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Treatment and prevention: integrated methadone and antiretroviral therapy among people who inject drugs in Dar es Salaam, Tanzania

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Treatment and prevention: integrated methadone and antiretroviral therapy among people who inject drugs in Dar es Salaam, Tanzania

A dissertation submitted in partial satisfaction of the requirements for the degree Doctor of Philosophy in Community Health Sciences

by

Alexis Cooke

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ABSTRACT OF THE DISSERTATION

Treatment and prevention: integrated methadone and antiretroviral therapy among people who inject drugs in Dar es Salaam, Tanzania

by

Alexis Cooke

Doctor of Philosophy in Community Health Sciences

University of California, Los Angeles, 2017

Professor Deborah C. Glik, Chair

In this dissertation, I assess the feasibility of an integrated methadone and antiretroviral therapy (IMAT) intervention in Dar es Salaam, Tanzania. The IMAT intervention seeks to integrate HIV care and treatment into an existing methadone maintenance clinic for seropositive people who inject drugs. Findings indicate variations in regard to intervention implementation which may ultimately impact patient outcomes.

Data were collected in 2015, six-months post IMAT implementation and were collected from the methadone clinic at Muhimbili University Hospital, in Dar es Salaam, Tanzania. This data collection was done to assess early implementation efforts and the way in which the clinic and people involved in the intervention (patients and providers) experienced and moved through the intervention. Data came from observations conducted at the methadone clinic, patients' clinic and laboratory data, as well as in-depth interviews with patients and providers involved in the IMAT intervention.

The first study (Aim 1) documented the visit process and care delivery in relation to the IMAT intervention. This study documented variation in the time patients spend receiving various clinic services, as well as variation in the types of services providers engage in. Results from this research aim also show variation in the degree to which patients received integrated care. The second study (Aim 2) examined the impact participation in the IMAT intervention had on patient attendance at the methadone clinic. Results indicate that participation in IMAT had a positive effect on patient attendance.

The third study (Aim 3) examined patient and provider perceptions of the IMAT intervention to better understand factors that might have influenced their participation. Providers felt the ability of the intervention to incorporate patient needs, fit into clinic procedures, and evidence for the effectiveness of the intervention had a positive influence on implementation effectiveness. Strong positive influences included adaptability, and perceptions of the advantage of implementing IMAT compared to alternative solutions. Resources dedicated to intervention such as physical space and time presented a challenge to implementation effectiveness. Patients felt the ability to receive anti-retroviral medication in the clinic made it easier for them to receive care. Patients identified challenges to implementation, such as clinic resources, consistent access to nutrition, and concerns about stigma from their fellow patients. Patients enrolled in IMAT felt positively about the program overall, indicating that IMAT improved care receipt, and streamlined the care process.

Implementing HIV care and treatment and methadone treatment concurrently in health care settings with marginal resources poses a challenge. Access and availability of treatment is an important issue when considering the link between injection drug use and HIV, especially for those who are HIV positive. While it is possible to implement this intervention in this setting

attention should be placed on issues of care retention and attendance. This dissertation seeks to better understand these issues outside of a western care context, with the hopes of documenting core components.

The dissertation of Alexis Cooke is approved.

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University of California, Los Angeles

2017

DEDICATION PAGE

To the ancestors

To my parents

To my sisters

To the sun, the sky, the earth, and the oceans

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ABBREVIATIONS

- AIDS: Acquired Immunodeficiency Syndrome
- ART: Antiretroviral therapy
- ARV: Antiretroviral
- CBO: Community Based Organization
- CD4: Cluster of differentiation 4
- CFIR: Consolidated Framework for Implementation Research
- CTC: Care and treatment clinic
- EBI: Evidence Based Intervention
- HIV: Human Immunodeficiency Virus
- HSCL-25: Hopkins Symptom Checklist-25
- IMAT: Integrated methadone and antiretroviral therapy
- MCS-12: Mental Health Composite Score
- MMT: Methadone maintenance therapy
- MNH: Muhimbili National Hospital
- ORCA: Organizational Readiness to Change Assessment
- PCS-12: Physical Health Composite Score
- PWID: people who inject drugs
- SSA: Sub-Saharan Africa
- STI: Sexually Transmitted Infection

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Presentations

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Chapter 1: Introduction

Public health threats have long been caused by opportunistic infectious diseases, whose ability to flourish is exacerbated by certain risky human behaviors. Such threats have been documented in numerous cases, ranging from typhoid outbreaks as a result of travel, to recent outbreaks of measles resulting from vaccination refusal (Phadke, Bednarczyk, Salmon, & Omer, 2016; Ryan, Hargrett-Bean, & Blake, 1989).

Policies, programs, and treatments based on epidemiological, clinical and behavioral assessments of disease risk are devised to maintain, prevent or minimize the impact of outbreaks, epidemics and other health trends. However even when significant evidence exists regarding the efficacy of interventions, the issue always remains how to deliver and sustain these efforts in ways that are effective, timely and of high quality, especially in low-resource settings or among vulnerable populations. These issues are compounded when interventions based on science from western countries are translated to the global south. In these cases, interventions have to contend with issues related to cultural appropriateness, resource limitations, and political will.

In this dissertation, I will assess the implementation of an evidence based program in Dar es Salaam, Tanzania, designed to change risk factors for the ongoing transmission of HIV among people who inject drugs (PWID). This presents an emerging health issue in sub-Saharan Africa (SSA). Using implementation science methods, my major study goal was to assess how an evidence based program to mitigate harm caused by high risk behaviors was established and whether such efforts to change human behavior in under resourced and highly vulnerable populations are feasible.

Human behavior has long been intimately connected to the expanding global epidemic of human immunodeficiency virus (HIV), a virus transmitted most successfully through blood and

other bodily fluids entering the blood stream through mucous membranes. Sub-Saharan Africa (SSA) remains the region in the world most severely impacted by the global HIV epidemic with an estimated 24.7 million people living with HIV, accounting for almost 71% of the global total (Joint United Nations Programme on HIV/AIDS (UNAIDS), 2015). There are specific areas in SSA where the spread of HIV is coupled with higher general prevalence, namely in south and east Africa.

There is no single apparent cause of the higher rates of HIV in SSA generally, or in south and east Africa specifically, but the higher rates may reflect continued regional and political destabilization, which can create a sociopolitical context within which people engage in high-risk behaviors that outpace prevention efforts (Buvé, Bishikwabo-Nsarhaza, & Mutangadura, 2002). Geospatial clustering of HIV in SSA also indicates that community viral load levels may be higher in south and east Africa. These higher viral load levels result in the general population being at increased risk, even if they don't engage in high-risk sexual or injecting drug behaviors (Abu-Raddad et al., 2013). While HIV prevalence has remained stable in east Africa for the past decade, introduction of a high-risk seropositive population whose members inject drugs has the potential to generate a substantial increase in HIV prevalence across the region.

Prior to the 1980s, injection drug use using heroin was rare in East Africa. The region acted mainly as a transit port for drug traffickers *en route* to Europe and North America from Afghanistan, Pakistan, the United Arab Emirates and India (Timpson et al., 2006). In SSA, injection drug use only became a factor in HIV transmission beginning in the early 2000s (Nyindo, 2005). In contrast, in eastern Europe and central Asia, adults become infected with HIV primarily through injection drug use (Buvé, 2006).

In Tanzania, where this dissertation research takes place, injecting heroin began to increase in the early 2000s as cheap heroin entered the market, trafficked into the country through international airports and ports of call (S. McCurdy, Kilonzo, Williams, & Kaaya, 2007; Sheryl A. McCurdy, Ross, Williams, Kilonzo, & Leshabari, 2010a). Various African regions have a long history as points of production and transportation for illicit drugs. Thus, drug use in coastal east African countries like Tanzania has been facilitated by the area's geographic location and involvement in trade. The increase in heroin use began and continues even as east African nations are attempting to manage their HIV epidemics. As mentioned previously, injection drug use became a more significant factor in HIV incidence beginning in the early 2000s, with heroin users mainly injecting the drug (Ndeti, 2004; Needle, Kroeger, Belani, & Hegle, 2006; Odek-Ogunde, 2004). Research confirms the increasing role of injection drug use in the spread of HIV, indicating that people who inject drugs (PWID) in east Africa had higher HIV prevalence compared to non-PWID populations (Deveau, Levine, & Beckerleg, 2006; S. R. Reid, 2009).

Another human behavior, drug trafficking, has also substantially increased due to globalization. With increased globalization, the relative lack of security and interception infrastructure for drug trafficking and its traffickers, the often high rates of unemployment, and unending political instability, African countries have become attractive targets for drug traffickers (Brooke Stearns Lawson & Phyllis Dininio, 2013; WACD, 2014). In 2009, estimates suggested that 40 to 45 tons of heroin went into Africa, with research pointing to increases in consumption (Brooke Stearns Lawson & Phyllis Dininio, 2013; Mbwambo et al., 2012). While drug trafficking has had a long history in north Africa, this trend is hitting both east and west Africa hard at present, especially their urban coastal areas.

Decades of research and program implementation in developed countries suggest that there are a number of solutions for lowering rates of drug use and HIV-risk behaviors among PWID who are in treatment (MacArthur et al., 2012; Metzger et al., 1993). A major method to curb heroin use is methadone maintenance therapy, however, it has mainly been used in Western contexts. Methadone maintenance therapy provides patients with an orally administered opioid to meet patients' opioid dependence. Methadone maintenance therapy allows for a once-daily administration, and is more effective than individual abstinence and has no long term effects (Ward, Bell, Mattick, & Hall, 2012). In addition to reducing drug injections, the main transmission route for infectious disease in this population, methadone maintenance therapy can also help PWIDs recover social function (Pang et al., 2007).

Another well-developed method to reduce HIV risk is timely initiation of antiretroviral therapy (ART). ART is a vital component of effective HIV prevention, care and treatment, however PWID are less likely to receive ART than their non-drug using counterparts (Mathers, Degenhardt, Ali, Wiessing, Hickman, Mattick, Myers, Ambekar, Strathdee, et al., 2010). PWID consistently face barriers, such as laws and policies, which limit their access to HIV prevention and treatment interventions (Gruskin, Ferguson, Alfven, Rugg, & Peersman, 2013). Where programs exist, many fail to reach those who could benefit due to requirements that make it difficult for people to enter and remain in services (Keeney & Saucier, 2010). Individual and structural barriers, such as inadequate knowledge of ART, untreated mental illness, unstable housing, fear of criminalization, and stigmatization impact the use of HIV services among PWID (Krüsi, Wood, Montaner, & Kerr, 2010; Mimiaga et al., 2010; Wood, Kerr, Tyndall, & Montaner, 2008). In some settings, clinicians have delayed or withheld ART from people who use drugs for fear of non-adherence and development of drug resistance (Rhodes & Sarang,

2012; Wolfe, Carrieri, & Shepard, 2010). As a result, only 4% of HIV-positive people who inject drugs receive ART globally (Mathers, Degenhardt, Ali, Wiessing, Hickman, Mattick, Myers, Ambekar, Strathdee, et al., 2010).

Integrated treatment for HIV and substance use disorders (including heroin use) has been shown to improve HIV and other health outcomes (Batkis, Treisman, & Angelino, 2010). Methadone maintenance therapy has been shown to improve PWID's adherence to antiretroviral (ARV) drug regimens and can even predict medication adherence (Bouhnik et al., 2002; Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; MacArthur et al., 2012). Accordingly, methadone maintenance therapy can act as both primary and secondary HIV prevention -- it can reduce the acquisition of other infectious disease, and also helps to connect PWID to regular clinical care (Bruce, 2010). The issue for SSA, then becomes if these programs can become successfully established and reach sufficient populations to prevent HIV rates from rising, given the current trends in drug use behaviors among those who are seropositive in this region. While this is a large question this dissertation cannot completely address, an opportunity to assess a recently established clinical program in Tanzania presented itself as I became in interested in this issue, and allowed me to conduct research about the viability of integrated care approaches for this highly vulnerable population and serious health threat.

To address delays in ART initiation and improve clinical outcomes, an integrated HIV and methadone service delivery model was developed for a pre-existing methadone clinic at Muhimbili National Hospital, located in Dar es Salaam, Tanzania. Called the Integrated Methadone and Antiretroviral Therapy (IMAT) intervention, this program was initiated in 2015. At the time of data collection, the proposed IMAT model included four key components: 1) in-house point-of-care (POC) CD4 testing; 2) in-house HIV clinical management by methadone

clinic providers trained in comprehensive HIV management, with referrals to the HIV clinic for developing needs; 3) ART delivery through the methadone clinic; and 4) an electronic information system to help providers monitor methadone clinic patients along the continuum of HIV care.

To best describe and assess the different components of this program, this dissertation was developed as a mixed-methods study, to evaluate the feasibility and viability of this specific IMAT intervention, which uses established treatment protocol (methadone maintenance and ART therapy) integrated into one clinic. For this dissertation research, I used both qualitative interview data, as well as quantitative data detailing patient characteristics, and clinic implementation processes and outcomes.

Observational data collected from visits at the methadone clinic were used to understand implementation and fidelity processes from the perspective of patients and providers. Quantitative data on patient adherence, patient attrition, along with patient characteristics, were used to analyze how the intervention and its implementation is related to patient participation with the clinic. Lastly, qualitative data from in-depth interviews were used to understand patients' and providers' perceptions of the IMAT intervention and how these perceptions might impact implementation outcomes.

Currently, HIV prevalence in Tanzania is approximately 6%, but research indicates that HIV prevalence is higher among PWID and that potentially half of PWID are HIV-positive (Hargreaves & Howe, 2010; Sheryl A. McCurdy et al., 2010a). Given the high HIV prevalence among PWID in Tanzania, integrating ART with methadone maintenance therapy may optimize treatment and prevention benefits, and therefore may represent an innovation in health care delivery. However, this integrative method has to be well-implemented to be effective. Thus, it is

important to understand the viability of care integration in resource limited contexts, and how it is related to patient satisfaction, patient retention, patient receipt of services, providers giving services, as well as the duration and quality of time spent in provider patient exchanges. These issues comprise the overall focus and approach of this research study.

While there are no comprehensive data on illicit drug use in countries in the global south, as there are for western countries, anecdotal evidence suggests that injection drug use continues and may be increasing, hence increasing risk that HIV rates can also go up. Of importance to this study are articulating best practices and ways to address illicit drug use and HIV in countries with little to no history in dealing with these issues and which lack the adequate infrastructure to do so. My decision to use a mixed-method approach allows for an understanding of patient related, provider related, programmatic, organizational and contextual factors which impact intervention feasibility. Thus, this is a single case study approach which may have limited generalizability. However, as I hope to convey in the remainder of this study, it does address many issues which are important in translating similar work to other settings.

Conclusion

Work in implementation science typically focuses on how proven interventions, such as methadone maintenance can be made to work, with similar effects under different social, cultural and political contexts (Rhodes & Sarang, 2012). However, substance use is a complex issue without a universal policy approach or treatment, and in SSA the history and resources allocated for substance use, especially in the context of chronic health management and/or co-morbid diseases is limited. As countries in SSA become open to substance use treatment, especially in the context of infectious disease treatment and prevention, research in this area should be open to grounding knowledge within local contexts. This research aims to add to global work on

substance use, particularly in looking at injection drug use and infectious disease to explore how local contexts shape the translation, transformation or resistance of policy adaptations.

Chapter 2 : Literature Review

While public health and clinical care services have established many evidence based policies and programs to improve health over past decades, successful adaptation of these interventions for different contexts, cultures or conditions has never been assured. Interventions can become difficult to implement when they involve instituting highly demanding regimens for vulnerable patients with chronic health conditions in under resourced health systems. All of these potential barriers to successful implementation characterize issues with treating drug use among people who are seropositive in health settings in SSA, despite well established and effective medical and clinical protocols. These issues, which comprise the basic focus of this dissertation, will be addressed in the latter parts of this chapter. First, I will review basic or core epidemiologic, social and behavioral risk factors in regard to populations of interest.

Global drug use and HIV

Illicit drug use, is generally regarded as a problem faced primarily by western countries. The drug trade has, however, long impacted countries in the global south, though these impacts have traditionally been framed by the countries' roles as sites of manufacture and export. Globalization, urbanization, and changes in politics and economic policies have facilitated a shift in developing countries, many of which are in the global south, whereby they have also become major consumers of illicit drugs (Needle et al., 2006).

There are no comprehensive estimates of illicit drug use on the global scale, but research indicates that drug use and dependence can be found in most countries (Degenhardt et al., 2011). An estimated 500,000 people in east Africa use opioids for non-medical reasons, and on the mainland of Tanzania, there are an estimated 30,000 people who inject drugs (PWID), primarily

heroin (Csete et al., 2016; Dutta, Barker, & Makyao, 2014). The rapid escalation of injection drug use, in the context of a generalized HIV epidemic, has resulted in a high burden of HIV among PWID. HIV prevalence among PWID in Tanzania is estimated at 35% compared to 5.1% among the general population in the country (Dutta et al., 2014; TACAIDS & NBS OCGS, 2013).

The co-occurrence of HIV and injection drug use is a challenge for many countries in the global south, particularly countries in south Asia given their proximity to opiate production. Globally, HIV prevalence hovers around 19% among PWID. Recent increases in HIV prevalence in eastern Europe and central Asia have been attributed to injecting drug use (Wilson, Donald, Shattock, Wilson, & Fraser-Hurt, 2015). Estimates indicate that over half of those with opioid dependence live in Asia, and HIV prevalence among PWID in south Asia is between 20-25% (Drugs & Crime, 2011; G. Reid, Sharma, & Higgs, 2014). Evidence shows that opioid substitution therapy targeted at PWID is an effective tool for HIV prevention. But, despite the high need and prevalence estimates, it appears that few get access to treatment, with only 3% of PWID in south Asia have access to opioid substitution therapy (G. Reid et al., 2014).

Injection drug users of any kind are at higher risk of HIV compared to non-injectors (Tavitian-Exley, Vickerman, Bastos, & Boily, 2015). While overall HIV prevalence in Dar es Salaam, Tanzania has declined from approximately 10% in the early 2000s to approximately 5%, research indicates that prevalence is higher among PWID and postulates that potentially half of PWID are HIV positive (Dutta et al., 2014; Hargreaves & Howe, 2010; Ministry of Health and Social Welfare – Tanzania, 2013). The high prevalence of HIV among PWID has the potential to undo national HIV prevention efforts (Lambdin et al., 2013).

Data on HIV prevalence and injection drug use in other east African countries is similar. A 2001 study found that in Mauritius, 64% of new HIV infections occurred through heterosexual contact, while injection drug use accounted for only 7%, of new infections, however by 2005 only 6% of new HIV cases were through heterosexual contact while, 90% were through injection drug use (Needle et al., 2006). Two 2004 surveys were conducted with injection drug users in Kenya. The first surveyed 120 drug users and found 49.5% were HIV positive, while the second surveyed 332 heroin users and found current PWID had an HIV prevalence of 52.5% (Ndeti, 2004; Odek-Ogunde, 2004). In a study of 1000 Kenyan PWID, 31% were HIV positive (Deveau et al., 2006). HIV prevalence among PWID in Zanzibar is 28%, compared to only 5% among non-injection drug users (S. R. Reid, 2009). In a sample of PWID in Tanzania, 58% of women and 27% of men were found to be HIV positive. Tanzania aims to decrease its HIV prevalence to 4% by 2020, a goal that will remain unobtainable without first addressing the treatment needs of PWID population (Ministry of Health and Social Welfare – Tanzania, 2013).

Injection Drug Use in Tanzania

A 2006 study in Tanzania found that male PWID were older, more likely to be married or living with a partner, had more education, and lived in their own homes compared to female PWID. While research suggests that there are more male than female PWID in Tanzania, females PWID are more likely to be housing insecure, be sex workers and single (M. L. Williams et al., 2006). Due to stigma around drug use, many PWID have to hide their drug use from friends and family, and do so by finding "underground" places where they can use without fear of discovery (S. A. McCurdy, Williams, Kilonzo, Ross, & Leshabari, 2005; S. R. Reid, 2009; Yamanis, Maman, Mbwambo, Earp, & Kajula, 2010). These "underground" locations can potentially facilitate the spread of HIV because of shared needles and unsanitary conditions. Many men in

Tanzania inject drugs in sites called "camps," which act as social gathering places, while youth inject in *maskanis* ("open space areas") or *mageto* ("private areas") (Yamanis et al., 2010). All are used for social gatherings at which initiates will inject drugs for the first time. Such spaces also facilitate communal sharing of equipment and are places where female commercial sex workers will trade sex for heroin (S. A. McCurdy et al., 2005). PWID in Tanzania also commonly inject in places called "shooting galleries," where they can both purchase and use drugs. PWID will commonly leave their needles in these shooting galleries so that others can use them in their absence (Timpson et al., 2006).

Injection drug use commonly co-occurs with needle sharing, lack of information around HIV transmission risk and high mobility (Wodak A & Crofts N, 1993). Tanzania, like many other African countries, has focused on faithfulness and abstinence as a means of HIV prevention (S. McCurdy et al., 2007). While these campaigns have had some success, studies show that not all groups have seen the same declines, leaving out those with less education, rural populations, as well as PWID (Hargreaves & Howe, 2010; S. McCurdy et al., 2007; Mwaluko, Urassa, Isingo, Zaba, & Boerma, 2003; Wamoyi, Fenwick, Urassa, Zaba, & Stones, 2011). That HIV can be transmitted through the sharing of various injection supplies has been documented in a variety of settings (Aceijas, Stimson, Hickman, Rhodes, & others, 2004). In addition to the sharing of equipment, many PWID also report inconsistent condom use and either trade or sell sex to support drug habits (Needle et al., 2006). Many PWID do not fully understand the risk relationship between drug use and HIV transmission (Ahmed, 2014; S. R. Reid, 2009).

A number of PWID are aware of their serostatus and continue to engage in HIV risk behaviors (Avants, Margolin, Usubiaga, & Doebrick, 2004; Gossop, Griffiths, Powis, & Strang, 1993). For these users, drug addiction may be their main focal point, so that they are less likely

to monitor their HIV-related risk behaviors compared to their drug use (Avants et al., 2004). Drug addiction may override PWID's desire to protect themselves or others from HIV. Research shows that PWID who happen to be more dependent heroin users were at a greater risk of sharing needles than those who were less dependent (Gossop et al., 1993).

Addiction may also lead to new behaviors that put PWID at even more risk of contracting or spreading HIV. "Flashblood," for example, is a relatively new practice in which a user injects a full syringe of blood into themselves donated by someone who has recently injected heroin into their bloodstream. This is commonly thought of as an altruistic practice performed to help out a fellow user who might not be able to afford heroin at that time (Sheryl A. McCurdy, Ross, Williams, Kilonzo, & Leshabari, 2010b). Obviously, the potential for HIV transmission through such a direct exchange of blood is extremely high. "Flashblood" is more commonly practiced among female commercial sex workers, who are already at an increased risk of contracting HIV and have the potential to transmit HIV to their clients (Sheryl A. McCurdy et al., 2010b). In Tanzania, many female commercial sex workers are also PWID, and have reported an average of three (3) sexual partners per heroin binge, with an average of 61.2 partners in the last month. Men, in contrast, average 2.4 partners per month (S. A. McCurdy et al., 2005).

Harm Reduction, Methadone Maintenance and Current Work

During the 1990s the European Commission, the largest single donor agency in Africa at the time, stipulated that aid was contingent on countries having passed legislation criminalizing drug production and use, even if drug use was either an indigenous traditional or cultural practice (Klein, 2011). This policy has had a number of negative consequences for controlling the injection drug use problem in Africa. It has hampered the ability of many countries in SSA to launch widespread, comprehensive treatment and prevention programs for PWID, as

implementing those would result in a loss of aid money. This history is related to the lack of substance use treatment options in SSA, and the hesitancy that various agencies and groups have towards working with people who use drugs. For example, the Kenyan National Campaign Against Drugs Abuse Authority has commented that syringe exchange programs and methadone maintenance contradict government policy which only supports "total abstinence and a drug free lifestyle" (National Campaign Against Drug Abuse Authority, 2009). Unlike other countries in the area, the Tanzanian Ministry of Health is supportive of methadone clinics, however there is no current support or plan to fund additional measures such as syringe exchange (Wolfe & Csete, 2010).

It should also be noted that the opiate prevalence rate is higher in east Africa than it is in other sub regions. Heroin use in Mauritius is 0.91% and 0.73% in Kenya, but there are no reliable national prevalence rates for heroin use in either Tanzania or Uganda (Drugs & Crime, 2011). Dependence on heroin is chronic and relapse from abstinence is frequent. Kenya and Tanzania have attempted community outreach and education programs for PWID, focusing on sexual faithfulness and condom usage to prevent the spread of HIV, but have not focused on harm reduction methods such as needle exchange programs or methadone treatment. These programs have had limited success as they don't take into account issues of poverty and hunger. There is also limited political and financial support as the PWID population in east Africa is not highly prioritized (Lambdin et al., 2013; S. McCurdy et al., 2007).

Developing countries have neither the resources nor the political will to eradicate drug trafficking completely. And, reducing drug supply will only become effective when demand has decreased. Elimination and abstinence from drugs, both for countries and individuals may not be an appropriate or tangible goal (Klein, 2011; Wodak A & Crofts N, 1993). However, given the

impact of PWID and HIV, methods must be developed to mitigate these effects. Harm reduction is a model which focuses on the consequences of drug use rather than eliminating the use itself. It recognizes drug use as a fact, rather than something that must be controlled and punished. By attempting to mitigate the negative effects of drug use for individuals and communities and not emphasizing abstinence, harm reduction programs present a "come as you are" attitude (Marlatt, 1996; Single, 1995). Mauritius has been the example of an east African country that has implemented harm reduction programs with its HIV and AIDS act of 2006, implementing a needle exchange and methadone maintenance therapy (MMT) program (Abdool, Sulliman, & Dhannoo, 2006).

Tools to curb heroin use commonly include MMT. Methadone maintenance therapy provides patients with an orally administered opioid to meet patients' opioid dependence. MMT allows for a once-daily administration, is more effective than individual abstinence and has no long term effects (Ward et al., 2012). Research points to lower rates of drug use and HIV-risk behaviors among PWIDs who are in treatment (MacArthur et al., 2012; Metzger et al., 1993). In addition to reducing drug injection MMT can also help PWIDs recover social function (Pang et al., 2007).

Research indicates that MMT is most effective when long term maintenance, rather than abstinence, is the goal (Connock et al., 2007; Ward et al., 2012). PWID, however, are typically confronted with criminalization and stigma regarding their drug use. Law enforcement detention has been shown to be related to MMT drop out (Bouhnik et al., 2002; Metzger et al., 1993; Pang et al., 2007). Despite strong evidence against these punitive measures and the criminalization of PWID, establishing MMT programs in east Africa continue to prove difficult.

Current Guidelines for HIV/AIDS Care

Global recommendations for HIV prevention among injecting drug users include a comprehensive package including: needle and syringe programs, opioid substitution therapy, HIV testing and counselling, antiretroviral therapy, prevention and treatment of sexually transmitted infections, condom program, education, viral hepatitis prevention and vaccination and prevention, and diagnosis and treatment of tuberculosis (World Health Organization, 2012). Globally, injecting drug users receive little care in terms of HIV prevention, treatment, and care. In developing countries, ART treatment for injecting drug users is less than 1 per 100, whereas this same coverage is as high as 100 per 100 in European countries (Mathers, Degenhardt, Ali, Wiessing, Hickman, Mattick, Myers, Ambekar, & Strathdee, 2010). Following WHO guidelines, diagnosis of HIV is to be done via rapid testing and counselling should be done before and after testing, regardless of reactivity (World Health Organization, 2012). Tanzanian national guidelines support ART initiation for patients with a CD4 count less than 250, patients with active tuberculosis, patients with hepatitis B, and women who are pregnant and breast feeding (Ministry of Health and Social Welfare – Tanzania, 2013). Currently there are four methadone clinics in Tanzania, none of which provide all of the WHO recommendations for HIV treatment.

Research suggests that HIV positive persons in Tanzania face stigma, which creates barriers in obtaining treatment and care, and de-incentivizes serostatus disclosure (Mutalemwa, Kisoka, Nyingo, Barongo, & Malecela, 2008; Tan, Kapiga, Khoshnood, & Bruce, 2015). PWID with HIV have internalized stigma around their HIV status, and worry that they will be perceived as criminal if others learn of their status, not wanting to be labeled as drug addicts as well as HIV positive (Saleem et al., 2015). These multiple layers of stigma de-incentivize HIV testing and

subsequent treatment, as well as disclosure even to medical providers whose job it is to help them care for their health.

Methadone Maintenance and HIV Care Integration

For PWID, co-location alone of integrated services can reduce barriers to accessing care, as HIV positive PWID have trouble initiating and adhering to ART regimens (Lambdin, Mbwambo, Josiah, & Bruce, 2015). Integrating HIV care with other disease management for PWID can result in care that is more convenient to patients, improves monitoring of drug use and drug interactions/side effects, and can help health systems through the cross-training of generalists and specialists (Sylla, Bruce, Kamarulzaman, & Altice, 2007).

Untreated substance use among HIV patients can decrease the likelihood patients engage in HIV care and increase risk of HIV transmission (Martin & Wang, 2013). Patients attempting to curb or eliminate their heroin use independently are not likely to succeed, nor can people obtain ART without engaging in some kind of clinical system. Injection drug users tend to not seek health care regularly, even when needed MMT can lead to quality of life improvements that facilitate ART adherence (Mlunde et al., 2015; B. X. Tran, Ohinmaa, Duong, Do, et al., 2012). The requirements of these treatment regimens and the patients impacted lend themselves to care integration.

From a health systems perspective, the logistics, planning, and purchasing required to distribute and make ARTs available can also be leveraged to deliver other types of care (Remien et al., 2008). If HIV positive PWID are already engaging with the health system at one point of care, then this initial point of contact can be used and expanded upon to deliver a wide array of services. Injection drug use is intimately connected to HIV transmission. Integrated treatment for HIV and substance use disorders has been shown to improve HIV and other health outcomes

(Batkis et al., 2010). MMT has been shown to improve PWID adherence to ART regimens, and MMT can even predict medication adherence (Bachireddy et al., 2014; Bouhnik et al., 2002; Catz et al., 2000; MacArthur et al., 2012). MMT acts as primary and secondary HIV prevention, as it can reduce the requisition of other infectious diseases, and also helps to connect PWID to regular clinical care (Bruce, 2010).

Among patients enrolled in MMT, ART has been shown to significantly decrease viral load levels (Lucas et al., 2006). However, HIV positive injecting drug users are often hard to reach, often have co-morbidities and lower adherence to treatment regimens (Lert & Kazatchkine, 2007). Integrating HIV care and treatment with MMT is one possible way to address the multiple issues facing HIV positive injection drug users. Integration of ART with MMT is associated with reduced heroin use and increased adherence to antiretroviral medication (Berg, Litwin, Li, Heo, & Arnsten, 2011; Palepu et al., 2006). Additionally, research shows that combining MMT and ART is both cost effective and helps care providers to monitor and observe patient treatment (B. X. Tran, Ohinmaa, Duong, Nguyen, et al., 2012).

Understanding Care Contexts for HIV AIDS/ MMT Integration in Africa

Delivering care with limited resources poses numerous challenges. As well, delivering care to patients with complex health and social needs can also be a challenge. This dissertation examines the clinic visit process from the perspective of patients and providers in order to understand the context in which HIV and MMT care is delivered in a developing world context, and how this specific context is related to the quality and feasibility of intervention implementation. MMT can be considered acute addiction treatment, but many patients stay enrolled in care for multiple years, hence it becomes more similar to chronic care management.

Managing patients with chronic health conditions can require complex care, especially when there are a large number of patients requiring care. Discovering the optimal care for chronic care patients in low resource settings requires figuring out how to optimize clinician time and to cost-effectively scale up (Wanyenze et al., 2010). In developing world contexts, care settings should ensure that the best possible care is maximized within their limited resources, such that patients' flow through the care environment is improved and timely treatment maximizing available resources is provided (Jacobson, Hall, & Swisher, 2006).

In recent years, efforts have increased to implement ART in SSA. This has resulted in clinics with limited resources (primarily in terms of infrastructure and human resources) becoming overwhelmed by the increase in the volume of patients requiring care. In one study Wanyenze et. al conducted a time-and-motion study in three Ugandan HIV clinics to better understand issues about clinic efficiency. Patients were randomly selected and their visits were tracked allowing researchers to collect data on time waiting and time spent with various providers. Researchers observed long wait times, resulting in clinic bottlenecks. On average, patients in all the three of the clinics saw three to four providers on each visit, however new patients and those undergoing preparation for ART initiation saw more than five providers. Researchers identified points to alleviate bottlenecks including redistributing appointment times throughout the day, task-shifting to lower-level clinicians, and streamlining activities for doctors and counselors specifically (Wanyenze et al., 2010).

Understanding clinic efficiency is an important part in understanding the ability of low resource care settings to provide adequate care. Were et al. examined two large HIV clinics in Uganda to identify opportunities to improve quality of care. Clinicians and patients were observed using time motion methods. Clinicians were observed for three full workdays, while

patients were observed for an entire clinic visit. Provider tasks and patient activities were recorded using an electronic tablet to record the beginning and end time for each activity. Researchers found variation in workday start times at each of the clinics. Patients were found to spend over 60% of their time at the clinics waiting for care, while providers spent 60% of their workday providing direct care. Researchers suggest that these findings indicate that a large portion of provider workdays are spent on non-patient centered tasks (logging in patient data, administrative work, etc.) which contributes to patient delays. Results from this research point to potential improvements in care that could be achieved through ensuring that clinicians spend the most time as possible providing direct care to patients, especially in low-resource setting with few trained clinicians (Were et al., 2008).

