adopted easily (Greenhalgh, 2007). This interagency collaborative effort successfully introduced the concept of LCIVF initiatives to participants and subsequently facilitated its implementation in MWH. Similar findings were reported in a systematic review on affordable IVF in LMIC which reported that the WHO, ESHRE, other non-governmental organizations (NGOs) such as the American Society for Reproductive Medicine (ASRM), the International Federation of Gynecology and Obstetrics (FIGO), the International Federation of Fertility Societies (IFFS) and the International Committee for Monitoring Assisted Reproductive Technologies (ICMART), were involved in initiatives aimed at improving access to ART in LMIC (Chiware et al., 2022). In Nigeria, the University of Benin Teaching Hospital (UBTH) launched an infertility management program with support of a 5-year grant from the WHO to implement an infertility program with a fully equipped unit and laboratory (Orhue & Aziken, 2008; Orhue et al., 2012). Therefore, these findings suggest that interorganizational support from leading organizations such as the WHO and access to LCIVF knowledge from organizations like the Walking Egg/ESHRE on LCIVF initiatives can facilitate its implementation in the public health sector.

6.4.4. Low-cost IVF: To be or not to be?

Participant perspectives on the viability of LCIVF initiatives varied, which influenced acceptability of the innovation. Proponents of LCIVF initiatives put forward justifications from a moral and ethical standpoint, in which the desire to achieve pregnancy and be assisted was seen as an individual's God given and human right. Additionally, some participants drew upon a cultural lens, emphasizing the value of children in a pronatalist African culture. In particular, one participant cited, "*All in all, IVF brings new quality of life and also stabilization of families. …we are talking about the inheritances in the African sense."* Other explanations for offering LCIVF initiatives included countering the negative impact of family planning on fertility unbeknown to its users and poor patient response to treatment due to high treatment costs.

These results correspond with studies that have highlighted the role of culture and religion on acceptability and accessibility of ART (Adamson et al., 2016; Chiware et al., 2021; de Mouzon et al., 2020; Serour & Serour, 2021). Uganda is a predominantly Christian, pronatalist nation; majority of whom are Roman Catholic (39.3%) and Anglican (32%), followed by Muslim (13.7%) (UBOS, 2014). Religious perceptions of IVF in this study are comparable to previous studies on Christianity and ART; whereby ART was permissible or moderately permissible among the Protestant and Anglican denominations but less so, within the Roman Catholic church (Best, Sleasman, Hegedus & Schlub, 2019; Dutney, 2007; Schenker, 2000). The findings are also consistent with studies that underscore the value of children in African culture and the role of IVF as a viable solution for infertile couples (Hiadzi, Boafo & Tetteh, 2021; Dierickx et al., 2019, Fabamwo & Akinola, 2013; Faria, 2018; Hiadzi, Jegede & Fayemiwo, 2021). For instance, a study by Hiadzi and colleagues (2021) on religion and ART in Ghana found that participants' desperate desire to have children compelled them to make accommodations for ART procedures they were otherwise uncomfortable with due to their religious beliefs. Conversely, some studies have reported negative perceptions of religion and culture on ART in Africa (Aluko-Arowolo & Ayodele, 2014; Fabamwo & Akinola, 2013; Okafor, Joe-Ikechebelu & Ikechebelu, 2017). In a study of native culture and religious beliefs in Nigeria, Aluko-Arowolo & Ayodele (2014) reported that respondents' negative attitudes towards ART were based on beliefs that ART was in contradiction to the cultural practices in Ijebu and an affront to God's creative power. Therefore, these findings suggest that healthcare provider beliefs and perceptions of LCIVF initiatives in similar contexts can influence their acceptability in clinical practice.

Furthermore, participants' perceptions on the causal association between family planning and infertility align with several African studies that cited normative beliefs on contraceptives as cause of infertility (Adongo et al., 2014; Asemota & Klatsky, 2015; Bornstein et al., 2020; Kabagenyi et al., 2016; Kudesia et al., 2018; Gueye et al., 2015; Hindin et al., 2014; Schwarz et al., 2019; Sedlander et al., 2018; Sedlander et al., 2021; Sedgh & Hussain, 2014). For example, in a Kenyan study on beliefs about contraception and infertility, respondents indicated that use of contraceptives at an early age made women infertile and observance of women who could not get pregnant after using contraceptives affirmed these beliefs (Sedlander et al., 2018). Similarly, a survey of 100 infertile Ugandan women revealed a fear of infertility as a barrier to contraceptive use (Kudesia et al., 2018). Thus, limited understanding of infertility and its causes within healthcare professionals (and the public) fuels misinformation, perpetuates myths and increases reluctance of the public to seek treatment (Asemota & Klatsky, 2015; Kudesia et al., 2018). Regarding the impact of high cost of treatment on patient treatment response and outcomes, to my knowledge, there is no study on direct correlation between these factors. While controversial, some studies

have shown that anxiety, depression and stress (which may be heightened by financial burden of treatment) can affect the number of gametes, embryos and positive pregnancy tests by changing hormone levels associated with human fertility (Campagne, 2006; Gürhan, Akyüz, Atici & Kisa, 2009; Ramezanzadeh et al., 2007; Rooney & Domar, 2018; Terzioglu et al., 2016; Valiani, Ahmadi & Pahlavanzade, 2014; Xu et al., 2017). Furthermore, the negative impact of failed IVF cycles on patients' mental health and wellbeing has been well documented (Gameiro et al., 2014; Howard, 2018; Casale & Carlqvist, 2021). Therefore, these findings suggest that contextual normative, religious and cultural attitudes of healthcare providers that favour access to ART are more likely to facilitate uptake and implementation of LCIVF initiatives.

With regard to ethical arguments, acknowledging the human right to start a family and provide access to care are consistent several studies giving claim to the right to IVF treatment from an ethical standpoint (Asplund, 2020; Patrizio et al., 2022; Kawwass, Penzias, Adashi, 2021; Paulk, 2014; Tännsjö, 2008; Uniacke, 1987; United Nations, 1948; Zegers-Hochschild, Dickens & Dughman-Manzur, 2013). Ethics is described as a systematic reflection on human values and actions, therefore as values change, so do ethical considerations (Asplund, 2020). Having a child if and when desired have been posited as a fundamental component of human life (Gipson, Bornstein & Hindin, 2020). Early ethical questions asked whether it was morally right to create life in a dish, to the moral status of an embryo, but later concerns shifted to the right of an individual to reproduce, third party donation and debates about defining infertility as a disease (Wymelenberg, 1990). Recent research shows that most contexts no longer have ethical discussions regarding IVF itself but rather on who should have access, owing to advancements in evidence-based regulations and clinical recommendations (Asplund, 2020; Dadiya, 2022). Costa Rica for instance, banned IVF for sixteen years due to protections of the embryo based on Catholicism, but recently overturned its decision and had the first IVF baby born in 2017 (Valerio, Vargas & Raventós, 2017). To address some of these ethical dilemmas, a study on ART challenges in Nigeria emphasized the need for stakeholders (clients, fertility specialists, professional organizations, religious bodies, bioethicists, and government) to work together to develop cultural and context-specific guidelines on ART practice. These findings suggest that ethical dispositions of contexts implementing affordable fertility treatment can influence or hinder its implementation and access.

In regard to participants' remarks on the government's role in funding IVF; these findings are consistent with studies that reported benefits of public funding in removing major financial barriers to treatment (Inhorn & Gürtin, 2012; Media, 2017). Researchers have proposed government subsidization of 2-3 IVF cycles as an option in improving access to fertility care in select African countries (Inhorn & Gürtin, 2012). Furthermore, from a patient perspective, a European study of over 6,000 respondents on attitudes towards publicly funded IVF revealed that 93% agreed that the 1st IVF cycle should at least be publicly funded (Fauser et al., 2019). While public funding is beneficial to equitable access to care, it raises questions about who should receive access to fertility treatment and how it is distributed (Media, 2017). For instance, a study of regulation of ART in Brazil's free healthcare system reported that policy makers faced political, economic and ethical challenges in determining allocation of funds to meet the growing demand for fertility services (Garcia & Bellamy, 2015). As the authors posit, questions emerged regarding whether the government should implement a National Policy for Assisted conception that was 100% publicly funded (Garcia & Bellamy, 2015). Furthermore, if ART was to be provided in full, which population groups would have access to fertility services and which would be left out (Garcia & Bellamy, 2015). In New Zealand, government funding for IVF was restricted to women with a body mass index (BMI) <32 kg/m2 on the

basis that women above this BMI were susceptible to miscarriages and complications (The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2014). Furthermore, publicly funded IVF programs are vulnerable to policy changes and healthcare budgets (Media, 2017). Examples of policy changes were reported in a study of IVF treatment coverage in Quebec; IVF coverage started in 2010, but in 2015, a new government administration withdrew fully funded IVF programs to optimize resources and reallocated them to other areas, including cancer care (De Simone, 2019). Therefore, these findings suggest that perceptions of the benefits of IVF facilitate public funding and support implementation, but sustainability considerations need to be weighed given changing political priorities.

6.4.5. Skepticism of LCIVF initiatives

While most participants appreciated and supported initiatives that reduced the cost of fertility treatment on patients (*relative advantage*); there was reported skepticism regarding the innovation itself. Firstly, only 2 of the respondents were able to clearly articulate any specific clinical protocols associated with LCIVF initiatives. Many admitted to the fact that they could not keep up with the scope of initiatives, given rapid advancements in the field (*complexity*). Furthermore, some participants pointed to a lack of sufficient clinical evidence and use of LCIVF innovations from countries in which they are developed (*evidence strength and quality*). As described by a clinical participant, opponents of LCIVF asserted; "*Why do you talk about low-cost IVF in Africa when you don't do it in your countries?*". There was also a lack of consensus around the applicability of LCIVF initiatives as well. One participant asserted that LCIVF was not universal to every patient and would require an individualized approach based on patient factors (*knowledge and beliefs*). For instance, an older couple who required more medication or third-party intervention would not be suitable for LCIVF treatment. Additionally, some participants hinted at the idea that low-cost IVF was perceived as of a lower standard, inferior to conventional IVF practice (*knowledge and beliefs*). Conversely, some proponents of LCIVF suggested that those in opposition of the technology may have been more interested in the revenue opportunities of conventional IVF. Additionally, one participant revealed that the IVF department at MWH was conceived by some to be the revenue generating department for the hospital.

The results here underscore individuals' roles as active participants in considering an innovation's viability and their perceptions of evidence strength and quality. As Greenhalgh and colleagues (2007) assert; "People are not passive recipients of innovations but rather seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them…" (Greenhalgh et al., 2007). Some participants' negative perceptions towards LCIVF evidence base and quality unfavoured implementation at the micro level. The paucity of evidence of safety and efficiency of LCIVF was similarly reported in a systematic review of affordable ART in LMIC (Chiware et al., 2022). Furthermore, the rapidly evolving nature of IVF technologies, let alone, LCIVF initiatives in the literature led to enormous diversification and barriers to remaining abreast for practitioners (Gerrits, 2016; Gullo et al., 2021, Hreinsson, 2019).

Several strategies to reduce costs of IVF treatment have been cited in literature, a majority of which are described in feasibility and efficacy studies (Chiware et al., 2022). These strategies include careful selection of patients (Ojha, Philips and Darne, 2003; Teoh & Maheshwari, 2014), simplification of investigations (Helmerhorst, Oei, Bloemenkamp & Keirse, 1995; Ojha, Philips and Darne, 2003), reduced costs of ovarian

stimulation (Baart et al., 2007; Nargund et al., 2001; Verberg et al., 2009), simplified laboratory costs (Gunalp et al., 2001; Menkveld et al., 2001) and reduced complications (Alper et al., 2002; Lass & Brinsden, 2002). Even with increased recommendations regarding basic investigative methods, there has been significant variability in its applications in developed countries (Helmerhorst, Oei, Bloemenkamp & Keirse, 1995). For instance, instead of costly hysteroscopies, use of the clinically approved transvaginal hydrolaparoscopy technique, which allows direct visualization of the reproductive organs and assessment of tubal patency in an outpatient setting (Brosens, Campo, Puttemans & Gordts, 2002; Cicinelli et al., 2001; Watrelot et al., 2003) was adopted in the Republic of China but not in the United Kingdom or the United States (Ezedinma & Phelps, 2012). These inconsistencies, without standard protocol, lead to large differences in investigative costs and adoption (Ojha, Philips and Darne, 2003).

Furthermore, some recommendations as cited in this study could be considered as contextually unfit. For instance, guidance to omit tubal patency tests such as laparoscopies to reduce overall treatment costs (Mol et al., 1999; Teoh & Maheshwari, 2014), may not be applicable in many African contexts where tubal blockage (85%) is a major cause of infertility (Abebe, Afework & Abaynew, 2020; Ombelet, 2009). Similarly, recommendations for a mild stimulation approach, which has revealed lower pregnancy rates and requires higher laboratory performance with lower margins for error (Teoh & Maheshwari, 2014; Verberg et al., 2009) may not be practical in a low resource context, particularly in a public facility. A study of ART in Ghana and Uganda revealed that while clinicians were aware of ESHRE's single embryo transfer recommendations (ESHRE, 2008), they set their own local standard transferring up to five embryos to increase chances of conception, out of fear of failure and high financial burden of treatment on patients (Hörbst & Gerrits, 2016). While participants in this study alluded to low-cost meaning low quality; the innovators of LCIVF initiatives insist that low-cost alternatives should not result in poor quality care and safety standards should not be compromised at the expense of reduced costs (Ombelet, 2011). However, wider evidence of quality, safety and uptake of LCIVF initiatives is yet to be seen. As Bahamondes and Makuch (2014) note, most of these initiatives are from high-income countries and despite research studies and efforts, they are still not immediately transferable to all LMIC settings. Some participants in this study argued that first, they would like to see these low-cost initiatives routinely performed in the countries in which they are developed before adopting them.

With regards to the revenue generating opportunities of standard IVF services, these findings correspond with literature on infertility as lucrative business around the world (Hörbst & Gerrits, 2016; Patrizio et al., 2022; Wahlberg, 2016). What began as an academic, innovative research endeavour, fertility treatment has become a commercialized and profit driven service (Patrizio et al., 2022). An extensive list of medical interventions termed as "add ons" have been developed, escalating patient costs, increasing investor interests and enhancing revenues generated by fertility practices; yet limited in their evidence of improving pregnancy outcomes (Harper et al., 2017; Patrizio et al., 2022; Wilkinson et al., 2019). The same study by Hörbst & Gerrits (2016) reported that doctors' entrepreneurial interests enabled them to capitalize on demand for fertility treatment within their private clinics. As the authors assert, "unwanted childlessness promises to be a lucrative field for biomedical interventions" (Hörbst & Gerrits, 2016). Globally, the estimated worth of the fertility industry is USD $25 billion and is predicted to grow to $41 billion by 2026 (Strodel, 2020). Thus, the revenue generating limitations of low-cost options may present barriers to adoption by healthcare practitioners in low-resource contexts. Indeed, researchers have cautioned on the detrimental impact of "industrialization and commodification of IVF" on patients and their quality of care

(Gleicher, Kushnir & Barad, 2019; Resneck, 2018). Gleicher and colleagues (2019) reported on implications of fertility commercialization citing increased costs of IVF, reduced live birth rates and poor patient satisfaction. Therefore, these findings suggest that the rapidly evolving, overwhelming dearth of literature on LCIVF initiatives coupled with limited clinical evidence and use in innovators' countries impedes implementation of LCIVF initiatives. Furthermore, perceptions of revenue loss associated with lower cost IVF, pose significant barriers to implementation and adoption of LCIVF initiatives in public hospitals interested in generating considerable revenues from provision of fertility services.

6.4.6. Pricing Debates

Pricing of IVF services at MWH brought about considerable debate and contention from various stakeholders. Non-physician participants mostly had different interpretations of LCIVF initiatives. To them, LCIVF initiatives were a government funded intervention that enabled subsidization of conventional IVF treatment for the benefit of citizens. By providing government resources to develop infrastructure, equip and train salaried staff, participants framed LCIVF as an internally developed initiative through the MoH (*intervention source*). This lens lent itself to the argument that fertility services at MWH ought to be offered for free or at a subsidized cost. As one participant phrased it: "*This hospital is built by the African Development Bank loan, which loan everybody pays for…you cannot refuse or ask patients to pay because they are the owners…they are the taxpayers.*" This rationale for offering LCIVF initiatives gave rise to opposition when it came to pricing the service. MWH established a three-tiered pricing plan from the most basic (Silver), intermediary (Gold) and highest (Platinum) treatment packages, that for the most part determined the type of accommodation (general/private/VIP) provided to patients on admission. Local Ugandan Media reported that the VIP and VIIP services will be on the 9 floor of MWH and the suites are customized with DSTV Services, private cooking areas and guest room, among others (Waswa, 2018). However, when the cost of tiered IVF treatment was released in the press, quoting 14 million Uganda Shillings (approximately $4,000) for the silver package, there was public outcry including parliamentarians citing, "Mulago Specialised Women hospital charges too expensive for an ordinary woman" (*cost*) (Nakalema, 2018). Still, the Minister of Health reported that the prices were based on similar services in the country and abroad (Waswa, 2018).

Clinical participants who had set IVF treatment prices, argued that it was cheaper than private facilities and that offering IVF at a lower cost or for free would not be sustainable for the government, more so with the ever-changing national priorities. Indeed, with the on-set of the COVID-19 pandemic, participants reported that like the rest of the world, government priorities and resources shifted towards COVID-19 treatment and vaccination efforts. Furthermore, they stated that IVF services were costly to maintain and despite overwhelming need, rampant poverty made universal access untenable; a predicament termed as, "The paradox of the typical IVF practitioner in Africa". Nonetheless, some participants recommended other alternatives to reducing treatment costs including batching patients and allowing those who could afford to subsidize those who could not. Furthermore, a hospital administrator gave assurances that referral patients who could not afford IVF services would be eligible to payment waivers administered through a waiver committee. Patients could be referred from any facility in the country including regional referral hospitals, private hospitals, private not for profit and tertiary facilities. Still, for some, this was a big failure and departure from the vision of a women's hospital that would be accessible to all women (*reflection and evaluation*).

