STUDIES ON PREVENTION AND MANAGEMENT
OF HIV/AIDS IN THE ERA OF HIGHLY ACTIVE
ANTIRETROVIRAL THERAPY (HAART)

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More than 25 years have passed since the first cases of HIV/AIDS were reported and a decade since highly active antiretroviral therapy (HAART) was introduced as part of the continuum of care for people living with HIV/AIDS (PLWHA). The introduction of HAART as a continuum of care for PLWHA positively changed the characteristics of HIV/AIDS epidemic, contributing for significant declines of HIV/AIDS-related morbidity and mortality rates. Thus, a new era began with HAART, often referred as the “HAART era”. However, HAART also brought with it new challenges and issues for researchers working in the field of HIV/AIDS.

This thesis comprises several studies that were designed to gain understanding of some issues on prevention and management of HIV/AIDS that emerged in the current HAART era. The review of the literature points out for many emergent issues in HAART era, but only some issues were researched and presented in this thesis.

The HIV/AIDS epidemic in Australia continues to affect mainly men who have sex with men (MSM). Rates of unprotected anal intercourse (UAI) and sexually transmitted infections (STIs) among MSM, both HIV-negative and HIV-positive, are reported to be increasing in Australia and particularly in the state of Victoria. It has been suggested that these increases in UAI and STIs were partly because of the success of HAART in reducing HIV-related illnesses and death. Thus, both prevention studies presented in this thesis were carried among MSM.
The first study ("Perceptions Study") aim was to assess whether the sexual practices of HIV-negative or untested MSM was related to their perceptions of what it is like to live with HIV/AIDS, their beliefs or their attitudes to HAART. This study found no significant differences between beliefs, attitudes and perceptions about HIV/AIDS, knowledge of post-exposure prophylaxis (PEP) or exposure to the HIV/AIDS epidemic among those who had had UAI with casual partners and those that had not (P>0.12). Those who considered that low levels of viral load and withdrawing before ejaculation reduced the risk of HIV transmission were significantly more likely to have had UAI with a casual partner (P>0.03). Only a minority of MSM engaging in UAI were optimistic about antiretroviral therapy. These study participants were in general pessimistic about life with HIV/AIDS despite their risk-taking sexual behaviour.

The second study ("HIV-superinfection Study") aim was to determine the upper limit for the incidence of clinically important HIV-superinfection by determining the incidence at which HIV-infected MSM showed an unexplained and sustained decline in CD4 T-cell counts and/or unexplained increases in their plasma HIV RNA and determine if they were more likely to have engaged in unsafe sex with their casual partners than other HIV-infected MSM. Ten cases were identified from 145 eligible MSM (7%, 95% confidence interval 3 to 11%), comprising a rate of 3.6 per 100 person-years at risk. There were no statistically significant differences between cases and controls in regard to sexual practices that may have exposed them for acquisition of HIV-superinfection (p-value ≥0.4) or in their perceptions/beliefs of HIV superinfection (p-value ≥0.3).
Only a minority of the study participants reported no previous knowledge of HIV-superinfection (17%, 5/30). Overall, both cases and controls were engaging frequently in unsafe sexual practices with casual partners who were HIV-infected (80% and 52% respectively; p-value=0.4) and/or whose HIV-serostatus were unknown (40% and 50% respectively; p-value=1.0). The rate of clinically significant HIV-superinfection in this cohort of sexually active MSM was likely to be less than 4% per year. This estimate is similar to what other investigators have reported of between 0 to 6.5% per year.

Within “HIV/AIDS management” subheading two studies were presented in this thesis: “Adherence Study” and “Evaluation of an individually tailored intervention “Health Map” for improving self-care of PLWHA on HAART”.

With “Adherence Study” the primary aim was to understand from patients’ own perspectives and experiences what resulted in some individuals having 100% adherence to HAART while others having poor-adherence (<95% adherence). Thus, a two part study was carried out: the first part related to 100% adherence to HAART while the second part related to poor-adherence to HAART (defined as <95% adherence). Many similar experiences and perceptions between those with 100% adherence and those with poor-adherence were found. On the other hand there were also some unique experiences and perceptions found from accounts of those who had self-reported poor-adherence to HAART. Overall, poor-adherence was an incidental occurrence and was mainly due to forgetfulness. In general, the findings of both parts of
adherence study confirms currently established knowledge that adherence to HAART is a dynamic behaviour determined by various interrelated experiences and perceptions that changes over time.

Finally, the last study presents baseline data from an individually tailored intervention for self-care of PLWHA on HAART (“Health Map” trial). This intervention was carried out because there are suggestions that appropriate management of dyslipidemia as well as lifestyle modification, such as smoking cessation, proper diet and exercise might help PLWHA living longer and healthier. Thus, with the evaluation of “Health Map” the aim was to characterize the clinical and other features of PLWHA on HAART (e.g. HAART adherence, depression, modifiable cardiovascular risk factors). Unfortunately, due to time-limitations I was unable to present the complete evaluation of “Health Map” in this thesis. I have presented the development of the web based program and the baseline evaluation only. I will be involved in its evaluation at a future date in collaboration with others at MSHC. However, the preliminary data of “Health Map” shows that a significant proportion of its participants have a number of modifiable risk factors for heart disease (47% were smokers; 48% had insufficient physical activity; and 51% were overweight or obese according to their Body Mass Index calculation). Furthermore, there were also some “Health Map” participants with comorbidities, including: 1% on treatment for diabetes; and 33% on lipid lowering drugs 9% on treatment for high-blood pressure. Although no final conclusion can be made about the effectiveness of “Health Map” at this stage, similar interventions to facilitate
behavioural change of multiple risk factors in primary healthcare setting proved to be significantly valuable for patients according to currently available literature. Therefore, it is expected that “Health Map” intervention would be also valuable for patients who took part in it to improve their health by modification of risk factors for heart disease and adopting healthier lifestyles.

The thesis concludes with a discussion of the implications of the research and recommendations. The research presented in this thesis confirms that there is still an enormous need for additional research regarding prevention as well as management of HIV/AIDS in current HAART era.
DECLARATION

This is to certify that:

• This thesis comprises only my original work towards the PhD except where indicated in the Preface;

• Due acknowledgement has been made in the text to all other material used in this thesis;

• The thesis is less than 100,000 words in length, excluding tables, figures, references, and appendices.

Mohsin M Sidat
I started my candidature in the 28\textsuperscript{th} of August 2003. During my candidature I have attended many seminars and lectures offered by School of Graduate Studies within their UPSKILLS PROGRAM. Furthermore, to enable me to carry out qualitative studies I have also attended two academic subjects offered by the School of Population Health for postgraduate students:

- Subject 505921: Principles of Research Design (\textit{mark: 077; Grade: H2A});
- Subject 505922: Research Methods in Social Health (\textit{mark: 082; Grade: H1});

During my candidature I have carried out mainly three original research works and an open non-randomised clinical trial. However, I would like, at this point, to duly acknowledge the contributions of others in the studies presented in this thesis:

- Study presented in Chapter 3: this study ("Perceptions Study") was in the early stages of development when I started my candidature and the ethics application had already been submitted when I joined the study. However, after joining the study group I made significant changes in the study protocol and also some changes in the questionnaire and applied for amendments to the ethics committee. I also contacted the doctors to assist me in recruiting eligible participants at Melbourne Sexual Health Centre. All the data collection, data entry, data analysis and drafting the research article for publication of this
study was carried by me. Nevertheless, I would like to acknowledge the contributions at different stages of this study of the following researchers: Prof Christopher Fairley Nichole Lister, Patrick Rawstorne, Anthony Smith and Sue Kippax.

- Study presented in Chapter 4: this study ("HIV Superinfection Study") was designed from the scratch by me with the assistance of Prof. Christopher Fairley. I have submitted the ethics committee application and conducted the recruitment of the study participants. All the data collection, data entry, data analysis and drafting the research article for publication of this study was carried by me. Kerri Watson, from the Infectious Disease Department at The Alfred Hospital assisted with clients’ information for recruitment of study participants. However, following researchers also contributed at different stages of the study: Anne Mijch, Jennifer Hoy, Jane Hocking and Sharon Lewin.

- Studies presented in Chapter 5 and Chapter 6: this study (a two part “Adherence Study”) was designed from the scratch by me with the assistance of Dr Jeffrey Grierson. I have submitted the ethics committee application and conducted the recruitment of the study participants. I’ve also carried out all the study interviews, verbatim transcriptions of all the interview recordings, data analysis and drafting the research article for publication of this study. Prof
Christopher Fairley also made significant contributions in this study at different stages.

- Study presented in Chapter 7: this study was a result of clinical trial ("Health Map") that I developed with assistance of the following people: Prof Christopher Fairly, Tim Read and Kerri Boyd from the HIV Referral Clinic at Melbourne Sexual Health Centre (MSHC); Jun Kit Sze and Marc C-Scott from the I.T. Department of MSHC. Data collection, data processing and analysis were carried all by me. However, only interim analysis is presented in this chapter as the follow-up time for participants of this trial goes beyond my study period.

All research articles (published and/or submitted for publication) arising from my PhD studies were written and submitted for publication by me. However, I would like to acknowledge that all contributions (mainly comments and orthographic corrections) of co-authors of my different articles were taken into account. Finally, I would like to acknowledge the assistance in recruitment of study participants for studies presented in this thesis of many doctors, nurses and administrative staff of both Clinics at Melbourne Sexual Health Centre and also at The Alfred Hospital (Infectious Disease Unit).
ACKNOWLEDGEMENTS

This thesis and its completion would not have been possible without the assistance and support of many people who have somehow contributed to the success of my studies and to my life during almost four years of my stay in Melbourne, Australia. Even though I am aware that there aren’t enough words to express my thanks to all of them I would still like to make use of this opportunity to acknowledge every one for their encouragement, support, guidance and friendship all along my studentship and social life in Melbourne (Australia).

First and foremost, I would like to thank my Principal Supervisor, Prof. Christopher K Fairley, who offered continual guidance and support throughout my studies. Prof Fairley shared his time, knowledge, experience and wisdom. His guidance helped me to gain knowledge of research process and practice as well as to develop proficiency in writing scientific articles.

I would also wish to thank my Co-Supervisor, Dr Jeffrey Grierson (Australian Research Centre in Sex, Health and Society), for his assistance and support particularly with my qualitative studies, allowing me to gain a deeper understanding and appreciation of qualitative research, in particular with the data analysis process and the presentation of findings. Dr Grierson’s guidance also contributed significantly to improvements in my understandings of psychosocial issues related to HIV/AIDS, particularly from social science perspective.
The research work for my candidature was predominantly carried out at the Melbourne Sexual Health Centre (MSHC) where I was based and where I felt very welcomed since the commencement of my studies. I wish to thank all the staff at this Clinic who welcomed and helped me in various ways, including with my research work. In addition, I am also profoundly grateful to the participants of my studies who contributed to the study with their time and by sharing their experiences so willingly and with all sympathy. I would also like to thank the I.T. Department of MSHC for their assistance in my different research projects. I am also very grateful to James Unger (P.A. of Prof C Fairley) for his friendship and assistance at various occasions during my studies.

I would also like to express my gratitude to all co-researchers of my studies for their contributions at different stages of my diverse research projects and also for their contributions in co-authoring my research papers arising from work that I carried out for this thesis (see the publications arising from the work presented in this thesis).

I am profoundly grateful to the Capacity Building Project of the University Eduardo Mondlane that granted me with a scholarship that allowed for my full-time doctoral studies at The University of Melbourne, in Australia. I am proud of being offered this unique opportunity to progress in my Academic career. This opportunity allowed me not only to enrich my academic-scientific knowledge, but also to broaden my understandings of general socio-cultural issues. I hope to make most of the social and scientific links that I had the opportunity to develop during my studies and I
look forward, in near-future, to establish socio-scientific collaborations between Mozambique and Australia.

I also want to thank all those who supported me and my family in different ways and provided us with many wonderful moments throughout our stay in Melbourne, in particular: Dr Julie Cliff and her father Ray Cliff; Dr Jim Black, Jackie Mansourian and their dearest family; John Sinnott (from AMOZA, Australian-Mozambican Association); Grace Conway and all the staff at the Westgarth Primary School (Northcote, Victoria); to all my fellow Mozambicans and South Africans who are/were living and/or studying in Melbourne.

I wish to express also my sincere thanks to Mr Martin Fergusson (MP, Labour Party) and the Department of Education of Victoria for all their support and the opportunity given to my son to attend generously the Westgarth Primary School until completion of my PhD studies.

I thank with all of my heart to my wife Sumeya, whose patience, support and wisdom knows no limits. I would also like to thank my children, Muhammad and Fayzah, for all their patience and understanding for times that I was unable to be there when they needed me. I would like to extend my thanks to all my family members in Maputo, Mozambique, and especially to my parents. They have all been very supportive all along my studies.

I would like to finalize these acknowledgements by dedicating this thesis to my parents, Mahomed Adam Sidat and Hagira Seedat, whom always inspired and supported me to pursue the path of knowledge and excellence.
Publications arising from the work presented in this thesis:


2. **Sidat M**, Fairley CK, and Grierson J. Experiences and Perceptions of Patients With 100% Adherence to HAART – A Qualitative Study. AIDS Patient Care and STDs 2007; 21(7): 509 – 520.


4. **Sidat M**, Fairley CK, and Grierson J. Experiences and Perceptions of Patients With Self-Reported Poor-Adherence to HAART – A Qualitative Study. (paper in preparation to be submitted for publication).
Published Conference Abstracts arising from research contained in this thesis (presenter underlined):

1. **Sidat M**, Rawstorne P, Lister N, and Fairley CK. Association between risk of acquiring HIV and beliefs and perceptions about the lived experience of HIV/AIDS among HIV-negative or untested men who have sex with men. Poster presented at (Poster 157) the 17th Annual Conference of the Australasian Society for HIV Medicine, August 2005, Hobart, Australia.

2. **Sidat M**, Fairley CK, Grierson J. Experiences and perceptions of HIV-infected individuals with 100% adherence to HAART - A Phenomenological Study. Oral poster (Poster 152) presented at the 18th Annual Conference of the Australasian Society for HIV Medicine, October 2006, Melbourne, Australia - **awarded with "The 2nd prize for the Social Research"** (see Appendix 1).

Other publications during candidature (not peer-reviewed):


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### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired immune deficiency syndrome</td>
</tr>
<tr>
<td>ANCHARD</td>
<td>Australian National Council on HIV/AIDS, Hepatitis C and Related Disorders</td>
</tr>
<tr>
<td>ARCSHS</td>
<td>Australian Research Centre in Sex, Health and Society</td>
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<tr>
<td>ASHM</td>
<td>Australasian Society for HIV Medicine</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>HAART</td>
<td>Highly active antiretroviral therapy</td>
</tr>
<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>IDU</td>
<td>Injecting drug use(r)</td>
</tr>
<tr>
<td>MSM</td>
<td>Men who have sex with men</td>
</tr>
<tr>
<td>NCHSR</td>
<td>National Centre in HIV Social Research</td>
</tr>
<tr>
<td>NCHECR</td>
<td>National Centre in HIV Epidemiology and Clinical Research</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health &amp; Medical Research Council</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>PLWHA</td>
<td>People living with HIV/AIDS</td>
</tr>
<tr>
<td>PY</td>
<td>Person-years</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
</tr>
<tr>
<td>UAI</td>
<td>Unprotected anal intercourse</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Chapter 1: Background and scope of the thesis

1.1. Background for the selection of thesis subject

Acquired immune deficiency syndrome (AIDS) was first documented in 1981 affecting young men who had sex with men (MSM) (CDC, 1981). Subsequently, in 1983, the causative agent of AIDS was identified and named as human immunodeficiency virus or HIV (Adler MW, 2001). In mid-1980s the HIV screening and detection tests became available (Adler MW, 2001) and almost immediately after the large-scale availability and use of these tests the real worldwide impact of HIV/AIDS became evident (Merson MH, 2006).

According to the latest AIDS Epidemic Update (UNAIDS/WHO, 2006) the HIV/AIDS epidemic continues to grow in many parts of the World with an estimated 39.5 million (34.1 – 47.1 million) people living with HIV/AIDS (PLWHA) at the end of 2006 worldwide. Furthermore, an estimated 4.3 million (3.6 – 6.6 million) new HIV/AIDS cases occurred and an estimated 2.9 million (2.5 – 3.5 million) people died of HIV/AIDS (UNAIDS/WHO, 2006).

Sub-Saharan Africa continues to be the region with the largest burden of HIV/AIDS (UNAIDS/WHO, 2006). In Mozambique, my home-country, the HIV/AIDS epidemic continues to grow with the latest estimation indicating 1.6 million PLWHA (UNAIDS/WHO, 2006). Presently, HIV/AIDS represents the leading cause of mortality in Mozambique (Mozambique News Agency AIM Reports, 2004). Thus, my current interest in working on HIV/AIDS emerged,
particularly after working for several years as lecturer and researcher at the Medical Faculty of the University Eduardo Mondlane in the field of Infectious Diseases.

In Mozambique, as in many developing countries, as part of the World Health Organization’s (WHO) 3 by 5 initiative (Gilks CF et al., 2006), highly active antiretroviral therapy (HAART) was introduced and gradually extended to include more people living with HIV/AIDS (PLWHA) since 2003 (Mozambican News Agency AIM Reports, 2006). In fact, the WHO’s initiative came after available evidence from developed countries showed that HAART extended substantially the lifespan and the quality of the life of PLWHA (Gilks CF et al., 2006). On the other hand, it is also believed that expanding free access of HAART worldwide would contribute substantially in strengthening the HIV/AIDS prevention efforts and thus contribute to curb the growth of HIV/AIDS epidemic globally (Montaner JSG et al., 2006).

In Australia, as in many other developed countries, HAART was introduced as part of the continuum of care for PLWHA since 1996 (Kaldor J and McDonald A, 2003). It was estimated that more than 53% of PLWHA in Australia in 2004 were receiving HAART (UNAIDS/WHO, 2006). Considerable experience and knowledge have been gathered in regard to HIV/AIDS, particularly in the past decade since HAART was introduced in developed countries. Australia has also contributed significatively in the advancement of our current knowledge on HIV/AIDS (Lewin SR et al., 2006).
I have chosen to study some of the issues that have apparently emerged in current HAART era which I will review and discuss in the Chapter 2. Nevertheless, for didactical reasons I will present my rationale for carrying out each study in the introduction section of the each corresponding chapter. My motivations to choose the title for this thesis as “Studies on Prevention and Management of HIV/AIDS in HAART era” are mainly related to my personal:

- desire to understand better some issues brought by the introduction of HAART as part of the standard care continuum for PLWHA; and
- interest in dedicating my future academic life, after completion of my PhD studies, at the Medical Faculty of the University Eduardo Mondlane in researching topics related to HIV/AIDS in Mozambique.

There are certainly many other pertinent issues related to HIV/AIDS prevention and management in the present HAART era, but I will limit my review (Chapter 2) to those relevant to the work presented in this thesis. The research in this thesis was undertaken between 2003 and 2006.

1.2. Overview and scope of the thesis

The overall aim of this thesis was to improve the understanding of some issues related to HIV/AIDS that have apparently emerged in HAART era. In the Chapter 2 I intend to present in a more detail way the rational for the studies that I have presented as part of this thesis. However, below I will present, in brief, my rationale and aims for the studies that are part of this thesis.
The rationale for the two studies related to HIV/AIDS prevention in HAART era was: rates of unprotected anal intercourse (UAI) and sexually transmitted infections (STIs) among men who have sex with men (MSM), both HIV-negative and HIV-positive, are reported to be increasing in Australia (National Centre in HIV Epidemiology and Clinical Research, 2006), particularly in the state of Victoria (Department of Human Services of Victoria (Australia), 2006). MSM continues to represent more than two thirds of all PLWHA as well as newly diagnosed HIV infections in Australia (National Centre in HIV Epidemiology and Clinical Research, 2006; UNAIDS/WHO, 2006). It has been suggested that these increases in UAI and STIs are partly because of the success of HAART in reducing HIV-related illnesses and death (Van de Ven et al., 1998). Thus, my aims for the first two studies were:

- **Study 1**: To examine the beliefs and perceptions of HIV-negative or untested men who have sex with men (MSM) about the lived experiences of being HIV-infected and about HAART and whether such beliefs and perceptions were related or not to sexual practices that may place them at risk of acquiring HIV;

- **Study 2**: To determine the incidence rate at which HIV-infected MSM showed an unexplained and sustained decline in CD4 T-cell counts and/or sudden increase in plasma HIV RNA levels and determine if they were more likely to have engaged in unprotected anal intercourse (UAI) with their casual sexual partners than a random selection of other HIV-infected MSM.
The rationale for the two studies related to HIV/AIDS management in HAART era was: the introduction of HAART has reduced morbidity and mortality related to HIV/AIDS and transformed HIV-infection into a chronic, manageable disease (Siegel K and Lekas H-M, 2002). However, the success of HAART requires near perfect adherence to its therapeutic regimens (Wright MT, 2000). On the other hand, HAART also brought with it concerns of iatrogenic toxicities related to anti-HIV drugs *per se*, such as lipodystrophy, hyperlipidemia and other toxicities (Smith CJ et al., 2004). It has been suggested that appropriate management of dyslipidemia as well as lifestyle modification, such as smoking cessation, proper diet and exercise might help PLWHA living longer and healthier (Dubé MP et al., 2003). Therefore, I have chosen these two issues, namely adherence to HAART and management of HIV/AIDS as a chronic disease, which I have considered of paramount importance in present HAART era and carried out two additional studies aiming:

- **Study 3:** To determine what makes some people living with HIV/AIDS (PLWHA) on HAART having 100% adherence while others having poor-adherence (<95% adherence); and

- **Study 4:** To map the clinical and other characteristics of PLWHA on HAART (e.g. HAART adherence, depression, modifiable cardiovascular risk factors) and to determine how a self-tailored feedback provided to them by “Health Map” (see Chapter 6 for “Health Map”) assisted in modifying their risk factors for cardiovascular disease.
All the studies presented in this thesis were carried out in Melbourne, Australia. However, as much as possible, these studies are discussed within the broader Australian and international context (mostly of developed or industrialized countries).

1.3. Terminology
I use a number of terms throughout this thesis which require clarifications. Throughout the thesis, the terms HIV and HIV-1 are frequently used interchangeably. Unless otherwise stated, the term “HIV” in this thesis is meant to specifically refer to “HIV-1”. I will refer to individuals infected with HIV as people living with HIV/AIDS (PLWHA) or HIV-infected individuals whereas those not infected with HIV I will refer them as “HIV-negative”.

Another term frequently used throughout this thesis is “men who have sex with men” (MSM) and it refers to any man who has engaged in any form of sexual relationship with another man as referred generally in the literature(Pitts MK et al., 2006; Stall RD et al., 2000; UNAIDS, 2000). My preference for the use of the term “MSM” instead of any other is simply because of its common usage in sexual surveys worldwide(Stall RD et al., 2000) and also in the biomedical literature(Pitts MK et al., 2006). Furthermore, not all men who are involved in sexual relationship with other men consider themselves “gay”, “homosexual” or “bisexual”, with many men having sex with other men infrequently or episodically(Hewitt C, 1998; Pitts MK et al., 2006; UNAIDS, 2000). Nevertheless, I am aware of some criticism raised in regard to the use of the term “MSM”
(Pitts MK et al., 2006; Young RM and Meyer IH, 2005), but the lack of an alternative popular term at present (e.g. like MMSP for male-to-male sexual practices suggested by Pitts MK et al.) made me persist in using the term “MSM” throughout the studies presented in this thesis.

I will also be referring often to unprotected anal intercourse (UAI) and it is meant to refer to any anal intercourse (receptive and/or insertive) without using condom. I’ll be using the definition of anal intercourse suggested by Gary Smith is his review article: “anal intercourse narrowly refers to one form of anal sex: penis in anus sex” (Smith G, 2001).

Finally, I’ll be considering in this thesis as indicator of unsafe sexual practices by MSM only when they self-report engaging in UAI with casual partners (Kippax S et al., 1995). The term “casual partners” is used only in the context of sexual relationship. Thus, it refers to single and/or multiple sexual contacts with partners during a study period who are not in steady (regular) relationship and might be well-known and/or even unknown (anonymous) to them. The assessment of sexual practices as “unsafe” within regular partnership is more complex to infer/analyse and thus was not dealt with in the studies presented in this thesis.

1.4. Organisation of the thesis
This thesis is comprised of eight chapters and begins with an overview and the scope of the thesis presented here in Chapter One.
Chapter Two is based on the literature review. In this chapter I will review general clinical and epidemiological aspects of HIV/AIDS briefly. I will also discuss the literature on some issues on prevention and management of HIV/AIDS that seemed to have emerged in HAART era. The discussion related to HIV/AIDS prevention will mainly focus on MSM as they represent the majority of PLWHA as well as the newly diagnosed HIV cases in Australia (National Centre in HIV Epidemiology and Clinical Research, 2006; UNAIDS/WHO, 2006), and particularly in Victoria (National Centre in HIV Epidemiology and Clinical Research, 2006). Finally, I will present my rationale for carrying out the studies presented in this thesis.

Subsequently, I will present two studies related to HIV/AIDS prevention among MSM in the HAART era. Thus, in Chapter Three I will present the study that I have carried out to assess the association between the risk of acquiring HIV and beliefs and perceptions about the lived experience of HIV/AIDS among HIV-negative or untested MSM. Similarly, in Chapter Four I will present the study assessing the association between engagement in UAI among HIV-infected MSM and the unexplained and sustained decline in CD4 T-cells count and sudden increase in viral loads.

In Chapters Five and Six I will present the findings of a two-part qualitative study that I have carried out to understand experiences and perceptions of two distinct groups of PLWHA on HAART, respectively those who had 100% adherence and those with poor-adherence (<95%) to HAART. Also within HIV/AIDS management issues in the HAART era, I will present my final study in Chapter Seven. In this
chapter I will assess how PLWHA on HAART make use of self-tailored guidance provided to them by the computer program I have designed in collaboration with experts on information technology a program to assist PLWHA on HAART to modify their risk factors for cardiovascular disease. This computer program was named “Health Map” and was aimed to assist participants of this trial in reducing their risk of developing cardiovascular disease. However, in this thesis I will only be presenting the baseline assessment because of limited time for the completion of my PhD candidature and the follow-up evaluation is planned to occur after I leave Australia.

Finally, in Chapter Eight I will discuss the overall conclusions and recommendations from my entire research work presented in this thesis and by taking into account the best currently available knowledge. I also provide some suggestions for future research that might help in the understanding some issue of concern in current HAART era.

2.1. The HIV/AIDS epidemic before and after HAART introduction as continuum of care for PLWHA

A quarter of a century has passed since the first cases of HIV/AIDS were reported by CDC in 1981 (CDC, 1981). Since the first cases of HIV/AIDS were reported more than 65 million individuals have been infected with HIV and more than 25 million have died of HIV/AIDS-related illnesses (Merson MH, 2006). However, extensive research in the past two and a half decades has led to great advances in our current knowledge on HIV/AIDS (Gottlieb MS, 2001), including great understanding of the molecular biology of HIV (Weiss RA, 2003) and also the epidemiology and pathogenesis of HIV-infection (Fauci AS, 2003; Stevenson M, 2003). Australia has also contributed significantly in the advancement of our current knowledge on HIV/AIDS (Lewin SR et al., 2006). These advances also included the discovery of several classes of antiretroviral drugs (Fauci AS, 2003) which culminated with the introduction of a therapeutic strategy coined “highly active antiretroviral therapy (HAART)” as part of a continuum of care for PLWHA since mid-1996 in all industrialized countries (Pomerantz RJ and Horn DL, 2003).

Soon after the introduction of HAART as a continuum of care for PLWHA, it became clear that it positively changed the characteristics of HIV/AIDS epidemic, contributing for significant declines of HIV/AIDS-related morbidity and mortality rates (Gottlieb MS, 2001; Sabin CA, 2002). In fact, HAART allowed the discontinuation of prophylaxis
against recurrent opportunistic infections in HIV-infected individuals (Kaplan JE et al., 2002), improved the longevity and the quality of life of PLWHA (Nunez M et al., 2001) and transformed HIV/AIDS into a chronic and manageable illness (Siegel K and Lekas H-M, 2002). Thus, a new era began with HAART (Elford J, 2006; Gottlieb MS, 2001), often referred as the “HAART era” (Sabin CA, 2002) or post-HAART (Elford J, 2006). However, I will prefer the term “HAART era” instead of “post-HAART era” as the first is more commonly used in biomedical literature.

The advent of HAART was indeed considered as the second most striking scientific advance in the HIV/AIDS epidemic after the identification of HIV as the causative agent for AIDS (Fauci AS, 2003). Furthermore, HAART was also considered as one of the most cost-effective treatment made available for any currently recognized chronic disease (Jones R and Gazzard B, 2006).

However, HAART does not lead to a cure of HIV/AIDS and thus new therapeutic strategies are needed for a cure to be achieved (Smith KA, 2001). On the other hand, the epidemiological impact of HAART has proved to be complex and also brought some new challenges and concerns for researchers working in the field of HIV/AIDS (Blower S et al., 2003). Researchers making use of mathematical modelling of the dynamics of HIV transmission predicted significant public health benefit, such as declines in HIV incidence and AIDS-related mortality rates, with the widespread use of HAART given that there were no increases in risky behaviours for transmission/acquisition of HIV (Blower SM et al., 2000; Law MG et al., 2001). However,
if increases in risky behaviour took place then HIV incidence rates were expected to increase according to these models (Blower SM et al., 2000; Velasco-Hernandez JX et al., 2002). Extensive usage of HAART over time could also produce negative consequences for public health if resistance to anti-HIV drugs occurred and is spread widely among HIV-infected individuals (Blower SM et al., 2000; Velasco-Hernandez JX et al., 2002).

2.2. Emerging issues on prevention and management of HIV/AIDS in HAART era

The transformation of HIV/AIDS as a chronic manageable disease since the introduction of HAART brought new issues on prevention and management of HIV/AIDS. Thus, for didactical reason I will classify these emerging issues in two different categories:

(1) those directly related to the use of HAART which includes for example the toxicity related to anti-HIV drugs and the challenges posed by adhering to complex and demanding HAART regimens;

(2) those indirectly related to the use of HAART which include for example the increase in unsafe sexual practices due to optimism related to HAART.

Thus, I will review below the literature for the former category under the subtitle “Issues on Management of HIV/AIDS in HAART era” and the later under the subtitle “Issues on Prevention of HIV/AIDS in HAART era”. However, I will start first by presenting below an overview on the HIV/AIDS epidemiology in Australia and subsequently in Victoria. I will restrict my review only to topics related
to research presented in this thesis. In addition, in the background section of each chapter I will present a brief review and rationale for carrying out the research presented in that respective chapter.

2.3. The HIV/AIDS epidemiology in Australia

The first case of HIV/AIDS in Australia was reported in December 1982 and soon after, in 1983, six more cases were reported (Crofts N, 1992). All these initial cases were reported among MSM in Sydney (Crofts N, 1992). Testing for HIV antibody was made widely available in Australia since early 1985 (Crofts N, 1992). Serological examinations of stored sera provided evidence of the presence of HIV in Australia since early 1980 (Crofts N, 1992).

In Figure 2.1 I have summarized the reported cases of HIV and AIDS in Australia between 1988 and 2005. Between 1982 and 1988 the number of reported cases of HIV-infection and AIDS in Australia grew rapidly (Carr A, 1992). However, after HIV-infection incidence peak in 1983-1984 (Becker NG et al., 1993), the HIV-infection and AIDS rates plateaued from 1988 to 1990 (Carr A, 1992).

After many years of decline of HIV-infection cases (Kaldor J and McDonald A, 2003), the annual number of new HIV diagnoses in Australia has gradually increased from 656 cases in 2000 to 930 in 2005 (National Centre in HIV Epidemiology and Clinical Research, 2006). However, according to NCHECR the number of AIDS cases in Australia peaked in 1994 at 953 cases and then declined rapidly to
212 in 1999 (National Centre in HIV Epidemiology and Clinical Research, 2006).

Figure 2.1. Summary of HIV and AIDS cases reported by year in Australia between 1988 and 2005 (source: Annual Surveillance Reports from National Centre in HIV Epidemiology and Clinical Research).