Research on clinic efficiency has also turned to specialist clinics, which might be better equipped to absorb patients with complex care needs. Work by Zhu et. al collected data from an outpatient clinic of a Singapore government hospital. In this study, patients at a specialist outpatient clinic were followed for the duration of their visit. Time from patient arrival to patient departure was observed and the possible factors causing long waiting times were analyzed. Researchers found issues such as late appointments, irregular calling sequence (where patients aren't called by the order they arrive), uneven distribution of appointments throughout the day, and unused session time contributed to wait times and patient delays. While specialist outpatient clinics which focus on one type of disease are equipped to handle the nuances of complex health conditions, they face increasing pressure to handle larger populations, resulting in increased workload and clinic congestion. This can lead to long wait times, which negatively impact patient satisfaction and increase provider burden (Zhu, Heng, & Teow, 2012).

Research by Alamo et.al, evaluated clinic efficiency following changes in clinic procedures designed to take place over 6-months. Researchers examined community-based ART clinics in Uganda, using time and motion methods, involving the tracking of patients from the time of arrival to exit on a single clinic visit. All clinic activities were documented including services provided, types of providers seen, and the time waiting to see and time spent with each provider. Additionally, interviews were conducted to assess perceptions of a new triage system and longer appointment intervals in relation to how they influenced patient flow, satisfaction, and the efficiency of the information and records management. Results showed decreases in median wait times over the study period, with simultaneous increases in the patient population. Patients felt like congestion in the clinic decreased over the study period, and the longer intervals of time between appointments made scheduling easier for them. These results indicate that in adding or scaling up programs located in low resource settings, the impacts to clinic efficiency and patient flow is an important point of consideration in monitoring patient and provider satisfaction, and in understanding service delivery as well as service uptake (Alamo et al., 2013).

Outside of looking at the ways in which clinics operate, research in east Africa has also been done to examine factors related to retention for those enrolled onto ART. In a longitudinal study Geng et. al followed 18,081 patients enrolled onto ART over 2.5 years in 14 clinics in Uganda, Tanzania, and Kenya. Two years after initiating onto ART 69% of patients were enrolled in care at their original clinic and 18% were lost to follow up. Of those that were lost to follow up 579 (18%) of these patients were traced. Among lost patients who were able to find care elsewhere, structural barriers (e.g., transportation) were most prevalent followed by clinic-based (e.g., waiting times) and psychosocial (e.g., stigma). Among lost patients not in care

elsewhere, psychosocial barriers were most prevalent, followed by structural and clinic based factors (Geng et al., 2016).

A number of studies looking at implementation processes in low resources settings have been conducted suggesting organizational, provider and patient related barriers. However, most studies found focused on ART or MMT rather than integrated care models. To some degree this may simply be due to the fact that care integration is a relatively new innovation in this part of the world. Given the efforts to provide integrated care at Muhumbili clinic, this study will explore those factors that impede or facilitate care delivered in this manner. Studying these efforts is important as Tanzania, like many countries in east Africa has greatly reduced the incidence and prevalence of HIV over the past two decades. The increasing consumption of heroin becomes a concern because of health problems associated with injection drug use. As an injected substance, heroin is intimately connected to the spread of blood-borne pathogens such as Hepatitis C and HIV (Carrier & Klantschnig, 2012). Thus, the region as a whole is increasingly vulnerable to the secondary effects of heroin consumption, namely the spread of infectious diseases.

In Chapter 3 I will describe the theoretical frameworks from implementation science that inform this this study. Chapter 4 discusses research designs and the methods and analysis plan based on the frameworks articulated in Chapter 3. In Chapter 5, 6, and 7, I present results for each of the three research Aims. Chapter 8 concludes the dissertation with a discussion of the findings and implications as well as a review of the strengths and limitations of the dissertation.

Chapter 3: Theoretical Frameworks

Implementation Science

To better describe the approach taken in this study, we turn to the emergent field of implementation science, which refers to the evaluation of programs in real world settings. Implementation science often falls under the larger umbrella of translational research. Translational research is the process of translating scientific discoveries and research to clinical and practical applications (Drolet & Lorenzi, 2011). The translation continuum describes the progression of steps needed in the overall translation process. As applied to public health, this continuum starts at T0, which includes basic descriptions and discovery of health outcomes, to T4, which assess the effectiveness of interventions on population health outcomes (Khoury, Gwinn, & Ioannidis, 2010). Implementation science occurs in the third step of the continuum, T3, which involved the implementation and dissemination of guidelines into practice and the overall translation of guidelines to real-world health applications (Drolet & Lorenzi, 2011; Khoury et al., 2010).

Implementation science has specifically been applied to HIV prevention and care to address the gap between proven clinical interventions and uptake by care providers, communities, and individuals (Bhardwaj, Carter, Aarons, & Chi, 2015). As applied in sub-Saharan African, implementation science work can add to an in-depth examination of specific care contexts and identification of key intervention components and resources such as staffing and medical resources (Gray, Wawer, & Kigozi, 2013). Given that many countries in SSA have specific policies and goals related to HIV transmission, implementation science contributes to the ability to scale up and expand various interventions and programs through understanding the various

processes and steps necessary for implementation (Chi, Stringer, & Moodley, 2013). An understanding of context, resources, and processes can be used to create and shore up programs that are both effective and sustainable.

Given the high HIV prevalence among people who inject drugs in Tanzania, integrating ART with methadone maintenance therapy capitalizes on the combination of treatment and prevention benefits. It is important to understand how the implementation of integrating these programs carried out, and how it is related to patient satisfaction, patient retention, patient receipt of services, providers giving services, time spent in provider patient exchanges and why. Through identifying factors that facilitate or prevent successful implementation of evidence-based interventions (EBI), as well as ways to overcome these barriers, implementation science seeks to translate these interventions into practices and policies. Implementation itself is a necessary condition for intervention success, thus measuring implementation separately from intervention outcomes helps to evaluate overall effectiveness as it documents the underlying elements crucial for program outcome success (Proctor et al., 2011). This allows for an examination of EBIs in light of the multiple interacting and interdependent parts constantly in flux (Kroelinger et al., 2014).

Understanding implementation within complex health care systems also allows for the identification of fundamental relationships and intervention points that allow for successful implementation (Kroelinger et al., 2014). Of key importance is an understanding of implementation outcomes with a focus on implementation fidelity. By assessing implementation fidelity, the degree to which practices conform to an ideal protocol, we can assess the contribution of the intervention to the outcomes (Carroll et al., 2007), the notion underlying this being that specific actions or treatments administered in a certain way will lead to specific

outcomes. Without an understanding of implementation fidelity we are unable to determine if it lack (or the presence) of impact on patients is due to non-adherence to intervention protocol or if there are flaws in the theoretical underpinnings of the program itself (Chaudoir, Dugan, & Barr, 2013; Kutash, Cross, Madias, Duchnowski, & Green, 2012). Implementation outputs are indicators of the various implementation processes, and understudying the relationship between the process and outputs helps to link them to the outcomes of the intervention itself. (Proctor et al., 2011).

Theoretical Frameworks in Implementation Science

The use of theory in implementation science is relatively new for the field, with few implementation science studies explicitly employing theory (Davies, Walker, & Grimshaw, 2010; Nilsen, 2015). While various theories used in implementation science are useful for explaining potential relationships and guiding the translation of research into practice, few theories map on to the practical limitations of intervention contexts and often data limitations that occur (Bhattacharyya, Reeves, Garfinkel, & Zwarenstein, 2006; Nilsen, 2015). The conceptual framework which guides this dissertation integrates three frameworks from implementation science and the health care services literature; Chaudoir's multilevel framework which is used for understanding and explaining organizational influences on implementation; the Consolidated Framework for Implementation Research which specifies determinants that influence implementation; and Carroll's framework which focuses on implementation fidelity (Carroll et al., 2007; Chaudoir et al., 2013; Damschroder et al., 2009). In addition to these frameworks, I also reference implementation fidelity concepts drawn from Gearing (Gearing et al., 2011).

Implementation Fidelity

By assessing implementation fidelity, the degree to which practices conform to an ideal protocol or standard of care, we can then assess the contribution of the intervention on the outcome (Carroll et al., 2007). While the conceptual model of this dissertation does not focus solely on implementation fidelity, Carroll's framework underscores the importance of understanding factors related to the ability of the intervention to be implemented as intended. Carroll *et al.*'s framework focuses on implementation fidelity, and includes five elements: adherence, dose, quality of delivery, patient responsiveness and program differentiation. The elements of this framework are defined in Table 3.1. Without an understanding of implementation fidelity, we are unable to determine if lack (or presence) of a program's impact is due to non-adherence to the protocol or due to a problem with the intervention itself (Kutash et al., 2012).

Table 3.1: Elements of Carroll et al's Conceptual framework for implementation fidelity

Framework elements	Definition
Adherence	Whether an intervention is being delivered as it was designed or written
Dosage/exposure	The amount of an intervention received by patients
Quality of delivery	The manner in which an intervention is delivered
Participant responsiveness	How participants respond to, or are engaged by an intervention
Program differentiation	The unique features of an intervention without which the intervention would not have its intended effects

Any measure of implementation fidelity needs to account for all of the factors related to fidelity. Measures that focus only on one element, e.g. adherence, while ignoring other components, e.g. intervention delivery, do not adequately assess fidelity or the barriers and facilitators related to implementation (Carroll et al., 2007). Gearing *et. al* conducted a

comprehensive review to identify core components of intervention fidelity (Gearing et al., 2011). This review prompted the authors to identify four core components of intervention delivery, which are described in Table 3.2 below. The authors believe these components are necessary to every stage of an intervention, yet found they were less emphasized in the design stages, and emphasized more during training, implementation, and receipt of services stages. The authors did not include participant enactment (whether participants apply the skills learned in treatment in his or her daily life) as they felt this was more related to treatment effectiveness and not to intervention fidelity.

Table 3.2: Gearing et. al's Components of Fidelity

Component	Definition
Design	The intervention theory, goals, and strategies, including how a program should be organized and delivered, and the role and responsibilities of interventionists
Training	Adequate training and supervision of interventionists
Monitoring of intervention delivery	Elements that focus on fidelity during the course of the intervention
Monitoring of intervention receipt	Elements that focus on whether participants received the treatment

Chaudoir's Multilevel Framework Predicting Implementation

Chaudoir *et a*l. (Chaudoir et al., 2013) developed a framework which posits that macro/meso level factors of structural, organizational, patient-provider, and innovation level characteristics are causally linked to implementation outcomes. Chaudoir's framework was developed to address the lack of clarity and agreement regarding the measurement of implementation phenomena. While implementation science as a field has identified a range of variables and constructs that effect implementation, there is considerable heterogeneity with respect to these variables and their relationships. In Chaudoir's model, larger implementation

factors are causally linked to implementation outcomes, which the authors define as those services or exposures participants receive. These elements are not directly linked to the outcomes of the intervention itself. One key distinction is that this framework models implementation rather than patient outcomes, for the researchers aimed to measure the implementation of an intervention alone.

This framework takes into account the fact that implementation outcomes neither exist nor arise in a vacuum. The left hand side of the model pushes us to consider the role of context, which refers to the set of circumstances or unique factors that surround a particular implementation effort, and which must be accounted for in data interpretation (Lobb & Colditz, 2013). Doing so allows us to assess whether intervention success or failure is due to problems with the protocol, or due to the intervention occurring in a context without adequate resources, support, and without the systems necessary for success. The definitions and examples of constructs related to the factors included in Chaudoir's framework are included in Table 3.3.

Table 3.3: Implementation Factor Definitions and Constructs

Implementation Factor	Definition	Example Constructs
Structural	Represent the outer setting or external structure of the broader sociocultural context or community in which a specific organization is nested	Physical environment Social climate Economic climate Infrastructure
Organizational	Aspects of the organization in which an innovation is being implemented	Innovation climate Leadership effectiveness Organization attitudes towards innovation
Provider	Aspects of the individual provider who implements the innovation with a patient or client	Provider attitudes towards innovation Perceived control in implementing intervention
Patient	Characteristics of patients involved in the intervention which can impact implementation outcomes	Patient satisfaction Motivations Barriers Patient buy-in Patient clarity regarding intervention procedures
Innovation	Characteristics of the intervention to be implemented	Acceptability Appropriateness Feasibility

Implementation outcomes in Chaudoir's framework are defined in Table 3.4. While there are tools that can be used to measure these implementation outcomes, they are not standard and measurement tends to be context specific. For example, in a care setting with extensive electronic documentation it might be possible to use electronic medical records to assess penetration, while interviews might be necessary in a care setting without electronic documentation. The measurements relating to implementation outcomes should be tied to and

reflect the outcome definitions, but should mainly refer to outcomes defined in the context of organization or provider.

Table 3.4: Implementation outcomes possible measurements

Implementation outcome	Definition
Adoption	The intention, initial decision or action to try or employ an innovation or evidence-based practice
Fidelity	The degree to which an intervention was implemented as planned
Implementation Cost	The cost impact of an innovation
Penetration	Integration of a practice within a service setting and its subsystems
Sustainability	The extent to which a new treatment is maintained or institutionalized within a service setting

Consolidated Framework for Implementation Research

Similar to Chaudoir's work, the Consolidated Framework for Implementation Research (CFIR) was developed to further implementation theory, as well as to define constructs and their relationships to each other. CFIR consists of five domains, each of which is theorized to interact with the other and impact implementation. The five domains included in CFIR are: implementation characteristics, outer setting, inner setting, characteristics of individuals involved and process of implementation (Damschroder et al., 2009). In this model, implementation is the critical step between adoption of an intervention and routine use of the intervention. The CFIR model highlights an importance in understanding the specific characteristics of an intervention in order to assess its implementation. In this model, all of the various elements of CFIR impact and affect each other. There is no specific directionality or explicit relationships other than understanding all of these elements as working together in relation to a specific intervention.

Some of these processes might be more essential to implementation than others, depending on the nature of the intervention itself.

Table 3.5: Domains of the Consolidated Framework for Implementation Research

Domain	Definition	Constructs
Implementation characteristics	The characteristics of the intervention being implemented	Intervention source Evidence strength/quality Relative advantage Adaptability Trialability Complexity Design quality and packaging Cost
Outer setting	The economic, political, and social context within which an organization resides	Patient needs and resources Cosmopolitanism Peer pressure External policies and incentives
Inner setting	Features of structural, political, and cultural contexts through which the implementation process will proceed	Structural characteristics Networks and communications Culture Implementation climate
Characteristics of individuals involved	Individuals involved with the intervention and/or implementation process.	Knowledge and beliefs about the intervention Self-efficacy Individual stage of change Individual identification with organization Other personal attributes
Process of implementation	The activities involved in implementing an intervention	Planning Engaging Executing Reflecting and evaluating

Similar to Chaudoir's work, the CFIR includes fives domains which relate to the context within which an intervention occurs. The domains can be assessed at various levels within an interventions context, e.g. among individuals, for an organization, across teams. This allows researchers to measure implementation domains at the level in which they are most salient. Damshroder *et al.*, encourages researchers to operationalize the constructs in terms of the specific study they are examining and determine the level at which each domain should be examined and measured.

Mixed Methods research in Implementation Science Research

As applied to implementation science research, qualitative methods are most often used to obtain depth relating to implementation successes of failure, or to identify strategies for implementation, while quantitative methods are used to test hypotheses from existing conceptual models or to understand the role of predictors in facilitating implementation (Palinkas et al., 2011). Quantitative methods are especially useful to health services research to evaluate efficiency and efficacy in regards to interventions and their ability to improve quality of life and care (Krumholz, 2005). Compared to quantitative methods, qualitative methods are better suited to examine more complex relationships such as organizational change, patient perceptions and more nuanced information about health care delivery systems (Curry, Nembhard, & Bradley, 2009). Data triangulation, the combination of multiple kinds of methods or data, is important in mixed methods research to help validate and provide more depth into research studies. In combining these qualitative and quantitative research, the use of mixed methods in implementation science research allows for data triangulation, through the use of a variety of

sources in a study, and methodical triangulation which applies multiple methods to a single study (Janesick, 1994).

Mixed method implementation science studies commonly utilize document review, interviews, focus groups, questionnaires and participant observations (Bryman, 2006; Palinkas, 2014). These methods can be combined in a sequential way, where the qualitative method precede the quantitative method, qualitative findings are then used to inform the quantitative methods then quantitative results are used to inform and interpret qualitative findings (or vice versa). Mixed methods may also be combined in a convergent design where quantitative and qualitative methods are integrated from data collection through analysis, here the methods are employed in a complementary rather than sequential design (Creswell & Clark, 2007). Combining qualitative and quantitative methods can be used to help interpret quantitative findings, generalize qualitative findings, and can help better understand the impacts, causes and effects particularly for new interventions and phenomena (Pluye & Hong, 2014).

As an example, mixed methods were used to examine mental health services in Montreal used a combination of a quantitative survey and qualitative interviews provided a more nuanced understanding of mental health problems in a Vietnamese community. For the quantitative portion researchers used the General Health Questionnaire as a measure of distress, as well as sociodemographic variables and measures of acculturation, cultural identity and health care utilization. This quantitative phase of the study was then followed by a qualitative stage which if used semi-structured qualitative interviews with participants that aimed to understand how social and cultural contexts mediated the health behaviors of distressed immigrants. The combination of qualitative and quantitative methods was used to develop an intervention that was specially

tailored to, and took into account the cultural norms and needs of the community (Groleau, Pluye, & Nadeau, 2007).

While these studies can take place in a variety of settings, they commonly take place in clinic settings during some stage of implementation. The placement of mixed-methods implementation science studies based in "real-world" settings focuses on the impact of contextual factors in implementation, rather than thinking of them as confounders (Green et al., 2015). Mixed methods studies are used to evaluate and compare various implementation strategies, which is especially useful in adapting interventions new or different areas and communities. This helps researchers understand issues related to organizational and community changes need to sustain evidence based interventions, as well as their related cost-effectiveness in hard to reach populations. This is seen in a study conducted in rural Appalachia. Researchers wanted to examine the effectiveness of an Availability, Responsiveness and Continuity model which utilizes multiple intervention components which are integrated within a broader system perspective. To see if this kind of system level change was possible in this specific community, researchers used change agent logs which were both qualitative and quantitative. As a qualitative measures these logs documented contacts with key opinion leaders, as a quantitative measure these logs documented the duration of the intervention phases. Regardless of the specific sites of study, or measures used, it is important that the method and designs of studies match their ultimate goal.

In implementation science research, mixed methods have been used to develop a base of knowledge around implementation, especially in the case of new evidence based interventions and programs (Proctor et al., 2011). In the literature, mixed methods have been used in implementation science researchers to get in-depth information about how to adapt existing

clinical practice guidelines to facilitate the uptake of evidence based intervention. (Dogherty, Harrison, Baker, & Graham, 2012). This research provides insight relating to the implementation environment as well as the necessary actors involved in implementation. This type of data has also been used to get a holistic picture of implementation, describe the extent of implementation fidelity and identify barriers and facilitators related to implementation (Green et al., 2015). At later stages in the implementation process, results from mixed-methods studies can be used to highlight areas of dissonance and concordance with idealized protocols. These findings go beyond simply pointing out deviances in study protocols, by providing a more nuanced interpretation for these areas of discordance compared analyses that are only qualitative or quantitative (Tonkin-Crine et al., 2016).

As applied to implementation science, a strength of mixed-methods research is to identify gaps between evidence-based aims and the practical application of these aims. This is exemplified in work which examined the implementation of chronic condition management policy, through understanding the role of research evidence in this implementation and related decision making. As the quantitative portion of this work, researchers surveyed health service commissioners in Wales. This was followed by in-depth interviews which were conducted with representatives of local health boards. Results from this study indicated that representatives of local health boards did examine scientific literature before implementing interventions but this was done in an inconsistent and non-standardized manner. With this mixed-methods study researchers documented a gap between the evidence-based aims of national health policy and how health services are commissioned, implemented, and evaluated at local level.(Evans, Snooks, Howson, & Davies, 2013; Palinkas et al., 2011).

Mixed methods approaches are not without challenges. They can add burden to study participants, through the use of multiple data collection tools, and true integration of qualitative and quantitative results can be difficult (G. A. Aarons, D. L. Fettes, D. H. Sommerfeld, & L. A. Palinkas, 2011; Tonkin-Crine et al., 2016). This research is also used to identify and improve specific implementation strategies in order to link them to intervention outcomes. The idea of convergence, whether or not quantitative and qualitative data provide the same answers to the same question, is an especially important consideration in implementation studies with small sample sizes (G. A. Aarons et al., 2011). Conversely, differences in a study's qualitative and quantitative results do not indicate study failure, but can provide deeper understanding for future study (O'Cathain, Murphy, & Nicholl, 2010).

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Chapter 4: Methods

Introduction

The conceptual framework that guides this dissertation combines the theories described in Chapter 3 to examine the relationships that impact the implementation of the integrated methadone and antiretroviral therapy (IMAT) intervention, that this study is documenting. In this section I first describe the conceptual framework that guides the dissertation and then the functional or operationally defined models for each aim. I provide definitions of related constructs, as well as their relationships based on available data and research questions. I go on to describe the setting and finally describe the basic methods for sampling, data collection, and data analysis used for this dissertation. While I collected primary data such as observations of clinic practices and interviews of providers and patients, I also describe in detail secondary data sources, which come from the methadone clinic at Muhimbili National Hospital, where the integrated methadone and antiretroviral (IMAT) intervention takes place.

Conceptual Framework

The theoretical models described in Chapter 3 are useful to understand theoretical relationships related to implementation, but are not specific in terms of operationalization. As described by Carroll and Chaudoir these models can be used to guide measurement of implementation outcomes, but do not provide standards and measurement tools. Moreover operationalization of these constructs should be specific to the intervention (Carroll et al., 2007; Chaudoir et al., 2013). The conceptual framework, and functional models presented here identify measures used to provide evidence that is supported by theoretical ideas. Specific measurement tools are described later in this chapter.

The conceptual framework posits that the environment and people involved in an intervention impacts implementation processes or the way the implementation of study is carried out. Specific characteristics of the intervention may influence its implementation; as well elements of the clinic environment, patient characteristics and provider characteristics may also influence the processes of implementation. These relationships in turn impact patient outputs, and ultimately patient outcomes.

In the conceptual framework, intervention context refers to the relationship between the economic, political, and social contexts within which an intervention exists. This reflects Chaudoir's model, leveraging its importance to the role of context in examining implementation, as well as the Consolidated Framework for Implementation Research (CFIR) (Chaudoir et al., 2013; Damschroder & Lowery, 2013). However, since this dissertation was conducted at one site, intervention context, denoted by the dashed arrow, is not measured as this study represents a single case study. This conceptual framework is depicted in Figure 4.1.

Figure 4.1, focuses on factors that impact implementation of the intervention, but does not focus on or include the theories or potential causal pathways relating to the health outcomes of the intervention itself. Therefore, patient outcomes, denoted by the dashed arrow, are not measured. The elements of the conceptual framework are described in Table 4.1.

Figure 4.1: Conceptual framework

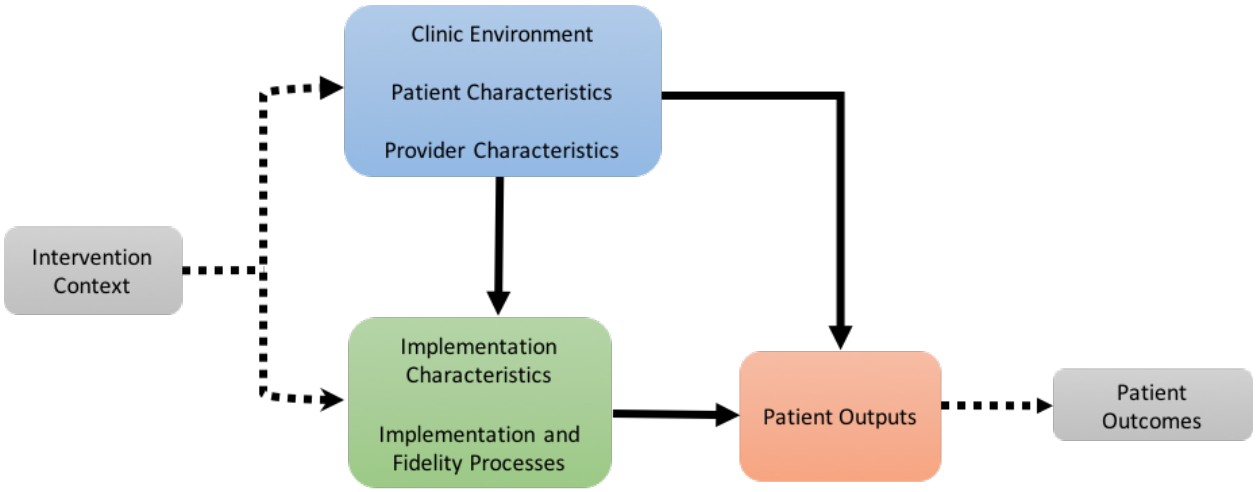


Table 4.1: Conceptual framework elements

Element	Definition	Theoretical Source
Clinic Environment	Refers to the aspects of an organization in which an intervention processes occur	• Chaudoir
Patient Characteristics	Aspects of individuals receiving care which impact implementation	• Chaudoir • CFIR
Provider Characteristics	Aspects of individuals involved in providing care which impact implementation	• Chaudoir • CFIR
Implementation Characteristics	The components of a particular intervention that affects its ability to be implemented.	• CFIR
Implementation and Fidelity Processes	The ways in which an intervention is carried out in order for it to be delivered as intended	• Chaudoir • Gearing
Patient Outputs	The ways in which patients interact or engaged by the intervention	• Gearing • Carroll

The conceptual framework presented in Figure 4.1, was used to guide this dissertation research, using the frameworks discussed in Chapter 3 to define theoretical constructs and relationships. However, these frameworks do not offer specificity in relation to measurement and operationalization of these more theoretical ideas. It is difficult to have global measurements of implementation that would apply to all interventions, as these measures need to be appropriate for the intervention, setting, population, and other influences (Breitenstein et al., 2010). In other words, the work is applied and therefore specific to particular intervention being studied. Similarly, study designs using mixed methods approaches for implementation science may also be unique to the intervention. By examining intervention specific components, researchers are better able to understand the elements of an intervention itself that are vital, core components and the main drivers of observed change (Abry, Hulleman, & Rimm-Kaufman, 2015). These components can then be matched with the most appropriate and available measurement tools. For this reason, functional models for each aim focus on specific elements and relationships in the conceptual framework, and propose potential modes of measurement. These functional models aim to add to the literature by attempting to ground these theoretical ideas and relationships in an active clinic setting through use of available data.

Aim 1

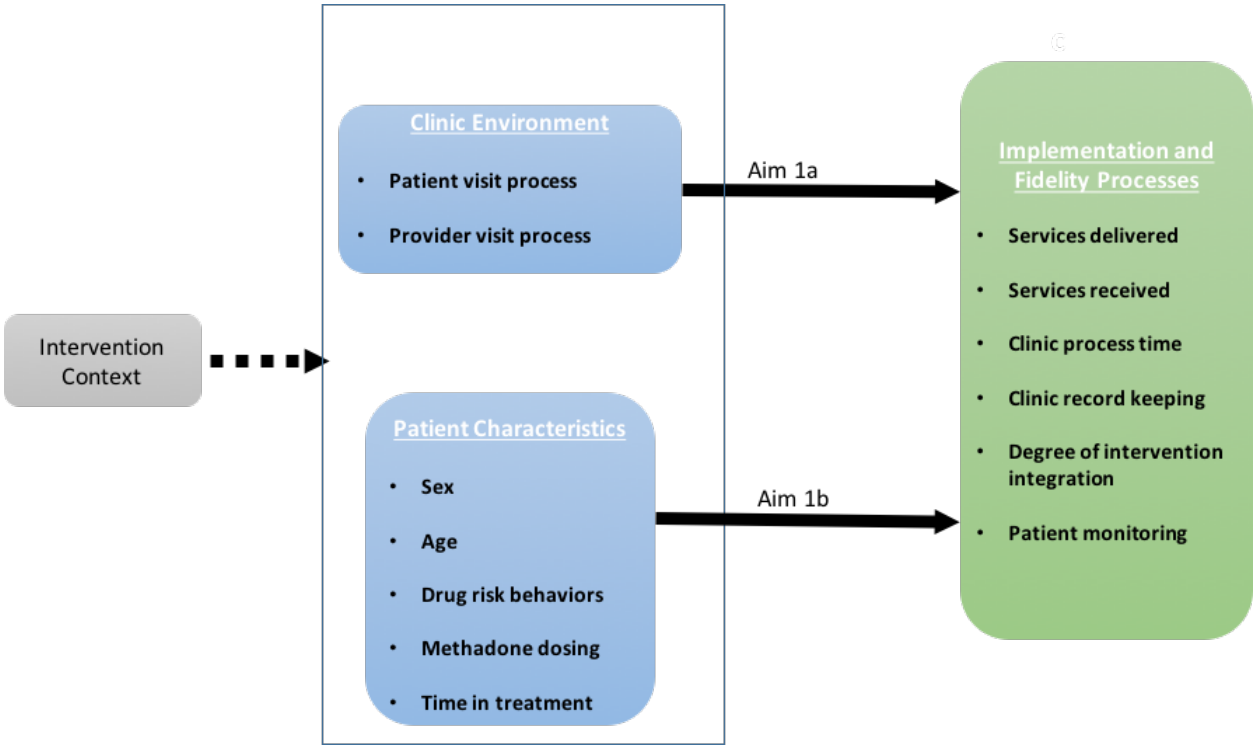
In relation to the conceptual framework in Figure 4.1, Aim 1 focuses on the relationship between the clinic environment, patient characteristics and implementation and fidelity processes. Implementation and fidelity processes reflect the ways in which an intervention is carried out in order for it to be delivered as intended. Constructs for these processes come from Chaudoir's model relating to implementation factors and implementation outcomes, and the

domain of inner setting from the CFIR. The functional model for Aim 1 is depicted in Figure 4.2 below.

Aim 1a examines the relationship between the clinic environment and implementation and fidelity processes. In Aim 1a data from clinic observations are used to describe the clinic environment and how it may be related to services delivered, services received and clinic process time. . Elements of the clinic environment examined here include patient wait times, number of procedures delivered, and the amount of time various procedures take to complete. With these data, I examine the relationship of the clinic environment in relation to intervention implementation. This is in alignment with implementation science literature that posits a clinic's capacity to conduct an intervention does not necessarily reflect whether the intervention is effective or ineffective, but rather whether the intervention is implemented as intended in a particular context (Breitenstein et al., 2010).

Aim1b examines the relationship between patient characteristics and implementation and fidelity processes. Patient characteristics reflect aspects of individuals receiving care which impact their ability to engage in the intervention, thus influencing implementation. In Aim 1b, data are from patient clinical and laboratory records, which includes information on; sex, age, drug risk behaviors, methadone dosing and time in treatment. These data are used to assess services delivered, services received, clinic record keeping, patient monitoring and degree of intervention integration (the amount of intervention a patient received). With these data, I explored the relationship between characteristics of the people receiving the intervention and the way in which the intervention is carried out for patients served.

Figure 4.2: Functional Model: Aim1



Aim 2

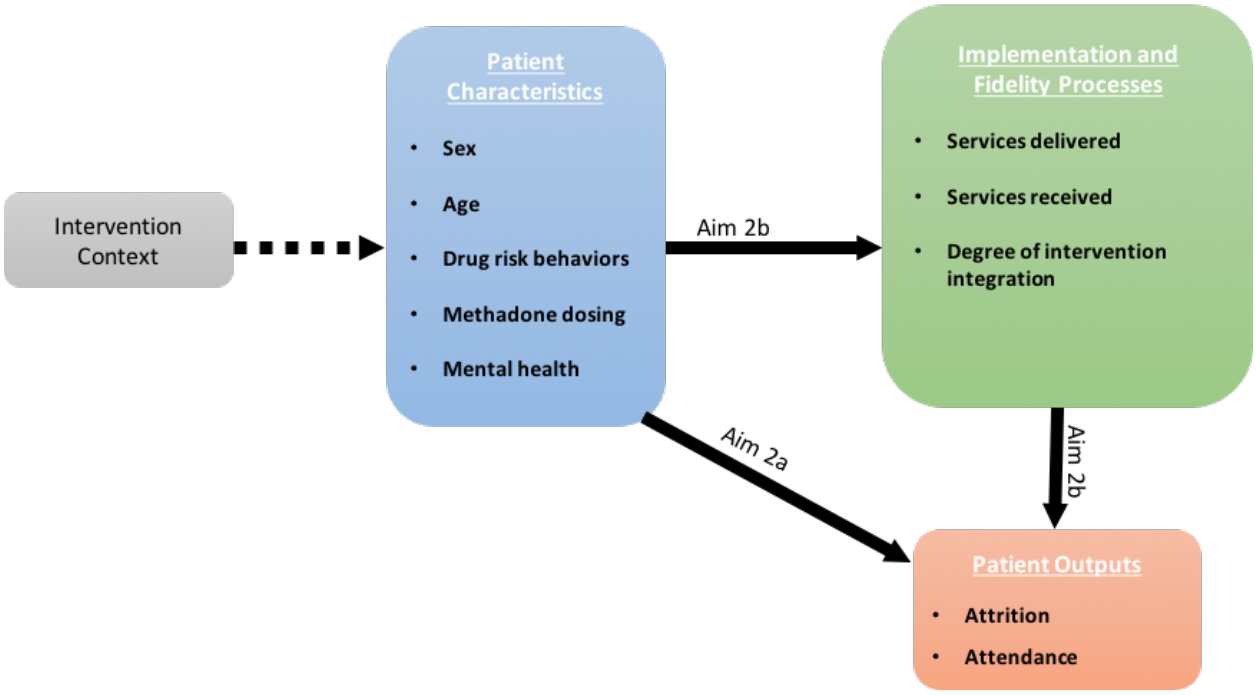
In relation to the conceptual framework in Figure 4.1, Aim 2 focuses on the relationship between patient characteristics, implementation and fidelity processes and patient outputs. Patient outputs for this aim refer to the ways in which patients interact or engaged by the intervention and include patient attendance and attrition. These are outputs related to Carroll's conceptual framework for implementation fidelity and Gearing's components of fidelity. Rather than focusing on the ultimate health impacts, which may not be seen for months or years, patient outputs focuses on the degree and manner in which patients receive, perceive and engage with the intervention. The functional model for Aim 2 is depicted in Figure 4.3 below.