These findings echo research from several authors on lack of consensus on how inclusion of fertility care should be adapted and implemented in different contexts (Dierickx et al., 2019; IFFS, 2016; Serour et al., 2019). Implementation science emphasizes the importance of clearly described, aligned and well understood implementation strategies for successful change in healthcare practice (Proctor, Powell, & McMillen, 2013). Implementation strategies are methods or techniques utilized to enhance adoption, implementation, and sustainability of a clinical intervention or practice (Curran, Bauer, Mittman, Pyne & Stetler, 2012). While there is evidence of an increase in implementation strategies, there are limitations on their specificity; strategies are often poorly described, inconsistently labelled, infrequently justified and understood (Michie et al., 2009). Developing clear implementation strategies that include definition of the actor(s), the action, action targets, implementation outcomes addressed, and theoretical justification, can help overcome barriers as described in this study and increase effectiveness of implementation (Eccles et al., 2009; Proctor, Powell, & McMillen, 2013).

Multi-faceted strategies, like implementation of LCIVF initiatives are inherently complex social interventions as they address multifaceted and complicated processes within interpersonal, organizational, and community contexts (Alexander & Hearld, 2012; Craig et al., 2008; Mittman, 2012). Therefore, a deeper understanding of all stakeholder priorities, expectations, incentives and intended strategies is critical to driving successful use and implementation of interventions (Lyles et al., 2021; Steenkamer et al., 2019; Wanjau et al., 2021). An example of the impact of poor implementation strategies is reported in a Kenyan study, where misaligned priority setting for non-communicable disease control between international funders and national priorities hindered implementation of contextually specific NCD control priority areas that existed locally (Wanjau et al., 2021). As in this study, a lack of clear strategy and expectations on IVF costing resulted in misalignment of pricing expectations and friction, with opposing views between the service providers, government and public actors. Therefore, given the multilayered complexity of implementing LCIVF initiatives, strategies for implementation ought to be clear, stakeholders aligned and capable of addressing the myriad of variables to facilitate successful implementation efforts and sustainability.

Furthermore, previous studies have reported similar contentions between high user fees in government hospitals and public protestation against them (Hongoro & McPake, 2004; McPake, Hongoro & Russo, 2011; Webster, 2015). For instance, a case study of public hospitals in LMICs found that most government hospitals continued to charge user fees to manage debts incurred and maintain costs of operations (Webster, 2015). Additionally, special services or wards became increasingly common to attract affluent customers and increase revenues for underfunded hospitals (McPake, Hanson & Adam, 2007). In a study on tiered funding in LMICs, McPake and colleagues (2007) found that governments actively pursued two-tier user fees packages to support cross-subsidy from superior to basic service users (McPake, Hanson & Adam, 2007). This tiered pricing, as hospital officials often justified, took advantage of users who were willing to pay to compensate for basic services and create equitable access (McPake, Hanson & Adam, 2007). However, there was no evidence that this form of pricing produced equitable outcomes and quite possibly did the opposite (McPake, Hanson & Adam, 2007). These outcomes were reflected in a newly built government hospital in Lesotho, in which much controversy was generated over its high fees; while the fees were justified as part of its cost recovery, they did not guarantee access for all citizens and deepened inequities in healthcare access to tertiary institutions (Webster, 2015). However, a Nigerian study in the

University of Benin Teaching Hospital (UBTH) has been able to show how a public hospital can reduce IVF costs through patient batching (Orhue et al., 2012) as recommended by participants in this study.

Provision of treatment waivers was reported in local Ugandan press to address public outcry, "There will however be a waiver system for patients unable to pay for the services. A committee will be set up to assess the eligibility of the patients seeking a waiver" (Waswa, 2018). Treatment waivers have also been documented in previous studies on waiver systems in developing countries (Bitrán & Giedion, 2003; Kamanda, Kimengi & Nangami, 2015; Mamdani & Bangser, 2004; Tien & Chee, 2002). Countries like Tanzania, Thailand, Cambodia and Indonesia designed and implemented detailed waiver systems to give poorer people free access to healthcare services (Giedion, 2003; Mamdani & Bangser, 2004). However, a study on waiver policies in Zambia found that in practice, these policies did not meet desired outcomes and were underutilized due to a lack of clarity and consistency in their implementation (Mamdani & Bangser, 2004; Tien & Chee, 2002). Furthermore, previous studies have cited the need for strong referral systems at different levels of care including public–private and traditional–modern for efficient provision of fertility care (Dyer, 2008; van Balen and Gerrits, 2001)). Other cost-saving practices were found in a study in Ghana and Kenya where practitioners negotiated treatment protocols like egg sharing to reduce treatment cost to patients (Hörbst & Trudie, 2016). Therefore, these findings suggest that pricing of LCIVF initiatives requires stakeholder consensus and clear implementation strategies that consider equitable access to facilitate implementation and sustainability of LCIVF initiatives in a public facility.

6.4.7. Preparations for LCIVF Service Delivery

At the time of this study, MWH had not yet started offering IVF services, primarily because the clinical team had no embryologist. Nonetheless, the team had drafted clinical protocols and strategies on how IVF services would be run at MWH, managed and delivered to patients. Firstly, participants shared their intention in offering these services incrementally through free trials on patients that would then be published (*trialability*). Given the plethora of LCIVF initiatives, participants discussed plans to exercise caution by offering uncomplicated treatment options first, like intra-uterine insemination (IUI), and then work their way to more complicated treatment protocols (*complexity*). Participants reflected on their own modest self-efficacy in relation to advanced IVF treatment, as a clinical participant asserted, "*we do not want to bite what we cannot swallow*" and lack of legislation to guide them. In particular, participants were concerned about third party IVF treatment (i.e., gamete donation and surrogacy). On the other hand, participants spoke favourably regarding flexibility in application of LCIVF treatment, with multiple pathways that could considered when providing treatment citing IUI or time sexual intercourse for simpler protocols (*adaptability*).

These results highlight the importance of trialability of LCIVF interventions in facilitating implementation in the public health sector. The findings correspond with previous literature that suggests innovations in which intended users can experiment within a limited time period, are more likely to be adopted (Greenhalgh et al., 2004; Rogers, 1995). As new IVF technologies are developed at a fast pace, the interventions have become more complex and sophisticated including techniques such as cryopreservation of gametes or embryos, IVF and ICSI (Afferri, 2022; Zegers-Hochschild et al., 2017). Strengthening the "trialability space" for experimenting with LCIVF initiatives will be essential to allow practitioners to gain confidence and practice as they deliver care. This participant's strategy to start with IUI procedures agrees

with literature that suggests that IUI should be used as a first-line treatment, especially for unexplained infertility (Asemota & Klatsky, 2015). The IVF department needs to be a continuous learning organization through which experience, feedback and tolerance for members to try new things should be encouraged (Hreinsson, 2019). Furthermore, given the complexity of LCIVF strategies, many of which are still undergoing feasibility and efficacy testing, concerns have been raised regarding the replicability of various techniques in different laboratory environments (Chiware et al., 2022). Therefore, the findings suggest that the opportunity for practitioners to experiment with LCIVF initiatives in their own clinical settings is advantageous to implementation.

Interestingly, when asked about LCIVF initiatives, one clinician revealed that low-cost referred to the reduced amount of money patients would have to pay for treatment but not to the standard of care, which would remain the same (*knowledge and beliefs*). This interpretation was validated by the hospital's purchase of high end, specialized equipment to offer the full array IVF services (*cost*). This costly, specialized equipment required an IVF lab with particular specifications and a well-trained technical team to manage it (*complexity*). At the time of the study, the clinical team had not received training to operate this expensive equipment due to the COVID-19 pandemic. Most of the equipment was procured from overseas, where the trainers were also located and could not travel to Uganda to train staff because of travel restrictions (*access to knowledge*). Furthermore, one participant reported that the department had issues of compatibility with the equipment and sourcing of consumables given limited manufacturers available (*complexity*).

Similar findings were reported in studies of the integration of LCIVF in Africa, which reported that the high price attached to IVF implementation was largely due to expenditures on laboratory equipment amongst other costs (Teoh & Maheshwari, 2014; Serour et al., 2019). Laboratory equipment over time has become more complex, with additional laboratory interventions like intracytoplasmic sperm (ICSI), leading to a rise in cost (Teoh & Maheshwari, 2014). The average estimated cost of setting up an IVF laboratory as previously highlighted is €1.5–€3.0 million (Klerckx, 2013). A study on the major cost-drivers of IVF in South Africa, revealed 35% was attributable to laboratory expenses including the laboratory, use equipment, disposables, culture media and staff expenditures (Huyser & Boyd, 2013). Like in this study, all the laboratory items were imported from various parts of the world to South Africa (Huyser & Boyd, 2013). Training challenges associated with use of specialized equipment were similarly highlighted in a study on prospects and challenges to setting up and running a successful IVF program in Africa (Adageba, Maya, Annan & Damalie, 2015). In their review, Adageba and colleagues (2015) reported that the set up and servicing of IVF equipment by skilled personnel in Africa was a challenge. Companies that set up IVF laboratories were often from overseas and regular maintenance of equipment was problematic and costly to bring service engineers from abroad (Adageba, Maya, Annan & Damalie, 2015). These challenges were reported to have a negative influence on laboratory conditions and success rates of IVF treatment (Adageba, Maya, Annan & Damalie, 2015). Therefore, these findings suggest that complexity of IVF procedures, compatibility of imported specialist equipment and equipment training requirements to deliver these quality services pose considerable barriers to implementation in public hospitals in Africa.

In terms of day-to-day operations, the departmental document titled “How to successfully run an IVF facility in a Mulago National Referral Hospital” provided guidance to ensure quality care. Quality control was of particular concern, from the medication, retrieval, incubators, implantation to pregnancy. The manual drew attention to the importance of strict internal quality control measures (e.g., strictly controlled

laboratory environment, meticulous record keeping and accountability) to monitor performance and external quality assurances (e.g., backup power supply, access to quality medicines and training) to ensure quality fertility services and avert legal threats that would arise from poor management and delivery of services. These results are consistent with literature on setting up an IVF laboratory in Africa in which recommendations of stable power supply to overcome frequent power outages and fluctuations in many African countries are emphasized (Adageba, Maya, Annan & Damalie, 2015). The authors, like in this IVF manual, recommend a comprehensive and reliable power back-up system, routine maintenance of equipment, training and access to reliable quality drugs (Adageba, Maya, Annan & Damalie, 2015). Lack of reliable supply to quality drugs, consumables, and culture media in Africa is a serious challenge as there are few manufacturers because few African countries prioritize treatment of infertility. (Adageba, Maya, Annan & Damalie, 2015). In the author's facility, drug supplies were often imported from India, Denmark and Switzerland, were erratic which affected planning for IVF cycles and cold chains were impractical due to unreliable power supply in supplier depots (Adageba, Maya, Annan & Damalie, 2015). Therefore, these results suggest that the strict operational systems and adequate access to IVF supplies is needed to guarantee service quality and efficiency in a public health sector. Furthermore, African countries should consider local manufacturing of IVF equipment, fertility drugs and consumables to curb the high costs of importation, incompatibility challenges and unreliable supply chains.

6.4.8. Patient-Centered Care

Participants emphasized commitment and personal interest as major contributing factors towards the successful implementation of IVF services (*knowledge and beliefs*). Provision of IVF services was said to be a sensitive and time-consuming speciality that required passion and compassion to improve patient satisfaction. One participant emphasized this saying; "*among us service providers, interest is a prerequisite to giving quality services…if not, someone will prioritize money…I have already seen it*". This was important, more so, in the context of counseling of fertility patients, which required time and compassion (*patient needs and resources*). These results are consistent with research on the importance of good communication and empathetic skills during patient-clinician interactions in fertility care (García et al., 2013; Klitzman, 2018). The high emotional burden of infertility on patients has been widely documented (Dierickx et al., 2018; Dierickx et al., 2019; Dimka & Dein, 2013; Faria, 2018; Hollos & Whitehouse, 2014; Naab, Yakubu & Donkor, 2019). Furthermore, patients undergoing IVF treatment are at significant risk of psychiatric disorders and psychological destabilization due to cost, uncertainty, worry, anxiety associated with treatment and repeated failures (Boivin et al., 2012; Palmer-Wackerly, Voorhees, D'Souza, & Weeks, 2019; Rooney & Domar, 2018). Thus, emphasizing the importance of recognizing, acknowledging and assisting these patients as they cope with their infertility diagnosis and treatment (Rooney & Domar, 2018).

Studies show that patients place significant emphasis on patient-provider communication and relationships, and insensitive care provision worsens an already formidable treatment experience (Aarts et al., 2011; Boivin et al., 2012; Klitzman, 2018; van Empel et al., 2010). In fact, previous studies revealed that patients often chose IVF clinics based on quality of care and success rates (Dancet et al., 2010; Marcus & Marcus, 2005). For instance, a study of 'patient-centred infertility care' from patients' perspective in Belgium and the Netherlands reported human factors associated with staff attitude and relationships, communication, privacy and support as critical (Dancet et al., 2011). In this study's review of communication, patients felt that staff should be friendly, give them time, opportunities to ask questions and provide emotional support

(Dancet et al., 2011). Likewise, in a Dutch study on fertility care from the patient's perspective, patients indicated that they would trade 9.8% of their pregnancy rate to be seen by a friendly and interested doctor rather than an unfriendly and uninterested one (van Empel et al., 2010). However, a study of workplace stressors reported that fertility providers had difficult trade-offs to make between balancing the high workload and adequately supporting patients (Boivin et al., 2017). Those that concurrently experienced stress reactions at work had less energy and mental resources to support patients, affecting the latter's outcomes (Boivin et al., 2017). Therefore, these findings suggest that positive attitudes and interactions between clinical staff and patients during IVF treatment should be encouraged and supported to enhance service quality and utilization.

Another clinical participant revealed the burden of complex IVF treatments stating, "*these were all issues…which were emotionally draining*" and described IVF as a very taxing speciality, both mentally and emotionally (*knowledge and beliefs*). Additionally, the participant cited that most patients perceived their failure to conceive after fertility treatment as a dexterity deficiency on the part of the physician and not on the technology itself, thus placing blame on the practitioner (*patients needs and resources*). These findings align with literature on "emotional labor" ART health care workers, having to engage challenging patients and navigate disappointing results (Fitzgerald, Legge & Frank, 2013). In a study of the emotional labor of embryologists in New Zealand, Fitzgerald and colleagues (2013) found that embryologists took on technical and emotional care roles; in the latter having to manage difficult patients, 'talk up' bad news and preserve hope and meaning, yet remaining truthful (Fitzgerald, Legge & Frank, 2013). In particular, the scientists felt heavy hearted in dealing with patients who were receiving bad news; some wanted the briefest information and would likely hang up the phone (Fitzgerald, Legge & Frank, 2013). In their reflections, they cited that the role required clinicians with personalities that were not easily stressed and who could cope with difficult situations easily (Fitzgerald, Legge & Frank, 2013).

A study of the educational gaps of fertility healthcare providers revealed that 39% of physicians reported that managing patients' emotional distress was outside of their competencies (Péloquin et al., 2021). Similarly, patient-centered interactions are not typically taught in scientific training; yet there is increasing interaction between embryologists and patients, posing considerable challenges (Campbell et al., 2022). Patient blame of doctors over disappointing news has also been reported in the literature as a stressor (Klitzman, 2018). Clinicians may not respond to these negative results well, exhibit trouble discussing them and fear potential lawsuits thereby distancing or withdrawing themselves from patients worsening their treatment experiences (Klitzman, 2018). Thus, attention to the mental health of clinical healthcare providers is on the rise (Campbell, et al., 2022). Literature suggests the need for empathetic and stress management training for clinicians, along with involvement of mental health providers and provision of psychological interventions into routine practice to counsel and support patients confronting treatment failures and other stresses (Aarts et al., 2012; Boivin et al., 2012; Fitzgerald, Legge & Frank, 2013; García et al., 2013; Klitzman, 2018; Rooney & Domar, 2018). Infertility counseling should be incorporated, defined as a professional intervention delivered with the intention of mitigating the physical, emotional and psychosocial consequences of infertility (Zegers-Hochschild et al., 2017). However, few countries have a legal mandate for infertility counseling and supportive care in reproductive health programs (Blyth, 2012). Therefore, these findings suggest emotional competencies of clinicians and incorporation of mental health providers should be considered and supported to enhance patient centered care principles (i.e. information

quality, communication skills, and time dedication), increase patient satisfaction and improve quality of care.

When it comes to internal team dynamics, participants reported that IVF treatment required significant collaboration between team members as each member's action influenced the success of the next (*complexity*). That is, if the specialist doctor did not retrieve ample numbers of quality eggs, it affected the embryologists' ability to produce quality embryos for transfer. This dependency was further confounded by the fact that in a public hospital like MWH, there was many staff, hired centrally and rotated within the department (*compatibility*). Staff rotations were said to complicate consistency, accountability and quality of care given different dexterity of clinicians. As a participant put it, "*this made the department prone to clinical error*" and reported seeing similar challenges in a public health facility in South Africa were rotating of staff resulted in poor pregnancy rates. These issues were seen to be major barriers to quality of care (*compatibility*).