It has been suggested that the declines observed for AIDS cases between 1996 and 2001 were due to the declines in HIV incidence in mid-1980s and the widespread use of HAART since 1996 (National Centre in HIV Epidemiology and Clinical Research, 2006). On the other hand, the declines in HIV incidence in mid-1980s observed in Australia occurred in parallel with declines in other industrialized countries where the HIV/AIDS epidemic was also mainly driven by MSM (Carr A, 1992; Hulse GK, 1997; Parnell B, 1992; Stall RD et al., 2000). It has been suggested that these declines were the direct results of mass campaigns of HIV/AIDS
awareness and adoption of safer sexual practices for MSM carried out by the gay communities (Australian Institute of Family Studies - Commonwealth of Australia, 1989; Carr A, 1992; Hulse GK, 1997; Parnell B, 1992; Stall RD et al., 2000). However, compared to other countries, the gay community campaigns were relatively more successful in Australia (Carr A, 1992; Hulse GK, 1997), particularly amongst MSM actively associated with gay communities or organizations (Australian Institute of Family Studies - Commonwealth of Australia, 1989). Nevertheless, in Australia, HIV-infection and AIDS cases continues to affect primarily MSM who accounted for about 86% of newly acquired HIV infection (National Centre in HIV Epidemiology and Clinical Research, 2006). These newly acquired HIV-infections occurred mainly among people who were born in Australia (National Centre in HIV Epidemiology and Clinical Research, 2006).

Although adoption of safer sexual behaviour was observed among both HIV-infected and HIV-negative MSM (Prestage G et al., 2005), the later group of MSM were more likely to have changed their sexual behaviours out of fear of becoming HIV-infected (Australian Institute of Family Studies - Commonwealth of Australia, 1989). It was suggested that safer sexual practices adoption by MSM during this period was not an isolated individual behaviour change but rather a social phenomenon embedded within a gay community sexual ethics that resulted in a collective response against the HIV/AIDS epidemic (Kippax S and Kinder P, 2002).

In general, the number of new HIV diagnoses in Australia increased by 41% between 2000 and 2005 and the current
estimated AIDS incidence in Australia is 1.3 per 100,000 population (National Centre in HIV Epidemiology and Clinical Research, 2006). By the end of 2005, it was estimated that there were 15,310 PLWHA in Australia with an estimated 70% of them on HAART (National Centre in HIV Epidemiology and Clinical Research, 2006). People born in Australia accounted for 65% of AIDS diagnoses in the period between 2001 and 2005 (National Centre in HIV Epidemiology and Clinical Research, 2006). Furthermore, since the introduction of HAART as standard of care for PLWHA in Australia, the median survival among people diagnosed with AIDS has increased from 18 months prior to 1996 to 36 months for cases diagnosed in 2003 (National Centre in HIV Epidemiology and Clinical Research, 2006). In a recently published survey of 982 PLWHA from all states and territories from Australia, known as HIV FUTURES 5, 68.1% rated their health as good or excellent and 60.1% rated their general well being as good or excellent (Grierson J et al., 2006).

Recent increases in HIV cases in Australia appeared to have paralleled increases in UAI with casual partners among MSM that have recently been reported in Australia (National Centre in HIV Social Research (NCHSR), 2006; Van de Ven et al., 2002). Overall, HIV-infected MSM in Australia were more likely to have engaged in UAI with casual partners and have more casual partners than were HIV-negative MSM (National Centre in HIV Social Research (NCHSR), 2006).

On the other hand increases in STIs were also observed since 1996, in particular amongst MSM (National Centre in HIV Epidemiology and Clinical Research, 2006). I will
discuss further the sexual practices of MSM in section 2.4. with emphasis on changes occurred in their engagement in UAI with casual partners and its consequences for the incidence of STIs and HIV/AIDS among them in HAART era.

2.4. The HIV/AIDS epidemiology in Victoria, Australia

In Victoria, between 1983 and 2001 there were 1,942 cases of AIDS and 4,629 cases of HIV reported (Victorian Department of Human Services, 2006). The cases of AIDS peaked in 1994 when 203 diagnoses were recorded, but since then AIDS cases in Victoria have been falling as a result of the widespread use of HAART since 1996 (Victorian Department of Human Services, 2006).

The State of Victoria reported the second highest rate, after New South Wales, of diagnosis of AIDS (0.9 per 100,000 population) and HIV infection (4.5 per 100,000 population) during 2001-2005 (National Centre in HIV Epidemiology and Clinical Research, 2006). In the Figure 2.2. I have summarized the evolution of HIV and AIDS cases reported by year in Victoria between 1988 and 2005.

The increases in HIV cases in Victoria were first observed in 2000 and continued thereafter until 2006 (Department of Human Services of Victoria (Australia), 2006). The increase in HIV cases were primarily observed among MSM (Department of Human Services of Victoria (Australia), 2006).
Figure 2.2. Summary of HIV and AIDS cases reported by year in Victoria between 1988 and 2005 (source: Annual Surveillance Reports from National Centre in HIV Epidemiology and Clinical Research).

However, MSM have been the most affected group since the beginning of HIV/AIDS epidemic accounting for about 86% of all HIV/AIDS notifications in Victoria between 1983-2001 and 78.9% between 2001-2005 were amongst MSM (Victorian Department of Human Services, 2006).

In the Figure 2.3. I have summarized the frequency of HIV diagnoses reported in Victoria by exposure category between 1997 and 2005. Periodic surveys of MSM in Melbourne conducted since 1998 show that although UAI was more commonly practiced within regular sexual partnership there has been a significant upward trend in the rate of UAI with casual partners (p<0.001 (Hull P et al., 2006).
Furthermore, as shown in the Table 2.1, a higher proportion of HIV-positive MSM engaged in UAI than MSM who were HIV-negative or whose HIV-serostatus was unknown (p<0.001) (Hull P et al., 2006). However, caution in interpreting the findings of these periodic surveys were suggested because risk reduction strategies that some MSM might have practiced were not assessed (Hull P et al., 2006).

But an upward trend in gonorrhoea amongst MSM has been observed since 1996 and it concords with upward trend in UAI among MSM (National Centre in HIV Epidemiology and Clinical Research, 2006). In fact, in Victoria, the rate of rectal gonorrhoea among men increased from 1.2 per 100,000 population in 1996 to 3.1 per 100,000 population in 2003 and then declined to 2.1 per 100,000 population in 2005 (National Centre in HIV Epidemiology and Clinical Research, 2006).

A reliable indicator of unsafe sexual practice by MSM is engagement in UAI with casual partners (Kippax S et al., 1995) and thus in this thesis I will be focusing only on UAI with casual partners as marker of unsafe sex among MSM. I have reviewed and summarized in the Table 2.1, only data related to sexual practices of MSM with their casual partners in Melbourne between 1998 and 2005.
Figure 2.3. Summary of HIV cases reported by exposure category in Victoria between 1997 and 2005 (source: Department of Human Services of Victoria (Australia) (2006)).
Table 2.1. Summary of selected data (casual sexual relationship) obtained by cross-sectional periodic surveys of MSM in Melbourne conducted between 1998 and 2005 (Source: (Hull P et al., 2006)).

<table>
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<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Only in casual sexual relationship</td>
<td>472</td>
<td>25.6</td>
<td>374</td>
<td>24.4</td>
<td>420</td>
<td>25.3</td>
<td>449</td>
</tr>
<tr>
<td>Any sexual contact with casual partners</td>
<td>1362</td>
<td>72.0</td>
<td>1123</td>
<td>71.2</td>
<td>1209</td>
<td>66.1</td>
<td>1268</td>
</tr>
<tr>
<td>Any anal intercourse with casual partners</td>
<td>971</td>
<td>71.3</td>
<td>832</td>
<td>75.0</td>
<td>911</td>
<td>75.4</td>
<td>971</td>
</tr>
<tr>
<td>Any UAI with infected casual partner by HIV-serostatus</td>
<td>45</td>
<td>33.3</td>
<td>40</td>
<td>36.4</td>
<td>57</td>
<td>49.6</td>
<td>70</td>
</tr>
<tr>
<td>HIV-negative Unknown HIV-serostatus</td>
<td>162</td>
<td>15.9</td>
<td>192</td>
<td>22.2</td>
<td>209</td>
<td>23.0</td>
<td>239</td>
</tr>
<tr>
<td>HIV-infected Unknown HIV-serostatus</td>
<td>41</td>
<td>21.6</td>
<td>30</td>
<td>20.4</td>
<td>44</td>
<td>24.3</td>
<td>46</td>
</tr>
</tbody>
</table>

Note: UAI = unprotected anal intercourse; N = means the number in the study on which the percentage (%) given is based
Although often used and reported in surveys of sexual practices of MSM, this indicator (UAI with casual partners) does not take into account that some MSM might adopt risk reduction strategies (e.g. serosorting and strategic positioning) when engaging in UAI with their casual partners (Hull P et al., 2006). Thus, to overcome this limitation it was suggested that the context of sexual encounters should also be assessed (Grulich A, 2000). However, this detailed assessment of sexual practices might not always be possible in survey-type of studies such as those presented in this thesis. Therefore, the findings presented in Chapters 3 and 4 should be interpreted with this limitation in mind.

2.5. Issues on Prevention of HIV/AIDS in HAART era

In Australia, as in many other developed countries, the HIV/AIDS epidemic began with and has been mainly driven by MSM (National Centre in HIV Epidemiology and Clinical Research, 2006; Stall RD et al., 2000; UNAIDS/WHO, 2006). Thus, it is not surprising that the behavioural surveillance as well as studies of issues related to HIV/AIDS prevention have been conducted in these countries mainly among MSM (Grulich AE et al., 2003; Kaldor J and McDonald A, 2003).

Hence, in this section I will only examine issues on prevention of HIV/AIDS in HAART era related to MSM and particularly in Australia. Since the beginning of HIV/AIDS epidemic in Australia MSM has been the major sexually-identified group affected or “at-risk” of developing HIV/AIDS (Kaldor J and McDonald A, 2003), particularly in

2.5.1. The concept of “at-risk” in the context of HIV/AIDS epidemic

The terms “at-risk” or “at high-risk” were mainly developed from epidemiological perspective and emerged mainly because of the fact that MSM were more likely to engage in UAI with other MSM who were already HIV-infected (Parnell B, 1992). It has been advocated by some researchers that behaviours leading individuals “at-risk” are not randomly distributed in the population and that they are determined by the behaviour of the group to which they belong or identify with (Aral SO et al., 2005; Cohen DA et al., 2006). Therefore, development of surveillance systems, in particular those attempting to ascertain for risk factors for acquiring/transmitting HIV/AIDS, such as STIs and engagement in unsafe sexual practices, were regarded essential to monitor trends in HIV/AIDS (McDavid K and McKenna MT, 2006).

2.5.2. The importance of different surveillance systems in HIV/AIDS epidemic

In Australia since the early years of the HIV/AIDS epidemic different surveillance systems were put in place to monitor HIV/AIDS epidemic including behavioural surveillance, incidence of STIs and incidence of HIV/AIDS (Kaldor J and McDonald A, 2003).
The surveillance of STIs in particular is essential because of its unique relationship with high-risk sexual practices (Fleming DT and Wasserheit JN, 1999; Quinn TC, 1996; Stall RD et al., 2000). Thus, it provides a unique opportunity to monitor trends in sexual risk practices at the population level for two main reasons: (1) STIs represents a kind of biological marker for unsafe sexual practices and (2) STI increase the probability of acquisition/transmission of HIV (Fleming DT and Wasserheit JN, 1999; Quinn TC, 1996; Stall RD et al., 2000).

However, behavioural surveillance system is also indispensable as it enables the description of population patterns of high-risk sexual practices for STIs and HIV/AIDS transmission/acquisition (Donovan B and Ross MW, 2000) and thus assists in guiding initial public health interventions to bring under-control the occurrence of STIs as well as the HIV/AIDS epidemic (Brody S and Potterat JJ, 2004; McGarrigle CA et al., 2002). On the other hand, surveillance system are also useful to inform prospective research agenda (Brody S and Potterat JJ, 2004; Dukers NHTM et al., 2004).

Independent assessment of data obtained from different surveillance systems have limitations which in inherent to each system per se and only the triangulation of data from different systems is of value (Wellings K and Cleland J, 2001) for appropriate prevention and care interventions at the population level (McFarland W and Caceres CF, 2001). Thus, the combinations of different surveillance systems referred to above allowed to identify increases in UAI and STIs among MSM, both HIV-negative as well as HIV-positive,
since 1996 in Australia (National Centre in HIV Social Research (NCHSR), 2006; Van de Ven et al., 2002), including in the state of Victoria (Department of Human Services of Victoria (Australia), 2006) and also in some other industrialized countries (Nicoll A and Hamers FF, 2002; Race KD, 2003; Simon PA et al., 1999).

These increases in STIs and UAI among MSM occurred after the introduction of HAART as part of the continuum of care for PLWHA in 1996. Recently, increases in HIV cases were also observed in Australia, including in Victoria (National Centre in HIV Epidemiology and Clinical Research, 2006).

2.5.3. The emergence of “treatment optimism” amongst MSM

The introduction of HAART as a continuum of care improved the longevity and the quality of life of PLWHA (Nunez M et al., 2001) and transformed HIV/AIDS as a chronic and manageable illness (Siegel K and Lekas H-M, 2002). Indeed, HAART allowed PLWHA to resume relatively normal lives (Rofes E, 1998). Thus, with fewer PLWHA noticeably sick (Grierson J et al., 2004) HIV/AIDS became relatively hidden illness. Therefore, some researchers in the field of HIV/AIDS hypothesized that success of HAART showed the way for some MSM to be less concerned about acquiring HIV and the increases in UAI were the reflection of this optimism related to HAART (often called as “treatment optimism”) (Stall RD et al., 2000).
However, it has also been suggested that the eventual failure amongst many MSM in sustaining safer sexual practices indefinitely (called as “safe sex fatigue” or “prevention burnout”) may have also played a role (Piot P et al., 2001; Stall RD et al., 2000). Thus, although there have been numerous variables identified as affecting sexual risk-taking practices of MSM (Piot P et al., 2001; Stall RD et al., 2000) I will concentrate in this part of the thesis only in reviewing the literature related to “treatment optimism”. I am considering “treatment optimism” as an indirect consequence of HAART and thus an issue related to HIV/AIDS prevention that emerged in HAART era.

2.5.4. “Treatment optimism” amongst MSM in Australia

A number of studies were carried out in Australia (International Collaboration on HIV Optimism, 2003; Knox S et al., 2001; Van de Ven et al., 2000a; Van de Ven et al., 1999; Van de Ven et al., 2005; Van de Ven et al., 2000b; Van de Ven et al., 1998) and internationally (Crepaz N et al., 2004; Demmer C, 2003; Elford J et al., 2002; International Collaboration on HIV Optimism, 2003; Remien RH et al., 1998) trying to assess the relationship between UAI and “treatment optimism” with contradictory results which I will discuss in more detail below.

In the Table 2.2. I have summarized findings from the studies on “treatment optimism” carried out in Australia since the introduction of HAART. In general, there were two main dimensions of “treatment optimism” assessed in these
studies: one related to severity of HIV/AIDS and the other related to susceptibility to HIV-infection (Crepaz N et al., 2004; Demmer C, 2003).

For didactical reasons, I will examine the literature on "treatment optimism" first for HIV-negative MSM as they represent the group "at-risk" of acquiring HIV/AIDS. I will also examine how the availability of HAART affected the sexual practices of those who are/were already HIV-infected. The "treatment optimism" studies among HIV-infected individuals were carried out when the HIV-superinfection wasn't an issue due to the lack of evidence and I will discuss this issue later in this chapter.

2.5.4.1. HIV-negative MSM and "treatment optimism"

An overall analysis of the Table 2.2. indicates less contradictory findings across the studies carried out in Australia in regard to association between "treatment optimism" and engagement in UAI with casual partners by MSM although there were some methodological differences amongst them. Interestingly, all reviewed studies point towards increases in UAI with casual partners over time. All studies, except one (Van de Ven et al., 1998), show (see Table 2.2.) that HIV-negative MSM who engage in UAI with casual partners are more optimistic about HAART than their counterparts who do not report UAI with casual partners (International Collaboration on HIV Optimism, 2003; Knox S et al., 2001; Van de Ven et al., 2000a; Van de Ven et al., 1999; Van de Ven et al., 2005; Van de Ven et al., 2000b). Furthermore, in general, HIV-negative MSM seemed less optimistic about HAART compared to HIV-infected MSM.
However, consistently across all studies where the association between “treatment optimism” and engagement in UAI with casual partners was found, only a small fraction of HIV-negative MSM accounted for the optimistic attitudes/believes about HAART (International Collaboration on HIV Optimism, 2003; Knox S et al., 2001; Van de Ven et al., 2000a; Van de Ven et al., 1999; Van de Ven et al., 2005; Van de Ven et al., 2000b). However, I found only one study showing no association between UAI with casual partners and “treatment optimism” and that was carried out early in HAART era (Van de Ven et al., 1998).

Demmer C, et. al. presents a detailed review of studies carried out in other countries and comparing different groups including HIV-infected and HIV-negative MSM. In this review (Demmer C, 2003) disparities were also observed in regard to “treatment optimism” and engagement in high-risk sexual practices among MSM. It was suggested that these disparities across studies were due to methodological differences in assessing “treatment optimism” and its relationship with UAI with casual partners amongst MSM (Demmer C, 2003).
### Table 2.2. Studies assessing the impact of “HAART optimism” on sexual behaviour of HIV-negative and HIV-infected MSM in Australia

<table>
<thead>
<tr>
<th>Study reference</th>
<th>Research design and study location</th>
<th>Sample size</th>
<th>Key findings</th>
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| Van de Ven P, et al. (1998) | Five consecutive periodic (6 monthly) cross-sectional surveys in Sydney from February 1996 to February 1998; Self-administered anonymous questionnaires; | 2,863 | - Engagement in UAI with casual partners varied over time with significant upward linear trend:  
  - HIV-negative MSM: $\chi^2$ p<0.001, Mantel-Haenszel p<0.05;  
  - HIV-infected MSM: $\chi^2$ p<0.05, Mantel-Haenszel p<0.01;  
- HIV-infected MSM had more realistic assessment of viral load testing and HAART than HIV-negative MSM;  
- Overall, UAI with casual partners was unrelated to “treatment optimism”; |
| Van de Ven P, et al. (1999) | Two cross-sectional surveys: Sydney (February 1998) and Melbourne (January 1998); Self-administered anonymous questionnaires; | 2,200 (Sydney) 1,891 (Melbourne) | - HIV-infected MSM were more likely to engage in UAI with casual partners;  
- Significant relationship was found between engagement in UAI with casual partners and certain aspects of “treatment optimism”.  
- About 67.5% (359/532) MSM had casual partners and 19.2% (102/532) had UAI with casual partners;  
- MSM reporting UAI with casual partners were significantly more optimistic than those who did not report UAI with casual partners (p<0.001);  
- Differences were not found when taking into account HIV-status. |
| Van de Ven P, et al. (2000a) | A cross-sectional (6 monthly) survey in Sydney (February 1998); Self-administered anonymous questionnaires; | 532 | -  

Continuation of Table 2.2. Studies assessing the impact of “HAART optimism” on sexual behaviour of HIV-negative and HIV-infected MSM in Australia

<table>
<thead>
<tr>
<th>Study reference</th>
<th>Research design and study location</th>
<th>Sample size</th>
<th>Key findings</th>
</tr>
</thead>
</table>
| Van de Ven P, et al. (2000b) | Periodic (6 monthly) cross-sectional surveys between February 1996 and February 2000 in Sydney; Self-administered anonymous questionnaires; | 10,960 | - Increased UAI with casual partners along the time were observed among both, HIV-infected and HIV-negative MSM;  
- HIV-infected MSM had higher rates of UAI with casual partners than HIV-negative MSM;  
- HIV-negative MSM who had UAI with casual partners were more optimistic about HAART than their counterparts who reported no UAI with casual partners (p=0.003);  
- HIV-infected MSM who had UAI with casual partners were more optimistic about HAART than their counterparts who reported no UAI with casual partners (p=0.002);  
- Found significant association between sexual risk behaviour and “treatment optimism”;  
- HIV-infected MSM became more optimistic over time about the efficacy of HAART, but more sceptical about the ability of HAART to prevent HIV transmission;  
- Only a minority of MSM (regardless of HIV-status) had optimistic believes about HIV transmission in regard to HAART; |
Continuation of Table 2.2. Studies assessing the impact of “HAART optimism” on sexual behaviour of HIV-negative and HIV-infected MSM in Australia between 1996 and 2005.

<table>
<thead>
<tr>
<th>Study reference</th>
<th>Research design and study location</th>
<th>Sample size</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Collaboration on HIV Optimism</td>
<td>International cross-sectional survey between January and December 2000 in Australia and other countries (Canada, UK and France); In Australia it was carried out in Sydney and Melbourne;</td>
<td>3,120 (Australia)</td>
<td>- Only data from Australia: 18.7% (584/3,120) reported UAI with casual partners; - 76.3% (2,382) were HIV-negative and 14.1% (439) were HIV-infected; - Mean optimism scores varied by HIV-status: mean score for HIV-infected was 6.5 and HIV-negative 6.4 (p&lt;0.05); - Only a minority of MSM are optimistic in regard to HAART (&lt;20% in any City included in the study); - MSM reporting UAI with casual partners had higher mean optimism scores that those who reported no UAI with casual partners (p&lt;0.001); - 37 MSM reported some UAI; - In multivariate analysis, “treatment optimism” significantly predicted engagement in UAI (OR 4.98; 95% CI, 1.25-1.98; p=0.02) as well as did the self-reported undetectable viral load (OR 2.88; 95% CI, 1.13-7.37; p=0.03); - However, strategic positioning was observed among those engaging in UAI in about 3/4 of the study participants (both HIV-infected and HIV-negative);</td>
</tr>
<tr>
<td>Van de Ven P, et.al. (2005)</td>
<td>Cross-sectional study nested within two cohort studies (HIM and PH), from July 2001 to August 2003; Self-administered identified questionnaires Participants were in HIV serodiscordant regular relationship of at least 6 months duration;</td>
<td>45 HIV-negative 74 HIV-infected</td>
<td></td>
</tr>
</tbody>
</table>

31
Overall, the studies reviewed by Demmer et. al. found that a small but significant proportion of HIV-negative MSM were optimistic about HAART (Demmer C, 2003). Similar findings were reported in a recently published meta-analysis (OR 1.82; 95% confidence interval, 1.52 – 2.17, k=18) (Crepaz N et al., 2004). The effect of increases in UAI was greater in those who held “treatment optimism” beliefs/attitudes (median 49%, 17-81%) compared to their counterparts (median 38%, 9-68%) (Crepaz N et al., 2004). In general, there were no significant differences in findings between studies assessing “treatment optimism” in United States and elsewhere (Crepaz N et al., 2004).

Nevertheless, because of the cross-sectional nature of most studies assessing “treatment optimism” causality was not possible (Elford J, 2006). To establish causality researchers carried out longitudinal studies which also yielded conflicting results with some reporting high-risk sexual practices associated with treatment optimism while others did not (Elford J, 2006).

From the review of the literature it seems clear that in Australia and in other developed countries only a minority of HIV-negative MSM (10-20%) (International Collaboration on HIV Optimism, 2003) engage in UAI with casual partners because of their optimism towards HAART. It has been argued that even if there was any causal relationship between UAI and treatment optimism at the population level this would account for only about 10% of the increase in high-risk sexual behaviours (Elford J, 2004).
Suggestions for further research with larger samples and new reliable assessment tools were made to try to clarify disparities observed in currently available literature (Demmer C, 2003; Stolte IG and Coutinho RA, 2002). It has been claimed that the reasons for MSM engaging in high-risk sexual practices are complex and multifactorial (Sullivan PS et al., 2007). Thus, by carrying out the study presented in the chapter 3 I have attempted to respond to this referred suggestion. I will present in the background section of the next chapter a more detailed rationale for carrying out the study that I will call as “Perceptions Study”.

2.5.4.2. HIV-infected MSM and “treatment optimism”
In regard to HIV-infected MSM the Australian studies in relation to “treatment optimism” discussed above, as well as the studies carried elsewhere, the findings are not much different from that of HIV-negative MSM (see Table 2.2). Likewise with HIV-negative MSM, only a minority of HIV-infected MSM engage in UAI with casual partners with other MSM (in either seroconcordant or serodiscordant relationship) because of believes/attitudes related to “treatment optimism” (Crepaz N et al., 2004; Demmer C, 2003; Elford J et al., 2001; Elford J et al., 2002; Elford J et al., 2007; Grulich A, 2000; Holmes WC and Pace JL, 2002; Knox S et al., 2001; Stolte IG et al., 2004; Strathdee SA et al., 2000; Van de Ven et al., 2000a; Van de Ven et al., 1999; Van de Ven et al., 2005; Van de Ven et al., 2000b; Van de Ven et al., 1998).
However, in general HIV-infected MSM had higher rates of UAI with casual partners than their HIV-negative counterparts and they were more optimistic about HAART than their HIV-negative counterparts (see Table 2.2). One study assessing this over time in consecutive surveys between 1997 and 1999 found that HIV-infected MSM became more optimistic over time about the efficacy of HAART, but more sceptical about the ability of HAART to prevent HIV transmission (Knox S et al., 2001). This finding is explicable if one takes into account that HAART was introduced in 1996 and PLWHA were experiencing improvements in their health and well-being as a direct result of HAART. In fact, HAART allowed PLWHA to resume relatively normal lives (Rofes E, 1998), including resuming their normal sexual activities (Kippax S et al., 2007).

Although many HIV-infected MSM usually change their sexual behaviour after testing positive for HIV (Elford J et al., 2001; Tchamouroff SE, 1996) a significant minority continues to engage in unsafe sexual practices with their casual partners as shown by behavioural surveillance in Australia (Department of Human Services of Victoria (Australia), 2006; National Centre in HIV Social Research (NCHSR), 2006) and elsewhere (CDC, 2004; Elford J et al., 2007).

Based on the articles I have reviewed, I can conclude that “treatment optimism” studies among PLWHA, in particular among HIV-infected MSM, were carried out before tangible evidence for the occurrence of HIV-superinfection (or HIV-reinfection) was available. I consider that the lack of this concrete knowledge might have contributed to many HIV-
infected MSM not being worried about HIV-superinfection (Blackard and Mayer, 2004) and thus engaging more often in UAI with casual partners than their HIV-negative counterparts as shown in one survey assessing knowledge about HIV-superinfection and engagement in unsafe sexual practices (Colfax et al., 2004) and in another qualitative study (Adam et al., 2005). The knowledge of the possibility of HIV-superinfection occurring and with detrimental effects in an already HIV-infected individual (Chan, 2004; Smith et al., 2005a; Steain et al., 2004), particularly with the possibility of acquiring HIV strains that are eventually resistant to one or multiple anti-HIV drugs (Chakraborty et al., 2004; Smith et al., 2005b), might somehow contribute for the adoption of more safer sexual practices among HIV-infected MSM.

Before the availability of evidence of HIV-superinfection there was some reluctance in targeting HIV-infected individuals in HIV/AIDS prevention activities (Gerjo, 1999). However, since the availability of HAART a shift in this reluctance has been observed (Demmer, 2003; DiClemente RJ et al., 2002) and with the growing evidence of HIV-superinfection occurrence targeting HIV-infected individuals has became more imperative (Gerjo, 1999).

There are real needs of studies exploring believes/attitudes of HIV-infected individuals (including MSM) in regard to HIV-superinfection. In one Multicenter AIDS Cohort Study HIV-infected MSM less concern about HIV transmission with the use of HAART was associated with increased UAI (Ostrow DE et al., 2002). Thus, in the chapter 4 I have attempted to understand the association between
engagement in UAI with casual partners among HIV-infected MSM and the incidence of unexplained and sustained decline in CD4 T-cell counts and sudden increase in viral loads. I have also attempted to determine the relationship between engagement in UAI with casual partners and attitudes/believes about HIV-superinfection. I will present a more detailed rationale for carrying out the study (that I will call as “HIV-superinfection Study”) in the background section of the chapter 4.

2.6. Issues on Management of HIV/AIDS in HAART era

The biomedical and social research in HIV/AIDS field in the past 25 years has made possible important advances in prevention and management of HIV/AIDS. The introduction of HAART as a continuum of care for PLWHA indeed represented “an important turning point” in HIV/AIDS epidemic(Gottlieb MS, 2001) and transformed HIV-infection into a chronic and manageable disease(Siegel K and Lekas H-M, 2002). The introduction of HAART, since 1996 in many developed countries including Australia(Kaldor J and McDonald A, 2003), contributed significantly to declines in HIV/AIDS related deaths and opportunistic infections(Correl PK et al., 1998; Holtgrave DR, 2005; Law MG et al., 2000; Mocroft A et al., 2003; Palella FJ et al., 2006; Stene JAC et al., 2005; The Antiretroviral Therapy (ART) Cohort Collaboration, 2006; The Antiretroviral Therapy Cohort Collaboration, 2005). In fact, HAART allowed the discontinuation of prophylaxis against recurrent opportunistic infections in HIV-infected individuals(Kaplan JE et al., 2002), improved the longevity and the quality of life of PLWHA(Nunez M et al., 2001). Furthermore, HAART was
also considered as one of the most cost-effective treatment made available for any currently recognized chronic disease (Jones R and Gazzard B, 2006).

However, HAART does not lead to a cure of HIV/AIDS and thus new therapeutic strategies are needed for a cure to be achieved (Smith KA, 2001). Furthermore, HAART regimens are relatively complex and indisputably poses many challenges for patients taking these therapies as well as for clinicians caring for these patients (Lesho EP and Gey DC, 2003; Sabin CA, 2002). The challenges for clinicians are related to management of complex regimens (including supporting patients to maintain high levels of therapeutic adherence) and their associated toxicities and interactions with other drugs and/or diet (Lesho EP and Gey DC, 2003). On the other hand, the challenges for patients are related to adhere to complex and demanding HAART regimens and to cope with their short and long-term toxicities or side-effects (Lesho EP and Gey DC, 2003).

Some of the challenges related to HAART that I have mentioned above were met well with the development of more potent HAART regimens with lower pill burden and reduced toxicity (Dore GJ and Cooper DA, 2006).

Like other chronic diseases, the current goal of medical care of PLWHA is slowing the progression of HIV-infection and the management of symptoms and requires considerable self-care from patients’ themselves (Siegel K and Lekas H-M, 2002). On the other hand, PLWHA are faced with some degree of stigma, a varied level of dependency (social, clinical, etc), psychological distress and varied coping
strategies (Schonnesson LN, 2002; Siegel K and Lekas H-M, 2002). It has been suggested that the psychosocial impact of living with HIV/AIDS might have changed with the transformation of HIV-infection into a chronic disease by use of HAART but studies in this area are lacking and no definite conclusions can be made (Pierret J, 2000). A few studies are available on the psychosocial effects of HAART, mostly longitudinal, have so far showed contradictory results varying from no effect at all to only marginal effect (Siegel K and Lekas H-M, 2002). However, it has been suggested that many psychosocial issues faced by PLWHA in HAART era are similar to those in pre-HAART era (Schonnesson LN, 2002). Overall, PLWHA are faced with multiple psychosocial challenges whether on HAART or not and recurring to varying strategies to cope with them and to adjust to being HIV-infected (Bogart LM et al., 2000; Tsasis P, 2000).

It has been shown that how PLWHA perceive and adjust to their HIV-infection and how well they cope with the psychosocial issues of being HIV-infected and on HAART definitely affects how they look after themselves (self-care) and also affects their levels of adherence to their HAART regimens (Vervoort SCJM et al., 2007). Thus, while I am aware that there are many other issues related to HIV/AIDS management that emerged in the HAART era, for the thesis, I will restrict my discussion to the two themes discussed above, namely: adherence to HAART and self-care for PLWHA in the context of HIV/AIDS as a chronic disease. Below I will present separately the review of available literature for these two issues starting with the issue of adherence to HAART regimens.
2.6.1. Adherence to HAART regimens

The transformation of HIV/AIDS to a manageable chronic disease by the introduction of HAART brings new challenges for both patients as well as clinicians (Dore GJ and Cooper DA, 2006; Lesho EP and Gey DC, 2003; Sabin CA, 2002). One of the challenges is adherence to complex and demanding HAART regimens (Siegel K and Lekas H-M, 2002). In fact, to succeed patients receiving HAART need high levels of adherence to its regimens which requires an enormous long-term commitment (Friedland GH and Williams A, 1999; Ickovics JR and Meade CS, 2002; Siegel K and Lekas H-M, 2002).

