

An Evaluation of Nai Zindagi's ART Adherence Unit

- A therapeutic community facility that aims to improve HIV treatment outcomes for people who inject drugs in Pakistan

April 2016

Acknowledgements

Nai Zindagi would like to thank Mainline, which supported the ART Adherence Unit (AAU) under the Bridging the Gaps initiative of the Dutch Ministry of Foreign Affairs from January 2014 to December 2015, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, which began supporting the facility in 2016 in addition to providing support to CoPC+ sites.

Acronyms and Abbreviations

AAU	ART Adherence Unit
AIDS	Acquired Immune Deficiency Syndrome
APLHIV	Association of People Living with HIV
ART	Antiretroviral Therapy
ARV	Antiretroviral
CCM	Country Coordinating Mechanism
CoPC+	Continuum of Prevention and Care
DUNE	Drug Users Network
GARP	Global AIDS Response Progress Report
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
IDU	Intravenous Drug User
LTFU	Loss to Follow Up
NACP	National AIDS Control Programme
NGO	Non-Governmental Organization
OI	Opportunistic Infection
OST	Opioid Substitution Therapy
PIMS	Pakistan Institute of Medical Sciences
PLHA	People Living with HIV/AIDS
PLHIV	People Living with HIV
PPTCT	Prevention of Parent to Child Transmission
PR	Principal Recipient
PWID	People Who Inject Drugs
SPSS	Statistical Package for the Social Sciences
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organization

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1. Executive Summary

The ART Adherence Unit (AAU) is a residential rehabilitation facility for HIV+ PWID that combines treatment for opioid dependence with HIV treatment adherence support. It aims at stabilising the client so that HIV treatment becomes a realistic and achievable proposition for them. After just over two years of operation it has achieved considerable success in increasing the flow of PWID into the HIV treatment programme.

The facility is operated by Nai Zindagi, the civil society PR for the Global Fund HIV grant in Pakistan. It operates in the context of an HIV epidemic that is primarily driven by PWID but where treatment coverage for this population is very low. Previous studies have revealed very high rates of loss to follow up for PWID initiating treatment and this has led to a very cautious and restrictive approach to treatment initiation based on anticipated treatment failure.

The evaluation study detailed in this report was commissioned by Nai Zindagi to try and better understand the AAU's contribution to addressing the treatment coverage problem for PWID in Pakistan. It took place in the first quarter of 2016 and was designed and overseen by three independent consultants. The study consisted of five separate methodological components including a cross-sectional survey of ART-initiated PWID, a series of focus group discussions with ART clinic staff, PWID family members and spouses, a survey of the Nai Zindagi staff team, and an observational residency at the AAU conducted by an international harm reduction expert.

The study found a statistically significant impact on ART adherence for clients who had attended AAU when compared to those who had not. AAU attendees were 43-51 times more likely to be adherent in a period between 7 and 19 months of treatment initiation. There was also preliminary evidence suggestive that adherence rates were dropping off at a much slower rate for those attending AAU. We conclude that the AAU is achieving its primary objective of improving ART adherence rates for PWID.

There was also encouraging evidence that PWID who initiate ART treatment and then subsequently relapse to drug use can still continue to adhere to their HIV treatment with an appropriate level of support. It is therefore strongly recommended that HIV treatment and related support services adopt a more accommodating approach to the relapse cycles that are a fact of life for many PWID in Pakistan. In particular a coordinated approach to combining treatment for opioid dependence and treatment for HIV stands a better chance of securing more successful outcomes in both spheres.

This report makes a series of recommendations based on the study's findings which we hope will be of interest to the full range of stakeholders involved in Pakistan's HIV programme.

2. The AAU and its Context

2.1 The Challenge of Achieving Adequate ART Coverage for PWID in Pakistan

By the end of 2014 people who inject drugs (PWID) formed the single largest group of an estimated 91,340 people living with HIV (PLHIV) in Pakistan.¹ They also accounted for “the bulk of new infections.”² The most recent Global AIDS Response Progress (GARP) Report for the country declared that the HIV epidemic is “mainly driven by PWID,” with the weighted national HIV prevalence among injecting drug users estimated to be 37.8%.³ This makes the issue of securing adequate coverage of Antiretroviral Treatment (ART) for this population critical to the control of what is still a growing epidemic. However, achieving adequate treatment coverage for PWID with HIV in Pakistan has proved particularly challenging. The GARP report estimates less than 10% ART coverage of all eligible people by the end of 2014.⁴ It further reveals that of 5,019 who had been put on treatment in the same timeframe only 20% were PWID, despite the fact that they constitute an estimated 40% of those infected with HIV.⁵ This is corroborated by a cascade analysis conducted in Punjab in 2013, which declared “the gap between need for ART and those currently on ART is most acute for PWID.”⁶ That report goes so far as to state “the majority of PWIDs living with HIV who are enrolled in HIV care and eligible for ART are not receiving treatment.”⁷ It is highly unlikely that the prevention benefits of full treatment coverage will be realised if these low treatment coverage rates prevail.⁸ Treatment and treatment need are simply not aligned.

To understand the challenge that the country faces in addressing this problem it is important to break down “treatment coverage” into its constituent, and sequential, components of treatment initiation, retention in treatment, and adherence to treatment. Put simply, adherence depends on retention, which, in turn, presupposes initiation. Strong adherence outcomes will simply not be possible if initiation is restrictive and/or retention is poor. These different stages have different success factors, which require different strategies. Moreover, solving problems with one component without addressing the problems with the other two will have only limited impact on the overall coverage rates. The aim should be to optimise all three by identifying and addressing barriers to initiation, understanding and addressing causes of loss to follow up, and understanding and addressing causes of non-adherence. At this current point in time in Pakistan it is arguable that it is particularly poor results in ART *retention* for PWID that are (a) constraining adherence rates (you cannot adhere to a treatment if you fail to return to a clinic for your next prescription) and (b) leading to a restrictive approach to initiation. There is, if you like, a “negative feedback loop”, which serves to limit treatment initiation for this population. Anticipated adverse treatment outcomes create a systemic caution around prescribing treatment. As one report puts it: it is “pre-emptively assumed that PWID [will] not adhere to treatment and should not be initiated.”⁹ This assumption needs to be addressed if the treatment coverage problem is to be resolved.

The conundrum is illustrated by one of the few pieces of research that has been conducted into ART compliance among PWID in Pakistan. A descriptive observational study tracked 162 patients (81

¹ *Epidemiological Analysis of HIV Epidemic and AIDS Response in Pakistan*, Research report

² *Pakistan Global AIDS Response Progress Report (GARPR) 2015*, NACP, p8

³ *ibid*, p8 & p11.

⁴ *ibid*, p19

⁵ *Epidemiological Analysis of HIV Epidemic and AIDS Response in Pakistan*, Research report, p12

⁶ *Test-Treat-Retain Cascade Analysis, Punjab Province, Findings Report*, Final Revised 28.08.14, p13

⁷ *ibid*, p30.

⁸ For treatment to have a prevention effect at population level it is typically recommended that ART coverage rates (of those eligible for treatment) need to be in excess of 75%. See, for example, *Expanded Access to Highly Active Antiretroviral Therapy: A Potentially Powerful Strategy to Curb the Growth of the HIV Epidemic*, Lima et al, HAART and HIV Prevention, JID 2008:198. A number of variables can influence the required level of coverage including adherence rates, and eligibility criteria. WHO currently recommends that all those testing positive regardless of CD4 count should initiate treatment. See: *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*, WHO, September 2015. UNAIDS has set reference targets of 90% of HIV infected individuals diagnosed, 90% of those diagnosed on treatment, and 90% of those on treatment virally suppressed. See: *90-90-90, An Ambitious Treatment Target to Help End the AIDS Epidemic*, UNAIDS, October 2014.

⁹ *ibid*, p30

PWID, 81 non-PWID) for five years from 2008-2012.¹⁰ By the end of the study 59% of the PWID were lost to follow up and only 20% were compliant. By comparison the non-PWID were 90% compliant and only 2% were lost to follow up. Although the paper acknowledges that “people who inject drugs can successfully undergo treatment and benefits from ARVs”, and that “ensuring adherence to ARVs in IDUs can significantly prevent the spread of HIV in Pakistani population”, its main conclusion is that illiteracy, poor socio-economic status and multiple comorbidities “contribute to poor compliance in IDUs and rampant spread of resistant organisms ... which contribute to majority of HIV cases in Pakistan.” The only suggestion the paper makes on how to address the problem is that “NGOs working in this field should work vigilantly and ensure complete rehabilitation and proper follow-up of IDUs before they are sent back to their homes.”

The paper’s conclusions are questionable. As mentioned above, adherence (or compliance) rates are dependent on retention rates. If 60% of patients are lost to follow up then adherence rates will inevitably be low, regardless of the demographic and disease characteristics of the client group. And it is not at all clear how illiteracy, poor socio-economic status and multiple comorbidities would contribute to loss to follow up (the mere presence of these characteristics in the group does not of itself establish a causal link with their tendency to drop out of treatment.) There is no real analysis of the causes of the remarkably high loss to follow up rates.¹¹ The author’s suggestion that the solution is for NGOs to ensure “complete rehabilitation” indicates that they are perhaps aware of this and are inclined to attribute the cause to drug use itself, though this is not explicitly stated and would, in any case, have very weak explanatory value; drug users are lost to follow up because they are drug users. Regardless of the explanation there is clearly a very significant problem with retaining PWID in ART treatment in Pakistan and adherence rates will not increase unless this *retention* problem is properly understood and addressed.

The recommendation for “complete rehabilitation” requires further elaboration, especially if we are to fully understand the “negative feedback loop” - from anticipated adverse treatment outcomes to restrictive treatment initiation - referred to above. The Daud *et al* paper evidences the adverse treatment outcomes (although wrongly weights them as compliance issues rather than retention issues.) A large portion of PWID initiating ART between 2008 and 2012 were lost to follow up. This has fuelled concerns among clinicians about the potential emergence of treatment resistant strains. During the development of Pakistan’s recent HIV Concept Note in 2015 these concerns were one of the main reasons given by clinicians for still insisting that PWID undergo two weeks detoxification prior to ART initiation, despite the fact that national guidelines no longer require this.¹² Again, the implication is that drug use itself is perceived to be the main cause of loss to follow up and if we can convert a drug user into a ex-drug user we will stand a much better chance of retaining him in treatment. This is why “complete rehabilitation” is viewed as a solution.