The findings are in parallel with studies underscoring the importance of sustained teamwork across multiple departmental areas, such as nursing, administrative, laboratory, and clinical to successfully provide IVF treatment (Campbell, et al., 2022). An IVF team includes gynecologists, nurses, embryologists, urologists, pharmacists, counselors and the other professionals all of whom have to function together to deliver consistent, safe and efficient patient-centered care (Campbell, et al., 2022). The IVF process is described as a series of precisely controlled events that require meticulous attention to detail, orchestrated by a clinical team whereby each member must play their part (Campbell, et al., 2022; Zegers-Hochschild et al., 2017). It is a process that is strongly dependent on the dexterity of the embryologist and the laboratory IVF cycle involves teamwork that is heavily dependent on consistent and collective competence to mitigate risk (Campbell, et al., 2022; Hreinsson, 2019; Jimena et al., 2016). Therefore, as reported in a study of workplace stressors in a fertility clinic, clinicians ranked organization, team and management issues including working on a good team as some of the highest stressors (Boivin et al., 2017). Furthermore, when it comes to staff rotations, a systematic review on quality improvement and strengthening African healthcare systems revealed that staff rotations steadily diluted capacity for improvement in teams (Heiby, 2014). These rotations disrupted continuity, accountability and quality care (Heiby, 2014), which is crucial in ART. To counter these challenges, Hreinsson (2019) recommends training in non-technical skills (i.e., good communication, teamwork, decision making, situational awareness, managing stress, coping with fatigue) (Flin, 2008) and documentation of routines on how to act in various situations as a time-saving measure. Therefore, these findings suggest that a competent, cooperative and consistent clinical teams and teamwork is beneficial in facilitating implementation, quality and sustained service provision of LCIVF initiatives in a public hospital.

6.4.9. No Embryologist, No IVF

The reproductive medicine department held monthly meetings to discuss matters arising from within the department including reminders to put pressure on management to facilitate speedy action (*networks and communications*). Of which, the most critical matter was the absence of an embryologist on the team (*available resources*). Participants reported providing management with different suggestions for recruiting an embryologist including hiring a consultant or entering a public-private partnership with a private fertility hospital (*networks and communications*). However, having received no feedback on their suggestions and

without an embryologist, the IVF department was paralysed and unable to start offering IVF services to patients (*available resources*). The only services available to patients were hormonal blood tests, transvaginal scans, semen analysis, diagnostic surgeries and hormone replacement treatment. Participants reflected on this communication deficiency emphasizing that change in political leadership and thus ministerial support, had a detrimental impact on implementation. Specifically, the reassignment of the previous MoH to another ministry had adverse repercussions on implementation progress (*leadership engagement*). Participants described her as a strong advocate and good leader, passionate about infertility, willing to take on any repercussions on behalf of the team (*learning climate*) and cited her departure as a huge loss to the department. They felt safe as one participant stated: "s*he understood us, their intentions and was the biggest tool*" in propelling implementation efforts. Furthermore, there was consensus that MoH had different priorities and fertility was not a major one (*external policy and incentives*). Without strong political support and with the on-set of COVID-19, participants reported feeling powerless to revamp discussions with the new MoH on commencing IVF services and hiring an embryologist (*identification with organization*). Many of the respondents expressed disappointment and loss of morale concerning the delay of IVF service provision at MWH and hoped it would start soon (*reflection and evaluation*).

These findings aligned with other studies in Africa that have reported on the scarcity of embryologists (Gerrits, 2016; Hammarberg et al., 2018; Hörbst and Gerrits, 2015; Ombelet, 2019; Serour et al., 2019). The role of an embryologist is relatively new in the medical field, only coming into recognition in 1980 (Campbell et al., 2022). Yet, the role of an embryologist in an embryology laboratory is indispensable to the performance of IVF in clinics (Choucair, Younis, & Hourani, 2021). In their role, a "good" embryologist performs meticulous gamete/embryo manipulation with firm hand-eye coordination and dexterity (Campbell et al., 2022; Choucair, Younis, & Hourani, 2021). Yet the scarcity of well-trained, locally available embryologists is commonplace in Africa. For instance, a study of ART in Ghana, found that many private clinics, through transnational networking, flew in qualified embryologists from Europe to carry out laboratory procedures (Gerrits, 2016). Similarly, in a study on improving ART access in low-income settings, the authors experienced challenges establishing an IVF clinic in Zimbabwe because there were no trained embryologists available (Hammarberg et al., 2018). Another study on ART in Uganda reported that a private fertility clinic relied on foreign embryologists from Belgium, Kenya, and Nigeria who flew in and out of the country to run the clinic which raised the cost and was not sustainable (WHO, 2010). Similarly, researchers have advocated for sharing of embryologists between fertility clinics to reduce the cost of procedures (Khalifa & Ahmed; 2012). Therefore, the role of private facilities or actors through public-private sector partnerships (Bittaye et al., 2023; Serour et al., 2019) as recommended by the participants in this study could be considered. Furthermore, without strong leadership and ministerial prioritization, participants in this study felt that they were not able to take extraordinary measures necessary to identify and recruit an embryologist for MWH. In a press report on why the IVF department had not started at the hospital, hospital management reported that there are no embryologists in Uganda and that this scarcity had delayed establishment of IVF (Kiwuuwa, 2021). Hospital management reported that the hospital was supposed to have three embryologists, but none had been recruited and requested Parliament to appropriate funds of one billion Uganda Shillings (approximately USD $264,172) for training abroad (Karugaba, 2021; Kiwuuwa, 2021). Therefore, these findings underscore the critical role of embryologists in IVF, their scarcity in Africa and importance of political support to leverage transnational networks while building local capacity of embryologists to facilitate implementation of LCIVF initiatives.

To summarize this section, micro-level factors that significantly facilitated implementation of LCIVF at MWH included clinician interest in specializing and appreciation for the burden on infertility, knowledge exchange with LCIVF innovators and experts, trialability and adaptability of LCIVF initiatives. Other moderately facilitating factors included benchmarking visits to IVF facilities and moral & ethical beliefs supporting intervention. The main factor that ultimately impeded implementation of LCIVF service delivery was lack of an embryologist. Other significant barriers included insufficient clinical evidence of LCIVF initiatives, limited adoption in innovator countries, lack of consensus on pricing services, perceived revenue loss associated with LCIVF initiatives. Other barriers included scope, complexity and rapid evolution of LCIVF initiatives, some initiatives had poor contextual fit, few (foreign) manufacturers of IVF equipment and drugs, emotionally taxing speciality and concern for internal quality controls and external measures to guarantee service provision.

6.5. Conclusions

In conclusion, the findings of this study may contribute to knowledge of factors influencing implementation of LCIVF initiatives in a Sub-Saharan context. In this thesis, the author reported on multi-level facilitators and barriers to implementation of LCIVF initiatives within the public health system in Uganda. The research was conducted over a duration of five months in the field through Mulago Women's Hospital to study the genesis of LCIVF services in this specialized hospital, its organizational structures, internal and external processes and social interactions within the hospital setting. The author carried out field visits, interviews and document reviews to examine and explain barriers and facilitators to LCIVF implementation in a public health system of a low-resource context.

Through extensive data analysis, factors identified as facilitators and inhibitors to LCIVF implementation are summarized in five main domains based on the CFIR framework and further sub-categorized into thirty six themes including: intervention source, evidence strength & quality, relative advantage, trialability, adaptability, complexity, cost, patient needs and resources, cosmopolitanism, peer pressure, external policies and incentives, benchmarking, structural characteristics, networks & communications, culture, tension to change, compatibility, relative priority, relative priority, organizational incentives & rewards, goals & feedback, learning climate, leadership engagement, available resources, access to knowledge & information, knowledge and beliefs about innovation, self-efficacy, individual stages of change and individual identification with organization, planning, engaging (opinion leaders, formally appointment internal implementation leaders, champions, external change ages), executing, reflecting and evaluation and an inductive theme on reputation of implementer.

6.5.1 Objective 1: Macro-level (broader) factors that LCIVF implementation in Uganda's public health system.

Within the broader context, implementation of LCIVF initiatives in this study was facilitated most notably by favourable international policy on infertility, strong political support and interorganizational collaboration, followed by adequate financial resources and public demand for affordable fertility services. International policy recognition of infertility as a reproductive disease by the WHO and the UN Universal Declaration of Human Rights outlining the right to marriage and founding a family, served as justification for the MoH to support implementation of LCIVF initiatives in the public sector. The designated 'disease

status' of infertility symbolized the government's obligation to support its citizenry through access to publicly funded, affordable fertility care within the public health system.

Furthermore, strong political support and advocacy in the initial stages of implementation drove approval for the women's specialist hospital, securing of government funding and oversight of implementation process for LCIVF services at MWH. The then Minister of Health acted as a fierce political advocate, strongly supporting LCIVF implementation; along with women parliamentarians who acted as allies, galvanizing their male counterparts to successfully approve a $34 million dollar proposal to fund and develop a formal implementation strategy for establishment of the women's hospital.

Multi-sectoral collaboration with international experts and associations on fertility (WHO, IFFS, ESHRE, ASRM, MERCK, The Walking Egg), funding entities (African Development Bank and Islamic Development Bank), patient advocacy groups, professional medical associations, teaching institutions, press media houses and private practitioners facilitated implementation of LCIVF initiatives through expert guidance, professional training, public awareness, policy and advocacy support. More notably, the patient-led advocacy organization (Joyce Fertility Support Center) played a deterministic role as a grassroots organization in mobilizing international and local stakeholders to host the first LCIVF conference in Uganda that championed LCIVF and became instrumental in propelling the idea of affordable fertility services in the public sector. Furthermore, collaboration with MERCK foundation was critical to bringing awareness of the burden of infertility at the ministerial/national level through their "More than a Mother" campaigns amplifying public demand for affordable fertility services.

On the other hand, there were considerable barriers to implementation that included loss of political support and limited engagement with opinion leaders (traditional, cultural and religious leaders) as the most impactful, followed by discontinued stakeholder engagement, insufficient public awareness, and absence of national legislation on ART. The loss of a key political champion through the MoH diminished implementation momentum, deprioritized infertility in national discourse and stagnated implementation efforts. Furthermore, while an ART bill had been drafted and introduced within parliament, limited understanding of IVF procedures amongst policy makers and engagement of key opinion leaders resulted in misinterpretations and resistance to the bill's approval in parliament. More broadly, the exclusion of opinion leaders was detrimental to public sensitization and acceptance of the burden of infertility, its social stigma and the role of IVF technologies in overcoming the condition, accessible through MWH. Lastly, the disengagement of key stakeholders (e.g., patient advocacy groups and advisors) also led to diminished involvement and disenchantment with the implementation process. Therefore, this study highlights the critical role of favourable international policy, sustained political and opinion leader support, interorganizational collaboration, financial resources and public awareness on the implementation of LCIVF initiatives in a low-resource context.

6.5.2. Objective 2: Meso-level (hospital-based) factors that influenced LCIVF implementation at MWH.

The meso-level findings of this study revealed factors that facilitated and hindered implementation efforts of LCIVF. Significant drivers of implementation included availability of financial resources, restructuring of the health services, clinician advocacy and prioritization of specialist care, followed by

interorganizational knowledge exchange & benchmarking and specialist training. The hospital's infrastructure at the time was considered to be unacceptable. The maternity ward was overcrowded, unhygienic, with mothers laying on the floor and under beds giving rise to missed opportunities and poor health outcomes. These inferior hospital conditions, along with strong technical advocacy towards specialist care by the then Head of Obstetrics and Gynecology and clinical colleagues compelled female political leadership and hospital management to approve decongestion of the hospital by establishing a new women's specialist facility. This restructuring created the opportunity to incorporate IVF services as part of its offerings. Furthermore, clinical teams were able to access funds to conduct international benchmarking visits to other womens' hospitals to gain knowledge of its feasibility, in addition to specialist training abroad to gain necessary knowledge to adequately plan and champion the implementation of LCIVF services at MWH.

On the other hand, factors that impeded LCIVF implementation in this study consisted of fragmented leadership engagement, communication gaps and centralized processes. Other barriers included limited specialist training and poor work culture. Notably, weaknesses in communication with top and procedural bureaucracy throughout the implementation process led to delays in decision making, construction errors and diminished stakeholder engagement. There was limited feedback, if any, internal power struggles and repercussions for having opposing views. Furthermore, centrally managed human resource, salary remuneration and procurement management by the MoP, MoF and MoF respectively; impeded autonomous decision making to improve recruitment efficiency, offer salary incentives and improve service quality. The major hindrance, however, was the inability to incentivize staff through salary increments. Furthermore, lack of locally accessible, on-going specialist training amidst rapidly evolving IVF technologies limited staff competency and increased hesitancy towards offering complex IVF treatment.

These findings highlight the importance of available resources to incorporate IVF services, cosmopolitanism, specialist training and sustained leadership communication, support and engagement with key stakeholders to facilitate safe learning climate, innovative collaboration and sustainability of LCIVF initiatives at MWH. Furthermore, greater hospital autonomy can facilitate efficient recruitment, incentivization and retention of quality staff to improve workforce performance and procurement of essential supplies for quality of LCIVF services. Lastly, access to local, continuous specialist training of IVF teams to maintain quality standards of care in fertility services.

6.5.3. Objective 3: Micro-level (clinical) factors that influenced implementation of LCIVF initiatives within the department.

Within the clinical setting, this study revealed micro-level factors in the reproductive medicine department that facilitated and impeded implementation of LCIVF initiatives. The preeminent facilitators to LCIVF implementation consisted of: increased patient demand for comprehensive fertility treatment that included IVF technologies, interest in specialization, access to knowledge, intervention adaptability and trialability. Other facilitators included relative advantage and favourable beliefs about the intervention. Prior to implementation, the obstetrics and gynecology team were compelled to move beyond basic fertility care towards providing more advanced IVF treatment options to better meet patients' needs. Furthermore, individual interest in specialization of IVF technologies aided opportunities for benchmarking visits to IVF facilities abroad, clinical electives, IVF conferences, training workshops for knowledge exchange and

networking with fertility experts. Though, most clinicians were introduced to LCIVF initiatives through participation in the first LCIVF conference in Kampala, which ignited the idea. The trialability, adaptability and relative advantage of offering affordable fertility treatment compared to the costly standard IVF in the private sector facilitated implementation. Furthermore, grounds for inclusion of these initiatives in the public health sector consisted of individuals' God given and human right to found families, value of children in African culture and the role of governments in providing affordable treatment options for all citizens including persons suffering with infertility.

Nonetheless, there were considerable barriers to implementation, most notably the lack of clinical embryologists that halted service provision at MWH. Other impediments to implementation included limited knowledge of, evidence strength and quality of intervention, intervention source, complexity and pricing debates for LCIVF services. The clinical team lacked an embryologist to perform IVF laboratory procedures, a constraint attributed to a scarcity of well-trained embryologists in the country. Nonetheless, there was skepticism regarding the strength of evidence supporting LCIVF initiatives. Questions emerged as to why these technologies had not been adopted in the innovators' countries, with assumptions that low-cost was low quality. Additionally, the complexity of rapidly evolving LCIVF initiatives presented barriers to knowledge upkeep and hindered consensus regarding adaptation in the clinical context. Debate over the universal applicability of LCIVF initiatives stemmed from arguments that some cases were more complicated than others and would require an individualized approach. Furthermore, contentions regarding perceived loss of revenue in offering LCIVF initiatives versus standard IVF treatment ensued. In addition, there were varied interpretations and pricing debates of LCIVF initiatives i.e., a government funded initiative that would provide free or subsidized fertility treatment costs in contrast to externally developed, clinical protocols that would be applied on a case-by-case basis and charged accordingly. Furthermore, beliefs that IVF services were costly to maintain, amid rampant poverty made universal access untenable; a predicament termed as, "The paradox of the typical IVF practitioner in Africa". Lastly, anticipated challenges associated with service provision included patient-centered care, provider mental wellbeing and ample operational provisions (e.g., consistent power supply, equipment maintenance and quality control).

6.6. Usefulness of the Consolidated Framework for Implementation Research (CFIR)

This study identified twenty-nine facilitators and twenty-four barriers to implementation of LCIVF initiatives at MWH that were associated with the CFIR domains and constructs. The framework was useful in guiding data collection and analysis to develop themed categories for classification as facilitators and barriers to implementation, that could then be considered in different contexts. For instance, while some aspects associated with inner organizational settings and individual characteristics may have been unique to this study; factors such as complexity and evidence strength and quality of LCIVF initiatives and availability of resources (embryologists) may be applicable to similar implementation contexts. Much as most of the factors fit well within CFIR's framework, there were factors that cut across multiple levels, interacting in varied ways and some factors which presented uncertainty as their allocation in the framework such as poor reputation of implementer organization, the impact of COVID-19 pandemic and concerns regarding intervention sustainability.

When considering the relationships between constructs, it was expected that frameworks do not facilitate these explanations as they only describe empirical phenomena by fitting them into set categories (Frankfort-

Nachmias & Nachmias, 1999; Sabatier, 2007). The CFIR framework acknowledges interactions between constructs but is not able to clarify them (Damschroder et al., 2009; Nilsen, 2015). Consequently, this was a limitation of the CFIR framework in this study. Furthermore, while the implementer's reputation as a construct partially fits into the outer settings domain, it was not associated with any of the four constructs. Likewise, sustainability could partially fit within the reflections and evaluation construct, however, a specific construct addressing this would have been valuable. Therefore, the author suggests that the CFIR framework could be adapted to include broader community factors and sustainability of interventions.

Similarly, a systematic review on use of the CFIR in low-and middle-income settings reported comparable challenges to its usefulness, suggesting modifications to CFIR that accommodate system-level characteristics, concepts of sustainability and long-term use of interventions within multiple levels of the health system (Means et al., 2020). In particular, CFIR could be modified to include a *system architecture* (characteristics of system) construct capturing administrative design and interactions of health systems that influence implementation (e.g., Ministry of Health, Finance and Public Service in this study) (Means et al., 2020). Other useful constructs relevant to this study included *resource continuity* (characteristics of system) described as uninterrupted, adequate resources over implementation duration, *decision-making* (process of implementation) to capture type, duration of decision (e.g. highly bureaucratic approval systems) and *community characteristics* (outer setting) to capture public or community characteristics (socio-cultural and religious factors) that affect willingness or ability for organizations to engage with implementation (Means et al., 2020). Contrary to the incompatibility of *individual stages of change* in their review, explained by the hierarchical nature of healthcare systems in LMICs (Means et al., 2020); this study revealed that participants' interest and enthusiasm for fertility specialization (characterized by preparation/determination and action) facilitated implementation of LCIVF initiatives.