However, many individuals receiving HAART fail to achieve the required levels of adherence (Ickovics JR and Meade CS, 2002; Singh N et al., 1996; Wright MT, 2000) which may result in the emergence of drug-resistant HIV strains and consequently treatment failure, progression to AIDS, and eventually death (Chesney M, 2003; Ickovics JR and Meade CS, 2002; Paterson DL et al., 2000; Read T et al., 2003). Moreover, the emergence of anti-HIV drug resistant strains also represents a threat to public health through transmission of drug-resistant HIV strains to other individuals (Chesney MA et al., 2000; Friedland GH and Williams A, 1999; Wainberg MA and Cameron DW, 1998; Wu AW et al., 2002). Several studies found that patients who are nonadherent to HAART are also more likely to engage in higher-risk sexual practices (Diamond C et al., 2005; Kalichman SC and Rompa D, 2003).

Considerable research on adherence to treatment has been carried out even before HAART was introduced and it was
recognized to be a significant problem, particularly for long-term therapies (Chesney MA et al., 2000; Christensen DB, 1978; Vermeire E et al., 2001; World Health Organization, 2003).

In the earlier research the term “compliance” was used instead of adherence (Chesney MA et al., 2000; Vermeire E et al., 2001). The term ‘compliance” was criticised by a group of sociologists and anthropologists in the late 1970s and early 1980s (Mykhalovskiy E et al., 2004). The replacement of the term “compliance” by the term “adherence” was mainly because of the negative connotations entrenched in “compliance”, mainly related to acceptance and submission to doctors’ recommendations by patients’ (Chesney MA et al., 2000; Mykhalovskiy E et al., 2004). In fact, the term “compliance” was viewed as highly value-laden term, particularly in the sense that it implied doctors’ dominance in doctor-patient relationships and it was examined only in terms of medical cost-benefit ignoring completely patients’ reasoned decision-making ability (Broyles LM et al., 2005b; Donovan JL and Blake DR, 1992; Mykhalovskiy E et al., 2004; Vermeire E et al., 2001).

However, as alternative to compliance two other terms emerged: “concordance” and “adherence” (Vermeire E et al., 2001), but the term “adherence” was preferred and became popular in biomedical literature (Mykhalovskiy E et al., 2004; World Health Organization, 2003). Although “adherence” has been regarded as less paternalistic than “compliance” both terms are often used interchangeably (Mykhalovskiy E et al., 2004). Nevertheless, it has been argued that compliance/adherence represents
more than a mere concept as it reflects more complex and heterogeneous experience than a plain power relationship issue between doctors and patients implied often by the criticism of the term compliance/adherence (Mykhalovskiy E et al., 2004).

Because the term “adherence” is more popular in medical literature I will be using it consistently throughout my thesis instead of “compliance”. Thus, I will adopt the definition for “adherence” given by the World Health Organization (WHO): “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” (World Health Organization, 2003). This definition places an emphasis on shared decision-making practice in any therapeutic recommendation between health care providers and patients (World Health Organization, 2003).

An enormous amount of research has been undertaken in relation to adherence involving variable methodological quality and diverse assessment methods with variable reliability mainly because of lacking gold standard measure for comparison which poses enormous difficulty in generalizing the findings across studies (Chesney MA, 2000; Paterson DL et al., 2002; Turner BJ, 2002; Vermeire E et al., 2001). Thus, for research on adherence to progress it has been suggested that there is an imperative need to come up with reliable and valid methods for measuring adherence and to reach consensus in these HAART adherence measurements (Chesney MA, 2000).
Largely the initial research on adherence was focused on factors of poor or nonadherence without any attempt to obtain the patients’ perspectives (Vermeire E et al., 2001). More than 200 variables related to adherence were identified (Vermeire E et al., 2001). These variables are usually grouped in the following categories: 1) patient variables; 2) treatment regimens; 3) disease characteristics; 4) patient-provider relationship; and 5) clinical setting or health system factors (Chesney M, 2003; Chesney MA, 2000; Christensen DB, 1978; Friedland GH and Williams A, 1999; Ickovics JR and Meade CS, 2002; Tsasis P, 2001; World Health Organization, 2003).

The available research clearly establishes that adherence to HAART is difficult (Chesney MA, 2000). It emphasizes that therapeutic adherence is a complex phenomenon (Vervoort SCJM et al., 2007). However, the existing literature, primarily survey based, is mostly made up of studies taking a limited approach to the problem, where patients are often made solely responsible for poor-adherence (Vervoort SCJM et al., 2007). Therefore, it has been suggested that qualitative studies may assist in improving our current understanding of HAART adherence, particularly by gaining insight on patients’ own experiences and perspectives (Vervoort SCJM et al., 2007). Furthermore, it has been suggested that qualitative research on adherence can make an important contribution in advancing our understanding on this complex phenomenon and designing appropriate interventions particularly by taking into account respondents’ own perspectives (Vervoort SCJM et al., 2007). Thus, I have carried out a two-part qualitative study on adherence during my PhD candidature. I will present the first part in
Chapter 5 (related to 100% adherence to HAART) and the second part in Chapter 6 (related to poor-adherence to HAART). In the background section of each chapter I will present a more detailed rationale for carrying out each part of the study.

2.6.2. Self-care in HIV/AIDS as chronic disease

HAART has helped to transform HIV into a manageable chronic disease. The chronic nature of the HIV disease course and the increasing burden of cumulative HIV-related morbidity and treatment-related toxic effects pose new challenges to the care of patients over time (Selwyn PA and Forstein M, 2003). Furthermore, now that PLWHA are growing older, health care professionals working in the field of HIV/AIDS are faced with age-related issues, such as: diabetes, hyperlipidemia and cardiovascular diseases, overlapping toxicities and interactions related to drugs for other concurrent illnesses (Manfredi R, 2004). For PLWHA to have a healthier and longer life-span it is necessary that health care professionals start prioritizing primary care issues (Justice AC, 2006). Thus, the comprehensive management of HIV disease needs to routinely include assessment and treatment dyslipidemias, metabolic complications, and multifactorial hepatic disease (Justice AC, 2006). It has been suggested that health care professionals should start focusing their attention to promote healthy behaviours, including promoting adherence to HAART and other drug regimens (for diabetes, high-blood pressure, etc), promote exercise, healthy diet and promote prevention of smoking and other toxic substance abuse (alcohol, illicit drugs) (Justice AC, 2006).
In particular, it has been recommended that PLWHA on HAART should be assessed for the traditional cardiovascular risk factors according to the Framingham risk score and intervene on those that can be modified following the same guidelines as those prescribed for the general population (Dubé M P et al., 2003).

The Framingham risk scores has been used by clinicians to tailor a plan for coronary heart disease (CHD) risk factor management and it has also proved to be useful for education and motivation of patients (Grundy S M et al., 1998). Studies carried out to assess the Framingham risk score in HIV-infected patients on HAART showed that they are twice as common (Bergersen B M et al., 2004). Therefore, HIV/AIDS patients on HAART should be screened for modifiable CHD risk factors and offered more intensive interventions (Bergersen B M et al., 2004), such as those related to the lifestyle (i.e. smoking cessation in smokers, increase in physical activities or adoption of healthy diets). Multiple risk factors might be identified in each patient on HAART requiring multiple changes in lifestyle that might prove difficult to achieve (Strecher V et al., 2002) and combination of intervention would be necessary to achieve desired outcomes.

One commonly used strategy is providing health education materials (HEM), often as brochures, booklets or pamphlets, to help individuals to change their behaviour or lifestyles (Holt C L et al., 2000). The HEM usually are designed for the general population or some targeted demographic sub-groups (Holt C L et al., 2000). The availability of computer technology brought some innovative
changes in HEM, allowing individually tailored HEM to be produced (Holt C L et al., 2000). Computer-tailored HEM provide people with information that is based on their individual characteristics making it personally relevant and are more effective in motivating people to adopt recommended behaviour(s) (Brug J et al., 2003). It seems that the effectiveness of the computer-tailored HEM is partly due to the impact produced by printed personalized feedback based on responses of each participant (Brug J et al., 2003).

As with other chronic diseases, PLWHA should be involved in their self-care issues to fully benefit from HAART. Thus, based on the above, I prepared with the help of experts in information technology (I.T. experts) as well as clinicians working at HIV Referral Clinic in Melbourne Sexual Health Centre a computer program (named “Health Map”) assessing following issues: adherence level to HAART and medication self-efficacy; perceived stress level; physical activity level; smoking habit and willingness to quit; general knowledge on HIV/AIDS; awareness of monitoring of their lipid profiles, glycaemia and blood-pressure; their body mass index (BMI) calculation; and willingness to know their risk of developing heart disease. This program (“Health Map”) was trialled in an open and non-randomized study at the HIV Referral Clinic in Melbourne Sexual Health Centre. The questions used to develop “Health Map” were selected from currently available and validated assessment tools for each topic assessed. This intervention may significantly reduce modifiable risk factors for heart disease and motivate the participants to attain desirable levels of adherence to HAART. The importance of this study stands on
eventually overcoming dyslipidemias and other risk factors for heart disease without increasing the pill burden on patients on HAART as well as increasing the motivation for keeping high levels of adherence to HAART.

Thus, in Chapter 7 I will present the baseline data of this open non-randomized clinical trial. I will present in the background section of the chapter 6 a more detailed rationale for carrying out this study that I will call as “Health Map”.

2.7. Concluding remarks

With the introduction of HAART as a continuum of care for PLWHA a new era began, the so-called HAART era. The great benefit brought by introduction of HAART was the transformation of HIV/AIDS into a chronic and manageable disease. However, HAART also brought with it some relatively new issues on prevention and management of HIV/AIDS. Among these emerging issues in HAART era I have singled out some that were of particular interest to me during my candidature which I have discussed in this chapter and presented my research findings in subsequent chapters.

Thus, within prevention issues I have focused my interest in studying MSM, both HIV-negative (study presented in chapter 3) and HIV-infected MSM (study presented in chapter 4). On the other hand, within management issues I have included both male and female participants and focused my attention on HAART adherence (presented in chapters 5 and
6) and promotion of self-care among PLWHA who are on HAART (presented in chapter 7).

Before each upcoming chapter I will present a brief background and rationale to carry out each study.
Conference presentation:

Sidat M, Rawstorne P, Lister N, and Fairley CK. Association between risk of acquiring HIV and beliefs and perceptions about the lived experience of HIV/AIDS among HIV-negative or untested men who have sex with men. Poster presented at (Poster 157) the 17th Annual Conference of the Australasian Society for HIV Medicine, August 2005, Hobart, Australia.

Study publication:

Sidat M, Rawstorne P, Lister N, and Fairley CK. Association between risk of acquiring HIV and beliefs and perceptions about the lived experience of HIV/AIDS among HIV-negative or untested men who have sex with men. AIDS Care 2006; 18(8): 934 – 941.
3.1. Study abstract
The study aim was to assess whether the sexual practices of HIV-negative or untested MSM was related to their perceptions of what it is like to live with HIV/AIDS, their beliefs or their attitudes to HAART. Any UAI with casual partners was used as the sexual-risk indicator. The study enrolled 261 MSM. There were no significant differences between beliefs, attitudes and perceptions about HIV/AIDS, knowledge of post-exposure prophylaxis (PEP) or exposure to the HIV/AIDS epidemic among those who had had UAI with casual partners and those that had not (P>0.12). Those who considered that low levels of viral load and withdrawing before ejaculation reduced the risk of HIV transmission were significantly more likely to have had UAI with a casual partner (P>0.03). Only a minority of MSM engaging in UAI were optimistic about antiretroviral therapy. The study participants were in general pessimistic about life with HIV/AIDS despite their risk-taking sexual behaviour.
3.2. Study background

In Australia, as in many other developed countries, the HIV/AIDS epidemic has began and has been mainly driven by MSM (National Centre in HIV Epidemiology and Clinical Research, 2006; Stall RD et al., 2000; UNAIDS/WHO, 2006). Thus, it is not surprising that the behavioural surveillance as well as studies researching issues related to HIV/AIDS prevention have been conducted in these countries mainly among MSM (Grulich AE et al., 2003; Kaldor J and McDonald A, 2003). In Victoria, MSM accounted for about 86% of all HIV/AIDS notifications in Victoria between 1983-2001 and 78.9% between 2001-2005 were amongst MSM (Victorian Department of Human Services, 2006).

In Victoria, likewise in other parts of Australia (National Centre in HIV Social Research (NCHSR), 2006; Van de Ven et al., 2002) and other developed countries (Bergersen BM et al., 2004a), there has been a significant upward trend in the rate of STIs and UAI with casual partners among MSM (Hull P et al., 2006; National Centre in HIV Epidemiology and Clinical Research, 2006; National Centre in HIV Social Research (NCHSR), 2006). In fact, in Victoria, the rate of rectal gonorrhoea among men increased from 1.2 per 100,000 population in 1996 to 3.1 per 100,000 population in 2003 and then declined to 2.1 per 100,000 population in 2005 (National Centre in HIV Epidemiology and Clinical Research, 2006). Engagement by MSM in UAI with casual partners have been considered a reliable indicator of unsafe sexual practices (Kippax S et al., 1995).
Because these increases in STIs and UAI among MSM occurred after the introduction of HAART as part of a continuum of care for PLWHA in 1996 some researchers in the field of HIV/AIDS hypothesized that success of HAART showed the way for some MSM to be less concerned about acquiring HIV and the increases in UAI were the reflection of this optimism related to HAART (often called as "treatment optimism") (Stall RD et al., 2000). Indeed, HAART allowed PLWHA to resume relatively normal lives (Rofes E, 1998) and leading the way for HIV/AIDS to become a relatively hidden illness with fewer PLWHA noticeably sick (Grierson J et al., 2004), despite the fact that the signs of lipodystrophy may identify some people with HIV (Nunez M et al., 2001).

A number of studies were carried out in Australia (International Collaboration on HIV Optimism, 2003; Knox S et al., 2001; Van de Ven et al., 2000a; Van de Ven et al., 1999; Van de Ven et al., 2005; Van de Ven et al., 2000b; Van de Ven et al., 1998) and internationally (Crepaz N et al., 2004; Demmer C, 2003; Elford J et al., 2002; International Collaboration on HIV Optimism, 2003; Remien RH et al., 1998) trying to assess the relationship between UAI and "treatment optimism" with contradictory results. In general, there were two main dimensions of "treatment optimism" assessed in these studies: one related to severity of HIV/AIDS and the other related to susceptibility to HIV-infection (Crepaz N et al., 2004; Demmer C, 2003). Suggestions for further research with larger samples and more reliable assessment tools were made to try to clarify disparities observed in currently available literature (Demmer C, 2003; Stolte IG and Coutinho RA, 2002).
Thus, it was hypothesized that the public receding of HIV may have brought about a greater optimism or even naivety among HIV-negative MSM about what it is like to live with HIV. Such naivety, if present, may translate into greater risk taking by MSM when engaging in sexual practices. There is a paucity of studies that have addressed such perceptions among HIV-negative MSM.

### 3.3. Study aims

The aim for carrying out this study was to examine the perceptions, beliefs and attitudes that HIV-negative MSM have about the lived experience of HIV/AIDS and to HAART, and whether such perceptions are related to sexual practices that may place them at risk of acquiring HIV-infection. Studies to date have generally addressed "treatment optimism" without considering the accuracy of perceptions that HIV-negative MSM have about the lived experience of HIV/AIDS. In this study, I wanted to examine both aspects.

### 3.4. Methodology

This was a cross sectional study of MSM seen at Melbourne Sexual Health Centre (MSHC), between February and August 2004. MSHC is Victoria’s largest and only publicly funded sexual health centre in Melbourne with about 25,000 consultations per annum. It has an electronic computerized system that captures routine surveillance data, such as number of partners (men/women) a client had sex with in the previous 12 months.
For this study, men were eligible to participate if they had had sex with another man in the previous 12 months and considered themselves HIV-negative (i.e. although untested in the past) or had negative HIV test result in the past. Clinicians at MSHC were briefed about the study and asked to invite eligible MSM to participate. The ethical approval of this study (see Appendix 2) was obtained from the HREC of the Department of Human Services of Victoria (HREC No: 86/01) and was registered at The University of Melbourne (HREC register No: 040425).

Those willing to participate provided written informed consent and completed a self-report questionnaire (see Appendix 3 and Appendix 4). The questionnaire asked about sexual practices, HIV testing, contact with the HIV/AIDS epidemic, HIV treatments optimism and the perceived medical and social impact of being HIV-positive. Where possible, it was ensured that the questions were similar to recent surveys in Australia (Grierson J et al., 2004; Hull P et al., 2006; International Collaboration on HIV Optimism, 2003; Van de Ven et al., 2000a; Van de Ven et al., 1999). And that the treatment optimism questions were the same as those in published studies (International Collaboration on HIV Optimism, 2003; Van de Ven et al., 2000a; Van de Ven et al., 1999).

To assess the understandings and perceptions that HIV-negative MSM have about aspects of the lived experience of HIV, the study participants’ were asked to estimate the proportion of PLWHA in Australia who experience specific issues related to health, access to a preferred doctor, treatments side-effects, mental health problems, sexual
fulfillment, employment, and discrimination. Participants were asked to select a response from 0 to 100% from a scale made available in the answering sheet. These data were then analysed against the reporting of UAI and against the responses of HIV-positive people in a nationwide cross-sectional survey study of PLWHA in Australia, known as FUTURES 4 (Grierson J et al., 2004).

Data were analysed using SPSS 12.0.1 for Windows (SPSS Inc, 2003). Categorical data were analysed using a Chi square of Fishers exact test and ordinal or continuous variables were analysed by a t test or the appropriate non-parametric test. In this study I have used any UAI (insertive and/or receptive) with casual partners as the appropriate sexual risk indicator based on the sexual health promotion strategy for MSM in Australia (Kippax S et al., 1995).

The study had 80% power to detect an odds ratio of 2.3 or more for UAI between those with and without certain characteristics if they were present in between 30-50% of those who did not practice UAI, assuming P=0.05 (2 sided) and that about one third of participants practice UAI with causal partners.

3.5. Results

During the study period 619 men who had sex with men (MSM) were seen at the MSHC. Of these 85 were not asked, and 58 were HIV positive and therefore not eligible for the study. The remaining 476 men were invited by their attending clinician (nurse and/or doctor) to participate in this study. Of those invited, about 61% (288/476) agreed to
participate in the study and about 91% (261/288) of these people actually returned the completed study questionnaire.

The age of participants ranged from 17 to 73 years (mean=32 years, SD=9.6 years). About 67% (171/261) of participants reported Australia as being their place of birth and 51% (133/261) indicated they were of Anglo-Australian ethnic background (46% or 120/261 were from other diverse ethnic background, including, Chinese, Philippine, Thai, Italian, Vietnamese, etc and only about 3% or 8/261 did not respond to this question). About 87% (226/261) of the study participants had had an HIV blood test in the past, and the remaining 13% (34/261) believed that they were HIV-negative but had not been tested. Four percent (10/261) reported the IDU in the past 6 months. Most study participants had a University education (56% or 146/261) and only 5% (14/261) had less than 3 years of high school education. About 50% (131/261) were employed full-time, 18% (44/261) were in part-time, 8% (22/261) were unemployed, 18% were students and about 2% (5/261) were pensioners and/or on social security benefit.

About half (53%, 139/261) of the study participants had both regular and casual partners in the previous 6 months. One third (31%, 81/261) of participants had casual partners only and about 14% (37/261) had regular partners only. A significant proportion of participants reported unprotected insertive (30% and 26%) or receptive anal sex (28% and 20%) with both regular and casual partners respectively.
Table 3.1.: "Perceptions of how people with HIV/AIDS live" among those with and without self-reported engagement in unprotected anal intercourse (UAI).

<table>
<thead>
<tr>
<th>Questions used in the study to assess &quot;Perceptions of how people with HIV/AIDS live&quot;</th>
<th>Sexual relationship with casual partners</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Freq.</td>
<td>Score (SD)</td>
<td>Freq.</td>
<td>Score (SD)</td>
<td>P values</td>
<td>Mean Score (SD)</td>
<td>Data from FUTURES 4¹ (in %)</td>
<td>P values (study score vs. Future 4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. % regarding their health as excellent or good.</td>
<td>135</td>
<td>48 (23)</td>
<td>83</td>
<td>49 (23)</td>
<td>0.55</td>
<td>49 (23)</td>
<td>67.8</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. % regarding their access to a preferred HIV doctor as convenient or well suited to their needs.</td>
<td>133</td>
<td>64 (22)</td>
<td>83</td>
<td>64 (21)</td>
<td>0.95</td>
<td>64 (22)</td>
<td>na*</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. % of people living with HIV/AIDS visiting their doctor at least once every three months.</td>
<td>134</td>
<td>71 (23)</td>
<td>82</td>
<td>71 (22)</td>
<td>0.95</td>
<td>71 (22)</td>
<td>na*</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. % currently taking anti-HIV drugs.</td>
<td>131</td>
<td>74 (20)</td>
<td>82</td>
<td>74 (20)</td>
<td>0.96</td>
<td>74 (20)</td>
<td>70.6</td>
<td>0.29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. % taking daily more than 10 prescribed pills associated with HIV infection.</td>
<td>132</td>
<td>54 (26)</td>
<td>82</td>
<td>56 (23)</td>
<td>0.68</td>
<td>54 (25)</td>
<td>24.0</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. % experienced diarrhoea related to HIV or anti-HIV drugs in the past month.</td>
<td>129</td>
<td>55 (25)</td>
<td>81</td>
<td>62 (22)</td>
<td>0.04</td>
<td>57 (24)</td>
<td>23.6</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. % experienced lipodystrophy symptoms related to HIV or anti-HIV drugs in the past year.</td>
<td>128</td>
<td>43 (22)</td>
<td>78</td>
<td>45 (20)</td>
<td>0.57</td>
<td>44 (21)</td>
<td>35.7</td>
<td>0.02</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. % regarding their sleeping patterns as poor.</td>
<td>127</td>
<td>53 (20)</td>
<td>78</td>
<td>55 (22)</td>
<td>0.46</td>
<td>54 (21)</td>
<td>49.3</td>
<td>0.20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes: (1) Score refers to the mean score on the scale between 0 and 100 in relation to each question; (2) Data from FUTURES 4 was used to compare the estimates given by the study participants and where data from FUTURES 4 were unavailable for comparison we indicated as 'na*, meaning "not available".
Continuation of the Table 3.1.: “Perceptions of how people with HIV/AIDS live” among those with and without self-reported engagement in unprotected anal intercourse (UAI).

<table>
<thead>
<tr>
<th>Questions used in the study to assess “Perceptions of how people with HIV/AIDS live”</th>
<th>None UAI</th>
<th>Any UAI</th>
<th>P values</th>
<th>Data from FUTURES 4¹ (in %)</th>
<th>P values (study score vs. Future 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual relationship with casual partners</td>
<td>Freq.</td>
<td>Score (SD)</td>
<td>Freq.</td>
<td>Score (SD)</td>
<td>Score (SD)</td>
</tr>
<tr>
<td>9. % experienced mental health symptoms (depression/anxiety) related to HIV or from taking anti-HIV drugs.</td>
<td>129</td>
<td>65 (22)</td>
<td>78</td>
<td>70 (19)</td>
<td>0.12</td>
</tr>
<tr>
<td>10. % regarding their libido (sex drive) as poor.</td>
<td>127</td>
<td>49 (22)</td>
<td>78</td>
<td>47 (22)</td>
<td>0.62</td>
</tr>
<tr>
<td>11. % of gay men living with HIV/AIDS not having sex at present.</td>
<td>130</td>
<td>36 (24)</td>
<td>78</td>
<td>35 (20)</td>
<td>0.69</td>
</tr>
<tr>
<td>12. % of gay men living with HIV/AIDS currently in paid full time work.</td>
<td>128</td>
<td>64 (20)</td>
<td>77</td>
<td>66 (20)</td>
<td>0.44</td>
</tr>
<tr>
<td>13. % of gay men experienced at work in the past less favourable treatment than other people as a result of having HIV/AIDS.</td>
<td>130</td>
<td>62 (27)</td>
<td>78</td>
<td>64 (24)</td>
<td>0.68</td>
</tr>
<tr>
<td>14. % of gay men experienced at a medical service in the past less favourable treatment than other people as a result of having HIV/AIDS.</td>
<td>130</td>
<td>44 (26)</td>
<td>78</td>
<td>43 (28)</td>
<td>0.89</td>
</tr>
</tbody>
</table>

Notes: (1) Score refers to the mean score on the scale between 0 and 100 in relation to each question; (2) Data from FUTURES 4 was used to compare the estimates given by the study participants and where data from FUTURES 4 were unavailable for comparison we indicated as ‘na’, meaning “not available.”
Table 3.2.: Relationship between ever testing for HIV, knowing or hearing about PEP and contact with HIV/AIDS epidemic and UAI with casual partners

<table>
<thead>
<tr>
<th>Statements related to HIV testing and other personal experiences</th>
<th>UAI (insertive / receptive) with casual partner</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any UAI n (%)</td>
</tr>
<tr>
<td>1. Ever had HIV-Test</td>
<td>Yes 77 (93)</td>
</tr>
<tr>
<td></td>
<td>No 6 (7)</td>
</tr>
<tr>
<td>2. Heard about post-exposure prophylaxis (PEP)</td>
<td>Yes 51 (61)</td>
</tr>
<tr>
<td></td>
<td>No 32 (39)</td>
</tr>
<tr>
<td>3. Have received PEP in the past 6 months</td>
<td>Yes 4 (5)</td>
</tr>
<tr>
<td></td>
<td>No 78 (95)</td>
</tr>
<tr>
<td>4. Heard of anyone who had received PEP</td>
<td>Yes 14 (17)</td>
</tr>
<tr>
<td></td>
<td>No 68 (83)</td>
</tr>
<tr>
<td>5. Free time spent with HIV -positive people</td>
<td>None 50 (61)</td>
</tr>
<tr>
<td></td>
<td>Any 32 (39)</td>
</tr>
<tr>
<td>6. Close friends who are HIV-positive</td>
<td>None 59 (71)</td>
</tr>
<tr>
<td></td>
<td>Any 24 (29)</td>
</tr>
<tr>
<td>7. Know people who are HIV-positive</td>
<td>None 30 (37)</td>
</tr>
<tr>
<td></td>
<td>Any 52 (63)</td>
</tr>
<tr>
<td>8. Know people who died of AIDS related illness in the past 12 months.</td>
<td>None 77 (93)</td>
</tr>
<tr>
<td></td>
<td>Any 6 (7)</td>
</tr>
</tbody>
</table>

PEP = post exposure prophylaxis, UAI = unprotected anal intercourse, OR = odds ratio
<table>
<thead>
<tr>
<th>Statements of attitudes and perceptions related to HIV/AIDS and the new antiretroviral treatments</th>
<th>UAI (insertive / receptive) with casual partner</th>
<th>Any UAI n (%)</th>
<th>None UAI n (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. New treatments will take the worry out of sex</td>
<td>Strongly agree/Agree</td>
<td>20 (24)</td>
<td>17 (12)</td>
<td>2.3 (1.1 – 4.6)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>63 (76)</td>
<td>121 (88)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. People with undetectable viral load do not need to worry so much about infecting others with HIV</td>
<td>Strongly agree/Agree</td>
<td>3 (4)</td>
<td>4 (3)</td>
<td>1.3 (0.3 – 5.8)</td>
<td>0.77</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>80 (96)</td>
<td>134 (97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Withdrawing before ejaculation (cumming) is a way for a sexual partner to reduce the risk of transmitting HIV</td>
<td>Strongly agree/Agree</td>
<td>26 (32)</td>
<td>24 (18)</td>
<td>2.2 (1.2 – 4.2)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>56 (68)</td>
<td>113 (82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. You can tell if someone has or hasn’t got HIV/AIDS by the way they look and what they do sexually</td>
<td>Strongly agree/Agree</td>
<td>3 (4)</td>
<td>10 (7)</td>
<td>0.5 (0.1 – 1.8)</td>
<td>0.27</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>80 (96)</td>
<td>128 (93)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. If a sexual partner wants to have unprotected sex, I can assume that he is the same HIV status as me (i.e. he is HIV-negative)</td>
<td>Strongly agree/Agree</td>
<td>3 (4)</td>
<td>2 (1)</td>
<td>2.6 (0.4 – 15.6)</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>80 (96)</td>
<td>136 (99)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. HIV is less of a threat because the epidemic is on the decline</td>
<td>Strongly agree/Agree</td>
<td>3 (4)</td>
<td>2 (2)</td>
<td>2.6 (0.4 – 15.6)</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>78 (96)</td>
<td>133 (98)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. HIV/AIDS is a less serious threat than it used to be because of the new treatments</td>
<td>Strongly agree/Agree</td>
<td>10 (12)</td>
<td>23 (17)</td>
<td>0.7 (0.3 – 1.5)</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>71 (88)</td>
<td>111 (83)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. I feel more confident about unprotected sex because of the new anti-HIV treatments</td>
<td>Strongly agree/Agree</td>
<td>4 (5)</td>
<td>4 (3)</td>
<td>1.7 (0.4 – 7.0)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>77 (95)</td>
<td>130 (97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Undetectable viral load means HIV is unlikely to be transmitted to a sexual partner even when a condom is not used.</td>
<td>Strongly agree/Agree</td>
<td>11 (14)</td>
<td>7 (5)</td>
<td>2.9 (1.1 – 7.7)</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree/Disagree</td>
<td>70 (86)</td>
<td>127 (95)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

UAI: Unprotected Anal Intercourse; OR: Odds Ratio
The mean age for those who reported any UAI with casual partners was 31 (SD = 9, Median = 30) and mean age of those who reported no UAI with casual partners was 33 (SD = 10, Median = 33).

**Table 3.1.** shows the relationship between UAI with casual partners and perceptions about “how people with HIV/AIDS live”. There were no significant differences in the perceptions about living with HIV/AIDS among those who did and did not have UAI with casual partners, except for the proportion who experienced diarrhoea related to HIV or anti-HIV drugs in the past month, which was higher among those who did have UAI (p = 0.04). In comparison to FUTURES 4 (Grierson J et al., 2004), this study participants were in general more pessimistic about all issues relating to living with HIV, except in regard to the health status (item 1, **Table 3.1.**) and libido (item 10, **Table 3.1.**) of PLWHA.

**Table 3.2.** shows the relationship between UAI with casual partners and individual’s knowledge or exposure to the HIV/AIDS epidemic or post-exposure prophylaxis (PEP). There were no significant differences in knowledge or levels of contact with the HIV/AIDS epidemic (**Table 3.2.**, items 5, 6, 7 and 8) or PEP (**Table 3.2.**, items 2, 3 and 4) among those who did and did not have UAI with casual partners (lowest P >0.13).

**Table 3.3.** shows the relationship between UAI with casual partners and an individual’s attitudes and beliefs about HIV/AIDS and its treatment. Three questions relating to the likelihood of HIV transmission were significantly different among those who did and did not have UAI (P<0.03). Those who
considered that new treatments take the worry out of sex and that low levels of viral load and/or withdrawing before ejaculation reduced the risk of HIV were significantly more likely to have had UAI with a casual partner.

3.6. Discussion

The current study found that there were no significant differences between beliefs, attitudes and perceptions about HIV/AIDS, knowledge of PEP or exposure to the HIV/AIDS epidemic among those who had had UAI with casual partners and those that had not. However, the study did find that those who considered that low levels of viral load and withdrawing before ejaculation reduced the risk of HIV transmission or agree with the statement that “new anti-HIV treatments take the worry out of sex” were significantly more likely to have had UAI with a casual partner. Though, as shown in the Table 3.3., only minorities of the study participants were engaging in UAI due to their beliefs or perceptions about HIV/AIDS and there were no significant differences in socioeconomic characteristics between those not engaging in UAI and those who were doing so.

This study found lack of association between UAI among HIV-negative or untested MSM and optimistic beliefs or perceptions about new antiretroviral treatments. In fact, from four statements related to treatment optimism (statements 1, 7, 8 and 9 from Table 3.3), only the first statement showed statistical significance. In contrast some previously published studies have found this association though usually only a minority of MSM were optimistic (Dilley et al., 2003; Elford J, 2004; Elford J et al., 2002; International
Collaboration on HIV Optimism, 2003; Knox S et al., 2001; Stolte IG et al., 2002; Stolte IG et al., 2004; Van de Ven et al., 1999; Van de Ven et al., 2000b). For example in a study carried out in Sydney and Melbourne, Van de Ven et al. found that few men were optimistic about HIV treatments (Van de Ven et al., 1999). This Australian study found that people who were less concerned about HIV because of new treatments were more likely to have had UAI with casual partners (Van de Ven et al., 1999). Similar results were observed in an international study on treatment optimism carried out in five major cities in Australia, Canada, England, and France in the year 2000 (International Collaboration on HIV Optimism, 2003). In this same study, in three out of four cities (in London, Paris, Sydney/Melbourne, but not in Vancouver), mean optimism scores were higher for MSM who reported UAI with casual partners compared with those who did not engage in any UAI (International Collaboration on HIV Optimism, 2003).