The main problem with the “no initiation without rehabilitation” approach to treating HIV infected PWID in the Pakistan context is the limited availability of quality services for addressing opioid dependence. With no OST programmes in place¹³, this makes the coverage of treatment (at the initiation end of the continuum) totally dependent on the capacity and availability of quality detoxification services. The Punjab cascade analysis report cited above concludes “the limited availability and accessibility of detoxification services...effectively excludes most HIV-positive PWID

¹⁰ *Anti-Retroviral Drugs Compliance In Intravenous And Non Intravenous Drug Abusers*, Daud et al, J Ayub Med Coll Abbottabad 2014;26 (4)

¹¹ Clinicians interviewed by the Punjab Cascade Analysis singled out clinic distance and the number of clinic appointments needed to initiate treatment as being the main cause of LTFU: “The primary reason for LTFU, in the opinion of the clinic staff, was the distance to be travelled and the number of appointments that were necessary for good clinical management, especially for families traveling from Gujrat, Faisalabad and Sargodha.” *Test-Treat-Retain Cascade Analysis, Punjab Province, Findings Report*, Final Revised 28.08.14, p29.

¹² See, *Applicant Response Form p7*, submitted to the Global Fund in response to feedback from the Technical Review Panel on the 1st iteration of the HIV Concept Note.

¹³ A pilot OST programme was originally budgeted into the first iteration of Pakistan’s HIV Concept Note. It was taken out for the second iteration because strong political opposition meant that there would be a high risk of non-implementation in the relatively short timeframe of the grant. It is currently thought unlikely that the requisite approvals for an OST programme to go ahead will be secured before the end of 2017.

from accessing ART even when they otherwise qualify on the basis of CD4 count or clinical staging.”¹⁴ There was extensive discussion of the role of detoxification as a gateway service for ART initiation by a range of stakeholders during the development of Pakistan’s HIV Concept Note for the Global Fund in 2015.¹⁵ Clinicians tended to view detoxification primarily as a way of reducing the likelihood of adverse treatment outcomes. However, for those working directly with PWID, on the other side of the gateway, the issue was more about uptake than retention. They pointed out that whilst there is a pre-existing demand for detoxification services within the PWID community the same could not be said for ART initiation. In fact, frontline workers felt that detoxification was important in supporting clients to a point where they were interested and motivated to initiate ART. In this view detoxification is a treatment access facilitator rather than an access barrier. Both clinicians and frontline workers see detoxification as essential for treatment preparedness, only for different reasons. The problem is quality detoxification services are in scarce supply.

It is clear from the above analysis of the challenges and issues around achieving adequate ART coverage for PWID that the situation is a complex one. Much of what has been presented above was discussed extensively during the development of the second iteration of Pakistan’s HIV Concept Note for the Global Fund. In that document commitments were made to a number of measures to attempt to resolve the problem. These included boosting the provision of ART adherence support services to PWID to address non-adherence, integrating services for supporting ART treatment with services for treating opioid dependence, better tailoring treatment, care and support services to the life circumstances of PWID, further training clinicians in the provision of HIV treatment for active opioid users, and formalizing referrals and linkages to reduce client loss between cascade segments.¹⁶ A collaborative, coordinated and fully integrated approach is required in order to boost treatment outcomes for this population.¹⁷ This might well mean a new level of on-going treatment access support to ensure that PWID initiating treatment stay adherent and make it back to their next appointment. Dispensing the medications and scheduling the next clinic appointment alone is unlikely to suffice. This is particularly so given that clinics are often situated a long way from the client’s place of residence and multiple visits are often required. These issues will be returned to throughout the course of this report. It is within the context of the challenges outlined above that we can now introduce the ART Adherence Unit (AAU) run by Nai Zindagi, the civil society PR for Pakistan’s current HIV grant from the Global Fund.

2.2 The ART Adherence Unit

In terms of the cascade of services from prevention through to treatment and care, the AAU sits at the threshold of treatment initiation. It is an 8-week residential care programme that is specifically designed to simultaneously address the opioid dependence and HIV treatment adherence support needs of HIV positive PWID.¹⁸ Its clients have all been certified by clinics as eligible for treatment¹⁹ and are just beginning their opioid-free treatment journey. Opening in January 2014, the facility is operated by Nai Zindagi, and was funded in its first two years by the Dutch Ministry of Affairs through the Mainline Foundation in the Netherlands. It has recently secured further support from the Global Fund to continue its operation until the end of 2017. The original design of the AAU

¹⁴ *Test-Treat-Retain Cascade Analysis, Punjab Province, Findings Report*, Final Revised 28.08.14, p30.

¹⁵ See, *Applicant Response Form* p7, submitted to the Global Fund in response to feedback from the Technical Review Panel on the 1st iteration of the HIV Concept Note, for an account of different stakeholders views on the role of detoxification services in the treatment cascade for PWID.

¹⁶ *ibid*

¹⁷ This point is well made in *Test-Treat-Retain Cascade Analysis, Punjab Province, Findings Report*, Final Revised 28.08.14, see for example p35 where it is stated that “to the extent that HIV care and treatment can be effective it requires a highly coordinated and collaborative team approach involving services and organisations addressing drug dependence as well as HIV care, treatment and support providers.”

¹⁸ The description of the AAU service model in this section pertains to the model as it was during the timeframe covered by the evaluation study. The model has since evolved. Changes in the model are discussed in later sections in relation to the findings of the evaluation. See Section 4.3 below pp25-26.

¹⁹ At present a patient must have a CD4 count of 500 or below to be eligible for treatment unless the patient’s spouse is already HIV positive.

service was built around the ART treatment centres' requirement that PWID clients undergo a minimum of 2 weeks detoxification prior to treatment initiation. Detoxification and ART initiation support were initially provided in two separate residential facilities some distance apart. A client who had been tested HIV positive, and who had a CD4 count of 500 or below, would undergo residential detoxification for two weeks before being escorted to the clinic to initiate treatment. After treatment initiation the client would then be taken to the AAU for a therapeutic community programme based on behaviour shaping strategies and tools.

The overall objective of the AAU is primarily about supporting the client to reorient their life so that lifelong treatment with ART becomes a realistic and achievable proposition for them. Each newly admitted client has just completed opioid detoxification and is ready to begin ART treatment. The unit provides a foundation course in treatment preparedness specifically designed for a person who has recently stopped taking heroin or other drugs²⁰. ART treatment is initiated in the early stages of the residency and supervised by the facility's Medical Officers. The service model is designed in recognition of the fact that the transition from active opioid user to ex-drug user is a process with many potential stumbling blocks and cycles of relapse along the way. It is based on principles of respect for the client's life choices and an understanding that the healing process that the client needs to go through in order to regain his sense of self-worth has only just begun. The service is consensual; a client is free to leave at any time. The approach is intended to be entirely non-coercive and founded on principles of mutual respect between staff and client. Structure and order are provided in the form of a fixed schedule of daily activities that include individual and group therapy sessions, lectures and presentations on various topics around HIV/AIDS (treatment adherence, safer behaviours, OIs,) sessions on psychosocial issues (goal setting, family reintegration, anger management, disclosure and risk, relapse prevention,) and family call time and diary writing. The facility is staffed by a mixed gender team of Medical Officers (4), Paramedics (6), Psychologists (8), Counsellors (10), and a complement of administrators, with several of the counsellors themselves being ex-users. Medical services provided include basic health care, treatment of OIs (as recommended by the special clinic,) STI treatment, ARV adherence monitoring, diagnosis and treatment of TB, and medical referrals.

The AAU currently has a 100-bed capacity. By the end of 2015 a total of 1083 clients had been admitted to the AAU in the two years it had been operating. Of these 71% completed the entire 8-week programme and were discharged back to their communities. A further 14% left against medical advice, 3% were asked to leave and 4% were referred out to other medical services due to urgent healthcare needs. The remaining 8% were still in residence at the end of 2015. After being discharged from the AAU the client returns home where the Social Mobiliser working at the CoPC+ site that originally referred the client to the AAU assists with adherence either by collecting the medications from the clinic and distributing them to clients or by escorting clients to clinics when they are required to attend in person. Additional post-AAU adherence support is provided by Female Outreach Workers by involving the spouses of the clients. By means of this continuum of support from detoxification, through treatment initiation and lifestyle stabilization, and on to reintegration, it is arguable that the advent of the AAU has already had a significant impact on the rates of initiation of ART treatment by PWID in Pakistan. From 2011 to 2013 PWID as a percentage of all PLHA on treatment remained relatively stable at a rate of 11-13%. After 2 years of operation for AAU, the absolute numbers of PWID on treatment increased 288% from 441 at the end of 2013 to 1710 at the end of 2015. People attending AAU represented 40% of all PWID on treatment in 2014 and 2015, or 85% of the growth in numbers of PWID on treatment in those two years. As a percentage of all PLHA on treatment PWID had doubled in these two years to 23%. Of course, these figures still represent very low coverage rates overall but they do suggest a dramatic and much needed change in rates of ART initiation among PWID.²¹ This was achievable because of a

²⁰ Whilst Heroin is the main drug used it is not the only one. Many of the clients at AAU have been injecting pharmaceutical preparations and the locally manufactured drug "Marfia".

²¹ *Pakistan Global AIDS Response Progress Report (GARPR) 2015*, NACP, p20. Figures for 2015 provided by NACP.

high degree of collaboration between the clinics and the AAU.

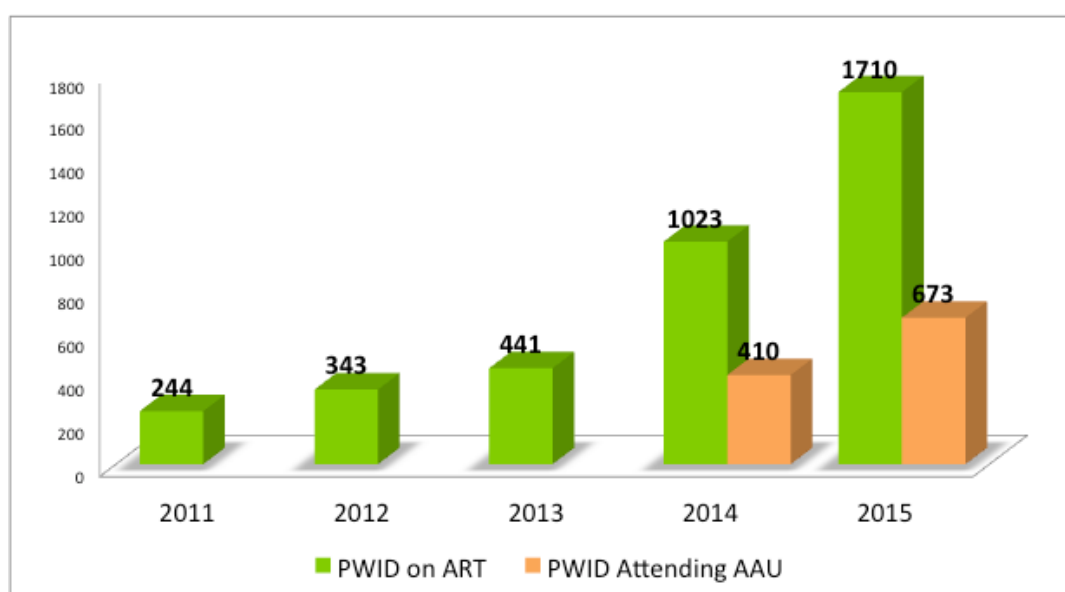


Figure 1: The Rise in PWID on ART Coincides with the Operation of AAU

In the first two years of operation the interface between the ART clinics and the AAU typically worked as follows. Knowing that the client would not be initiated on ART without having a CD4 count of 500 or below (unless part of a serodiscordant couple,) and without being detoxified, the CoPC+ site staff would only initiate detoxification for clients whose CD4 counts indicated they were treatment eligible.²² After completing two weeks detoxification the client would then be escorted to the ART centre. Once baseline tests were completed and eligibility confirmed the clinic would prescribe treatment, giving two months medication to the Nai Zindagi Social Mobiliser who had accompanied the client to the clinic. The Social Mobiliser would then escort the client back home and arrange admission to the AAU. Once admission arrangements had been confirmed the client and the medication would then be taken to the AAU where treatment would be initiated under the supervision of the Medical Officers at the AAU. This process required a temporary transfer of treatment oversight at the start of treatment initiation from the clinic to the AAU and back again. Clinics agreed to this on the understanding that the aim was to improve treatment outcomes for PWID.