In Aim 2a data are from patient clinical and laboratory records, which includes information on; sex, age, drug risk behaviors, methadone dosing and mental health. These data are used to assess the relationship of patient attributes with degree of integration and how this

leads to patient attrition. Patient attrition refers to leaving or not completing an intervention. With these data, I explored the relationship between whether characteristics of the people for which an intervention is designed is related to whether they get services or even stay in the program. In the previously mentioned theoretical frameworks patient outputs are influenced both by characteristics of people involved in the intervention, as well as the implementation and fidelity processes themselves. Aim 2a focuses specifically on this first relationship.

Aim 2b then focuses on the relationship between implementation and fidelity processes and patient outputs. In the relationships described in Aim2b patient outputs are influenced by the patient characteristics directly as well as through implementation and fidelity processes. For this aim, data from patient clinical and laboratory records, which includes information on; sex, age, drug risk behaviors, methadone dosing and mental health are analyzed in relation to services received and degree of intervention integration, and their impact on patient attendance.

Figure 4.3: Functional Model: Aim 2



Aim 3

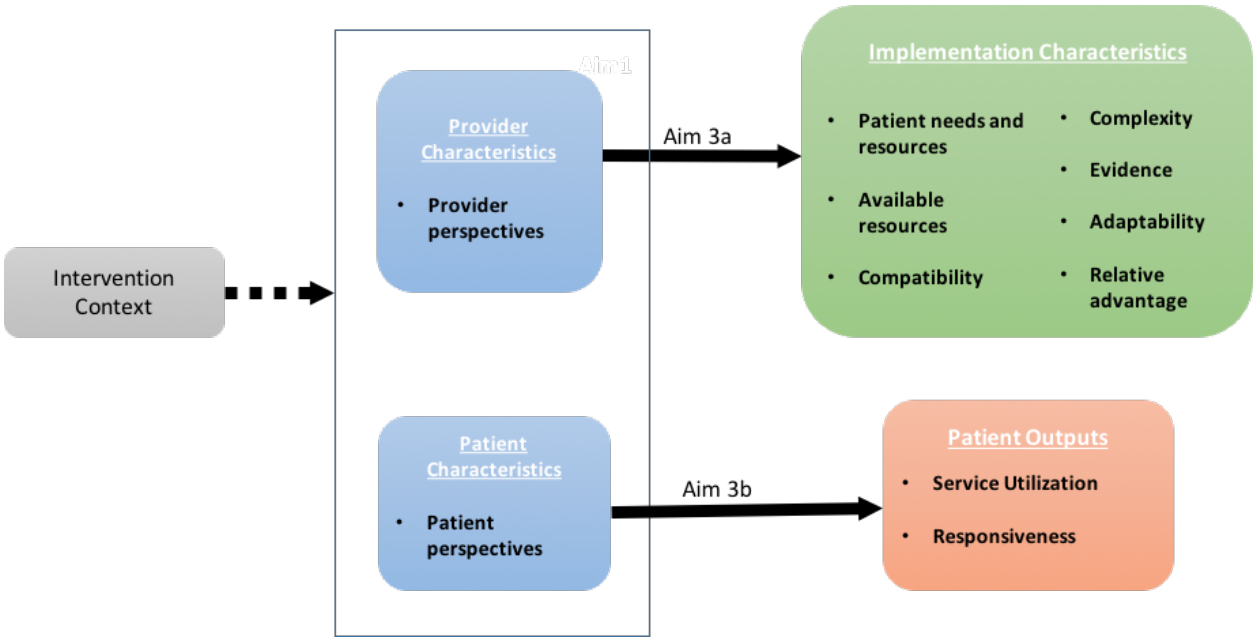
In relation to the conceptual framework in Figure 4.1, Aim 3 focuses on the connection between patient characteristics and patient outputs, as well as the relationship between provider characteristics and implementation characteristics. Implementation characteristics are the components of a particular intervention that affects its ability to be implemented. As conceptualized in this dissertation, implementation characteristics were developed using elements of the CFIR and include patient needs and resources, available resources, compatibility, complexity, evidence, adaptability, and relative advantage. The functional model for Aim 3 is depicted in Figure 4.4 below.

Aim 3a focuses on provider characteristics and perceptions. Provider characteristics refer to aspects of individuals involved in providing care, which impact implementation such as training, thoughts about the intervention, perceptions of the intervention, and their role within the clinic environment. Qualitative data were collected to examine provider perspectives related to the IMAT intervention implementation and the methadone clinic's capacity. These qualitative data were also used in combination with provider survey data to obtain providers' perspectives regarding patient needs and resources, available clinical resources, compatibility, complexity, evidence, adaptability and relative advantage. Analysis for this aim allows for an examination of providers' perception of an intervention in relation to the acceptability and feasibility of that intervention. It is important to investigate provider perceptions of implementation characteristics to ascertain whether or not people understand the characteristics of the intervention they are delivering.

Aim 3b focuses on patient characteristics and perceptions using qualitative data from in-depth interviews. This aim allows for an understanding how patients might view the

acceptability and feasibility of the intervention being studied. This aim specifically focuses on patient perceptions related to outputs of service utilization. Specifically, these data allow analysis of the degree to which patients followed the steps of the intervention protocol, and their responsiveness to the intervention.

Figure 4.4: Functional Model: Aim 3



Introduction to Study Design

This dissertation uses a mixed method approach. Data came from five sources: 1) clinic observations (primary data), 2) patient clinical baseline surveys (secondary data), 3) patient clinical records (secondary data), 4) in-depth interviews with patients and providers (primary data) and 5) surveys with providers (secondary data). Each Aim utilized a different combination of these data sources which are described in this chapter.

An overview of the study clinic setting is given followed by a discussion about the study population and a description data collection procedures. For each study aim the chapter

explicates the measurement and operationalization of the constructs assessed in the study and the statistical procedures used to address the specific aims and corresponding research questions of this dissertation.

Study Setting

Research for this dissertation was conducted at the methadone-assisted therapy clinic at Muhimbili National Hospital in Tanzania. The clinic was opened in 2011 in response to the HIV epidemic among PWID in Dar es Salaam by the Tanzanian Ministry of Health and Social Welfare, Muhimbili University and Hospital of Allied Sciences and the Drug Control Commission, in partnership with Pangaea Global AIDS Foundation and with funding from the U.S. Centers for Disease Control (Lambkin et al., 2013). This clinic is the first publically funded methadone-assisted therapy clinic on mainland SSA, and has enrolled over one-thousand patients to date (Saleem et al., 2015).

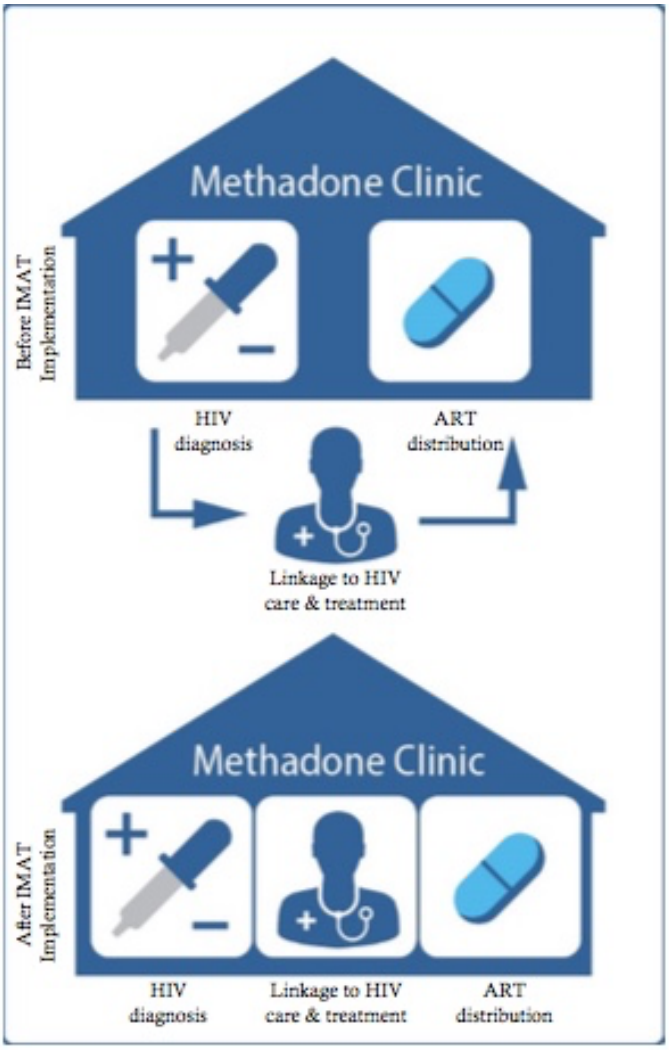
Enrollment into the methadone maintenance program requires referral from a community-based organization (CBO) for men, whereas women do not require a CBO referral to enroll. Women can enroll independently or through a CBO referral to the methadone clinic. Each patient appears at the clinic for intake and eligibility screening. In order to be eligible for methadone maintenance therapy, individuals had to 1) present with opioid dependence, 2) have evidence of recent drug injection, and 3) test positive for opiates through urine screening. Men who enroll are required to be injection drug users, rather than those who smoke heroin. As part of the CBO enrollment, men are required to attend a series of educational sessions on HIV, sexually transmitted infections (STI), medication adherence, and supportive services provided by CBOs.

Once enrolled in methadone maintenance, methadone is provided to patients seven days a week at the clinic. Clients visited the clinic on a daily basis to receive in-person, directly observed, methadone dosing. Default from the program is defined as twenty-one consecutive missed doses, with the patients' last pharmacy refill assigned as their date of attrition. Those who default are contacted by the CBO that referred the patient to conduct follow-up. Outreach workers find out if the client passed away or if they have chosen to not return to the clinic. Family members verify deaths that may have occurred outside of a medical facility. Deaths occurring within a medical facility are verified based on information recorded within the client's medical chart by the clinician responsible for their care.

Prior to IMAT the methadone clinic offered provider-initiated HIV testing and counseling for its patients at enrollment and after every six months. For linkage to HIV care and treatment, HIV-positive patients could have their blood drawn at the methadone clinic, which would be sent to the central pathology laboratory for CD4 assessment. Patients were then provided an escorted referral to the HIV care and treatment clinic at Muhimbili National Hospital, located about 500 meters from the methadone clinic on the same campus, for clinical visits to discuss CD4 results, co-morbidities, other aspects of clinical management, and to initiate people onto ART once they became eligible. At the time of this study, Tanzania's national HIV management guidelines specified a CD4 count of less than 500 copies/mL to be eligible for ART (The United Reupublic of Tanzania Ministry of Health and Social Welfare National AIDS Control Programme, 2015). Once initiated onto ART, patients could pick-up their ART medications from the methadone-dispensing window at the methadone clinic. Yet despite daily encounters with the methadone clinic, less than half of all treatment-eligible patients had initiated ART within three months of being deemed eligible for treatment (O. C. Tran et al., 2015). To

address delays in ART initiation and improve clinical outcomes, the IMAT model was launched in October of 2015. The proposed IMAT model includes four key components: 1) in-house point-of-care CD4 testing; 2) in-house HIV clinical management; 3) ART delivery through the methadone clinic; and 4) an electronic information system to help providers monitor patients along the continuum of HIV care. The flow of care before compared to after IMAT initiation is depicted in Figure 4.5.

Figure 4.5: HIV care and treatment for seropositive patients at the methadone clinic before and after IMAT



Study Population

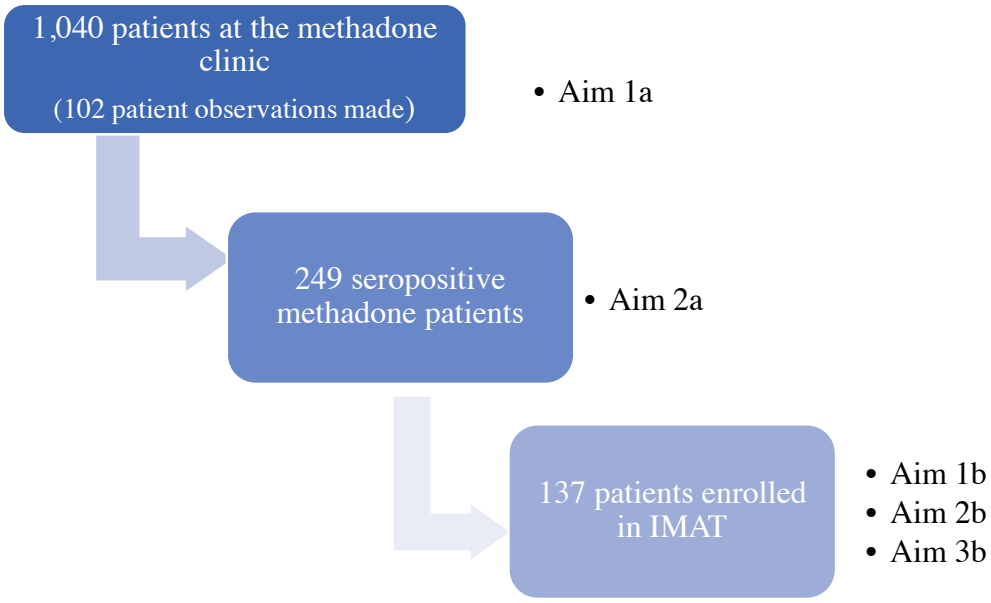
The methadone clinic at Muhimbili National Hospital, where the IMAT intervention takes place comprises the organizational context of this study. At the time of data collection there were 1,040 patients enrolled in care at the methadone clinic. Different analytic samples were utilized for analysis based on the study aims described above. Of these patients 249 (24%) were seropositive, and of the seropositive patients 137 (55%) were enrolled in the IMAT intervention during the time frame of the study (early 2016). Observations for Aim1 were done for the entire

MAT clinic, and so the 1,040 patients represent the potential pool for Aim 1a. Information on the 249 seropositive patients was used for Aim 2a, and data on the 137 patients enrolled onto IMAT was used for Aims 1b, 2b, and 3b. A flowchart of the patient samples used in each aim is depicted in Figure 4.6. Data were only available and collected from patients who remained engaged in care at the methadone clinic. It was not possible to collect data regarding current health information for patients who left the methadone clinic prior to data collection, nor was it possible to interview IMAT eligible patients who left the clinic.

Data from providers working in the IMAT clinic (n = 8) were the study sample for Aim 3a. These care providers were all working at the methadone clinic at the time of the study. Of the nine (9) direct care providers at the methadone clinic, five (3 nurses and 2 medical doctors (MD)) providers were specifically designated to work with IMAT patients. These 5 providers comprise the sample for Aim 3a, in combination with other support care staff, including:

- 3 Nurses
- 2 MD
- 1 Pharmacist
- 1 Social Worker
- 1 Administrative person

Figure 4.6: Flowchart of patient samples



A power analysis was conducted to determine if sample size for quantitative aims using data from patient samples was sufficient for statistical analysis. An effect size of 0.25 was chosen, as it is reflective of both HIV literature, and literature on HIV and methadone maintenance (Cohen, 1988; Kalichman, Carey, & Johnson, 1996; Marsch, 1998; StataCorp, 2013). A sample of 128 is needed to have 80% power, assuming alpha=0.05. To have 70% power to detected a 25% difference in groups a sample of 101 is needed assuming alpha=0.05. Therefore, for Aim 1n (n=137), Aim 2a (n=249) and Aim 2b (n=137) there was sufficient sample size to detect an effect of this magnitude.

Data Collection

All data were collected in Dar es Salaam, six (6) months after implementation of IMAT intervention in early 2016. All patients enrolled in the IMAT intervention came from the methadone clinic at Muhimbili National Hospital. Patient and provider observations which

formed the basis for data for Aim 1a were conducted by study staff familiar with the methadone clinic and fluent in Swahili. Observational data were collected using forms in either English or Swahili on KoboToolbox (data collection software) for Android© tablet. Study staff were trained to use software and observational data collection form, as well as to conduct observational data collection. English and Swahili versions of this form were developed to check for consistency, data were automatically uploaded into a secure-password protected study account.

For Aims 1b, 2a, and 2b, patient clinic and laboratory records were collected via hard copy as part of usual care, by providers at the methadone clinic. The hard copy records are then entered into an electronic database by a data transcriptionist. These records were then abstracted for use in this study, and stored electronically using Microsoft Excel.

In-depth interviews, for study Aim 3 with patients and providers were collected in a private room outside of the methadone clinic by trained study staff. These interviews were conducted, audio-recorded and transcribed in Swahili by study staff and then translated into English by a trained translator.

Lastly, providers were also given a questionnaire, the Organizational Readiness for Change Assessment which was administered by study staff. In total 8 providers were surveyed, including 2 physicians, 1 pharmacist, 3 nurses, 1 social worker, and 1 administrator.

Research Aim 1a

Research Aim 1a examines the context in which the intervention was delivered, and how people involved in the intervention (patients and providers) experienced components of the intervention.

Sample: Aim 1a

Data for this aim were collected in the first six months of the program. Observational data were collected for 102 patients and 6 providers (1 social worker, 1 MD, 1 pharmacist and 3 nurses) at the methadone clinic. All observations were done at the methadone clinic where the IMAT intervention occurs, however because there is no way to tell which patients are and are not enrolled in the intervention observations include both seropositive and seronegative patients who may or may not have been involved in IMAT.

Data Collection: Aim 1a

I developed time-motion data collection tools based on literature reviewed to collect data for Aim 1a—one used for patient visit observations, and one used for provider visit observations. Data were collected via KoboToolbox (data collection software) for Android© tablet, for each recorded activity, the device automatically recorded a beginning and an end time. Study staff were trained in both use of the observational data collection tool, as well as observational data collection methods.

Observational data came from examining the physical space that patients have to travel to in the clinic, as well as interactions that occurred. Observations were done with sensitivity to patient confidentiality. The beginning and end time was recorded for various services received in the methadone clinic (e.g. time spent in counseling), resulting in records of total time per visit, and time per service received.

To understand the operation of the clinic from the perspective of providers, each provider was observed during the time they spent at the methadone clinic. Clinic providers observed were: social worker, MD, pharmacist, and nurse. Each service provider was observed for a full workday, per their availability. While there are more than 6 providers at the methadone clinic, the nurses and MD observed were those involved in the IMAT intervention. The IMAT

intervention does not have a dedicated pharmacist or social worker. We attempted to account for the fact that there was no way to visually tell patients enrolled in IMAT vs. regular methadone patients by observing the only MDs involved in IMAT. The tools used for data collection are included in Appendix A: Observational Data Tool—patient visits and Appendix B: Observational Data Tool—provider visits.

Measures: Aim 1a

In research Aim 1a the observational data for patients and providers were collected to examine clinic process time which means how long it took for services to be delivered and received. More specifically these data comprise how long various services received took (e.g. time spent in counseling). This resulted in records of total time per visit, and time per service received, which in turn are reported as 207 patient interaction observations for 102 unique patients over three days.

For providers, data collected comprise a record of a whole work day, along with time spent per work element (e.g. time spent drawing labs) so that overall 146 interactions were recorded. These data are not linked to patient identification numbers, or to patient characteristics. I obtained Institutional Review Board (IRB) approval for the protection of human subjects in research at the University of California, Los Angeles (UCLA) as well as Muhimbili University of Health and Allied Sciences to collect and record these data.

Research Method: Aim 1a

This aim assesses the implementation of the intervention, to see if it occurs in a manner that effectively meets the needs of HIV positive PWID and their providers. Aim 1a evaluated the context in which the intervention was delivered, and how patients and providers experience elements of the intervention. As noted above, I used observational data on patients enrolled in

care at the methadone clinic to examine how the steps of the integrated methadone and antiretroviral treatment intervention were carried out to determine how patients and providers experience the visit process at the methadone clinic. Observational data allows for an examination of the relationship between the care environment and context and implementation and fidelity processes.

Research Question: Aim 1a

The first part of this data analysis is descriptive based on the data I collected. The specific research question for Aim 1a is:

After IMAT implementation, how do patients and providers experience the visit process at the methadone clinic?

- H1: Patients who see a MD will spend more time waiting, in minutes, than patients who do not see a MD.
- H2: While MD will not see the largest number of patients, they will spend the greatest amount of time, in minutes, with patients.

Analysis: Aim 1a

Data from the time-motion survey was used to describe the visit processes from the provider and client perspective. For provider-level time-motion data, I calculated the mean time spent performing different work elements, and for client-level time-motion data, I calculated the average waiting and visit times. All data was entered in to STATA, quantitative analysis software for analyses (*Stata Statistical Software*, 2015). Observational data collection was chosen for research Aim 1a in order to get accurate records of time, and to not disturb the visit process. For this data, I used descriptive univariate and bivariate statistics given the nature of the

data, research questions and related hypotheses. Time-motion methods were analyzed to be consistent with the implementation science literature and to provide descriptive analysis of the clinic environment (Alamo et al., 2013).

Research Aim 1b

Research Aim 1b looks at associations between patient characteristics and intervention receipt, or the degree to which patient characteristics (such as age, sex, mental health) are linked to whether they get care or not.

Sample: Aim 1b

Data for this aim were different than for Aim 1a. These data were from a sample of 137 individuals who were HIV positive persons who inject drugs and who are patients at the methadone clinic at Muhimbili National Hospital. These individuals were involved in the integrated clinic and had clinical records. Methods used to collect data and measures used are described below.

Data Collection: Aim 1b

Patient characteristics

Patient characteristics for research Aim 1b are collected in two ways. They are either abstracted from the methadone clinic's baseline survey (Table 4.2), which is collected for all patients upon enrollment as part of routine clinical care or they abstracted from clinic records. The baseline survey was developed by the methadone clinic and is used by providers in delivering patient care. All clients were administered face-to-face baseline and follow-up assessments interviews by clinic staff. These data include simple demographic data such as age, sex and number of children, as well as multi-question assessments which detail patient history and behaviors, such as condom use/history of use, and depressive incidents/history of depression.

These survey data also include information on addiction severity, HIV Risk, and Johns Hopkins Symptom checklist for anxiety and depression as well as information on patient demographics, and drug use history. These data were abstracted by me, using the patients' methadone clinic identification numbers—which they are assigned upon enrollment, so they could be de-identified. These data were entered into Stata version 14 and cleaned for accuracy and consistency. Gaps were found in the baseline survey records, such that not all participants had complete data sets. It is unclear if these gaps reflect issues with record keeping, if patients never finished these assessments or if there were other issues in administration and/or data entry.

Clinical services rendered

Data from clinic records that were entered into a clinic database by clinic staff were also abstracted by me using STATA version 14 (*Stata Statistical Software*, 2015). These measures are more specific to the intervention and includes such variables complexity of ARV regimen (operationalized as the number of pills), average methadone dose received at the methadone clinic, proportion of visits kept and engagement in drug risk behaviors as measured by engagement in flashblood (in which a user injects a full syringe of blood into themselves donated by someone who has recently injected heroin into their bloodstream). These clinic records are also part of routine care, such that they are used for regular patient monitoring by care providers, and not meant to be used just for the IMAT intervention. Details about these measures are presented in Data were also obtained from the clinic records detailing patient visit history, services received at the clinic, and methadone dose. Specific variables and measures from the clinical records are detailed in Table 4.3. Clinic and laboratory records were used to understand how well patients' clinic records were kept and maintained. These clinic records are the only way for providers to keep track of patients' clinical care data. If patients receive care, but it is not

recorded in clinical records, there is no way for providers to know the care was delivered. This reflects both poor record keeping, in that a service which was delivered was not recorded as such, and poor patient monitoring, as providers are not able to accurately track patient progress.

Table 4.3, as well as Cronbach's alpha for scaled measures. Gaps and inconsistencies were also found in this clinical data. It is unclear if these gaps represent gap in clinical care, or if these gaps represent care that was provided but never recorded.

Table 4.2: Variables and Measurement Tools from Baseline Survey

Variable	Measure/Tool	Data Type	Cronbach's alpha
Sex	Male/Female	Binary	
Age	Years	Continuous	
Referral NGO	NGO of record	Categorical	
Number of Children	Number	Continuous	
Educational Level	Highest education achieved	Categorical	
Employment History	From past three years	Categorical	
Employment	Usual or last occupation	Categorical	
Income	Tanzanian Shillings	Continuous	
Living arrangement	Current Status	Categorical	
Marital Status	Current Status	Categorical	
Substance Use History	Last 30 days and lifetime	Binary	
Importance of Drug treatment	Patient Rating Scale	Likert	
Substance Dependence	12-month substance use recall	Binary	0.87
Quality of Life	SF-12 Patient Questionnaire	Categorical/Likert	0.80
Multiple Sex Partners	Risk Assessment Battery	Binary	
Condom Usage	Risk Assessment Battery	Binary	
Sharing Needles	Risk Assessment Battery	Binary	
Sharing Equipment	Risk Assessment Battery	Binary	
Depression	Johns Hopkins Checklist	Likert	0.90
Anxiety	Johns Hopkins Checklist	Likert	0.88
Physical and Sexual Abuse	Risk Assessment Battery	Binary	
Criminal History-Arrests	Risk Assessment Battery	Binary/Categorical	

Measures: Aim 1b

Baseline survey measures

Survey measures: Specific variables and measures from the baseline survey are detailed in Table 4.2. These data are collected as part of routine clinic care at the methadone clinic and are also used in Aims 2a and 2b. These data include simple demographic data such as age, sex

and number of children, as well as multi-question assessments which detail patient history and behaviors, such as condom use/history of use, and depressive incidents/history of depression.

Clinic and laboratory records

Data were also obtained from the clinic records detailing patient visit history, services received at the clinic, and methadone dose. Specific variables and measures from the clinical records are detailed in Table 4.3. Clinic and laboratory records were used to understand how well patients' clinic records were kept and maintained. These clinic records are the only way for providers to keep track of patients' clinical care data. If patients receive care, but it is not recorded in clinical records, there is no way for providers to know the care was delivered. This reflects both poor record keeping, in that a service which was delivered was not recorded as such, and poor patient monitoring, as providers are not able to accurately track patient progress.

Table 4.3: Variables and Measurement Tools from Clinic Records

Variable	Measure/Tool	Data Type
Methadone Dose	Milligrams	Continuous
Time in treatment	Years	Continuous
Attendance	Daily attendance	Binary
HIV test record	Date of test	Binary
CD4 test record	Date of test	Binary
ART initiation	Date of initiation	Binary
ART regimen	Specific regimen	Categorical
ART regimen complexity	Number of pills	Continuous
Location of ART dispensing	Location	Categorical
Method of ART dispensing	Daily or monthly	Categorical

Research Method: Aim 1b

Degree of intervention integration

For research Aim 1b clinic and laboratory records were used to track IMAT patients' statuses as the patients proceeded through the intervention. These data which consist of clinic and laboratory records were used to understand what elements of the intervention patients actually received. To initiate on ARV treatment, patients need to 1) be given an HIV test, 2) have their CD4 levels tested, 3) see a medical doctor to determine ARV regimen and dosing, and 4) then be placed on an ARV dosing plan. Analyses were done to see how many and which patients received which intervention procedures. I then used these data to develop scores relating to the degree of integration. Patients were coded as fully integrated if they (1) were linked to ARVs, (2) received their ARV medications and (3) received HIV lab work at the methadone clinic, partially integrated if they received two of these services at the methadone clinic, and minimally integrated if they only received one service at the methadone clinic. Full integration was given a value of 3, partial integration a value of 2, and minimal integration a value of 1.

To understand the degree to which patients were integrated onto IMAT data from the baseline survey was used as well as clinical records to get information on patient characteristics. Degree of integration was chosen as a measure of implementation and fidelity processes, because deviations from full integration are indicators that fidelity was not met for all patients. As related to the functional model for this aim, degree of integration tells us information related to the concepts of adoption, receipt, penetration and design. These variables can also be abstracted from clinical records, which may be a more objective measure of implementation and fidelity processes compared to self-report data from patients and providers. It is through clinic records that intervention participants (care providers here) are able to comprehend that services are being delivered as intended. The keeping of patient clinic data is a necessary part of the intervention itself, thus in a way the intervention process data from Aim 1b doubly acts as an indicator of fidelity. Aim 1b used data from 132 patients enrolled in IMAT to understand what intervention procedures were actually delivered to patients compared to the ideal IMAT protocol. The patient characteristics give information about aspects of individuals receiving care, which might impact these implementation and fidelity processes.

Research Question: Aim 1b

Research Aim 1b examined if patients were getting the elements of the intervention as intended. Specific research questions are:

What is the relationship between patient characteristics, implementation characteristics and implementation processes and fidelity?

Assuming a specific care cascade, how is the observed integrated methadone and antiretroviral treatment intervention protocol different from the ideal protocol?

- H3: Patients who engage in flashblood will have lower degrees of intervention integration compared to patients who do not engage in flashblood.
- H4: Patients with Hopkins Symptom Checklist-25 (HSCL-25) scores indicative of depression will have lower degrees of intervention integration compared to those who do not have scores indicative of depression.
- H5: The more complex the ART regimen (defined as the number of pills) the greater the intervention integration.

Analysis: Aim 1b

Univariate statistics, including frequencies the mean, median and quartiles were obtained to describe the degree to which patients were integrated onto the intervention. Bivariate linear regression, and chi-square tests were conducted to examine significant relationships between patient characteristics and degree of integration across a range of continuous and categorical variables. Variables that showed significant relationships between patient characteristics and degree of integration were considered for inclusion in the final ordinal logistic model. Ordinal regression was chosen to examine the relationship between patient characteristics and degree of integration. Ordinal regression was chosen to use patient characteristics to predict degree of integration, an ordinal variable. These significant variables were considered for inclusion in the ordinal logistic model if they had a p-value ≤ 0.2. Forward stepwise regression with a criterion p-value of 0.35 was used in to confirm variables for inclusion in the final ordinal logistic regression (Bursac, Gauss, Williams, & Hosmer, 2008; K. I. Lee & Koval, 1997). Correlations were used to determine variables included in models run. Because of small sample size nested models with likelihood ratio test were used to determine model fit (Turnbull & Weiss, 1978; Vuong, 1989).

Research Aim 2a

Research Aim 2a assesses the relationship between patient characteristics and patient participation in the IMAT intervention. Patient characteristics such as their health, mental health, drug use history, education may impact which patients engage with the intervention and thus impacts patient outputs. By directly comparing patients who left the program with those that enrolled in IMAT, I am better able to understand the issues and relevant characteristics of this target key population (seropositive PWID). Data for this aim utilizes routinely collected programmatic data. This is advantageous in terms of issues related to feasibility and cost.

Sample: Aim 2a

Data for Aim 2a were collected for all of the 249 HIV positive patients enrolled at the methadone clinic, as depicted in Figure 4.6. This sample was selected to see what characteristics might impact intervention enrollment specifically for the target population

Data Collection: Aim 2a

Data for patient characteristics were abstracted from the same clinic records used in Aim 1b, but now included all of the HIV positive patients enrolled at the methadone clinic. Data were collected using the same procedures described in Aim 1b.

Measures: Aim 2a

Baseline survey measures

Data from the methadone clinic's patient baseline survey was extracted to understand the patient characteristics of the 249 HIV positive methadone clinic patients for research Aim 2a. Details about these measures are presented in Table 4.2.

The risk assessment batteries described in Table 4.2 include various multi-question assessments. The 12-Item Short Form Survey (SF-12) and its component scores are typically scored, and then normed using a US based norming distribution (Gandek et al., 1998). Ideally country specific norming distributions should be used for the SF-12, however none currently exist for Tanzania. The scores of the SF-12 can be used to describe the distribution of a specific population. For this population, scores for the SF-12 as well as the Mental and Physical Component Summaries were collapsed into a 3-category variable; '1' if the value was below one standard deviation of the sample average, '2' if the value was within one standard deviation of the sample average, and '3' if the value was more than one standard deviation above the sample average. This gives an idea of how patients at the methadone clinic are doing in terms of mental and physical health in relation to their counterparts. A score of '1' indicated comparatively poor mental or physical health, '2' indicated average mental or physical health, and '3' indicated comparatively good mental or physical health. Drug risk behavior score is a 5-item summative scale indicating participation in injection drug use risk behaviors, such as flashblood and sharing syringes. The higher the score, the more risk behaviors a patient engages in. Research in Tanzania has validated a cut off of 1.75 for the HSCL-25, and its related subscales (Kaaya, Lee, Mbwambo, Smith-Fawzi, & Leshabari, 2008).

Clinic and laboratory records

Data regarding methadone dose, ART regimen, HIV test date and CD4 test date were obtained from clinic records. As CD4 and HIV tests predate IMAT implementation, these were turned into binary variables where 1 indicated that a patient had a record of these tests and 0 indicated that a patient did not have a record of these tests, respectively. Details about these measures are presented in Table 4.3. These data were also used in Aim 1b, however here the data

are analyzed for all of the seropositive methadone clinic patients, not only those who participated in the IMAT intervention.