HIV treatment optimism was also one of the reasons given by MSM, who participated in focus groups discussions in five California cities, for their HIV risk taking practices (Morin et al., 2003). A recently published meta-analysis examining studies related to treatment optimism from January 1996 to August 2003, also found that the likelihood of UAI was higher in people who agreed that the availability of HAART reduces their concerns about having unsafe sex (Crepaz N et al., 2004).

In contrast, few studies, found that HIV optimism could not explain (Elford J et al., 2002) or predict (Huebner et al., 2004) increases in UAI among gay men. Discrepancies in these findings were explained by Van de Ven et al. as result of statistical artefacts (Van de Ven et al., 1999), differences in
sexual cultures and different types of questions used to assess treatment optimism (Demmer C, 2003).

This study participants were generally more pessimistic about what it would be like to live with HIV/AIDS when compared with data from surveys of individuals with HIV/AIDS, such as an Australian survey known as FUTURES 4 (Grierson J et al., 2004). HIV FUTURES are periodic cross-sectional national surveys of HIV positive Australian residents and are probably the most reasonably accurate reflection of what it is like to live with HIV, at least in Australia. Although, this study sample involved only MSM which makes it demographically different from FUTURES 4 (Grierson J et al., 2004) it was still a useful comparison tool for this study purposes. Thus the comparison carried out in this study indicated that overall participants, including those who engage in UAI with casual partners, were pessimistic about life with HIV despite their risk taking behaviour. Although these perceptions about the lived experience of HIV appear unrelated to sexual risk practices, they nonetheless suggest that there is a certain naivety among HIV-negative men about the lived experience of HIV. This reaffirms the view that HIV is receding in visibility in Australia and other developed countries where HAART has been used as part of the standard of care for PLWHA since the mid-1990s. At a theoretical level, the poor association between beliefs and attitudes with sexual practices reaffirms some of the limitations inherent in cognitive rational models such as the Health Belief Model (Rosenstock I et al., 1994) and the Theory of Reasoned Action (Ajzen I and Fishbein M, 1980) for predicting and explaining the complexity around sexual practices (Crepaz N et al., 2004).
The strength of this study is that it assessed in one single study the role of different parameters which have been used single-handedly in other studies in promoting unsafe or safer sexual practices. By assessing different aspects directly as well as indirectly related to new antiretroviral therapy I have tried to examine the effects of treatment optimism among HIV-negative MSM from different perspectives. Thus, I have also assessed the following parameters regarded as indirectly related to treatment optimism: (a) knowledge of post-exposure prophylaxis (PEP); (b) HIV testing; and (c) contact with the HIV/AIDS epidemic. It was assumed that all these parameters may have contributed somehow in shaping the contemporary sexual behaviours of MSM in the era of HAART.

In this study I did not find any significant association between those who had knowledge of PEP or used PEP in the past with engagement in UAI with casual partners. These results are consistent with a similar study carried out in San Francisco (Waldo CR et al., 2000). In this later study (Waldo CR et al., 2000), MSM who knew about the availability of PEP did not report more risky sexual behaviour than those who did not know that PEP was available. However, different results were obtained in another study (Kalichman SC, 1998) where MSM who had knowledge and planned to use PEP were more optimistic in relation to anti-HIV treatments as well as more likely to practice receptive UAI with multiple partners. These discrepancies might be partly due to differences in study participants’ demographic characteristics, their sexual cultures and/or due to differences in PEP knowledge assessment strategies used.
It has been suggested that social contact or distance with PLWHA can influence HIV risk behaviour (Hughes R, 2000). Thus, I have also assessed in this study the contact of the study participants with the HIV/AIDS epidemic (items 5, 6, 7 and 8 in Table 3.3). However, I did not observe any significant differences between high and low risk groups of MSM for all assessed parameters for the contact with HIV/AIDS epidemic (Kelly et al., 1992). These results are similar to other related studies (Kelly et al., 1992; Mansergh G et al., 2000) when analyzing the sexually protective role of knowing people with HIV/AIDS. Although I did not assess the level of emotional closeness with PLWHA, it was suggested by the study of Mansergh et. al. (2000) that the likelihood of high risk sexual practices, found particularly among younger MSM (18 – 25 years), was apparently due to being less emotionally close with PLWHA.

3.7. Study limitations

There are a number of limitations associated with the present study. The first is that the participants in this study were taken from a clinic rather than a community setting and I did not collect information about their bisexual behaviour. They were however demographically similar to those of other previous community based studies among MSM in Melbourne (Hull P et al., 2006), particularly in regard to age, ethnicity, educational background and employment status. However, this study participants were very different demographically from that of FUTURES 4 (Grierson J et al., 2004), particularly in regard to the gender and sexual orientation. In this study only MSM were surveyed. Because this study was measuring differences within the single sample the selection bias is
less important in this situation than when one is measuring the characteristics of an entire sample.

The second weakness of this study is that it was a cross-sectional study, similarly to most previous studies in this area. It is therefore not possible to say that the knowledge, beliefs or perceptions that was found in this study, were or were not causally associated with the behaviour. Also, if for example, there was more UAI in those who knew people with HIV than in those who did not know someone with HIV, it is possible that exposure to these individuals reduced their risk behaviours to a level that was similar to those who did not know what it was like to live with HIV. It has been shown in two different cohort studies examining HAART-related beliefs and engagement into UAI that MSM who considered less HIV/AIDS threat since the availability of HAART were more likely to change from protected to UAI(Huebner et al., 2004; Stolte IG et al., 2004).

3.8. Conclusions

The study findings presented in this chapter shows that only a minority of the study participants were engaging in UAI due to their beliefs or perceptions about HIV/AIDS, confirming previous studies (see Chapter 2, section 2.4.4.). This study also confirms that that sexual practices among MSM is a complex and multifactorial issue(Crepaz N et al., 2004; Sullivan PS et al., 2007). Additional studies are needed to understand other factors responsible for the increases in UAI and STIs among MSM observed since the introduction of HAART as a standard of care for PLWHA in many developed countries.
Chapter 4: “HIV-superinfection Study”

Study publication:

4.1. Study abstract:
To determine the upper limit for the incidence of clinically important HIV-superinfection by determining the incidence at which HIV-infected MSM showed an unexplained and sustained decline in CD4 T-cell counts and/or unexplained increases in their plasma HIV RNA and determine if they were more likely to have engaged in unsafe sex with their casual partners than other HIV-infected MSM. This was a retrospective cohort study and nested case-control study. Graphical data of all MSM who were not on HAART between June 2003 and June 2005 were reviewed to select cases and controls. Participants were given self-administered questionnaire to answer. Ten cases were identified from 145 eligible MSM (7%, 95% confidence interval 3 to 11%), comprising a rate of 3.6 per 100 person-years at risk. Cases had an annual decline in CD4 T-cell counts of 200 cells/µl compared to 9 cells/µl for controls. There were no statistically significant differences between cases and controls in regard to sexual practices that may have exposed them for acquisition of HIV-superinfection (p-value≥0.4) or in their perceptions/beliefs of HIV superinfection (p-value ≥0.3). Only a minority of the study participants reported no previous knowledge of HIV-superinfection (17%, 5/30). Overall, both cases and controls were engaging frequently in unsafe sexual practices with casual partners who were HIV-infected (80% and 52% respectively; p-value=0.4) and/or whose HIV-serostatus were unknown (40% and 50% respectively; p-value=1.0). The rate of clinically significant HIV-superinfection in this cohort of sexually active MSM was likely to be less than 4% per year. This estimate is similar to what other investigators have reported of between 0 to 6.5% per year.
4.1. Study background

Men who have sex with men (MSM) comprise the majority of persons living with HIV/AIDS (PLWHA) in most developed countries (UNAIDS/WHO, 2006), including Australia (UNAIDS/WHO, 2006; Volk JE et al., 2006). Unprotected anal intercourse (UAI) between HIV-infected MSM may expose them to HIV-reinfection (also known as HIV-superinfection) (Blackard JT and Mayer KH, 2004). HIV-superinfection can contribute to a deterioration in immune function and consequently to a rapid progression of HIV-infection to AIDS (Blackard JT and Mayer KH, 2004; Smith DM et al., 2005a; Steain MC et al., 2004). In fact, sudden and sustained declines in CD4 T-cell counts and increases in plasma HIV RNA have been observed in nearly all reported cases of HIV-superinfection, including cross-sectional studies of large number of HIV-infected individuals (Allen TM and Altfeld M, 2003; Blackard JT and Mayer KH, 2004; Chan DJ, 2004; Gottlieb GS et al., 2004; Smith DM et al., 2005a; Steain MC et al., 2004). It has been suggested that HIV superinfection should be considered if an HIV-infected individual shows a sudden, unexplained and sustained decline in CD4 T-cell counts or unexplained increase in plasma HIV RNA (Steain MC et al., 2004).

Recently, increases in unsafe sexual practices and sexually transmitted infections (STIs) in PLWHA have been reported among MSM (Blackard JT et al., 2002) potentially increasing the risk of HIV-superinfection. While the precise incidence of HIV-superinfection is unknown, some recent cohort studies of PLWHA at risk of HIV-superinfection through unprotected sexual practices (Chohan B et al., 2005; Fang G et al., 2004; Grobler J et al., 2004; Manigart O et al., 2004) and intravenous drug
users (Tsui R et al., 2004; Yerly S et al., 2004) attempted to estimate it. Others have estimated the incidence of HIV-superinfection by phylogenetic analysis of stored plasma samples from HIV-infected individuals without identification of their risk group (Gonzales MJ et al., 2003; Smith DM et al., 2004). Thus, by using different methodologies for selection of study samples and also different laboratory assessment strategies the currently available estimate for the frequency of HIV-superinfection varies from 0 to 6.5% per year (Chohan B et al., 2005; Fang G et al., 2004; Gonzales MJ et al., 2003; Grobler J et al., 2004; Koelsch KK et al., 2003; Manigart O et al., 2004; Smith DM et al., 2004; Smith DM et al., 2005b; Tsui R et al., 2004; Yerly S et al., 2004). Exposure to similar subtypes of HIV (Tsui R et al., 2004) and the use of HAART (Gonzales MJ et al., 2003) in two large cohort studies, were believed to be responsible for the lack of detection of HIV-superinfection after 215 person-years of exposure (n = 37 active injection drug users) and 1072 person-years of observation (n = 718 HIV-infected individuals), respectively. Nevertheless, cases of HIV-superinfection involving similar HIV subtypes (Brenner B et al., 2004; Koelsch KK et al., 2003; Smith DM et al., 2005b; Yang OO et al., 2005) and among individuals on HAART (Chakraborty B et al., 2004) have also been reported, the latter occurring only among those superinfected with drug-resistant mutants of HIV (Chakraborty B et al., 2004). Based on the above, it was hypothesized that HIV-infected MSM who were not on HAART and who showed a sudden, unexplained and sustained decline in their CD4 T-cell counts and/or increases in their plasma HIV RNA might be engaging more often in unsafe sexual practices with other MSM who are HIV-infected, a potential surrogate marker for risk of HIV-superinfection.
4.2. Study aims
The aim of this study was to determine the incidence at which HIV-infected MSM showed a sudden, unexplained and sustained decline in CD4 T-cell counts and/or increases in their plasma HIV RNA values and to determine if these individuals were more likely to have engaged in unsafe sexual practices (e.g. UAI) with their casual partners than a random selection of HIV-infected MSM with stable immune and viral status.

4.3. Methodology
The study was a retrospective cohort study and nested case-control study, carried out at two sites, the HIV Clinic at Melbourne Sexual Health Centre and the HIV Clinic at the Alfred Hospital in Melbourne, Australia. Individuals were eligible for the study if they were HIV-infected MSM, who had not been on any antiretroviral treatment in the 2 years before their files were audited (in June 2005) and had at least four CD4 T-cell counts and plasma HIV RNA readings over this 2 year period. The identification of cases and controls were made by three investigators (myself and two other senior co-researchers) independently visually assessing the graphs of CD4 counts and viral loads between June 2003 and June 2005 of all eligible patients.

The decision to use these two biological parameters was based on available evidence from the published literature showing that there was an association between unexplained and sustained declines in CD4 T-cell counts and/or increases in plasma HIV RNA values and occurrence of HIV-superinfection (Allen TM and Altfeld M, 2003; Blackard JT and
Individuals showing a sudden, unexplained and sustained declines in CD4 T-cell counts and/or unexplained and sustained increases in plasma HIV RNA were identified as cases. We defined a clinically important, sudden and sustained decline in CD4 T-cell counts over a period of 3 months or more of at least 100 cells/µl and/or a sustained increase in plasma HIV RNA values for the same period of at least 1 log_{10} copies/ml. These cut-off points for CD4 T-cell counts and plasma HIV RNA values we expected to reliably select our study cases as reported in one study for cases suggestive of HIV superinfection (Yerly S et al., 2004). Those without these changes were categorized as controls. Agreement in the selection of cases and controls was reached by consensus after each of the three investigators had separately assessed each patient’s graph.

Cases and controls were recruited consecutively as they presented for their ongoing clinical care over the study period. For each case, four controls were consecutively selected from the next patients attending after the case. After they provided written informed consent (see Appendix 6), each participant was asked to answer a questionnaire (see Appendix 7) of their self-reported sexual practices, use of injecting recreational drugs and sharing of injecting equipment, self-reported history of illness, other infections and/or hospitalizations, self-reported history of vaccination and their perceptions/beliefs of HIV-superinfection. The questions related to the perceptions on HIV-superinfection were adapted from a recent publication (Colfax GN et al., 2004).
2004). The values of CD4 T-cell counts and plasma HIV RNA values for each study participant were retrieved from their electronic files for the period between June 2003 and July 2005. Ethics permission was obtained from the Alfred Hospital Ethics Committee and also by the HREC of The University of Melbourne (see Appendix 5).

Data were analysed using SPSS 12.0.1 for Windows (SPSS Inc, 2003). Crude odds ratios and 95% confidence intervals were calculated for some of the categorical variables assessed in this study. For ordinal and continuous variables we used non-parametric Mann-Whitney U Test. An appropriate adjusted analysis was undertaken on the basis of the findings of the crude analysis. With 290 person-years of observations, the study had reasonably tight confidence intervals (1.4 to 5.9) around the proportion with unexplained and sustained declines in CD4 T-cell counts and increase in plasma HIV RNA values. The sexual-risk indicator defined for this study was any UAI (receptive and/or insertive) with casual partners based on sexual health promotion strategy for MSM in Australia (Kippax S et al., 1997).

4.4. Results

Figure 4.1. gives a breakdown of all patients attending both study sites. There were a total of 1,901 patients seen during the previous two years at the two sites. Of these, 145 patients had not received HAART at any time during the study period (290 person-years at risk) and who also had at least four measurements of CD4 T-cell counts and plasma HIV RNA available. Ten of the 145 eligible patients were identified as
cases (6.9%, 95% confidence interval 3 to 11%) giving a rate of 3.6 per 100 person years at risk.

**Figure 4.1.**: Clients seen in the last two years (June 2003 to June 2005) at Melbourne Sexual Health Centre and The Alfred Hospital and their eligibility for the study.

The **Figure 4.2.** gives an example of one study case. Six of the 10 cases and 25 controls were recruited into the nested
case control study. The remaining 4 cases were not included because one died prior to interview (suicide); one was not fluent in English, one did not return to the clinic during the study recruitment period and one declined participation.

![Laboratory measurement dates](image)

**Figure 4.2.:** An example of one study case (CASE 002) showing (short arrow) unexplained and sustained decline in CD4 T-cell counts and sustained rise in HIV RNA plasma viral loads (Log 10 copies/ml). The long arrow marks the point when HAART was introduced.

The 10 cases had an average drop in CD4 T-cell counts of 39% based on calculations of average values of before and after the decline (see Table 4.1.). When the CD4 T-cell values over the study period of the 10 cases were plotted, the line of best fit gave a reduction in CD4 T-cell counts of 201 cells/mm$^3$ per year. All cases had an increase of at least 1 log$_{10}$ in plasma HIV RNA levels, although only one case showed a sustained rise over time (Case 2, shown in Figure 4.2.). The 25 controls had an average decline of CD4 T-cell counts of 9 cells/mm$^3$ per year.
Table 4.1.: Values of CD4 T-cell counts (pre-decline and post-decline) among eligible cases and the percentage of decline observed.

<table>
<thead>
<tr>
<th>Cases</th>
<th>Average CD4 T-cell values Pre-decline (cells/mm³)</th>
<th>Average CD4 T-cell values Post-decline (cells/mm³)</th>
<th>Percentage of CD4 T-cell values decline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>416</td>
<td>254</td>
<td>39</td>
</tr>
<tr>
<td>Case 2</td>
<td>591</td>
<td>270</td>
<td>54</td>
</tr>
<tr>
<td>Case 3</td>
<td>267</td>
<td>163</td>
<td>39</td>
</tr>
<tr>
<td>Case 4</td>
<td>670</td>
<td>468</td>
<td>30</td>
</tr>
<tr>
<td>Case 5</td>
<td>244</td>
<td>166</td>
<td>32</td>
</tr>
<tr>
<td>Case 6</td>
<td>232</td>
<td>168</td>
<td>28</td>
</tr>
<tr>
<td>Case 7</td>
<td>547</td>
<td>257</td>
<td>53</td>
</tr>
<tr>
<td>Case 8</td>
<td>1119</td>
<td>675</td>
<td>40</td>
</tr>
<tr>
<td>Case 9</td>
<td>601</td>
<td>463</td>
<td>23</td>
</tr>
<tr>
<td>Case 10</td>
<td>706</td>
<td>314</td>
<td>55</td>
</tr>
<tr>
<td><strong>Total average decline in percentage (%)</strong></td>
<td><strong>39</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean age for cases was 38 years (median 37.8; range 30 to 50 years) and for controls was 41.7 years (median 42; range 23 to 64 years). There were no significant differences in other demographic characteristics between cases and controls (p-value ≥0.4). Overall, 84% of study participants were of Anglo-Australian ethnic background and 58% were employed in full-time basis.

There were no statistically significant differences between cases and controls in regard to practices that may have exposed them for acquisition of HIV superinfection (see Table 4.2.).
Table 4.2: Some clinical and sexual relationship characteristics of the study sample (past 2 years prior to the time of study participation).

<table>
<thead>
<tr>
<th>Clinical and sexual relationship characteristics</th>
<th>Frequency (%)</th>
<th>Odds Ratio* (95% C.I.)</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Used illicit injecting drugs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (25)</td>
<td>1.5</td>
<td>1.0</td>
</tr>
<tr>
<td>No</td>
<td>3 (75)</td>
<td>(0 - 27.3)</td>
<td></td>
</tr>
<tr>
<td>2. Stayed away from work for ≥7 days due to illness.</td>
<td>4 (17)</td>
<td>4.8</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (50)</td>
<td>(0.5 - 51.4)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>18 (82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Admitted to the Hospital because of illness.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (50)</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>20 (80)</td>
<td>(0.2 - 18.1)</td>
<td></td>
</tr>
<tr>
<td>4. Received any vaccination.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (67)</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>13 (52)</td>
<td>(0.2 - 18.1)</td>
<td></td>
</tr>
<tr>
<td>5. Had regular sexual partners.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (83)</td>
<td>2.8</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>16 (64)</td>
<td>(0.2 - 74.2)</td>
<td></td>
</tr>
<tr>
<td>6. Had any UAI with regular sexual partners who were HIV-positive.</td>
<td>1 (17)</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (60)</td>
<td>(0.1 - 8.5)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>9 (36)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Had any UAI with regular sexual partners who were of unknown HIV-status.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (40)</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3 (60)</td>
<td>(0.1 - 22.5)</td>
<td></td>
</tr>
<tr>
<td>8. Had casual sexual partners.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (83)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1 (17)</td>
<td>(0 - 14.9)</td>
<td></td>
</tr>
<tr>
<td>9. Had any UAI with casual sexual partners who were HIV-positive.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (80)</td>
<td>3.7</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>12 (52)</td>
<td>(0 - 100.1)</td>
<td></td>
</tr>
<tr>
<td>10. Had any UAI with casual sexual partners who were of unknown HIV-status.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (40)</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3 (60)</td>
<td>(0.1 - 6.8)</td>
<td></td>
</tr>
</tbody>
</table>

Notes: * Odds Ratio calculated only by taking into account Yes/No responses (missing data not included); ** P-value calculated by using Fisher exact test; *** P-value calculated by non-parametric Mann-Whitney U test.
Table 4.2. (continuation): Some clinical and sexual relationship characteristics of the study sample (past 2 years prior to the time of study participation).

<table>
<thead>
<tr>
<th>Clinical and sexual relationship characteristics</th>
<th>Cases</th>
<th>Controls</th>
<th>P-value***</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Number of regular sexual partners</td>
<td>Median 3</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Range 0 – 10</td>
<td>0 – 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Median 1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>12. Number of regular sexual partners who were</td>
<td>Range 1 – 3</td>
<td>0 – 5</td>
<td>0.8</td>
</tr>
<tr>
<td>HIV-positive.</td>
<td>Median 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>13. Number of regular sexual partners who were</td>
<td>Range 0 – 1</td>
<td>0 – 4</td>
<td>0.9</td>
</tr>
<tr>
<td>of unknown HIV-status.</td>
<td>Median 15</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>14. Number of casual sexual partners</td>
<td>Range 0 – 80</td>
<td>0 – 500</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Median 5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>15. Number of casual sexual partners who were</td>
<td>Range 1 – 15</td>
<td>1 – 150</td>
<td>0.9</td>
</tr>
<tr>
<td>HIV-positive.</td>
<td>Median 3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>16. Number of casual sexual partners who were</td>
<td>Range 0 – 75</td>
<td>0 – 200</td>
<td>0.7</td>
</tr>
<tr>
<td>of unknown HIV-status.</td>
<td>Median 1</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Notes: * Odds Ratio calculated only by taking into account Yes/No responses (missing data not included); ** P-value calculated by using Fisher exact test; *** P-value calculated by non-parametric Mann-Whitney U test.
Table 4.3.: Perceptions and/or beliefs of the study participants (N=31 HIV-positive MSM) about HIV-superinfection.

<table>
<thead>
<tr>
<th>Statements assessing perceptions/beliefs about HIV superinfection</th>
<th>Cases (%)</th>
<th>Controls (%)</th>
<th>Odds Ratio* (95% CI)</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Heard of HIV superinfection before taking part in the study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (67)</td>
<td>21 (84)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2 (33)</td>
<td>3 (12)</td>
<td>0.3 (0 - 35)</td>
<td>0.3</td>
</tr>
<tr>
<td>Did not answer</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Believed that reinfection with HIV-1 can occur if someone who is HIV-positive engages in unprotected sexual intercourse with a partner who is also HIV-positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly disagreed/Disagreed</td>
<td>1 (17)</td>
<td>1 (4)</td>
<td>4.8 (0 - 234.2)</td>
<td>0.4</td>
</tr>
<tr>
<td>Strongly agreed/Agreed</td>
<td>4 (66)</td>
<td>19 (76)</td>
<td>0.5 (0 - 1.0)</td>
<td></td>
</tr>
<tr>
<td>Didn’t know</td>
<td>1 (17)</td>
<td>4 (16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not answer</td>
<td>0</td>
<td>1 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Concerned with becoming reinfected with HIV-1 and thus always try to avoid engaging in unprotected sexual intercourse with partner(s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly disagreed/Disagreed</td>
<td>1 (17)</td>
<td>8 (32)</td>
<td>0.5 (0 - 4.5)</td>
<td></td>
</tr>
<tr>
<td>Strongly agreed/Agreed</td>
<td>4 (66)</td>
<td>16 (64)</td>
<td>1.0 (0 - 3.0)</td>
<td></td>
</tr>
<tr>
<td>Didn’t know</td>
<td>1 (17)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not answer</td>
<td>0</td>
<td>1 (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4.3. (continuation): Perceptions and/or beliefs of the study participants (N=31 HIV-positive MSM) about HIV-superinfection.

4. Concerned with becoming reinfected with HIV-1 if engaged in unprotected sexual intercourse, because of the believe that reinfection with HIV-1 can damage one’s health

<table>
<thead>
<tr>
<th>Response</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly disagreed/Disagreed</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>(17)</td>
<td>(20)</td>
<td></td>
</tr>
<tr>
<td>Strongly agreed/Agreed</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>(66)</td>
<td>(56)</td>
<td>0.7</td>
</tr>
<tr>
<td>Didn’t know</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>(17)</td>
<td>(20)</td>
<td>10.6</td>
</tr>
<tr>
<td>Did not answer</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

5. Concerned with becoming reinfected with HIV-1 and thus always use condom (i.e. safer sex practices) if engaged in any sexual intercourse with a sexual partner who is HIV-positive or whose HIV-status is unknown

<table>
<thead>
<tr>
<th>Response</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly disagreed/Disagreed</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>(33)</td>
<td>(36)</td>
<td></td>
</tr>
<tr>
<td>Strongly agreed/Agreed</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>(50)</td>
<td>(56)</td>
<td>1.0</td>
</tr>
<tr>
<td>Didn’t know</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>(17)</td>
<td>(4)</td>
<td>10.3</td>
</tr>
<tr>
<td>Did not answer</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(17)</td>
<td>(4)</td>
<td></td>
</tr>
</tbody>
</table>

Notes: * Odds Ratio calculated only by taking into account Yes/No, Strongly disagreed/Disagreed and Strongly agreed/Agreed; Missing data and “didn’t know” responses not included for OR calculations; ** P-value calculated by using Fisher exact test.
The Table 4.3. summarizes the perceptions/beliefs of our study participants about HIV superinfection. There were no statistically significant differences between cases and controls in regard to perceptions/beliefs of HIV superinfection (p-value ≥0.3). Only a minority of the study participants reported no previous knowledge of HIV superinfection (17%, 5/30).

4.5. Discussion

In this study it was found that only a small proportion (about 3% per year) of eligible HIV-infected MSM had a sudden, unexplained and sustained fall in CD4 T-cell counts and/or increase in plasma HIV RNA values that could be consistent with possible superinfection. This finding is similar to the reported rates of HIV superinfection in the literature that range from 0 to 6.5% per year (Chohan B et al., 2005; Fang G et al., 2004; Gonzales MJ et al., 2003; Grobler J et al., 2004; Koelsch KK et al., 2003; Manigart O et al., 2004; Smith DM et al., 2004; Smith DM et al., 2005b; Tsui R et al., 2004; Yerly S et al., 2004). Furthermore, these rates are comparable to the incidence rate of new HIV infection reported in recent studies among cohorts of HIV-negative MSM from Sydney (0.94 per 100 person-years) (Jin F et al., 2006) and elsewhere where it varied from about 1.55 per 100 person-years (95% CI 1.23 - 1.95; over 18 months of follow-up) (Buchbinder SP et al., 2005) to 3.33 per 100 person-years (95% CI 1.93 - 4.67; over 5 years of follow-up) (Sutmoller F et al., 2002). In USA, an overall incidence of HIV found from cohorts of young MSM followed in seven different cities was 4.4% (95% CI 2.9 - 6.7) (CDC, 2001). The findings from cohort studies of possible HIV-superinfection support the observation that HIV-superinfection may occur at a similar rate.
to HIV incidence among HIV-negative MSM although there may be differences in exposure risk in primary HIV infection (Buchbinder SP et al., 2005; CDC, 2001; Jin F et al., 2006; Sutmoller F et al., 2002).

No published cohort studies attempting to estimate the incidence of HIV-superinfection that also assessed the risk factors for it among exclusively HIV-infected MSM were found in the literature search I carried out. However, there are many reported cases of HIV superinfection among HIV-infected MSM. The risks reported among these cases were mainly: short period of susceptibility after primary HIV infection (Brenner B et al., 2004; Gross KL et al., 2004), not being on HAART (Altfeld M et al., 2002; Smith DM et al., 2004), superinfected with antiretroviral resistant strains (Koelsch KK et al., 2003; Smith DM et al., 2004), and engagement in high-risk sexual practices (Smith DM et al., 2004; Yang OO et al., 2005).

There are a number of reasons for the low but variable incidence rate of HIV-superinfection reported in the literature, including: a short period of susceptibility to HIV-superinfection after primary HIV infection (Brenner B et al., 2004; Gross KL et al., 2004), the difficulty in detecting HIV-superinfection when it occurs with antigenically closely-related HIV subtypes (Altfeld M et al., 2002; Steain MC et al., 2004), the use of HAART which may protect against HIV-superinfection as it does with antiretroviral drugs administered as post-exposure prophylaxis (Gonzales MJ et al., 2003), and the difficulty in locating the individual who was the source of HIV-superinfecting strain (Brenner B et al., 2004).
There were no significant differences between cases and control in regard to their perceptions/beliefs about HIV-superinfection. Furthermore, only a minority of the study sample had no prior knowledge of HIV-superinfection. This was similar to other studies where high proportions were aware of the risk of HIV-superinfection when engaging in UAI (Colfax GN et al., 2004; van Kesteren et al., 2005). In addition, a significant majority of the study participants believed that HIV-superinfection was possible and were concerned with becoming superinfected with HIV as well as with its damaging effects to one’s health (Table 4.3.). However, these beliefs and concerns were not reflected in adoption of safer sexual practices (Table 4.2.). Similar findings were reported in two qualitative studies assessing HIV-superinfection risk among MSM (Adam BD et al., 2005; van Kesteren et al., 2005). In contrast, one survey-type study that looked at believes/perceptions of HIV-superinfection and engagement in UAI showed that many MSM were choosing to reduce UAI with sexual partners who were HIV-infected and/or of unknown HIV-serostatus (Colfax GN et al., 2004)

4.6. Study limitations

There are a number of limitations associated with this study. Firstly, because of the small number of individuals with unexplained and sustained CD4 T-cell counts falls (cases), this study has limited statistical power to look for small or moderate differences in risks between these individuals and controls. Specifically, the study could not reliably detect an odds ratio of less than 23 if 15% of controls were exposed and an 80% power with only 6 cases. However, the study was able to estimate the incidence of unexplained and sustained CD4 T-cell
counts falls with tight confidence intervals. This provides an upper limit for possible HIV-superinfection given that there may be other reasons for the changes in CD4 T-cell declines. What is evident is that individuals in this study had frequent UAI with other MSM who were HIV-infected or were likely to have HIV infection.

Secondly the study did not perform phylogenetic laboratory analysis that is sometimes used to assess the occurrence of HIV superinfection (Blackard JT et al., 2002). Although, phylogenetic analysis of stored plasma samples collected from each study participant along the course of their care for HIV infection might have helped to establish probable HIV-superinfection, this would not allow to identify the HIV-superinfecting strain from source partners to definitely establish the occurrence of HIV-superinfection and simultaneously exclude HIV-coinfection among the study cases (Blackard JT and Mayer KH, 2004). However, not performing phylogenetic analysis from stored plasma samples for this study participants, both cases and controls, also means that it may have missed cases of possible HIV-superinfection that did not adversely affected the CD4 T-cell counts and/or plasma HIV RNA, such as with the occurrence of HIV-superinfection with antigenically closely-related HIV subtypes (Blackard JT et al., 2002; Steain MC et al., 2004). On the other hand, one could also argue that most cases of HIV-superinfection are associated with significant decline in CD4 T-cell counts and increase in plasma HIV RNA as shown by cohort studies and reported cases of HIV-superinfection (Allen TM and Altfeld M, 2003; Blackard JT and Mayer KH, 2004; Chan DJ, 2004; Gottlieb GS et al., 2004; Jost S et al., 2002; McCutchan FE et al., 2005; Smith DM et al., 2005a; Steain MC et al., 2004; Van der Kuyl et al., 2005).
and if they are not, they might be of limited clinical relevance.