It is important to consider the travel distances involved in the service flow and what they might mean to a PWID. The AAU and detox centre are situated just outside Islamabad in Bara Kahu. Clients are being referred in from 28 Global Fund supported Continuum of Prevention and Care (CoPC+) sites across 3 provinces²³. These sites refer clients to 9 different clinics for treatment initiation. At the very least a client must travel from CoPC+ site to detox centre and back, then to clinic and back, and then to AAU and back, with spells at home between trips²⁴. In some cases multiple clinic visits are required prior to AAU in order to complete the baseline investigations necessary to begin treatment initiation. Distances between CoPC sites and clinics range from 2 to 12 hours return trip journey time. Distances from CoPC sites to the detox centre or AAU range from 2 to 60 hours return trip journey time. Nai Zindagi arranges transport and escort for all these trips but they nonetheless place considerable demands on a clientele group that struggle with schedules and appointments due to the chaotic nature of their lifestyle. Many of these trips can involve travel

²² Nai Zindagi have a mobile CD4 machine that they can use for field-based CD4 testing.

²³ CoPC+ sites provide a range of front-end prevention services for PWID including needle exchange, wound and abscess care, HTC and CD4 tests for those testing HIV positive. They represent an entry point to the service cascade for PWID.

²⁴ As mentioned above, this description of the AAU service model pertains to the model as it was during the timeframe covered by the evaluation study. The model has since evolved and the detox centres have been closed and merged into the AAU unit. Changes in the model are discussed in later sections in relation to the findings of the evaluation. See Section 4.3 below pp25-26.

across security checkpoints requiring proof of identification, which the clients may be unable to produce. Throughout this journey the client may be experiencing a nagging desire for another fix of heroin. There is a significant risk that the logistics (time, distance, effort) of getting from a positive diagnosis for HIV to an effective treatment for it will seem insurmountable to the client and not worth the effort.

In the second year of operation of the AAU Pakistan was going through a process of developing an HIV Concept Note for submission to the Global Fund. By September 2015 the Global Fund's Technical Review Panel had responded to the first iteration of the Concept Note expressing strong concern about the high rates of loss to follow up for PWID on ART.²⁵ It was requested that the second iteration contain measures to further address this problem. At this point it had already become apparent that the prospect of OST securing political approval within the lifetime of the grant was extremely remote. Thus one major tool for helping to stabilise the lifestyles of PWID to make treatment more effective was not going to be available for the foreseeable future. The issue of treatment support for PWID was pushed to the fore and there was a need to understand the extent to which the AAU, already part of the original Concept Note but placed in the Above Allocation budget, was helping to address the problem. Although Nai Zindagi's service data appeared to be showing favourable outcomes in terms of post-AAU ART adherence there was a demand for an independent assessment of the model to better understand its impact on improving treatment outcomes for PWID. The evaluation study that is the subject of this report was commissioned in response to that demand.

²⁵ This was largely based on the data from the Daud *et al* paper, which was included in the Concept Note.

3. The Evaluation Study

3.1 Study Overview

The study was designed by a team of three consultants with expertise in programme evaluation, harm reduction, Global Fund grant oversight and community systems strengthening. The consultant team led a study design workshop from 19th to 21st January 2016 with participation from the Nai Zindagi staff team. Once the basic methodology of the study had been mapped out it was presented to a group of around 40 stakeholders in a consultation meeting held on the 22nd January. In addition to the consultant and Nai Zindagi teams participants included representatives from the National and Provincial AIDS Control Programmes, ART clinics from the federal capital and all four provinces, provincial treatment coordinators, the Association of PLHIV (APLHIV) and the Drug Users Network (DUNE), the CCM Secretariat and UNICEF. Feedback received helped fine-tune the study design.

Three broad objectives were agreed upon for the study:

- To determine what impact completion of a full residency (8 weeks) at the AAU has on ART adherence and drug relapse outcomes for HIV+ PWID initiating ART.
- To identify other factors that influence ART adherence and drug relapse outcomes for HIV+ PWID initiating ART.
- To identify opportunities to further improve the AAU model.

A range of quantitative and qualitative methodologies were selected for the evaluation which was to consist of the following components:

1. A quantitative cross-sectional survey of ART-initiated PWID
2. A series of focus group discussions with staff of ART clinics
3. A series of focus group discussions with spouses and family members of ART-initiated PWID
4. A quantitative survey of Nai Zindagi staff members
5. An observational residency at the AAU to assess service quality.

Although data secured from each of the study components would likely be useful in helping to address all three objectives of the study, it was designed in such a way that the client survey was to be the main vehicle for answering the primary research question of “what impact is AAU attendance having on ART adherence and drug relapse rates among PWID?” The focus group discussions and staff survey were to help identify factors influencing adherence and relapse outcomes, and the observational residency at AAU was to help formulate recommendations for improving the service model. More details about the proposed methodology and scope of each of the 5 components are given below. A detailed schedule of the study is contained in the annex to this report.

3.2 Methodology

3.21 Cross-Sectional Survey of ART-Initiated PWID

In order to assess the impact of AAU on ART adherence and drug relapse rates it was decided to do an analytical comparison of outcomes for two groups of ART-initiated PWID; one group exposed to AAU, the other unexposed. The following were agreed upon as sample inclusion criteria:

- To be eligible to participate the client must be an HIV+ PWID who initiated ART at some point between 1st July 2014 and 30th June 2015.
- Nai Zindagi must have a record of the ART registration number of the client.

- (AAU exposed group only) The client must have completed the full 8 weeks residency at AAU.
- (AAU naïve group only) The client must never have attended AAU.
- The client must be from a city that meets the city inclusion criteria (see below.)

A couple of points regarding the client inclusion criteria require elaboration. For the eligibility timeframe it was felt that since AAU only opened in January 2014 we did not want to include people who were admitted in the first 6 months start-up phase while the service was finding its feet. We also wanted to allow for a reasonable length of post AAU time given that adherence rates could be expected to drop over time and relapse rates rise; hence the June 2015 cut-off. This meant that the possible ART adherence period of any participant would range from a minimum of 7 months to a maximum of 19 months since treatment initiation. The ART registration number criterion was included so that we could triangulate the client's self-reported adherence with the clinics' records of medicine dispensing. There was some discussion at the stakeholder consultation about whether it was appropriate to limit the control group to Nai Zindagi clients. The consultant team felt that this was the only way to ensure maximum similarity between intervention and control group participants in terms of exposure to services other than AAU, which may affect outcomes. AAU is part of a continuum of Nai Zindagi services from prevention through to treatment and care. By restricting eligibility to Nai Zindagi clients we could ensure that the main service exposure difference between the two groups was the one we wanted to measure the impact of: AAU attendance.

As mentioned in the previous section clients are referred into the AAU from 28 CoPC+ sites in 3 provinces. We developed a set of criteria to determine which of these sites we would sample from as follows:

- A participating city must have a minimum of 2 clients, from among those meeting the client inclusion criteria above, who have been contacted by Nai Zindagi in the last month.
- The city must be in Punjab province (AAU was not available to clients in other provinces until February 2015 so we would not have been able to achieve an even distribution of the participants from other provinces across the sampling timeframe.)
- Overall city selection was to include cities referring clients to at least 5 different ART clinics.
- Overall city selection was to include a broad and representative range of clinic travel distances.

The first of these criteria was to ensure that we could recruit an adequate number of respondents from each site. There was some discussion at the stakeholder consultation meeting about whether we could sample from other provinces but given the non-availability of AAU in other provinces until February 2015 the consultant team felt this might bias results. The criteria regarding clinic exposure and clinic distance were to ensure that the results were not unduly biased by travel times and/or exposure to particular treatment centres.

A particular consideration in the sampling process was the distribution of the sample (in terms of ART initiation date) across the time period between 1st July 2014 and 30th June 2015. We needed to ensure that the intervention and control groups were evenly distributed across the sampling timeframe given that adherence and relapse rates could reasonably be expected to vary over time. To achieve this we divided our timeframe into four quarters and set recruitment targets for each group (intervention/control), for each city, and for each quarter. We set targets of 20% of the total population for each group i.e. 20% of the total population of HIV+ PWID from the selected cities who had initiated ART and been regularly discharged²⁶ from AAU for the intervention group, and 20% of the total population of HIV+ PWID from the selected cities who were clients of Nai Zindagi services but had never attended AAU for the control group. The cities originally selected on the basis of the

²⁶ Regular Discharge means that the client completed the entire 8 weeks of the residency.

city selection criteria above were: Gujrat, Jhang, Jhelum, Kasur, Khanewal, Rahimyarkhan, Rawalpindi, and Sahiwal. Khanewal later looked unfeasible due to issues with staff turnover in the CoPC+ site there and was substituted by Okara. The sampling criteria outlined above meant that our overall sample of clients would be stratified in three ways: by exposure/non-exposure to AAU, by city, and by time period of ART initiation.

Participants were selected for inclusion by the consultant team from a full list of the total population of eligible clients provided by Nai Zindagi. This list was broken down by the three strata of the overall sample so that we could short-list evenly across the four quarters and from each city in proportion to the total number of clients there. We short-listed more than the sampling targets to allow for the fact that some clients may prove unreachable. In all, 169 clients from 10 cities were interviewed of which 128 were deemed fully eligible. Of these 128, 104 were in the intervention group and 24 in the control group. In addition to the 128 that conformed to our eligibility criteria there were a further 13 individuals who were originally assigned to the control group but were later deemed ineligible when it transpired during data cleaning that they had never actually initiated ART. We retained this group for analysis on the grounds that they may shed some light on the “loss to follow up” problem but they were not included in the analysis of adherence and relapse outcomes. A key challenge in the survey proved to be recruiting sufficient individuals into the control group. Many people who were short-listed by the consultant team turned out to be unreachable for a number of reasons, including, in some cases, death. In order to address the shortfall in control group participants we sampled a further two cities exclusively for the recruitment of controls. These were Khanewal and Muzaffargarh. All 10 included cities met the city inclusion criteria. As mentioned above we had set ourselves targets of recruiting 20% of the total population for each group (intervention and control) into our sample. An analysis of the final sample (128) showed that we had recruited 40% of the intervention group population and 22% of the control group population from the 10 selected sites.