It is important to note, that as of 2022, the CFIR framework was updated by the authors based on reviews of the framework in systematic research articles and feedback from authors who utilized the framework (Damschroder et al., 2022). In this new version, the COVID-19 pandemic would have been captured under the *critical incidents* construct and poor public perception of the implementer under *local attitudes* (Damschroder et al., 2022). Furthermore, reflections regarding innovation versus implementation in the new framework would have better captured reflections and evaluation findings reported in this study. Other more appropriate constructs in the new framework (including outer setting domain: local conditions, financing and market pressure; inner setting domain: physical infrastructure, incentive systems, mission alignment and teaming; process domain) would have further improved understanding of the factors salient to implementation. Refer to Appendix C for descriptions on the additional domains and constructs of the updated CFIR framework.

6.7. Research Contributions

This exploratory research took on a case study approach to provide in-depth understanding of implementation of affordable fertility care in the public sector in a Sub-Saharan context. Infertility is a reproductive disease that impacts millions of people worldwide, with an estimated twenty-five million couples in the Global South including Africa and Asia (Mascarenhas et al., 2012). Sub-Saharan Africa has one of the highest infertility rates globally, attributable to poor maternal services, unsafe abortions and untreated sexually transmitted infections (King, 2018; Ombelet, 2019). Yet, the high cost of conventional IVF treatment continues to be a significant barrier to equitable access (Ombelet & Onfre, 2019). These technologies are rapidly evolving, becoming increasingly complex and costly to use. Thus, the emergence of low-cost initiatives has been inspired by increasing demand for affordable fertility care in low-resource contexts. While LCIVF initiatives have been available for over a decade, gaps in knowledge of implementation have been identified (Afferri et al., 2022). This study responds to calls for further research on context-specific analyses of fertility care and low-cost treatment approaches on equitable access to these new technologies in Africa (Afferri et al., 2022; Starrs et al., 2018). It contributes to knowledge of implementation of affordable ART in LMICs and provides insight into how policymakers, stakeholders and practitioners perceive implementation of affordable fertility care as part of its public healthcare offerings. To my knowledge, this is the first study that has examined implementation of LCIVF initiatives in the public sector of a Sub-Saharan African context. By employing a multi-level analytical approach, contributions of this study to the body of knowledge of implementation of LCIVF in a Sub-Saharan context are reported correspondingly to macro-, meso- and micro-level research considerations.

Macro-level contributions. Broader, contextual factors that facilitated implementation of LCIVF in Uganda's public sector included favourable international policy, political support, interorganizational collaboration and patient advocacy and public engagement. This study contributes to literature on the importance of recognition of infertility as a disease and disability in international policy as a foundation by which governments can justify provision of publicly funded, fertility care as part of their reproductive services. Furthermore, this study contributes to knowledge on the critical role of political support and advocacy in successful implementation of LCIVF initiatives. In particular, the role of women politicians as advocates and champions for implementation of fertility services should not be underestimated and can serve as a leverage point to garner broader political support and policy development that improve access to quality, affordable fertility care. With regards to policy development, this study contributes to research on the challenges in achieving consensus when designing legislation for ART in African contexts. They highlight the need for early and broad stakeholder engagement, public and policymaker education of IVF technologies and expert support to draw up policies that are contextually appropriate and meet the needs of the population.

Multi-sectoral collaboration also stood out as an important factor in implementation of LCIVF initiatives in Uganda. This study contributes literature of the significance of multi-sectoral partnerships in facilitating implementation of affordable fertility services. Engagement of fertility experts, patient groups, professional associations, private sector actors, banking institutions and international organizations such as MERCK foundation, the WHO, IFFS and the Walking Egg generated opportunities for knowledge transfer, best practices, and financial support to incorporate affordable, quality fertility care within the public health sector. The findings also underlined the importance of establishing institutional partnerships as opposed to

personal ones, to sustain collaboration over the long-term. Furthermore, this study contributes to knowledge on the vital role of patients and patient-led organizations in advocating for affordable fertility care in the public sector. Similarly, engagement or lack thereof, with cultural, traditional and religious play a deterministic role in how LCIVF initiatives are perceived and received in Sub-Saharan contexts. Therefore, these findings contribute to studies that have emphasized the need to engage multiple stakeholders to facilitate implementation of these initiatives.

Meso-level contributions. The findings in this study contribute to understanding of how public hospitals can organize themselves to be better positioned to deliver affordable fertility care. Public hospitals need to consider availability of resources and state of the infrastructure in delivering quality LCIVF services. As highlighted by several authors, IVF services are highly specialized, requiring specific infrastructure, equipment, and supplies. Strengthening of hospital infrastructure can create opportunities to incorporate fertility services. Therefore, hospital administrators and clinicians need to take advantage of these opportunities to advocate for inclusion of fertility services as part of reproductive health offerings. Furthermore, advocating for tax breaks of IVF supplies which are often imported, can reduce costs of implementation. Strong hospital and departmental leadership, championship and communication is also essential to pushing agendas on inclusion of fertility services, supporting specialist training, promoting intervention ownership and creating a positive learning environment for clinicians. Additionally, collaboration with political leaders on fertility inclusion priorities can strengthen implementation momentum and reduce resistance. This study also revealed challenges associated with centralized processes in government hospitals. Individuals within public hospitals need to consider limitations associated with centralized human resource management and procurement processes to deliver quality specialist services. Ability to autonomously hire and fire staff to sustain good quality fertility teams is important. Furthermore, being able to adequately remunerate staff through salary incentives is crucial to retention in public health systems. Inability to do so, can lead to demoralization and loss of talent into the private sector, where there is better pay. Staff rotations amongst specialists should also be minimized to prevent loss of technical knowledge and promote team cohesion and quality services. Lastly, emergency procurements are commonplace in IVF service delivery, therefore systems that support securance of emergency supplies will be beneficial to implementation. Bureaucratic procurement processes run the risk of delaying procurement of necessary supplies that diminish success of IVF services in public hospitals.

Micro-level contributions. This study revealed several considerations that need to be made when implementing LCIVF services within the departmental level. Firstly, this study demonstrates the importance of clinician interest, their beliefs and advocacy in facilitating implementation of specialized fertility care. Clinicians as technical advocates have first-hand experience of patient needs and are likely motivated to meet those needs through advancing implementation of LCIVF services as shown in this study. Furthermore, interested clinicians are likely to be more willing to take personal initiative to acquire knowledge to provide quality fertility care. Secondly, the study findings highlight the need for specialist training, particularly for embryologists, that is locally accessible, hands-on, and culturally appropriate. While traveling abroad for training is beneficial in the short-term, this study contributes to literature on the need to build local capacity as a core consideration to enhancing specialist knowledge and wider access to fertility care. Lack of embryologists paralyzed the whole mission. Therefore, while developing LCIVF initiatives is important in reducing treatment cost and increasing access to affordable fertility services, absence of specialist talent presents an even bigger challenge. To address this barrier, the author proposes

that incorporating local IVF training into medical school curricula, engaging international partners (such as WHO, IFFS, ESHRE, Walking Egg) and providing practical training through accredited private sector fertility clinics, could do better in sustainably mitigating supply side barriers. Strengthening the fertility provider pool would address specialist knowledge gaps, widen access to fertility professionals and consequently, reduce treatment costs due to increased provider competition. These recommendations are pertinent considering the complexity of LCIVF technologies, limited clinical evidence, skepticism surrounding their quality, limited adaptability, and resistance to adopt lower cost IVF treatment protocols given their undesirable impact on the revenue generating interests of some providers. Furthermore, promoting local manufacturing of IVF equipment, drugs and supplies can reduce costs associated with limited [overseas] suppliers, importation levies, and address procurement and equipment incompatibility related challenges; while supporting locally developed, low-cost innovations that would increase ownership and adoption. Fertility practitioners in low-resource contexts often justify high treatment fees by costly overseas training to acquire fertility specialist knowledge and investments in setting up an IVF lab. By intensifying efforts to support local capacity building and innovation of IVF equipment/drugs/consumables, practitioners may be more inclined to reduce cost of care and thus, the goal of widening access to affordable fertility care may become a more realistic endeavour in low-resource settings. Lastly, this study contributes to literature on the importance of promoting patient-centered care that considers the psychological wellbeing of patients and providers, through inclusion of mental health care supports and empathy provider training.

Taken together, these findings can be applicable to similar contexts within Africa and the developing world. Though contexts are diverse in their social, economic, political and cultural structures, there is evidence of the need to support contextually appropriate strategies of implementing affordable fertility care in low-resource contexts.

6.8. Strengths and Limitations

The strength of this thesis lies in the relevance, novelty of the research question in Sub-Saharan Africa and the rigorous research process to best answer it. Additionally, the researcher had prior expertise in fertility care in the study context. The use of qualitative methods to understand salient factors to implementation was similarly beneficial to illuminate the importance of the different factors/determinants from the participants' perspective. Using surveys or questionnaires of instance would introduce researcher bias on selection of determinants (Nilsen, 2015). While the CFIR guided development of interview questions, there was flexibility for participants to describe factors beyond the scope of the interview.

Despite the substantive contributions of this study, this thesis was not without limitations. Firstly, as a qualitative, single case study based on retrospective accounts, may introduce recall bias. Interviewing participants later in the implementation process could diminish certainty of findings. Secondly, the sample size was limited and could have benefitted from inclusion of more patients, external actors and government officials. A few key stakeholders relevant to implementation had moved away from their then roles, while others were hesitant to speak to the implementation process, citing contentious political underpinnings. In one case, a prospective government participant asked why the author was pursuing this research topic, stating that it was a political minefield and declining to participate. Another limitation was that inter-coder reliability was not performed and the author solely coded and analysed all the data. Furthermore, there were

limited opportunities for the author to observe hospital operations and dynamics. This was because data collection took place during a highly sensitive period, when national, presidential elections and the COVID-19 pandemic were happening concurrently. Hospital resources and priorities were directed towards management of the pandemic and all other services were deprioritized. Lastly and more notably, absence of LCIVF treatment at MWH impeded opportunities to understand how these technologies could be adopted in a clinical setting and the implications of access and affordability of fertility services in the public sector.

6.9. Recommendations for Future Research

While this study was useful in enhancing understanding of factors salient to implementation of LCIVF initiatives, there is a need for a detailed ethnographic investigation of implementation of LCIVF at the clinical level. As mentioned in this thesis, the opportunity to examine the adaptation, utilization and sustainability of LCIVF initiatives in the public sector of low-resource contexts are needed. Further, comparative data on knowledge of- and success rates of LCIVF initiatives compared to conventional IVF will be needed to enhance acceptability of low-cost options in these contexts. From a patient perspective, addressing questions as to whether LCIVF initiatives increase access and affordability to fertility services without compromising treatment outcomes will be critical. Research on the precise reduction in cost that implementation of LCIVF initiatives offers within the public sector will be beneficial. Furthermore, review on the revenue loss associated with implementation of LCIVF initiatives should be considered.

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Appendix – A: Consolidated Framework for Implementation Research (CFIR) - A priori codes

Domain	**Construct**
Intervention Characteristics	Intervention Source Evidence Strength and Quality Relative Advantage Adaptability Trialability Complexity Design Quality and Packaging Cost
Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policy and Incentives
Inner Setting	Structural Characteristics Networks and Communications Culture Implementation Climate *1) Tension for change 2) Compatibility 3) Relative Priority 4) Organizational incentives and rewards 5) Goals and Feedback 6) Learning Climate* Readiness for Implementation *1) Leadership engagement 2) Available resources 3) Access to knowledge and information*
Characteristics of Individuals	Knowledge and Beliefs About the Intervention Self-Efficacy Individual Stage of Change Individual Identification with Organization Other Personal Attributes
Process	Planning Engaging *1) Opinion leaders 2) Formally Appointment Internal Implementation Leaders 3) Champions 4) External Change Agents Executing* Reflecting and Evaluating

Consolidated Framework for Implementation Science (CFIR) domains and constructs (Damschroder et al., 2009).

Appendix – B: Original CFIR (published in 2009) constructs mapped against updated CFIR (published in 2022) constructs.

<table>
<tr><td colspan="2">Original CFIR
No specific guidance provided at the framework-level in the original CFIR</td><td colspan="2">Updated CFIR
Framework Guidance:
The CFIR is intended to be used to collect data from individuals who have power and/or influence over implementation outcomes. See the CFIR Outcomes Addendum for guidance on identifying these individuals and selecting outcomes [1].

The CFIR must be fully operationalized prior to use in a project:
1) Define the subject of each domain for the project (see guidance for each domain below).
2) Replace broad construct language with project-specific language if needed.
3) Add constructs to capture salient themes not included in the updated CFIR.</td></tr>
<tr><td colspan="2">I. INTERVENTION CHARACTERISTICS DOMAIN
No specific guidance provided at the domain-level in the original CFIR.</td><td colspan="2">I. INNOVATION DOMAIN
Innovation: The “thing” being implemented [2], e.g., a new clinical treatment, educational program, or city service.

Project Innovation: [Document the innovation being implemented, e.g., innovation type, innovation core vs. adaptable components, using a published reporting guideline [3–6]. Distinguish the innovation (the “thing” that continues when implementation is complete) [2,7] from the implementation process and strategies used to implement the innovation [8,9] (activities that end after implementation is complete) [10].]</td></tr>
<tr><td>Old Construct Name</td><td>Old Construct Definition</td><td>Construct Name</td><td>Construct Definition
The degree to which:</td></tr>
</table>

Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.	A. Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable.
Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.	B. Innovation Evidence-Base	The innovation has robust evidence supporting its effectiveness.
Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.	C. Innovation Relative Advantage	The innovation is better than other available innovations or current practice.
Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.	D. Innovation Adaptability	The innovation can be modified, tailored, or refined to fit local context or needs.

Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.	E. Innovation Trialability	The innovation can be tested or piloted on a small scale and undone.
Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.	F. Innovation Complexity	The innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps.
Design Quality and Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.	G. Innovation Design	The innovation is well designed and packaged, including how it is assembled, bundled, and presented.

Cost	Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs.	H. Innovation Cost	The innovation purchase and operating costs are affordable.
II. OUTER SETTING DOMAIN *No specific guidance provided at the domain-level in the original CFIR.*		**II. OUTER SETTING DOMAIN** ***Outer Setting:*** The setting in which the Inner Setting exists, e.g., hospital system, school district, state. There may be multiple Outer Settings and/or multiple levels within the Outer Setting (e.g., community, system, state). ***Project Outer Setting(s):*** [Document the actual Outer Setting in the project, e.g., type, location, and the boundary between the Outer Setting and the Inner Setting.]	
Old Construct Name	**Old Construct Definition**	**Construct Name**	**Construct Definition** *The degree to which:*
Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.	*None*	*Construct separated and relocated; see Roles Subdomain: Innovation Recipients; Characteristics Subdomain: Need; and Inner Setting Domain: Culture: Recipient-Centeredness.*

None	*Construct added in the updated CFIR.*	A. Critical Incidents	Large-scale and/or unanticipated events disrupt implementation and/or delivery of the innovation.
None	*Construct added in the updated CFIR.*	B. Local Attitudes	Sociocultural values (e.g., shared responsibility in helping recipients) and beliefs (e.g., convictions about the worthiness of recipients) encourage the Outer Setting to support implementation and/or delivery of the innovation.
None	*Construct added in the updated CFIR.*	C. Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation.
Cosmopolitanism	The degree to which an organization is networked with other external organizations.	D. Partnerships & Connections	The Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks.

External Policies & Incentives	A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.	E. Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation.
None	*Construct added in the updated CFIR.*	F. Financing	Funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation.
None	*Construct added in the updated CFIR.*	G. External Pressure	External pressures drive implementation and/or delivery of the innovation. *Use this construct to capture themes related to External Pressures that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Societal Pressure	Mass media campaigns, advocacy groups, or social movements or protests drive implementation and/or delivery of the innovation.

Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically, because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge.	2. Market Pressure	Competing with and/or imitating peer entities drives implementation and/or delivery of the innovation.
None	*See Outer Setting: External Policies & Incentives construct.*	3. Performance-Measurement Pressure	Quality or benchmarking metrics or established service goals drive implementation and/or delivery of the innovation.
III. INNER SETTING DOMAIN *No specific guidance provided at the domain-level in the original CFIR.*		**III. INNER SETTING DOMAIN** ***Inner Setting:*** The setting in which the innovation is implemented, e.g., hospital, school, city. There may be multiple Inner Settings and/or multiple levels within the Inner Setting, e.g., unit, classroom, team. ***Project Inner Setting(s):*** [Document the actual Inner Setting in the project, e.g., type, location, and the boundary between the Outer Setting and the Inner Setting.]	
Old Construct Name	**Old Construct Definition**	**Construct Name**	**Construct Definition** *The degree to which:*

None	*No specific guidance provided at the domain-level in the original CFIR.*	*Note:*	*Constructs A – D exist in the Inner Setting regardless of implementation and/or delivery of the innovation, i.e., they are persistent general characteristics of the Inner Setting.*
Structural Characteristics	The social architecture, age, maturity, and size of an organization.	A. Structural Characteristics	Infrastructure components support functional performance of the Inner Setting. *Use this construct to capture themes related to Structural Characteristics that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Physical Infrastructure	Layout and configuration of space and other tangible material features support functional performance of the Inner Setting.
None	*Subconstruct added in the updated CFIR.*	2. Information Technology Infrastructure	Technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting.
None	*Subconstruct added in the updated CFIR.*	3. Work Infrastructure	Organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting.
Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.	B. Relational Connections	There are high quality formal and informal relationships, networks, and teams within and across Inner Setting boundaries (e.g., structural, professional).