Finally, other possible factors might have contributed for sustained declines in CD4 T-cell counts amongst cases selected in this study. Although the pathogenesis of CD4 T-cell declines is known to be complex and multifactorial (Deeks SG et al., 2004), the natural history of HIV-infection is indeed characterized by a progressive decline in CD4 T-cell counts (Lewin S et al., 2002). Some factors contributing for sudden CD4 T-cell declines, apart from HIV superinfection includes, for example: concurrent infections such as syphilis (Buchacz K et al., 2004), psychological distress (Vassend O and Eskild A, 1998) or depression (Burack JH et al., 1993), and certain immunizations (Stanley SK et al., 1996). Furthermore, declines in CD4 T-cell counts were also related to the so-called “phenotypic switch” which is manifested by change on HIV co-receptor usage from CCR5-using viruses (designated R5 viruses) to CXCR4-using viruses (named X4 viruses) (Connor RI et al., 1997; Keet IP et al., 1994; Moore JP et al., 2004; Schuitemaker H et al., 1992; Tersmette M et al., 1989). However, the aim of this study was to detect an upper limit for clinically relevant HIV-superinfection rather that an absolute estimate.

It may be that the actual rate of HIV-superinfection in this study is very substantially lower than the estimate of the upper limit. This might be because of the reasons listed above for it (Buchacz K et al., 2004; Burack JH et al., 1993; Connor RI et al., 1997; Deeks SG and Martin JN, 2007; Keet IP et al., 1994; Moore JP et al., 2004; Schuitemaker H et al., 1992; Stanley SK et al., 1996; Tersmette M et al., 1989; Vassend O
and Eskild A, 1998). Furthermore, the similarities in the numerical risk profiles in the Table 4.1. shows that a substantial proportion of cases had CD4 T-cell counts changes but few had significant changes in plasma HIV RNA levels (data not shown in Table 4.1., but discussed in results section) suggesting that few cases may have had actual HIV-superinfection. It nevertheless does provide clinicians with a guide to what might be the upper limit of clinically important superinfection when counselling HIV-infected MSM.

4.7. Conclusions

The strength of this study is that this is first study, to my knowledge, that has used a structured questionnaire to assess the association between sudden, unexplained and sustained declines in CD4 T-cell counts, increases in plasma HIV RNA and sexual practices among HIV-infected MSM. The study findings indicate that considerable unsafe sexual practices occur despite a growing number of HIV-superinfection cases reports in biomedical literature(Blackard and Mayer, 2004). Without a doubt there continues to be a need for more research aimed to enhance the current understanding on HIV-superinfection. It has been suggested that to elucidate better clinicians and public health professionals about HIV-superinfection there is a need of longitudinal long-term cohort studies involving HIV-infected individuals at-risk of HIV-superinfection (e.g. MSM) and the studies need to also assess risk factors (should include behavioural, clinical and biological) (Blackard and Mayer, 2004).
Chapter 5: “Adherence study: Part I”

Conference presentation:

Sidat M, Fairley CK, and Grierson J. *Experiences and perceptions of HIV-infected individuals with 100% adherence to HAART – A Phenomenological Study.* Oral poster (Poster 152) presented at the 18th Annual Conference of the Australasian Society for HIV Medicine, October 2006, Melbourne, Australia – awarded with “The 2nd prize for the Social Research” (see Appendix 1).

Study publication:

Sidat M, Fairley CK, and Grierson J. *Experiences and Perceptions of Patients With 100% Adherence to HAART – A Qualitative Study.* AIDS Patient Care and STDs 2007; 21(7): 509 – 520.
5.1. Study abstract

A decade has passed since the introduction of highly active antiretroviral therapy (HAART) as standard of care for HIV/AIDS patients. The success of HAART is largely dependant on almost 100% adherence to it. With this study the primary aim was to understand from patients’ own perspectives and experiences what resulted in them having 100% adherence to HAART. Thus, the study purposefully recruited for in-depth interviews 10 participants (7 men and 3 women) with 100% adherence to HAART (≥ 6 months previous to the interviews). All interviews were transcribed verbatim and analysed by employing Giorgi’s Phenomenological analysis approach. The following issues emerged from the analysis: readiness to go on HAART; HAART viewed as a life-line; maintenance of 100% adherence related with willingness to live longer and healthier; optimal ongoing patient-physician relationship, better coping and/or lack of perceived side-effects and improvements in clinical condition as well as in CD4 T-cell counts and HIV RNA plasma levels reinforced the motivation to keep 100% adherence. The study findings were considered to be helpful for health professionals caring for HIV-infected individuals on HAART.
5.2. Study background

The introduction of highly active antiretroviral therapy (HAART) as standard of care for people living with HIV/AIDS (PLWHA) contributed significantly in reducing HIV-related morbidity and mortality (Murphy et al., 2001; Palella et al., 1998; Paterson et al., 2000) and has transformed HIV/AIDS into a chronic, manageable disease for many people (Siegel and Lekas, 2002). However, to succeed HAART requires high levels of adherence to its regimens which requires an enormous long-term commitment from HIV-infected persons taking these medications (Siegel and Lekas, 2002). Many individuals receiving HAART fail to achieve required levels of adherence (Singh et al., 1996; Wright, 2000) which may result in the emergence of drug-resistant HIV strains and consequently treatment failure, progression to AIDS, and eventually death (Chesney, 2003; Paterson et al., 2000; Read et al., 2003). Moreover, the emergence of anti-HIV drug resistant strains also represents a threat to public health (Wainberg and Cameron, 1998) through transmission of drug-resistant HIV strains to other individuals.

Patient adherence is a complex phenomenon that can be affected by a number of variables (Vermeire et al., 2001) and many factors for poor-adherence to HAART were identified and reported in the literature (Chesney, 2003; Chesney, 2000; Ickovics and Meade, 2002; Singh et al., 1996; Wilson et al., 2004; Wright, 2000). However, the existing literature, primarily survey based, is mostly made up of studies taking a limited approach to the problem, where patients are often made solely responsible for poor-adherence (Wright, 2000). Therefore, it has been suggested that qualitative studies may assist in
improving the current understanding of HAART adherence, particularly by gaining insight on patients’ own experiences and perspectives (Laws et al., 2000). Different people have different experiences taking medications and lead different lives. Using phenomenological methodology, a qualitative research method that was first developed by Edmund Husserl (1859-1939) (Wertz, 2005), I conducted a two part study: the first part with patients categorized as having 100% adherence (presented in this chapter) and the second part with those having poor-adherence (presented in Chapter 6). I have chosen the phenomenological method because it permits insights and understandings of people’s experiences from which a broad overview of the phenomena under study can be structured (Giorgi, 2005; Moustakas, 1994; Sadala and Adorno, 2002; Wertz, 2005).

This study aimed to gain insight into the complexities of daily-life experiences and perceptions of patients on HAART with 100% adherence (at least for the past 6 months). The adoption of phenomenological method was congruent with ontological and epistemological essence of the phenomenon under-study. By the time this study was carried out, only two other published qualitative studies have looked at the experiences of patients with 100% adherence to HAART (Lewis et al., 2006; Malcolm et al., 2003), but no reference was made on their ontological and/or epistemological assumptions. I contend that therapeutic adherence is a complex phenomenon that can be affected by a number of variables, including the difficulty of the treatment regimen, physician-patient communication, and concerns about adverse effects and patient’s belief about the efficacy of the treatment (Vermeire et al., 2001).
The concept of “therapeutic adherence” has evolved over time (Lutfey and Wishner, 1999) and gained particular interest for health care providers in the context of HIV/AIDS, in particular due to the public health implications of poor/non-adherence to HAART (Wainberg and Cameron, 1998).

5.3. Study aim

The primary aim, for this part of the study, was to understand from patients’ own perspectives and experiences what results in 100% adherence to HAART.

5.4. Methodology

This study was conducted at the HIV Clinic in Melbourne Sexual Health Centre (MSHC). The study was approved by the Ethics Committee from The Alfred Hospital and The University of Melbourne (see Appendix 8). Participants for this part of the study were recruited between February 2005 and June 2005. Clinicians and Nurses working at this HIV Clinic were informed about the study and requested to invite clients to participate if they fulfilled the following criteria:

1. ≥ 18 years of age, HIV-infected and currently on HAART for at least past 6 months;
2. having 100% adherence to HAART in the past ≥ 6 months assessed by their self-reported adherence (regimen characteristics and missed doses for the past 7 days and the past 28 days) recorded on “Every visit adherence questionnaire” (completed by every patient on HAART at each clinical appointment they attend at the Clinic and stored electronically) congruent with their biological parameters (clear improvements in CD4 T cell counts and decline in viral
loads leading to undetectable levels during monitoring period of at least past 6 months while on HAART); (3) able to communicate in English; and (4) willing to take part in an interview.

Written informed consent was obtained from all clients who agreed to participate in this study (see Appendix 9).

A purposive sample of 7 men and 3 women were recruited for this study. Clients who met inclusion criteria were approached by their clinician on their routine clinical appointment and were invited to take part in this study. All interviews were carried out in one room at the study site by me. Participants were informed at the end of each interview about the nominal reimbursement for participation ($20), but only 4 participants accepted this offer. Apart from the questions from the interview guide, questions and comments by the interviewer were restricted to requests for clarification. All interviews were recorded and transcribed verbatim also by me. In order to capture the “life-world” of the study participants with an open mind, I have always attempted, during the interview process, to consciously suspend prior knowledge gained through literature review. This process is known as phenomenological stance of bracketing (Giorgi, 1985; Giorgi, 2005; Moustakas, 1994; Sadala and Adorno, 2002; Wertz, 2005), and it regarded essential for the study because allows the researcher(s) to set aside possible biases.

A phenomenological approach was utilized for this study because it calls for descriptions about the phenomenon from individuals who experience them in the manner in which they are experienced (Giorgi, 1985; Giorgi, 2005; Moustakas, 1994; Sadala
and Adorno, 2002; Wertz, 2005). Data were analyzed based on the method proposed by Giorgi (Giorgi, 1985). This method offers a clear structure to the process of analysis and is comprised of four steps: grasping the sense of the whole; discrimination of meaning units; transforming everyday expressions into phenomenological language; and synthesizing transformed meanings into a descriptive structure (Giorgi, 1985). Because Giorgi’s method only allows the description of the phenomenon under-study I attempted to move beyond this by searching for underlying meanings within the common lived experiences of the study participants who were 100% adherent to HAART.

In establishing inclusion criteria for this study I implicitly characterized the definition of 100% adherence. Because medication adherence may vary over time (Pound et al., 2005; Vermeire et al., 2001) I looked for patients with 100% adherence to HAART for at least 6 months as I considered this as sufficient period to allow patients on these complex medications to have considerable experiences with HAART and thus to narrate their experiences and perceptions within an interview context. To capture these experiences, I have developed a semi-structured interview schedule with open-ended questions, including questions about: decision to go on HAART; managing HAART in relation to their daily-lives; coping with side-effects and HIV/AIDS as a chronic illness; and strategies to sustain 100% adherence to HAART (see Appendix 10).

The analysis of this study was guided by Giorgi’s phenomenological method (Giorgi, 1985). I adopted this method due to its explicit step-by-step analytic process. It enables novice researchers in Phenomenology like me to rigorously and systematically analyse data by making explicit at each step
exactly what should be done. The analysis started with repeated listening to recorded interviews and readings of transcripts to gain a sense of the participants’ entire experiences, always within phenomenological stance of bracketing. Subsequently, units of meaning were identified by intuitively making sense of the data and then transformed by extracting the underlying psychological content. Subsequently, I moved beyond the descriptive paradigm by interpreting and searching for underlying meanings within the common lived experiences of being 100% adherent to HAART. This process was also recursive and aimed to capture the phenomenon under-study in its wholeness.

Analyses of data obtained in this study was shared, discussed, and compared for interpretive consistency by me and my both co-supervisors. Reliability was supported through strict adoption of Giorgi’s phenomenological analysis method. A data analysis trail was also produced and followed strictly. Furthermore, I present some of the quotes of the study participants after editing for readability purposes only. I strived to stay true to lived experiences of participants by focusing on participants’ views (emic) instead of imposing my own views (etic).

5.5. Findings

5.5.1. Generalities

In this study 10 participants were selected purposefully. PLWHA are a diverse population and have different experiences taking HAART and therefore I considered that 10 participants (7 men and 3 women) would be sufficient to provide the study with varied and detailed accounts of the experiences of having 100%
adherence to HAART. The demographic characteristics of our participants are summarized in Table 5.1.

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
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<tbody>
<tr>
<td><strong>Age</strong></td>
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<tr>
<td>Range</td>
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<tr>
<td>Average participants age</td>
<td>45.6 years</td>
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<tr>
<td>Male average age</td>
<td>47.2 years (P1, P2, P3, P4, P5, P7, P8)</td>
</tr>
<tr>
<td>Female average age</td>
<td>41.6 years (P6, P9, P10)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
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<tr>
<td>Married</td>
<td>3 participants (P1, P5, P6)</td>
</tr>
<tr>
<td>Single</td>
<td>6 participants (P2, P3, P4, P7, P8, P10)</td>
</tr>
<tr>
<td>Divorced</td>
<td>1 participant (P9)</td>
</tr>
<tr>
<td><strong>Sexual orientation</strong></td>
<td></td>
</tr>
<tr>
<td>MSM</td>
<td>5 participants (P2, P3, P4, P7, P8)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>5 participants (P1, P5, P6, P9, P10)</td>
</tr>
<tr>
<td><strong>Country of Birth</strong></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>6 participants (P2, P3, P4, P7, P8, P9)</td>
</tr>
<tr>
<td>Other</td>
<td>4 participants (P1, P5, P6, P10)</td>
</tr>
<tr>
<td><strong>Ethnic Background</strong></td>
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</tr>
<tr>
<td>Anglo- Australian</td>
<td>6 participants (P2, P3, P4, P7, P8, P9)</td>
</tr>
<tr>
<td>Other</td>
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</tr>
<tr>
<td><strong>Highest Educational level achieved</strong></td>
<td></td>
</tr>
<tr>
<td>Year 10</td>
<td>1 participant (P6)</td>
</tr>
<tr>
<td>Year 12</td>
<td>3 participants (P2, P4, P8)</td>
</tr>
<tr>
<td>TAFE</td>
<td>2 participants (P1, P7)</td>
</tr>
<tr>
<td>UNI/CAE</td>
<td>4 participants (P3, P5, P9, P10)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
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<td>Full-time</td>
<td>3 participants (P1, P2, P8)</td>
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<td>Part-time</td>
<td>3 participants (P4, P7, P9)</td>
</tr>
<tr>
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<tr>
<td>Student</td>
<td>1 participant (P10)</td>
</tr>
<tr>
<td>Pensioner</td>
<td>1 participant (P3)</td>
</tr>
</tbody>
</table>

P = represents the participant in the study.
The study participants can be regarded as well experienced with antiretroviral therapy, with some participants starting AZT monotherapy in early 1990’s (P1 and P3). The majority of the study participants have been on different HAART regimens over time, except three participants who were only exposed to the regimens they were at the time of the interviews (P2, P9, and P10). The average HAART regimen time was 26 months, with a minimum of 8 months (P6) and a maximum of 74 months (P3). The average CD4 T-cell counts at the time of the interviews was 504/µl (range: 294 to 687/µl). At the time of the interviews all participants had undetectable levels of plasma HIV RNA for ≥ 6 months, except participant P8 who experienced a single “viral load blip” of 5,660 copies/ml which returned to undetectable 7 weeks later (apparently associated with an episode of syphilis). The interviews lasted between 12 and 37 minutes (average of 22 minutes).

5.5.2. Decision to go on HAART

Understanding how the study participants made the decision to go on HAART was relevant for the analysis of the study findings, in particular with respect to their knowledge of HAART and readiness to take them. In this study only two participants had to start antiretroviral therapy immediately after being diagnosed with HIV/AIDS (P1 and P8) and they agreed to do so because they saw no other life-saving options. For these participants the immediate impact of being on antiretroviral therapy resulted in rapid improvements in their clinical conditions and consequently motivated them to adhere to HAART. Furthermore, they feared that failing to take their medications may result in deterioration of their health and finally leading to death.
“Because basically I didn’t have any other choice. I didn’t know that I was HIV-positive and when we did the test for the first time it came positive, the CD4 cells count was like 10. It was very low and the doctor told me to start some treatment immediately and back in 1996 I would have been dead already…” (P1)

The majority of the study participants started HAART after having their CD4 T-cell counts and plasma HIV RNA levels monitored for some time before starting HAART. These participants were provided with the information about HAART and eventual prospects of starting them sometime along the course of their illness by their health care providers. Interestingly, these participants refer the decision to start HAART as shared between them and their clinicians which undoubtedly affected their choice of taking their medication as “agreed”.

“Well, I had a high viral load. I reckon was ok and what it was. May be 500 thousand or something and then I think it stabilized at about 100 thousand and then when my CD4 count… We’ve had agreed that when they got down, you know, to the three hundred and something that I should start and that’s when I had holidays at the time for two weeks so that’s when I started.” (P9)

Nevertheless, even after a period of monitoring some participants felt reluctant to go on HAART as it reminded them of being HIV-infected. They had difficulties coping with being “HIV-infected” and with the possibility that taking HAART would confront them with this difficult and unresolved issue on daily basis. This included the psychological and emotional
implications of treatment as well as the impact on adherence to their medication.

“They did mention it (about HAART) all through that time like that five years (since tested HIV-positive). They sort of started to mention to me about medication but I was not prepared to even think about it. I didn’t want to start the treatment actually. It was my doctor that basically talked me into it. I mean I was very scared. There’s a trend... and I think that acknowledging that I was HIV-positive, I mean... and that would take my attention... took probably about four months to think about it...” (P7)

One of the study participant (P4) had trouble taking HAART in the past and decided to stop taking them and also to change his health care provider at that time. This highlights the importance of the clinician-patient relationship issue and its relevance to adherence to any therapeutic recommendations.

“They asked me to go on medication. They took one reading from me and... they didn’t check my viral load or anything. Everything that was going up or down or whatever so they just took one reading... I thought they knew what they are talking about so I went along with it and I found since then that it wasn’t up for negotiation. I didn’t felt very supported there so I took it on myself to change who was looking after me by coming to here... and also to take out myself from medication that was just making myself ill” (P4)

However, this same participant (P4) restarted HAART about 3 years after his first unpleasant experience with HAART. During this 3 years period his laboratory markers were monitored and
he felt better supported and prepared to go on HAART again with 100% adherence since on medication.

“...she (HIV Clinician) started to track my viral load and my T cells counts and see how it was going and she said alright I didn’t have to be on medication straightaway (in 2001) because my T cells were ok and so we have been negotiating ever since” (P4).

Although, readiness to go on HAART was expressed by the majority of the study participants, only one participant was put on “jelly-bean” trial to assess readiness. However, this trial was not taken seriously and was considered simply as a “waste of time” (P9).

5.5.3. Managing HAART on daily basis

Five of the study participants were, at the time of the interview, on once a day regimens (P4, P5, P6, P7, P8) and other four on twice a day regimens (P1, P2, P9, P10). Only one participant was on thrice a day regimen (P3). However, there were no fundamental differences in the ways participants were managing their medications on daily basis. All participants reported that their current HAART regimens were well suited to their life-styles and this was a mutual decision they made with their health care providers. The most common strategy used by the participants to remember of taking their HAART pills was to link it with their daily routines. They felt that by linking with their daily routines it was much easier for them to remember to take their medications.
“Basically I found that you really have to set yourself a certain time of the day that you want to do it. Same time everyday and I made it breakfast time because I always have breakfast. So it’s a routine to get up, have a meal with cup of tea and piece of toast and take my medication. It was just too hard to try to remember that… So it’s always after my breakfast. I make sure I can get up and have my breakfast and have my medication”. (P7)

Interestingly, each participant seems to have sought a different but individually suitable strategy for their particular regimen and lifestyle.

“I just like to have Metamucil… I was just going to say that that’s what helped me to remember, because the Metamucil sits on the bench and I remind that being there and just have all the morning tablets with Metamucil so, that actually helps me. I just think it becomes a habit. But, I mean to start with I think may be the habit was formed by sms’s (reminders send at the beginning of her therapy) and by having Metamucil in the morning. Definitely you need a routine”. (P9)

The participants were similar when referring to ending up “in a routine” in taking their HAART pills after being on medication for some time. After getting into a routine, any change in HAART regimen was perceived for some participants (e.g. P3) negatively. However, it seems that the twice and/or thrice a day regimens were harder to fit appropriately into daily routines, in particular for those who had to take one of the doses at a workplace. The main reasons I found for these were working commitments (e.g. heavy workload leading to forgetfulness) and/or inability to simply take pills because of
fear of being identified as “HIV-infected” and thus being discriminated against or stigmatized within their work environment (P2, P4, P7). In fact, the fear of being identified as “HIV-infected” also made the study participants to keep their pills concealed when going out for leisure time (P5, P6) and/or even in their own homes (P6, P8, P9). However, most of the study participants carry their pills (at least a few doses) hidden with their belongings whenever they go out for work and/or leisure time, in case they need to take them. Nevertheless, they usually prefer to take their pills at home privately. Actually, some delay their medication taking for few hours until they are back home or even miss an occasional dose when unable to return home because of this same fear. But no missed doses were reported for the period assessed for this study by any participant and therefore I assumed that an occasional missed dose might have happen in the past when many of them were taking complex HAART regimens. The situation exemplified above highlights the importance of well-established routines and the negative consequences of its disruption on medication adherence.

Most commonly used reminders by the study participants were: receiving sms’s (messages in their mobile phones organized by the Clinic and provided free of charge by one pharmaceutical company for P7, P9), setting up mobile phone alarm (P2, P6, P7 and P9) or table clock alarm (P10) and using pill-boxes (P1, P3, P4, P5, and P9). These different reminding strategies were used sometimes in combination and were regarded important for initial stages of HAART until getting into a daily routine. Having daily routine facilitates habit building and thus adherence to medication.
"Usually I find I have taken the medication before I receive the sms so I feel that I could do it without it, yeh...But I guess I still do it for those days yeh...Occasionally you still have the days where something’s sort of are taking you out of your routine and you find that you have forgotten and the sms’s are reminder of you haven’t done that, yeh...". (P7)

"Well, somehow presumably you know... something could happen that you don’t plan for and you can forget you know but it can be adjusted. That’s what I do by just getting up at night or whatever... but I make sure that I have a least a days worth on me if not two days. So, you just think ahead a bit, but just like brushing your teeth or you know, you have a shower every morning or hum..." (P3)

In general, there were no major changes or efforts to change the usual life-styles of our study participants after starting HAART, except reduction of alcohol consumption (P1, P5, P7 and P8), improvements in diet (P5) and increase in physical activity (P5, P6). However, all participants somehow referred to taking more care of their health and well-being after becoming HIV-infected and in particular after starting HAART.

5.5.4. Managing Side-effects
HIV-infected individuals experience diverse side-effects related to HAART. Some side-effects appear soon after starting HAART and last a few weeks (i.e. nausea, diarrhoea, vomiting, etc), but others only emerge after some time on HAART (i.e. lipodystrophy and other HAART-related metabolic disorders). Most participants who experienced side-effects after starting HAART reported that they were tolerable and lasted for short
time. For one participant (P5), however, the persistent diarrhoea secondary to his antiretroviral drugs considerably affected his social life. However, with time, this same participant apparently succeeded in bringing his diarrhoea under control by simply adjusting his diet.

Individuals on HAART experiencing intense and/or persistent side-effects related to their medication which affects their quality of life may feel discouraged to continue adhering to their medication. However, patients on HAART make assessments of the importance of side-effects in different ways and use different strategies to cope with them. A good knowledge of the type, duration and severity of the expected side-effects with different antiretroviral drugs seems important for some participants and this knowledge was regarded as an important tool in gaining a sense of control over their health.

“So there’s lots of things that you can do to lessen side-effects while taking the same drugs and what to look out for in side-effects. There’re lots of people that don’t know that Zerit or d4T causes really bad lipodystrophy and that if you watch your legs and see veins in your legs you are getting lipodystrophy, pretty simple stuff. But you know of course if the doctor don’t take my pants off so how they’ll know. I see myself naked everyday and I looked and I said ohh!!... I know that I am having a situation going on. To know that is important and you know what to look for but you also have to watch that you don’t start looking for things that aren’t there” (P5)
5.5.5. Relationship with health care providers

All participants in this study reported having optimal relationship and felt very well supported by all the staff at the Clinic. Actually, doctors were regarded as their main source of support and information regarding their health and/or medication issues and they fully trusted their recommendations. As discussed earlier, only one participant reported having changed his health care provider and having stopped treatment in the past because he did not feel appropriately supported by his previous doctor.

Managing HAART over time is not only an issue for the patients on these complex therapies, but also for their clinicians. The availability of new anti-HIV drugs and the emerging evidence of the effectiveness of new regimens sometimes appeals to the clinicians to suggest new regimens to their patients’. However, any change of regimen might affect patients’ already established routines and clinicians should always try to understand the reasons behind eventual resistance for regimen changes. Any forced regimen change may result the patient falling into a poor medication adherence, even if the new regimen is more simplified and beneficial for the patient.

"Last year some time (in 2004) the Doctor here was trying to convince me to take I think one pill twice a day at the time I think I was taking three (pills) three times a day. I said ohh, I have got years to swallow painful of pills and what’s the advantage and he was pressing it on me and I said ohh back-off... but I didn’t like his approach. It was like he was trying assuming his roles voiceless. Is there any real advantages, because I have got use to it, I have got a routine... taking two..."
doesn’t make any difference to me and why don’t just I stick with it”. (P3)

5.5.6. Future outlook and motivation to maintain adherence to HAART

Overall, the study participants felt very optimistic in regard to their future outlook with HAART. They repeatedly referred to HAART as responsible for improvements they observed in their health and well-being as well as in their biological parameters (CD4 T-cell counts and plasma HIV RNA levels). Apparently, these improvements have contributed to encouraging and reinforcing their commitment to remain 100% adherence to HAART. It also contributed to optimism in regard to the availability of additional HAART regimen options, improved quality of life and longevity.

“Definitely lot brighter simply because there are so many combinations of drugs that you can take and I am only on to my second combination with minimal side-effects, no side-effects basically. I look to it as being almost manageable as is at this stage and that I know that there’s no cure and the management is coming along very well. Taking medication showed me that its manageable and they have controlled it and that is where I get more confidence and start to realize that the dreadful part is the back thing, they are actually helping me and probably giving you more longevity in life...less opportunistic infections” (P7)

Finally, most of the study participants consider HAART an integral part of their life. They have incorporated HAART into their life-styles easily without apprehension. Nevertheless,
being on HAART has made them somehow more aware of healthy life-styles and more self-conscious about the prospects of living longer and healthier. They also consider HAART as a kind of life-line that if interrupted may contribute to shortening their lives. Successful experience with HAART (both in clinical and biological terms) and with minimal or no perceived HAART related side-effects reinforces their commitment in keeping 100% adherence.

“You know, I have been on medication now for 8 years and its such a part of my life and the knowledge, the simple knowledge that if I had not taken my pills I would’ve been dead by now its enough to keep me taking my pills. I am healthy as anything. I’d probably never been as healthier as I am right now but live and I assume I’d be dead so... you know....” (P5)

5.6. Discussion

This qualitative study was designed to explore experiences and perceptions of HIV-infected individuals with 100% adherence to HAART. From the accounts of the study participants I found that having 100% adherence to HAART resulted from the combination of the following issues: trust in the effectiveness of HAART; readiness to go on HAART; optimal integration of HAART regimens into individual life-styles; daily routinization of HAART pills taking behaviour; planning ahead for events disrupting daily routines to avoid missing or forgetting to take HAART pills; adequate knowledge of side-effects and working out of best possible coping strategies; use of personalized tools and reminders for HAART pills taking times; development of trust and best possible relationship with personal clinicians and other healthcare workers; as a consequence of being on HAART,
attitudes of healthiness and improved wellbeing was developed which was reinforced by improvements in biological parameters that are routinely used to assess HIV-infection progression; HAART viewed as a life-line and thus as an integral part of their lives; with continuous development and availability of new/alternative HAART regimens optimism and positive future outlook was reinforced. This study findings are consistent with the findings of other studies on HAART adherence, but particularly with similar qualitative studies (Lewis et al., 2006; Malcolm et al., 2003). In fact, this study findings reemphasizes the notion that medication adherence is a complex phenomenon affected by multiple issues (Alfonso V et al., 2006b; Vermeire et al., 2001).

The decision to go on HAART is a complex process (Johnson M O et al., 2006) and are not only dependent on patient’s medical characteristics (CD4 T-cell counts and plasma HIV RNA levels), but also among other things on patients’ beliefs about HAART (Johnson M O et al., 2006; Kremer H et al., 2006; Remien et al., 2003) and the relationship with their caregivers (Erlen J A and Mellors M P, 1999; Remien et al., 2003). It has been shown that HIV-infected individuals differ widely in their HAART information needs when faced with the decision to go on HAART and those who started HAART were more satisfied with the information they had received about HAART than those who refused to go on it (Gellaitry G et al., 2005). Clinicians were the main source of information in our study and this was congruent with other study findings (Meredith K L et al., 2001). Although it’s not known if the perceptions held before starting HAART are maintained or changed after being on HAART (Johnson M O et al., 2006) the study findings suggests that reinforcement may be related to perceived positive outcomes of being on
HAART. However, as the findings of other studies illustrates (Cooper V et al., 2002; Horne R et al., 2004) individuals with doubts about their needs for HAART and with concerns about HAART-related side-effects were more likely to decline to go on HAART and/or have poor-adherence to HAART when pushed into it. In addition, when patients decide to go on HAART, after considering their beliefs/perceptions, it is more likely to result in positive outcomes than when a prescriptive approach is implemented (Gold R S and Ridge D T, 2001). Therefore, it seems important that the decision to start HAART is a collaborative decision between doctor and patient(Gold R S and Ridge D T, 2001) and that HAART is started only when patients are ready for it(Cooper V et al., 2002; Enriquez M et al., 2004a; Gellaitry G et al., 2005; Gold R S and Ridge D T, 2001; Horne R et al., 2004; Meredith K L et al., 2001). In fact, optimal adherence to HAART has been observed as a consequence of becoming “ready” among patients who previously failed multiple times to adhere to HAART(Enriquez M et al., 2004a; Enriquez et al., 2004).

On the other hand, lack of readiness to go on HAART was also responsible for refusal to go on HAART when clinically indicated(Maisels L et al., 2001). Usually “placebo practice trials” are employed to assess readiness to adhere to HAART(Wagner G et al., 2002). In this study there was only one participant who went through the placebo trial experience with jelly-beans and this was regarded as “a waste of time” by the participant. However, it has been suggested that readiness to start treatment as well as to maintain optimal lifelong adherence to HAART are both important(Gebrekristos H T et al., 2005). Although we did not assess readiness per se(Highstein G R et al., 2006; Morgenstern T T et al., 2002), some of the
study data, particularly those related to how HAART was managed on daily basis, could be useful in understanding readiness to remain 100% adherent for longer periods (in our case ≥ 6 months). Accordingly, it was found that the belief in HAART efficacy, the desire for a longer and healthier life and viewing HAART as a life-line, motivated this study participants to maintain 100% adherence. These motivating factors were also shown in other similar studies (Gao X et al., 2000; Lewis et al., 2006; Malcolm et al., 2003).

It has been shown that individuals who maintain 100% adherence to HAART achieved higher quality of life scores at 12 months compared to those with poorer adherence (Mannheimer S B et al., 2005). It was also demonstrated that emotional distress and perceptions about HAART were associated with changes in biological markers of HIV-infection (Kalichman S C et al., 2002). The participants of this study did not refer, during the interviews, to issues related to depression, stigma, physical/sexual abuse or other psychologically traumatic events. However, a recent study showed that psychological traumatic events had a significant effect on adherence to HAART (Mugavero M et al., 2006).

The study participants used different tools as reminders and established a daily pill-taking routine to facilitate 100% adherence to HAART. The importance of a regimen tailored to each participant’s life-style was another significant finding in this study. Use of reminders and routinization both seemed to facilitate and maintain optimal adherence to HAART, as observed in other studies (Golin et al., 2002; Lewis et al., 2006; Malcolm et al., 2003; Ostrop N J and Gill M J, 2000;
Finally, an optimal patient-clinician relationship was also regarded as an important issue by the study participants not only when starting HAART but also to maintain 100% adherence for long-lasting periods, corroborating other previous studies (Dibben M R and Lean M E J, 2003; Ingersoll K S and Heackman C J, 2005; Marelich W D et al., 2002; Roberts K J, 2002; Russell J et al., 2004; Schneider J et al., 2004).