Total Sampled	169	
Ineligible	41	
	Outside of Sampling Timeframe	Never Initiated ARVs
	28	13
Eligible	128	
	Intervention	Control
	104	24

Figure 2: The Structure of the Final Sample

In order to triangulate the client’s self-reports of ART adherence or non-adherence we agreed with clinicians and the AIDS Control Programmes that once the survey had been completed we would check back with the clinics on the clinic attendance records of the clients in the sample. Clinics typically prescribe no more than 2-3 months ART medication therefore a client reporting adherence ought to have visited the clinic at most 3 months before the survey and, conversely, a client reporting non-adherence would not be expected to have attended a clinic within the last 3 months before the survey.

3.22 Focus Group Discussions with ART Clinic Staff

It was originally planned to conduct 2 focus group discussions with staff at ART clinics in Faisalabad and DG Khan. As the study rolled out it was suggested by Punjab AIDS Control programme that we also conduct a focus group discussion with staff at the ART clinic in Jinnah Hospital, Lahore. This

was agreed to. In all a total of 13 clinic staff participated in the 3 discussions; 6 in DG Khan, 3 in Faisalabad and 4 in Lahore. These included 3 clinicians in charge, 2 medical officers, 2 counsellors, a staff nurse, a clinical psychologist, 2 PPTCT case managers and 2 data entry operators. The discussions were facilitated by a member of the consultant team and permission was sought to audio record the proceedings. This was only granted for one of the three discussions. Notes were taken in the other two during the discussion. Summary notes were produced for each of the three discussions.

3.23 Focus Group Discussions with Spouses and Family Members of ART-Initiated PWID

These were to take place in each of the 8 sites originally selected to participate in the client survey: Gujrat, Jhang, Jhelum, Kasur, Okara²⁷, Rahim Yar Khan, Rawalpindi, and Sahiwal. They were facilitated by trained facilitators and all 8 were audio recorded. Summary notes were then produced from the recordings. There was an initial concern about whether it was appropriate to mix spouses in with family members or separate them out. The concern was that spouses might not actively participate in a mixed group. After field testing this concern proved unfounded. The number of participants in each group ranged from 6 to 18.

3.24 Survey of Nai Zindagi Staff

It was originally planned to conduct a series of focus group discussions with different contingents of the Nai Zindagi staff team but this idea had to be revisited when available resources proved insufficient. Instead we opted for a self-administered quantitative survey. Surveyed staff included the 8 Social Mobilisers and 8 Female Outreach Workers at the CoPC+ sites in the 8 cities originally selected for inclusion in the client survey. These staff members provide, among other things, pre AAU support to HIV+ PWID (detoxification, treatment registration,) and post AAU support (medication collection, clinic visit escort, family/spouse support for adherence.) Additionally we surveyed 12 staff at the AAU (6 Counsellors, 2 Medical Officers and 4 Paramedics.) The aim was to get greater insight into factors influencing ART take up and adherence and relapse outcomes from staff who support clients at different points in the continuum (pre-initiation, during initiation and stabilisation, and after reintegration into the community.) In all 28 staff members were surveyed. The data was entered into an Access database and then uploaded into SPSS for analysis.

3.25 Observational Residency at AAU

The Observational Residency at AAU was conducted by the harm reduction expert on the consultant team. The aim was to collect qualitative data from both participatory observation and informal interviews with staff and clients at the facility. After an introductory visit during which he was introduced to the staff and clients, and the purpose of his residency explained, the consultant spent a total of 4.5 days at the facility, joining in proceedings at the start of the day and leaving at the end of the day's scheduled activities. In the course of the residency 15 AAU staff and 15 clients were interviewed. The results of the interviews and observations were written up in three separate documents; one summarizing discussions with staff, one summarizing discussions with clients and one giving an overview of findings from the residency. The consultant was in touch with the remainder of the consultant team regarding issues arising from other study components that could usefully be triangulated with observations being made at the AAU.

3.3 Research Tools, Field Testing and Interviewer Training

A set of purpose-made research tools were developed for each of the study components as follows:

- A client questionnaire

²⁷ In the original process of city selection (see above) we had selected Khanewal rather than Okara. This was changed in the early stages of sampling and Okara was substituted for Khanewal because it was thought unlikely we could successfully reach recruitment targets for the client survey in Okara. Khanewal was later brought back on when we needed to increase numbers recruited into the Control Group – see discussion above.

- 2 focus group discussion guides; one for discussions with ART clinic staff, one for discussions with families/spouses of PWID
- 1 observation guide for the AAU residency with adapted versions of staff and client questionnaires to help guide the informal interviews.

The client questionnaire and the focus group discussion guide for spouses/family members were both translated into Urdu and field-tested in Rawalpindi before being finalised. A team of four interviewers/discussion facilitators were trained by a member of the consultant team to use the client questionnaire and family/spouse focus group guides. This included a demonstration, and observation and feedback on a facilitated focus group discussion with family members/spouses. A particular concern was to ensure that interviewers and facilitators were non-directive when conducting interviews and facilitating discussions.

3.4 Data Entry, Cleaning and Analysis

Data from the client and staff questionnaires were inputted into a purposely-designed Access database before being uploaded into SPSS for analysis. An extensive data cleaning process took place. Data cleaning included but was not limited to:

- Checking that respondents met eligibility criteria
- Verifying appropriate allocation to intervention and control groups
- Removing ineligible respondents from the sample (this included respondents in the intervention group who had not completed the full 8 weeks residency at AAU, and respondents in both groups who had initiated treatment after the last date of the sampling timeframe.)
- Ensuring consistency in question answering patterns (e.g. making sure that questions applicable to people attending AAU only were only answered by those affirming AAU attendance.)
- Correcting incorrect ART registration and Nai Zindagi codes by cross-checking with client records
- Extensive cross checking of data entered in SPSS with the original hard copy questionnaires
- Random checking selected hard-copy questionnaires against data entered once all data had been cleaned.

The main impact of the data cleaning was the loss of a considerable portion of those from the control group due to either their having been initiated on ART after the end of the sampling timeframe or their never having been initiated on ART.

A weighting was applied to the final sample based on the 3-tiered structure in the design to adjust for under and over-sampling. To develop the weighting we divided the 10 participating cities into two clusters: those for which round-trip CoPC+-to-clinic travel time was 2 hours or less and those for which round-trip CoPC+-to-clinic travel time was greater than 2 hours. Group 1 cities thus consisted of Guirat, Jhelum, Kasur, Okara and Rawalpindi (served by clinics in Faisalabad, Gujrat, Islamabad and Lahore,) and group 2 cities consisted of Jhang, Khanewal, Muzaffargarh, Rahim Yar Khan and Sahiwal (served by clinics in DG Khan and Faisalabad.) This produced a table of 16 levels (2 groups (intervention/control), x 4 quarters, x 2 city clusters.) We knew the population sizes for each of these levels and used the proportional distribution of the total population across these levels to weight the sample. The result of the weighting is to make the sample look closer to the population so that the results can be generalised back to the population as a whole.

Group	Quarter	City	Population	%	Sample	%	Weight (to sample)
Intervention	1	Grp 1	25	6.7%	16	11.3%	0.59383
Intervention	1	Grp 2	27	7.3%	8	5.7%	1.28268
Intervention	2	Grp 1	31	8.4%	14	9.9%	0.84155
Intervention	2	Grp 2	49	13.2%	13	9.2%	1.43251
Intervention	3	Grp 1	39	10.5%	17	12.1%	0.87189
Intervention	3	Grp 2	42	11.3%	11	7.8%	1.45111
Intervention	4	Grp 1	18	4.9%	11	7.8%	0.62191
Intervention	4	Grp 2	32	8.6%	14	9.9%	0.86869
Control	1	Grp 1	5	1.3%	7	5.0%	0.27147
Control	1	Grp 2	20	5.4%	2	1.4%	3.80054
Control	2	Grp 1	10	2.7%	6	4.3%	0.63342
Control	2	Grp 2	22	5.9%	9	6.4%	0.92902
Control	3	Grp 1	5	1.3%	2	1.4%	0.95013
Control	3	Grp 2	12	3.2%	3	2.1%	1.52022
Control	4	Grp 1	14	3.8%	3	2.1%	1.77358
Control	4	Grp 2	20	5.4%	5	3.5%	1.52022

Total 371 100.0% 141 100.0%

Figure 3: Sample-Weighting Table

Before running the impact analysis we conducted a number of checks on the weighted sample to ensure comparability between the intervention and control groups. The first check was to compare the distribution of the control and intervention groups across the first and second 6 months of the sample timeframe (we opted for 6 months rather than 4 quarters due to the relatively small size of the control group.) This analysis showed that both control and intervention groups were split 50/50 across the first and second halves of the sample time frame thereby removing the possibility of the impact results being biased due to the groups being significantly skewed towards different ends of the timeframe.

The second check was to compare the distribution of key demographic characteristics between the two groups after weighting. This comparison revealed a broadly similar demographic profile for both groups. We were not able to attribute any particular significance to such variability as was detected due to the relatively small size of the sample. The control group tended to be younger – 82% being younger than 40 compared to 60% for the intervention group. Marriage rates were similar: 47% of the intervention group were married compared to 57% of controls. Rates of secondary school education were 38% for intervention and 40% for controls though the controls were more likely to have no education (47% versus 35%.) Rates of living in parents house were 74% for the intervention group and 65% for controls, though controls reported slightly higher rates of living on streets (18% versus 11%) and living with other PWID (21% versus 12%.) For income, 43% of the intervention group and 39% of the control group reported earning daily wages, though controls had higher rates of no income (16% versus 2%) and higher rates of receiving financial support from their families (26% versus 13%.)