		C. Communications	There are high quality formal and informal information sharing practices within and across Inner Setting boundaries (e.g., structural, professional).
Culture	Norms, values, and basic assumptions of a given organization.	D. Culture	There are shared values, beliefs, and norms across the Inner Setting. *Use this construct to capture themes related to Culture that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Human Equality-Centeredness	There are shared values, beliefs, and norms about the inherent equal worth and value of all human beings.
None	*Subconstruct added in the updated CFIR.*	2. Recipient-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of recipients.
None	*Subconstruct added in the updated CFIR.*	3. Deliverer-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of deliverers.
None	*See Inner Setting: Learning Climate construct.*	4. Learning-Centeredness	There are shared values, beliefs, and norms around psychological safety, continual improvement, and using data to inform practice.
None	*No specific guidance provided at the domain-level in the original CFIR.*	*Note:*	*Constructs E – K are specific to the implementation and/or delivery of the innovation.*

Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.	*None*	*Construct removed from the updated CFIR; reclassified as an antecedent assessment in the CFIR Outcomes Addendum* [1].
Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.	E. Tension for Change	The current situation is intolerable and needs to change.

Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.	F. Compatibility	The innovation fits with workflows, systems, and processes.
Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.	G. Relative Priority	Implementing and delivering the innovation is important compared to other initiatives.

Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect.	H. Incentive Systems	Tangible and/or intangible incentives and rewards and/or disincentives and punishments support implementation and delivery of the innovation.
Goals & Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.	I. Mission Alignment	Implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the Inner Setting.

Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.	*None*	*Construct renamed and relocated; see Inner Setting: Culture: Learning-Centeredness.*
Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.	*None*	*Construct removed from the updated CFIR; reclassified as an antecedent assessment in the CFIR Outcomes Addendum* [1].

Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.	*None*	*Construct separated, renamed, and relocated; see Individuals Domain: Roles Subdomain: High-Level & Mid-Level Leaders; and Characteristics Subdomain: Motivation.*
Available Resources	The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time.	J. Available Resources	Resources are available to implement and deliver the innovation. *Use this construct to capture themes related to Available Resources that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Funding	Funding is available to implement and deliver the innovation.
None	*Subconstruct added in the updated CFIR.*	2. Space	Physical space is available to implement and deliver the innovation.
None	*Subconstruct added in the updated CFIR.*	3. Materials & Equipment	Supplies are available to implement and deliver the innovation.

Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.	K. Access to Knowledge & Information	Guidance and/or training is accessible to implement and deliver the innovation.
IV. CHARACTERISTICS OF INDIVIDUALS *No specific guidance provided at the domain-level in the original CFIR.*		**IV. INDIVIDUALS DOMAIN** ***Individuals:*** The roles and characteristics of individuals.	
None: Roles Subdomain added in the updated CFIR.		**ROLES SUBDOMAIN** ***Project Roles:*** [Document the roles applicable to the project and their location in the Inner or Outer Setting.]	
Old Construct Name	**Old Construct Definition**	**Construct Name**	**Construct Definition**
None	*See Inner Setting: Leadership Engagement.*	A. High-level Leaders	Individuals with a high level of authority, including key decision-makers, executive leaders, or directors.
None	*See Inner Setting: Leadership Engagement*	B. Mid-level Leaders	Individuals with a moderate level of authority, including leaders supervised by a high-level leader and who supervise others.
None	*See Process: Engaging: Opinion Leaders.*	C. Opinion Leaders	Individuals with informal influence on the attitudes and behaviors of others.

None	*See Process: Engaging: External Change Agents.*	D. Implementation Facilitators	Individuals with subject matter expertise who assist, coach, or support implementation.
None	*See Process: Engaging: Formally Appointed Internal Implementation Leaders & Champions.*	E. Implementation Leads	Individuals who lead efforts to implement the innovation.
None	*Construct added in the updated CFIR.*	F. Implementation Team Members	Individuals who collaborate with and support the Implementation Leads to implement the innovation, ideally including Innovation Deliverers and Recipients.
None	*Construct added in the updated CFIR.*	G. Other Implementation Support	Individuals who support the Implementation Leads and/or Implementation Team Members to implement the innovation.
None	*Construct added in the updated CFIR.*	H. Innovation Deliverers	Individuals who are directly or indirectly delivering the innovation.
None	*See Outer Setting: Patient Needs & Resources.*	I. Innovation Recipients	Individuals who are directly or indirectly receiving the innovation.
None: Characteristics Subdomain added in the updated CFIR.		**CHARACTERISTICS SUBDOMAIN** ***Project Characteristics:*** [Document the characteristics applicable to the roles in the project based on the COM-B system [11] or role-specific theories.]	

Old Construct Name	**Old Construct Definition**	**Construct Name**	**Construct Definition:** *The degree to which:*
Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	*None*	*Construct removed from the updated CFIR.*
Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.	*None*	*Construct removed from the updated CFIR.*
Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.	*None*	*Construct removed from the updated CFIR.*

Individual Identification with Organization	A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization.	*None*	*Construct removed from the updated CFIR.*
Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.	*None*	*Construct removed from the updated CFIR.*
None	*Construct added in the updated CFIR.*	A. Need	The individual(s) has deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation.
None	*Construct added in the updated CFIR.*	B. Capability	The individual(s) has interpersonal competence, knowledge, and skills to fulfill Role.
None	*Construct added in the updated CFIR.*	C. Opportunity	The individual(s) has availability, scope, and power to fulfill Role.

None	*Construct added in the updated CFIR.*	D. Motivation	The individual(s) is committed to fulfilling Role.
V. PROCESS *No specific guidance provided at the domain-level in the original CFIR.*		**V. IMPLEMENTATION PROCESS DOMAIN** ***Implementation Process:*** The activities and strategies used to implement the innovation. ***Project Implementation Process:*** [Document the implementation process framework [12] and/or activities and strategies [8,9] being used to implement the innovation. Distinguish the implementation process used to implement the innovation (activities that end after implementation is complete) from the innovation (the "thing" that continues when implementation is complete) [2,7,10].]	
Old Construct Name	**Old Construct Definition**	**Construct Name**	**Construct Definition:** *The degree to which individuals:*
None	*Construct added in the updated CFIR.*	A. Teaming	Join together, intentionally coordinating and collaborating on interdependent tasks, to implement the innovation.
None	*Construct added in the updated CFIR.*	B. Assessing Needs	Collect information about priorities, preferences, and needs of people. *Use this construct to capture themes related to Assessing Needs that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Innovation Deliverers	Collect information about the priorities, preferences, and needs of deliverers to guide implementation and delivery of the innovation.

None	*Subconstruct added in the updated CFIR.*	2. Innovation Recipients	Collect information about the priorities, preferences, and needs of recipients to guide implementation and delivery of the innovation.
None	*Construct added in the updated CFIR.*	C. Assessing Context	Collect information to identify and appraise barriers and facilitators to implementation and delivery of the innovation.
Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods.	D. Planning	Identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance.
None	*Construct added in the updated CFIR.*	E. Tailoring Strategies	Choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context.

Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.	F. Engaging	Attract and encourage participation in implementation and/or the innovation. *Use this construct to capture themes related to Engaging that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Innovation Deliverers	Attract and encourage deliverers to serve on the implementation team and/or to deliver the innovation.
None	*Subconstruct added in the updated CFIR.*	2. Innovation Recipients	Attract and encourage recipients to serve on the implementation team and/or participate in the innovation.
Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.	*None*	*Subconstruct relocated; see Individuals Domain: Roles Subdomain: Opinion Leaders.*

Formally appointed internal implementation leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.	*None*	*Subconstructs combined, renamed, and relocated; see Individuals Domain: Roles Subdomain: Implementation Leads.*
Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the intervention may provoke in an organization.		

External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.	*None*	*Subconstruct renamed and relocated; see Individuals Domain: Roles Subdomain: Implementation Facilitators.*
Executing	Carrying out or accomplishing the implementation according to plan.	G. Doing	Implement in small steps, tests, or cycles of change to trial and cumulatively optimize delivery of the innovation.
Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.	H. Reflecting & Evaluating	Collect and discuss quantitative and qualitative information about the success of implementation and/or the innovation. *Use this construct to capture themes related to Reflecting & Evaluating that are not included in the subconstructs below.*
None	*Subconstruct added in the updated CFIR.*	1. Implementation	Collect and discuss quantitative and qualitive information about the success of implementation.

None	*Subconstruct added in the updated CFIR.*	2. Innovation	Collect and discuss quantitative and qualitative information about the success of the innovation.
None	*Construct added in the updated CFIR.*	I. Adapting	Modify the innovation and/or the Inner Setting for optimal fit and integration into work processes.

Consolidated Framework for Implementation Science (CFIR) domains and constructs (Damschroder et al., 2022)

Appendix – C: Letter of Intent and Consent form for Professional Participants

Title of the proposed study: Multi-level Analysis on Implementation of Low-Cost IVF in Sub-Saharan Africa: A Case Study of Uganda.

Version: #2

Investigators :
Principal Investigator: Margaret Mutumba, mjmutumb@uwaterloo.ca, +256 772 384551 or +1 226 899 6265 (The University of Waterloo, Canada)

A description of sponsors of the research project
This study is being funded by the University of Waterloo, Ontario, Canada through the Global Health Research Fund by Global Health Policy and Innovation Research Centre.

Background and rationale for the study:
Over the years, infertility has come to be recognized as a global reproductive health issue. Sub-Saharan Africa has one of the highest burdens of infertility, affecting 1 in 4 couples of reproductive age. However, there is limited access to and affordable fertility services in many African countries. Low-cost IVF (LCIVF) initiatives have been developed to improve access to infertility treatment by offering IVF at a reduced cost. Uganda is the first country in East and Central Africa to implement and provide LCIVF through its public health system.

Purpose:
The purpose of this study is to understand how low-cost IVF initiatives has been incorporated into Uganda's public health system, specifically at Mulago, Women's Hospital - Kampala, Uganda. As an individual or organization that was involved or impacted by the implementation of LCIVF in Uganda, we would like to understand your experience of this service. The questions will be largely semi-structured and will focus on specifically;

1. How has LCIVF been operationalized at the micro-level within the clinical practice? How has the assisted reproductive technology department organized itself, prioritized and adopted LCIVF treatment protocols?
2. How has the public hospital at the meso-level organized itself in order to facilitate the implementation and provision of LCIVF as part of its service delivery?
3. How have macro-level factors influenced the implementation of LCIVF within the public health system? Which "key players" have influenced the implementation of LCIVF in Uganda?
4. How effective has the implementation of LCIVF been in addressing affordability and accessibility within Uganda and more broadly, the East African region? What can the global community learn from this initiative? How sustainable is LCIVF in Sub-Saharan Africa?

The estimated duration the research participant will take to in the research project:
The duration of participant involvement during the research interview is approximately 60 minutes.

Procedures:
Participation in this study is voluntary. The interview should take approximately 60 minutes in a mutually agreed upon location (online or in person) and time. You may decline to answer any of the interview questions and withdraw anytime during the interview. Further, you can withdraw from this study by advising the student researcher within 2 months of the interview. With your permission, the interview will be audio recorded to facilitate collection of information, and later transcribed for analysis.

Description of the procedures of the study explaining how a participant will be involved and what is required of the participant.

Who will participate in the study:
The eligibility criteria for this study includes implementers, government officials, policy makers, funders, clinicians, international organizations, local organizations, professional organizations, hospital management, clinical directors, clinical staff, patients. The total number of research participants for this study is expected to be 30. Participants will be required to be active during their individual interview and member-checking of research outputs.

Risks/Discomforts:
This research study may present a perceived risk to your reputation or job status in speaking negatively about the intervention. However, I will be safeguarding your identity by de-identifying all your personal information and assigning identity codes stored in a separate file. The identity code will not offer any clue as to the identity of an individual. Participants will be given feedback on the progress and findings of the study.

Description of the possible risks and discomforts a participant might experience while in the study.

Benefits:

The study will not benefit directly, however, the findings will generate new knowledge of the applicability of LCIVF initiatives in Sub-Saharan Africa by providing a practical, holistic picture of the complex nature of implementation of LCIVF in Uganda.

Anticipated benefits of conducting the study including possible benefits to the participant, community and the entire scientific world.

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant

Confidentiality:
All information that can identify you will be removed from the data soon after collection. Your name or any other personal identifying information will not appear in the thesis paper or any publications resulting from this study. However, with your permission, anonymous quotations may be used in publications, teaching or research presentations. If you choose to participate in the interview online, internet privacy

cannot be guaranteed. There is always a risk your responses may be intercepted by a third party (e.g., government agencies, hackers). University of Waterloo researchers will not collect or use internet protocol (IP) addresses or other information which could link your participation to your computer or electronic device without first informing you. All data collected during this study will be retained for a minimum of 7 years. Only those associated with this study will have access to the records, which are password protected. It will not be possible to withdraw your consent once papers and publications have been submitted to publishers. All records will be destroyed according to University of Waterloo policy. The local Research Ethics Committee (REC) - Mildmay Uganda research ethics committee (MUREC) and Uganda National Council for Science and Technology (UNCST) may have access to private information that identifies the research participants by name.

Alternatives:
Participation in this study is not mandatory. Alternatively, you are welcome to provide any valuable information that may support the purposes of this study including referrals to other potentially relevant participants, documentation and resources by emailing mjmutumb@uwaterloo.ca.

Cost:
There are no anticipated costs to be incurred during the conduct of this study. However, if any do arise, the student investigator will meet the bill of paying for the costs.

The possible costs to be met during the conduct of the study as far as the particular participant is concerned. Explain the possible costs and who will meet the bill of paying for the costs.

Compensation for participation in the study:
Each participant will receive compensation of 20,000UGX payment in cash for the interview.

Reimbursement:
Reimbursement for internet usage during virtual interviews and travel for in-person interviews will be provided by student investigator.

Questions about the study:
For any questions regarding this study or additional information to assist you in reaching a decision about participation, please contact Margaret Mutumba (Student Investigator) at (256) 772 384551 or email mjmutumb@uwaterloo.ca.

Questions about participants rights:
If you have questions regarding your rights and welfare as a study participant, please contact Ms Susan Nakubulwa at (256) 0392174236 or murec@mildmay.or.ug.

Statement of voluntariness:
Participation in this study is voluntary and you may join on your own free will. You also have a right to withdraw from the study at any time without penalty.

Dissemination of results:

Research participants will get feedback on findings and progress of the study and that any new information that affects the study or data that has clinical relevance to research participants (including incidental findings) will be made available to research participants and/or their health care providers.

Ethical approval:
This study has been approved by MildMay Uganda Research Ethics Committee (MUREC).

Consent:

STATEMENT OF CONSENT/ASSENT
..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.
Name ……Signature/thumb print of participant ……Date ……
Name ……Signature of parent/guardian for minors (If applicable)…Date ……...
Name……Signature of witness (if applicable)……Date…….
Name …….Signature of interviewer/Person obtaining informed consent ……Date …….

Appendix – D: Letter of Intent and Consent form for Patient Participants

Title of the proposed study: Multi-level Analysis on Implementation of Low-Cost IVF in Sub-Saharan Africa: A Case Study of Uganda.

Version: #2

Investigators:
Principal Investigator: Margaret Mutumba, mjmutumb@uwaterloo.ca, +256 772 384551 or +1 226 899 6265 (The University of Waterloo, Canada)

A description of sponsors of the research project
This study is being funded by the University of Waterloo, Ontario, Canada through the Global Health Research Fund by Global Health Policy and Innovation Research Centre.

Background and rationale for the study:
Over the years, infertility has come to be recognized as a global reproductive health issue. Sub-Saharan Africa has one of the highest burdens of infertility, affecting 1 in 4 couples of reproductive age. However, there is limited access to and affordable fertility services in many African countries. Low-cost IVF (LCIVF) initiatives have been developed to improve access to infertility treatment by offering IVF at a reduced cost. Uganda is the first country in East and Central Africa to implement and provide LCIVF through its public health system.

Purpose:
The purpose of this study is to understand how low-cost IVF initiatives has been incorporated into Uganda's public health system, specifically at Mulago, Women's Hospital - Kampala, Uganda. As an individual who has accessed low-cost IVF treatment at Mulago Women's Hospital, we would like to understand your experience of this service. The questions will be primarily semi-structured and will focus on your experience and/or understanding on the low-cost fertility services in Mulago Women's Hospital. More specifically;

1. What is your understanding of low-cost IVF/fertility care?
2. Describe your experience with low-cost IVF services at the hospital.
3. Have you faced any barriers or facilitators in accessing and utilizing these services?
4. How has this service influenced accessibility and affordability of fertility care?

The estimated duration the research participant will take to in the research project:
The duration of participant involvement during the research interview is approximately 60 minutes.

Procedures:
Participation in this study is voluntary. The interview should take approximately 60 minutes in a mutually agreed upon location (online or in person) and time. You may decline to answer any of the interview questions and withdraw anytime during the interview. Further, you can withdraw from this study by advising the student researcher within 2 months of the interview. With your permission, the interview will be audio recorded to facilitate collection of information, and later transcribed for analysis.

Who will participate in the study:
The eligibility criteria for this study includes implementers, government officials, policy makers, funders, clinicians, international organizations, local organizations, professional organizations, hospital management, clinical directors, clinical staff, patients. The total number of research participants for this study is expected to be 30. Participants will be required to be active during their individual interview.

Risks/Discomforts:
This research study may present a perceived risk to your fertility treatment in speaking negatively about the intervention. However, I will be safeguarding your identity by de-identifying all your personal information and assigning identity codes stored in a separate file. The identity code will not offer any clue as to the identity of an individual.

Benefits:
The study will not benefit directly, but we hope that by understanding how low-cost IVF initiatives can be implemented in a Sub-Saharan context; this knowledge will facilitate universal access to fertility treatment.