Patient attrition

Data on attrition for research Aim 2a were obtained from clinic records. Attrition is a binary variable where 1=still an active patient and 0=no longer an active patient. Patients can become inactive by defaulting, defined as 21 consecutive missed doses, and patients' last pharmacy refill was assigned as their date of attrition, death, or by involuntary discharge—where they are asked by clinic staff to leave. If people stop taking their methadone they do not get their ARVs.

Research Question: Aim 2a

The specific research question and hypotheses are:

How do patient characteristics, behaviors and experiences impact participation, defined as attrition or its inverse in IMAT?

- H6: Patients with recorded HIV and CD4 tests are more likely to have a lower likelihood of attrition in IMAT compared to those without these records.
- H7: Younger, female patients will have a lower likelihood of attrition compared to older male IMAT patients.
- H8: Patients who receive a lower average methadone dose will have a higher likelihood of attrition compared to those with higher average methadone doses.

Analysis: Aim 2a

To examine patient characteristics related to patient participation defined here as attrition in the IMAT intervention, I first conducted analyses to examine differences between IMAT patients and those who left the clinic. Independent group t-tests, and chi-square tests were first

conducted to examine significant differences between IMAT patients and those who left the methadone clinic across a range of continuous and categorical variables. As attrition is a binary variable, logistic regression was chosen to examine which patient characteristics might be predictive. For variables with significant relationships forward stepwise logistic regression with a criterion p-value of 0.35 was used in to confirm variables for inclusion in the final multivariable logistic model (Lambdin et al., 2014; K. I. Lee & Koval, 1997).

Research Aim 2b

Research Aim 2b assesses the relationship between patient characteristics and patient attendance at the methadone clinic. This research Aim also seeks to understand if patient characteristics are related to patient outputs. However, this aim focuses specifically on how patients engage with the intervention itself defined as attendance, rather than the care environment as a whole. Patient characteristics such as their health, mental health, drug use history, education, etc., may impact how patients engage with the intervention and thereby affect patient outputs. For this exploratory aim, I used a quasi-experimental pre-post cohort design to examine client level changes in patient outputs after implementation of IMAT compared to before IMAT. For patients enrolled in care at the methadone clinic who receive the IMAT intervention, I assessed whether outcomes changed after IMAT implementation, compared to before IMAT implementation, while adjusting for differences in patient characteristics.

Sample: Aim 2b

Data for this aim were collected in the first six months of the IMAT intervention for the 137 patients enrolled in the intervention. This sample differs from Aim 2a in that not all of the 249 seropositive methadone clinic patients participated in the IMAT intervention. In Aim 2b I

am specifically looking at data for the 137 seropositive methadone clinic patients who participated in IMAT during the first six months of the intervention.

Data Collection: Aim 2b

Data collection for Aim 2b followed the same data collection procedures used in Aims 1b, and 2a. However, the sample for Aim 2b differs in that it only includes seropositive methadone clinic patients who enrolled in IMAT.

Measures: Aim 2b

Services delivered

In order to understand the role of the intervention in patient attendance, these data were examined pre-and post-intervention.

Patient characteristics

Data used to address research Aim 2b includes the same baseline clinic data used in Aim 2a, but only examined the data for patients enrolled in the intervention. These measures are presented in Table 4.2.

Patient Attendance

Patient attendance was a binary indicator variable. For each day patients were given a score of 1 if they attended the clinic that day and 0 if they did not. Attendance at the clinic was compared between March 1, 2015 and March 31, 2016—the IMAT intervention's start date was October 1, 2015, resulting in up to 397 observations per patient.

Degree of intervention integration

The measure of degree of intervention integration used in Aim 2b was developed using the categorization described in Aim 1b. As described earlier, this measure gives an indication of

how integrated patients were to the IMAT intervention, as well as information on the services they received at the clinic.

Research Question: Aim 2b

The specific research question and hypothesis is:

For seropositive methadone clinic patients, how does the IMAT intervention impact attendance at in the methadone clinic, compared to attendance prior to the intervention?

- H9: Patient attendance will improve after IMAT intervention implementation.
- H10: Improvement in patient attendance will be higher for patients fully integrated on IMAT compared to those who are partially or minimally integrated.
- H11: Male patient attendance will be higher compared to female IMAT patient attendance, post IMAT intervention implementation.

Analysis: Aim 2b

To test the hypotheses for research Aim 2b I examined the relationship between patient characteristics and patient attendance for the 6-months prior to intervention (pre) implementation, and for the 6 months following intervention (post) implementation. Patient attendance at the IMAT clinic was examined to see if the presence of the IMAT intervention and patient participation in the IMAT intervention impacted patient attendance patterns. Multivariate mixed-effects logistic regression was used to account for the patient specific factors that might cause some patients to have better attendance than others, as well as the fixed effects of patient characteristics that were recorded at baseline, or from their clinical records. The mixed effect logit model was used to see if participation in the intervention impacted patient attendance at the methadone clinic, through their daily visits. Interactions were included to build off what is already known about this population with the additional influence of the implementation and

fidelity processes. This allows for an examination of how different patients' attendance was or was not impacted by the intervention. Following this, marginal effects were calculated to examine differences in predicted probabilities for various kinds of patients (e.g. female vs. male patients) (R. Williams, 2012).

Research Aim 3a

Research Aim 3a, based on both qualitative and quantitative data examines the relationship between provider perspectives and implementation characteristics. Following the study's framework, it is necessary to get information on provider attitudes towards innovation, their perceived control in implementing intervention, clarity regarding intervention procedures as well as information around organization culture and capacity.

Sample: Aim 3a

Provider Data

There are 5 staff members at the methadone clinic directly involved in IMAT. Social workers and Pharmacists interact with IMAT patients in the same way they interact with MAT patients who are not enrolled in IMAT. There are 2 MDs involved in delivery care to IMAT patients who are responsible for prescribing ARTs and monitoring adherence/side effects. For providers to be included in the study they need to be directly involved in the IMAT intervention either through direct patient interaction or participation in protocol development. We administered the Organizational Readiness to Change Assessment (ORCA) and interviewed the following 8 providers:

- 3 Nurses
- 2 MDs
- 1 Pharmacist

- 1 Social Worker
- 1 Administrative person

Data Collection: Aim 3a

I submitted a letter to the Department of Psychiatry at Muhimbili University of Health and Allied Sciences explaining the study this letter was then submitted to clinic staff requesting they agree to be interviewed. Study staff approached clinic staff individually to set up a time to interview them. All interviews were done in a private room. Participants were given a Participant Identification Number (PIN) to assure their names were not associated with responses in any way. Providers interviewed signed a form of written consent. Before signing all providers were given sufficient information and were helped to reach an adequate understanding of what participation in this study involves. Informed verbal consent was also confirmed at the beginning of a participant's in-depth interview for audio-recording. No participant declined audio-recording. All interviews were conducted in Swahili and translated to English.

Semi-structured in-depth interviews were done with providers in order to obtain information about their experiences with the intervention and adapting to the new protocol. An interview guide was used for each interview, the interview guide is included in Appendix D: Provider Interview Guide. These interviews were conducted by project staff trained in qualitative research, fluent in Swahili and English. Interviews were conducted with providers involved in the intervention to understand the impact of the intervention from the perspective of providers and lasted for about 1.5 hours.

If the interviewee did not consent for audio recording, a note-taker, along with the interviewer, would have been present in each interview. No participants declined audio-recording. To minimize the risk of compromising confidentiality among our research participants

and to increase the likelihood of participation in the study, we allowed for both written and verbal informed consent. A waiver for the requirement for written documentation of informed consent was granted according to the University of California, Los Angeles Institutional Review # 15-000659. Consent forms were offered that convey the purpose of the study and include language indicating that it is the participant's choice to not answer any questions they did not care to answer, or to end the interview at any time. All interviews were conducted in Swahili and translated to English.

After completion of the interview, study staff administered the Organizational Readiness for Change Assessment (ORCA) to all providers. This assessment was translated to Swahili, and made available in English or Swahili depending on the providers preference. Training and cross translation was done with study staff to ensure accuracy and standardize data collection methods. Electronic and paper versions were made available to study staff. Survey completion took approximately 15minutes, all data were collected via KoboToolbox (data collection software) for Android© tablet and stored electronically.

Measures: Aim 3a

Provider Perceptions

Qualitative in-depth interviews were conducted with providers, 6-months post intervention. Providers (n=8) were asked questions about their reaction to and opinions of the IMAT intervention, their role in patient education, intervention procedures, ART dispensing and any feedback they might have regarding the intervention and its implementation.

Implementation Characteristics

For the quantitative surveys, constructs described in Chapter 3 help examine factors related to implementation outcomes. The constructs that received ratings using this qualitative

analysis were: patient needs and resources, available resources, compatibility, complexity, adaptability, relative advantage, and evidence. This information was obtained through an adaptation of the Organizational Readiness to Change Assessment (ORCA) tool (α=0.86) (Aarons, Cafri, Lugo, & Sawitzky, 2012; Helfrich, Li, Sharp, & Sales, 2009). The number of providers included allows for a survey of attitudes and beliefs based on position. The tool used for this study in included in Appendix E: Organizational Readiness for Change Assessment. Providers were asked about the strength of evidence regarding the intervention, using a Likert scale. Responses were coded as (1) Very Weak to (5) Very Strong. Providers were asked about the needs of the clinic, leadership/staffing, organizational innovation, organizational adaptability, clarity of implementation, and organizational capacity, also with a Likert scale. Responses to these topics were coded as (1) Strongly disagree to (5) Strongly Agree.

The organizational readiness to change assessment (ORCA) was used to gain information on providers' perspectives on the methadone clinic's capacity. Combining data in this way aligns with implementation science research targeted at exploration and hypothesis generation (Dogherty et al., 2012; Palinkas et al., 2011). The characteristics of the IMAT intervention were assessed using the intervention characteristics, presented in the functional model, as constructs that impact implementation effectiveness.

Research Question: Aim 3a

In this aim I sought to understand how the providers involved with the intervention, felt about the intervention to understand if it is burdensome, or if attitudes impact the implementation of the intervention. Specific research questions for Aim 3a are:

a) Are providers aware of the various implementation characteristics in a way that facilitates implementation?

b) What elements of the intervention are perceived of as barriers to implementation by providers?

c) How do providers think of stigma as it relates to frequency of care, low service utilization and decreased proactivity by patients?

d) How do providers feel about their participation in the IMAT intervention?

Analysis: Aim 3a

Qualitative data analysis Aim 3a

Following transcription and translation, interview data were entered into Dedoose (Dedoose Version 7.0.23, web application for managing, analyzing, and presenting qualitative and mixed method research data (2016). Los Angeles, CA: SocioCultural Research Consultants, LLC (www.dedoose.com)) for storage, organization, coding and analysis. Memos were used at each stage of data analysis to saturate analytic categories and facilitate the development of process theory around implementation. Provider interview data was analyzed using qualitative comparative analysis, through which implementation constructs were rated by their influence on implementation effectiveness (Damschroder & Lowery, 2013).

Qualitative comparative analysis (QCA) was used to analyze provider interviews using constructs described in Chapter 3. QCA is used in implementation science research to help determine necessary and sufficient conditions for implementation success (Cragun et al., 2016; Damschroder & Lowery, 2013). As applied to this dissertation QCA was used to help understand factors related to implementation outcomes. The constructs that received ratings using this qualitative analysis were: patient needs and resources, available resources, compatibility, complexity, adaptability, relative advantage, and evidence, ultimately creating a matrix that aggregates the entire data set. These constructs were then used as codes to assess the role of the

implementation characteristics in implementation effectiveness. To determine which provider statements would receive a particular code, the following schema was used. Codes related to the construct of patient needs and resources included statements that discussed awareness, or lack of awareness about the needs and resources of those served by the intervention. Codes related to the construct of available resources included statements related to the presence or absence of resources specific to the intervention. Codes for compatibility included statements that discussed the level of compatibility the intervention had with work processes and organizational values. Statements were coded for the construct of complexity if they discussed the complexity of the intervention itself. Codes related to the construct of adaptability included statements regarding the ability, or lack thereof, to adapt the intervention to the specific clinic context. Codes for relative advantage included statements demonstrating that the intervention was better or worse than existing programs, or having nothing in place of the intervention. Lastly, codes for evidence included statements related to providers' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes. These characteristics and definitions are summarized in Table 4.4. Provider statements could receive more than one code. For example, a provider might be speaking about relative advantage in the same statement they discuss evidence.

Each provider interview was coded by me, and these codes were used to develop case memos for each construct. These memos contained information regarding the rating given for the construct, a summary of all relevant codes for the construct, a rationale for the rating and the direct quotations related to the construct. Ratings reflect either a positive or negative influence on implementation effectiveness and the strength of this influence, ranging from +2 (strong positive influence) to -2 (strong negative influence). In total, seven constructs were assessed for

their relationship to implementation effectiveness. Each of these seven constructs was rated as having no bearing on implementation, having a weak positive or negative influence on implementation, or having a strong positive or negative influence on implementation. Three of these constructs were related to the intervention climate: patient needs and resources, available resources, and compatibility. Four constructs were related to the interventions characteristics: complexity, evidence, adaptability, and relative advantage. These data sources and analyses are used in conjunction, allowing for an in-depth examination of implementation effectiveness.

Table 4.4: Implementation Characteristics used for Qualitative Comparative Analysis with Provider Interviews

Implementation Characteristic	Definition
Patient Needs and Resources	Awareness, or lack of awareness about the needs and resources of those served by the intervention
Available Resources	The presence or absence of resources specific to the intervention
Compatibility	The level of compatibility the intervention had with work processes and organizational values
Complexity	The complexity (in terms of time, steps, or difficulty) of the intervention itself
Adaptability	The ability, or lack thereof, to adapt the intervention to the specific clinic context
Relative Advantage	Improvements or worsening by the intervention, compared to currently existing programs, or having nothing in place of the intervention
Evidence	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes.

Quantitative data analysis Aim 3a

Univariate statistics, including frequencies for categorical variables and the mean, median and quartiles for continuous variables, were also calculated from the organizational readiness for change assessment (ORCA) data to describe the distribution of how providers view issues of evidence, appropriateness and clinic capacity relating to the IMAT intervention. The domains of analysis included in the ORCA are presented in Table 4.5. The ORCA data comes from a small sample, but does comprise all of the providers involved in the IMAT intervention.

Table 4.5: Domains of the Organizational Readiness to Change Assessment

Measure	Domains	Measurement
Provider perceptions on clinic capacity (N=8)	• Strength of evidence • Clinic needs • Leadership/staffing • Organizational innovation • Organizational adaptability • Clarity of implementation • Organizational Capacity	• Likert scale: Very Weak to Very Strong • Likert scale: Strongly disagree to Strongly agree

Research Aim 3b

Research Aim 3a examines the relationship between patient perspectives and patient outputs. Understanding how patients enrolled in the IMAT intervention think about and experience the intervention gives insight into idea of service utilization and patient responsiveness. Intervention adherence (or lack of) ideal protocol may not determine implementation if there are more nuanced factors that impact patient engagement.

Sample: Aim 3b

Patient Data

In-depth interviews were conducted with 35 patients from the methadone clinic. Various patients were sampled to understand the range of experiences patients have with the IMAT intervention, their characteristics are as followed:

Table 4.6: In-depth interview patient characteristics

Patient Characteristic	Men	Women	Total
HIV positive methadone patients not on ART	1	2	3
HIV positive methadone patients not linked to ART before methadone clinic enrollment	7	7	14
HIV positive methadone patients not linked to ART before IMAT enrollment	16	2	18
Total	24	11	35

Data Collection: Aim 3b

Semi-structured in-depth interviews were done with patients in order to obtain information about their experiences with the intervention and adapting to the new protocol. An interview guide was used for each interview, interview guides for patients are included Appendix C: Patient Interview Guides. These interviews were conducted by project staff trained in qualitative research, fluent in Kiswahili and English. Patient interviews were audio-recorded, transcribed word-for-word in Swahili, and translated into English in total 35 patients were interviewed. Interviews were chosen to address issues of patient confidentiality and sensitivity of information and lasted 1-1.5 hours.

If the interviewee did not consent for audio recording, a note-taker, along with the interviewer, would have been present in each interview. No participants declined audio-recording. Past experience has shown that PWIDs in Tanzania are reluctant and sometimes unwilling to sign or carry consent forms for fear of loss of confidentiality and being tracked by police. Therefore, to minimize the risk of compromising confidentiality among our research

participants and to increase the likelihood of participation in the study, patient interviews we not linked to their methadone clinic patient identification number—this way a patient's interview cannot be link to their individual clinic record. Additionally, we allowed for both written and verbal informed consent. A waiver for the requirement for written documentation of informed consent was granted according to the University of California, Los Angeles Institutional Review # 15-000659.

Providers at the clinic determined if patients meet the eligibility requirements for in-depth interviews. Those who were eligible for study participation were asked if they were interested in participating during their private appointments, as to limit the risk of HIV status disclosure, or the disclosure of any other private information. If the person was interested in participating, they were then referred to a member of the study team. In a separate and private room, they were told about the study and asked if they wished to participate. Participants were told that they have the right to refuse or withdraw from study activities at any time. All participants were recruited through the methadone clinic with respectful consideration to avoid any situation that could be construed as coercive. If the individual was eligible and agreed to participate, study staff explained the terms of the study's consent form, which included a description of the purpose of the study, procedures to be followed, possible discomfort and risk, benefits, compensation and confidentiality. Participants were told that they have the right to refuse or withdraw from study activities at any time. Consent forms were offered that convey the purpose of the study and include language indicating that it is the participant's choice to not answer any questions they did not care to answer, or to end the interview at any time. All interviews were conducted in Swahili and translated to English.

Measures: Aim 3b

Patient Outputs

To address research Aim 3b qualitative in-depth interviews were conducted with HIV-positive patients, 6-months post intervention. Patients (n=35) were asked questions regarding their family and social background, experience with treatment, experience with the intervention, ART dispensing, stigma and any other feedback they may have in relation to the intervention. Following the theoretical framework of the intervention, as well as previous data collected on this patient population we asked patients questions relating to their satisfaction with the intervention, their clarity regarding intervention procedures as well as any motivations or barriers that impacted their participation.

Research Question: Aim 3b

This dissertation seeks to understand how the people involved with the intervention, patients and providers, feel about the intervention to understand if it is burdensome, or if attitudes impact the implementation of the intervention. Aim 3b of this dissertation seeks to understand patients' perceptions of the integrated methadone and antiretroviral therapy (IMAT) intervention. Specific research questions for Aim 3b are:

a) Are patients aware of the various intervention characteristics in a way that facilitates implementation?
b) What elements of the IMAT intervention do patients feel creates a barrier to implementation?
c) How do patients think of stigma as it relates to frequency of care, low service utilization and decreased proactivity by patients?
d) How do patients feel about the IMAT intervention?

Qualitative data analysis Aim 3b

Patient interview data for Aim three were analyzed using thematic content analysis, which will contribute to an in-depth understanding of the implementation process and perceptions of care integration. Following transcription and translation, initial line-by-line open coding of transcripts was used to develop topic codes relating to implementation for grouping and categorizing. Codes were then developed for the cluster of topics in the topic codes. These codes represented themes of patients' perceptions of the IMAT intervention that might impact implementation. Codes fit into four larger themes dealing with intervention implementation: ARV dispensing, patient barriers, stigma, and IMAT response.

Following transcription and translation, data were entered into Dedoose (qualitative software) for storage, organization, coding and analysis. Memos, created by me, were used at each stage of data analysis to saturate analytic categories and facilitate the development of process theory around implementation. Thematic content analysis approach to data analysis was used to understand experiences with the implementation process and perceptions of care integration. Example codes from this process included: patient monitoring, staff training, work load, privacy, intervention procedures, barriers to care and medication. These codes were aggregated into larger themes of: ARV dispensing, patient barriers and IMAT response. Major domains from patient interviews are presented in Table 4.7.

Table 4.7: Major domains from patient interviews

Measure	Major Domains	
Patient perceptions of IMAT (N=35)	• ARV dispensing • Stigma • Care receipt • Trust • Provider treatment	• Importance of care • Engagement in care • Organizational barriers • Time

Summary

The methods described in this chapter details how the conceptual framework of this study is related to the different functional models used to address each of the three research aims. A summary of the data sources, constructs and measures used for each aim are provided in Table 4.8, Table 4.9 and Table 4.10 respectively. The following three chapters each present results for each of the research aims, followed by a discussion of these results in Chapter 8.

Table 4.8: Summary of data sources, constructs, measures and measurement Aim 1

Data Source	Construct	Measures	Measure attributes	
Patient observations (N=207)	Clinic Environment Implementation and Fidelity Processes	• Patient visit process • Clinic process time • Services received	• Complete visit (from check in to check out) was recorded • Beginning and end time was recorded for various services received	
Provider observations (N=146)	Clinic Environment Implementation and Fidelity Processes	• Provider visit process • Clinic process time • Services delivered	• Complete work day was recorded • Time spent per work element	
Patient baseline survey (N=137)	Patient Characteristics	• Sex • Age • Drug risk behaviors • Methadone dosing • Time in treatment	• Sex • Age • Living situation satisfaction • Engagement in flashblood • Marital status • PCS 12 score • HSCL score	• Days received methadone • Average methadone dose • Anxiety score • ARV regimen complexity (as determined by number of pills)
Patient Clinical records (N=137)	Implementation and Fidelity Processes	• Patient monitoring • Degree of intervention integration • Clinic record keeping	• Full integration • Partial integration • Minimal integration	• HIV test record • CD4 test record • Proportion of visits kept

Table 4.9: Summary of data sources, constructs, measures and measurement Aim 2

Data Source	Construct	Measures	Measure attributes	
Patient Clinical records (N=249)	Patient Characteristics	• Sex • Age • Drug risk behaviors • Methadone dosing • Mental health	• Enrollment in IMAT • Age • Education • Self-Rated Health • HIV test record • CD4 test record	• Depression score • MCS 12 score • PCS 12 score • Drug Risk Score • Substance Dependency • Sexual Abuse History
Patient Clinical records (N=249)	Patient Outputs	• Patient attrition	• Active patient • Patient left (default, death or discharge)	
Patient Clinical records (N=137)	Patient Characteristics	• Sex • Age • Drug risk behaviors • Methadone dosing • Mental health	• Sex • Age • Self-Rated Health	• Depression score • MCS12 score • PCS 12 score
Patient Clinical records (N=137)	Implementation and Fidelity Processes	• Services delivered • Services received • Degree of intervention integration	• Average methadone dose • Record of ARV regimen • Degree of integration • HIV test record	
Patient Clinical records (N=137)	Patient Outputs	• Patient attendance	• Daily methadone clinic attendance	

Table 4.10: Summary of data sources, constructs, measures and measurement Aim 3

	Data Source	Construct	Measures	Measure attributes
Aim 3				
	Patient interviews (N=25)	Patient Perspectives Patient Outputs	• Service Utilization • Responsiveness	Patient Interviews
	Provider interviews (N=8)	Provider Perspectives Implementation Characteristics	• Patient needs and resources • Available resources • Compatibility • Complexity • Evidence • Adaptability • Relative Advantage	Provider interviews
	Organizational Readiness to Change Assessment (N=8)	Provider perspectives	• Compatibility • Available resources • Adaptability • Evidence	Provider survey

Chapter 5: Results Aim 1

As explained in Chapters 3 and 4, Aim 1 of this dissertation focused on the relationship between the clinic environment, patient characteristics and implementation and fidelity processes. Data for this aim were used to examine the role of the clinic environment in care delivery, and to explore the relationship between characteristics of the people receiving the intervention and the way in which the intervention is carried out to understand which procedures patients, do or do not receive and what factors contribute to both overall implementation and implementation and fidelity processes, which is ultimately linked to whether or not one can attribute an outcome effect to an intervention.

Findings Aim 1a

Aim 1a of this dissertation documents the delivery of Integrated Methadone and Anti-Retroviral (IMAT) intervention procedures. The sample for this aim were the 1,040 patients enrolled in care at the methadone clinic, which represents the potential pool of participants. The observations were collected from a sub-sample of this pool (n=102) and included IMAT and non-IMAT patients.

Table 5.1 details the time patients were recorded as participating in various procedures at the methadone clinic, the unit of analysis is individual patients. In total, there were 207 patient interaction observations for 102 unique patients, these patients represent the unit of analysis for Aim 1a. On average, each patient visit lasted 18.37 minutes at the clinic, with visits ranging from 15 seconds to 173 minutes (approximately 3 hours). In total 60 of the 102 patients were observed waiting. Among patients observed waiting, they spent an average of 40 minutes waiting at the

clinic. Time spent waiting comprised 90% of the total observed visit time. There was a large amount of variability with respect to time spent waiting among patients observed. We observed 37% of patients waiting 30 minutes or longer, and 22% of patients waiting 60 minutes or longer.

Table 5.1: Time patients spent engaged in various procedures at the methadone clinic

Procedure	Number of Patients	Total time	Avg. time	Min	Max	s.d.
Wait	86	3451	40.12	1	173	45.87
Other counseling	5	48	9.6	4	15	4.87
Follow-up visit	18	145	8.05	3	24	5.54
Other	4	24	6	2	12	4.32
CD4 test lab draw	4	21	5.25	4	6	0.95
VL Blood Draw	4	21	5.25	4	6	0.96
Baseline tests	1	5	5			
Lab Draw	2	9	4.5	4	5	0.71
ARV counseling	1	4	4			
Initial ARV pickup	1	4	4			
ARV daily pickup	9	29	3.2	2	6	1.48
CD4 results given	2	5	2.5	2	3	0.71
ARV month pickup	1	1	1			
Methadone pickup	77	74	.95	0.25	12	1.47
Total	102	3,451	37.28	0.25	249	55.82

In looking at the procedure patients received while at the clinic, patients were observed receiving between one and six procedures during any one visit, with an average of 3 procedures per visit. The procedure ‘other counseling’, can involve adherence counseling, behavioral counseling, substance use counselling, etc. and follow-up visits, and can involve filling out a patient questionnaire, discussing medication, and follow-up clinical care, had the highest average duration. Follow-up visits, other counseling, and the category of ‘other’ (which includes any

other procedure) had the highest standard deviations in regard to duration of visit, capturing the heterogeneity of these procedures. Despite the long times people spent for counseling session, the majority of procedures observed were completed with a few minutes time span. There was a small correlation found between number of procedures received and time spent at the clinic (r=0.29). A correlation was observed between if the patient was observed waiting and total time spent at the methadone clinic (r=0.50). There was a strong correlation between the number of procedures a patient received and if they were ever observed waiting (r=0.57), patients observed waiting received between 1 and 6 procedures, while those not observed waiting only received between 1 and 3 procedures. This relationship is depicted in Table 5.2. Patients who were observed waiting spent more time at the clinic, compared to those who were not observed waiting.

Table 5.2: Average time spent at the methadone clinic by number of procedures received, for patient observed waiting compared to those not observed waiting

Number of procedures received	Avg. visit time (minutes)	s.e.	Min time	Max time	N
Patients observed waiting					
1	61.73	13.33	5	173	19
2	66.54	25.25	3.35	249	12
3	21.78	10.73	5	106	9
4	76.12	15.55	2.5	191	16
5	48.42	14.56	22	72.25	3
6	109.25				1
Patients not observed waiting					
1	2.67	0.63	0.25	17	34
2	9.5	5.74	0.5	37	6
3	7.5	6.75	0.75	14.25	2

The amount of time patients at the methadone clinic spent with various service providers is detailed in Table 5.3. Since the majority of patients at the methadone clinic came in to pick up their daily methadone dose from the pharmacy, interactions with the pharmacist comprise the

majority of patient/provider interactions. Of the patients observed, 30 were seen by a Medical Doctor (M.D), 20 were seen by a nurse, 6 were seen by a social worker, and 79 were seen by the pharmacist. Medical Doctor (M.D) care involved the majority of patients' time, totaling 2,322 observed minutes (approximately 39 hours), and 58.05 minutes per visit on average across 40 patient interactions. Social workers saw fewer patients than the nurses, but averaged 19.20 minutes per patient visit comparted across 10 patient interactions. This is compare to an average of 10.15 minutes for nurse across 26 patient interactions.

Table 5.3: Number of patient interactions and time spent by each provider at the MAT clinic

	N	Mean time	Min	Max	s.d.	Total time
Pharmacist	131	7.82	.25	119	16.02	1025
M.D	40	58.05	3	173	57.26	2322
Nurse	26	10.15	1	57	13.90	264
Social Worker	10	19.2	4	82	23.61	192

In examining time spent at the clinic by the type of provider a patient saw, there were no strong correlations between whether or not a patient was observed waiting and the type of provider seen. As depicted in Table 5.4, patients who were observed waiting spent more time with each type of provider compared to patients who were not observed waiting. Overall more patients were observed waiting (60) compared to those who were not observed waiting (42).

Table 5.4: Average time spent at the methadone clinic by number of kind of provider seen, for patient observed waiting compared to those not observed waiting

Provider Seen	Avg. visit time (minutes)	s.e.	Average number of procedures received	Number of patients
Patients observed waiting				
MD	119.39	17.31	3.06	16
Nurse	34.03	9.21	3.68	8
Social Worker	11		4.22	1
Pharmacist	41.33	8.21	3.25	35
Patients not observed waiting				
MD	8.83	1.99	1.28	6
Nurse	5.6	1.63	1.57	5
Social Worker	37		2	1
Pharmacist	1.5	0.46	1.45	30

Provider work days

To understand the operation of the clinic from the perspective of providers, each provider was observed during the time they spent at the methadone clinic. During a typical work day at the methadone clinic a provider sees 10 patients. We obtained observations of 146 patients seen for 6 individual providers. Table 5.5 details the total time various providers were observed spending providing care and the number of patients they were observed having seen. These visits involved 159 procedures delivered. The M.D, we observed, spent the most time with patients, totaling 90 minutes over 6 procedures delivered—2 unique procedures, but only seeing 4 patients. On average this provider saw patients for 22.5 minutes. The third nurse observed spent the second largest amount of time with patients, delivering 4 unique procedures, and saw 18 patients for a total of 86 minutes, averaging 4.8 minutes per patient. The pharmacists saw the most patients observed, serving 110, and delivered 1 procedure for a total of 52.5 minutes, averaging 0.47 minutes per patient. The social worker we observed also spent a good deal of time with each patient, 12.75 minutes on average. Nurse 1 and Nurse 3, and the M.D all had high

standard deviations regarding the time spent with patients. More so than the other providers, however these higher standard deviations may be related to the smaller number of patients they saw compared to other providers. There is also some discrepancy in the amount of time different providers spend doing the same procedures. For example, Nurse 2 spent two minutes on the client assessment while the social worker spent 51 minutes. These differences in time may be due to how different providers perform the same procedures, for example the counseling done by nurses may be very different from the counseling done by social workers.

Table 5.5: Time (in minutes) providers spent providing care

Provider	Total Time	Mean	Min	Max	Patients Seen	s.d.
M.D	90	22.5	12	30	4	8.58
Nurse 3	86	4.78	1	17	18	4.91
Pharmacist	52.5	0.48	0.25	2	110	0.37
Social Worker	51	12.75	9	15	4	2.63
Nurse 1	31	6.2	2	15	5	5.49
Nurse 2	16	3.2	2	5	5	1.64
Total	326.5 mins	2.24	0.25	30	146	4.86

Table 5.6 describes the time providers were observed delivering various procedures at the methadone clinic. These observations indicated that while ARV counselling, Client assessment, and Baseline comprised a large amount of provider time at the methadone clinic, they were delivered relatively few times. For example, providers were observed administering the baseline assessment only 3 times, but this took up 78 minutes of provider time.

Table 5.6: Time (in minutes) spent on each procedure by provider

Procedure	Pharmacist	Nurse 2	Nurse 1	Nurse 3	Social Worker	M.D
Methadone Daily Dose	52.5 mins (n=110)					
Lab Order			8 mins (n=1)			
Lab Paperwork				17 mins (n=1)		
Daily ARV			6 mins (n=2)	6 mins (n=3)		
ARV Counselling		2 mins (n=1)				60 mins (n=3)
ARV monthly dose		16 mins (n=5)				
Baseline						78 mins (n=3)
Client Assessment		2 mins (n=1)			51 mins (n=4)	
Lab Draw				65 mins (n=7)		
Other counselling		12 mins (n=3)			51 mins (n=4)	
Other service			17 mins (n=2)	16 mins (n=9)		
Avg. time per patient	0.48	3.2	6.2	4.78	12.75	22.5
Total	52.5 mins	16 mins	31 mins	86 mins	51 mins	90 mins

On average patient visits were 18 minutes long, patients spent a large amount of time waiting and patients who received more services waited longer. There was a great deal of variation between providers in regard to the amount of time they spend with patients. Generally, M.D.s spent the most time with patients, while interactions with the pharmacist for medication pick up was the least amount of time spent in provider – patient interaction.

Aim 1b

Aim1b examines the relationship between specific patient characteristics and implementation and fidelity processes for the 137 patients enrolled in to the integrated methadone and antiretroviral therapy (IMAT) intervention. In this aim, data from patient clinical and laboratory recordswere used to assess services delivered, services received, clinic record keeping, patient monitoring and degree of intervention integration.

Descriptive Findings: Aim 1b

Demographic characteristics of the sample are presented in Table 5.7. There was a wide age range of patients with patients as young as 20 and as old as 70, with a median age of 38. Of these patients 19 (14%) are female and 118 (86%) are male. The majority of patients (79%) are single, 13% are married, and 8% of patients are divorced, separated, or widowed. Of the patients surveyed, 69% had at least one child, while the majority (90%) had one or two children. In terms of education, 13% of the sample completed no education, the majority (63%) of the sample completed primary education and only 24% of the sample completed lower and upper secondary school.