3.5 Issues Arising

Overall there were two main issues that arose from the sampling outcomes. The first of these was the relatively small size of the control group. Although we achieved our target as a proportion of the target population the absolute numbers were less than we had hoped for. The key lessons to be drawn from this relate to the critical issue of loss to follow up. Many of the individuals short-listed for the control group (from Nai Zindagi's client records,) turned out to be lost to follow up. In cases where reasons could be identified for this they included imprisonment and in some cases death. But the fact that this issue arose primarily for the control group and not for the intervention group suggests that the AAU may well be helping to address the loss to follow up issue. The second important issue arising from sampling outcomes also relates to the issue of dropouts and poor follow up for care & support services during the specified period. This is the case of the 13 individuals who

were originally assigned to the control group, but were later deemed ineligible when it transpired during data cleaning that they had never actually initiated ART. We compared the responses given in these 13 questionnaires with Nai Zindagi's records of detoxification attendance and the clinics' records of clinic attendance. On the basis of this comparison we can confidently say that at least 7 had completed detoxification (the evidence for the remaining 6 was contradictory,) and 10 had registered with ART clinics, though 2 of these were confirmed never to have had any medicines issued. Several of the individual responses, from among these 13, were self-contradictory so it was not possible to attach much weight to them. Overall the experience of these 13 is indicative of the significant dropout potential that lies at the intersection of every service segment in the cascade, and the challenges of supporting people with chaotic lifestyles through from one component to the next. These are the cascade dropouts that we need to be paying more attention to and further consideration of what we can learn from them will be given in subsequent sections of the report.

4. Findings

The following discussion is structured around the three objectives of the evaluation study:

- To determine what impact completion of a full residency (8 weeks) at the AAU has on ART adherence and drug relapse outcomes for HIV+ PWID initiating ART.
- To identify other factors that influence ART adherence and drug relapse outcomes for HIV+ PWID initiating ART.
- To identify opportunities to further improve the AAU model.


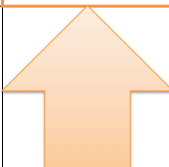


Unless otherwise specified all percentages pertain to the weighted sample and the control group excludes those who had never initiated ART. These results are therefore generalizable to the total population of ART initiated PWID using Nai Zindagi services in the cities included in the study.

4.1 The Impact of AAU on ART Adherence and Drug Relapse Outcomes

Before presenting the results of the client survey with regard to AAU's impact on ART adherence and drug relapse rates it is useful to present a simple framework for understanding and interpreting the results. The following matrix shows the four possible outcomes:

Adherence & Relapse Matrix	In Recovery (drug-free)	Relapsed (taking drugs)
ART-Adherent		
Non-Adherent		

Successful HIV treatment aims at supporting individuals into the upper two quadrants, whilst opioid dependence treatment aims at supporting individuals into the left-hand two quadrants²⁸:

Treating HIV	In Recovery (drug-free)	Relapsed (taking drugs)	Treating Opioid Dependence	In Recovery (drug-free)	Relapsed (taking drugs)
ART-Adherent			ART-Adherent		
Non-Adherent			Non-Adherent		

²⁸ This is of course an over-simplification and is in no way intended to deny the critical role of harm reduction programmes as a way of addressing opioid dependence. Harm reduction is further discussed below when we look the behaviours the clients reported relapsing to.

The objectives of the two treatments converge in the upper left-hand quadrant, but HIV treatment can be successful whilst accommodating horizontal movement between the upper two quadrants. We will return to this model below when we consider the results of the survey. It is important to bear in mind that our results capture the positions in the matrix of the individuals surveyed at the point of time the survey was conducted (which, due to the sampling timeframe, is between 7 and 19 months after their detoxification and initiation of ART treatment.) Movement between quadrants over time is possible in all directions but cannot be measured by a cross-sectional survey.

4.11 Adherence Outcomes

Results from the client survey showed an adherence rate of 77.4% for those who had completed residency at AAU compared to 51.1% for those who had never attended.

Q1-Q4	% Reporting Adherence	N	Error Margin	95% LCI	95% UCI
Intervention	77.4%	99.95	5.9%	71.6%	83.3%
Control	51.1%	24.66	14.1%	37.0%	65.2%

This result was statistically significant at a 95% confidence interval. In terms of probability this means that PWID in the sampled population were more likely to be adhering to ART if they had attended AAU than those who had never attended by a factor of 51 $((77.4/51.1)-1)$. This suggests that AAU is having a very large impact on ART adherence.

We ran the same analysis tabulating the adherence rates of both groups against the first and second halves of the sampling timeframe. We would expect adherence rates to be lower for people initiating treatment in the first two quarters (July - December 2014) than for people initiating in the second two (January - June 2015.) The analysis revealed that the difference in adherence rates between the two periods were very different between the two groups. For those attending AAU adherence rates were 78.3% for the later intake and 76.6% for the earlier intake. For those not attending AAU the figures were 73.3% and 28.9% respectively. The difference in adherence rates between later and earlier intake is 1.7% for those attending AAU versus 44.4% for those not attending. This would appear to indicate that adherence rates are declining over time at a much faster rate for those not attending AAU, though the result needs to be handled with some caution given the relatively small size of the control group and the fact that we are not tracking adherence rates in the same individuals across these two time periods.

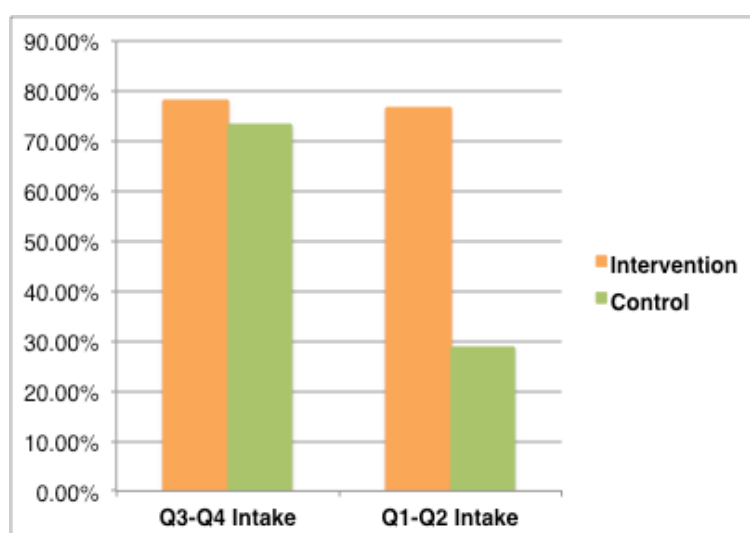


Figure 4: ART Adherence Rates by Timeframe

This observed difference in ART adherence drop-off rates was further supported by how those who

reported being non-adherent responded to a question about how long after ART initiation they stopped taking the medications. For the controls 23% stopped within the first few days and 75% in the first 1-3 months. For the intervention group the respective figures were 8% and 28%. This again suggests that AAU attendance improves adherence stamina.

The 77.4% adherence rate outcome for the individuals attending AAU is cross-sectional. As mentioned in the previous section the individuals in the study had initiated ART for a period of between 7 and 19 months. It makes no sense then to compare these outcomes with results from cohort studies that tracked adherence among the same PWID over extended time periods; ours is a cross-sectional study and we cannot deduce from our results what the adherence rates for the people surveyed will be like 5 years after initiation. That said, there is a very strong indication from these results of a much greater positive impact on ART adherence of attending as opposed to not attending AAU for PWID initiating ART. The unit can be said to be achieving its primary objective. Moreover, there is some reason to believe that AAU might be having success at sustaining adherence rates over a longer time period though this can only be tentative at this point in time given the limits of our study design.

The results above are based on the self-reported adherence of the clients at the point of the survey. We asked the clients whether they are currently taking ART, how often they are taking it and when they last took it. Among those indicating they are currently taking ART in both groups (intervention and control) there were very high rates (95%+) of taking medicines daily and having taken it within the last day, with no significant difference between the two groups. As mentioned in the previous section we did triangulate these self-reports by comparing them with clinic records of when the client last attended the clinic to have medicines dispensed. Of the people in our sample who reported being non-adherent 9 individuals had actually been dispensed medicines in February or March 2016. In 7 of these cases the medicines were likely to have been dispensed after the time at which we conducted the survey. This means it is possible that these 7 could have accurately reported non-adherence but later re-initiated treatment. A further 8 individuals who had reported being adherent in our survey had not attended the clinic in the three months prior to the survey. This makes it unlikely they were actually adherent, though it is possible some were taking medicines saved from previous visits after periods of non-adherence. Overall, data from the clinics verified 92% of those reporting to be adherent and 74% of those reporting non-adherence. To be on the safe side we ran the adherence impact analysis on the assumption that the clinic data was correct as opposed to the client reported data. The result was to increase the adherence rate of the AAU group to 78.1% and increase the adherence rate of the control group to 54.8%. This would reduce the adherence advantage of the AAU group from 51x to 43x more likely. The result is still statistically significant and the impact advantage of attending AAU in terms of adherence outcomes is still very strong.

Our data does not tell us if those reporting adherence have been consistently adherent since initiation. For example, in the course of data cleaning we discovered that 2 of the non-initiators had been back to the clinics where they originally registered and started treatment after we surveyed them. It is possible both that some people reporting adherence during the survey have had periods of non-adherence and that those reporting non-adherence will return to treatment at some future point. However, only a small percentage of those on treatment in our sample (4%) reported intermittently taking their medicines.

4.12 Relapse Outcomes

Results from the client survey show that for those who had completed residency at the AAU 42% had *not* relapsed to drug use compared to 34.8% for those who had never attended.

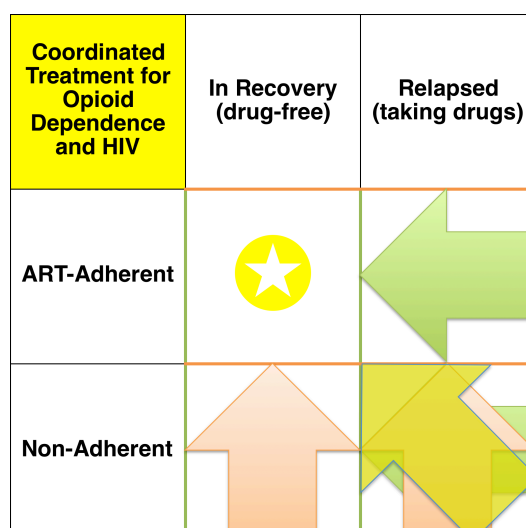
Q1-Q4	% Reporting No Relapse	N	Error Margin	95% LCI	95% UCI
Intervention	42.0%	99.95	6.9%	35.1%	48.9%

Control	34.8%	24.66	13.4%	21.4%	48.2%
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This means that 58% of those attending AAU and 65.2% of those not attending AAU had relapsed. There is little difference in relapse outcomes between the intervention and control groups and such difference as there is is not statistically significant. We also ran the results including the 13 individuals who had never initiated ART in the control group. This raised the relapse rate of the control group to 75.4% but there was still no statistically significant advantage for the intervention group with regard to relapse rates.

Overall 59% of the entire sample had relapsed to drug use within 7 to 19 months of completing detoxification. However, 60% of those reporting relapse are also reporting adherence to ART. Rates of maintaining adherence after relapse were higher for those who have attended AAU (63%) than for those who have not attended (50%.) These results show that the relationship between ART adherence and relapse to drug use may not be as simple as has previously been supposed. This is significant because much of the hesitation around putting PWID on ART in Pakistan has to do with the perceived likelihood of relapse and the assumption that non-adherence will inevitably follow. Whilst relapse is likely, as the results of this survey show, it is not inevitable that non-adherence will follow. Of all respondents reporting both adherence and relapse 63% had been relapsed for more than 6 months and this was virtually the same for both intervention and control groups (63%/62%.)