5.7. Study limitations
Limitations inherent in this study are related to those of qualitative methods, including purposefully selected small sample size, mostly made up of well-learned Anglo-Australians with an average age of 45.6 years. However, as with all qualitative studies, findings are not intended to be generalized. Furthermore, all the study participants had free access to HIV Care and HAART and thus our findings might not be realistic for circumstances where access to HIV Care and/or HAART is/are financially determined (Kumarasamy N et al., 2005). Nevertheless, some of our study findings confirm previous research in this area and may be more generalizable.

5.8. Conclusions
Based on findings from the present study as well as with the available knowledge on HAART adherence it is suggested that healthcare professionals should devise suitable strategies to facilitate optimal adherence for all those on HAART, but particularly for those individuals having trouble adhering to these medications.
Thus, I would like to emphasize the following issues that might be relevant in clinical practice in maintaining 100% adherence to HAART: the importance of a patients’ readiness to go on and maintain optimal adherence to HAART; the physicians encouragement and active involvement in the patients decisions about HAART that take into account the patients life-styles or preferences; encouragement to make most use of available reminder tools (e.g., pill-box, setting alarm, etc) and routinization.

Nonetheless, it should always be remembered that HAART adherence is “a dynamic process that requires ongoing attention from both the patient and care provider” (Alfonso V et al., 2006b), because adherence might significantly change over time for each patient (Godin G et al., 2005b; Martini M et al., 2002; Tesoriero J et al., 2003) and consequently continuous assessment and support based on best available evidence are of vital importance to keep patients having 100% adherence to HAART (Harman J J et al., 2005).
Chapter 6: “Adherence study: Part II”

Study publication:

Sidat M, Fairley CK, and Grierson J. Experiences and Perceptions of Patients With Poor-Adherence to HAART – A Qualitative Study. (paper in preparation to be submitted for publication).
6.1. Study abstract

The purpose of this qualitative study was to describe the lived experiences of HIV-infected patients who self-reported having poor-adherence (<95%) to HAART in the past 28 days at least once in the past 6 months. Descriptions were obtained from interviews of 8 purposefully selected male participants and were analyzed using Giorgi’s Phenomenological method. The analysis showed that poor-adherence to HAART is a sporadic experience which happens mainly because of the following issues separately and/or in combination: forgetfulness as a consequence of disruption of daily-routines or drug and/or alcohol binges; intolerable short-term side-effects (mainly nausea and vomiting); sleeping through HAART dose taking times; being away from home; fear of being identified as HIV-infected and other psychosocial issues related to living with HIV/AIDS (depression, socialization, etc). However, the study also found a number of similarities in experiences and perceptions with those who were 100% adherent to HAART, such as: readiness to go on HAART, viewing HAART as a life-line, good patient-doctor relationship, using reminders and adopting different strategies to overcome HAART related side-effects. The study findings reemphasize the need for ongoing support for HIV-infected individuals on HAART.
6.2. Study background

Highly active antiretroviral therapy (HAART) has transformed the clinical course of HIV/AIDS into a chronic and manageable disease (Gifford AL and Groessl EJ, 2002; Siegel K and Lekas H-M, 2002). However, unlike other chronic diseases, to succeed with HAART people living with HIV/AIDS (PLWHA) need life-long, enduring and near-perfect (≥95%) adherence to these therapies (Chesney M, 2003; Gifford AL and Groessl EJ, 2002). Moreover, failure to maintain lifetime high levels of adherence may result in the emergence of drug-resistant HIV strains (Bangsberg DR, 2006; Sethi AK, 2004) and consequently treatment failure (Bangsberg DR, 2006; Sethi AK, 2004), deterioration of quality of life (Mannheimer SB et al., 2005), progression to AIDS (Bangsberg DR, 2006; Bangsberg DR et al., 2001), and eventually death (Bangsberg DR, 2006). In addition, anti-HIV drug resistant strains also represent a threat to public health (Wainberg MA and Cameron DW, 1998).

However, a significant proportion of PLWHA on HAART fail to achieve desired levels of adherence to HAART (Chesney M, 2003; Wright MT, 2000). Several variables affecting adherence to HAART have been identified, including: patient variables, treatment regimen, disease characteristics, patient-provider relationship, and clinical setting (Chesney M, 2003; Friedland GH and Williams A, 1999; Ickovics JR and Meade CS, 2002).

Patients are less likely to adhere to HAART if they have doubts about necessity of being on HAART and are concerned with its side-effects (Horne R et al., 2004). Furthermore, from the large body of literature exploring adherence to HAART it is clear that adherence to these therapies is a complex and
dynamic issue (Godin G et al., 2005a; Levine AJ et al., 2005; Remien RH et al., 2003), which goes beyond exclusive patient-related problems (Broyles LM et al., 2005a). In addition, adherence to HAART might also fluctuate over time (Godin G et al., 2005a; Tesoriero J et al., 2003). Little attention has been paid to the perceptions, beliefs, experiences and motivations to adhere to HAART from the perspective of PLWHA on these complex and life-long therapies (Pound P et al., 2005). It has been suggested that qualitative studies may assist in improving our current understanding of adherence to HAART by taking into account the perspective of those who have experiences with HAART (Laws MB et al., 2000; Remien RH et al., 2003).

To date, few qualitative studies were carried out on adherence to HAART as shown by a recently published synthesis of qualitative studies of medicine taking (Pound P et al., 2005). It was shown that the perceptions and experiences of individuals affects enormously in their decision-making process to adhere or not to any prescribed treatment (Donovan JL and Blake DR, 1992). It is becoming increasingly important within health care setting to take into account patient’s point of view (Sullivan M, 2003).

Thus, using phenomenological methodology, a qualitative research method I have conducted a two part study: first with patients categorized as having 100% adherence (presented in Chapter 5) and second with those having <95% adherence to HAART (presented in this chapter). The choice to use <95% adherence to HAART as cut-off point for poor-adherence was based on the widely held notion within clinical practice that to achieve virological control, PLWHA on HAART need ≥95% adherence to
their treatment regimens (Read T et al., 2003). Different studies have shown that at least 95% adherence is required for optimal viral suppression (Gross R et al., 2006; Maniar JK, 2006; Paterson DL et al., 2000) and patients with <95% adherence are 1.66 (95% confidence interval: 1.38-2.01) more likely to experience virological failure than those with ≥95% adherence to HAART (Gross R et al., 2006).

As referred in the previous chapter, I have chosen a phenomenological approach because it allows the description of the phenomenon under-study (e.g. poor-adherence) from individuals who experience them and thus permits to stay true to participants’ experiences and perceptions (Giorgi A, 2005; Moustakas CE, 1994).

6.3. Study aim

The primary aim, for this part of the study, was to understand from patients’ own perspectives and experiences what results in <95% adherence to HAART.

6.4. Methodology

The study was carried out at the HIV Clinic in Melbourne Sexual Health Centre (MSHC). The study was approved by the Ethics Committee from The Alfred Hospital and The University of Melbourne (see Appendix 8). Participants were recruited between May 2006 and August 2006. Clinicians and Nurses working at this HIV Clinic were informed about the study and requested to invite clients to participate if they fulfilled the following criteria:

(1) ≥18 years of age, HIV-infected and currently on HAART for at least past 6 months;
(2) having at least one self-reported adherence to HAART of <95% in the past 6 months assessed by "every visit adherence questionnaire" which is completed by every patient on HAART at each clinical appointment (this information is entered in each patient’s electronic file which then stores automatically the % of adherence for the past 4, 7, and 28 days);

(3) able to communicate in English; and

(4) willing to take part in an interview.

Written informed consent was obtained from all clients who agreed to participate in this study (see Appendix 9). Participants were given a nominal reimbursement for participation ($20) at the end of each interview.

A purposive sample of 8 men was recruited for this study. No female clients were included in this arm of the study as there were no female clients that met the study selection criteria at the study site. In general, the majority of the clients on HAART at the HIV clinic at MSHC had levels of self-reported adherence above 95%. Those who had adherence levels <95% who had ongoing mental health difficulties were not approached for this study. Thus, only clients without mental health difficulties and who met above mentioned inclusion criteria were approached by their clinician on their routine clinical appointment and were invited to take part in this study.

All interviews were carried out in one room at the study site by me. An interview guide was used (see Appendix 10) and all interviews were recorded and transcribed verbatim also by me. I attempted also to keep at all stages of the interview process a phenomenological stance of bracketing (Giorgi A, 1985; Moustakas CE, 1994).
By establishing inclusion criteria for this part of the study I implicitly characterized the definition of poor-adherence as having self-reported <95% adherence to HAART in the past 28 days and at least once in the past 6 months. As adherence may vary over time I sought the experiences and perceptions of our study participants for every episodes of <95% adherence to HAART during the 6 months prior to interview. It has been shown that self-reported missed doses of HAART are very reliable when it comes to assess poor-adherence (Kimmerling M et al., 2003) although even missed doses tend to be biased towards greater adherence (Miller LG and Hays RD, 2000). During the interview I explored the following issues: decision to go on HAART; managing HAART in relation to daily-life; coping with side-effects and HIV/AIDS as a chronic illness; and strategies to overcome HAART adherence problems.

6.5. Findings
6.5.1. Generalities
For this study only 8 participants were consecutively recruited. I considered that 8 participants were enough for this study to provide with varied and detailed accounts of the experiences of having <95% adherence to HAART. The demographic characteristics of our participants are summarized in Table 6.1.

Two participants (P3 and P8) justified their returning to work on part-time basis because of the costs related to several optional therapies they required (e.g. treatment of lipodystrophy or other alternative therapies) as these therapies were costly and not covered by public health services.
Table 6.1. Demographic characteristics of the study participants with self-reported poor-adherence to HAART.

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
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</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>32 to 51 years</td>
</tr>
<tr>
<td>Average participants age</td>
<td>40 years</td>
</tr>
<tr>
<td><strong>Sexual orientation</strong></td>
<td></td>
</tr>
<tr>
<td>MSM</td>
<td>6 participants (P1, P2, P3, P4, P6, P8)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>2 participants (P5, P7)</td>
</tr>
<tr>
<td><strong>Country of Birth</strong></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>6 participants (P1, P2, P3, P4, P5, and P6)</td>
</tr>
<tr>
<td>Other</td>
<td>2 participants (P7, P8)</td>
</tr>
<tr>
<td><strong>Ethnic Background</strong></td>
<td></td>
</tr>
<tr>
<td>Anglo- Australian</td>
<td>7 participants (P1, P2, P3, P4, P5, P6, P8)</td>
</tr>
<tr>
<td>Other</td>
<td>1 participant (P7)</td>
</tr>
<tr>
<td><strong>Highest Educational level achieved</strong></td>
<td></td>
</tr>
<tr>
<td>Year 10</td>
<td>3 participants (P3, P5, P6)</td>
</tr>
<tr>
<td>Year 12</td>
<td>1 participant (P2)</td>
</tr>
<tr>
<td>University level</td>
<td>4 participants (P1, P4, P7, P8)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Part-time</td>
<td>4 participants (P2, P3, P5, P8)</td>
</tr>
<tr>
<td>Student</td>
<td>2 participants (P1, P4)</td>
</tr>
<tr>
<td>Pensioner</td>
<td>1 participant (P6)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>1 participant (P7)</td>
</tr>
</tbody>
</table>

P = represents the participant in the study.

The study participants can be regarded as highly experienced with antiretroviral therapy, with some participants starting on AZT monotherapy in early 1990’s (P3, P8). However, both participants (P3 and P8) went on AZT monotherapy while having doubts about its effectiveness. Both had friends (including partner for participant P8) who died despite being on AZT therapy for sometime.
One participant (P5) started HAART after being diagnosed with severe opportunistic infection (CMV-related infection). All other participants (P1, P2, P4, P6, and P7) started HAART after experiencing low CD4 T-cell counts and/or high of plasma HIV RNA levels. Some participants were doubtful about their necessity on starting HAART (P1, P2, and P4). Only two participants saw the need to have some time (two to three weeks) before deciding to go on HAART (P2, P4, P7). Only one participant had a treatment interruption for 3 to 4 years after discussing this with his doctor and went back to the same HAART regimen (P1). The majority of the study participants were exposed to different HAART regimens over time, except one participant who was only exposed to the regimen he was at the time of interview (P4). The average time on current HAART regimen was 11 months, with a minimum of 7 months (P4) and a maximum of 14 months (P2, P8).

The average CD4 T-cell counts at the time of the interviews was 422 cells/µl (range: 154 cells/µl (P6) to 790 cells/µl (P8)). At the time of the interviews only 3 participants (P4, P5, and P8) had undetectable levels of plasma HIV RNA. The highest level of plasma HIV RNA was observed in P6 (705,000 copies/l). The average levels of plasma HIV RNA for other participants varied between 883 copies/l (P7) and 11,200 copies/l (P2), with an average of 4,343 copies/l (average calculated only for P1, P2, P3, and P7). The average level of self-reported poor-adherence (average was calculated by taking into account only incidents of self-reported adherence below 95% in the past 6 months) for the study participants was 82% (range: 70% (P1, P6) to 92% (P4)). The average number of self-reported poor-adherence incidents within 6 months period was 2 (range: 1 (P4).
to 3 (P1, P6, and P7) incidents). The interviews lasted between 13 and 29 minutes (average of 21 minutes).

6.5.2. Decision to go on HAART

Once the decision to go on HAART is made, it is essential to maintain near perfect adherence for lifetime. Thus, understanding how participants made the decision to start HAART was critical in this study, in particular their perceptions and beliefs about HAART and their motivations for commencing treatment. None of the study participants needed to commence antiretroviral therapy (whether AZT monotherapy or HAART) immediately after testing positive. Although, some participants had doubts about starting antiretroviral therapy (P1, P2, and P4), the majority of them (except P5 who had severe CMV-related infection) started HAART at their doctors' suggestion, based on their declining CD4 T-cell counts and/or rising plasma HIV RNA levels.

"I have been trying to delay it (starting HAART) for a long time, but when my T-cells went below 200... I thought it was the more appropriate time to start. I had no other choice. I had to do something so I started." – (P2)

Both participants (P3, P8) who started at the time of AZT monotherapy expressed some doubts about the efficacy of this treatment and also about lack of reliable information at the time they started treatment. Nevertheless, by starting AZT they hoped to prolong their life at a time when being HIV-infected meant death in less than 10 years. They also hoped for better options in the future.
"I am already taking it for a lot of years. For about 10 years. When it first came out it was a single drug regimen and I didn’t see anybody nor had any information of whether they have done any good and my partner died in 1995. Just about that time it came out, the triple combination for HIV, and that seem to me the logical step because they were definitely the medications that were going to work and so I went on into it.” – (P8)

Some participants (P2, P4, and P7) had trouble starting HAART regimens even after they had agreed to do so. This reluctance to start HAART was related to difficulties experienced in coping with the psychological issues of being HIV-infected (P4, P7). Nonetheless, they acknowledged the need to start HAART and complied with their doctors’ recommendations.

"Initially I came in (to the Clinic) and found out that I needed to go on the medication and obviously I didn’t take it too well. I thought that commencing treatment will actually mean that the virus is taking hold of my body in a more exacerbated way. But having spoken to the doctor I felt a bit more assured that it was the best thing for me to do which is simply taking a couple of pills in the morning and at night and was nothing more to it and actually it was going to do to my body some good.” – (P4)

Even after agreeing to start HAART, one participant (P7) continued to face problems with his treatment because of lack of belief in its effectiveness.

"Everything changed after HIV. The relationship, the family, the employment, everything made me very depressed and even the
medication at that time. I didn’t take it (the medication) seriously. I didn’t think that the medication was going to help me.” – (P7)

All the study participants considered that they had a very good relationship with their doctor. Although all of them placed considerable trust in their doctors’ explanations and requests and they felt that the doctors were in better position to tell them what to do to improve their health and wellbeing.

“Well, I’ve left it (the decision to start HAART) to him (the doctor). If he thinks that I need these tablets than it is ok. I went on it (HAART). He is the expert and so I have to take his word for it.” – (P6)

6.5.3. Managing HAART on daily basis

Six of the study participants, at the time of the interviews, were on twice a day regimens (P1, P2, P4, P6, P7, and P8) and two on once a day regimens (P3, P5). I found no differences in the ways the participants managed HAART regimens on daily basis. The study participants felt that their current regimens were well-suited with their general life-styles. Some participants made minor adjustments in their life-style, for example P1 and P4 began having breakfast in order to take their morning doses. One participant (P1) who has been on a once a day regimen for some time switched to twice a day regimen due to virologic resistance felt the need to adjust to a new medication routine.

“I come from 4 tablets to about 24 tablets to take two times a day. Once a day was pretty easy. I never had breakfast in the
morning but I have now at least some toast to help me take my medications. It changed my life-style a bit. I also have a really big meal at night to take my other tablets. Not that I didn’t have a bigger appetite before but I never ate that much. I never had time for breakfast but now I have to force myself to eat something to take my tablets.” – (P1)

Study participants who were on twice a day regimen linked their dosing with meal times while those who were on once a day regimens took their medication in the morning immediately after waking-up (P3, P5). All participants discussed with their doctors the regimen periodicity that they preferred based on the options clinically indicated for them. The timing chosen for dosing was perceived by participants as relatively easy to follow and remember except when their daily routine was disrupted.

“Well, it suited me better to take it first in the morning, because at night I could not come back home or I could be at somewhere else. I have medications in two places so I’ve got them at my girlfriends place and I’ve got them at my place. Just sometimes I miss it and it will be because of being out whole night or very rarely but it happens that you get distracted and you think about other things and forget to take it.” – P5

In fact, forgetfulness was the most common reason for missing doses among study participants. Other reasons identified were: recreational drug (in particular amphetamine) and alcohol binges (P1), staying away from home (P1, P3, P5), sleeping through dose taking times (P1, P6), fear of being identified as HIV-infected by other members of family (P6, P7), severe side-
effects (P2, P4, and P8), severe depression (P4, P7), running out of tablets (P3), not having tablets while out of home (P3, P5) and experiencing severe migraine episodes (P8). Below, I present some accounts of participants which illustrates situations when HAART pills are not taken:

"It was basically just because of last years leave period. I had a bit of a drug binge with amphetamines and I didn’t take my medications for two weeks. But it only happen couple of times before. Mainly 2 or 3 days or something like that but not two weeks. I didn’t take HIV seriously. I’ve been positive since I was 16 or 17 years old and I thought I was a bit invincible. I didn’t really think that missing my tablets was that big deal. I gave the medication time to get resistance and when a restarted them again I started to get resistance. They were resistant to all of them and now I had to start on another regimen. I use to take 4 tablets a day and now I take about 24 tablets twice a day so it is a big deal" – P1

"I just rely on myself to remember and sometimes I forget to take them altogether, but most of the times I take it.” – P6

"I was very depressed and I didn’t want to take them (HAART pills). I wasn’t very, very sure about them. I knew they were working but I had doubts about them. Sometimes I was with friends and family and it was very hard to manage or take medication.” – P7

"I generally don’t miss them. I take them. But I suffer from chronic migraine and sometimes I get really bad headache and nausea and even if I take them (HAART tablets) I usually vomit them pretty quickly. Even if I don’t feel like taking it
because of migraine I know that I’ve at least tried. However, once I was really sick and I don’t know exactly why and HIV tablets were making it worse. I didn’t stop taking them but I didn’t take it the full amount…” – P8

All participants agreed that getting into a routine and linking their dosing with daily routines helped them to remember to take their HAART tablets. Some participants rely just upon their memory within daily routine (P1, P2, P6, P7, and P8). For others the avoidance of using any type of reminder and/or pill-box is related to their fear of being identified as HIV-infected. Study participants also emphasized that when their daily routines were disrupted they were more likely to forget to take medication (P1, P3, P5, and P6) or to find themselves without the medication with them (P1, P3, P4, and P5). From the accounts of participants it is clear that many were reluctant to take their tablets openly for fear of revealing their HIV-status to their family, friends and other people.

"Nobody in my family knows about my infection and I just keep the pills with me and I don’t need reminders. I just get up and take it. As soon as I remember I just take it.” – P6

"Get into a routine and as soon as you have a routine you know what to expect for and what to plan for. Having a pill-box as well really made a big difference.” – P8

Some participants also used some additional strategies to keep track or remind them to take medications, including: using a pill-box (P3, P4, P5 and P8), or a mobile phone alarm (P5).
“I always found it (the pill-box) useful. It saves time and you know what days you had and what days you haven’t had your pills so you can know which days you have missed. Taking out directly from the bottle you can’t really tell whether you have missed it or not. But I also use my mobile phone (alarm) to remind me by quarter to eleven to take my medication. But sometimes I miss it (taking dose) because of being out whole night or when I get distracted with other things and forget to take it.” – P5

In general, only minor life-style changes were made by the study participants after starting HAART, which included: starting to have breakfast (P1, P4), improvements in diet towards selection of “healthy-type” of foods (P1, P2, P4, P5, P7), use of multivitamins and other natural supplements (P1, P3, P8) and increase in physical activity (P4, P7, P8). Participants did not change their smoking and alcohol habits (whether social or binge drinking). Although all participants showed some evidence of practices that improved their health and well-being, they tended to avoid worrying about these issues too much.

“If it is time to go then it is your time to do (die). So there’s no point to worry about it. I can spend the rest of my life worrying about it and then what’s the point? You know you will eventually die one day so you don’t worry about it. You just try to enjoy as you can.” – P6

6.5.4. Managing Side-effects

The occurrence of HAART-related short-term and long-term side-effects is well known. Only four participants had their treatment regimens changed because of short-term side-effects
(P2 and P4, mainly because of intense nausea and vomiting) or long-term side-effects (P3, P5 and P8, mainly because of lipodystrophy).

For PLWHA starting HAART for the first time the ability to cope with short-term side-effects is essential for maintaining adherence to their regimens and for the success of the treatment. Among study participants, the coping abilities for short-term side-effects (most commonly nausea, vomiting, and diarrhoea) varied, with some tolerating these well (P1, P3, P5, P6, P7) while others struggled (P2, P4, P8). Participants reported that they were informed of the possibility of experiencing varied short-term side-effects and counselled to persevere with medication. Those experiencing more severe side-effects used different strategies to cope, from complete interruption of medication (P2) to adjustments in diet (P4, P8).

"I couldn’t cope. During the whole day I felt nausea. But I did stop (for while) because I was having really bad side-effects. They (doctor and counselling nurse) strongly suggested that I persevere with the side-effects because they eventually would start subsiding so I was just waiting until that happens." – P2

"Initially, I had problems with treatment and I could say that I was poor-adherent due to the effects of ill-feeling. My main concern was that of nausea which was quite common occurrence and intense. I used to get headaches and also had problems with my sleeping. Actually as I progressed with the treatment I found out that by adhering to the medication and also making sure that I eat well and do a bit of exercise... it did really help". – P4
Although, there were three participants who had their HAART regimens changed because of lipodystrophy (P3, P5, and P8) only one participant (P8) was concerned with these anti-HIV drugs related side-effects.

“When I came to realize that I have tablets that could cause certain amount of lipodystrophy I looked at ways that I could be able to manage lipoatrophy because if the physical expression might affect the way I look that would affect my state of mind so I look for what alternatives were available for lipoatrophy and now I have regular injections. It is also one of the reasons why I go out to work part-time because it is really expensive. I get injections of steroids too because of body wasting.” – P8

6.5.5. Relationship with health care providers
The relationships with healthcare professionals were well-regarded. This was particularly true with the doctors in whom they had high levels of trust and who were the exclusive source of information for HIV/AIDS health-related decisions. However, one participant (P8) felt less confidence and support from his doctor in relation to side-effect management. Another participant (P7) who had full trust in his doctor and the information he provided was less certain about the effectiveness of HAART.

“I have full trust in my doctor. I have known her for a long time and I just trust her. If she (the doctor) wants to make the decision for me then that’s ok. They studied for a reason and I don’t know why you should drain yourself by reading information on HIV and different diseases you can catch and
lipodystrophy and toxoplasmosis and stuff like that. I just think that that can have a more like negative effect on you. Just take your tablets and be a good-boy.” – P1

“I did research on how to manage my side-effects but nobody sort of said to me you are going to have these side-effects or these are the things that you sort of are going to experience and these are the things that you can do about them. I had to find out all about it by myself and then I went to healthcare providers and said to them that I am having these side-effects and these are the likely things that I can do about it. Which do you recommend? But nobody proactively said to me have you tried this or this could happen.” – P8

“He (doctor) did tell me to take (medications) these times but I wasn’t taking it very seriously and I didn’t think that the medication was going to help me. When I became HIV even if they have told me that it was going to help me I wasn’t convinced. People with HIV were dying and I thought they were just trying to be nice with me and it wasn’t really going to help me.” – (P7)

6.5.6. Future outlook and motivation to maintain adherence to HAART

Although participants were relatively experienced with HAART (except P4), had already experienced different regimens (except P4) and some had experienced resistance they remained optimistic about the future outlook. Frequently participants stated that with HAART they had lived longer than they had expected and remained hopeful that they would see improvements in quality of life and longevity. They were unconcerned about
having being on different regimens or carrying resistant strains of HIV. In general, they were optimistic that new drugs and better regimens would emerge in the future.

"I think that people are really scared of HIV. Just don’t be scared because there’s nothing to be scared especially if you are taking the first regimen (HAART). It’s really easy and it does make a difference. It’s not like the 80’s when overdosing with AZT were killing people and stuff like that. They have 20 years of research and it is only going to get better. If it wasn’t for antiretrovirals I would never even think that I am going to be here when I am 50. I have always been putting 3 to 4 years cap in my life, but antiretrovirals took that away so I have got a future.” - P1

"The only thing that is going to kill me is the old age and not the virus and this is because of treatment and I believe in the treatment and I won’t stop it.” - P5

However, one participant (P3), who has been on HAART and on different regimens for almost a decade, had a more pragmatic approach to his future outlook, particularly when he referred to “running-out of options (of HAART regimens)”: 

"It does worry me (running out of HAART regimen options) but I suppose that if my time is up then my time is up. But, you know, I like to think that I’ll be healthy for a long, long time... I look future optimistically but my future is also... even though I’m a Christian... that if I do get sick and I find out that my health is failing then I won’t be here (at the Clinic). I’ve made that decision and I spoke with my doctor about it". 
Overall, the study participants had a range of experiences with HAART which varied between periods of 100% adherence to periods with lesser than 95% adherence to HAART. Some participants even experienced episode(s) of complete interruption of HAART for erratic times (from few days for the majority of participants to few weeks in case of participants P1 and P7) and for diverse reasons (drug and alcohol binge; away from home; etc). As a result of erratic adherence to HAART at times some of the study participants developed resistance to several anti-HIV drugs which also led subsequently to treatment failure (P1, P3, P6, P7, and P8). In fact, this study participants viewed treatment failure mainly in two different ways: one characterized by individual commitment to improve adherence to near perfect levels and optimism related to the availability of new anti-HIV drugs and/or better HAART regimens (P1, P7, and P8) and the other was characterized by a more pessimistic view with a sense of hopelessness because of “running out of options” and viewing to face death more pragmatically (P3 and P6).

6.6. Discussion
This qualitative study was designed to explore experiences and perceptions of HIV-infected individuals with less than 95% adherence to HAART. From the accounts of the study participants it can be concluded that poor-adherence is an intermittent experience which happens mainly because of the following issues separately and/or in combination: forgetfulness as a consequence of disruption of daily-routines or drug and/or alcohol binges; intolerable short-term side-effects (mainly nausea and vomiting); sleeping through HAART dose taking times; being away from home; fear of being identified as HIV-infected and other psychosocial issues related to living with HIV/AIDS.
Depression, socialization, etc). Intermittent incidents of poor-adherence to HAART due to similar issues established in this study were also found in another qualitative study (Meystre-Agustoni G et al., 2000). However, it has been suggested that the occurrence of intermittent episodes of poor-adherence might be related with recurring psychosocial issues of living with HIV/AIDS (Enriquez M et al., 2004c).

A number of similarities between the participants in this study and the participants with 100% adherence (Chapter 5) were found. These similarities include: viewing HAART as a life-line for living longer and healthier; having a good relationship with healthcare professionals in general and regarding their doctors as the main source of information for their decision-making process for any issues related to HIV/AIDS; adopting a number of strategies to cope with side-effects related to anti-HIV drugs; adopting diverse strategies as reminders for timely medication taking (linking with daily routines, using pill-box, setting-up alarms); and usually planning ahead when intending to travel and/or stay away from home for short periods of time.

However, these similarities should be viewed within certain background as they might vary according to circumstances and psychosocial state of an individual living with HIV/AIDS. In fact, studies have shown that overcoming psychosocial issues contributes significantly for improvements in adherence levels (Alfonso V et al., 2006a; Enriquez M et al., 2004c) and patients on HAART with poor-adherence may change dramatically to become 100% adherent once they overcome psychosocial issues of living with HIV/AIDS (Enriquez M et al., 2004c). This fact was confirmed in several longitudinal studies that have shown that HAART adherence varies along the time and different
psychosocial factors and experiences with HAART accounts for different levels of adherence in different patients at different circumstances (Godin G et al., 2005a; Martini M et al., 2002; Schonnesson LN et al., 2006; Tesoriero J et al., 2003). Thus, I consider that the similar and dissimilar experiences and perceptions between those with 100% adherence and those with poor-adherence should be subjected to inferences within specific psychosocial and situational incident for each individual patient on HAART and within a specific time-interval. This consideration is also in accordance with currently well established knowledge that adherence to HAART is a dynamic behaviour determined by various interrelated experiences and perceptions that changes over time (Alfonso V et al., 2006a; Ickovics JR and Meade CS, 2002). Overall, this study findings are consistent with the findings reported in a recently published review of qualitative studies on adherence to HAART (Vervoort SCJM et al., 2007).

From the accounts of the study participants the most commonly cited reasons for missing HAART doses was occasional occurrences of forgetfulness particularly when their daily routines were disrupted for any reason. This finding is consistent with other qualitative as well as quantitative studies where forgetfulness was found to be commonly mentioned reason for missing HAART doses (Barfod TS et al., 2006; Laws MB et al., 2000; Meystre-Agustoni G et al., 2000; Roberts KJ, 2000). It was shown that when HAART doses are taken as a habit they were less likely to be forgotten (Fothergill-Bourbonnais F et al., 2002). Similar finding was observed in the study with PLWHA with 100% adherence to HAART (Chapter 5).
The most common reasons for forgetfulness reported in the literature were busyness (Roberts KJ, 2000), disruption of daily routines (e.g. on weekends) (Barfod TS et al., 2006; Roberts KJ, 2000; Westerfelt A, 2004), sleeping through doses times (Laws MB et al., 2000) and being away from home (Barfod TS et al., 2006; Roberts KJ, 2000). It has been suggested that patients experiencing intermittent incidents of poor-adherence because of forgetfulness generally do not take any precautions subsequently to avoid the recurrence of similar situations (Meystre-Agustoni G et al., 2000). This later point might also be the likely explanation for this study participants having self-reported poor-adherence despite having adopted a number of strategies to remember taking their HAART doses. Although often forgetfulness to take HAART pills is an unintentional occurrence as stated above, also shown in other study (Walsh JC et al., 2001), it might also happen as a result of patient’s reasoned-decision as shown in one study (Donovan JL and Blake DR, 1992). In fact, from the accounts of some of this study participants it can be inferred that reasoned-decision process was actually applied when HAART pills were not taken in certain circumstances such as: because of fear of being identified as HIV-infected (P1, P6, and P7) or to avoid experiencing side-effects perceived as intolerable like nausea and vomiting (P2, P4, and P8).

Overall, the decision to go on HAART as well as the relationship with healthcare professionals and particularly with HIV doctors was similar to those reported for patients’ with 100% adherence (Chapter 5). The doctors were their main source of information and trust regarding issues related to HIV/AIDS and HAART and this was congruent with other study findings (Meredith KL et al., 2001). However, one participant
(P7) felt that peer-support lacked in his struggle with depression (at times suicidal) and other psychosocial issues related to HIV/AIDS and HAART, viewing support provided by healthcare professionals as simply “professional duty”. In fact, a recent study showed that psychological traumatic events had a significant effect on adherence to HAART (Mugavero M et al., 2006). Another participant (P8) felt lack of guidance from healthcare professionals specifically in regard to dealing with lipodystrophy-related manifestations and looked for other sources of information (e.g. internet).