Of the patients surveyed, 4% had no stable housing, 11% lived alone, 68% lived with a family member or partner, and 4% lived with friends. In terms of employment, 76% of the sample was employed in elementary occupations, which includes tasks such as selling goods in the street, cleaning, and as working laborers. Over the previous three years, 84% of the sample reported that they spent the majority of their time unemployed, however, over a 30-day recall, 89% of respondents indicated that they had spent 30 days engaged in some kind of work.

The median income over a 30-day recall was 393,214 TzSh (approximately 176 USD). However, tests of kurtosis indicated that this variable was heavy-tailed and so the square

root of this variable was taken for a more normal distribution. The median amount of money spent on drugs in the last 30 days was 480,000 TzSh (214 USD), ranging between 0 and 2,160,000 TzSh (966 USD). Test of kurtosis also indicated that this variable was heavy-tailed, and so the square root was taken for a more normal distribution.

Table 5.7: Aim 1b Sample demographic characteristics

N=137	n	%	Mean	Median	s.d.
Age			38.51	38	6.28
Gender					
Male	118	86			
Female	19	14			
Marital Status					
Not married	119	87			
Married	18	13			
Housing					
Live alone	13	11			
Live with family member or partner	78	68			
Other	24	21			
Education					
No education	15	13			
Primary School	72	63			
Secondary	28	24			
Usual occupation					
None	25	21			
Elementary occupation	73	61			
Other	21	18			
Annual Income	98		393,214 (176 USD)	150,000 (67 USD)	1,519,395
Amount spent on drugs (past 30 days)	206		537,521 (240 USD)	480,000 (214 USD)	2,700,000

Health characteristics of the sample are presented in Table 5.8. Looking at self-rated health, 55% of the sample reported poor health, while only 15% report good, or very good health. In terms of impacts to mental health, the majority of the population had not experienced physical harm over the last 30 days (99%) or over the course of their life (86%). Similarly, 100%

of the sample had not experienced sexual abuse over the last 30 days, and 97% report never experiencing it or over the course of their lives. Of the sample, 83% reported having experienced no psychological problems in the last 30 days, only 2% of the sample did report experiencing psychological problems 30 of 30 days. The majority of patients, 81%, report not being bothered at all by psychological problems over a 30-day recall, while 13% report being extremely bothered by psychological problems over this period. Over the last 4 weeks, 47% of patients report that they accomplished less as a result of emotional problems, and 48% reported they did not do work or other activities as carefully due to emotional problems.

The Hopkins Symptom Checklist-25 (HSCL-25) is a 25 item inventory of depressive and anxiety symptoms and has been validated for use in Tanzania (Antelman et al., 2007; B. Lee, Kaaya, Mbwambo, Smith-Fawzi, & Leshabari, 2008). The optimal cut off for the Hopkins Symptom Checklist-25 (HSCL-25) and related depressive and anxiety sub-scales is 1.75. Using this cut off, 44% of the sample has scores indicative of depression, 37% of the sample has scores indicative of anxiety, and 41% of the sample has scores which indicative of general mental distress. The HSCL-25 demonstrated high internal reliability (α=0.93), as did the anxiety subscale (α=0.88), and depression subscale (α=0.89).

The short form-12 (SF-12), a measure of overall mental and physical health and its component scores are typically scored, and then normed using a US based norming distribution (Gandek et al., 1998). For this population, scores for the SF-12 Mental and Physical Component Summaries were collapsed into a 3-category variable; 1 if the value was below 1 standard deviation of the sample average, 2 if the value was within 1 standard deviation of the sample average, and 3 if the value was more than 1 standard deviation above the sample average. This gives an idea of how patients at the methadone clinic are doing in terms of mental and physical

health in relation to their counterparts. A score of 1 indicated comparatively poor mental or physical health, 2 indicated average mental or physical health, and 3 indicated comparatively good mental or physical health. The items used in the SF-12 demonstrated high internal reliability (α=0.91). In looking at the mental health component 17% of patients received scores indicating comparatively poor mental health, 55% scored with average mental health and 27% scored with higher than average mental health. Looking at the physical component, 17% of the sample received scored indicating comparatively poor physical health, 56% scored with average physical health, and 26% scored with higher than average physical health.

Table 5.8: Aim 1b: Health characteristics

N=137	n	%
Self-Rated Health		
Good+	17	14
Fair	36	30
Poor	65	55
Experience physical harm (30 days)		
Yes	1	1
No	114	99
Experience physical harm ever		
Yes	16	14
No	99	86
Experience sexual abuse (30 days)		
No	115	100
Experience sexual abuse ever		
Yes	3	3
No	112	97
Troubled by psychological problems (30 days)		
Not at all	88	81
Some	7	6
Extremely	14	13
Accomplish less as a result of emotional problems		
Yes	55	47
No	63	53
Did work less carefully as a result of emotional problems		
Yes	57	48
No	61	52
HSCL-25 cutoff		
Depression	61	44
Anxiety	50	37
General Mental distress	56	41
SF-12		
Below average mental health	24	17
Average mental health	76	55
Above average mental health	37	27
Below average physical health	24	17
Average physical health	77	56
Above average physical health	36	26

Drug use characteristics of the sample used for this analysis are presented in Table 5.9. At the time of completing the baseline survey 98% of the sample reported heroin use in the past 30-days. The majority of respondents (99%) report that treating their drug problems is extremely important to them. Using a seven-item measure of substance dependence, 70% of patients meet the cutoff indicating maladaptive pattern of substance use, leading to clinically significant impairment or distress (3 out of 7). This seven-item scale was found to have high reliability (α=0.89), and data were normally distributed. Median heroin use was 10 years, with a range of 0 to 31 years. For lifetime heroin use skewness is considered not seriously *violated.* The primary substance of use in the sample population was heroin, with cannabis being reported as the secondary substance of use for 58% of the population.

Patients were asked five questions to capture their injection risk behaviors. From the sample 1% engaged in 0 injection risk behaviors, while 38% engaged in 3 or more injection risk behaviors. A small proportion of the sample (10%) engaged in flashblood (in which a user injects a full syringe of blood into themselves donated by someone who has recently injected heroin into their bloodstream), while only 18% reported sharing needles at their last injection and 21% reported sharing any injection equipment at their last injection. These items are not intended to be used as a scaled measure and demonstrate low internal reliability (α=0.28). Measurement tools for the HSCL-25, injection risk behaviors, and substance dependence are presented in Appendix H: Substance Dependence, Appendix I: Supplementary Tables Chapter 5, and Appendix J: Supplementary Tables Chapter 6.

Table 5.9: Aim 1b: Drug use characteristics

N=137	n	%	Mean	Median	s.d.
Heroin use past 30 days					
Yes	109	98			
No	2	2			
Substance Dependence			4.69	7	3.15
Lifetime heroin use (years)			11.28	10	6.81
Primary substance of use					
Heroin	105	93			
Alcohol	3	3			
Methadone	4	4			
Cocaine	1	1			
Injection risk behaviors					
Injected drugs in last 12 months	108	92			
Ever used flashblood	12	10			
Shared syringes	21	18			
Shared injection equipment	25	21			
Doesn't clean syringes	9	8			

Details about patient characteristics in respect to clinic attendance are presented in Table 5.10. Overall the sample has a high rate of attendance with an average of 91% of visits kept. Typical methadone treatment starts at 40mg/day, with high doses being anything over 100 mg/day (D'Aunno, Pollack, Frimpong, & Wuchiett, 2014). The average methadone dose received was 106.32 mg/day, with a range of 0 to 382 mg. At the time of survey patients had been attending the methadone clinic for between 0 and 5 years, the median time at the clinic was 4 years.

Table 5.10: clinic attendance characteristics

N=137	Mean	Median	s.d.
Proportion of visits kept	0.91	0.98	0.18
Average methadone dose	128.48	106.32	76.73
Time at methadone clinic (in years)	3.64	4	1.30

Summary: Descriptive analysis

Data on patient characteristics show commonalities in relation to patient demographics. Patients are similar in relation to education and employment, with the majority of patients having finished primary school and engaged in elementary occupations. The majority of patients report poor health, and also report they are not troubled by psychological problems. Measures indicate patients that the majority of patients have average physical and mental health, but approximately 40% meet cutoffs for depression, anxiety and general mental distress. The majority of patients meet clinical cutoff for substance dependence, and have been using heroin for about a decade. Overall patients at the methadone clinic receive high methadone doses, have been at the methadone clinic for multiple years, and have kept the majority of their visits in the last year.

Findings Aim 1b: Patient receipt of care

The IMAT intervention was designed to facilitate patients' receiving integrated HIV care and methadone treatment during their visits at the MAT clinic. This is meant to include receipt of medications, HIV lab work, as well as HIV clinical care. Figure 5.1 represents the ideal care cascade for integrated methadone and ARV care. To receive HIV services patients, need to be given an HIV test, have their CD4 levels tested, see a M.D to determine which antiretroviral (ARV) regimen and dosing is suitable, and then be placed on an ARV dosing plan.

Figure 5.1: Integrated Care Cascade

Table 5.11 shows the delivery of key intervention procedures; CD4 test record, HIV test record, ARV regimen, Link to ARVs, ARV dispensing location, as well as client status, by sex. In total 128, or 93%, of eligible patients had a recorded HIV test prior to initiating onto IMAT, but more patients (135) were linked to ARV treatment than had a recorded HIV test. In the sample, 119, or 85%, of eligible patients had a recorded ARV regimen, but only 123 (89%) had a record of an ARV dispensing location. In regard to CD4 testing, 114 (82%) of eligible patients had a recorded CD4 test prior to initiating onto IMAT. These data indicate that there were discrepancies regarding the degree to which patients' HIV care was integrated into the existing services at the methadone clinic. Missing data result in analytical challenges, as only complete cases can be included in a regression, but missing data also suggest deviations from the ideal IMAT protocol depicted in Figure 5.1. While patients may have received care that was not recorded, gaps in clinic records make it difficult to supply follow up care and allow the patient to move through the intervention. For example, if a patient received an HIV test, but it was never recorded, then a subsequent provider would not know to give them a CD4 test in order to initiate ARVs.

Table 5.11: Patient procedure receipt

	Male	Female	Total (%n)
CD4 test record	98	15	113 (82%)
ARV regimen record	100	19	119 (86%)
HIV test record	117	20	128 (93%)
Link to ARVs	115	20	135 (99%)
ARV Dispensing Location			123 (89%)
At the methadone clinic	80	15	95
Outside of the methadone clinic	23	5	28
Client Status			137 (100%)
Active	113	20	133
Defaulted	2	0	2
Graduated	2	0	2

To understand the degree to which patients received integrated treatment a measure of care integration was derived using the clinic and lab records described above, patients were coded as fully integrated if they (1) were linked to ARVs, (2) received their ARV medications and (3) received HIV lab work at the methadone clinic, partially integrated if they received two of these services at the methadone clinic, and minimally integrated if they only received one service at the methadone clinic. Data regarding degree of integration was available for 132 patients during the first 6 months of the intervention. Table 5.12 contains the distribution IMAT integration by sex, two patients refused integrated care and data for 4 patients was missing.

Table 5.12: IMAT Patient Degree of Integration by Sex

Degree of Integration	Male (%n)	Female (%n)	Total
Full	74 66%	15 75%	89 67%
Partial	20 18%	2 1%	22 17%
Minimal	18 16%	3 15%	21 16%
Total	112	20	132

To better understand the role of these varying degrees of integration I examined relationships between patient characteristics and degree of integration. Bivariate linear regression and chi-square tests were conducted first to examine significant relationships between patient characteristics and degree of integration across a range of continuous and categorical variables, namely personal characteristics, health and mental well-being, methadone and addiction history and behavior. These variables were then considered for inclusion in an ordinal logistic model if they had a p-value ≤ 0.2. Categorical variables considered for inclusion in the logistic regression model included; having a record of an HIV test, having a record of a CD4 test, engagement in flashblood, marital status and ARV regimen complexity (as determined by number of pills), these results are presented in Table 5.13. Continuous variables considered for inclusion in the logistic regression model included; amount spent on drugs (transformed), proportion of visits kept, average methadone dose, and time enrolled at the methadone clinic.

Table 5.13: Bivariate associations between degree of integration and patient clinical indicators

Degree of Integration	Record of HIV test	No record of HIV test	Statistic
Full	88	1	
Partial	21	1	
Minimal	18	3	
Total	127	5	p=0.017
	Record of CD4 test	No record of CD4 test	
Full	79	10	
Partial	19	3	
Minimal	15	6	
Total	113	19	p=0.125
	Used flashblood	Never used flashblood	
Full	6	71	
Partial	5	14	
Minimal	1	15	
Total	12	100	p=0.054
	Not-married	Married	
Full	79	10	
Partial	18	4	
Minimal	17	4	
Total	114	18	p=0.476
	1 pill in regimen	2+ pills in regimen	
Full	23	62	
Partial	13	7	
Minimal	11	3	
Total	47	74	p=0.000

Table 5.14: Bivariate associations between degree of integration and various patient characteristics

	Amount spent on drugs	Proportion of visits kept	Average methadone dose	Time at methadone clinic
Co-efficient	0.0004	0.645	0.002	0.078
s.e	0.0002	0.374	0.001	0.050
p-value	0.073	0.087	0.062	0.123
95% CI	(-0.001, .000)	(-1.386, 0.095)	(-0.003, 0.000)	(-0.178, 0.21)
n	108	131	131	131

A correlation matrix is presented in Appendix I: Supplementary Tables Chapter 5, Table 9.1 to show the associations among degree of integration and other study variables. Correlations

between these variables included in the final logistic model were all found to be low. A table with listing missing data for all potential variables is presented Appendix I: Supplementary Tables Chapter 5, Table 9.2. Variables had between 1 and 25 missing observations.

Forced choice entry ordinal regression was conducted with all variables under consideration. These results are presented in Table 5.15. Results from ordinal logistic regression indicate that ARV regimen complexity and average methadone dose are significantly positively associated with degree of intervention integration. For a one unit increase in ARV regimen complexity we would expect a 1.31 (OR, 95% CI: 3.71 (2.01, 6.87)) increase in the log odds of being more integrated into the intervention. For a one unit increase in average methadone dose we would expect a 0.01 (OR, 95% CI: 1.01 (0.02, 1.00)) increase in the log odds of being more integrated into the intervention. However, given the sample size (n=96) and number of predictors (9) included, this model may not be the most appropriate fit. Following this forced choice regression, model building was conducted to find the most parsimonious model given these limitations.

Table 5.15: Forced choice regression on patient characteristics and degree of integration

n=96	Coefficient	OR (95% CI)	p-value
HIV test completed	1.91	6.74 (0.32, 142.50)	0.22
CD4 test completed	0.55	1.74 (0.23, 13.30)	0.59
Engagement in Flashblood	-1.44	0.24 (0.06, 0.96)	0.04*
Marital Status	0.89	2.45 (0.55, 10.90)	0.24
ARV regimen complexity	2.47	11.90 (3.64, 38.96)	0.00**
Amount spent on drugs	0.00	1.00 (0.99, 1.00)	0.40
Proportion of visits kept	-1.39	0.25 (0.012, 5.08)	0.36
Average methadone dose	0.01	1.01 (1.00, 1.02)	0.02*
Time enrolled at the methadone clinic	-0.04	0.97 (0.52, 1.76)	0.91
Pseudo R^2	0.23		
AIC	142.53		
BIC	167.70		

Forward stepwise ordinal regression was then conducted with these variables to determine which would be included in the final ordinal logistic regression using a criterion p-value of 0.35. Results of forward stepwise multiple regression indicated that ARV regimen complexity, HIV test record, average methadone dose, engagement in flashblood, marital status and proportion of visits kept at the methadone clinic should be included in the model presented in Table 5.17. Given the small sample size for the model, I ran nested models to determine if the full model was better fit than a model with fewer variables. The various models are described Table 5.16. Likelihood ratio tests indicated that the model with HIV test record and proportion of visits kept was a better fit compared to the full model, thus it was used for analyses.

Table 5.16: Nested models from ordinal logistic regression results of degree of patient integration

n=103	Full Model			Model 1			Model 2			Model 3		
	Co-efficient	z	p-value	Co-efficient	z	p-value	Co-efficient	z	p-value	Co-efficient	z	p-value
ARV regimen complexity	2.48	4.19	0.00	1.99	3.79	0.00				2.35	4.13	0.00
Average methadone dose	0.11	2.36	0.02	0.01	2.35	0.02				0.01	2.49	0.01
Engagement in Flash blood	-1.55	-2.18	0.03	-1.45	-2.14	0.03				-1.56	-2.29	0.02
HIV record	2.41	1.65	0.09				2.53	1.94	0.05			
Marital Status	1.08	1.46	0.15				-0.16	-0.25	0.81	1.29	1.74	0.08
Proportion of visits kept	-1.26	-0.82	0.41				0.94	0.81	0.42			
Pseudo R^2	0.22			0.18			0.17			0.20		
AIC	136.72			158.00			165.95			140.57		
BIC	155.16			173.81			179.12			141.04		
LR χ^2				23.28		0.00	30.92		0.00	3.58		0.17

Ordinal logistic results presented in Table 5.17 indicate that the complexity of ARV regimen complexity, average methadone dose, engagement in flashblood and marital status are significantly associated with degree of intervention integration. For a one unit increase in the number of pills involved in a patients ARV regimen we would expect a 2.35 (OR, 95% CI: 10.57 (3.45, 32.35)) increase in the log odds of being more integrated into the intervention, given that all of the other variables in the model are held constant. For a one unit increase in average methadone dose a patient takes we would expect a 0.01 (OR, 95% CI: 1.01 (1.00, 1.02)) increase in the log odds of being more integrated into the intervention, given that all of the other variables in the model are held constant. For patients who indicated they have engaged in flashblood we would expect a 1.56 (OR, 95% CI: 0.21 (0.05, 0.79)) decrease in the log odds of being more integrated into the intervention, given that all of the other variables in the model are held constant. Results of the ordinal logistic regression also indicate no significant relationship between degree of integration and marital status.

Table 5.17: Ordinal logistic results for patient characteristics and odds of increased intervention integration

n=103	Coefficient	OR (95% CI)	p-value
ARV regimen complexity	2.35	10.57 (3.45, 32.35)	0.00
Average methadone dose	0.01	1.01 (1.00, 1.02)	0.01
Engagement in flashblood	-1.56	0.21 (0.05, 0.79)	0.02
Marital Status	1.29	3.62 (0.85, 15.41)	0.08
Pseudo R^2	0.20		
AIC	140.57		
BIC	141.04		

Summary of Key Findings: Aim 1b

These data were used to document the varying degrees of integration that IMAT patients experienced as part of the intervention, indicating that clinical benchmarks (e.g. average

methadone dose) are positively related to intervention integration and high-risk injection drug use behavior (flashblood) is negatively related to intervention integration.

Chapter 6: Results Aim 2

Research aim two seeks to understand the relationship between implementation and fidelity processes and patient outputs. As described in the conceptual model this relationship is hypothesized to be influenced by characteristics of people involved in the intervention. Patient characteristics such as their health, mental health, drug use history, education may impact which patients engage with the intervention and thus impacts patient outputs. For patients to be eligible to participate in the integrated methadone and antiretroviral therapy (IMAT) intervention, they must be seropositive methadone clinic patients. IMAT patients are inherently different from non-IMAT patients by virtue of their serostatus. In this aim I compare eligible methadone clinic patients who are no longer active, with eligible methadone clinic patients who remained active and enrolled in IMAT, in order to examine the issues and relevant characteristics of this target key population (seropositive people who inject drugs). This research Aim also seeks to understand patient characteristics are related to patient outputs. For patients enrolled in care at the methadone clinic who receive the IMAT intervention, I assessed whether outcomes changed after IMAT implementation, compared to before IMAT implementation, while taking into account relevant patient characteristics.

Aim 2a

Research Aim 2a assesses the relationship between patient characteristics and patient participation in the integrated methadone and antiretroviral (IMAT) intervention. In this aim I compare characteristics of eligible patients (seropositive methadone clinic patients) who did not enroll into IMAT with those that did. Eligible patients who remained active were enrolled onto IMAT, while eligible patients who are no longer active (left the clinic) were not. In this aim patient participation, is determined by patient status (active vs. not-active) and used as a binary

variable where 1=still an active patient enrolled on to IMAT and 0=no longer an active patient (thus not enrolled onto IMAT).

Descriptive Findings: Aim 2a

The social and demographic, characteristics of the sample are summarized in Table 6.1. There are 249 individuals in the sample, which is comprised of HIV positive people who inject drugs and who are patients at the methadone clinic at Muhimbili University Hospital. This sample differs from the Aim1 in that it includes all seropositive patients and not just the ones who were enrolled onto the integrated methadone and antiretroviral (IMAT) intervention.

There was a wide age range of patients with patients as young as 20 and as old as 70, with a median age of 38. Of these patients 34 (14%) are female and 213 (86%) are male. The majority of patients (79%) are single, 13% are married, and 8% of patients are divorced, separated, or widowed. Of the patients surveyed, 67% had at least one child, while the majority (90%) had one or two children. In terms of education, 10% of the sample completed no education, the majority (61%) of the sample completed primary education and only 28% of the sample complete lower and upper secondary school.

Of the patients surveyed, 15% lived alone, and 65% lived with a family member or partner. In terms of employment, 78% of the sample was employed in elementary occupations, which includes tasks such as selling goods in the street, cleaning, and as working laborers. Over the previous three years, 87% of the sample reported that they spent the majority of their time unemployed, however, over a 30-day recall, 89% of respondents indicated that they had spent 30 days engaged in some kind of work.

The median income over a 30-day recall was 366,451 TzSh (approximately 163 USD). However, tests of kurtosis indicated that this variable was heavy-tailed and so the square

root of this variable was taken for a more normal distribution. The median amount of money spent on drugs in the last 30 days was 537,521TzSh (240 USD), ranging between 0 and 2,700,000 TzSh (1,207 USD). Test of kurtosis also indicated that this variable was heavy-tailed, and so the square root was taken for a more normal distribution.

Table 6.1: Aim 2a Sample social and demographic characteristics

N=249	n	%	Mean	Median	s.d.
Age			38.09	38	5.80
Gender					
Male	213	86			
Female	34	14			
Marital Status					
Married	196	79			
Not married	53	21			
Housing					
Live alone	31	15			
Live with family member or partner	138	65			
Other	42	20			
Education					
No education	22	10			
Primary School	129	61			
Low Secondary	60	28			
Usual occupation					
None	48	23			
Elementary Occupation	131	64			
Other	27	13			
How spent the past three years					
Unemployed	168	87			
Other	25	13			
Income			366,451 (163 USD)	150,000 (67 USD)	1,180,280
Amount spent on drugs (past 30 days)			537,521 (240 USD)	450,000 (200 USD)	408,222

Health characteristics of the sample are presented in Table 6.2. Looking at self-rated health, 56% of the sample reported poor health, while only 17% report good, very good or excellent health. In terms of impacts to mental health, the majority of the population had not

experienced physical harm over the last 30 days (97%) or over the course of their life (88%). Similarly, 98% of the sample had not experienced sexual abuse over the last 30 days, and 97% report never experiencing it or over the course of their lives. Of the sample, 83% reported having experienced no psychological problems in the last 30 days, only 2% of the sample did report experiencing psychological problems 30 of 30 days. The majority of patients, 77%, report not being bothered at all by psychological problems over a 30-day recall, while 16% report being extremely bothered by psychological problems over this period. Over the last 4 weeks, 47% of patients report that they accomplished less as a result of emotional problems, and 44% reported they did not do work or other activities as carefully due to emotional problems.

As described in chapter 5, the optimal cut off for the Hopkins Symptom Checklist-25 (HSCL-25) and related depressive and anxiety sub-scales is 1.75. Using this cut off, 45% of the sample has scores indicative of depression, 40% of the sample has scores indicative of anxiety, and 41% of the sample has scores which indicative of general mental distress. The HSCL-25 demonstrated high internal reliability (α=0.93), as did the anxiety subscale (α=0.87), and depression subscale (α=0.90).

Scores for the short form-12 (SF-12) Mental and Physical Component Summaries were collapsed into a 3-category variable; a score of 1 indicated comparatively poor mental or physical health, 2 indicated average mental or physical health, and 3 indicated comparatively good mental or physical health. The items used in the SF-12 demonstrated high internal reliability (α=0.91). In looking at the mental health component 18% of patients received scores indicating comparatively poor mental health, 60% scored with average mental health and 23% scored with higher than average mental health. Looking at the physical component, 18% of the

sample received scored indicating comparatively poor physical health, 59% scored with average physical health, and 22% scored with higher than average physical health.

Table 6.2: Aim 2a sample health characteristics

N=249	n	%
Self-Rated Health		
Good+	37	17
Fair	61	28
Poor	123	56
Experience physical harm (30 days)		
Yes	6	3
No	205	97
Experience physical harm ever		
Yes	24	11
No	197	89
Experience sexual abuse (30 days)		
Yes	3	1
No	208	98
Experience sexual abuse ever		
Yes	5	2
No	206	98
Troubled by psychological problems (30 days)		
Not at all	154	77
Slightly	3	1
Moderately	6	3
Considerably	5	2
Extremely	33	16
Accomplish less as a result of emotional problems		
Yes	105	47
No	116	53
Did work less carefully as a result of emotional problems		
Yes	98	44
No	123	56
HSCL-25 cutoff		
Depression	112	45
Anxiety	99	40
General Mental distress	103	41
SF-12		
Below average mental health	44	18
Average mental health	147	60
Above average mental health	58	23
Below average physical health	46	18
Average physical health	146	59
Above average physical health	57	23

Drug use characteristics of the sample are presented in Table 6.3. At the time of completing the baseline survey 99% of the sample reported heroin use in the past 30-days. The majority of respondents (98%) report that treating their drug problems is extremely important to them. Using a seven-item measure of substance dependence, 56% of patients score a 7 (out of 7). This seven-item scale was found to have high reliability (α=0.89), and data were normally distributed. Median heroin use was 10 years, with a range of 0 to 31 years. For lifetime heroin use skewness is considered not seriously *violated.* The primary substance of use in the sample population was heroin, with cannabis being reported as the secondary substance of use for 58% of the population.

Patients were asked five questions to capture their injection risk behaviors. A small proportion of the sample (14%) engaged in flashblood (in which a user injects a full syringe of blood into themselves donated by someone who has recently injected heroin into their bloodstream), while 21% reported sharing needles at their last injection and 22% reported sharing any injection equipment at their last injection. These items are not intended to be used as a scaled measure and demonstrate low internal reliability (α=0.24). Measurement tools for the HSCL-25, injection risk behaviors, and substance dependence are presented in Appendix H: Substance Dependence, Appendix I: Supplementary Tables Chapter 5, and Appendix J: Supplementary Tables Chapter 6.

Table 6.3: Aim 2a sample drug use characteristics

N=249	n	%	Mean	Median	s.d.
Injection risk behaviors					
Injected drugs in last 12 months	207	95			
Ever used flashblood	30	14			
Shared syringes	46	21			
Shared injection equipment	48	22			
Doesn't clean syringes	13	6			
Heroin use past 30 days					
Yes	202	98			
No	4	2			
Substance Dependence			4.55	7	3.22
Lifetime heroin use (years)			11.28	10	6.56
Primary substance of use					
Heroin	192	92			
Alcohol	7	3			
Methadone	9	4			
Cocaine	1	1			

Details about patient characteristics in respect to clinic attendance are presented in Table 6.4. The sample's attendance was moderately good, with 64% of visits kept. The average methadone dose received was 90.48 mg/day, with a range of 0 to 382 mg. At the time of survey patients had been attending the methadone clinic for between 0 and 5 years, the median time at the clinic was 4 years.

Table 6.4: Aim 2a sample clinic attendance characteristics

	Mean	Median	s.d.
Proportion of visits kept	0.64	0.93	0.44
Average methadone dose	90.48	86.71	86.12
Time at methadone clinic (in years)	3.78	4	1.21

Summary: Descriptive analysis

Data on patient characteristics show commonalities in relation to patient demographics. The majority of the patient population is male, married and live with either a family member or partner. Patients are similar in relation to education and employment, with the majority of patients having finished primary school and engaged in elementary occupations. Most patients

have spent the past 3 years unemployed and spend a considerable amount on drugs in relation to their incomes. The majority of patients report poor health, and also report they are not troubled by psychological problems. While there are some indications of depression and anxiety in the sample, measures indicate patients that the majority of patients have average physical and mental health. All patients in the sample have engaged in some injection risk behaviors, the majority meet criteria of substance dependence, and have been using heroin for about a decade. Overall patients at the methadone clinic receive high methadone doses, have been at the methadone clinic for multiple years, and have kept the majority of their visits in the last year.

Bivariate Statistics

To test for any statistically significant associations between various patient characteristics, which might be indicative of collinearity, bivariate analyses were conducted. A correlation matrix for these variables is presented in, Appendix J: Supplementary Tables Chapter 6, Table 9.3. Age was collapsed into a 3-category variable; 20-34, 35-44, and 45+. Fisher's exact test was done to account for small cell sizes. This test compares means of the same variable between two groups, statistically significant results indicate that the difference in means between groups is statistically significantly different from 0. A significant association was found between age and marital status, indicating that there is not equal likelihood relating to the distribution of marital status by age. Significant relationships were also observed between sex and employment history, indicating that there is not an equal distribution of employment history by sex, and between sex and patient status. Bivariate results also showed a significant association between categories of education and referral community based organization (CBO). For patient status, I observed significant associations between status (Active/Not-Active) and the importance of drug treatment. These data indicate that there is a statistically significant mean difference in the

importance of drug treatment by status. However, because of zero cell issues this association will not be used in further analyses. These bivariate results are presented in Table 6.5, Table 6.6, Table 6.7 and Table 6.8.

Table 6.5: Bivariate associations between age and marital status using Fisher's exact t-test

	20-34	35-44	45+	Total	Statistic
Marital Status					p=.001
Married	55	124	17	196	
Not married	5	33	13	51	

Table 6.6: Bivariate associations between Employment and Sex using Fisher's exact t-test

	Male	Female	Total	Statistic
Employment over past three years				p=0.000
Unemployed	152	16	168	
Other	12	13	25	

Table 6.7: Bivariate associations between education and referral CBO using Fisher's exact t-test

	Blue Cross	CHRP	Kimara	Yovaribe	Total	Statistic
Education						p=0.001
No education	11	4	4	3	22	
Primary	50	21	27	31	129	
Secondary	10	26	15	9	60	

Table 6.8: Bivariate associations between importance of drug treatment and patient status using Fisher's exact t-test

	Active	Not-Active	Total	Statistic
Importance of drug treatment				p=0.006
Not at all/Moderately	0	4	4	
Extremely	108	93	201	

Using the HSCL-25 cut-offs described previously a significant relationship was found for those who met the cutoff for depression and usual occupation. There were also significant

relationships between the anxiety scale and measures of physical and mental health using the Short-Form-12. Additionally, using the Short Form-12 (SF-12) categories described in Chapter 5, Fisher's exact test of association indicated significant associations between the 3 category Mental Component Summary of the SF-12 and marital status as well as between the 3 category Physical Component Summary and self-rated health. Significant relationships were also seen between self-rated health and employment. These results are presented in Table 6.9, Table 6.10, Table 6.11, Table 6.12, Table 6.13 and Table 6.14.

Table 6.9: Bivariate associations between occupation and depression using Fisher's exact t-test

	Depressive case	Non-depressive case	Total	Statistic
Occupation				p=0.001
Elementary	48	83	131	
None	32	16	48	
Other	11	16	27	

Table 6.10: Bivariate associations between anxiety and mental health

	Average mental health	Comparatively poor mental health	Comparatively good mental health	Total	Statistic
Anxiety Case					p=0.027
Anxiety	49	19	31	99	
No anxiety	98	25	27	150	

Table 6.11: Bivariate associations between anxiety and physical health

	Average physical health	Comparatively poor physical health	Comparatively good mental health	Total	Statistic
Anxiety Case					p=0.014
Anxiety	53	14	32	99	
No anxiety	93	32	25	150	

Table 6.12: Bivariate associations between marital status and mental health

	Average mental health	Comparatively poor mental health	Comparatively good mental health	Total	Statistic
Marital Status					p=0.05
Married	123	30	43	196	
Not-Married	24	14	15	53	

Table 6.13: Bivariate associations between self-rated health and physical health

	Average physical health	Comparatively poor physical health	Comparatively good physical health	Total	Statistic
Self-Rated Health					p=0.000
Good+	21	0	16	37	
Fair	49	1	11	61	
Poor	76	45	2	123	

Table 6.14: Bivariate associations between Employment and Self-rated health using Fisher's exact t-test

	Good+ Heath	Fair Health	Poor Health	Total	Statistic
Employment over past three years					p=0.016
Unemployed	24	49	91	165	
Other	8	2	15	25	

To examine significant relationships between continuous variables, bivariate regressions were conducted. A correlation matrix for these variables is presented in Appendix J: Supplementary Tables Chapter 6, Table 9.4. These regressions indicate that patients aged 35-44 are significantly more likely to have been enrolled at the methadone clinic longer than their younger counterparts. Significant relationships are observed between patient status (active/not-active) and time enrolled at the methadone clinic, indicating that patients who are active have been enrolled at the methadone clinic for less time than those who are no longer active. There was also a significant relationship between patient status and mean methadone dose. Patients who are active were significantly more likely to receive a higher methadone average dose than

those who are not active. Lastly there was a significant relationship between sex and income, with female patients reporting lower income compared to male patients. These results are presented in Table 6.15, Table 6.16, Table 6.17 and Table 6.18

Table 6.15: Bivariate regression between time enrolled at the methadone clinic and age

	Co-efficient	se	p-value	95% CI	n
Age					247
35-44	0.52	0.26	0.04*	(0.01, 1.03)	
45+	$-2.91*10e^{-15}$	0.38	1	(-0.75, 0.75)	

Table 6.16: Bivariate regression between time enrolled at the methadone clinic and patient status

	Co-efficient	se	p-value	95% CI	n
Patient Status					247
Active	-0.45	0.15	0.003*	(-0.75, -0.15)	

Table 6.17: Bivariate regression between average methadone dose and patient status

	Co-efficient	se	p-value	95% CI	n
Patient Status					204
Active	112.97	9.98	0.00	(93.27, 132.67)	

Table 6.18: Bivariate regression between sex and income

	Co-efficient	se	p-value	95% CI	n
Sex					
Female	-336.69	101.63	0.001	(-537.32, -136.08)	173

IMAT vs non-IMAT patients

To understand what patient characteristics might impact intervention enrollment specifically for the target population (seropositive people who inject drugs) differences between IMAT and non-IMAT patients were examined. In this aim, active patients are those who enrolled onto IMAT, while non-active patients are those who did not enroll onto IMAT. The methadone clinic at Muhimbili has been operating since 2011. At time of data collection, clinic records indicated that 249 of the 1045 (24%) patients enrolled at the methadone clinic are HIV positive,

thus this is potential pool for IMAT. Only 137 of these 249 patients kept their active status going into IMAT; 67 have defaulted, 46 have died, 2 have graduated and 1 has been discharged. Since the IMAT intervention began, 133 of 137 patients remained active, and 4 defaulted.