With this in mind, we can now return to the matrix presented above to describe the relationship between HIV treatment outcomes and opioid dependence treatment outcomes. Merging the two treatments into a single outcome framework gives us the following:



The upper left-hand quadrant represents the point at which the intended outcomes of the two treatments converge. The AAU has been presented in earlier sections of the report as an attempt to combine support for both types of treatment into a single service model. Moreover, the authors of the Punjab cascade analysis cite international evidence to support their argument that “to the extent that HIV care and treatment can be effective it requires a highly coordinated and collaborative team approach involving services and organisations addressing drug dependence as well as HIV care, treatment and support providers.”²⁹ We would therefore expect a combined approach to influence outcomes in the direction of the “golden quadrant.” To test this we compared the proportional distribution of intervention and control groups across the matrix. The results were as follows:

²⁹ Test-Treat-Retain Cascade Analysis, Punjab Province, Findings Report, Final Revised 28.08.14, p35

AAU	In Recovery (drug-free)	Relapsed (taking drugs)	Control	In Recovery (drug-free)	Relapsed (taking drugs)
ART-Adherent	41%	36%	ART-Adherent	18%	33%
Non-Adherent	1%	22%	Non-Adherent	17%	32%

The proportion of those who had attended AAU reporting being both drug free and ART adherent was more than double the proportion of those in the control group. This is an encouraging result though it needs to be born in mind that the only statistically significant impact we have demonstrated for AAU is in relation to ART adherence outcomes rather than drug relapse outcomes. That said, the fact that the main adherence gain is happening in the left-hand rather than the right-hand quadrant would lend support to the argument for a coordinated approach to treating HIV and opioid dependence.

Another important aspect to the issue of relapse is the question of what behaviours the drug user is relapsing to. We asked the clients who had relapsed what type of drugs they were using, whether or not these were the same drugs as they were using before detoxification, whether or not they were using the same quantities of the drug and, if different, whether they were using more or less. There was little if any difference between the intervention and control groups with respect to these questions. The results were as follows:

- 84% of those reporting drug use were using heroin
- 91% of those reporting drug use were using the same drug as they had used before
- 86% of those reporting drug use and using the same drug as before were not using the same quantity
- 93% of those reporting drug use, using the same drug as before and not using the same quantity reported using less of the drug.

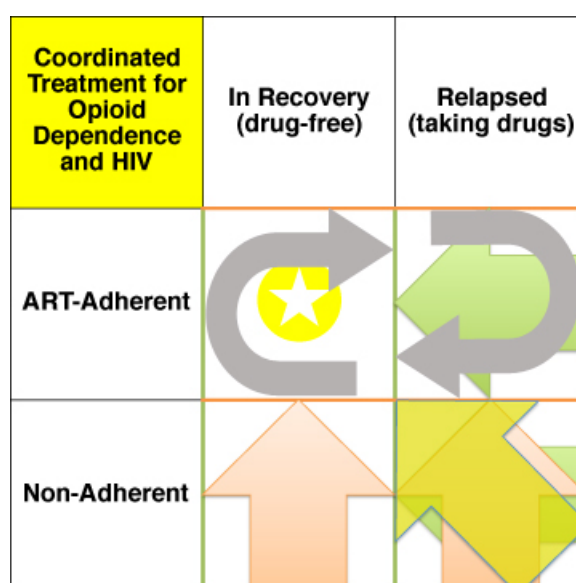
There is therefore some evidence here that those relapsing are using lower doses of their preferred drug than before. We also asked about frequency of use. Again there was little difference between the intervention and control groups. Among those currently using drugs 49% were taking drugs 1-2 times a day and 38% were taking drugs 3-4 times a day. We do not have their pre-detoxification rates to compare this to.

We also had a look at methods of taking drugs. Again, with little variance between intervention and control groups, 63% reported injecting, 53% snorting and 17% smoking (not mutually exclusive). Of all those reporting drug use at the time of the survey only 17% reported sharing a syringe or needle in the last month and 77% stated they had not shared any syringes, needles, ampoules or containers in the last month. We do not have any data on the sharing behaviours of our sample prior to detoxification but the 2015 GARP report cites that 71.5% of PWID in Pakistan inject 2-3 times a day and only 39% report always using a new syringe.³⁰ We cannot make a direct comparison here because the GARP figure pertains to 'always using' whereas our figure only pertains to sharing behaviour in the last month. However, testimony from participants in the

³⁰ Pakistan Global AIDS Response Progress Report (GARPR) 2015, NACP, p12

qualitative components of our evaluation suggest individuals exposed to Nai Zindagi services are relapsing to less harmful behaviours than the ones they had prior to service exposure. If this is true it is not an advantage of the AAU per se. The AAU sits in a continuum of prevention, care and treatment support services for PWID provided by the NGO any or all of which may be contributing to this outcome.

Despite the relatively high relapse rates we are reporting there are some positive messages in here that can be useful to the overarching aim of improving ART adherence rates among PWID. Our data shows that ART adherence is still possible for individuals who have relapsed to drug use and that individuals who do relapse may not be relapsing to behaviours that are as harmful as the ones they had prior to detoxification. A combined approach to treating opioid dependence and supporting HIV treatment can help boost adherence outcomes. With relapse being a likely prospect the issue becomes how to support PWID to maintain ART adherence over successive cycles of relapse and recovery. Illustrated graphically this means retaining the behaviour cycle within the upper two quadrants of our matrix:



This model implies a level of on-going case management support for PWID initiating ART that extends beyond the boundaries of both the ART clinics and the AAU. With regard to this the remaining objectives of our study can be considered.

4.2 Other Factors Influencing ART Adherence and Drug Relapse Outcomes

Whilst we have pointed out that ART adherence and drug relapse are not mutually exclusive this is not to deny that relapse to drug use has an impact on ART adherence rates. In our sample the overall ART adherence rate of people reporting relapse to drug use was 64.5% versus 86.7% among those who had not relapsed. For those attending the AAU and reporting relapse the adherence rate was 67.4% versus 54.3% for controls reporting relapse – the difference was not statistically significant. Relapse to drug use does have an impact on adherence and we therefore wanted to better understand factors leading to relapse. Furthermore, given that not all relapses lead to non-adherence it is worth trying to understand what factors (other than AAU exposure and relapse itself) influence adherence outcomes. We were particularly keen to understand what enables those who have relapsed to maintain adherence. Various components of our study gathered data relevant to these questions. To better understand causes of relapse and adherence-enabling factors we sought the views of multiple stakeholders; the clients themselves, their families and spouses, the ART clinic staff and the Nai Zindagi staff team.

4.21 Relapse

Regarding reasons for relapse the most common reasons given by PWID who had relapsed were

lack of family support (27%), lack of social service support (23%), and lack of employment or financial problems (23%) (answers not mutually exclusive.) In the qualitative narrative there were frequent references to the influence of being back with the same circle of friends in the same environment. Life problems could act as triggers; family disputes, divorce and relationship problems, traffic accidents, arrest and being made redundant were variously mentioned. Sexual dysfunction was also cited as a reason for relapse by a number of clients. We also asked those that had not relapsed what had helped them to stay away from drugs. The biggest motivator for the clients was health (75%), followed by family (68%) and spouse (34%,) (answers not mutually exclusive.) Just over half (54%) of those not currently taking drugs reported receiving support to help them stay off drugs. The sorts of support received to prevent relapse included family support (76%), Nai Zindagi Social Mobiliser or Outreach Worker Support (34%), and peer support (30%.) Overall it would seem that there is a case to be made for boosting post-detox relapse prevention support.

From the perspective of family members and spouses the continuity gap between detoxification, ART initiation and AAU residency was a significant factor in causing relapse. As discussed in the introductory section, for those in the sampling timeframe detoxification and AAU were housed in separate facilities and a break was required between the two in order to attend the clinic for ART initiation. AAU, detox unit and clinic were in three separate locations and for many clients this meant repeated trips over long distances. This is a historical issue. In 2016 Nai Zindagi has merged the detox unit into the AAU and negotiated with the clinics to secure medicines prior to detoxification. This effectively eliminates a crack in the service cascade that was leading to LTFU and relapse to drugs. It is at this point in the former service continuum that the 13 non-initiators we recruited into our control group disappeared from view. Their explanations for not continuing in the cascade lacked an overall coherence but included relapse, jail time, parental discouragement (suspicions about AAU's motives,) the need to stay home and care for relatives, relocation to another city, and negative peer reports about the use of ARVs. Other factors identified by family members and spouses as leading to relapse included the relative length of drug use in relation to the length of the rehabilitation process, financial issues including unemployment and trust issues around money, depression and low self-esteem (often related to not being able to earn a living,) and leaving detoxification early due to being homesick.

Feedback from the Nai Zindagi staff team reinforced a couple of the points coming up from the clients, their family members and spouses. Family support, outreach staff support and the clients own self-motivation were identified as being the main factors leading to a client's decision to detoxify. The main causes of relapse were thought to be the lack of family support and the lack of employment opportunities for PWID.

In general the input from the clinics was more about adherence than relapse, which is unsurprising given that their primary role is HIV treatment. But they did observe that quality detoxification and rehabilitation services are scarce. The AAU is one of a kind and there is a lack of quality district level detoxification services. This highlights a point made in the introductory section of this report about the scarcity of detoxification facilities that serves as a bottleneck that constrains client flow into HIV treatment. This bottleneck is a consequence of the combination of the "no initiation without rehabilitation" approach to HIV treatment for PWID and the scarce supply of detoxification facilities. Another point made by the clinics in relation to relapse was the need for continued third-party follow up of "old" cases. It is clear that the clinics are heavily reliant on external services to help them prevent LTFU due to drug relapse.

4.22 Adherence

The most common reasons for non-adherence cited by PWID who were no longer taking ART were side effects (47%) and relapse to drug use (37%.) Others mentioned spells in jail and a fear that simultaneous use for ARV and drugs would lead to death. This latter myth arose at several points in the study and it is possible that some health care workers may be using it to try and discourage

relapse. Unfortunately it can have the unintended consequence of discouraging ART adherence instead and it is highly recommended that treatment and rehabilitation centres attempt to dispel the myth. We asked about factors that motivate those adhering to adhere. The most commonly cited factors were support from Nai Zindagi Social Mobilisers and/or Outreach Workers (51%), support from family (46%), and self-motivation (43%), (answers not mutually exclusive.) The same question to those adhering who had relapsed produced similar answers in similar proportions. Other factors mentioned such as to strengthen the immune system, to prevent HIV and to increase one's lifespan, suggest an encouraging degree of treatment literacy. Overall, clients reporting adherence were also reporting a relatively high level of support. Some 87% reported receiving some kind of adherence support. This included being accompanied to clinics by Nai Zindagi Social Mobilisers (66%), having medicines brought from clinics by Social Mobilisers (21%), receiving motivational support from family members (67%) and Social Mobilisers (64%), and receiving medical (55%) and transportation support (43%), (answers not mutually exclusive.) Overall there is a strong correlation between adherence and the receipt of some kind of adherence support.