It has been suggested that the decision to start HAART should be a collaborative decision between doctor and patient (Gold RS and Ridge DT, 2001) and HAART should be started only when patients are ready for it (Cooper V et al., 2002; Enriquez M et al., 2004b; Gellaitry G et al., 2005). When patients decide to go on HAART based on their reasoned-decision it is more likely to result in optimal levels of adherence than when a prescriptive approach is implemented (Gold RS and Ridge DT, 2001). However, the findings presented here shows that even though if the decision to go on HAART is shared between patient-doctor and patients feel ready to go on these therapies it is still possible for patients to experience poor-adherence. On the other side, although the study participants perceived the positive outcomes of being on HAART, such as improvements in their health and well-being and also in their laboratorial biomarkers of HIV/AIDS illness progression, these were not enough motivators to maintain near-perfect adherence along the time. It might be that along the time this study participants were not overly concerned about missing occasionally HAART pills as accounts of some participants of this study implies (P1, P3, P6, and P7).
Although participants expressed concerns about treatment failure, development of resistance to multiple anti-HIV drugs and consequently having their HAART regimen options reduced, these concerns were reasoned against the self-appraisal of benefits already gained by being on HAART and living with HIV/AIDS quite well for quite a few years (P1, P3, and P6). They were concerned of “running-out of HAART options”, but they didn’t want to get anxious about it (P1, P3, P6, and P7) and felt psychologically prepared to face even if that meant the worse outcome which was dying of HIV/AIDS related illnesses (P3, and P6). From the accounts of various participants it seems that they have given priority to immediate enjoyments and benefits emerged from their various socializing and pleasurable events and were less concerned and/or didn’t want their HIV-infection or HAART interfere in their enjoyment options. The low priority placed for HAART was found significantly related to non-adherence (Odds Ratio 0.85, 95% confidence interval: 0.72 - 0.97; p-value = 0.013) in one study (Walsh JC et al., 2001).

In this study, the common reasons for placing low priority to HAART were related to alcohol and drug binges (P1 and P6), sexual encounters away from home (P1, P3, and P6) and partying along the night (P1, P3, and P5). Only one participant (P1) expressed clearly the feeling of invulnerability (“superman syndrome”) for his risk-taking behaviours while another participant (P7) blamed his depression and other psychosocial issues he was facing because of living with HIV-infection. It has been argued that these risk-taking behaviours should not be viewed simply within theoretical frameworks of Health Belief Model or Theory of Reasoned Action but it should also take into
account psychosocial issues (e.g. mood) (Sultan S and Bungener C, 2002).

Some participants who had to change regimens because of treatment failure and resistance to multiple anti-HIV drugs expressed commitment to have 100% adherence (P1, P3, and P7). In fact, one study showed that patients' on HAART with poor-adherence may change dramatically to become 100% adherent once they overcome psychosocial issues of living with HIV/AIDS (Enriquez M et al., 2004c). It is important that before starting HAART patients feel ready to go on these complex therapies, but it is eventually more important that they are ready to maintain optimal lifelong adherence (Gebrekristos HT et al., 2005). The findings of this study also prove that the readiness to maintain lifelong adherence is complex and challenging for many patients. Consequently, in every appointment healthcare professionals should assess the needs and the experiences with living with HIV/AIDS and/or of being on HAART and support should be offered appropriately as they are of vital importance to keep patients motivated and observant of keeping 100% adherence to HAART in all circumstances as acknowledged in some longitudinal studies (Godin G et al., 2005a; Martini M et al., 2002; Schonnesson LN et al., 2006; Tesoriero J et al., 2003).

6.7. Study limitations

Limitations of this study are similar to those reported in the previous study (Chapter 5). Furthermore, in this study I have established a specific definition of poor-adherence which does not take into account the characteristics of HAART regimens. It has been shown that the levels of adherence required for HAART
might vary according to HAART regimens (Knobel H, 2005). Possibly that might be one likely reason for some of this study participants showing undetectable levels of plasma HIV RNA (P4, P5, and P8) at the time when interviews took place despite having self-reported < 95% adherence to HAART.

Except for one participant (P4), these study participants were exposed to different HAART regimens in the past (including past 6 months) and thus it was difficult to precisely correlate the level of adherence to HAART regimens. On the other hand, the lack of “gold standard” in assessing poor-adherence (Gulick RM, 2006) supports for interpreting findings presented in this chapter with prudence by taking into consideration the limitations of the definition of poor-adherence presented for this study. Furthermore, the lack of “gold standard” definition of poor-adherence to HAART have made the task of synthesizing the findings across different studies an enormous challenge and an urgency to look for additional valid measures to assess adherence to HAART in clinical setting (Chesney MA, 2000).

6.8. Conclusions

Although the findings of this study corroborate previous research on adherence to HAART, as presented in discussion section, there is no intention to claim its generalizibility. In fact, this study reemphasizes that adherence to HAART is a dynamic and complex behaviour which changes overtime. Rather, it seems that PLWHA on and/or off HAART should be offered continuous support and any intervention to improve adherence to HAART should be based on best available evidence and tailored for patients’ specific needs or requirements.
Chapter 7: An individually tailored intervention for improving self-care of PLWHA on HAART: Baseline data from the “Health Map”.

Outcome arising from “Health Map” intervention:
A modified version of “Health Map” was developed for the internet (see Appendix 15). The website version of “Health Map” was funded by Department of Human Services.
7.1. Abstract

This chapter presents baseline data from an individually tailored intervention for self-care of PLWHA on HAART ("Health Map” trial). This intervention was carried out because there are suggestions that appropriate management of dyslipidemia as well as lifestyle modification, such as smoking cessation, proper diet and exercise might help PLWHA living longer and healthier. Thus, with the evaluation of “Health Map” the aim was to characterize the clinical and other features of PLWHA on HAART (e.g. HAART adherence, depression, modifiable cardiovascular risk factors). Unfortunately, due to time-limitations I was unable to present the complete evaluation of “Health Map” in this thesis. However, the preliminary data of “Health Map” shows that a significant proportion of its participants have a number of modifiable risk factors for heart disease (47% were smokers; 48% had insufficient physical activity; and 51% of were overweight or obese according to their Body Mass Index calculation). Furthermore, there were also some “Health Map” participants with comorbidities, including: 1% on treatment for diabetes; and 33% on lipid lowering drugs 9% on treatment for high-blood pressure. Although no final conclusion can be made about the effectiveness of “Health Map” at this stage, similar interventions to facilitate behavioural change of multiple risk factors in primary healthcare setting proved to be significantly valuable for patients according to currently available literature. Therefore, it is expected that “Health Map” intervention would be also valuable for patients who took part in it to improve their health by modification of risk factors for heart disease and adopting healthier lifestyles.
7.2. Intervention Background

The introduction of HAART in Australia and in many other developed countries since 1996 (Kaldor J and McDonald A, 2003) as the standard of care for PLWHA has contributed to a dramatic reduction in the morbidity and mortality associated with HIV/AIDS (Palella F J et al., 1998), even among those with advanced HIV/AIDS disease (Murphy E L et al., 2001). In fact, HAART has transformed HIV-infection into a chronic and manageable illness (Siegel K and Lekas H-M, 2002). However, as with other chronic illnesses, living longer and growing older with HIV/AIDS (Cassau NC, 2005; Grabar S et al., 2006; Pitts M et al., 2005) means that PLWHA will encounter new challenges over time (Currier JS and Havlir DV, 2005; Selwyn PA and Forstein M, 2003). Healthcare professionals working in the HIV/AIDS clinical setting are also encountering new challenges which include age-related issues of PLWHA and toxicities and/or interactions related to drugs for other concurrent illnesses (Cassau NC, 2005; Grabar S et al., 2006; Manfredi R and Chiodo F). Thus, suggestions to prioritise primary care issues in HIV/AIDS clinical setting has been emerging, including promotion of exercise, healthy diet and promotion of smoking cessation and avoidance of other toxic substances (alcohol, illicit drugs) (Justice AC, 2006).

Commonly the promotion of healthy behaviours is done by use of brochures, booklets or pamphlets and these materials are usually designed for the general population or some targeted demographic sub-groups (Holt C L et al., 2000). The availability of computer technology brought some innovative changes in health educational material(s) (HEM), allowing individually tailored HEM to be produced (Holt C L et al., 2000).
Computer-tailored HEM provide people with personalized information that is based on their individual characteristics making it more effective in motivating people towards recommended behaviour change (Brug J et al., 2003). Thus, with the assistance of experts in information technology (I.T. experts) as well as clinicians with expertise in HIV/AIDS care a computer program (named “Health Map”) was produced to help PLWHA on HAART to improve their self-care in the following issues: adherence to HAART; mental health; physical fitness; smoking cessation; self-monitoring of personal lipid profiles, blood sugar levels, blood-pressure, body mass index (BMI) and personal risk of developing heart disease. It was hypothesized that by providing personalized (tailored) information regarding healthier lifestyles this would help PLWHA on HAART to control dyslipidemias and other metabolic disorders and also assist in achieving desired levels of adherence to HAART. Thus, this trial was aimed to assist PLWHA on HAART to eventually overcome dyslipidemias and other risk factors for heart disease without increasing their pill burden. Furthermore, it also aimed to be of assistance in increasing the motivation for keeping high levels of adherence to HAART. This trial is unique in the sense that there are no similar interventions reported in the currently available literature on HIV/AIDS care context.

In this chapter I will present only the baseline data that is part of the evaluation of the “Health Map”. Thus, only the enrolment characteristics of the clients who took part in the “Health Map” as well as data retrieved from the “Health Map” program itself will be presented in this chapter. I will not present the follow-up data because the 12 months follow-up data will only be available in September 2007 and my international scholarship stipulates that I have to complete my PhD.
candidature by the end of March 2007. Therefore, I will be undertaking the outcome analysis at a later date.

7.3. Aims of “Health Map” trial evaluation

The aims of this evaluation were:

1. to determine if “Health Map” reduces risk factors for cardiovascular disease;
2. to determine if “Health Map” increases HAART adherence levels;
3. to identify if “Health Map” prompts clients, depending on their specific needs, to attend treatment adherence support, counselling, physical fitness and/or dietician consultations and to quit smoking;
4. to determine if “Health Map” prompted clinicians to monitor more regularly the clients blood pressure, blood sugar levels, lipid profile and other factors that increases the risk of PLWHA to develop cardiovascular disease.

7.4. Methodology

7.4.1. Intervention setting

This is an open non-randomized study of “Health Map” which was carried out at the HIV Referral Clinic in Melbourne Sexual Health Centre (MSHC). The clients who participated in this trial were recruited between May and September 2006. The questions used to develop “Health Map” were selected from currently available and validated assessment tools (please see the Appendix 12 for details of “Health Map” program development). Participants were invited (please see invitation pamphlet in Appendix 11) to take part in this trial if they had their complete care at MSHC (as there are many clients who
attend the clinic to see only dietician or counsellor, for example) and were on HAART at the time of the recruitment.

“Health Map” provided participants with self-tailored printed recommendations (see Appendix 13 for a report example). The recommendations were automatically generated based on answers to the questions and included, for example, advice to:

- See Dietician for advice on weight loss
- See a doctor for advice on medication for high blood lipids levels;
- See Physical Fitness Consultant to improve Physical activity and/or lose weight;
- Enroll in the QUIT Program (if smoker);
- See a clinician if blood pressure control needed;
- See a counsellor for depression;
- Participate in motivational counselling session if adherence to HAART needs to be improved;
- See a Clinician if Hepatitis B vaccination needed;
- Get screening for STIs and appropriate treatment if required;

The overall purpose of “Health Map” was to evaluate and improve the quality of health care delivered at the HIV Referral Clinic at Melbourne Sexual Health Centre. According to Australian NHMRC guidelines for quality assurance projects (National Health & Medical Research Council (Australia), 2003) no submission for HREC was required.
7.4.2. Data collection procedures

An audit of the clinical notes in each participant’s file for the past 12 months (will be called Audit $T_{-1}$) was carried out to assess some baseline characteristics and a similar audit for 12 months after the intervention (will be called Audit $T_{+1}$) is planned as to determine if the intervention has been successful. The intervention time-period was named $T_0$. In this thesis I will present only data collected from time-period A for Audit $T_{-1}$ (represented in the Figure 6.1.) and $T_0$ corresponding to data related to “Health Map”. Data related to time-periods B (collected but not analysed and thus not presented in this thesis), C and D (to be collected in September 2007) were not included in this thesis.

<table>
<thead>
<tr>
<th>Trial Participants</th>
<th>AUDIT $T_{-1}$ Past 12 months</th>
<th>Intervention $T_0$</th>
<th>AUDIT $T_{+1}$ 12 months after intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Health Map”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>participants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matched Controls</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 7.1.** Graphical representation of the time-periods established for the two audits that were planned for the “Health Map” evaluation.

The selection of clients as controls was made by matching the following characteristics: having attended the clinic in the same morning or afternoon as the clients who took part in the
“Health Map” trial; being seen by the same HIV clinician and also having complete clinical care at Melbourne Sexual Health Centre.

The following baseline characteristics for “Health Map” participants’ were assessed from their clinical files for \textit{Audit T\textsubscript{-1}}:

- number of consultations attended for HIV care in the past 12 months;
- if attended any consultation with a dietician, a counsellor and/or a physical fitness consultant;
- the lowest % of self-reported HAART adherence in the past 12 months;
- if attended any adherence support session;
- if had blood pressure measured or on medications for high blood pressure;
- if had blood lipids measured or on medications for lowering blood lipids;
- if had blood sugar controlled or on medications for lowering blood sugar;
- the latest results (before \textit{T\textsubscript{0}}) for CD4 T-cell counts and plasma HIV RNA levels;
- if on medications for depression;

As mentioned above, in this chapter I will only present data related to the intervention (\textit{T\textsubscript{0}}) and data related to \textit{Audit T\textsubscript{1}} (only data for time-period \textit{A} as shown in the Figure 6.1.) because of limited time I had to complete my PhD candidature. The follow-up evaluation of the “Health Map” trial (\textit{Audit T\textsubscript{1}}) is planned after my studies completion (September 2007).
7.4.3. Outcomes to be assessed for “Health Map”

The following outcomes (both process measures as well as clinical outcomes measures) will be assessed for “Health Map” participants and their respective controls after analysing data obtained from Audit T_{-1} and Audit T_{+1}:

- The difference in % of participants who reported 100% adherence to HAART;
- The difference in % of participants with high total cholesterol levels;
- The difference in % of participants who had at least one consultation with a dietician;
- The difference in % of participants who were taking lipid medications;
- The difference in % of participants who stopped smoking;
- The difference in % of participants who had any STIs screening test done and/or were treated for positive STIs;
- The difference in % of participants who were susceptible for Hepatitis B and were vaccinated;
- The difference in % of participants who had their blood-pressure recorded at least once;
- The difference in % of participants who attended Physical Fitness Consultation/Program;
- The difference in % of participants who attended at least once a Counsellor session;

Although the above mentioned outcomes were not presented in this thesis (for reasons above mentioned), I felt the need to describe them here as they represent an essential part of the “Health Map” intervention.
7.4.4. Rationale for the statistical analysis of the "Health Map" intervention

There were a number of variables that were assessed in this trial which include measuring blood-pressure, having serum lipids done, adherence and others. There were about 300 clients on HAART having their regular care at the MSHC – HIV Referral Clinic and 100 clients undertook the trial between May and September 2006. Assuming that the proportion in need of improvements in their healthcare characteristics is about 25% in the “Health Map” group and about 10% in control group, then with an alpha level of 0.05 we will have 80% power to detect a post-intervention level of 39% or higher. With this sample size it was expected that the trial will have greater power to address numerical variables and to undertake a paired analysis. A Paired t test or nonparametric equivalent will be used for continuous or ordinal data and a chi-square or McNemars test will be used for categorical data.

7.5. Results

7.5.1. Data from “Health Map” trial (T₀)

There were 100 clients who participated in “Health Map” trial and their demographic and other characteristics assessed by “Health Map” program are summarized in the Table 7.1. There were only five female participants. All participants who had a pill-box considered it somehow useful or very useful.
Table 7.1. Summary of demographic and other characteristics assessed by “Health Map”.

<table>
<thead>
<tr>
<th>Characteristics assessed</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age of participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>47.5</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>46.0</td>
<td></td>
</tr>
<tr>
<td>Std. deviation</td>
<td>10.6</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>32 – 77 years</td>
<td></td>
</tr>
<tr>
<td><strong>Gender of participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>95</td>
<td>95.0%</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>5.0%</td>
</tr>
<tr>
<td><strong>Self-Reported Missed HAART doses in the past 28 days</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>none</td>
<td>83</td>
<td>83.0%</td>
</tr>
<tr>
<td>some</td>
<td>17%</td>
<td>17.0%</td>
</tr>
<tr>
<td>range</td>
<td>0 – 14 doses</td>
<td></td>
</tr>
<tr>
<td><strong>Anti-HIV medication self-efficacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good self-efficacy</td>
<td>95</td>
<td>95.0%</td>
</tr>
<tr>
<td>Poor self-efficacy</td>
<td>5</td>
<td>5.0%</td>
</tr>
<tr>
<td><strong>Correlation of missed doses with anti-HIV medication self-efficacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR (95% CI)</td>
<td>3.6 (0.6 to 23.0)</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Owning a pill-box</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>56</td>
<td>56.0%</td>
</tr>
<tr>
<td>No</td>
<td>44</td>
<td>44.0%</td>
</tr>
<tr>
<td><strong>Physical Activity Assessment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sufficient</td>
<td>52</td>
<td>52.0%</td>
</tr>
<tr>
<td>Insufficient</td>
<td>48</td>
<td>48.0%</td>
</tr>
<tr>
<td><strong>Perceived Stress Assessment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Need counselling</td>
<td>17</td>
<td>17.0%</td>
</tr>
<tr>
<td>No need for counselling</td>
<td>83</td>
<td>83.0%</td>
</tr>
<tr>
<td><strong>Correlation between Perceived Stress and missing anti-HIV medication doses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR (95% CI) for counselling need</td>
<td>1.3 (0.9 to 1.9)</td>
<td></td>
</tr>
<tr>
<td>OR (95% CI) for no counselling need</td>
<td>0.4 (0.2 to 0.9)</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>48</td>
<td>48.0%</td>
</tr>
<tr>
<td>Overweight</td>
<td>47</td>
<td>47.0%</td>
</tr>
<tr>
<td>Obese</td>
<td>4</td>
<td>4.0%</td>
</tr>
</tbody>
</table>
Overall, the majority of participants were satisfied with their knowledge about HIV/AIDS and other HIV-related issues assessed by “Health Map”. About 95% (95/100) already knew that smoking greatly increases the risk of heart disease. About 69% (69/100) self-reported having been vaccinated for Hepatitis A and Hepatitis B.

Furthermore, the majority of participants of “Health Map” trial self-reported having done in the past 12 months the following laboratorial tests: cholesterol (72%, 72/100) and blood sugar (65%, 65/100). Although 76% had their blood pressure measured at Melbourne Sexual Health Centre, a significant minority did not (24%, 24/100).

About 47% (47/100) were self-reported being “smokers” and 81% (38/47) said that they would like to quit smoking. About 66% (66/100) of “Health Map” participants self-reported having had sex with other men in the past 12 months and about 80% (53/66) had annual routine screening for sexually transmitted infections (annual routine screening for sexually active MSM). Finally, 92% (92/100) expressed that they would like to know their risk of developing heart disease.

7.5.2. Evaluation of “Health Map” by trial participants

From 100 clients who took part in the “Health Map” trial only 64 clients completed the “Health Map” Evaluation Form (see Appendix 14). The data regarding this evaluation is summarized in the Table 7.2.
Table 7.2. Descriptive statistics from “Health Map” evaluation by clients who participated in the trial.

<table>
<thead>
<tr>
<th>Parameter evaluated</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58</td>
<td>9%</td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
<td>91%</td>
</tr>
<tr>
<td>20 – 30 years</td>
<td>4</td>
<td>6%</td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 – 40 years</td>
<td>29</td>
<td>45%</td>
</tr>
<tr>
<td>≥ 41 years</td>
<td>31</td>
<td>49%</td>
</tr>
<tr>
<td>Self-reported computer literacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>29</td>
<td>45%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>25</td>
<td>39%</td>
</tr>
<tr>
<td>Expert</td>
<td>10</td>
<td>16%</td>
</tr>
<tr>
<td>Very easy</td>
<td>39</td>
<td>61%</td>
</tr>
<tr>
<td>“Health Map” use easiness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy</td>
<td>22</td>
<td>34%</td>
</tr>
<tr>
<td>Neither easy nor difficult</td>
<td>3</td>
<td>5%</td>
</tr>
<tr>
<td>Very useful</td>
<td>14</td>
<td>22%</td>
</tr>
<tr>
<td>Useful</td>
<td>31</td>
<td>48%</td>
</tr>
<tr>
<td>Not sure</td>
<td>13</td>
<td>20%</td>
</tr>
<tr>
<td>Somehow useful</td>
<td>5</td>
<td>8%</td>
</tr>
<tr>
<td>Not useful</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Questionnaire preference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paper</td>
<td>4</td>
<td>6%</td>
</tr>
<tr>
<td>Electronic</td>
<td>60</td>
<td>94%</td>
</tr>
</tbody>
</table>
7.5.3. Data from time-period A (Audit $T_{-1}$)

The Table 7.3. presents a summary of data related to Audit $T_{-1}$. The average number of appointments attended by “Health Map” participants’ in 12 months period was 6 (ranging from 3 to 12). About 92% (92/100) had adherence to HAART >95% (ranging from 82.1 to 100.0%).

A significant number of participants did not have their blood lipids and blood sugar recorded in their files (43% and 41% respectively). A significant proportion never had their blood pressure measured (47%, 47/100). Only 33% (3/9) participants of those who were on drugs for high-blood pressure never had their blood pressure measurements recorded in their files in the past 12 months. About 17% (17/100) of participants attended at least one session for adherence support. However, only 41% (7/17) of these participants were on HAART for ≥6 months. Therefore, many of those who attended adherence support were indeed “new” to HAART.

Although Physical Consultant provides consultations every fortnight at the HIV Clinic in Melbourne Sexual Health Centre, none of “Health Map” participants attended the consultation during 12 months audit period. There were no records in participants’ files for smoking status except for 16% only (16/100) from which 9 were still smokers.
### Table 7.3. Summary of baseline data collected for “Health Map” trial participants as part of Audit T–1.

<table>
<thead>
<tr>
<th>Parameters assessed at Audit T–1</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On drugs for high-blood pressure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9</td>
<td>9.0%</td>
</tr>
<tr>
<td>No</td>
<td>91</td>
<td>91.0%</td>
</tr>
<tr>
<td><strong>Blood pressure measured</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>53</td>
<td>53.0%</td>
</tr>
<tr>
<td>No</td>
<td>47</td>
<td>47.0%</td>
</tr>
<tr>
<td><strong>On lipid lowering drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>33</td>
<td>33.0%</td>
</tr>
<tr>
<td>No</td>
<td>67</td>
<td>67.0%</td>
</tr>
<tr>
<td><strong>Blood lipids assessed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, at MSHC</td>
<td>54</td>
<td>54.0%</td>
</tr>
<tr>
<td>Yes, elsewhere</td>
<td>3</td>
<td>3.0%</td>
</tr>
<tr>
<td>Not recorded</td>
<td>43</td>
<td>43.0%</td>
</tr>
<tr>
<td><strong>On drugs for diabetes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>1.0%</td>
</tr>
<tr>
<td>No</td>
<td>99</td>
<td>99.0%</td>
</tr>
<tr>
<td><strong>Blood sugar assessed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, at MSHC</td>
<td>56</td>
<td>56.0%</td>
</tr>
<tr>
<td>Yes, elsewhere</td>
<td>2</td>
<td>2.0%</td>
</tr>
<tr>
<td>Not recorded</td>
<td>41</td>
<td>41.0%</td>
</tr>
<tr>
<td><strong>Plasma HIV RNA levels (virions/ml)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetectable</td>
<td>81</td>
<td>81.0%</td>
</tr>
<tr>
<td>detectable</td>
<td>19</td>
<td>19.0%</td>
</tr>
<tr>
<td><strong>Range (when detectable)</strong></td>
<td>94 - 644,000</td>
<td></td>
</tr>
<tr>
<td><strong>CD4 T-cell counts (cells/µl)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>597.7</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>567.5</td>
<td></td>
</tr>
<tr>
<td>Std. deviation</td>
<td>336.2</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>121 - 1827</td>
<td></td>
</tr>
<tr>
<td><strong>Appointments for HIV care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>mode</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Std. deviation</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>3 - 12</td>
<td></td>
</tr>
<tr>
<td><strong>Adherence to HAART (lowest self-reported in the past 12 months)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤95%</td>
<td>8</td>
<td>8.0%</td>
</tr>
<tr>
<td>&gt;95%</td>
<td>92</td>
<td>92.0%</td>
</tr>
<tr>
<td>Mean</td>
<td>98.6%</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>Std. deviation</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>82.1 - 100.0%</td>
<td></td>
</tr>
</tbody>
</table>
Continuation of Table 7.3. Summary of baseline data collected for “Health Map” trial participants as part of Audit T₁.

<table>
<thead>
<tr>
<th>Parameters assessed at Audit T₁</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time on HAART (past 12 months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>85</td>
<td>85.0%</td>
</tr>
<tr>
<td>&lt;12 months</td>
<td>15</td>
<td>15.0%</td>
</tr>
<tr>
<td>Mean</td>
<td>10.7 months</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>3.1 months</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>1 – 12 months</td>
<td></td>
</tr>
<tr>
<td>Attended HAART adherence support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17</td>
<td>17.0%</td>
</tr>
<tr>
<td>No</td>
<td>83</td>
<td>83.0%</td>
</tr>
<tr>
<td>Correlation between HAART duration (≥6 months vs. ≤5 months) and attending adherence support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR (95% CI)</td>
<td>0.01 (0 to 0.08)</td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Attended Dietician consultation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9</td>
<td>9.0%</td>
</tr>
<tr>
<td>No</td>
<td>91</td>
<td>91.0%</td>
</tr>
<tr>
<td>Attended Social Worker consultation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>2.0%</td>
</tr>
<tr>
<td>No</td>
<td>98</td>
<td>98.0%</td>
</tr>
<tr>
<td>Attended Counselling consultation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14</td>
<td>14.0%</td>
</tr>
<tr>
<td>No</td>
<td>86</td>
<td>86.0%</td>
</tr>
<tr>
<td>On drugs for depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>31</td>
<td>31.0%</td>
</tr>
<tr>
<td>No</td>
<td>69</td>
<td>69.0%</td>
</tr>
<tr>
<td>STIs routine annual screening (offered to all MSM only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Offered and accepted</td>
<td>39</td>
<td>39.0%</td>
</tr>
<tr>
<td>Offered but declined</td>
<td>28</td>
<td>28.0%</td>
</tr>
<tr>
<td>Not offered</td>
<td>22</td>
<td>22.0%</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>6</td>
<td>6.0%</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>5.0%</td>
</tr>
<tr>
<td>Smoking status recorded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, and still smoking</td>
<td>9</td>
<td>9.0%</td>
</tr>
<tr>
<td>Yes, and not smoking</td>
<td>7</td>
<td>7.0%</td>
</tr>
<tr>
<td>Not recorded</td>
<td>84</td>
<td>84.0%</td>
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</table>
7.6. Discussion
In this chapter I have presented only the baseline data from an intervention that was designed to promote self-care for participants of “Health Map” trial and to prompt clinicians to monitor more regularly the clients’ blood pressure, blood sugar levels, lipid profile and other factors that increase the risk of PLWHA to develop cardiovascular disease. In fact, HAART has helped to transform HIV into a manageable chronic disease. The chronic nature of the HIV disease course and the increasing burden of cumulative HIV-related morbidity and treatment-related toxic effects pose new challenges to the care of patients over time (Selwyn PA and Forstein M, 2003). Therefore, healthcare professionals working in HIV/AIDS clinical setting, particularly HIV clinicians, have been recommended to include within their caring activities the promotion of exercise, healthy diet and promotion of smoking cessation and avoidance of other toxic substances (alcohol, illicit drugs) (Justice AC, 2006). Thus, the comprehensive management of HIV disease needs to routinely include assessment and treatment dyslipidemias, metabolic complications, and multifactorial hepatic disease (Justice AC, 2006). In general, clinicians are recommended to routinely record in patients’ files the modifiable heart disease risk factors such as blood lipid measurements, blood pressure readings, smoking and diabetes status in view to assess not only the risk of developing heart disease but to intervene to modify them (Greenland P et al., 1998). However, often clinicians do not record these simple data within usual clinical care setting (Greenland P et al., 1998). But even when clinicians do identify these risk factors they often face enormous challenges to intervene successfully when multiple risks factors are identified (Greenland P et al., 1998). These challenges are in fact partly related to patients’
own perceptions who themselves often feel confused or overwhelmed about the need to modify a number of their behaviours (Strecher V et al., 2002). Thus, it has been suggested that patients with chronic diseases should become partners by empowering them to self-care (Holman H and Lorig K, 2000) and “Health Map” was designed just for this reason.

The “Health Map” is a unique trial in the sense that there were no similar trials reported in currently available literature. Although, in this chapter I was not able to present the follow-up data to assess the effectiveness of “Health Map”, the baseline data (obtained from auditing files for past 12 months from the intervention time) clearly shows that about 47% of clients had no records of their blood pressure measurements, 43% with no records on their blood lipids and 41% with no records of their blood sugar. Furthermore, 84% of clients had no records of their smoking status in the past 12 months. Additionally, although there were no records on physical activity status of clients whose files were assessed, data obtained from “Health Map” program and by using a validated physical assessment tool (Marshall AL et al., 2005) showed that about 48% of clients had insufficient physical activity. About 51% of “health Map” participants were overweight or obese according to their Body Mass Index calculation. Finally, the validated stress assessment tool used in “Health Map” (French T et al., 2005) accurately predicted poor-adherence to HAART (p-value = 0.03) as shown previously by French T et. al. (2005). Overall, the preliminary results confirm previous reports in medical literature that clinicians often fail to record these simple data within usual clinical care setting (Greenland P et al., 1998).
Comorbidity such as high-blood pressure and diabetes presented in this chapter was relatively similar (Table 7.3.) to that reported by DAD Study (Friis-Møller N et al., 2003). In DAD study (Friis-Møller N et al., 2003), about 8% had high-blood pressure and 2.5% had diabetes. About 51.5% of participants of DAD study (Friis-Møller N et al., 2003) were smokers while there were only 47% of smokers among “Health Map” participants. Higher prevalence of smoking was found among PLWHA on HAART than those that were HAART-naïve (54.5% vs. 30.1%; p<0.001) (Bergersen BM et al., 2004b). On the other hand, those on HAART also presented higher levels of total cholesterol when compared to those not on HAART (36.1% VS. 21.7%; p<0.001) (Bergersen BM et al., 2004b). Although, I did not present data on total cholesterol levels, there were about 33% of “Health Map” participants taking lipid lowering drugs and this value is comparable with that reported by the study of Bergersen BM et al. (2004). The study of Bergersen BM et al. (2004) also showed that there were twice as many patients on HAART (compared to those not on HAART) with as estimated 10-year risk of developing heart disease above 20%. Therefore, PLWHA should be encouraged to stop smoking, adopt healthy diets and increase physical activity (Bergersen BM et al., 2004b).

Usually, HIV clinicians are under time-pressure to assess in ongoing basis the risk factors for developing heart disease and promote healthy behaviour(s) accordingly. The “Health Map” program was designed to self-empower patients by providing self-tailored printed recommendations. While information/recommendation alone is not sufficient to promote behaviour change (Strecher V et al., 2002) it certainly represents a starting point for patients to reflect on recommendations provided and look forward to pursue healthy
behaviours (e.g. smoking cessation, increase physical activity, adopt appropriate diet to control hypercholesterolemia, etc). Therefore, although no final conclusion can be made about the effectiveness of “Health Map” (for reasons mentioned above), interventions to facilitate behavioural change of multiple risk factors in primary healthcare setting seems to be significantly valuable for patients (Goldstein MG et al., 2004).

7.6. Limitations of preliminary “Health Map” evaluation

The fundamental limitation of the preliminary evaluation of “Health Map” is related to the inability, at this time, to present follow-up data post-intervention and thus assess the effectiveness of the “Health Map” trial. Additionally, some clients may also be attending general practitioners or other healthcare settings for care of other clinical issues (e.g. heart disease, diabetes, high-blood pressure care, etc). Thus, data presented in this chapter should be interpreted with this matter in mind. Finally, the audit of clinical notes only looked at 12 months back from intervention date for each “Health Map” participant and therefore many clinical issues (e.g. smoking status, high-blood pressure, diabetic status, hypercholesterolemia, etc) might have been assessed by clinicians when first attended the client (often when a more detailed clinical history is taken) and/or sometime after the first attendance. Thus, the past 12 months audit period might have missed some of these issues and consequently overestimate the proportions of clients without records of above referred clinical data. Many of these factors however are always relevant to a consultation (e.g. blood pressure, weight) and it is recommended that they are dealt with at each consultation.
A further weakness was that this was not a randomized study. I specifically choose not to design this as a randomized study for two main reasons. The first was that the intervention itself may have been affected by the consent process. The consent form would have included a number of recommended issues (get your blood pressure checked etc) and therefore the consent process itself may have had an effect on doctors or clients behavior. However undertaking this as a real clinical tool, we offered to half of the clients avoided this issue. We won’t know until it is evaluated the size of the effect. We sought advice from the ethics committee in this regard and they were comfortable for us to run this as an audit.