Independent group t-tests, and chi-square tests were conducted to examine significant differences between IMAT patients (active) and those who left the methadone clinic and never participated in IMAT (non-active) across a range of continuous and categorical variables. Patients enrolled in IMAT are not different from patients who left the methadone clinic and never enrolled in IMAT in respect to their referral CBO, district of residence, physical/mental health measures, or scores of depression and/or anxiety. There were no differences between the two groups in regard to usual occupation, sex risk behaviors, or drug risk behaviors. The majority of respondents for both groups report poor health, and do not differ significantly in age, number of children, income from employment, substance dependency, anxiety, or number of friends who also use drugs.

Significant differences were found, however, between IMAT patients, and those who left the clinic in regard to time enrolled at the methadone clinic, importance of drug treatment, having a CD4 test record, and having an HIV test record. These differences are presented in Table 6.19. IMAT patients have been enrolled at the methadone clinic for a shorter amount of time, compared to non-IMAT. IMAT patients are more likely to think of drug treatment as important compared to non-IMAT patients, they are also more likely to have a record of a CD4 and HIV test compared to non-IMAT patients.

Table 6.19: Significant bivariate differences between IMAT vs Non-IMAT patients

	n or Mean (Non-IMAT patients)	n or Mean (IMAT patients)
Time at the methadone clinic	4.02	3.57 *
Importance of drug treatment	97	108*
CD4 test record	114	133**
HIV test record	114	133**

* $p < 0.5$
** $p < 0.001$

To examine which patient characteristics might be related to IMAT enrollment a forced entry logistic regression was fit with all candidate variables in Table 6.19. However due to small sample sizes related to drug treatment (only 4 patients responded drug treatment was not extremely important) it was left out of the analysis. Results of this regression are presented in Table 6.20 and indicate that HIV test record, CD4 tests record and time enrolled at the methadone clinic are significantly related to patient enrollment in IMAT.

Table 6.20: Forced logistic regression on Patient Characteristics related to IMAT enrollment

n=215	Co-efficient	OR (95% CI)	p-value
HIV test record	3.90	49.48 (9.58, 255.29)	0.000
CD4 test record	4.31	74.64 (15.81, 352.32)	0.000
Time at methadone clinic	-1.27	0.28 (0.155, 0.501)	0.000
Goodness of fit χ^2	13.14		0.52
Hosmer-Lemeshow χ^2	7.46		0.38
Pseudo R^2		0.77	

For patients with a recorded HIV and CD4 tests, the log odds of participation in IMAT increases by 49.48 and 74.64 respectively. Time enrolled at the methadone clinic was also found to be statistically significant indicated that for patients with a one unit increase in the time enrolled at the methadone clinic, the log odds of participation in IMAT decreases by 0.28.

Summary of key findings: Aim 2a

Patient characteristics indicate that IMAT and non-IMAT patients are similar across a range of demographic and health characteristics. Significant differences between seropositive methadone clinic patients who enrolled on to IMAT, and those that did not included, having a CD4 test record, and having an HIV test record. These factors are related to the IMAT intervention which sought to integrate those patients, and therefore these significant differences are expected. Time enrolled in care at the methadone clinic was also found to be significant, suggesting that the longer patients are enrolled at the clinic the less likely they are to be active.

Aim 2b

Aim 2b of this dissertation examines the relationship between patient characteristics and patient attendance for the 6-months prior to intervention (pre-) implementation, and for the 6 months following intervention (post-) implementation. As modeled in Chapter 4, Aim 2b seeks to understand how implementation and fidelity processes might mediate the relationship between patient characteristics and patient outputs. In this aim implementation and fidelity processes that are examined include intervention delivery, and degree of integration. The patient output under consideration in this aim is patient attendance at the methadone clinic.

Patient attendance at the IMAT clinic was examined to see if participation in the IMAT intervention impacted patient attendance patterns. Analyses included the 137 patients enrolled in IMAT during the first 6 months of the intervention. Attendance at the clinic was compared between March 1, 2015 and March 31, 2016—the IMAT intervention's start date was October 1, 2015, resulting in up to 397 observations per patient.

A bivariate multilevel mixed-effects logistic regression was conducted for Aim 2b to see if there was an impact of the intervention on attendance. The unit of analysis here is daily visits.

The results of this model are presented in Table 6.21 and indicates that the subject-specific log-odds of attendance increased after intervention implementation.

Table 6.21: Bi-variate multilevel mixed-effects logistic regression intervention and attendance

n=54,389	Co-efficient	OR (95% CI)	p-value
Intervention	0.745	2.10 (1.9, 2.27)	0.000
AIC	16554.54		
BIC	16580.68		

To examine the potential impact of patient characteristics and intervention factors might impact this patient participation a multivariate multilevel mixed-effects logistic regression was fit with covariates. Previous research at the methadone clinic found that sex and dose of methadone received were significantly associated with attendance at the methadone clinic. These data show that those who received less methadone were less likely to attend the clinic, and female methadone clinic clients were also found to have lower likelihood of attendance compared to males (Lambdin et al., 2014; Saleem et al., 2015; Zamudio-Haas, Mahenge, Saleem, Mbwambo, & Lambdin, 2016). These analyses were conducted on the entire sample of methadone clinic patients, and not just those who are HIV positive. These variables were chosen for inclusion in the final model to be consistent with previous research conducted at the methadone clinic. Degree of intervention integration, as described in Chapter 5 was also included in the model to understand the impact of the intervention on patient participation, as described in the conceptual model.

I first examined associations between these variables. A correlation matrix is presented in Appendix J: Supplementary Tables Chapter 6, Table 9.5, all correlations were found to be low. Degree of intervention integration was found to be significantly associated with sex, where female patients are significantly less likely to be fully integrated compared to the male counterparts. A significant relationship was found between degree of integration and average

methadone dose. Partially and minimally integrated patients received a significantly lower average dose compared to fully integrated patients. There was no significant relationship observed between sex and average methadone dose. These results are presented in Table 6.22, Table 6.23, and Table 6.24.

Table 6.22: Bivariate association between degree of intervention integration and sex

n=54,389	Co-efficient	s.e	p-value
Sex			
Minimal	-0.1	0.01	0.000

Table 6.23: Bivariate association between degree of intervention integration and average methadone dose

n=54,007	Co-efficient	s.e	p-value
Degree of integration			
Partial	-52.75	0.89	0.00
Minimal	-20.29	0.90	0.000

Table 6.24: Bivariate association between sex and average methadone dose

n=53,992	Co-efficient	s.e	p-value
Average methadone dose	-0.0002	.0000	0.15

Following this I ran bivariate regressions examining the relationship between average methadone dose, sex, and degree of integration on attendance. Bivariate regressions looking at these variables indicate that minimally integrated patients have significantly lower attendance than fully integrated patients, and patients with higher methadone doses have better attendance than those with lower methadone doses. Effects of sex were not found to be significant. These results are presented in Table 6.25, Table 6.26, and Table 6.27.

Table 6.25: Bi-variate multilevel mixed-effects logistic regression degree of integration and attendance

n=54,389	Co-efficient	OR (95% CI)	p-value
Degree of integration			
Partial	-1.25	0.28 (0.06, 1.32)	0.110
Minimal	-1.63	0.19 (0.04, 0.91)	0.037

Table 6.26: Bi-variate multilevel mixed-effects logistic regression sex and attendance

n=54,389	Co-efficient	OR (95% CI)	p-value
Sex			
Female	-0.67	0.51 (0.11, 2.46)	0.402

Table 6.27: Bi-variate multilevel mixed-effects logistic regression Average methadone dose and attendance

n=54,389	Co-efficient	OR (95% CI)	p-value
Average methadone dose	0.01	1.01 (1.01, 1.02)	0.000

Each variable was introduced into a multivariate mixed-effects logistic model to understand the potential inclusion effects. The three models are presented in Table 6.28. Between Model 1 and Model 2 the magnitude of the effect of degree of integration on attendance becomes larger after the inclusion of sex in the model, however the effect of the intervention on attendance is not impacted. After the inclusion of average methadone dose with Model 3 the magnitude of the effect of sex and degree of integration decreases.

Table 6.28: Multivariate mixed-effects logistic models on clinic attendance

	Model 1			Model 2			Model 3		
	Co-efficient	s.e	p-value	Co-efficient	s.e	p-value	Co-efficient	s.e	p-value
Intervention	0.76	0.04	0.00	0.76	0.04	0.00	0.76	0.04	0.00
Integration									
Partial	-1.30	0.66	0.05	-1.38	0.66	0.04	-0.86	0.63	0.17
Minimal	-1.73	0.70	0.01	-1.77	0.70	0.01	-1.57	0.64	0.01
Sex									
Female				-1.03	0.70	0.14	-0.96	0.64	0.13
Average methadone dose							0.01	0.00	
N	52,404			52,404			52,007		
AIC	20265.42			20265.89			20238.34		
BIC	20309.75			20319.09			20300.36		

Following this I ran a model with interactions to see if it accounted for any of the suppression/amplification effects. Likelihood ration test indicated the model with interactions was a better fit than the one without (LR Chi2(12) =208.57, p=0.000). The results of the full covariate model with interactions are presented in Table 6.29. In the multivariate model, there is a significant positive effect for the subject-specific log odds of attendance as a result of the intervention as well as a significant positive effect for the subject-specific log odds of attendance as a result of average methadone dose. There is a significant negative effect seen for the interaction between intervention and degree of intervention (for minimally vs. fully integrated patients), as well as for the interaction between intervention and sex. We also observe a significant positive effect for the subject-specific log odds of attendance as a result of the interaction between intervention, integration and sex.

Table 6.29: Multivariate mixed-effects logistic regression on IMAT patient attendance

n=44,861	Co-efficient	OR (95% CI)	p-value
Intervention	1.01	2.74 (2.41, 3.11)	0.000 *
Degree of Integration			
Partially integrated	-1.19	0.30 (0.05, 1.76)	0.184
Minimally integrated	-1.66	0.19 (0.03, 1.02)	0.052*
Intervention x Degree of integration			
Post-intervention x Partially integrated	0.35	1.42 (1.12, 1.78)	0.003
Post-intervention x Minimally integrated	-1.04	0.35 (0.28, 0.43)	0.000 *
Sex	-1.53	0.22 (0.04, 1.31)	0.96
Intervention x Sex			
Post-intervention x Female	-0.40	0.67 (0.54, 0.83)	0.000 *
Degree of integration x Sex			
Partially integrated x Female	1.54	4.70 (0.03, 657.86)	0.539
Minimally integrated x Female	3.32	27. 54 (0.37, 203.90)	0.131
Intervention x Degree of integration x Sex			
Post-intervention x Partially integrated x Female	1.30	3.67 (1.85, 7.32)	0.000*
Post-intervention x Minimally integrated x Female	-0.05	0.95 (0.56, 1.61)	0.839
Average Methadone Dose	0.02	1.01 (1.00, 1.02)	0.003*
AIC	20043.77		
BIC	20167.8		

To better understand the interactions in this model I used marginal effects to compare the pairwise predicted probabilities for patients using Bonferroni's adjustment to account for multiple comparisons. The significant contrasts are presented in Table 6.30. The predicted probability of attendance for two hypothetical patients with average values on all other covariates, is 0.78 1 higher after IMAT implementation, compared to prior to IMAT implementation.

For the interaction between intervention and degree of integration, the predicted probability of attendance is 0.81 higher for fully integrated patients after IMAT implementation compared to before IMAT implementation. The predicted probability of attendance for partially integrated patients is 1.81 higher post-IMAT intervention compared to prior to IMAT implementation. Looking at the interaction of intervention and sex results indicate that the predicted probability attendance for males is 0.78 higher after the intervention compared to before. Females also have a significant positive predicted probability (0.79) of attendance post-intervention implementation compared to pre-intervention implementation.

There are also significant results for the predicted probabilities in the three-way interaction between intervention, integration and sex. The predicted probability for fully integrated male patients 1.01 higher after IMAT implementation compared to before IMAT implementation. For fully integrated female patients after IMAT implementation, the probability of attendance is 0.60 higher compared to prior to intervention implementation. For partially integrated male patients, the predicted probability of attendance is 1.35 higher post IMAT-implementation compared to prior to intervention implementation. Partially integrated female patients also have a higher predicted probability of attendance post-IMAT implementation, compared to prior to intervention implementation, of 2.26.

Pairwise predicted probabilities looking at degree of integration were not significant, indicating that the predicted probability of attendance is not significantly different by degree of integration. The predicted probabilities of attendance by sex were not significant, indicating that the predicted probability of attendance is not significant different by sex.

Table 6.30: Predicted probabilities of patient attendance

	Contrast	Std. Error	p-value
Intervention			
Pre-Intervention vs Post intervention	0.78	0.07	0.000
Intervention x Degree of integration			
Post-intervention/ Fully integrated vs. Pre-intervention/ Fully integrated	0.81	0.05	0.000
Post-intervention/Partially integrated vs. Pre-intervention/Partially integrated	1.81	0.17	0.000
Intervention X Sex			
Male Post-intervention vs Male Pre-intervention	0.78	0.05	0.000
Female Post-intervention vs Female Pre-intervention	0.79	0.13	0.000
Intervention x Integration x Sex			
Post-intervention/Fully Integrated/Male vs Pre-intervention/Fully Integrated/Male	1.01	0.06	0.000
Post-intervention/Fully Integrated/Female vs Pre-intervention/Fully Integrated/Female	0.60	0.08	0.000
Post-intervention/Partially Integrated/Male vs Pre-intervention/Partially Integrated/Male	1.35	0.09	0.000
Post-intervention/Partially Integrated/Female vs Pre-intervention/Partially Integrated/Female	2.25	0.32	0.000

Summary of key findings: Aim 2b

These data were used to document characteristics related to attrition and attendance. Results indicated improvements to attendance, but only for those patients who are fully or partially integrated onto IMAT. While there is an overall benefit to attendance from the intervention, there are no observed significant differences in pre/post intervention attendance for minimally integrated patients.

Chapter 7: Results Aim 3

The qualitative approach for Aim 3 was used to understand how the people involved with the intervention—patients and providers—feel about the intervention and if their feelings impact implementation. Qualitative data collection was conducted through semi-structured, in-depth individual interviews with a purposeful sample of patients (n=35) and providers (n=8) at the methadone clinic involved in the IMAT intervention. These qualitative data were also used in combination with provider survey data to obtain providers' perspectives regarding patient needs and resources, available clinical resources, compatibility, complexity, evidence, adaptability and relative advantage.

Aim 3a

In Research Aim 3a, based on both qualitative and quantitative data examines the relationship between provider perspectives and implementation characteristics. Provider interviews were examined using the implementation characteristics described in Chapter 3 to help examine factors related to implementation outcomes. Information on provider attitudes towards innovation, their perceived control in implementing intervention, clarity regarding intervention procedures as well as information around organization culture and capacity was obtained through an adaptation of the Organizational Readiness to Change Assessment (ORCA) tool (Aarons et al., 2012; Helfrich et al., 2009).

Implementation Characteristics

Patient Needs and Resources

The ability of the intervention to be responsive to patient needs and resources contributes to implementation by fostering an understanding of the extent to which organizations provide tools and advice that are matched to patients' readiness to change. It also allows the program to

be tailored to the patient population. Providers felt that the ability of the clinic to understand the needs and barriers of IMAT patients had an overall positive influence on implementation effectiveness. This was mainly due to beliefs that the intervention was created with patient needs specifically in mind and was created to better serve them. Prior to the intervention, it was difficult for patients to initiate, obtain and adhere to HIV/AIDS care and services. The providers at the clinic are very aware of what patients' needs are and the limitations regarding the resources they have. They seem to do the best they can to adapt to patient needs, but there are some outstanding limitations that have not been addressed by the intervention and may negatively impact implementation.

> *The program is for the targeted group, these people are at risk. The drug users are at an increased risk of getting HIV so it is okay for this program to have the HIV services included in it. It is not okay to separate HIV services from this program. (Administrator)*

Available Resources

Provider interviews indicated that the level of resources dedicated to implementation—physical space and time—had an overall negative influence on implementation effectiveness. Some providers also mentioned that they needed technical resources like a viral load machine to adequately monitor patients. Providers at the clinic felt they did not have the proper human resources to carry out all intervention procedures. All providers mentioned that there were some features of the intervention that made it easier to implement, but, they also felt that the intervention increased their workload, for no staff were allocated to alleviate the additional work load. Providers also mentioned that the lack of space and the fact that there are some components of the intervention that limit the independence of the clinic, such as the need to use the care and

treatment clinic (CTC) to register patients receiving ARVs, inhibited implementation effectiveness.

> *We also wished to be able to open the cards and do the registration right here but there were complications that were explained by the hospital management. They told us that the registration number must come from the care and treatment center. There are things that I wish were here for the IMAT program to function ideally. It would have shortened the time and the services would have been run smoothly for clients. We can see it in the clients' faces when we inform them that they have to go to the care and treatment center or go to the pharmacy for counseling, they don't like it and one may give an excuse that he has not time for it on that day. It would have been easier if everything was done right here. Those are the things that are challenging us. (MD)*

Compatibility

Even with limitations in regard to resources and resource availability, providers at the clinic felt that the intervention procedures were easily incorporated into the clinic, and that familiarity with patients contributed to workflow. Overall these had a strong positive influence on implementation effectiveness. The appropriateness of the intervention to the setting and patient population had a positive influence on implementation. This is largely due to the stigma that PWID face, making it hard for them to receive care elsewhere. The patients at the IMAT clinic do not face the same stigma and providers are more welcoming to them, which means that the providers are more aware of patients' needs, can monitor patient care, and implement procedures in a way that is more connected to the target population. The providers also felt like it was easy for them to incorporate intervention procedures into existing workflows and systems at the clinic.

There is no gap because everybody has their own role to play. As a social worker, I know my roles at the clinic, the doctor knows his roles too. There are points in which I must consult the doctor or the nurse on duty. We can discuss about what to do on certain issues that may arise. We maintain confidentiality because it is very important. We can disclose some issues to the team members as we all work in the interest of the clients. As you have seen the one whom you wanted to interview about HIV issues, he was talking in a low tone but his voice came out after I have introduced you to him. They know that we work as a team. (Social Worker)

Complexity

While the providers did mention that the IMAT intervention has many steps, they felt that the complexity of the intervention did not seem to impact implementation effectiveness positively or negatively. Providers had mixed views about the impact of complexity on intervention implementation. To some of the providers, the many steps involved in the IMAT intervention make care delivery easier, and others mentioned some procedures of the intervention that made it more difficult, at least, to initiate care. While the providers did mention that there were many steps involved in the intervention, and some of these steps were highly technical and difficult there did not seem to be a large impact on intervention implementation.

Evidence

In the sixth months since intervention implementation, the providers felt they had already observed improvements in patients' health which lead them to believe in the intervention's effectiveness. The providers interviewed pointed to patient responses to care as evidence for the effectiveness of the intervention. Evidence supporting the use of an intervention is used by

providers to build a case for supporting implementation, as evidence for or against an intervention may make them more or less likely to adopt it. From these early improvements, the providers felt confident in the intervention, with an overall feeling that it was effective, resulting in a positive influence on implementation effectiveness.

> *Eeeh The goal has been reached. Many clients are on medications now as compared to the past. Many would have ended on the way if they had to go there for services but going there would have been so helpful to them if they were adhering. This has helped them because many of them are on taking the medications now. (Pharmacist)*

Adaptability

The providers interviewed felt that elements of the intervention can be adapted easily to meet the needs of IMAT patients, which had a strong positive influence on implementation effectiveness. Providers involved in the IMAT intervention felt that the ability of the intervention to be adapted to patient needs was very important. They spoke about this aspect most frequently in regard to medication dispensing, which they felt was essential to improving patient adherence. Providers also felt the procedures of the intervention could be easily absorbed into pre-existing clinic procedures, an adaptability important to figuring out different providers' roles and the details regarding implementation.

> *So I can say that there are points where we have to diverge from the IMAT principles but it is explainable. There are a few of us so things have to be done in that way. The tests are ran in the afternoon and the nurses prioritize patients let's say those who had fewer CD4 counts were given a priority when we were using the CD4 counts category for initiating treatment.*
>
> *I: Mmh*

R: So they prioritize clients, those who need to be seen by clinicians and those who can wait. (MD)

Relative Advantage

Interviews with providers indicated that the benefits of the intervention compared to continuing care as usual, was a strong positive influence on implementation effectiveness. Overall, the providers felt the IMAT intervention resulted in a strong relative advantage to the alternative solution (non-integrated care). Providers all felt, even in just the six months post-intervention implementation, that patient adherence had markedly improved. Many of the providers also felt the IMAT procedures simplified and stream-lined their responsibilities and gave them the tools and resources they needed to provide care.

It is not only one client, I remember so many clients. There were so many patients who were running and so there was a delay in getting their blood samples for CD4 counts. This program has made it easy for us; we take the blood samples directly from the clients. We will do the other baseline investigations if the CD4 counts are found to be very low and we would call the doctor to start that specific client on therapy. The procedures used to take so long in the past and there were no special doctors for that group of clients. It is easier now because I can just call the doctor because there is a specific doctor for that and he can start the therapy. (Nurse)

Organizational Readiness to Change Assessment

The Organizational Readiness to Change assessment (ORCA) was administered to obtain information on how the eight providers at the clinic view the acceptability and feasibility of the intervention, as well as other factors that contribute to or hinder implementation.

Provider Readiness to Change

Providers felt that there was either strong or very strong evidence to support the IMAT intervention's ability to improve outcomes for HIV positive PWID at the methadone clinic. Providers also agreed that substantial scientific evidence had been considered in designing the IMAT intervention, and which suggested its likelihood for effectiveness. Regarding patient acceptability, consideration of patient needs/preference, and apparent advantages vs. disadvantages for patients, IMAT providers strongly agreed that the IMAT intervention appealed to these metrics. Some providers disagreed that clinical innovation was rewarded at the IMAT clinic, but they felt that overall the clinic environment was receptive to innovation and changes in the clinical care process.

Interestingly most of the providers responded that they "did not know" regarding questions of allocating adequate resources in terms of budget, training, facilities and staffing for changes that happen at the clinic. One provider strongly disagreed that when changes in the clinic happened adequate staffing resources were made available. Providers agreed and strongly agreed that leadership at the MAT clinic took into consideration the appropriateness/feasibility, had clear goals, developed a project schedule and deliverables and designated a clinical champion for the IMAT intervention. Providers overall felt that leadership regarding the IMAT intervention had agreed on goals, was well informed and involved in IMAT, set a high priority for IMAT and agreed on the necessary resources.

While providers agreed and strongly agreed that team members shared responsibility for the success of the project and had clearly defined roles, some providers disagreed in terms of staff members' abilities to get release time or to complete IMAT tasks within their regular work load, and that there was staff support and other resources available to complete IMAT. Providers

also agreed that there was good project communication to identify specific roles and responsibilities, to clearly define tasks and timelines, to include provider/patient education and to acknowledge staff input and opinions. In terms of resources available to providers to make IMAT work, two providers strongly disagreed, two providers disagreed, and two providers strongly agreed respectively that appropriate staff incentives and provider buy in was available. In terms of equipment one provider disagreed, while the others either agreed to strongly agreed that it was adequately available for IMAT. In terms of patient awareness/need, and the intervention team and evaluation protocol, providers either agreed or strongly agreed that these resources were available to make IMAT work.

Aim 3b

To understand how patients enrolled in the IMAT intervention think about and experience the intervention Aim 3a examined the relationship between patient perspectives and patient outputs. Data in this aim gives insight into idea of service utilization and patient responsiveness.

Patient Interviews

ARV dispensing

A key component of the IMAT intervention is the ability to receive antiretroviral medication (ARV) at the methadone clinic directly. The majority of patients interviewed felt that receiving their medication at the clinic was a benefit and helped them engage in and adhere to care. Patients enrolled in IMAT can receive their ARVs in the clinic, or may be able to receive monthly take home doses. Patients who received their ARVs in the clinic felt that this was beneficial because it helped them adhere to treatment, ensured they took their medication daily,

and was an overall easier experience because they were able to receive multiple forms of care in one place. As one patient explained:

> *It is better to take them here because you may ignore them at home. You are sure of taking your medications if you are taking them here because you must come for methadone. You will pass there if you take methadone. It is easier. (Male IMAT patient)*

Some patients saw a benefit in being able to take medication at home. This was commonly because of the physiological responses to both methadone and ARVs. Patients expressed interest in being able to take their ARVs at home so they could take them with food, take them and be able to rest, or take them and be better able to deal with any side effects, a perspective expressed by a patient:

> *I: Mmh, why should it be changed that you should be given the medications to take at home?*
>
> *R: You will have enough time at home. You get feel dizzy when you take methadone and it gets worse when you take the ARVs. It is different if you get them to take at home because you can have time to rest and eat before taking the ARVs. (Female IMAT Client)*

Patient barriers

In regard to receiving care, patients did comment on some challenges. Patients felt that the clinic did not have all the resources and infrastructure necessary to meet the needs of all patients. Patients check in and receive their methadone at a dispensing window at the clinic. Only two pharmacists at a time can dispense medication and it is common to have long lines during operating hours, a situation described by a patient:

R: They should increase the number of pharmacists and the dispensing windows. There are four windows in Temeke. We should not stand in the queue for long; we should just get our medications and leave immediately. (Male IMAT patient)

Another patient commented that the time spent waiting at the dispensing window can have very serious repercussions for patients at the clinic.

R: I think there should be two windows where by one can get methadone even if he is late. This medication is so painful if it is missed. Denying someone of this medication is so bad. Others are not strong enough and they may go back to drugs. (Male IMAT patient)

Related to medication dispensing, the majority of patients interviewed expressed some difficulty have adequate and consistent nutrition. This is not surprising given that many of the patients at the clinic are unemployed and also experience issues related to stable housing. For patients on ARVs lack of nutrition can severely hinder their ability to engage in and adhere to treatment. As one patient described:

It is as I have told, how can I take methadone and the ARVs at the same time without taking food? I will fall down because both of the medications are strong. I am asking them to forgive me because you may hear that I have left their medications and have gone. (Male IMAT patient)

Stigma

Stigma was a common concern brought up by patients. Patients were glad that they had not felt stigmatization from providers at the methadone clinic, since they commonly had negative care experiences from outside providers who refused to provide care, or who treated them poorly due to their substance use. With integrating care, many of the HIV positive clients are worried

that their non-seropositive methadone clinic colleagues would find out their serostatus and begin talking about them. One patient compared this to a school environment:

I am still requesting for confidentiality between the clients and the doctors. This place is like a school and many people are bullying each other. (Male IMAT patient)

This type of stigma hinders implementation effectiveness because it can cause patients to disengage from care. The patient above continued, saying:

Others are weak and they may stop taking the medications because of that. I don't think if there will be such problems if confidentiality will be maintained. (Male IMAT patient)

Another client echoed this statement, and discussed how the stigma coming from other methadone clinic patients can dissuade people from taking medications and from fully engaging in HIV care and treatment.

There are some MAT members who are not infected and they like staying outside in groups, they tend to stigmatize those who are known to be taking the medications. Others don't like it and it becomes difficult for them to come and follow up on therapy. (Male IMAT patient)

Contrary to this there were many patients who did not feel a need to hide their serostatus or the fact that they were receiving HIV related care. Patients at the clinic were knowledgeable about HIV and the ways one can become seropositive, some felt that it was important to be open about their serostatus with the result that the threat of stigmatization did not hold weight for them.

I never hide my status. I just tell them openly that I am infected and all of this is God's plan. I don't care. Anybody can become infected. I have no time for anyone who will talk about it. Just trust me that is how I am. (Male IMAT patient)

For patients who were unconcerned about stigma their serostatus had become a normal aspect of life and they felt no shame around it—especially because many of the patients at the clinic are HIV positive. Drug use in Tanzania is highly stigmatized, which in many ways puts all of the methadone patients on equal footing regardless of their serostatus. As one patient describes it:

> *I: Have you ever been stigmatized or segregated here in the clinic because of your history of drug use?*
>
> *R: No, it has not happened in the clinic because all of us are coming from addiction except the service providers. We cannot laugh to each other because we know the challenges we face with addiction.*
>
> *I: What about stigmatization due to your HIV status?*
>
> *R: No, that is a very normal situation for me as I am not alone. About seventy percent of this project's clients are infected, only thirty percent is clear. These are normal things. (Male IMAT patient)*

IMAT response

Despite some challenges, patients enrolled in IMAT felt positively about the program overall. Many commented that IMAT made it easier for them, and streamlined the care process. They commented that the steps with IMAT were easier for them to follow.

> *I feel good because there are no circles in getting the medications. There are so many things to do in other hospitals. In here they just test you and start you on ARVs right away. Our doctor takes the medications for us. You just find your medications with him on your appointments. (Male IMAT patient)*

Patients also discussed the ways IMAT made it easier for them to receive care. The clinic environment in combination with the relationships they had with providers at the clinic provided a structure that has had a positive impact on intervention effectiveness. In the six months since IMAT implementation patients felt that they had already seen benefits to their health. On patient says:

> *I have an advantage on my health. My health has improved so mu8ch because I get all treatment at the same place. I am thankful for the providers because they are following us up closely. There are no disturbances when you get services at the same place. (Male IMAT patient)*

This sentiment was echoed by other patients at the clinic who felt that the structure and design of the IMAT intervention improved patients' ability to not just be given care, but to actually use and implement it. As one patient described IMAT:

> *They have created a new thing for us here; you take your ART right in the window after taking your methadone dose. That has helped us; it has helped me to live to this day. I was so stubborn; I never wanted to take the medications because I didn't believe that I was infected. You may have the tablets at home but may forget to take them. We are using Atripla which is one tablet dose per day so you take your tablet after the methadone dose. I am proud of methadone program because of that. They are really caring for us. (Female IMAT patient)*

Summary

In-depth interviews with providers 6-months post-implementation indicated that resources dedicated to intervention such as physical space and time presented a challenge to

implementation effectiveness, while the adaptability, incorporation of patient needs into IMAT and evidence for the effectiveness of the intervention had a positive influence on implementation effectiveness. Data from the ORCA echoed these sentiments as providers overall felt there was strong evidence to support IMAT implementation. Results from the ORCA also indicated some provider concerns regarding the allocation of sufficient resources to sufficiently carry out the procedures of the intervention. In both the ORCA and provider interviews, IMAT providers felt that the intervention appealed to patient needs and the intervention overall was accepted by IMAT patients.

IMAT patients felt the ability to receive ARVs in the clinic made it easier for them to receive care. Interviews indicate that IMAT improved care receipt, and streamlined the care process. In the clinic, the relationships with providers provided a structure, positively impacting intervention effectiveness. Patients identified challenges to implementation, such as lack of nutrition, which can severely hinder patient ability to engage in and adhere to treatment, as well as limitation regarding clinic resources. Patient interviews also indicated that some patients had concerns about stigma from their fellow patients, while others were not concerned about potential stigma regarding disclosure of the HIV and/or drug use status.

Chapter 8: Discussion

Introduction

The overall goal of this dissertation was to examine the implementation of an integrated antiretroviral therapy and methadone maintenance intervention in Dar es Salaam, Tanzania, that was initiated in 2015. To assess overall program feasibility, I investigated how the intervention's program components and procedures were experienced by patients and providers, the relationship between patient characteristics and intervention engagement, and patient and provider perceptions regarding the intervention. In this final chapter of the dissertation, the major findings are summarized and discussed, in relationship to overall research questions and address how findings support related literature, followed by an overview of the study's strengths and limitations. The chapter ends with a statement of conclusions, discussion of the public health implications of the study findings, and recommendations for directions for future research.