Confidentiality:
All information that can identify you will be removed from the data soon after collection. Your name or any other personal identifying information will not appear in the thesis paper or any publications resulting from this study. However, with your permission, anonymous quotations may be used in publications, teaching or research presentations. If you choose to participate in the interview online, internet privacy cannot be guaranteed. There is always a risk your responses may be intercepted by a third party (e.g., government agencies, hackers). University of Waterloo researchers will not collect or use internet protocol (IP) addresses or other information which could link your participation to your computer or electronic device without first informing you. All data collected during this study will be retained for a minimum of 7 years. Only those associated with this study will have access to the records, which are password protected. It will not be possible to withdraw your consent once papers and publications have been submitted to publishers. All records will be destroyed according to University of Waterloo policy. The local Research Ethics Committee (REC) - Mildmay Uganda research ethics committee (MUREC) and Uganda National Council for Science and Technology (UNCST) may have access to private information that identifies the research participants by name.

Alternatives:
Participation in this study is not mandatory. Alternatively, you are welcome to provide any valuable information that may support the purposes of this study including referrals to other potentially relevant participants, documentation and resources by emailing mjmutumb@uwaterloo.ca.

Cost:
There are no anticipated costs to be incurred during the conduct of this study. However, if any do arise, the student investigator will meet the bill of paying for the costs.

Compensation for participation in the study:
Each participant will receive compensation of 20,000UGX payment in cash for the interview.

Reimbursement:
Reimbursement for internet usage during virtual interviews and travel for in-person interviews will be provided by student investigator.

Questions about the study:
For any questions regarding this study or additional information to assist you in reaching a decision about participation, please contact Margaret Mutumba (Student Investigator) at (256) 772 384551 or email mjmutumb@uwaterloo.ca.

Questions about participants rights:
If you have questions regarding your rights and welfare as a study participant, please contact Ms Susan Nakubulwa at (256) 0392174236 or murec@mildmay.or.ug.

Statement of voluntariness:
Participation in this study is voluntary and you may join on your own free will. You also have a right to withdraw from the study at any time without penalty.

Dissemination of results:
Research participants will get feedback on findings and progress of the study and that any new information that affects the study or data that has clinical relevance to research participants (including incidental findings) will be made available to research participants and/or their health care providers.

Ethical approval:
This study has been approved by MildMay Uganda Research Ethics Committee (MUREC).
Consent:

Statement of consent after understanding the study and a signature portion.

STATEMENT OF CONSENT/ASSENT
..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.
Name ……Signature/thumb print of participant ……Date ……
Name ……Signature of parent/guardian for minors (If applicable)…Date ……...
Name……Signature of witness (if applicable)……Date…….
Name …….Signature of interviewer/Person obtaining informed consent ……Date …….

Appendix – E: Email Recruitment Script for Participants

Subject: UofWaterloo: Low-Cost IVF Implementation in Uganda's Public Health System

Dear _,

I am contacting you regarding participation in a research study on the implementation of low-cost IVF (LCIVF) in Uganda's public health system, specifically at Mulago, Women's Hospital - Kampala, Uganda.

Eligibility criteria: any key actor or organization that was involved or impacted by the implementation of LCIVF in Uganda including but not limited to implementers, government officials, policy makers, funders, clinicians, international organizations, local organizations, professional organizations, hospital management & administrators, clinical directors, clinical staff, patients.

As a participant in this study, you would be asked to take part in a semi-structured interview of approximately 40 - 60 minutes. The interview may be conducted over the phone, in-person if restrictions are lifted, or online. Renumeration includes 20,000UGX (CAN$8) per participant and reimbursement for internet usage during virtual interviews will be provided. The questions will focus on your involvement, experience and/or understanding on the LCIVF implementation in Uganda's public health system.

This research will not benefit you directly, but we hope it will generate new knowledge of the applicability of LCIVF initiatives in Sub-Saharan Africa by providing a practical, holistic picture of the complex nature of implementation of LCIVF in Uganda.

For more information about this study, or to volunteer for this study; please contact me via email at mjmutumb@uwaterloo.ca. Please share this communication with any persons you think would be interested in participating in this study.

This study has been reviewed and received local IRB approval through Mildmay Uganda Research Ethics Committee (MUREC) and the University of Waterloo Research Ethics Committee (ORE #42165). If you have questions regarding your rights and welfare as a study participant, please contact Ms Susan Nakubulwa at (256) 0392174236 or murec@mildmay.or.ug.

Yours Sincerely,

Margaret Mutumba *Student Investigator*

School of Public Health and Health Systems
University of Waterloo, Canada

Appendix – F: Phone Script for Participants

P = Potential Participant; I = Interviewer

I - May I please speak to [name of potential participant]?

P - Hello, [name of potential participant] speaking. How may I help you?

I - My name is Margaret Mutumba and I am a PhD candidate in the Public Health and Health Systems at the University of Waterloo, Canada. I am currently conducting research under the supervision of Professor Craig Janes on the implementation of low-cost IVF (LCIVF) in Uganda's public health system, specifically at Mulago, Women's Hospital - Kampala, Uganda. As part of a research project, I am conducting interviews with key persons involved with the implementation of LCIVF in Uganda. As you fit the criteria for this study, I would like to speak with you about your involvement in LCIVF implementation. Is this a convenient time to give you further information about the interviews?

P - No, could you call back later (agree on a more convenient time to call person back).

OR

P - Yes, could you provide me with some more information regarding the interviews you will be conducting?

I - Background Information:

- I will be undertaking interviews over the phone, in-person if restrictions are lifted or online starting on October 20th, 2020.
- The interview would last about 40 – 60 minutes and would be arranged for a time convenient to your schedule. You will receive remuneration of 20,000UGX and reimbursement for internet usage during virtual interviews.
- Involvement in this interview is entirely voluntary and there are no known or anticipated risks to participation in this study.
- The questions are semi-structured (for example, how did you become involved).
- You may decline to answer any of the interview questions you do not wish to answer and may terminate the interview at any time. With your permission, the interview will be audio-recorded to facilitate collection of information, and later transcribed for analysis.
- Your identity will be kept confidential. We will remove all information that could identify you from the data we have collected within 2 months of the interview and delete it permanently.
    - Notes/or audio recordings collected during this study will be retained for a minimum of 10 years in a locked office of Professor Janes and then destroyed. All records will be destroyed according to University of Waterloo policy.
- If you have any questions regarding this study or would like additional information to assist you in reaching a decision about participation, please feel free to contact Professor Craig Janes at (519) 888-4567 ext. 39149.

- I would like to assure you that this study has been reviewed and received ethics clearance through the University of Waterloo Research Ethics Committee (ORE#42165) and local IRB with Mildmay Uganda Research Ethics Committee (MUREC). However, the final decision about participation is yours.

With your permission, I would like to email/mail/fax you an information letter which has all of these details along with contact names and numbers on it to help assist you in making a decision about your participation in this study.

P - No thank you.

OR

P - Sure (get contact information from potential participants i.e., mailing address/fax number).

I - Thank you very much for your time. May I call you in 2 or 3 days to see if you are interested in being interviewed? Once again, if you have any questions or concerns please do not hesitate to contact me at 0772384551 or email mjmutumb@uwaterloo.ca.

P - Good-bye.

I - Good-bye.

Appendix – G: Verbal Script for Participants

Hi,

My name is Margaret Mutumba and I am a PhD candidate at the University of Waterloo, Canada, in the department of Public Health and Health Systems.I am conducting a study on the implementation of low-cost IVF (LCIVF) in Uganda's public health system, specifically at Mulago, Women's Hospital - Kampala, Uganda.

I would like to ask if you are willing to participate in this research. The eligibility criteria any individual or organization that was involved or impacted by the implementation of LCIVF in Uganda.

As a participant in this study, you will be interviewed for approximately 40 - 60 minutes either over the phone, in-person if restrictions are lifted or online. You will receive remuneration of 20,000UGX (CAN$8) for this interview and reimbursement for internet usage for virtual interviews. The questions will focus on your involvement and understanding on the LCIVF implementation in Uganda's public health system.

This study has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee and local IRB by Mildmay Uganda Research Ethics Committee (MUREC).

If you are interested, we can arrange a time now or at your convenience.

If you have any questions, I can be reached via email at mjmutumb@uwaterloo.ca.

Thank you for your help/time.

Appendix – H: Transcriber Confidentiality Agreement

Study Title: *Multi-level Analysis on Implementation of Low-Cost IVF in Sub-Saharan Africa: A Case Study of Uganda.*

A. INSTRUCTIONS

Please read through the entirety of this form carefully before signing.

Electronic signatures are not valid for this form. After completing the required fields, please print and sign this form in blue or black ink. After this form has been signed by the transcriber, it should be given to the principal investigator of the research study for submission. After receiving the *Transcriber Confidentiality Agreement*, the principal investigator should scan and upload the signed form to their project package.

The transcriber should keep a copy of the *Transcriber Confidentiality Agreement* for their records.

This agreement is for transcribers only. However, if your duties as a research assistant include transcription, you will need to review, sign, and submit the *Transcriber Confidentiality Agreement* as well as the *Research Assistant Confidentiality Agreement*.

B. CONFIDENTIALITY OF A RESEARCH STUDY:

Confidentiality is the treatment and maintenance of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure (the consent form) without permission. Confidential information relating to human subjects in a research study may include, but is not limited to:

- Name, date of birth, age, sex, address, and contact information;
- Current contact details of family, guardian, etc.;
- Medical or educational history and/or records;
- Service records and progress notes;
- Assessments or reports;
- Ethnic or racial origin;
- Political opinions, religious or philosophical beliefs.

As a transcriber you will have access to research information (e.g. audio or video recordings, DVDs/CDs, transcripts, data, etc.) that include confidential information. Many participants have only revealed information to investigators because principal investigators have assured participants that every effort will be made to maintain confidentiality. That is why it is of the upmost importance to maintain full confidentiality when conducting your duties as a transcriber during a research study. *Below is a list of expectations you will be required to adhere to as a transcriber. Please carefully review these expectations before signing this form.*

C. EXPECTATIONS FOR A TRANSCRIBER

In order to maintain confidentiality, I agree to:

1. Keep all research information that is shared with me (e.g. audio or video recordings, DVDs/CDs, transcripts, data, etc.) confidential by not discussing or sharing this information verbally or in any format with anyone other than the principal investigator of this study;

2. Ensure the security of research information (e.g. audio or video recordings, DVDs/CDs, transcripts, data, etc.) while it is in my possession. This includes:

- Using closed headphones when transcribing audio taped interviews;
- Keeping all transcript documents and digitized interviews on a password protected computer with password-protected files;
- Closing any transcription programs and documents when temporarily away from the computer;
- Keeping any printed transcripts in a secure location such as a locked file cabinet;
- Permanently deleting any digital communication containing the data.

3. Not make copies of research information (e.g. audio or video recordings, DVDs/CDs, transcripts, data, etc.) unless specifically instructed to do so by the principal investigator;

4. Give all research information (e.g. audio or video recordings, DVDs/CDs, transcripts, data, etc.) and research participant information, back to the principal investigator upon completion of my duties as a transcriber;

5. After discussing it with the principal investigator, erase or destroy all research information (e.g. audio or video recordings, DVDs/CDs, transcripts, data, etc.) that cannot be returned to the principal investigator upon completion of my duties as a transcriber.

Name of Transcriber:

Title of Research Study: Multi-level Analysis on Implementation of Low-Cost IVF in Sub-Saharan Africa: A Case Study of Uganda.

Name of Principal Investigator: Margaret Mutumba

By signing this form I acknowledge that I have reviewed, understand, and agree to adhere to the expectations for a transcriber described above. I agree to maintain confidentiality while performing my duties as a transcriber and recognize that failure to comply with these expectations may result in disciplinary action.

Signature of Transcriber Date

Print Name

Appendix – I: CFIR Interview Guide for Implementers

(Government officials & Implementation Team)

Hello, my name is Margaret Mutumba. I am a doctoral researcher at the University of Waterloo, Canada. I am conducting a study to document the process of implementing low-cost IVF at Mulago Women's Hospital. As part of this study, I would like to ask you some questions about your role in the implementation of low-cost IVF in the public health sector. This interview should take approximately an hour. Your participation is entirely voluntary; there is no penalty to you if you decide not to participate. You only need to respond to those questions you wish to answer, and you may stop the interview at any time. We will include your ideas in our write-up, but we will not use your name, and will take care that your comments cannot be attributed to you. Please read the informed consent form.

- Do you have any questions?
- Do you agree to participate in the interview? (Ask respondent to sign consent form)
- May I tape record our conversation?

Background Information

Please provide background information of institution/organization, occupation, education, capacity as it relates to the implementation of LCIVF in Uganda.

Intervention Characteristics

Intervention Source

1. Who developed the intervention?
    - What is your opinion of this group/individual?
2. Why is the intervention being implemented in your setting?
    - Who decided to implement the intervention?
    - How was the decision made to implement the intervention?

Evidence Strength & Quality

1. What kind of information or evidence were you aware of that shows whether or not the intervention will work in your setting?
    - What evidence have you heard about from your own research? Practice guidelines? Published literature? Co-workers? Other settings?
    - How does this knowledge affect your perception of the intervention?
2. What do influential stakeholders think of the intervention?
    - What do administrative or other leaders think of the intervention?
3. What kind of supporting evidence or proof was needed about the effectiveness of the intervention to get staff on board?
    - Co-workers? Administrative leaders?

Relative Advantage

1. How does the intervention compare to other similar existing programs in your setting?
    - What advantages does the intervention have compared to existing programs?
    - What disadvantages does the intervention have compared to existing programs?
2. Is there another intervention that people would rather implement?
    - Can you describe that intervention?
    - Why would people prefer the alternative?

Adaptability

1. What kinds of changes or alterations did you need to make to the intervention, so it works effectively in your setting?
    - Why or why not?
2. Who decided (or what is the process for deciding) whether changes are needed to the intervention so that it works well in your setting?
    - How will you know if it is appropriate to make any changes?
3. Are there components that could not be altered?
    - Which ones should not be altered?

Trialability

1. Was the intervention piloted prior to full-scale implementation?
    - [If Yes] Can you describe the piloting of the intervention?
    - [If No] Why not?

Complexity

1. How complicated is the intervention?

Design Quality & Packaging

1. What is your perception of the quality of the supporting materials, packaging, and bundling of the intervention for implementation?
    - Why?
2. What supports, such as online resources, marketing materials, or a toolkit, were/are available to help you implement and use the intervention?
    - How do you access these materials?
3. How will available materials affect implementation in your setting?

Cost

1. What costs were incurred to implement the intervention?
2. What cost were considered when deciding to implement the intervention?

Process

Planning

1. What plan did you have in place to implement the intervention?
2. Can you describe the plan for implementing the intervention?
    - How detailed was the plan? Who knew about it? Was the plan overly complex? Understandable? Realistic and feasible?
    - What was your role in the planning process?
    - Who was involved in the planning process? What were their roles?
    - Were the appropriate people involved in the planning process? How engaged are they?
    - Did you plan to track the progress of implementation based on your plan?
        - Did you modify or revise your plan due to barrier, errors, or mistakes?

3. What role did your plan for implementation play during implementation?
    - Was it used to guide implementation of the intervention?
    - Was it used to compare planned with actual progress?
    - Was the plan shared/reviewed with other stakeholders? How regularly?

Engaging

Opinion Leaders

1. Who were the key influential individuals to get on board with this implementation?
2. What were influential individuals saying about the intervention?
    - Who are these influential individuals?
    - To what extent will they influence others' use of the intervention? The success of the implementation?

Formally Appointed Internal Implementation Leaders

1. How did your organization become involved in implementing the intervention?
    - How was the decision made to participate in the intervention?
    - Who participated in the decision-making process?
    - Were you involved in this process?
2. Who led implementation of the intervention?
    - How did this person come into this role? Appointed? Volunteered? Voluntold?
    - What attributes or qualities did this person have that makes them an effective leader of this implementation? What attributes or qualities does this person lack?
    - Did this person have sufficient authority to do what is necessary to implement the intervention?
3. Who else was involved with leading the implementation?

Champions

1. Other than the formal implementation leader, are there people who championed (go above and beyond what might be expected) the intervention?
    - Were they formally appointed in this position, or was it an informal role?
    - What position did these champions have in your organization?

    - How do you think they will help with implementation? Getting people to use the intervention?
2. Can you describe people's perception of this champion/individual?
    - To what extent do you respect the opinions and actions of the champion?
3. What kinds of behaviors or actions do you think this individual/champion will exhibit?
    - For example, helping get senior leaders on board, helping solve problems? Or a small role?

External Change Agents

1. Did someone (or a team) outside your organization be helping you with implementing the intervention?
    - Can you describe this person/group?
    - How did they get involved?
    - What is their role?
    - What kind of activities will they be doing?
    - How helpful do you think he/she/they will be? In what ways?

Key Stakeholders

1. What steps were taken to encourage individuals to commit to using the intervention?
    - Which individuals did you target?
    - How did you approach them?
    - What information did you give them?
    - How frequently and how do you communicate with them?
2. What was your communication or education strategy (not including training, see Access to Knowledge and Information) for getting the word out about the intervention?
    - What materials/modes/venues did you plan to use? For example, e-bulletin boards, emails, brochures?
    - What process did you use to communicate? For example, going to staff meetings, talking to people informally?
3. Who were the key individuals to get on board with the intervention?
    - To encourage individuals to use the intervention? To help with implementation?

Executing

1. Was the intervention been implemented according to the implementation plan?
    - [If Yes] Can you describe this?
    - [If No] Why not?

Reflecting & Evaluating

1. What kind of information did you collect as you implement the intervention?
    - Which measures will you track? How will you track them?
    - How will this information be used?
2. Did you receive feedback reports about the implementation or the intervention itself?
    - What will they look like? Content, mode, form?

- How helpful do you think they will be?
- How could they be improved?
- How often will you get them? Where will they come from?
- Who is designing them?

3. How did you assess progress towards implementation or intervention goals?
    - How were the results of the evaluation be distributed to stakeholders?
4. Was feedback be elicited from staff? From the individuals served by your organization?
    - [If yes] What kind of feedback?
5. To what extent has your organization/unit set goals for implementing the intervention?
    - How will goals be communicated in the organization? To whom will they be communicated?