The focus group discussions with family members and spouses echoed much of what we heard from the clients with regard to adherence. Side effects, fear of death, and myths around simultaneous ART treatment and drug use were given as reasons for stopping ART. Support from Nai Zindagi was viewed as being highly instrumental in getting their spouse/family member into treatment (they would not have gone of their own motivation,) and the AAU was credited with maintaining ART adherence after drug relapse. All of this triangulates well with the client narrative though it is interesting that for many family members/spouses AAU is viewed primarily as a high quality and humane detoxification centre rather than as an ART adherence support centre.

Nai Zindagi staff members attributed much of the motivation for a client to initiate treatment to the client's own desire to stay healthy. It was felt that prior detoxification helped build this desire, which could be further nurtured by support from family members and outreach workers. Non-adherence was mainly attributed to relapse and lack of support from family or friends. There was also some acknowledgment of some of the myths around treatment that serve as a discouragement to adherence.

The clinics tended to view relapse as the primary cause of non-adherence though there was also recognition of the fact that greater family involvement could help improve treatment outcomes. A major concern on the part of clinics was the continuity of case management as the client moves across the cascade from clinic to AAU and back to clinic. The main issue here is how adherence can be tracked between services so as to reduce LTFU. Several practical suggestions were made about how this could be strengthened and these will be covered in the final section of the report.

4.3 Opportunities to Improve the Model

Before beginning an account of opportunities for improvement that were identified in the course of our study it is important to acknowledge how the model has already evolved since the end of our sampling timeframe. Some of these changes pre-empt recommendations that have arisen from our findings. They are as follows:

- **The merger of the detoxification unit into the AAU unit in 2016.** As previously discussed this has solved a significant problem with loss to follow up by enabling continuity of care in the same location from detoxification into treatment initiation, client stabilisation, and treatment preparedness support. Reducing the number of service segments in the cascade by merging segments, and reducing the number of long-distance trips a client is required to make, is a very efficient way of tackling LTFU. It is achievable only by strong coordination between HIV treatment and opioid dependence treatment service sectors. In general, any service development that reduces the number of inter-facility journeys the client has to make, the time and distance involved with these journeys, and pause time between them is likely to help reduce LTFU.

- **The doubling of AAU's bed capacity from 100 to 200 beds in 2016.** Scarcity of quality detoxification services has been identified by clinics as a major bottleneck constraining treatment initiation. Given that AAU has already had a significant impact on treatment uptake for PWID the doubling of its capacity is very welcome.
- **The In-Touch follow-up service for clients regularly discharged from AAU.** Starting in January 2016 and funded by Mainline through the Bridging the Gap Initiative of the Dutch Ministry of Health, this programme provides clients who have successfully completed a full residency at AAU with a mobile phone. A team of two Nai Zindagi staff contact the discharged clients on these phones on a weekly basis. This enables the provision of follow up support to promote adherence and prevent relapse, and also improves post-AAU client tracking.
- **Improved coordination between CoPC+ sites and ART Centres.** In a PR meeting held on the 14th March 2016 a number of measures were agreed between the PRs to improve coordination between clinics and CoPC+ sites. These included improved client tracking to prevent LTFU through monthly sharing of data regarding lost clients.
- **Upcoming.** Nai Zindagi has recently secured new funding from Mainline to further train staff in relapse prevention, to set up professionally facilitated self-help support groups for AAU clients and families in 4 districts, and to provide district level drug treatment services for relapsed clients through a mobile medical team across 4 locations. All of these developments are welcomed by the consultant team and very much in line with the recommendations arising from this study.

The observational residency we conducted at the AAU formed the main basis of our assessment of the quality of the services at the unit itself. It was clear from this residency, as from the other parts of the evaluation, that the primary motivator for clients to use the service was their desire to be drug-free rather than a desire for HIV treatment. The demand for effective treatment for opioid dependence outweighs the demand for HIV treatment. This is true of the families and spouses as well as of the clients. People have had their lives torn apart by drug use and they want to repair the damage and be free of the drug habit that caused it. It is this process of repair, of regaining lost self-respect, and reclaiming order from chaos, that builds a foundation from which adherence to HIV treatment can work. Treatment adherence requires a level of discipline, and that discipline thrives much better within the context of a stabilised lifestyle. So whilst there is a strong emphasis within the AAU on installing treatment literacy, and good evidence that this is succeeding, there is a much more important process going on with regard to helping the client rebuild and repair their sense of self-worth. This again speaks to the importance of concurrently treating opioid dependence and HIV.

During the consultant team's first visit to the AAU there was an opportunity to sit down with the clients and hear some of their stories. In these conversations it became clear that many had prior experience of other detoxification facilities with some clients reporting numerous attempts at detoxification. Some of the accounts given of the facilities they had experienced were horrific, with stories of being chained up and beaten. The approach was little more than incarceration and punishment. Rather than helping the clients rebuild a damage sense of self and nurture a sense of self-respect, these approaches would merely have reinforced a sense of worthlessness. It is no surprise that they returned to drug use. This helps reinforce the point raised by the clinic staff about the scarce supply of quality rehabilitation programmes that is restricting intake into ART treatment.

The approach to rehabilitation at the AAU stands in marked contrast to the facilities referred to in the previous paragraph. Unlike those outfits the AAU is founded on principles of genuine care and respect as an essential pre-requisite for any successful learning and recovery process. This was witnessed first-hand during the observational residency and asserted by our harm reduction expert to be one of the outstanding qualities of the unit. Both staff and clients refer to the family atmosphere at the facility and it is clear that this is helping to nurture a strong sense of solidarity

among the clients. Clients are treated as if they were paying guests. Interactions between staff and clients are genuine and authentic allowing clients to feel accepted and respected as individuals. It is this that enables the unit to successfully support the individual client through the transformation process. The staff team has a good mix of professionals (both medical and psychiatric) and peers (ex-users and former clients who work as counsellors.) This facilitates both an individualised approach to care and learning by example. Overall the essential ingredients of comprehensive care are present and practiced at the facility and it comfortably measures up to international standards. The consultant team's appreciation of the quality of services at the AAU was backed up by feedback from multiple stakeholders (clients, family members, spouses, and clinic staff,) all of whom primarily appreciate the AAU for its role in rehabilitation.

ART education is structured and fairly intensive with reinforcement for adherence given on a daily basis. Clients are able to state their own CD4 counts and light-hearted penalties for minor infringements of house rules included quiz questions, decided upon by the clients themselves, such as having to state the difference between viral load and CD4, or to explain how HIV is spread. The level of treatment literacy that results was evident from some of the answers given by clients during our client survey. Onsite medical supervision of treatment initiation is a core component of the unit's service. The clinicians have undergone training as required by some provinces and been certified to perform this role. The dispensation of medications takes place daily at 9am in the medical room and again at 9pm for clients requiring twice a day doses. As well as treatment oversight the medical team are also involved in client education sessions to improve treatment literacy.

Clients interviewed during the residency raised some minor issues mentioned with regard to food, recreational activities and on-going building work. These were echoed in feedback from clients received during the client survey with the addition of concerns about the washroom facilities. These concerns have already been relayed to the management for consideration. A repeated request from clients was for more linkages with employment opportunities (21%) and skills building and linkages with vocational training (24%.) Other recommendations coming out of the observational residency were as follows:

- There is a dilemma about how to communicate to clients about the importance of adhering to ARVs even if relapse occurs. This message requires acknowledging the possibility of future relapse when much of the rehabilitation process is founded on the hope of a life free from drugs. The same problem arises in relation to harm reduction messaging. Educating clients about less harmful ways of consuming drugs should relapse occur also requires acknowledging the possibility of relapse. Given the statistical likelihood of relapse for many of the clients it is important that these messages are communicated. It is particularly important that myths about the concurrent use of ARV and illicit drugs leading to death are challenged and corrected as there is evidence from this study that rather than discouraging relapse they discourage ARV treatment initiation and adherence.
- Further training for staff on relapse prevention is recommended though we note that recently secured funding (see above) will help address this. This will be particularly important for frontline staff who support clients upon return to their communities.
- Building on the camaraderie established between clients during residency it is recommended to create an alumni association for clients to enable the continuation of mutual support post-AAU. Again, it may be that the district-level self-help support groups for which funding has recently been secured could serve as a model for this.

Other, more general recommendations, pertaining to the whole service continuum in which the AAU is nested, can be found in the final section of this report.

5. Conclusions and Recommendations

The following conclusions and recommendations are drawn from the study in its entirety. They are made on the understanding that the AAU is part of a continuum of services provided by Nai Zindagi to PWID. For this reason they are not specific to the AAU and will require coordination with other service providers in order to be fully implemented.

5.1 Conclusions

We noted at the outset that improving ART coverage for PWID in Pakistan meant addressing issues around treatment initiation, retention and adherence together. This evaluation has found that the AAU is making a considerable contribution to this task.

Initiation

Our literature review found that the advent of the AAU has coincided with a significant increase in the numbers of PWID on ART treatment in 2014 and 2015. People attending AAU represent 85% of the growth in numbers of PWID on treatment in that period. AAU is clearly helping to address the bottleneck caused by the limited supply of quality detoxification services as identified by the ART clinics. The clinic's requirement that PWID undergo detoxification prior to treatment initiation, and the absence of OST for the foreseeable future, mean that AAU has an important role to play in increasing the flow of PWID into treatment.

There is a critical issue about treatment *readiness* that AAU is helping to address. For PWID this means supporting them to stabilise their lives to a point where HIV treatment is both desirable (for them) and practicable. It also means converting an existing demand to be drug free into a more general demand for health and well-being. Again, without OST programmes, AAU remains the only option we have to achieve this.

Retention

We identified a significant point in the cascade (between detoxification and treatment initiation support) where dropout was occurring; this has since been remedied by the merger of the detox unit into the AAU. There are some outstanding issues around tracking retention that are covered in the recommendations below. The study has gone some way to addressing the Technical Review Panel of the Global Fund's request that more evidence be gathered to "fully understand why patients fall off the care and treatment cascade."³¹

Adherence

The results of our study show that AAU is having a strong impact on ART adherence for PWID when compared to the alternative of not attending AAU, exposure to other services being equal. A person attending AAU was between 43 and 51 times more likely to be adherent to ART than a person who did not attend AAU. The difference is statistically significant at a 95% confidence interval. Overall the adherence rate was 77.4% for those attending AAU versus 51.1% for those not attending. This is an adherence rate for clients who have initiated treatment for between 7 and 19 months.