Summary of Major Findings

Clinic wait times

Results from Aim 1a indicate that providers spent a range of time with patients as a result of the intervention. Results from this aim also indicate that patients spend 40.12 minutes waiting on average, comprising a large amount of the visit process time. Patients who were observed waiting spent and saw a medical doctor had longer average visits than those who did not see a medical doctor, providing support for hypothesis H1 (H1: Patients who see a MD will spend more time waiting, in minutes, than patients who do not see a MD). While pharmacists saw the most patients (n=110) their interactions with patients are short, lasting for only about ½ a minute. The medical doctor saw fewer patients (n=4), but they spent an average of 22.5 minutes with

patients by comparison, supporting hypothesis H2 (H2: While MD will not see the largest number of patients, they will spend the greatest amount of time, in minutes, with patients).

Patients were observed spending a large amount of time in the methadone clinic waiting, much of this time spent waiting occurs at the beginning of their visits and between seeing different care providers. These long wait times at the methadone clinic may make adoption and penetration of the IMAT intervention difficult. While it remains unclear why patients spend a significant amount of time waiting for care at the methadone clinic, research indicating that decreasing undesirable states of care such as waiting time might improve patient access to care (Jacobson et al., 2006).

Providers at the methadone clinic are invested in serving as many patients as possible, however as the volume of patients increases, there is a need to focus on clinic efficiency. Visit patterns at the methadone clinic studied show similarities to other clinics in terms of bottlenecks and long wait times (Wanyenze et al., 2010). Prior research in SSA suggests that inefficient use of care providers' time can contribute to long wait times (Were et al., 2008). However, data from Aim 1 suggests that care providers at the methadone clinic both specialize and allocate their time. Time dedicated to patient-provider interactions depend on both the procedure and the provider. While the nurses that were observed appeared to provide more procedures to patients compared to doctors, the doctors were observed to have spent more time per patient. Patients were observed as spending an average of 58 minutes with a doctor, compared to 19.2 minutes with a social worker, and 10.15 minutes with a nurse. In examining the visit process from the perspective of patients and providers, there seems to be little overlap in the procedures delivered by type of provider. Results from Aim 1a indicate that efficiency at the methadone clinic might be improved through alleviating bottlenecks including redistributing appointment times

throughout the day, task-shifting and streamlining activities for doctors to reduce their appointment times.

Patient attendance

Aim 2b looked at factors related to patient attendance. While pure fidelity, in terms of strict adherence to the IMAT protocol and full integration for all patients, was not maintained, results from this dissertation indicated significant improvements in clinic attendance with the predicted probability of attendance for two hypothetical patients with average values on all other covariates, being 0.78 ($p < 0.001$) higher after IMAT implementation, compared to prior to IMAT implementation in support of hypothesis H9 (Patient attendance will improve after IMAT intervention implementation). Predicted probabilities indicate that improvements to attendance following the intervention are not impacted by degree of intervention integration or sex alone, which is not in support of hypotheses H10 and H11 (H10: Improvement in patient attendance will be higher for patients fully, H11: Male patient attendance will be higher compared to female IMAT patient attendance, post IMAT intervention implementation). Benefits to attendance do occur within sex and within integration group, such that the probability of attendance for both men and women improves post-intervention compared to pre-intervention, and the probability of fully and partially integrated patients improves post-intervention compared to pre-intervention.

Little research exists on retention in HIV care and treatment in the African context, and no research of which I am aware examines the HIV care cascade and treatment for seropositive people who inject drugs. Research in the United States has documented barriers related to injection drug use and ART receipt, however over time these disparities may decrease (Gebo et al., 2005; Lesko, Tong, Moore, & Lau, 2017). The methadone clinic at Muhimbili provides opportunity to examine longitudinal issues related to HIV care retention. Conceivably

seropositive PWID may consider the methadone clinic a place for long term care, as many patients have been receiving methadone at the clinic for multiple years. To better understand treatment decisions over time, researchers should develop contextual understandings of people's use and engagement with HIV care (Bolsewicz, Debattista, Vallely, Whittaker, & Fitzgerald, 2015).

Prior research in SSA has shown that a lack of connectedness to care, lack of provider trust and negative patient/provider interactions could be a barrier to ARV adherence for patients in sub-Saharan Africa (Gourlay et al., 2014; Ware et al., 2013). As improvements in clinic attendance were only seen for fully and partially integrated patients, the predicted probabilities in Aim 2b may be indicative of the intervention's impact related to these issues of connectedness to care, and patient/provider interaction for different kinds of patients. Reaching women who inject drugs has been a challenge for care providers in Dar es Salaam (Zamudio-Haas et al., 2016). This is particularly salient in relation to results from Aim 2b, which showed improvement to attendance for female patients after intervention implementation. For minimally integrated patients generally, we see no significant differences in probability of attendance post-IMAT implementation compared with before IMAT implementation. Taken together these results may suggest a limited impact on patients who do not get the complete intervention, which is especially relevant given the need to balance resources and efficiency in terms of care (Bruce, 2010; Ware et al., 2013).

Patient perceptions and issues of stigma

In-depth interviews with IMAT patients indicated that overall patients were satisfied with the intervention, and felt that the ability to receive HIV care and methadone treatment in one place streamlined care receipt. Patients expressed that the ability to receive ARVs in the clinic

made it easier for them to receive care. Patients identified challenges to implementation, such as clinic resources, consistent access to nutrition, and concerns about stigma from their fellow methadone clinic patients. Fear of inadvertent disclosure by accessing HIV care within an integrated setting has been previously reported in the literature (Saleem et al., 2015). However, there were patients enrolled onto IMAT who did not voice concerns about disclosure of their serostatus, and in fact were very comfortable disclosing their status to family and their fellow methadone clinic patients. Provider interviews did not point to issues related to stigma in the treatment and care of seropositive methadone patients. Prior to IMAT patients would be referred to a specialty HIV care and treatment clinic. Patients may have had fear around the inadvertent disclosure that could result if they were seen going to a specialty HIV care and treatment clinic. This issue is reflected in provider interviews which discussed the difficulty in getting patients to go to HIV care and treatment appointments for which they were referred.

Other study results

Intervention integration

Aim 1b examined what elements of the intervention were delivered to patients and how. Results from this aim indicated deviations in what was delivered to patients, compared to the study protocol indicating a lack of overall implementation fidelity. While patients were found to be integrated onto the IMAT intervention in varying degrees, this was not an intended outcome or part of the original IMAT model. Patients were coded as fully integrated if they (1) were linked to ARVs, (2) received their ARV medications and (3) received HIV lab work at the methadone clinic, partially integrated if they received two of these services at the methadone clinic, and minimally integrated if they only received one service at the methadone clinic. For patients enrolled onto IMAT 67% were found to be fully integrated, 17% partially integrated and

16% were minimally integrated. Engagement in flashblood and ARV regimen complexity was found to be negatively associated with degree of intervention integration ($p = 0.02$ and $p < 0.01$ respectively), providing support for hypotheses H3 and H5 (H3: Patients who engage in flashblood will have lower degrees of intervention integration compared to patients who do not engage in flashblood, H5: The more complex the regimen the greater the intervention integration). Scores on the Hopkins Symptom Checklist-25 (HSCL-25) for anxiety, depression and general mental distress were not found to be significantly related to degree of intervention integration, thus these data do not support hypothesis H4 (H4: Patients with Hopkins Symptom Checklist-25 (HSCL-25) scores indicative of depression will have lower degrees of intervention integration compared to). Variations in the degree to which patients are integrated into the intervention suggest that patient outcomes may ultimately be variable despite this not being an intended outcome of the intervention.

Results from Aim 1b show gaps in clinical care records that may or may not be indicative of gaps in clinical care. The recording of the clinical processes are themselves part of the intervention, so gaps in record keeping reflect a deviation from implementation fidelity. Lack of recorded intervention procedure can be considered lack of received intervention procedure even if patients received intervention procedures that were not recorded. Without the records, there is no way for other providers at the clinic to know this care was received, nor is there a way to progress a client through the intervention without these records. This is related to patient outputs as well as to general patient outcomes, for research indicates that delays in ARV receipt is associated with poor care engagement (Mugavero, Amico, Horn, & Thompson, 2013).

Patient characteristics linked to attrition

Patients in this population studied were by definition high risk and vulnerable. Analyses did show however that some patients were less likely to benefit from the establishment of the

integrated clinic in Mumbihili. Results from Aim 2a showed a range of commonalities between eligible patients who enrolled in IMAT and eligible patients who did not. The majority of patients are male, married and live with a family member or partner. Most patients have completed primary school, are engaged in an elementary occupation, and have spent the past three years unemployed. Patients report poor health, have no experiences of physical or sexual abuse and the majority report not being troubled by psychological problems. Approximately 40% of the sample meets cut offs for depression, anxiety and general mental distress, and approximately 60% score as having average mental and physical health. Patients have been using heroin for about a decade, and the majority meet clinical criteria for substance dependence. Differences between IMAT and non-IMAT patients were seen in relation to having a CD4 test record, and having an HIV test record ($p < 0.001$ for both) providing support for hypothesis H6 (H6: Patients with recorded HIV and CD4 tests are more likely to have a lower likelihood of attrition in IMAT compared to those without these records). Sex, age and average methadone dose was not found to be related to patient attrition, these results do not support hypotheses H7 and H8 (H7: Younger, female patients will have a lower likelihood of attrition compared to older male IMAT patients, H8: Patients who receive a lower average methadone dose will have a higher likelihood of attrition compared to those with higher average methadone doses).

As a health service model, methadone maintenance clinics can facilitate the improvement of health-related outcomes for patients and have proven to be a successful venue for treatment of infectious diseases such as HIV (Bachireddy et al., 2014; Kresina & Lubran, 2011; Lin, Li, & Cao, 2016; Lucas et al., 2006). Previous research in this population found age and dose of methadone received were negatively associated with attrition from the methadone clinic, meaning that older patients, and patients who get a higher dose of methadone have lower

attrition. Female methadone clinic clients were also found to have lower attrition compared to males, and clients with a history of sexual abuse had a higher likelihood of attrition (Lambdin et al., 2014). This previous research was done on the entire sample of methadone clinic patients, and not just those who are HIV positive.

Results from this dissertation indicate significant differences between seropositive patients who left the program and seropositive patients who remained enrolled in care in regard to having a prior record of an HIV test and having a prior record of a CD4 test and depression score. Record of HIV and CD4 testing may be reflective of patient activation, or the ability of patients to be partners in their health care (Mugavero et al., 2013; Roy et al., 2016; Ware et al., 2013). While not recorded in the data, patients who receive HIV and CD4 tests typically also receive HIV and/or ARV counseling. The significant relationship between having these test records and retention in care may be a result of patient increases in knowledge about HIV general, or their particular health and management skills.

Provider perceptions

Aim 3a used qualitative data from in-depth interviews with providers, along with quantitative survey data to examine how providers involved with the intervention, felt about the intervention to understand if it is burdensome, or if attitudes impact the implementation of the intervention. Providers identified implementation characteristics that both aided and impeded intervention implementation. Providers felt the ability of the intervention to incorporate patient needs, fit into clinic procedures, and evidence for the effectiveness of the intervention had a positive influence on implementation effectiveness. Strong positive influences included adaptability, and perceptions of the advantage of implementing IMAT compared to alternative solutions. Physical space and time presented a challenge to implementation effectiveness with

providers raising concerns about having the adequate space and time to deliver the intervention as intended. These concerns were echoed in the organizational readiness for change assessment (ORCA) which also indicated that providers had concerns about the resources allocated to making IMAT successful.

Results from the provider ORCA indicate that providers felt the IMAT intervention was strong in regard to patient acceptability, consideration of patient needs/preference, and apparent advantages vs. disadvantages for patients. These views were echoed from in-depth interviews with care providers. Providers felt the ability of the intervention to incorporate patient needs, fit into clinic procedures, and evidence for the effectiveness of the intervention had a positive influence on implementation effectiveness. Strong positive influences included adaptability and perceptions of the advantage of implementing IMAT compared to alternative solutions. Results of the ORCA also indicate disagreement among providers in relation to resources available for the intervention, particularly in terms of staffing, incentives, and clinic resources. This was also reflected in provider interviews, in which resources dedicated to intervention such as physical space and time presented a challenge to implementation effectiveness.

Implications for local programming

Despite daily encounters with the methadone clinic, less than half of all treatment-eligible patients at the MNH methadone clinic had initiated ART within three months of being deemed eligible for treatment (O. C. Tran et al., 2015). For minimally integrated patients generally, we see no significant differences in probability of attendance post-IMAT implementation compared with before IMAT implementation. Taken together these results may suggest a limited impact on patients who do not get the complete intervention, which is especially relevant given the need to

balance resources and efficiency in terms of care (Bruce, 2010; Ware et al., 2013). As degree of integration was not an intended aspect of IMAT, these results suggest that ensuring patients are only fully or partially integrated to the intervention might be the most beneficial way to ensure patients receive the benefits of care integration.

Maintaining confidentiality was a concern echoed by both patients and providers. Concerns about stigma in integrated settings has been documented in the literature (Edelman et al., 2016). Interestingly, results from in-depth interviews with patients indicated that stigma was a major concern to some patients, while other patients had no problems with potential disclosure, and chose to disclose themselves. To address both perspectives, it would be beneficial to develop a revised IMAT strategy that allows patients to select one of three ART dispensing models: 1) directly administered ART by a clinician in a private setting, 2) directly administered ART at the methadone dispensing window, or 3) monthly supplies of ART, which is the standard of care in Tanzania. ART dispensing options would also help to alleviate burden for providers, and may help address long wait times at the clinic associated with daily observed ART administration.

Methadone clinic providers are perfectly positioned to provide culturally competent services for PWID, compared to most other health care providers, and can assist in the cultivation of a welcoming environment for the provision of services. However, as seen in study Aim 2a, many patients experienced attrition at the methadone clinic indicating that recruitment and retention are major issues within this population who are have limited income, are in poor health and may have unstable living situations. The proposed IMAT strategy included training for two dedicated HIV care and treatment physicians within the methadone clinic. However, in light of findings related to long wait times, and variations in time spent with patients by provider type it would be more beneficial to build HIV care and treatment capabilities among more

clinicians, including both physicians and nurses, within the methadone clinic to prevent increasing the workload and overburdening individual providers. Training several clinicians would also provide flexibility in scheduling patients for clinical visits and follow-up consultations, increasing the capacity of the MNH methadone clinic to provide HIV care to patients.

Patients, especially, expressed a desire to have more flexibility in clinic policies especially in terms of time and availability of resources to deal with outside concerns (e.g. food). Methadone is administered once daily in the morning at the clinic, however some patients might benefit from taking ART medications in the evening, in the privacy of their homes, or at a time they might be more likely to have food. An option for take-home dosing of ART medications—such as a monthly supply of medication as practiced at HIV clinics—rather than daily, observed therapy could also be implemented to help ensure privacy and alienate provider burden. In interviews patients also mentioned external issues such as transportation and lack of food. The clinic might be able to improve attendance and create a more supportive environment if they were able to assist patients, either through providing food at the clinic, or through some kind of transportation program.

Implications for sub-Saharan Africa

The methadone clinic at MNH is a highly structured environment. Methadone dosing is highly restricted and the clinic is required to monitor their supply strictly. Patients visit the clinic on a daily basis to receive in-person, directly observed methadone dosing, and patients are required to adhere to clinic guidelines (no arguing, no loitering, no stealing) and to follow care and treatment guidelines relating to managing opiate use. Once enrolled in methadone maintenance, methadone is provided to clients seven days a week at the clinic. This type of

structure is necessary, given that methadone is tightly controlled in Tanzania, however this type of environment may not be feasible for other care environments.

Previous research conducted at the MNH methadone clinic has identified challenges around initiating HIV-positive methadone patients onto ART, including delays in CD4 testing, the inconvenience of off-site HIV clinics, and stigma (Lambdin et al., 2014). Research suggests that HIV positive persons in Tanzania face stigma, which creates barriers in obtaining treatment and care, and de-incentivizes serostatus disclosure (Mutalemwa et al., 2008; Tan et al., 2015). PWID with HIV have internalized stigma around their HIV status, and worry that they will be perceived as criminal if others learn of their status, not wanting to be labeled as drug addicts as well as HIV positive (Saleem et al., 2015). These multiple layers of stigma de-incentivize HIV testing and subsequent treatment, as well as disclosure even to medical providers whose job it is to help them care for their health. Methadone clinic providers (clinicians and nurses) have medical expertise that can be enhanced with additional training to provide HIV care and treatment. HIV-positive methadone clients are familiar with, and comfortable in, the methadone clinic environment where they feel respected by methadone clinic providers. For these reasons, the IMAT model is, potentially, a more feasible intervention than providing methadone in existing HIV clinics. Those interested in replicating this work in SSA should take these factors into account. Simply trying to replicate the IMAT model in other country settings may not be successful if patients feel stigmatized and judged by their care providers and have concerns (stigma, criminalization, etc.) about engaging in care.

Efforts to expand HIV care and treatment in SSA have focused mainly on securing ART and providing treatment to as many people as possible, with little work and attention to the efficiency of clinic operations (Wanyenze et al., 2010). These data are an initial step in patient

flow analysis and aids in understanding the care process, as well as in evaluating an intervention's impact on clinic efficiency (Potisek et al., 2007). If clinics are interested in integrated care, understanding the visit process from the perspective of patients and providers is important in ensuring that patients do not disengage in care due to long wait times, and that for highly trained clinicians specifically, their time is maximized to care for as many patients as possible.

Similar to other countries, HIV care and treatment in Tanzania occurs separate from other services. As people do not experience health conditions discreetly, countries have become more accepting and interested in adopting more integrated HIV prevention programs, particularly in relation to injection drug use (Volik et al., 2012). Interviews with patients and providers speak to the benefits of providing integrated treatment. For patients, it is easier to receive all their care in one place, and for providers it is beneficial for them to have a more holistic understanding of their patients' care. Data used in this study show gaps in clinical care records that may or may not be indicative of gaps in clinical care. Clinics in low-resource areas should work to ensure completeness of clinical records. This could be done by having full or part time data transcriptionists, incentivizing record keeping, and conducting regular audits of clinical records. Without the records, there is no way for other providers at the clinic to know this care was received, nor is there a way to progress a client through the intervention without these records.

Global Implications

Though timely initiation of antiretroviral therapy (ART) is a vital component of effective HIV prevention, care and treatment, PWID are less likely to receive ART than their non-drug using counterparts (Mathers, Degenhardt, Ali, Wiessing, Hickman, Mattick, Myers, Ambekar, Strathdee, et al., 2010). PWID consistently face barriers, such as laws and policies, which limit

their access to HIV prevention and treatment interventions (Gruskin et al., 2013). Where programs exist, many fail to reach those who could benefit due to requirements that make it difficult for people to enter and remain in services (Keeney & Saucier, 2010). Individual and structural barriers, such as inadequate knowledge of ART, untreated mental illness, unstable housing, fear of criminalization, and stigmatization impact the use of HIV services among PWID (Krüsi et al., 2010; Mimiaga et al., 2010; Wood et al., 2008). Results from this study point to the importance of developing and cultivating a positive patient and provider relationship, and the need to ensure providers are able to deliver care and aren't hampered by legal or policy guideline (e.g. mandated reporting, registering PWID).

The predicted probabilities in Aim 2b may be indicative of the intervention's impact related to these issues of connectedness to care, and patient/provider interaction for different kinds of patients. In adapting this to western countries, it highlights the importance of having multiple points of connection for patients and providers. There may be limited benefits of having only one point of connection for patients (e.g. only picking up ARV medication), and multiple points of connection (e.g. picking up ARV medication, viral load monitoring, and mental health care) may help retain patients in care.

Western and high-resource settings can also take lessons from the potential benefits of combining methadone and HIV services, especially in addressing patient concerns around the time required to receive both kinds of care. In this study, providers recognized the clinic level changes that would be needed to provide integrated care, such as a system to manage and monitor patient care, which would be fully functional and include technical assistance. Clinics providing integrated care, regardless of location should take these resources into account and

work to find ways to account for resources they don't have to ensure resources are used in the most efficient way possible.

Limitations

Study results are considered in context of its limitation. This kind of program monitoring approach is not perfect because it is dependent on the data available, both in terms of primary data and already existing clinical data. There were gaps in the process data that were collected (from the baseline survey and clinical records) it is unclear why these gaps exist. There could have been issues related to time, patient unwillingness to answer questions, provider issues, or other issues that might lead to gaps in clinic records and record keeping. Gaps in clinic records make it difficult to determine if patients truly did or did not receive certain services or if these records are just missing. In regard to the baseline and clinic data it is hard to ascertain exactly how accurate some of this data might be in really capturing patient social and health demographics. For example, it is unclear if variables such as record of a CD4 and HIV test remain significant in models because they have some effect, or if these variables are just reflecting some aspect of intervention enrollment. Future work at the methadone clinic should first examine why these data gaps exist and work to address them.

As it relates to the current study, interpretation of the findings may call for caution due to specific characteristics of the data, the analytic sample, and the data analysis. In regard to Aim 1, observational data were collected for all patients, not just those involved in the IMAT intervention. There is no way to visibly distinguish IMAT patients from non-IMAT patients, so it is possible that the observations include all or mostly non-IMAT patients. The data regarding patient characteristics is cross-sectional, so it is unclear how patients' responses on their baseline questionnaire are related to their present state. Data were collected up to 6-months after

intervention implementation, thus it is possible that not all of the relevant dynamics or information were recorded or available at the time of collection. While the data collection time-period allowed for the examination of immediate implementation, and effects on the care environment, it did not allow for an examination of important health outcomes such as HIV viral load. Thus, there are limitations to the generalizability of the data and conclusions that will come from this dissertation. There were also issues in relation to the distribution of sample characteristics as there was not much variation across the sample in regard to demographic, health, mental health and drug use history characteristics. It is also possible that some of the questionnaire items were not appropriate for the study population and/or setting. While best efforts were made to collect as much data as possible from a range of patients, it is possible that not enough data was collected in terms of the questions asked to patients and providers, or some patients may not have been fully surveyed (e.g. female patients).

We only interviewed patients currently enrolled and providers working at the MNH methadone clinic. Patients who have defaulted or who were not currently enrolled in care for other reasons may have very different perspectives around these issues. Thus, patient interview data may be biased in only collecting the experiences of those who have been successful in treatment. Patients who were the most vulnerable and/or those with fewer resources to support their treatment may have dropped out of care, excluding these perspectives. Patients may not have felt comfortable talking about some topics and so may not be forthcoming with information or in their responses to questions. Providers may also worry that negative feedback about their workplace could jeopardize their employment or reflect badly on them, and patients may be hesitant to "complain" about the care they are receiving. Lastly, these interviews were coded by one person, having multiple coders could have resulted in different interpretations and

understandings.

The MNH methadone clinic is one of four methadone clinics in Tanzania. Had there been another clinic implementing this intervention, data between the two settings could have been compared to better understand contextual factors related to implementation. Since there is only one site being used for analysis, applying this information to contexts outside of data collection will have to be done with caution. Findings from this study and the integrated HIV and methadone delivery model that was developed to address some of the challenges and recommendations identified by participants, may not be applicable to the other methadone clinics given the high-level of resources available at the MNH methadone clinic.

Strengths

This dissertation allows for the comprehensive, if geographically limited, documentation of the inner workings of all the steps of the IMAT intervention. While there are limitations in regard to breadth (only one study site was used), the data used here allowed for an in-depth examination of a single case. The data used in this dissertation are mainly cross-sectional which allows for an in-depth examination of a specific time. Regardless of the patients who were observed the data does give some indication as to how the IMAT intervention impacts patient flow at the clinic. While I was unable to look at the specific patient health outcomes, this research focused on examining the role of the intervention itself. Data used in this dissertation allow for documentation, in a comprehensive way, of the inner workings of all the steps of the IMAT intervention which form the basis of making a case about its feasibility. The use of a mixed-method approach allows for an understanding of contextual factors, which may be country—or site—specific, as well as more general issues and factors that are important in translating similar work to other settings.

The IMAT intervention was developed using evidence based practices. This has relevance in that the intervention of study is not unique or esoteric, but is more generalizable to the kind of intervention that would be seen in many different settings. Data for this intervention were collected at the initial stages of the IMAT intervention, providing information on early stage intervention implementation and feasibility. This research was also timely in that it was collected during a time of national support and buy-in. Thus, it gives contextual information on the kinds of interventions, specifically for PWID, that can be implemented in a supportive environment.

Future directions

In a number of east African countries there is recent support for harm reduction as a measure of HIV and hepatitis C prevention among PWID (Rhodes & Abdool, 2016). There is an interest and need to implement these intervention and policy innovations in new settings. However even within this there are some potential issues. Work in implementation science typically focuses on how taking an evidence-based intervention (e.g. methadone), and adapting it to different social and cultural context. This translation of evidence tends focus on reproducing what is already known. In this framework evidence-based interventions are meant to have the same impact regardless of context. These interventions do not take into account the specific policy, social, and care context which influence if and how interventions are able to be implemented (Ratliff, Kaduri, Masao, Mbwambo, & McCurdy, 2015). It is important to remember that interventions do not take place in a vacuum, and that multiple competing actors (e.g. government, individuals, care settings) influence the understanding of interventions as well as how they are carried out.

Instead there is a need to support ‘evidence-making interventions’ which focus on how

the knowledge and meaning of an intervention is made locally through its implementation (Rhodes, Closson, Paparini, Guise, & Strathdee, 2016). Within this understanding future research in this area could ask: what are the ways in which target populations and social contexts impact the implementation of integrated interventions for PWID in low-resource settings? Given the stigma around drug use described by patients and providers, it is not clear how locally defined understandings of substance use, addiction, substance treatment, etc., may impact policies, interventions and programs for people who use drugs. Locally produced knowledge might inform how understand the integration of such interventions and how these perceptions are informed by specific points in historical time and social meanings.

Substance use moreover isn't a universal concept. It is thought about differently in the US compared to Tanzania, or under a harm reduction compared to abstinence framework. This idea is echoed in interviews with patients who discuss the compassion in the care they receive at the methadone clinic compared to other care settings. In taking best-practices from the IMAT intervention it is important to understand how methadone clinic patients are treated outside of the clinic. An area of future research could interrogate how non-methadone clinic providers perceive PWID, and how does their effect access to care? While patients mention that the methadone clinic is where they are able to get compassionate care, it is not a holistic care setting. Methadone clinic patients are bound to interact with other care providers, either through major life events (e.g. births), acute health issues (e.g. emergency room visits), etc. It is important to understand what influence non-methadone clinic providers might have in shaping the overall health and wellbeing of methadone clinic patients, and how this might impact the ways patients engage with care in and receive treatment from the methadone clinic.

Global work on substance use, particularly in looking at the intersection of injection drug

use and infectious disease should explore how different contexts shape the translation, transformation or resistance of policy adaptations. Future research in this area might ask, how do PWIDs' experiences interact with social and care context to impact issues of attrition and retention? Given limitations in regard to the baseline and clinic data, it is not clear that the MNH methadone clinic has a good way to characterize patients likely to drop out or have difficult in the program. Related to this, an understanding of how new intervention opportunities exist in relation to drug use are positioned among competing, often more immediate, everyday concerns, e.g. transportation, food, housing, etc.

Future work in this area should also aim to improve this research. Data from the methadone clinic would be better served by consistent and systemic data collection. This would hopefully reduce gaps in baseline and clinic records. Observational data is a useful tool for understanding clinic flow and efficiency, ways to collect data on specific kinds of patients (e.g. seropositive patients, patients on high methadone doses, etc.) would strengthen this data. Lastly a way to obtain information about those patients who have left the methadone clinic would contribute to an understanding of factors related to patient drop out and ways to retain patients into care.

Conclusion

The methadone clinic at is located in the national hospital of Tanzania, Muhimbili is a somewhat unique environment as it has more resources in terms of staffing, technology and finances compared to other hospitals in Tanzania. However, there are many lessons that can be learned from this study and applied to care setting in east Africa, SSA and beyond. While the IMAT intervention itself is interesting and innovative, it is important to understand that addressing HIV transmission among people who inject drugs is not simply a medical issue. The

problem is not as simple as providing the medication and health care needed, and there is a need to understand how this intervention functions regardless of patient outcomes. Regardless of the outcomes we need to understand how all of the components are working together to even get to the outcomes. If we don't understand the processes of how to get to the patient outcomes then this is of limited utility, especially in settings with limited resources. Simply applying interventions and programs based on western models, or standards of care does not necessarily translate to settings in the global south. It is important to understand implementation in this context in order to address the reality of translating it to similar country settings.

While some studies may target disease outcomes (e.g. CD4), this study focused on the intervention itself. Addressing HIV transmission among people who inject drugs is not simply a medical issue; therefore, effective solutions necessarily involved more than merely providing medication and health care. While the methadone clinic has a history of substance use treatment it may be more difficult for them to incorporate HIV care and treatment such at the uptake and adherence of ARTs. It is important to understand how the integration care impacts and affects the delivery of each of the care components. The implementation and working of the intervention itself is complex, and there is a need to understand how all of the components are working together to even be able to predict any of the possible patient outcomes. Illuminating the processes by which patients achieve desired outcomes is crucial, especially in settings with limited resources. Simply applying interventions and programs based on western models and standards of care does not necessarily translate to settings in the global south. It is important to understand implementation in this context in order to address the reality of translating it to similar country settings

Data for this dissertation were collected at an early stage of understanding and creating care models for substance use that don't simply translate western models. This project represents a chance to deeply understand the issues involved at this early stage, both to inform immediate programming as well as to inform long term policy guidelines. Finding highlight the challenges related to integrating HIV care into the methadone clinic setting. The methadone clinic can leverage the compassionate care offered by methadone clinic providers, however specific attention will be needed to structure services so that providers are not overburdened and confidentiality regarding patients' HIV status is maintained.

Improvements for any measure of global health must be highly contextualized. While the data collected for this dissertation comes from one clinic, it allows for an in-depth examination of the contextual issues that impact program implementation. The complexity of the data itself is intentional as it reflects the intervention and issue and the importance of monitoring and evaluating complex systems that are constantly in flux. Data used here come from a real world setting and so reflect issues relating to service delivery, as well as separate issues around patient and provider characteristics, and the care environment. This dissertation allows for a comprehensive documentation of the inner workings of all the steps of the IMAT intervention, contributing to theoretical understandings of these issues and essential for translating the intervention to other clinic and/or country settings and the development of supporting policy, and providing a pathway to understanding interventions that engage and provide care to stigmatized populations.

Data from this dissertation indicate that overall the IMAT intervention is feasible in this setting. It was well regarded by patients and providers and helped to streamline care within the methadone clinic. Some aspects of the methadone clinic may make applying IMAT in different

settings difficult. Other country and clinic settings should take note of issues around patient stigma, patient and provider relationships and intervention adaptability. The combination of HIV care and treatment with methadone treatment is as essential step in national HIV prevention efforts. In light of data which suggests issues around retaining patients into care, work is needed to better understand issues of retention and daily attendance.

Chapter 9 : Appendices

Appendix A: Observational Data Tool—patient visits

Time Motion Study: IMAT Patients

INTERVIEWER *
- ◯ Frank Kusaga
- ◯ Jackline Respick
- ◯ Alexis Cooke

Patient Service

EIN *

MAT NUMBER
if you know it

SERVICE PROVIDED *
- ☐ Baseline tests
- ☐ Follow-up visit
- ☐ CD4 test lab draw
- ☐ CD4 test result given
- ☐ ARV counseling
- ☐ Other Counselling
- ☐ Receive perscription
- ☐ Initial ARV pick up
- ☐ ARV daily dose pick up
- ☐ ARV month dose pick up
- ☐ Methadone daily dose
- ☐ CTC transport
- ☐ Lab draw
- ☐ Viral load blood draw
- ☐ VL results view
- ☐ Wait
- ☐ Other service

OTHER SERVICE *

PROVIDER *
- ☐ Clinician
- ☐ Nurse
- ☐ Social Worker
- ☐ Pharmacist
- ☐ Other

OTHER SERVICE *

START TIME *
hh:mm

END TIME *
hh:mm

VISIT NOTES
for example what labs were done, was there a problem, very long wait, etc

Appendix B: Observational Data Tool—provider visits

Time Motion Study: IMAT providers

INTERVIEWER *

- ◯ Frank Kussaga
- ◯ Jackline Respick
- ◯ Alexis Cooke

Patient Service

EIN *

.....

MAT NUMBER
if you know it

.....

SERVICE PROVIDED *

- ☐ Client assessment- Baseline tests
- ☐ Client assessment-Follow up
- ☐ CD4 test lab draw
- ☐ CD4 test result given
- ☐ ARV counseling
- ☐ Other Counselling
- ☐ Prescribing medication
- ☐ ARV daily dose dispensing
- ☐ ARV month dose dispensing
- ☐ Methadone daily dose administration
- ☐ Lab paperwork
- ☐ Lab draw
- ☐ Lab order
- ☐ Lab results view
- ☐ Other service

OTHER SERVICE *

.....

START TIME *

hh:mm

.....

END TIME *

hh:mm

.....

VISIT NOTES
for example what labs were done, was there a problem, very long wait, etc

.....

Appendix C: Patient Interview Guides

Oral Consent Script for Patients

Good morning/afternoon/evening thank you so much for participating in this interview. We would like to understand the feasibility and effectiveness of integrating select HIV care services into the range of services provided at the MAT clinic. As you may know, the clinic recently began a new program that connects HIV care with methadone treatment. We are studying this program as well as people's thoughts and experiences with it. If you agree to participate we will ask you to answer some questions about your overall thoughts as a patient in this clinic, your interactions with providers, as well your experience with certain program components. This interview will last for about 2 hours. If you have any questions about the research you are welcome to contact Alexis Cooke as the PI of the study at a.cooke@ucla.edu, or Dr. Jessie Mbwambo jmbwambo@gmail.com; 255.767.339.74. If you have any questions about the study's ethics please contact Professor Mainen Moshi, +255.22.215.2489; drp@muhas.ac.tz.