What are the goals? How and to whom will they be communicated

Outer Setting

Patient Needs & Resources

1. To what extent were you aware of the needs and preferences of the patients?
2. To what extent were the needs and preferences of the patients considered when deciding to implement the intervention?
    - Can you describe specific examples?
    - Was the intervention altered to meet patient needs and preferences?
3. How well do you think the intervention meets the needs of the patients?
    - In what ways does the intervention meet their needs? E.g. improved access to services? Reduced wait times? Help with self-management? Reduced travel time and expense?
    - What are their perceptions of the intervention?
    - Can you describe what kind of specific information you have heard?
4. Have you heard stories about the experiences of participants with the intervention?
    - Can you describe a specific story?

External Policies & Incentives

1. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention?
    - How will the intervention affect your organization's ability to meet these measures, policies, regulations, or guidelines?
2. What kind of financial or other incentives influence the implementation of this intervention?
    - How will the intervention affect your organization's ability to receive these incentives?
    - How will the new intervention affect payment or revenue for your organization?

Appendix – J: CFIR Interview Guide for Hospital Team

(Hospital management, administrators, clinical team, supportive staff)

Hello, my name is Margaret Mutumba. I am a doctoral researcher at the University of Waterloo, Canada. I am conducting a study to document the process of implementing low-cost IVF at Mulago Women's Hospital. As part of this study, I would like to ask you some questions about role in implementing of low-cost IVF in the hospital. This interview should take approximately an hour. Your participation is entirely voluntary; there is no penalty to you if you decide not to participate. You only need to respond to those questions you wish to answer, and you may stop the interview at any time. We will include your ideas in our report, but we will not use your name, and will take care that your comments cannot be attributed to you. Please read the informed consent form.

- Do you have any questions?
- Do you agree to participate in the interview? (Ask respondent to sign consent form)
- May I audio record our conversation?

Background Information

Please provide background information of institution/organization, occupation, education, capacity as it relates to the implementation of LCIVF in Uganda.

Intervention Characteristics

Intervention Source

1. Who developed the intervention (low-cost IVF)?
2. What is your opinion on the developer/s?
3. Why was low-cost IVF implemented in your hospital?

    - Who decided to implement the intervention?

Evidence Strength & Quality

1. What kind of information or evidence were you aware of that shows whether or not the intervention will work in your setting?

Relative Advantage

1. How does the intervention compare to other similar or alternatives that may have been considered or that you know about?

Adaptability

1. What kinds of changes or alterations did you need to make to the intervention, so it works effectively in your setting?
    - Why or why not?

2. Who decided (or what is the process for deciding) whether changes are needed to the intervention so that it works well in your setting?
3. Are there components that could not be altered? Which ones?

Complexity

1. How complicated is the intervention? (duration, scope, intricacy and number of steps involved and whether the intervention reflects a clear departure from previous practices).

Design Quality & Packaging

1. What is your perception of the quality of the equipment, supporting materials, packaging, and bundling of the intervention for implementation?
    - Why?
2. What supports, such as online resources, marketing materials, or a toolkit, were/are available to help you implement and use the intervention?

Cost

1. What costs were incurred to implement the intervention?

Outer Setting

Patient Needs & Resources

1. To what extent is staff aware of the needs and preferences of the individuals being served by your organization?
    - How "in touch" are staff and leadership with the individuals served by your organization?
2. To what extent were the needs and preferences of the individuals served by your organization considered when deciding to implement the intervention?
    - Can you describe specific examples?
    - Will the intervention be altered to meet their needs and preferences?
3. How well do you think the intervention meets the needs of the individuals served by your organization?
    - In what ways does the intervention meet their needs? E.g. improved access to services? Reduced travel time and expense?
4. How have the individuals served by your organization responded to the intervention?
5. What barriers do the individuals served by your organization face to participating in the intervention?
6. Have you heard stories about the experiences of patients with the intervention?
    - Can you describe a specific story?

Cosmopolitanism

1. To what extent do you network with colleagues or people in similar professions/positions outside your setting?
2. What kind of information exchange do you have with others outside your setting, either related to the intervention, or more generally about your profession?

- What professional networking do you engage in? Local or national conferences? Trainings?

3. To what extent does your organization encourage you to network with colleagues outside your own setting?
    - Are you able to attend local/national conferences? Other venues?

Peer Pressure

1. Can you tell me what you know about any other organizations that have implemented the intervention or other similar programs?
    - How has this information influenced the decision to implement the intervention?
2. To what extent would implementing the intervention provide an advantage for your hospital compared to other facilities in the area?
    - Is there a competitive advantage?
    - Is there something about the intervention that would bring more individuals into your organization, instead of another one in your area?

External Policies & Incentives

1. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention?
2. What kind of financial or other incentives influence the implementation of this intervention?

Inner Setting

Structural Characteristics

1. How does the infrastructure of your organization (social architecture, age, maturity, size, or physical layout) affect the implementation of the intervention?
    - How does the infrastructure facilitate/hinder implementation of the intervention?
    - How do you work around structural challenges?
2. What kinds of infrastructure changes were needed to accommodate the intervention?
    - Changes in scope of practice? Changes in formal policies? Changes in information systems or electronic records systems? Other?
    - What kind of approvals were needed? Who will need to be involved?

Networks & Communications

1. Do you meet (formally or informally) with a team of people?
    - How often do you meet? Formally? Informally?
2. Can you describe your working relationship with leaders?
    - Your supervisor? Supervisors of other colleagues?
3. Can you describe your working relationship with influential stakeholders?
4. Are meetings, such as staff meetings, held regularly?
    - Do you typically attend?
    - Who typically attends?
    - What proportion of staff typically attend?

- How often are the meetings held?
- What is a typical agenda? How helpful are these meetings?

5. How do you typically find out about new information, such as new initiatives, accomplishments, issues, new staff, staff departures?
6. When you need to get something done or to solve a problem, who are your "go-to" people?
    - Can you describe a recent example?

Culture

1. How would you describe the culture of your organization? Of your own setting or unit?
    - Do you feel like the culture of your own unit is different from the overall organization? In what ways?
2. How do you think your organization's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of the intervention?
    - Can you describe an example that highlights this?
3. To what extent are new ideas embraced and used to make improvements in your organization?
    - Can you describe a recent example?

Implementation Climate

1. What was the general level of receptivity in your organization to implementing the intervention?
    - Why?

Compatibility

1. How well does the intervention fit with your values and norms and the values and norms within the organization?
2. Can you describe how the intervention was integrated into current processes?
    - How will it interact or conflict with current programs or processes?
3. Will the intervention replace or compliment a current program or process?
    - In what ways?

Relative Priority

1. What kinds of high-priority initiatives or activities are already happening in your setting?
2. How did you juggle competing priorities in your own work? How will your colleagues juggle these priorities?

Organizational Incentives & Rewards

1. What kinds of incentives were there to help ensure that the implementation of the intervention is successful?
    - What is your motivation for wanting to help ensure the implementation is successful?
2. Were there any special recognitions or rewards planned that are related to implementing the intervention?
    - Can you describe them?
    - Will these be targeted to groups/teams/units or individuals?

Goals & Feedback

1. Have you/your unit/your organization set goals related to the implementation of the intervention?
    - [If yes] What are the goals?
2. To what extent does your organization/unit set goals for current programs/initiatives?
    - How are goals communicated in the organization? To whom are they communicated?
    - Can you give an example of a goal? How and to whom is it communicated?
    - Are changes made based on how things are going? Can you give an example?
3. To what extent are organizational goals monitored for progress?
    - Can you give an example of monitoring in terms of the type of information, who is informed, and how?
4. Do you get any feedback reports about your work?
    - What do they look like? Content, mode, form?
    - How helpful are those reports?
    - How can they be improved?
    - How often do you get them? Where do they come from?
    - Who designed them?

Learning Climate

1. Can you describe a recent quality improvement initiative or an implementation of a new program?
2. If you saw a problem in your own setting, what would you do?
    - Can you tell a story about a recent problem you resolved or initiative you participated in?
3. To what extent do you feel like you can try new things to improve your work processes?

Readiness for Implementation

Leadership Engagement

1. What level of endorsement or support have/did you seen or heard from leaders?
    - Who are these leaders and how did this affect things so far? Going forward?
2. What level of involvement did leadership at your organization have with the intervention?
    - Do they know about the intention to implement the intervention?
    - Who are these leaders? How do attitudes of different leaders vary?
    - What kind of support have they given you? Can you provide specific examples?
3. What kind of support or actions did you expect/receive from leaders in your organization to help make implementation successful?

Available Resources

1. Did you have sufficient resources to implement and administer the intervention?
2. How did procure necessary resources?
    - Who will be involved in helping you get what is needed?
    - What challenges do you expect to encounter?

Access to Knowledge & Information

1. What kind of training was offered for you? For colleagues?
    - Did you feel the training prepared you to carry out the roles and responsibilities expected of you? Can you explain?
    - What are the positive aspects of planned training?
    - What is missing?
    - What kind of continued training is taking place?
2. What kinds of information and materials about the intervention were made available to you?
    - Copies of materials?
    - Personal contact?
    - Internal information sharing; e.g., staff meetings?
    - Has it been timely? Relevant? Sufficient?
3. Who do you ask if you have questions about the intervention or its implementation?
    - How available are these individuals?

Characteristics of Individuals

Self-efficacy

1. How confident were you to successfully implement the intervention?
    - What gave you that level of confidence (or lack of confidence)?
2. How confident do you think your colleagues felt about implementing the intervention?
    - What gave them that level of confidence (or lack of confidence)?

Appendix – K: CFIR Interview Guide for Key Stakeholders

(Funders, I/NGOs, Professional Associations, Champions, Key Informants)

Hello, my name is Margaret Mutumba. I am a PhD student at the University of Waterloo, Canada. I am conducting a study to document the process of implementing low-cost IVF at Mulago Women's Hospital. As part of this study, I would like to ask you some questions about your experience, role or engagement with the implementation of low-cost IVF in the public health sector. This interview should take approximately 45 minutes to an hour. Your participation is entirely voluntary; there is no penalty to you if you decide not to participate. You only need to respond to those questions you wish to answer, and you may stop the interview at any time. We will include your ideas in our write-up, but we will not use your name, and will take care that your comments cannot be attributed to you. Please read the informed consent form.

- Do you have any questions?
- Do you agree to participate in the interview? (Ask respondent to sign consent form)
- May I audio record our conversation?

Background Information

Please provide background information of institution/organization, occupation, education, capacity as it relates to the implementation of LCIVF in Uganda.

Interview Questions

1. What is your opinion of low-cost IVF? What is it?
2. Is there a strong need for this intervention?
3. What advantages or disadvantages does the low-cost IVF program have? How does it compare to alternatives?
4. How did you come to be involved with the implementation of low-cost IVF? (formally appointed or not)
    - What level of endorsement or support did you have with the intervention?
    - To what extent does this intervention align with your personal goals or values?
    - What level of involvement did you have with the intervention?
    - What kind of support or actions did you take to help make implementation successful?

5. Do you think the intervention has been successful in meeting the needs of the people it serves?
6. How has it impacted accessibility and affordability of fertility care?

7. Are there components that could not be altered? Which ones?
8. Who else has been involved with leading the implementation of low-cost IVF?
9. Would you recommend low-cost IVF services provided by the hospital?
10. What is your opinion on the sustainability of this intervention?

Appendix – L: CFIR Interview Guide for Patients

Name of Person Interviewed: _____(Optional)
Occupation: _____
Age: _____
Gender: _____
Date of Interview: _____
Person conducting the interview: _____

Hello, my name is Margaret Mutumba. I am a doctoral researcher at the University of Waterloo, Canada. I am conducting a study to document the process of implementing low-cost IVF at Mulago Women's Hospital. As part of this study, I would like to ask you some questions about your experience with low-cost IVF in the hospital. This interview should take approximately 45 minutes to an hour. Your participation is entirely voluntary; there is no penalty to you if you decide not to participate. You only need to respond to those questions you wish to answer, and you may stop the interview at any time. We will include your ideas in our report, but we will not use your name, and will take care that your comments cannot be attributed to you. Please read the informed consent form.

- Do you have any questions?
- Do you agree to participate in the interview? (Ask respondent to sign consent form)
- May I audio record our conversation?

Background Information

Please provide background information of name, age, gender and occupation.

Interview Questions

1. What is your opinion of low-cost IVF?
2. How did you come to know about low-cost IVF services at this hospital?
3. Had you considered care from other facilities or people prior to coming to this hospital?
4. What is your experience with the service and care at this hospital? How have you been served?
5. Are there specific positive and/or negative experiences you have had navigating care at this hospital?
6. Have you faced any barriers accessing low-cost IVF services?
7. At what stage in the treatment process are you?
8. Do you think this intervention is effective?
9. How do you feel low-cost IVF has impacted accessibility and affordable fertility care?
10. Do you think this service is sustainable?
11. Would you recommend this service to other people seeking care?
12. How would you want low-cost IVF services offered generally speaking?

Appendix – M: Letter of Appreciation

Dear _____,

I would like to thank you for your participation in the study I am conducting for my PhD research at the University of Waterloo. The principal investigator is Margaret Mutumba. As a reminder, the purpose of this study is to examine how low-cost IVF (LCIVF) has been implemented in Uganda's public health system, specifically at Mulago, Women's Hospital - Kampala, Uganda.

The data collected during interviews will generate new knowledge of the applicability of LCIVF initiatives in Sub-Saharan Africa by providing a practical, holistic picture of the complex nature of implementation of LCIVF in Uganda.

This study has been reviewed and received local IRB approval through Mildmay Uganda Research Ethics Committee (MUREC) and the University of Waterloo Research Ethics Committee (ORE #42165). If you have questions regarding your rights and welfare as a study participant, please contact Ms Susan Nakubulwa at (256) 0392174236 or murec@mildmay.or.ug.

For all other questions, please contact the principal investigator - Margaret Mutumba via email: mjmutumb@uwaterloo.ca or (256) 772 384 551.

Please remember that any data pertaining to you as an individual participant will be kept confidential. Once all the data are collected and analyzed for this study, we plan on sharing this information with the research community through seminars, conferences, presentations, and journal articles. If you are interested in receiving more information regarding the results of this study, or would like a summary of the results, please provide your email address, and when the study is completed, Margaret Mutumba will send you the information. Please do not hesitate to contact me by email or telephone as noted below.

Sincerely,

Margaret Mutumba MPH

PhD Candidate

School of Public Health and Health Systems

University of Waterloo

Appendix –N: Observation Data Collection

Project Name				**Note: Users only need to keep the constructs that they intend to assess in the template, however, it is important to capture any other notes that may seem relevant. Prior to conducting the site visit, users will want to consider how they will operationalize the constructs. For example, noting physical characteristics of the space under structural characteristics.**
Site Observation Notes				
Date:				
Observers:				
DOMAIN & CONSTRUCT		**OPERATIONALIZATION**	**DATA**	
I. INNOVATION CHARACTERISTICS				
A	Innovation Source			
B	Evidence Strength & Quality			
C	Relative Advantage			
D	Adaptability			

E	Trialability			
F	Complexity			
G	Design Quality & Packaging			
H	Cost			
II. OUTER SETTING				
A	Needs & Resources of Those Served by the Organization			
B	Cosmopolitanism			
C	Peer Pressure			
D	External Policy & Incentives			
III. INNER SETTING				

A	Structural Characteristics	Mostly observed pregnant women walking into the facility for deliveries or possible checkups. In waiting rooms many pregnant women or parents with young children are seen. On one particular day, COVID vaccinations were taking place for selected persons e.g. VIPs possibly		
B	Networks & Communications			
C	Culture			
D	Implementation Climate			
1	Tension for Change			
2	Compatibility			
3	Relative Priority			
4	Organizational Incentives & Rewards			

5	Goals & Feedback			
6	Learning Climate			
E	Readiness for Implementation			
1	Leadership Engagement	Monthly departmental meetings		
2	Available Resources			
3	Access to Knowledge & Information			
IV. CHARACTERISTICS OF INDIVIDUALS				
A	Knowledge & Beliefs about the Innovation			
B	Self-efficacy			

C	Individual Stage of Change	Loss of morale amongst staff regarding delayed IVF start		
D	Individual Identification with Organization			
E	Other Personal Attributes			
V. PROCESS				
A	Planning			
B	Engaging			
1	Opinion Leaders			
2	Formally Appointed Internal Implementation Leaders			
3	Champions			

4	External Change Agents			
5	Key Stakeholders			
6	Innovation Participants			
C	Executing			
D	Reflecting & Evaluating			

Appendix – O: LCIVF Implementation Analysis Level compared to CFIR constructs

Domain	Construct	Level of Analysis		
		Macro	**Meso**	**Micro**
Intervention Characteristics	**Intervention Source**	· Interpretation of LCIVF as a government funded intervention internally developed intervention		· Interpretation of LCIVF as clinical adapted protocols by external innovators to reduce the cost of treatment
	Evidence Strength and Quality	· Government's role in providing subsidized fertility care to citizens · Low cost perceived to mean low quality		· Insufficient clinical evidence-based reports from intervention developers.

	Relative Advantage		· Cost treatment in the private sector too high and would be more affordable in a public hospital	· LCIVF cheaper than conventional IVF treatment · More comprehensive fertility treatment options compared to status quo (diagnostic & minor surgeries) · Barrier to revenue generating opportunities associated with conventional IVF
	Adaptability			· Plethora of LCIVF initiatives that can be adapted
	Trialability			· Trial simpler procedures and advance to complicated ones · Offer free treatment trials to patients and publish findings

	Complexity	Rapidly evolving scope of LCIVF initiatives being developed difficult to keep track	· LC/IVF still requires specialized infrastructure, equipment, and staff	· Vast scope of LCIVF initiatives not well understood or appreciated. · Treatment depends on multiple factors and come be complicated e.g. when engaging third parties through surrogacy or donation · Concern over complicated cases dictated by patient related factors that would necessitate third parties. · Perceived higher risk for clinical error as each member's success depends on the competency of the team.