There was some indication that rates at which adherence declines over time are considerably slower for those attending AAU but this has to be tentative given the cross-sectional nature of our investigation.

There is encouraging evidence that adherence can and is being maintained during relapse for a significant portion of those who relapse. The data suggests that the provision of on-going post-AAU support is an important enabling factor. A cohort study would be required to determine whether this achievement is sustainable over time.

³¹ See, *Applicant Response Form* p4, submitted to the Global Fund in response to feedback from the Technical Review Panel on the 1st iteration of the HIV Concept Note.

With regard to relapse the rates for our intervention and control groups were 58% and 65.2% respectively. The difference was not statistically significant.

Concurrent treatment of opioid dependence and HIV

Despite the fact that we were unable to detect a significant difference in drug relapse rates between intervention and control group, the consultant team believes that it is the fact that the AAU combines opioid dependence treatment support with HIV treatment support that is leading to successful outcomes in supporting ART treatment adherence. The facility creates an environment where it is possible to foster a high degree of treatment literacy that stands its clients in good stead regardless of whether or not they eventually relapse to drug use. There is a broader need for HIV treatment services to adapt to the fact of relapse and further develop support services to help clients maintain adherence over the relapse cycle (see below.) The AAU provides a good foundation to help make this achievable. Overall the AAU is a high quality, humane, rehabilitation service that plays a significant role in stabilising PWID so that they can adhere to HIV treatment.

5.2 Recommendations

The following recommendations are based on the findings of this report and are listed in no particular order:

- There needs to be stronger coordination between CoPC+ sites and clinics around intake of new clients. There are particular issues around clinic visit logistics management that need to be addressed. New clients are required to complete a series of clinic baseline checks prior to treatment initiation. These are often not available at the clinics themselves and require trips to other facilities. There are scheduling issues because the tests need to be taken before a certain time in order to get the results back the same day. Failure to take the test before that time can mean an additional visit for the client and a risk that other baseline test reports go missing in the meantime. At the moment the responsibility for escorting clients through the baseline test process has been taken up by Nai Zindagi. There are sometimes issues with the completeness of the baseline checks that can serve to delay treatment initiation and require a return visit to the clinic. Every time a PWID is required to make a further trip to complete a further process step presents a risk of LTFU. This is particularly so when the distances involved are considerable. There needs to be a coordinated effort to manage these logistics and where possible simplify the process. To begin with it is recommended that there be stronger coordination between CoPC+ site managers and clinic managers to ensure that clinics visits are conducted in accordance with a shared schedule. This includes coordination between different CoPC+ sites that are referring to the same clinics so that their clinic visits do not overlap. This will help avoid situations where there is an unanticipated inflow that overwhelms a particular facility's ability to manage intake. For the longer term there needs to be further discussion between clinics, Nai Zindagi and other stakeholders, about how baseline testing procedures can be simplified in such a way as to reduce risk of LTFU. A particular focus should be on reducing the number of site-to-facility trips required.
- There needs to be a balance between the focus on new client initiation and the follow up of old clients. Maximising intake at the expense of follow up will only result in increased LTFU. Nai Zindagi has already secured new funding to strengthen post-AAU support services for clients but this is limited to four sites. The resources required for keeping treatment initiated PWID adherent will only grow as the number of initiations increases. With only one Social Mobiliser and one Female Outreach Worker available per CoPC+ site there is a risk that services could be overwhelmed without further investment. There needs to be an appreciation among all stakeholders, including donors, about the resources that will be needed to address the retention problem through an appropriate level of post-initiation support.

- The current arrangement between the clinics and AAU requires a transfer of case management from clinic to AAU and back again. This is not just a question of having the pills follow the patient. There needs to be a two-way flow of information about the client's progress in following treatment so that both sides of the cascade transfer point are in the picture about outcomes. This is particularly so for clients that do not initiate despite being registered and having medicines dispensed, and for those who drop out of the cascade during or immediately after AAU. A strongly coordinated oversight process will make it less likely that clients are LTFU. Related to this point there is an urgent need for better integration of the respective M&E systems of the clinics and Nai Zindagi. Shared client identifier codes would be a good start but the over-arching system also needs to work in such away as to ensure that the point of treatment initiation and the point of LTFU (if it occurs) is not off-radar to one system because it occurs in another segment of the treatment cascade with another system.
- The period immediately following AAU discharge is likely to be a risk point for potential LTFU. It is recommended that a coordinated schedule of short-term support over the months immediately following discharge is shared between clinic, AAU and CoPC+ site. All parties should be aware of the date of discharge, the date of the clients next clinic appointment and the length of time that the client's existing supply of medications will last for. In this regard it was noted that there may be a possibility that clinics are taking the date they dispense the medications as the date of treatment initiation when in fact the initiation begins after the client has been admitted to AAU and undergone preliminary detoxification. It would be useful for all to be aware of the exact date of treatment initiation for a given client so that dispensing schedules and adherence records can be kept accurate and up to date.
- There is a recognised need for more relapse prevention support with which the consultant team concurs. But there is also a need for relapse management support to ensure that when relapse does occur it does not result in non-adherence. We note that the country's Concept Note for its new Global Fund grant includes a proposal to further train clinicians in the management of opioid dependent patients. There needs to be a shift in mind-set that accommodates relapse as a fact of life for a considerable population of PWID on treatment and adjusts services accordingly with a view to supporting adherence across the relapse cycle. In relation to this it is highly recommended that healthcare and related support workers at all stages in the cascade avoid perpetuating the myth that relapse + ARV = death. The intention may be to discourage relapse. The effect is to discourage initiation and adherence to ARV.
- There is considerable demand for a scale up of the AAU from all quarters including clinics and clients and their families. This is not just an issue of more beds but of more facilities in different locations. Although some wanted the facility closer to home it was acknowledged by others that being away from the client's routine environment and all its temptations was an important part of the rehabilitation process. Nonetheless the demand for more faculties is an important one particularly given the fact of the detox bottleneck that has been discussed at several points in the report. This kind of scale up would require additional donor support.
- Nai Zindagi could usefully review its M&E system to identify opportunities for improved centralisation and standardisation across the various organizational units. There is always a risk with organizations dependent on funding from multiple donors with different reporting requirements against different sets of indicators that institutional M&E systems can become fragmented. Different parts of the system have different data refresh rates and certain data is locatable in one place but not in another. This was illustrated to some extent by our client short-listing process; the fact that some clients who had registered for treatment had never in fact initiated treatment did not appear to be visible at central level. Given that clients need to be tracked from CoPC+, through AAU and back to CoPC+, with follow-up support from the In

Touch programme and other soon-to-be-started support services it would be extremely useful to have a centralised data system that tracked an individual client's exposure to each service component with appropriate indicators for tracking significant outcomes.

- We have noted the limitations of this study in terms of tracking adherence rates over time. Our sample was cross-sectional and we would discourage the temptation to treat the results as if they resulted from a longitudinal study. There may well be a need for that longer-term picture in which case we would recommend that Nai Zindagi consider a longitudinal methodology for any further examination of adherence outcomes over time.

Finally, we discussed in the earlier part of the report that clinicians' concerns about the low rates of adherence among PWID were leading to a restrictive approach to ART initiation for this population. At the time these concerns emerged the primary problem was retention; most PWID initiating treatment were simply lost to follow up. As post-initiation support services evolve and prove their worth it is to be hoped that a less restrictive approach to treatment initiation will emerge for PWID. This will depend on a well-coordinated case-management approach to treatment-initiated PWID that simultaneously addresses their opioid dependence and HIV treatment support needs. To achieve this a high level of cooperation and information sharing between clinics and support services is essential. There is already a strong foundation in place from which to achieve this. We have been impressed by the collaborative arrangements that have been put in place to enable treatment initiation oversight to transfer from clinic to AAU and back again. We hope that the recommendations contained in this report will help all stakeholders collectively strengthen this collaboration and thereby improve the country's support for HIV infected PWID.

6. Annex: Evaluation Study Schedule and Scope

1. Schedule

The following is a schedule of the main activities of the study.

Activity	Location	Date
Study Design Meeting	Islamabad	19 th to 22 nd Jan 2016
Design Consultation Meeting	Islamabad	22 nd Jan 2016
Evaluation Tools Development		25 th Jan to 9 th Feb 2016
Interviewer/Facilitator Training		9 th Feb 2016
Pilot Client Survey	Rawalpindi	10 th to 11 th Feb 2016
Client Survey	Gujrat Jhang Jhelum Kasur Khanewal Muzaffargarh Okara RahimYarKhan Rawalpindi Sahiwal	10 th to 26 th Feb 2016
Focus Group Discussions with ART Clinics	DGK Faisalabad Jinnah	18 th to 22 nd Feb 2016
Focus Group Discussions with Spouses and Family Members	Gujrat Jhang Jhelum Kasur Okara RahimYarKhan Rawalpindi Sahiwal	11 th to 25 th Feb 2016
Self Administered Nai Zindagi Staff Questionnaire		15 th to 7 th Mar 2016
Observational Residency in AAU	AAU	27 th Feb to 5 th Mar 2016
Data Inputting, Cleaning and Analysis		27 th Feb to 24 th Mar 2016
Presentation of Preliminary Findings to Nai Zindagi Team	Islamabad	16 th Mar 2016
Triangulation of Client Reported Adherence with Clinic ART Dispensing Data		17 th Feb to 27 th Mar 2016
Report Writing		21 st to 6 th Apr

2. Scope

The following is a summary of the number of respondents and participants in the various components of the study.

Client Survey

- 169 Clients from 10 cities were interviewed of which 128 were deemed fully eligible
- The cities were: Gujrat, Jhang, Jhelum, Kasur, Khanewal, Muzaffargarh, Okara, Rahim Yar Khan, Rawalpindi, Sahiwal
- 104 of the 128 were in the intervention group
- 24 of the 128 were in the control group
- A further 13 were of interest because of LTFU

Focus Group Discussions with Clinicians

- 3 were held in 3 different clinics: DGK, Faisalabad, and Jinnah.
- A total of 13 people participated
- Participants included clinicians in charge of clinics (3), medical officers (2), counsellors (2), a staff nurse (1), a clinical psychologist (1), PPTCT case managers (2), and data entry operators (2).

Focus Group Discussions with Spouses and Family Members

- 8 were held in 8 different cities: Gujrat, Jhang, Jhelum, Kasur, Okara, Rahim Yar Khan, Rawalpindi, Sahiwal
- Numbers participating in each group ranged from 6 to 18

Survey of Nai Zindagi Staff

- 28 staff members completed a self-administered questionnaire
- From CoPC+ sites this included 8 Social Mobilisers and 8 Female Outreach Workers
- From the AAU this included 6 Counsellors, 2 Medical Officers and 4 Paramedics

AAU Observational Residency

- Total of 4.5 days observational residency
- 15 AAU clients interviewed
- 15 AAU staff interviewed