Before we begin, I would like to remind you that participation in this interview is voluntary and anything you say will be kept confidential your response will be assigned an ID number and not associated with your name. Participation will not impact the care you are currently receiving or the care you will receive in the future. With your permission, your responses will be audio recorded; however they will only be shared with other people as part of a summary report, excluding names and other identifying information. You are welcome to review the audio tapes at any time. Study data will be stored and used for possible future research. You can stop the interview at any point or pass on questions you would prefer not to answer. Before we get started, do you have any questions for me?

HIV positive IMAT patients not linked to ART

Based on the Grounded Theory model, not all questions will be asked of all participants. In addition, some questions that do not appear on this list but are of a similar scope as the questions presented here may be included if relevant to the course of the interview.

[Consent Script]

I. Patient background

1. How are you doing today?
2. To start I would like to ask a little about your family.
    a. Do you have any children?
    b. How many?
    c. How old are they?
    d. Do they live with you?
    e. If not, where do they live?
3. Are you married or in a relationship?
    a. Does your partner use drugs?
    b. Did your partner use drugs in the past?

c. Is your partner in drug treatment?
d. If your partner is in drug treatment, did you start treatment together? If your partner uses drugs and is not in drug treatment, why not?

4. If not in a relationship, can you tell me about your last relationship?
    a. Why did it end?
    b. Did your last partner use drugs?
5. When did you start using drugs?
    a. Can you tell me why you started using drugs?
    b. Where would you go to use drugs?
    c. Where would you go to find drugs? How did your drug use affect any relationships you may have had
6. How has your drug use affected your employment opportunities?
    a. Did you have a different job before you began using drugs?
    b. How did you support yourself when you were using drugs?
    c. How do you support yourself now?
7. Where do you live in relation to the clinic?
    a. How often do you come to the clinic?
    b. How do you get to the clinic?
    c. How often have you missed appointments due to difficulties getting to the clinic?

II. Experiences with treatment

8. Can you tell me what you like about being on methadone?
    a. Have there been any challenges with being on methadone?
9. Have you ever stopped treatment in the past?
    b. Why or why not?
10. Do you know anyone who has ever dropped out of methadone treatment?
    c. Why did they drop out?
11. Tell me about your experiences been like with the providers at the MAT clinic?
    d. Can you tell me about any problems you may have had at the MAT clinic?
    e. Have you ever experienced discrimination or stigma here because of your drug use?
    f. Have you ever experienced discrimination or stigma here because of your HIV status?
12. Do your other medical providers know you are on methadone and about your HIV status?
    g. How do they know
    h. Do you feel like they treat you differently?
13. Can you tell me about the NGO that referred you to the clinic?
    i. What was the referral process like for you?

III. Experiences with intervention

14. How do you feel about having HIV medication and methadone in one place?
15. Can you describe your experience with HIV testing in the clinic?
    a. How did you feel about the pre-test counseling?
    b. How did you feel about the post-test counseling?
16. How would you describe your experience with various providers in the clinic?
    c. Do you feel like these providers explained everything about your care well?

d. What things, if any, did you not understand?
e. What things, if any, did you not expect?

17. Can you describe your experiences with CD4 testing?
    f. Can you explain to me what this information means?
       (note do not ask for specific results, just if the patient generally understands what the test results mean)
    g. How was information regarding your CD4 count explained to you?
18. After taking the HIV test and getting your CD4, do you think you will start ART?
    h. Why or why not?
    i. (if yes) Do you feel that the medication will be easy to take?
    j. (if yes) What concerns do you have about ARTs
19. What were some outside factors (i.e. transportation, time, cost) that might affect your ability to fully participate?
    k. What are some things that might eliminate these factors?
    l. What are some things the clinic could do to help with these factors?
20. After taking the HIV test and getting your CD4, what do you think has delayed your ART initiation?
    m. (prompt) Were you told to come back to start ART?
    n. (prompt) Was a clinician not available to start your ART?
    o. Did you talk with the staff at the clinic about when you would start your ART?
    p. Do you think it will be easy for you to start on ART?

IV. Stigma

21. Can you tell me about concerns you have regarding people finding out your HIV status?
    a. What ways do you think someone might be able to tell you are taking ARTs?
    b. Has anyone you know, ever missed an ART dose because they were concerned someone would find out?
22. What would you change about the way your methadone is dispensed?
    c. Why would you make this change?
23. How would you like your ARVs to be dispensed?

V. Ending Questions:

24. To end is there any advice or feedback you would like to give to the clinic or providers?
25. Do you have anything else you would like to add or questions for me?

HIV positive MAT patients not linked to ART before MAT enrollment who have completed CD4 testing

[Consent Script]

I. Patient background

1. How are you doing today?
2. To start I would like to ask a little about your family.
    a. Do you have any children?
    b. How many?
    c. How old are they?
    d. Do they live with you?
    e. If not, where do they live?
3. Are you married or in a relationship?
    f. Does your partner use drugs?
    g. Did your partner use drugs in the past?
    h. Is your partner in drug treatment?
    i. If your partner is in drug treatment, did you start treatment together? If your partner uses drugs and is not in drug treatment, why not?
4. If not in a relationship, can you tell me about your last relationship?
    j. Why did it end?
    k. Did your last partner use drugs?
5. When did you start using drugs?
    l. Can you tell me why you started using drugs?
    m. Where would you go to use drugs?
    n. Where would you go to find drugs? How did your drug use affect any relationships you may have had
6. How has your drug use affected your employment opportunities?
    o. Did you have a different job before you began using drugs?
    p. How did you support yourself when you were using drugs?
    q. How do you support yourself now?
7. Where do you live in relation to the clinic?
    r. How often do you come to the clinic?
    s. How do you get to the clinic?
    t. How often have you missed appointments due to difficulties getting to the clinic?

II. Experiences with treatment

8. Can you tell me what you like about being on methadone?
    j. Have there been any challenges with being on methadone?
9. Have you ever stopped treatment in the past?
    k. Why or why not?
10. Do you know anyone who has ever dropped out of methadone treatment?
    l. Why did they drop out?
11. Tell me about your experiences been like with the providers at the MAT clinic?

m. Can you tell me about any problems you may have had at the MAT clinic?
n. Have you ever experienced discrimination or stigma here because of your drug use?
o. Have you ever experienced discrimination or stigma here because of your HIV status?

12. Do your other medical providers know you are on methadone and about your HIV status?
    p. How do they know
    q. Do you feel like they treat you differently?
13. Can you tell me about the NGO that referred you to the clinic?
    r. What was the referral process like for you?

III. Experiences with intervention

14. How do you feel about having your HIV medication and methadone in one place?
    q. How well did you understand where in the clinic you were supposed to go for certain appointments
    r. What are some differences in the care you received before the program and now?
15. How easily were you able to follow the steps in the program?
    s. What things, if any, would you change about the program?
16. Can you describe your experience with HIV testing in the clinic?
    t. How did you feel about the pre-test counseling
    u. How did you feel about the post-test counseling
17. How would you describe your experience with various providers in the clinic?
    v. Do you feel like these providers explained everything about your care well?
    w. What things, if any, did you not understand?
    x. What things, if any, did you not expect?
18. Can you describe your experiences with CD4 testing
    y. Can you explain to me what this information means?
    (note do not ask for specific results, just if the patient generally understands what the test results mean)
    z. How was information regarding your CD4 count explained to you?
19. What are some things that made you want to participate in the program?
    aa. Looking ahead, how well do you think you'll be able to participate in the program?
20. What were some outside factors (i.e. transportation, time, cost) that might affect your ability to fully participate?
    bb. What are some things that might eliminate these factors?
    cc. What are some things the clinic could do to help with these factors?

IV. Stigma

21. Can you tell me about concerns you have regarding people finding out your HIV status?
    d. What ways do you think someone might be able to tell you are taking ARVs?
    e. Have you, or anyone you know, ever missed an ART dose because they were concerned someone would find out?
22. What would you change about the way your methadone is dispensed?
    f. Why would you make this change?
23. What would you change about the way ARVs are dispensed?

24. Why would you make this change?

V. Ending Questions:

25. To end is there any advice or feedback you would like to give to the clinic or providers?
26. Do you have anything else you would like to add or questions for me?

HIV positive MAT patients not linked to ART before MAT enrollment who have initiated ART counseling

[Consent Script]

I. Patient background

1. How are you doing today?
2. To start I would like to ask a little about your family.
    a. Do you have any children?
    b. How many?
    c. How old are they?
    d. Do they live with you?
    e. If not, where do they live?
3. Are you married or in a relationship?
    a. Does your partner use drugs?
    b. Did your partner use drugs in the past?
    c. Is your partner in drug treatment?
    d. If your partner is in drug treatment, did you start treatment together? If your partner uses drugs and is not in drug treatment, why not?
4. If not in a relationship, can you tell me about your last relationship?
    a. Why did it end?
    b. Did your last partner use drugs?
5. When did you start using drugs?
    a. Can you tell me why you started using drugs?
    b. Where would you go to use drugs?
    c. Where would you go to find drugs? How did your drug use affect any relationships you may have had
6. How has your drug use affected your employment opportunities?
    a. Did you have a different job before you began using drugs?
    b. How did you support yourself when you were using drugs?
    c. How do you support yourself now?
7. Where do you live in relation to the clinic?
    a. How often do you come to the clinic?
    b. How do you get to the clinic?
    c. How often have you missed appointments due to difficulties getting to the clinic?

II. Experiences with treatment

8. Can you tell me what you like about being on methadone?

a. Have there been any challenges with being on methadone?

9. Have you ever stopped treatment in the past?
    b. Why or why not?
10. Do you know anyone who has ever dropped out of methadone treatment?
    c. Why did they drop out?
11. Tell me about your experiences been like with the providers at the MAT clinic?
    d. Can you tell me about any problems you may have had at the MAT clinic?
    e. Have you ever experienced discrimination or stigma here because of your drug use?
    f. Have you ever experienced discrimination or stigma here because of your HIV status?
12. Do your other medical providers know you are on methadone and about your HIV status?
    g. How do they know
    h. Do you feel like they treat you differently?
13. Can you tell me about the NGO that referred you to the clinic?
    i. What was the referral process like for you?

III. Experience with Intervention

14. How do you feel about having your HIV medication and methadone in one place?
    a. How well did you understand where in the clinic you were supposed to go for certain appointments
    b. What are some differences in the care you received before the program and now?
15. How easily were you able to follow the steps in the program?
    c. What things, if any, would you change about the program?
16. How did participating in the intervention allow you to interact with different kinds of providers?
    d. Can you describe any differences in the services you received?
    e. How do you feel about these new services and providers?
17. Can you describe your experience with HIV testing in the clinic?
    f. How did you feel about the pre-test counseling
    g. How did you feel about the post-test counseling
18. How would you describe your experience with various providers in the clinic?
    h. Do you feel like these providers explained the program well?
    i. How well do you think the different providers communicated with each other?
19. Can you describe your experiences with CD4 testing
    j. Can you explain to me what this information means?
    k. How was information regarding your CD4 count explained to you?
20. How did you feel about the ART counseling that you received?
    l. How did the ART counseling impact your understanding of the medication?
    m. After this counseling what were some concerns you had about your MAT treatment
    n. After the ART counseling, how did you feel about the clinic and the services you would get in the future?
    o. How comfortable did you feel asking questions during the counseling?
    p. If you had questions, do you feel they were answered clearly?

21. What were some outside factors (i.e. transportation, time, cost) that might affect your ability to fully participate?
    q. What are some things that might eliminate these factors?
    r. What are some things the clinic could do to help with these factors?
22. What are some things that made you want to participate in the program?
    s. How well do you think you'll be able to participate in the program?

IV. Stigma

23. Can you tell me about concerns you have regarding people finding out your HIV status?
    a. What ways do you think someone might be able to tell you are taking ARVs?
    b. Have you, or anyone you know, ever missed an ART dose because they were concerned someone would find out?
24. What would you change about the way your methadone is dispensed?
    c. Why would you make this change?
25. What would you change about the way ARVs are dispensed?
26. Why would you make this change?

V. Ending Question

27. To end is there any advice or feedback you would like to give to the clinic or providers?
28. Do you have anything else you would like to add or questions for me?

HIV positive MAT patients not linked to ART before intervention who have completed CD4 testing

[Consent Script]

I. Patient background

1. How are you doing today?
2. To start I would like to ask a little about your family.
    a. Do you have any children?
    b. How many?
    c. How old are they?
    d. Do they live with you?
    e. If not, where do they live?
3. Are you married or in a relationship?
    a. Does your partner use drugs?
    b. Did your partner use drugs in the past?
    c. Is your partner in drug treatment?
    d. If your partner is in drug treatment, did you start treatment together? If your partner uses drugs and is not in drug treatment, why not?
4. If not in a relationship, can you tell me about your last relationship?
    a. Why did it end?
    b. Did your last partner use drugs?

5. When did you start using drugs?
    a. Can you tell me why you started using drugs?
    b. Where would you go to use drugs?
    c. Where would you go to find drugs? How did your drug use affect any relationships you may have had
6. How has your drug use affected your employment opportunities?
    a. Did you have a different job before you began using drugs?
    b. How did you support yourself when you were using drugs?
    c. How do you support yourself now?
7. Where do you live in relation to the clinic?
    a. How often do you come to the clinic?
    b. How do you get to the clinic?
    c. How often have you missed appointments due to difficulties getting to the clinic?

II. Experiences with treatment

8. Can you tell me what you like about being on methadone?
    a. Have there been any challenges with being on methadone?
9. Have you ever stopped treatment in the past?
    b. Why or why not?
10. Do you know anyone who has ever dropped out of methadone treatment?
    c. Why did they drop out?
11. Tell me about your experiences been like with the providers at the MAT clinic?
    d. Can you tell me about any problems you may have had at the MAT clinic?
    e. Have you ever experienced discrimination or stigma here because of your drug use?
    f. Have you ever experienced discrimination or stigma here because of your HIV status?
12. Do your other medical providers know you are on methadone and about your HIV status?
    g. How do they know
    h. Do you feel like they treat you differently?
13. Can you tell me about the NGO that referred you to the clinic?
    i. What was the referral process like for you?

III. Experiences with intervention

14. Can you describe your experience at the MAT clinic?
15. How easily were you able to follow the steps in your care?
    a. What things, if any, would you change about the program?
16. Can you describe your experience with HIV testing in the clinic?
    b. How did you feel about the pre-test counseling
    c. How did you feel about the post-test counseling
17. How would you describe your experience with various providers in the clinic?
    d. Do you feel like these providers explained the program well?
18. How do you feel about receiving care in one location impact you
    e. How well did you understand where in the clinic you were supposed to go for certain appointments

19. Can you describe your experiences with CD4 testing
    f. Can you explain to me what this information means?
    g. How was information regarding your CD4 count explained to you?
20. What are some things that made you want to participate in the program?
    h. How well do you think you'll be able to participate in the program?
21. What were some outside factors (i.e. transportation, time, cost) that might affect your ability to fully participate?
    i. What are some things that might eliminate these factors?
    j. What are some things the clinic could do to help with these factors

IV. Stigma

22. Can you tell me about concerns you have regarding people finding out your HIV status?
    a. What ways do you think someone might be able to tell you are on ART?
    b. Have you, or anyone you know, ever missed an ART dose because they were concerned someone would find out?
23. What would you change about the way your methadone is dispensed?
    c. Why would you make this change?
24. What would you change about the way ART dispensing?
    k. Why would you make this change?

V. Ending Questions

25. To end is there any advice or feedback you would like to give to the clinic or providers?
26. Do you have anything else you would like to add or questions for me?

HIV positive MAT patients not linked to ART before intervention who have initiated ART counseling

[Consent Script]

I. Patient background

1. How are you doing today?
2. To start I would like to ask a little about your family.
    a. Do you have any children?
    b. How many?
    c. How old are they?
    d. Do they live with you?
    e. If not, where do they live?
3. Are you married or in a relationship?
    a. Does your partner use drugs?
    b. Did your partner use drugs in the past?
    c. Is your partner in drug treatment?

d. If your partner is in drug treatment, did you start treatment together? If your partner uses drugs and is not in drug treatment, why not?

4. If not in a relationship, can you tell me about your last relationship?
    a. Why did it end?
    b. Did your last partner use drugs?
5. When did you start using drugs?
    a. Can you tell me why you started using drugs?
    b. Where would you go to use drugs?
    c. Where would you go to find drugs? How did your drug use affect any relationships you may have had
6. How has your drug use affected your employment opportunities?
    a. Did you have a different job before you began using drugs?
    b. How did you support yourself when you were using drugs?
    c. How do you support yourself now?
7. Where do you live in relation to the clinic?
    a. How often do you come to the clinic?
    b. How do you get to the clinic?
    c. How often have you missed appointments due to difficulties getting to the clinic?

II. Experiences with treatment

8. Can you tell me what you like about being on methadone?
    a. Have there been any challenges with being on methadone?
9. Have you ever stopped treatment in the past?
    b. Why or why not?
10. Do you know anyone who has ever dropped out of methadone treatment?
    c. Why did they drop out?
11. Tell me about your experiences been like with the providers at the MAT clinic?
    d. Can you tell me about any problems you may have had at the MAT clinic?
    e. Have you ever experienced discrimination or stigma here because of your drug use?
    f. Have you ever experienced discrimination or stigma here because of your HIV status?
12. Do your other medical providers know you are on methadone and about your HIV status?
    g. How do they know
    h. Do you feel like they treat you differently?
13. Can you tell me about the NGO that referred you to the clinic?
    i. What was the referral process like for you?

III. Intervention Experiences

14. Overall how do you feel about the services you have received at the MAT clinic?
    a. How do you feel about the services since HIV care became integrated with methadone treatment
    b. In what ways did the intervention impact your MAT care?
15. How easily were you able to follow the steps of the program?
    c. What things, if any, would you change about the plan?

16. What were the parts of the program that were confusing, or not easy to understand?
    d. How well did you understand where in the clinic you were supposed to go for certain appointments
17. Can you describe your experience with HIV testing in the clinic?
    e. How did you feel about the pre-test counseling
    f. How did you feel about the post-test counseling
18. How would you describe your experience with various providers in the clinic?
    g. Do you feel like these providers explained the program well?
    h. How well do you think the different providers communicated with each other?
19. How did you feel about the ART counseling that you received?
    i. How did the ART counseling impact your understanding of the medication
    j. After this counseling what were some concerns you had about your MAT treatment
20. What were some outside factors (i.e. transportation, time, cost) that might affect your ability to fully participate?
    k. What are some things that might eliminate these factors?
    l. What are some things the clinic could do to help with these factors?
21. What are some things that made you want to participate in the program?
    m. How well do you think you'll be able to participate in the program?
    n. Did completing the CD4 testing and ART counseling make you feel more confident in participating?

IV. Stigma

22. Can you tell me about concerns you have regarding people finding out your HIV status?
    a. What ways do you think someone might be able to tell you are taking ARVs?
    b. Have you, or anyone you know, ever missed an ART dose because they were concerned someone would find out?
23. What would you change about the way your methadone is dispensed?
    c. Why would you make this change?
24. What would you change about the way ARVs are dispensed?
    d. Why would you make this change?

V. Ending Questions

25. To end is there any advice or feedback you would like to give to the clinic or providers?
26. Do you have anything else you would like to add or questions for me?

Appendix D: Provider Interview Guide

Oral Consent Script for Providers

Good morning/afternoon/evening thank you so much for participating in this interview. Before we begin, I would like to give you some background on the rationale for this research. We would like to understand the process of integrating select HIV care services into the range of services provided at the MAT clinic. We are studying the implementation of this integration as well as people's thoughts and experiences with it. During this interview, we would like to learn your perspective as a provider about how this intervention worked, how it changed your daily activities, as well as changes you may have seen with your patients or in interacting with other providers. If you agree to participate we will ask you to answer some questions about your understanding and experiences regarding the intervention, this interview will last for about 2 hours. If you have any questions about the research you are welcome to contact Alexis Cooke as the PI of the study at a.cooke@ucla.edu, or Dr. Jessie Mbwambo jmbwambo@gmail.com; 255.767.339.74. If you have any questions about the study's ethics please contact Professor Mainen Moshi, +255.215.2489; drp@muhas.ac.tz.

Before we begin, I would like to remind you that participation in this interview is voluntary, not part of your job responsibilities and anything you say will be kept confidential your response will be assigned an ID number and not associated with your name. With your permission, your responses will be audio recorded; however they will only be shared with other people as part of a summary report, excluding names and other identifying information. You are welcome to review the audiotapes at any. Study data will be stored and used for possible future research. You can stop the interview at any point or pass on questions you would prefer not to answer. Before we get started, do you have any questions for me?

I. Intervention reactions

1. Before the intervention started how clear were you in regards to the new protocol?
    a. What elements of the intervention were easy to adapt to?
    b. Were there parts of the intervention that were unclear or hard to follow?
2. Can you describe how the intervention impacted the linking of services throughout the clinic?
    a. Do you communicate more often with different kinds of providers?
    b. Can you identify any gaps in the linking of care?
3. Describe any situations where you may have been unable to follow the intervention guidelines exactly.
    a. In these situations, what did you do?
    b. Did you ever feel like you had to figure things out on your own?
4. Were there any parts of the intervention you found to be unnecessary, or didn't follow?
    a. Were there any parts of the intervention you found to be very important, and made sure you always followed?
5. How do you think ARTs should be dispensed to patients? For example, monthly, daily, is there a way that is best?

6. For IMAT patients, have they expressed any concerns about receiving their HIV care at the MAT clinic?
    a. Are they concerned about getting their ARTs from MAT and other people finding out?
7. What policies at MUHAS or in the MAT clinic might hinder care integration?
8. Can you tell me what systems are in place to monitor patients and made sure they adhere to their ART regimens?
    a. Do you have concerns about patient adherence?
    b. Is it easy for patients to miss follow-up visits and labs?
9. In expanding the intervention, or making it more successful what things would you need? For example, more space, more staff, different resources?
10. When you discuss CD4 with patients, do you feel they understand this information and what the number means?
    c. How about viral load? Do you discuss this with patients?
11. How do you feel about integrating non-methadone services into the clinic?
    d. What kinds of care might you be interested in integrating?

Appendix E: Organizational Readiness for Change Assessment

The purpose of this survey is to understand how providers think about IMAT intervention, adherence to the IMAT protocol as well as other factors that contribute to or hinder the implementation of IMAT

What is your position? _____

I am going to read you a statement: The development of an integrated methadone and antiretroviral therapy strategy will improve ART initiation among people who inject drugs.

1. Using your opinion, please rate the strength of the evidence for this statement, on a scale of 1 to 5 where 1 is very weak evidence and 5 is very strong evidence:

Very Weak	Weak	Neither strong nor weak	Strong	Very Strong	Don't know/Not applicable
1	2	3	4	5	6

2. How do you think respected clinical experts at MAT feel about the strength of the evidence, on a 1 to 5 scale similar to the one above:

Very Weak	Weak	Neither strong nor weak	Strong	Very Strong	Don't know/Not applicable
1	2	3	4	5	6

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 4 (strongly agree)

1. The IMAT intervention changes are supported by clinical trials or other scientific evidence from the MAT clinic

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

2. The IMAT intervention changes are supported by clinical trials or other scientific evidence from other health care settings

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

3. The IMAT intervention changes should be effective, based on current scientific knowledge

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

4. The IMAT intervention changes are supported by clinical experience with MAT patients

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

5. The IMAT intervention conforms to the opinions of clinical experts at MNH

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

6. The IMAT intervention has been well-accepted by MAT patients

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

7. The IMAT intervention took into consideration the needs and preferences of the MAT clinic

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

8. The IMAT intervention appears to have more advantages than disadvantages for MAT patients

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

9. Senior leadership/clinical management at the MAT clinic rewards clinical innovation and creativity to improve patient care

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

10. Senior leadership/clinical management at the MAT clinic solicits opinions of clinical staff regarding decisions about patient care

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

11. Senior leadership/clinical management at the MAT clinic rewards clinical innovation and creativity to improve patient care

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

12. Senior leadership/clinical management at the MAT clinic seeks ways to improve patient education and increase patient participation in treatment

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

13. Staff at the MAT clinic have a sense of personal responsibility for improving patient care and outcomes

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

14. Staff at the MAT clinic cooperate to maintain and improve effectiveness of patient care

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

15. Staff at the MAT clinic are willing to innovate and/or experiment to improve clinical procedures

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

16. Staff at the MAT clinic are receptive to change in clinical processes

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

17. Staff members at the MAT clinic cooperate to maintain and improve effectiveness of patient care

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

18. In general in the clinic, when there is agreement that change needs to happen we have the necessary support in terms of budget or financial resources

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

19. In general, in the clinic, when there is agreement that change needs to happen we have the necessary support in terms of training

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable

1	2	3	4	5	6

20. In general, in the clinic, when there is agreement that change needs to happen we have the necessary support in terms of facilities

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

21. In general in the clinic, when there is agreement that change needs to happen we have the necessary support in terms of staffing

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

22. In regards to the IMAT intervention senior leadership/clinical management has proposed a project that is appropriate and feasible

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

23. In regards to the IMAT intervention senior leadership/clinical management has provided clear goals for improvement in patient care

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

24. In regards to the IMAT intervention senior leadership/clinical management has established a project schedule and deliverables

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

25. In regards to the IMAT intervention senior leadership/clinical management has designated a clinical champion(s) for the project

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

26. In regards to the IMAT intervention senior leadership/clinical management agree on the goals for this intervention

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

27. In regards to the IMAT intervention senior leadership/clinical management will be informed and involved in the intervention

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

28. In regards to the IMAT intervention senior leadership/clinical management agree on adequate resources to accomplish the intervention

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

29. In regards to the IMAT intervention senior leadership/clinical management has set a high priority on the success of the intervention

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

30. All staff and clinicians involved in the intervention share responsibility for the success of this project

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

31. Staff and clinicians involved in the intervention have clearly defined roles and responsibilities

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

32. Staff and clinicians involved in IMAT can accomplish intervention tasks within their regular work load

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

33. Staff and clinicians involved in IMAT have staff support and other resources required for the project

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

34. The implementation plan for IMAT identifies specific roles and responsibilities

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

35. The implementation plan for IMAT clearly describes tasks and timelines

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

36. The implementation plan for IMAT includes appropriate provider and patient education

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

37. The implementation plan for IMAT acknowledges staff input and opinions

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

38. The following are available to make the selected plan work:

Staff incentives

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

Equipment and materials

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

Patient awareness/need

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

Provider buy-in

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

Intervention team

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

Evaluation protocol

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Don't know/Not applicable
1	2	3	4	5	6

Appendix F: HSCL-25

HOPKINS SYMPTOM CHECKLIST-25 *(MAT FORM8- DEPRESSION AND ANXIETY SCALES)*

Instructions: Listed below are some symptoms or problems that people sometimes have. Please listen to each one carefully and decide how much the symptoms bothered or distressed you in the last week, including today.

Ja. ANXIETY SYMPTOMS

Suddenly scared for no reason	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX1	
Feeling fearful	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX2	
Faintness, dizziness, or weakness	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX3	
Nervousness or shakiness inside	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX4	
Heart pounding or racing	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX5	
Trembling	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX6	
Feeling tense or keyed up	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX7	
Headaches	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX8	
Spells of terror or panic	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX9	
Feeling restless, can't sit still	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-ANX10	

Jb. DEPRESSION SYMPTOMS

1. Feeling low in energy, slowed down	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP11	
2. Blaming yourself for things	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP12	
3. Crying easily	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP13	
4. Loss of sexual interest or pleasure	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP14	
5. Poor appetite	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP15	
6. Difficulty falling	1=NOT AT	2=A	3=QUITE A	4=EXTR-		

asleep, staying asleep	ALL	LITTLE	BIT	EMELY	MAT-DEP16	
7. Feeling hopeless about the future	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP17	
8. Feeling blue	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP18	
9. Feeling lonely	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP19	
10. Thoughts of ending your life	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP20	
11. Feeling of being trapped or caught	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP21	
12.Worrying too much about things	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP22	
13.Feeling no interest in things	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP23	
14. Feeling everything is an effort	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP24	
15. Feelings of worthlessness	1=NOT AT ALL	2=A LITTLE	3=QUITE A BIT	4=EXTR-EMELY	MAT-DEP25	

Appendix G: injection drug use risk behaviors

1. Have you injected drugs at least once in the last 12 months?	NO	0 [ ]
	YES	1 [ ]
2. Have you ever used Flashblood	NO	0 [ ]
	YES	1 [ ]
3. Have you shared needles/syringes with other users at last injection?	NO	0 [ ]
	YES	1 [ ]
4. Have you shared other injection equipments with other users at last injection?	NO	0 [ ]
	YES	1 [ ]

5. If **yes**, how did you clean the needles/syringes? (Can check more than one)?

SOAP AND WATER	1 [ ]
ALCOHOL	2 [ ]
BLEACH	3 [ ]
BOILING WATER	4 [ ]
CLEANED BY OTHER WAYS (SPECIFY): ----------	5 [ ]

6. If **no,** have you ever left your needles in some place for fear of police and you were not sure of some else had used your needle and syringe before you next used it?

NO	0 [ ]
YES	1 [ ]

Appendix H: Substance Dependence

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, **as manifested by 3 (or more)** of the following, occurring within a 12-month period:		
1. Tolerance: a need for increased amounts of the substance to achieve intoxication or desired effect or a diminished effect with continued use of the same amount	0	No [ ]
	1	Yes [ ]
2. Withdrawal: manifestation of the characteristic withdrawal syndrome or the same (or a closely related) substance is taken to relieve or avoid symptoms	0	No [ ]
	1	Yes [ ]
3. The substance is often taken in large amounts or over a longer period than was intended	0	No [ ]
	1	Yes [ ]
4. There is a persistent desire or unsuccessful efforts to cut down or control use	0	No [ ]
	1	Yes [ ]
5. A great deal of time is spent in activities necessary to obtain, use, or recover from use of the substance	0	No [ ]
	1	Yes [ ]
6. Important social, occupational, or recreational activities are given up or reduced because of substance use	0	No [ ]
	1	Yes [ ]
7. Substance use is continued despite knowledge of having a persistent or a recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance	0	No [ ]
	1	Yes [ ]
TOTAL SCORE FOR SUBSTANCE DEPENDENCE [ ]		

Appendix I: Supplementary Tables Chapter 5

Table 9.1: Correlation between variables included in the ordinal logistic regression results of degree of patient integration

	Degree of integration	HIV test record	CD4 test record	Engagement in Flashblood	Marital Status	Number of pills	Proportion of Visits kept	Average methadone dose	Time at methadone clinic	Amount spent on drugs
Degree of integration	1									
HIV test record	0.23	1								
CD4 test record	0.16	0.26	1							
Engagement in Flashblood	-0.09	-0.16	-0.03	1						
Marital Status	-0.02	0.05	-0.04	-0.36	1					
Number of pills	0.42	0.03	0.14	-0.17	-0.37	1				
Proportion of visits kept	0.07	0.14	0.04	-0.10	-0.17	0.19	1			
Average methadone dose	0.26	0.12	0.02	-0.10	-0.10	0.23	0.34	1		
Time at methadone clinic	-0.01	-0.06	0.25	-0.03	-0.03	0.07	-0.04	-0.26	1	
Amount spent on drugs	0.06	-0.03	0.06	0.03	0.02	0.01	-0.11	-0.11	0.26	1

Table 9.2: Missing data for potential variables for inclusion in ordinal logistic regression

Variable	Missing	Percent missing
Degree of integration	5	3.65
HIV test record	0	0
CD4 test record	0	0
Flashblood	20	14.60
Marital Status	1	0.73
ARV regimen complexity	18	13.14
Amount spent on drugs	25	18.25
Proportion of visits kept	1	0.73
Average methadone dose	1	0.73
Time at methadone clinic	1	0.73

Appendix J: Supplementary Tables Chapter 6

Table 9.3: Correlations between patient characteristics Aim 2a

	Time at methadone clinic	Age	Patient Status	Average methadone dose	Days of Methadone	Marital Status	Treatment importance	PCS12	MCS12	Self-Rated Health
Time at methadone clinic	1									
Age	-0.04	1								
Patient Status	0.10	-0.06	1							
Average methadone dose	-0.22	0.05	-0.57	1						
Days of Methadone	-0.11	0.16	-0.79	0.73	1					
Marital Status	-0.11	0.21	-0.02	-0.05	0.03	1				
Treatment importance	0.01	0.11	-0.18	0.14	0.17	-0.12	1			
PCS12	-0.36	-0.05	0.03	0.02	-0.02	0.14	-0.00	1		
MCS12	-0.17	0.07	-0.03	-0.04	-0.03	-0.08	-0.01	0.27	1	
Self-Rated Health	0.21	0.05	0.19	-0.17	-0.15	-0.08	0.05	-0.09	-0.09	1

Table 9.4: Correlation between potential variables to be included in the ordinal multivariate logistic regression on patient characteristics related to IMAT enrollment

	IMAT enrollment	HIV test record	CD4 test record	Depression	PCS12	Self-Rated Health
IMAT enrollment	1					
HIV test record	0.81	1				
CD4 test record	0.86	0.84	1			
Depression	-0.14	-0.03	-0.05	1		
PCS12	0.02	-0.02	-0.05	-0.19	1	
Self-Rated Health	0.07	0.03	0.08	0.14	-0.54	1

Table 9.5: Correlation between potential variables to be included in the multivariate mixed-effects logistic models on clinic attendance

	Integration	Sex	Average methadone dose	Attendance	Intervention
Integration	1				
Sex	-0.05	1			
Average methadone dose	-0.16	-0.01	1		
Attendance	-0.14	-0.00	0.23	1	
Intervention	0.00	0.00	-0.00	0.06	1

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