	Cost	· Debate over offering free vs subsidized IVF services · LCIVF may not be applicable to all patients	· MWH offered 3-tiered package for fertility treatment. · Treatment waivers provided to referred patients who couldn't afford payment	· High initial investment required to set up IVF department · High cost of maintaining IVF related equipment and ensuring adequate supply of quality drugs
Outer Setting	**Patient Needs and Resources**	· Public sensitization on infertility needed to combat stigma and increase health seeking at fertility hospitals · Institutional Recognition of Infertility as part of reproductive health practice · Regulation of fertility practitioners to ensure patient safety · Presence of patient advocacy group and demand for fertility services	· Patients that seek care in public hospitals often are of lower SES thus requiring affordable treatment options · Privacy when receiving fertility care in hospital i.e. private rooms, spacing, partitioning	· Comprehensive fertility treatment options · IVF counseling to address gap in treatment knowledge · Patient satisfaction through empathy and compassionate care

	Cosmopolitanism	· Partnerships with local and international organizations i.e. Makerere University, Uganda Fertility Society, WHO, IFFS, ESHRE, ASRM, MERCK · Engagement with patient-led advocacy group i.e. JFSC · Collaborated with politicians as allies to approving finances and ART bill · Knowledge exchange with private sector to train medical students & embryologists		
	Peer Pressure	· Competitive market taken up primarily by the private sector		

	External Policy and Incentives	· International declarations of infertility as reproductive diseases by WHO, UN · National focus on mitigating high population growth rate prioritizing family planning and neglect of fertility patients · Development of an Assisted Reproductive Bill · Resistance of ART bill by some politicians and religious leaders · Government funding to finance hospital construction, staff training, equipment, and information system · Regulation of financing, procurements and staff hiring by MoF, MoH and MoPs respectively	· Benchmarking visits to women focused hospitals e.g. Ethiopia	· Benchmarking visits to centres with IVF departments e.g. India, South Africa, Canada, U.K

Inner Setting	**Structural Characteristics**		· Longevity of Mulago having undergone multiple renovations · MWH operated through two systems, mainly through a hospital referral system and a self-referred system · Staff transfers created team instability, loss of specialist knowledge and diminished quality of care · Limited autonomy to make decisions as a department as quickly	
	Networks and Communications	· Contentious communication with MoH · Poor communication and misunderstandings with civil works contractor · Interorganizational discord due to institutional boundaries and power dynamics	· Limited feedback from hospital management	· Monthly departmental meetings

	Culture	· Bureaucratic nature of the public system	· Culture of lateness in the public health sector · Poor culture of work in public hospitals i.e. absenteeism, excuses, money-mindedness	
	Implementation Climate			
	1) Tension for change	· Prioritization of fertility patients	· Decongestion of Mulago Hospital due to high patient volumes · Gross overcrowding of maternity ward · Unbearable patient conditions	· Compelling statistics on infertility rates

	2) Compatibility	· Existing centralized procurement process through National Medical Stores · Non-Interoperability of IVF Equipment given limited suppliers, located overseas · Staff employed centrally through the Ministry of Public Service · Embryologist role absent from employment existing structure · Centralized reimbursement of staff through Ministry of Finance	· Reorganized of obstetrics and gynecological department into specialized teams	· Non-Interoperability of IVF equipment with existing infrastructure · Rotation of clinical staff on duty within the department hindered workflow, accountability, and quality of work

	3) Relative Priority	· Followed the global trend towards specialization. · Government social contract to citizens in providing all services including ART. · Low economic status of patients often sought free or affordable healthcare in public facilities	· As a government hospital, MWH had access to a pool of specialists to offer fertility care · The national referral hospital would act as a model to the government for the feasibility offering fertility services at regional facilities as well	
	4) Organizational incentives and rewards		· Public hospitals provided opportunities for further training and career development.	· Absence of financial incentives was a limitation towards staff morale, retention and quality of care in the public sector
	5) Goals and Feedback	· Government monitoring and audits of the implementation process was conducted		

	6) Learning Climate			· Early in the implementation process, strong political support created a positive learning climate · Later, the change in political leadership and therefore, weakened support resulted in a precarious learning climate
	Readiness for Implementation			
	1) Leadership engagement	· Strong political leadership and advocacy through the MoH early in the implementation process · Weakened leadership engagement with political changes and priorities		· Provision of on-going support and engagement by departmental heads to the clinical team

	2) Available resources	· Financial resource availability from the government · Clinicians received specialist training to acquire knowledge	· MWH dedicated a whole floor to the Reproductive Medicine department · Procured high end IVF equipment · All specialist departments received relevant specialist training	· Clinical team did not have an embryologist on staff
	3) Access to knowledge and information	· Access to local, experienced fertility specialists in the private sector for further training and expert guidance.		· Development of a "How to successfully run an IVF facility in a Mulago National Referral Hospital" document · Inability to utilized high end equipment due to absence of locally available training

Characteristics of Individuals	**Knowledge and Beliefs About the Intervention**	· Cultural lens – individuals should have the right to children given the value of children in African culture and ability of IVF to stabilise families · Incorporation of LCIVF services in an African hospital as symbolic for other nations on the continent. · Use of family planning purported to be a cause of infertility · High cost of treatment in the private sector increased patient failure rates	· Construction of a new specialist women's hospital was said to present a timely opportunity to include the IVF services, which would have not happened otherwise.	· Moral beliefs – ability to have a child is a God given right for all individuals · Personal interest of clinical staff in fertility care was perceived to be a strong prerequisite for employability and reduced staff turnover · LCIVF clinical protocols not applicable to all patient cases. · Emotional burden of fertility as a speciality on clinicians when providing the service.
	Self-Efficacy			· Low self-efficacy attributable to the limited practical training they had received, the delayed start of the IVF department and absence of an embryologist.

	Individual Stage of Change			· Regarded themselves to be passionate, self-motivated practitioners and took personal initiative in pursuing opportunities for further training · Loss of enthusiasm due to the delayed start of IVF department
	Individual Identification with Organization	· Cautious of their perceived capacity at the ministerial level.	· Strong service commitment to the public health sector	
Process	**Planning**	· Development of a national implementation plan · Formally appointment implementation team · Establishment of planning committees	· Poor planning of hospital staff volumes · Pre-existing sub-specialities guided construction	· Departmental preparation through planning IVF unit ahead of construction · Development of an IVF concept paper to guide implementation · Planned incremental service provision to avoid errors

	Engaging	· Consultation with diverse stakeholders (e.g. maternal & patient organizations, lobbyists, external consultants) · Favourable working relationship with Civil works contractor · Engagement of media to guide journalists communicating accurate facts · External consultants from India and the US provided expert advice during construction		
	1) Opinion leaders	· Limited engagement with cultural and traditional leaders as social influencers		
	2) Formally Appointment Internal Implementation Leaders		· Highly engaged internal implementation team	

	3) Champions	· Former Minister of Health was a strong political champion · Joyce Fertility and Support Center (JFSC) were a significant grassroot, patient-led organization champion	· Former Head of Obstetrics and Gynecological department was an avid technical champion	· IVF departmental heads championed implementation efforts
	4) External Change Agents Executing	· MERCK foundation provided public awareness to infertility, training opportunities and technical expertise · WHO, IFFS and ESHRE also provided expert advice and technical support from LCIVF initiatives.		
	Execution	· Delays in release of funds by government	· Civil works for hospital construction delivered on time	· Construction errors in the IVF department led to delays · Procurement of quality IVF equipment

	Reflecting and Evaluating	· Sustained engagement of end users (clinicians & patients) throughout the implementation process · Need for continued political support throughout implementation process · Cultural and religious opinion leaders needed further engagement · Development of policy and guidelines on IVF and fertilization treatment to ensure effective use of the facility. · Provide clear building designs from the start to ensure desired outcomes for all stakeholders. · Garnering local interest in IVF technologies through teaching it in medical schools and providing on-going practical training that is locally accessible.	· Recommendation to construct the IVF department as a turnkey operation. · There was pride in the successful achievement of the vision to develop a specialist hospital focused on women and led by a woman.	· Recommendation to outsource embryologist, consider contracts with external embryology groups or private-public partnerships with local private fertility clinics to loan their embryologists. · Need for additional IVF training due to the delayed start and rapid evolution of new LCIVF innovations · Good quality equipment procured for the department · Implement strict operational guidelines including reliable power supply (powerful UPS systems and generators) · Ensure proper quality control (document control, competence testing, quality

		· Tax waivers for imported IVF drugs to reduce treatment costs · Academic institutions better suited for implementation of LCIVF initiatives given their ability to offer alternative incentives e.g. publications		control records, equipment maintenance, inter-laboratory benchmarking, audits and accreditation.) · Offer financial incentives to retain highly sought-after IVF staff · Grant departmental autonomy to address hiring, remuneration, pricing and procurement activities. · Use an individualized approach to offer LCIVF services given that it may not be universally feasible · Consider longer term strategies that support self-reliance for sustainability of the department away from governmental reliance · Participants reported sadness and disappointment at the

				fact that IVF services were not offered at the hospital.

Implementer Reputation (Inductive Theme)		· Public reputation of Mulago was poor, with the public perceiving its services to be substandard.		

Appendix – P: Detailed Overview of Facilitators and Impediments to Implementation of LCIVF initiatives in Uganda.

Domain	Theme/Sub-Theme	Factors that facilitated implementation	Factors that impeded implementation
Intervention Characteristics	**Intervention Source**	· Perception of internally developed, government funded and subsidized intervention	· Skepticism regarding why LCIVF is only discussed in the African contexts and not developed countries as well
	Evidence Strength and Quality	· Perceived duty of the government to provide subsidized fertility care to citizens	· Insufficient clinical evidence in developer contexts to justify use. · Low-cost perceived as low-quality
	Relative Advantage	· Cost treatment in the private sector too high and would be more affordable in a public hospital · LCIVF cheaper than conventional IVF treatment · Need for more comprehensive fertility treatment options compared to status quo (diagnostic & minor surgeries)	· Barrier to revenue generating opportunities associated with conventional IVF
	Adaptability	· Breadth of LCIVF initiatives that can be adapted to fit the organization's needs.	

	Trialability	· Opportunity to start with uncomplicated procedures and then working up to more complication treatment protocols · Offer free trials to patients to test and publish results	
	Complexity		· LCIVF still required highly specialized infrastructure, equipment, and a dedicated, multi-disciplinary team. · Rapidly evolving scope of LCIVF initiatives being developed difficult to keep track · Concern over complicated cases dictated by patient related factors that would necessitate third parties. · Perceived higher risk for clinical error as each member's success depends on the competency of the team.
	Cost	· Treatment waivers provided to referred patients who couldn't afford payment	· High initial investment for setting up an IVF department · High cost of maintaining IVF related equipment and ensuring adequate supply of quality drugs · Considerable debate regarding whether IVF services should be free or subsidized and applicable to all fertility patients · MWH offered a 3-tiered package for fertility treatment which was heavily disputed.

Outer Setting	**Patient Needs and Resources**	· Growing public demand for affordable fertility treatment · Presence of patient advocacy group and demand for fertility services	· Public sensitization on infertility needed to combat stigma, misconceptions and increase health seeking at fertility hospitals
	Cosmopolitanism	· Partnerships with local and international organizations i.e., Makerere University, Uganda Fertility Society, WHO, IFFS, ESHRE, ASRM, MERCK · Engagement with patient-led advocacy group i.e., JFSC · Collaborated with politicians as allies to approving financing of MWH and ART bill · Knowledge exchange with private sector to train medical students & embryologists	
	Peer Pressure	· Competitive market taken up primarily by the private sector	
	External Policy and Incentives	· WHO declaration on infertility as a global reproductive disease · UN Universal Declaration for Human Rights Declaration (Article 16) · Development of a national ART Policy · International benchmarking visits to women's hospitals and IVF departments · Government funding to finance hospital construction, staff training, equipment, and information system	· Regulation of financing, procurement and employment by MoF, MoH and MoPs respectively

Inner Setting	**Structural Characteristics**	· Longevity of Mulago having undergone multiple renovations · National referral system and walk in system made IVF services accessible to all citizens	· Staff transfers created team instability, loss of specialist knowledge and diminished quality of care · Limited autonomy to make decisions as a department as quickly
	Networks and Communications	· Monthly departmental meetings promoted inclusivity in the meetings in facilitating team cohesion and accountability.	· Contentious communication with MoH · Limited feedback from hospital management · Poor communication and misunderstandings with civil works contractor led to errors · Interorganizational discord due to institutional boundaries and power dynamics
	Culture		· Bureaucratic nature of the public system delayed decision making · Culture of lateness in the public health sector · Poor culture of work in public hospitals i.e., absenteeism, excuses, money-mindedness
	Implementation Climate		
	1) Tension for change	· Decongestion of Mulago hospital · Overcrowded maternity ward · Poor patient conditions · Compelling statistics on infertility rates · Prioritization of fertility patients	

	2) Compatibility	· Reorganized of obstetrics and gynecological department into specialized teams	· Existing centralized process of procurement through National Medical Stores causing delays and bureaucracy to procurement of IVF supplies · Non-Interoperability of IVF equipment with existing infrastructure · Centralized employment through the Ministry of Public Service impacted the hiring of an embryologist as the role did not exist in structure · Centralized reimbursement through Ministry of Finance restricted the ability to offer financial incentives to staff · The rotation of clinical staff on duty within the department hindered workflow, accountability, and quality of work
	3) Relative Priority	· Clinicians interest in following the global trend towards medical specialization. · Government social contract to citizens in providing all services including ART. · Low economic status of patients often sought free or affordable healthcare in public facilities · As a government hospital, MWH had access to a pool of specialists to offer fertility care · The national referral hospital would act as a model to the government for the feasibility offering fertility services at regional facilities as well	

	4) Organizational incentives and rewards	· Public hospitals provided opportunities for further training and career development.	· Absence of financial incentives was a limitation towards staff morale, retention, and quality of care in the public sector
	5) Goals and Feedback	· Government monitoring and audits of the implementation process was conducted	
	6) Learning Climate	· Early in the implementation process, strong political support created a positive learning climate	· Later, the change in political leadership and therefore, weakened support resulted in a precarious learning climate
	Readiness for Implementation		
	1) Leadership engagement	· Strong political leadership and advocacy through the MoH early in the implementation process · Provision of on-going support and engagement by departmental heads to the team	· Weakened leadership engagement with political changes and priorities
	2) Available resources	· Financial resource availability from the government · Dedicated a whole floor to the Reproductive Medicine department · All specialist departments received relevant specialist training	· However, specialist training was reportedly too short, generic, and partly, poorly delivered · Clinical team did not have an embryologist on staff · Lack of locally accessible IVF specialist trainers

	3) Access to knowledge and information	· Access to local, experienced fertility specialists in the private sector for further training and expert guidance. · Development of a "How to successfully run an IVF facility in a Mulago National Referral Hospital" document	· Inability to utilized high end equipment due to absence of locally available training
Characteristics of Individuals	**Knowledge and Beliefs About the Intervention**	· Moral beliefs – ability to have a child is a God given right for all individuals · Cultural lens – individuals should have the right to children given the value of children in African culture and ability of IVF to stabilise families · Incorporation of LCIVF services in an African hospital as symbolic for other nations on the continent. · Construction of a new specialist women's hospital was said to present a timely opportunity to include the IVF services, which would have not happened otherwise. · Mass use of family planning purported to be a cause of infertility requiring support for treatment · High cost of treatment in the private sector increased patient failure rates	· Personal interest of clinical staff in fertility care was perceived to be a strong mediator for employability, reduced staff turnover and quality of care · LCIVF clinical protocols would not be applicable to all patient cases. · Emotional burden of fertility as a speciality on clinicians when providing the service.
	Self-Efficacy		· Low self-efficacy attributable to the limited practical training they had received, the delayed start of the IVF department and absence of an embryologist.

	Individual Stage of Change	· Regarded themselves to be passionate, self-motivated practitioners and took personal initiative in pursuing opportunities for further training	· Loss of enthusiasm due to the delayed start of IVF department
	Individual Identification with Organization	· Strong service commitment to the public health sector	· Cautious of their perceived capacity at the ministerial level.
Process	**Planning**	· Availability of a national implementation plan · Formally appointment implementation team · Establishment of planning committees · Pre-existing sub-specialities guided construction · Departmental preparation through planning IVF unit ahead of construction · Development of an IVF concept paper to guide implementation · Planned incremental service provision to avoid errors	· Poor planning of hospital staff volumes

	Engaging	· Favourable working relationship with Civil works contractor · Consultation with diverse stakeholders (e.g. maternal patient organizations, lobbyists, external consultants) · Engagement of media to guide journalists communicating accurate facts · External consultants from India and the US provided expert advice during construction	
	1) Opinion leaders		· Limited engagement with cultural and traditional leaders as social influencers
	2) Formally Appointment Internal Implementation Leaders	· Highly engaged internal implementation team	
	3) Champions	· Former Minister of Health was a strong political champion · Former Head of Obstetrics and Gynecological department was an avid technical champion · IVF departmental heads championed implementation efforts · Joyce Fertility and Support Center (JFSC) were a significant grassroot, patient-led organization champion	· Loss of political support due to government change MoH head and priorities · Discontinued engagement with patient-led organizations

	4) External Change Agents Executing	· Consultation with diverse stakeholders (e.g. maternal patient organizations, lobbyists, external consultants) · MERCK foundation provided public awareness to infertility, training opportunities and technical expertise · WHO, IFFS and ESHRE also provided expert advice and technical support from LCIVF initiatives.	
	Execution	· Civil works for hospital construction delivered on time	· Construction errors in the IVF department led to delays · Delays in release of funds by government
	Reflecting and Evaluating		· COVID-related halted implementation efforts as hospitals redirected attention to vaccination and treatment.
Implementer Reputation (Inductive Theme)			· Public reputation of Mulago was poor, with the public perceiving its services to be substandard.