7.6. Conclusions

The preliminary data of “Health Map” shows that a significant proportion of its participants have a number of modifiable risk factors for heart disease (47% were smokers; 48% had insufficient physical activity; and 51% of were overweight or obese according to their Body Mass Index calculation). Therefore, it is expected that “Health Map” intervention would assist those in need to improve their health by modification of risk factors for heart disease. However, there were also some “Health Map” participants with comorbidities, including: 1% on treatment for diabetes; and 33% on lipid lowering drugs 9% on treatment for high-blood pressure. Regrettably, I was unable to present the complete evaluation of “Health Map” in this thesis due to time-limitations (as explained above).
Chapter 8: Conclusions and Recommendations

8.1. Introduction

More than 25 years have passed since the first cases of HIV/AIDS were reported in 1981 (CDC, 1981). Since the beginning of the HIV/AIDS epidemic, extensive research was carried out and great advances were made in our current knowledge on HIV/AIDS (Gottlieb MS, 2001). Australian researchers have also contributed significantly in the advancement of our current knowledge on HIV/AIDS (Lewin SR et al., 2006). According to one notorious researcher in the field of HIV/AIDS (Fauci AS, 2003), the advent of HAART was the second most striking advance after the identification of HIV as the causative agent for AIDS. Furthermore, HAART is considered as one of the most cost-effective treatment made available for any currently recognized chronic disease (Jones R and Gazzard B, 2006).

In Australia, as in many other developed countries, HAART was introduced as part of the continuum of care for PLWHA since 1996 (Kaldor J and McDonald A, 2003). However, health care in Australia is distinctive from many other developed countries in the sense that it is of relatively high-standard and it is fully funded and freely provided by the Australian Federal Government. Furthermore, PLWHA in Australia have free access to a diverse range of anti-HIV drugs, including those that are newly released in the market. These characteristics of health care in Australia are relevant when interpreting the findings of several studies presented in this thesis (e.g. adherence studies or evaluation of “Health Map”).
There is no doubt that the introduction of HAART as a continuum of care for PLWHA positively changed the characteristics of HIV/AIDS epidemic, contributing for significant declines of HIV/AIDS-related morbidity and mortality rates (Gottlieb MS, 2001; Sabin CA, 2002). In fact, HAART allowed the discontinuation of prophylaxis against recurrent opportunistic infections in HIV-infected individuals (Kaplan JE et al., 2002), improved the longevity and the quality of life of PLWHA (Nunez M et al., 2001) and transformed HIV/AIDS into a chronic and manageable illness (Siegel K and Lekas H-M, 2002). Thus, a new era began with HAART (Elford J, 2006; Gottlieb MS, 2001), often referred as the “HAART era” (Sabin CA, 2002). However, HAART also brought with it new challenges and issues for researchers working in the field of HIV/AIDS (Blower S et al., 2003).

Some of these issues are directly related to the use of HAART while others are indirectly related to HAART. Issues indirectly related to HAART were dealt in this thesis under the subheading “Issues on prevention of HIV/AIDS in HAART era” (studies presented in Chapters 3 and 4). On the other hand, those directly related to the use of HAART were dealt under the subheading “Issues on management of HIV/AIDS in HAART era” (studies presented in Chapters 5, 6 and 7). Thus, in this chapter of my thesis I will present first the key findings of my studies under the above mentioned subheadings and subsequently I will suggest some implications and recommendations based on findings of studies presented in this thesis within same subheadings.
8.2. Key findings from studies presented in the thesis
8.2.1. From HIV/AIDS prevention studies

Within “HIV/AIDS prevention” subheading I have presented two studies: “Perceptions Study” (in Chapter 3) and “HIV-superinfection Study” (in Chapter 4). In both studies the participants were MSM mainly because MSM continues to represent more than two thirds of all PLWHA as well as newly diagnosed HIV infections in Australia (National Centre in HIV Epidemiology and Clinical Research, 2006; UNAIDS/WHO, 2006).

The first study (“Perceptions Study”) aimed to assess whether the sexual practices of HIV-negative or untested MSM was related to their perceptions of what it is like to live with HIV/AIDS, their beliefs or their attitudes to HAART. This study did not find significant differences between beliefs, attitudes and perceptions about HIV/AIDS, knowledge of post-exposure prophylaxis (PEP) or exposure to the HIV/AIDS epidemic among those who had had UAI with casual partners and those that had not (P>0.12). Those who considered that low levels of viral load and withdrawing before ejaculation reduced the risk of HIV transmission were significantly more likely to have had UAI with a casual partner (P>0.03). Only a minority of MSM engaging in UAI were optimistic about antiretroviral therapy. The study participants were in general pessimistic about life with HIV/AIDS despite their risk-taking sexual behaviour. This later finding nonetheless suggests that there is a certain naivety among HIV-negative or untested MSM about the lived experience of HIV/AIDS. This naivety, if truly present, may reaffirm the view held by many people that HIV/AIDS is receding in visibility in Australia and other developed countries where
HAART has been used as part of the standard of care for PLWHA since the mid-1990s.

The second study ("HIV-superinfection Study") aimed to determine the upper limit for the incidence of clinically important HIV-superinfection by determining the incidence at which HIV-infected MSM showed an unexplained and sustained decline in CD4 T-cell counts and/or unexplained increases in their plasma HIV RNA and also to determine if they were more likely to have engaged in unsafe sex with their casual partners than other HIV-infected MSM. In this study it was found that only a small proportion (about 3% per year) of eligible HIV-infected MSM had a sudden, unexplained and sustained fall in CD4 T-cell counts and/or increase in plasma HIV RNA values that could be consistent with possible HIV-superinfection. This finding is similar to the reported rates of HIV-superinfection in the literature (as discussed in Chapter 4). There were no statistically significant differences between cases and controls in regard to sexual practices that may have exposed them for acquisition of HIV-superinfection (p-value ≥0.4) or in their perceptions/beliefs of HIV superinfection (p-value ≥0.3). Only a minority of the study participants reported no previous knowledge of HIV-superinfection (17%, 5/30). Overall, both cases and controls were engaging frequently in unsafe sexual practices with casual partners who were HIV-infected (80% and 52% respectively; p-value=0.4) and/or whose HIV-serostatus were unknown (40% and 50% respectively; p-value=1.0). The rate of clinically significant HIV-superinfection in this cohort of sexually active MSM was likely to be less than 4% per year. This estimate is similar to what other investigators have reported of between 0 to 6.5% per year.
8.2.2. From HIV/AIDS management studies

Within “HIV/AIDS management” subheading I have presented two studies: “Adherence Study” (divided in two parts, part I presented in Chapter 4 and part II in Chapter 5) and “Health Map” trial evaluation (in Chapter 7).

The success of HAART is largely dependant on almost 100% adherence to it. With “Adherence Study” the primary aim was to understand from patients’ own perspectives and experiences what resulted in some individuals having 100% adherence to HAART while others having poor-adherence (<95% adherence). Thus, a two part study was carried out: the first part related to 100% adherence to HAART while the second part related to poor-adherence to HAART (defined as <95% adherence).

From the accounts of the participants who took part in the first part, I found that having 100% adherence to HAART resulted from the combination of the following issues: trust in the effectiveness of HAART; readiness to go on HAART; optimal integration of HAART regimens into individual life-styles; daily routinization of HAART pills taking behaviour; planning ahead for events disrupting daily routines to avoid missing or forgetting to take HAART pills; adequate knowledge of side-effects and working out of best possible coping strategies; use of personalized tools and reminders for HAART pills taking times; development of trust and best possible relationship with personal clinicians and other healthcare workers; as a consequence of being on HAART, attitudes of healthiness and improved wellbeing was developed which was reinforced by improvements in biological parameters that are routinely used to assess HIV-infection progression; HAART viewed as a life-
line and thus as an integral part of their lives; with continuous development and availability of new/alternative HAART regimens optimism and positive future outlook was reinforced. This study findings were consistent with the available literature on adherence, particularly with those reporting on 100% adherence to HAART (as discussed in Chapter 5).

From the accounts of the study participants who took part in the first part, I found that having 100% adherence to HAART I concluded that poor-adherence is an intermittent experience which happens mainly because of the following issues separately and/or in combination: forgetfulness as a consequence of disruption of daily-routines or drug and/or alcohol binges; intolerable short-term side-effects (mainly nausea and vomiting); sleeping through HAART dose taking times; being away from home; fear of being identified as HIV-infected and other psychosocial issues related to living with HIV/AIDS (depression, socialization, etc). Intermittent incidents of poor-adherence to HAART due to similar issues established in this study were also reported in the literature as discussed in Chapter 6.

However, there were a number of similarities between the findings of the two parts of “Adherence Study”. These similarities include: viewing HAART as a life-line for living longer and healthier; having a good relationship with healthcare professionals in general and regarding their doctors as the main source of information for their decision-making process for any issues related to HIV/AIDS; adopting a number of strategies to cope with side-effects related to anti-HIV drugs; adopting diverse strategies as reminders for timely
medication taking (linking with daily routines, using pill-box, setting-up alarms); and usually planning ahead when intending to travel and/or stay away from home for short periods of time. However, these similarities should be viewed within certain background as they might vary according to circumstances and psychosocial state of an individual living with HIV/AIDS. In fact, previous studies have shown that overcoming psychosocial issues contributes significantly for improvements in adherence levels (Alfonso V et al., 2006a; Enriquez M et al., 2004c) and patients on HAART with poor-adherence may change dramatically to become 100% adherent once they overcome psychosocial issues of living with HIV/AIDS (Enriquez M et al., 2004c). Several longitudinal studies have shown that HAART adherence varies along the time and different psychosocial factors and experiences with HAART accounts for different levels of adherence in different patients at different circumstances (Godin G et al., 2005a; Martini M et al., 2002; Schonnesson LN et al., 2006; Tesoriero J et al., 2003). Thus, I consider that the similar and dissimilar experiences and perceptions between those with 100% adherence and those with poor-adherence should be subjected to inferences within specific psychosocial and situational incident for each individual patient on HAART and within a specific time-interval. This suggestion is also in accordance with currently established knowledge that adherence to HAART is a dynamic behaviour determined by various interrelated experiences and perceptions that changes over time (Alfonso V et al., 2006a; Ickovics JR and Meade CS, 2002).

Overall, the study findings of both parts are consistent with the findings reported in a recently published review of qualitative studies on adherence to HAART (Vervoort SCJM et al., 2007) and reemphasizes the notion that medication adherence is
a complex phenomenon affected by multiple issues (Alfonso V et al., 2006b; Vermeire et al., 2001).

Finally the in Chapter 7 I presented baseline data from an individually tailored intervention for self-care of PLWHA on HAART (“Health Map” trial). This intervention was carried out because there are suggestions that appropriate management of dyslipidemia as well as lifestyle modification, such as smoking cessation, proper diet and exercise might help PLWHA living longer and healthier (Dubé MP et al., 2003). Thus, with the evaluation of “Health Map” I aimed to characterize the clinical and other features of PLWHA on HAART (e.g. HAART adherence, depression, modifiable cardiovascular risk factors). Unfortunately, due to time-limitations I was unable to present the complete evaluation of “Health Map” in this thesis.

Overall, participants of “Health Map” felt that the computer program was very easy to use and that the recommendations it provided were very useful. Furthermore, the preliminary data of “Health Map” shows that a significant proportion of its participants have a number of modifiable risk factors for heart disease (47% were smokers; 48% had insufficient physical activity; and 51% of were overweight or obese according to their Body Mass Index calculation). Additionally, there were also some “Health Map” participants with comorbidities, including: 1% on treatment for diabetes; and 33% on lipid lowering drugs 9% on treatment for high-blood pressure. Although no final conclusion can be made about the effectiveness of “Health Map” at this stage, similar interventions to facilitate behavioural change of multiple risk factors in primary healthcare setting proved to be significantly valuable for patients according to currently
available literature. Therefore, it is expected that “Health Map” intervention would be also valuable for patients who took part in it to improve their health by modification of risk factors for heart disease and adopting healthier lifestyles.

8.3. Implications and recommendations

8.3.1. From HIV/AIDS prevention studies

Both studies presented under the subheading of “HIV/AIDS Prevention” (Chapters 3 and 4) in this thesis showed poor association between perceptions/beliefs and attitudes with sexual practices. Although these studies were not intended for testing any particular theories, the findings presented in this thesis reaffirms some of the limitations inherent in some often employed theoretical models for predicting and explaining some risky human behaviours, including unprotected sexual practices (Weinstein ND, 2007). The fact that human behaviour is very complex and theoretical models are of limited usefulness in analysing these behaviours was, in my opinion, very adequately stated by one social scientist in the following way: “Risk perception depends more on contexts and situations than on knowledge or intrinsic individual characteristics, as assumes individualistic models, like notably the Health Belief Model.” (Paicheler G, 1999).

The “Perceptions Study” showed that some study participants were engaging in UAI due to their beliefs or perceptions about HIV/AIDS, confirming previous studies (see Chapter 2, section 2.4.4.). On the other hand, the “HIV-superinfection Study” findings indicate that considerable unsafe sexual practices occur despite a growing number of HIV-superinfection cases reports in biomedical literature.
Considerable UAI seems to be occurring among both HIV-negative as well as HIV-infected MSM and this confirms recent behavioural reports from Australia (National Centre in HIV Social Research (NCHSR), 2006), particularly from Victoria (Hull P et al., 2006). Increases in UAI in HAART era poses additional concerns related to transmission or acquisition of drug-resistant HIV strains, which might restrict treatment options for a newly HIV-infected individual or also for an individual already infected with HIV and consequently leading to a rapid progression of HIV-infection to AIDS and eventually death (Blackard JT and Mayer KH, 2004; Smith DM et al., 2005a; Steain MC et al., 2004).

Altogether, both studies illustrate that HIV prevention (primary and secondary HIV prevention) continues to be a challenge and that there continues to be a need for more research, particularly in current HAART era, aimed to enhance our current understanding on “issues of HIV/AIDS prevention in HAART era” presented in this thesis or other issues not discussed here (e.g. role of post-exposure prophylaxis in non-occupational prevention of HIV infection). It has been suggested that HIV prevention research studies need to be comprehensive and multidisciplinary targeting both primary and secondary HIV prevention and should take into account behavioural, clinical and biological factors related to HIV/AIDS (Auerbach JD and Coates TJ, 2000). Future research on HIV prevention should also need to take into consideration risk reduction and risk minimization strategies that many MSM might be adopting, as suggested by some researchers (Van de Ven et al., 2002). Australia has some successful experiences in the past with an inclusive, multisectoral and multilevel HIV prevention and care programs (Moodie R and Parnell B, 1994).
which, in my opinion, needs to be revisited and revitalized in present HAART era.

8.3.2. From HIV/AIDS management studies

Since the introduction of HAART a decade has passed and many advances were made, including: best regimens for HAART-naïve or HAART-experienced patients, as well as salvage therapy strategies; the importance of near perfect HAART adherence and implications of poor adherence; the clinical and laboratorial monitoring of HIV/AIDS. Furthermore, HAART-related metabolic side-effects and other toxicities were also identified (Carr A and Cooper DA, 2000; Simon K and Rotter K, 2002; Smith CJ et al., 2004) and suggestion were made to overcome and/or minimize their negative effects (Dubé MP et al., 2003).

Based on findings from both parts of “Adherence Study” and in accordance with currently available knowledge on HAART adherence I would recommend that all healthcare professionals working in HIV Care setting should develop suitable strategies to facilitate optimal adherence for all those on HAART and particularly for those individuals self-reporting difficulties in adhering to these medications.

Thus, with the above mentioned in mind, I would like to recommend the following issues that might be relevant in clinical practice in assisting PLWHA in maintaining 100% adherence to HAART: assessment of readiness to go on and to maintain optimal adherence to HAART; active involvement of PLWHA in the decisions about ARVT; considerations about the patients life-styles or preferences; encouragement to use
available reminder tools (e.g., pill-box, setting alarm, etc) and encouragement to establish daily routinization.

Nonetheless, it is important to keep in mind that adherence is “a dynamic process that requires ongoing attention from both the patient and care provider” (Alfonso V et al., 2006b) and adherence might significantly change over time for each patient (Godin G et al., 2005b; Martini M et al., 2002; Tesoriero J et al., 2003). Consequently continuous assessment and support based on best available evidence are of vital importance to keep patients having 100% adherence to HAART (Harman J J et al., 2005).

Finally, as HAART transformed HIV/AIDS into a chronic and manageable disease (Siegel K and Lekas H-M, 2002), PLWHA should be helped and encouraged to develop self-care strategies for longer and healthier lives. The “Health Map” program was designed to self-empower patients by providing self-tailored printed recommendations. While information/recommendation alone is not sufficient to promote behaviour change (Strecher V et al., 2002) it certainly represents a starting point for patients to reflect on recommendations provided and look forward to pursue healthy behaviours (e.g. smoking cessation, increase physical activity, adopt appropriate diet to control hypercholesterolemia, etc). Therefore, although no final conclusion can be made about the effectiveness of “Health Map” (for reasons mentioned above), interventions to facilitate behavioural change of multiple risk factors in primary healthcare setting seems to be significantly valuable for patients (Goldstein MG et al., 2004).
8.4. Concluding remarks

The scientific discovery of HIV as the causative agent of AIDS soon after first cases of HIV/AIDS were reported (Gallo RC and Montagnier L, 2003) was an important stepping-stone for subsequent scientific advances that has taken place and which culminated to the advent of HAART as a standard of care for PLWHA since 1996 (Fauci AS, 2003). However, HAART is not able to cure HIV infection and there is no effective preventative and/or therapeutic vaccine in prospect for the near future (McMichael AJ, 2006). Furthermore, according to the latest AIDS Epidemic Update (UNAIDS/WHO, 2006) the HIV/AIDS epidemic continues to grow in many parts of the World with an estimated 39.5 million (34.1 – 47.1 million) people living with HIV/AIDS (PLWHA) at the end of 2006 worldwide. There were an estimated 4.3 million (3.6 – 6.6 million) new HIV/AIDS cases reported worldwide and an estimated 2.9 million (2.5 – 3.5 million) people died of HIV/AIDS (UNAIDS/WHO, 2006). The socio-economic impact of HIV/AIDS pandemic continues to grow unabatedly, particularly in developing countries (UNAIDS, 2006).

A decade has past since HAART was introduced and because of its effectiveness in reducing morbidity and mortality related to HIV/AIDS many public health authorities have been working to expand prevention activities by including promotion of voluntary counselling and testing (particularly for at-risk subgroups of population such as HIV-negative MSM or sex-workers) and preventative counselling for PLWHA within the continuum of care (CDC, 2006; DiClemente RJ et al., 2002; Piot P et al., 2001; Valdiserri RO et al., 2003).
The great benefit brought by introduction of HAART was the transformation of HIV/AIDS into a chronic and manageable disease. However, in present HAART era, the challenges for health care workers and researchers working in the field of HIV/AIDS are enormous. In HIV prevention area the challenges includes better understanding of behavioural factors related to HIV infection transmission/acquisition with at-risk groups and/or among the general population. On the other hand, in HIV/AIDS management area includes not only discovery of new anti-HIV drugs with less toxicity but also improvements in care of PLWHA as many are now growing older and consequently predisposed to common age-related diseases. Therefore, efforts should continue on primary and secondary prevention of HIV infection/reinfection and should integrate HIV/AIDS prevention and care activities in concert (Auerbach JD and Coates TJ, 2000; Moodie R and Parnell B, 1994).
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active men engage in unprotected anal intercourse with regular and with casual partners. AIDS Care 14, 335 - 341.


Appendix 1: Award Certificate from oral poster presentation at 18th Annual Conference of the Australasian Society for HIV Medicine.
18th Annual Conference of The Australasian Society for HIV Medicine Inc.

is pleased to award

Mohsin Sidat

The 2nd prize for the Social Research Oral Poster entitled:

EXPERIENCES AND PERCEPTIONS OF HIV-INFECTED INDIVIDUALS WITH 100% ADHERENCE TO HAART – A PHENOMENOLOGICAL STUDY
Appendix 2: Ethics Committee approval letters for “Perceptions Study”.

224
15 February 2002

Professor Christopher Fairley
Director
Melbourne Sexual Health Centre
580 Swanston Street
CARLTON 3053

Dear Professor Fairley

Re: 86/01- Perceptions of how people live with HIV

The Department of Human Services Human Research Ethics Committee, at its meeting of 6 February 2002, considered and approved the amendments to the above project as outlined in your letter of 17 December 2001.

Yours sincerely

[Signature]

PROFESSOR JULIAN SAVULESCU
CHAIR
9 December 2003

Professor Christopher Fairley
Director
Melbourne Sexual Health Centre
580 Swanston Street
CARLTON 3053

Dear Professor Fairley

Re: 86/01- Perceptions of how people live with HIV

The Department of Human Services Human Research Ethics Committee, at its meeting of 3 December 2003, considered and approved the amendments to the above project as outlined in your amendment request of 7 November 2003 (including Plain Language Statement and Consent Form Version 1.2, dated 31 October 2003). Please make the following minor corrections to the Participant Information and Consent Forms:

1. Item 10 (page 3) – please note that Dr Cohen is the Executive Officer of the DHS HREC, not the Chair of the Committee
2. Consent Form – remove the phrase "in my first language" from the first sentence if the Participant Information and Consent Forms are not going to be translated into other languages.

Please forward the corrected documents to the Executive Officer of the DHS HREC for the Committee's records.

Yours sincerely

[Signature]

A/PROFESSOR MARJORIE DUNLOP
CHAIR
To:
Kate Murphy
Executive Officer
Human Research Ethics
Melbourne Research and Innovation Office
The University of Melbourne
VIC 3010
Australia
Telephone: +61 3 83442073
Fax: +61 3 93476739

Date: April 20, 2004

Dear Kate,

Subject: Registering studies approved by another Institution with MRIO.

My name is Mohsin M Sidat and I am a PhD Research Student (Melbourne University student number 193667) based in Melbourne Sexual Health Center. Professor Christopher Fairley is my supervisor. I am currently running a project entitled "PERCEPTIONS OF HOW PEOPLE LIVE WITH HIV". The Ethical Approval of this research protocol was obtained from Human Research Ethics Committee - Department of Human Services - 18/120 Spencer Street - Melbourne VIC 3000. I would like to register my current research project with MRIO and, therefore, I am sending, attached to this letter, the ethics approval letter from above mentioned Institution.

Yours Sincerely,

Mohsin M Sidat

Signature of Professor Christopher Fairley
29 June 2004

Professor C Fairley & M Sidat
Melbourne Sexual Health Centre, Public Health

Dear Professor C Fairley & M Sidat

Project Title: Perceptions of how people live with HIV
Principal Investigator/s: Professor C Fairley & M Sidat
HREC Register No: 040425

I am writing to advise you that the above project has been registered at this University as approved by another institution. Please take note of our HREC reference number above.

Please also note that you will need to submit an annual report to the Human Research Ethics Committee at the end of 2004. Requests for annual reports will be sent out in December 2004.

Yours sincerely,

Kate Murphy,
Executive Officer,
Human Research Ethics

e-mail: k.murphy@unimelb.edu.au

c.c. Chair, DHEAG, Melbourne Sexual Health Centre, Public Health
Appendix 3: Plain language statement and consent form used for the “Perceptions Study”.
PLAIN LANGUAGE STATEMENT

Version: 1.2
Dated: 31st October 2003
Site: Melbourne Sexual Health Centre
Full Project Title: Perceptions of how people live with HIV.

Principal Researcher: Christopher K Fairley
Associate Researchers: Susan Kippax, Marian Pitts, Anthony Smith, Patrick Rawstorne and Mohsin Siddat

This Plain Language Statement and Consent Form is 3 pages long. Please make sure you have all the pages.

1. Your Consent
You are invited to take part in this research project.

This research will contribute to the completion of a degree of PhD in Public Health by the student researcher Mohsin Siddat.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the Statement. You may also wish to discuss the project with a relative or friend or your local health worker.

Once you understand what the project is about and if you agree to take part in it, you will be asked to complete a questionnaire.

You will be given a copy of this Plain Language Statement to keep as a record, and a consent form to sign (attached).

2. Description of the Project
The purpose of this project is to determine how HIV-negative men who have sex with men (MSM) perceive the medical and social impact of being HIV-positive. To do this 260 MSM who are HIV negative will be asked to participate in this study.
The study is being conducted to identify if educational material may be improved. Recent reports have indicated an increase in the proportion of MSM who have been participating in unsafe anal intercourse (UAI). Reasons for the increase in unprotected sex are unclear. Anecdotal reports have suggested that many MSM have grown tired of the existing safe sex messages and are dismissive of the threat of HIV/AIDS. It is possible that some MSM are 'out of touch' with the lived experience of HIV-positive MSM, which has contributed to their safe sex complacency. Findings may result in the development of more effective and comprehensive education messages in the future.

You are invited to participate in this research project because you are attending the Melbourne Sexual Health Centre today.

Participation in this project will involve answering a questionnaire about your sexual practices.

3. Possible Benefits
Participation may increase your basic knowledge and personal concern about HIV, and possibly encourage safe sex practices.

4. Possible Risks
Answering the questionnaire may cause some anxiety.

We have trained counselling staff at the Melbourne Sexual Health Centre should you need or request this, and other specialised staff on hand to answer any questions you may have regarding HIV/AIDS.

5. Alternatives to Participation
You don't need to participate in this study. If you have any questions about HIV/AIDS and safe sex practices, the Centre's nurses are available to assist with information or referral.

6. Confidentiality and Disclosure of Information
Your participation is confidential.

The questionnaire will be stored in a locked cabinet in the research unit (separate from the clinic) and will remain confidential. No questionnaires will have your name on them. Following completion of the study all related documents or information will be archived for a minimum of seven years (according to A GUIDE TO GOOD RESEARCH PRACTICE – MELBOURNE SEXUAL HEALTH CENTRE)

7. New Information Arising During the Project
Findings may highlight how to encourage safe sex practices of individuals most at risk of infection.

8. Results of Project
The Results will be published in the Melbourne gay press but without any identifying information (for example, it may report that 30% of the group thought drugs were difficult to take for HIV positive people). If you would like a detailed report please indicate this to us and we will provide you with it once the study is complete.

9. Further Information or Any Problems
If you require further information or if you have any problems concerning this project, you can contact the principal researcher Christopher Fairley on 03 9347 0244 or Anthony Smith on 03 9285 5304.

Melbourne Sexual Health Centre
10. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact

Name: Christopher K Fairley
Position: Director, Melbourne Sexual Health Centre
Telephone: 03 9347 0244

In the event that you have complaints about this study, and you are not satisfied that your concerns have been addressed, then you may contact

Name: Dr Donna Cohen
Position: Executive Officer, Human Research Ethics Committee, Department of Human Services
Address: Department of Human Services
         18/120 Spencer Street, Melbourne VIC 3000

11. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Melbourne Sexual Health Centre.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw.

12. Ethical Guidelines

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of this Institution.

This study has also been approved by the Melbourne Sexual Health Centre.
CONSENT FORM

I have read, or have had read to me, and I understand the Plain Language Statement version 1.2 dated 31-10-03.

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have a copy of the Plain Language Statement and the Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant’s Name (printed) ..............................................................
Signature  Date

Witness to Signature (printed) ..........................................................
Signature  Date

Researcher’s Name (printed) ..............................................................
Signature  Date
Appendix 4: Questionnaire used for "Perceptions Study".
complete this questionnaire, please follow the instructions in each SECTION.

Participation in this project involves answering this questionnaire. To future participation in this project involves answering this questionnaire. To development of more effective and comprehensive education messages in the impact of being HIV-positive. Findings of this study may result in the to determine how you as HIV-negative person perceive the medical and social to determine how you as HIV-negative person perceive the medical and social

Thank you for participation in this project. Your participation is very important

CONFIDENTIAL QUESTIONNAIRE
VERSION: 1.2 - DATED: 31ST OCTOBER 2003
PROJECT: PERCEPTIONS OF HOW PEOPLE LIVE WITH HIV.
This section asks for your perceptions (what you think) about people living with HIV/AIDS.

For each question, please mark your answer as demonstrated below:

Example Question
A. What percentage of people living with HIV/AIDS do volunteer work?

[ ] 0% (none) [ ] 10% [ ] 20% [ ] 30% [ ] 40% [ ] 50% [ ] 60% [ ] 70% [ ] 80% [ ] 90% [ ] 100% (all)

SECTION 1.

1. What percentage of people living with HIV/AIDS would regard their general health as excellent or good?

[ ] 0% (none) [ ] 10% [ ] 20% [ ] 30% [ ] 40% [ ] 50% [ ] 60% [ ] 70% [ ] 80% [ ] 90% [ ] 100% (all)

2. What percentage of people living with HIV/AIDS are currently taking anti-HIV drugs?

[ ] 0% (none) [ ] 10% [ ] 20% [ ] 30% [ ] 40% [ ] 50% [ ] 60% [ ] 70% [ ] 80% [ ] 90% [ ] 100% (all)

3. What percentage of people living with HIV/AIDS visit their doctor at least once every three months?

[ ] 0% (none) [ ] 10% [ ] 20% [ ] 30% [ ] 40% [ ] 50% [ ] 60% [ ] 70% [ ] 80% [ ] 90% [ ] 100% (all)

4. What percentage of people living with HIV/AIDS are currently taking anti-HIV drugs?

[ ] 0% (none) [ ] 10% [ ] 20% [ ] 30% [ ] 40% [ ] 50% [ ] 60% [ ] 70% [ ] 80% [ ] 90% [ ] 100% (all)

5. What percentage of people living with HIV/AIDS experienced diarrhea related to HIV or from taking anti-HIV drugs?

[ ] 0% (none) [ ] 10% [ ] 20% [ ] 30% [ ] 40% [ ] 50% [ ] 60% [ ] 70% [ ] 80% [ ] 90% [ ] 100% (all)

6. In the past month, what percentage of people with HIV/AIDS experienced diarrhea related to HIV or from taking anti-HIV drugs?
14. As a medical service, what percentage of gay men living with HIV/AIDS report that they have at some point in the past experienced less favorable treatment as a result of having HIV/AIDS?

13. At work, what percentage of gay men living with HIV/AIDS have at some point in the past experienced less favorable treatment than other people as a result of having HIV/AIDS?

12. What percentage of gay men living with HIV/AIDS are currently in paid full-time work?

11. What percentage of gay men living with HIV/AIDS are not having sex at present?

10. What percentage of people with HIV/AIDS regard their idiosyncratic (sex drive) as poor?

9. How many (depression or lack thereof) led to HIV or from taking anti-HIV drugs?

8. What percentage of people with HIV/AIDS would regard their sleeping patterns as poor?

7. In the past year, what percentage of people with HIV/AIDS experienced productive symptoms related to HIV or from taking anti-HIV drugs?

6. In the past week, what percentage of people with HIV/AIDS experienced emotional problems (such as depression, frustration, irritability, tension, or anxiety)?

5. In the past month, what percentage of people with HIV/AIDS experienced emotional problems?

4. In the past year, what percentage of people with HIV/AIDS experienced emotional problems?
This section asks how much you agree with the following statements.

**SECTION 2.**

[Example statement: Drug companies are more concerned with profit than providing safe treatments.]

For each statement, please tick the correct answer as demonstrated below:

- Strongly agree
- Agree
- Disagree
- Strongly disagree

1. If a sexual partner wants to have unprotected sex, I can assume that he is the
same HIV status as me.
2. You can tell if someone has or hasn't got HIV/AIDS by the way they look and
what they do sexually.
3. Withdrawing before ejaculation (cumming) is a way for a sexual partner to
reduce the risk of transmitting HIV.
4. People with undetectable viral load do not need to worry so much about infecting
others with HIV.
5. New treatments will take the worry out of sex.
6. People with undetectable viral load do not need to worry so much about infecting
others with HIV.
7. You can tell if someone has or hasn't got HIV/AIDS by the way they look and
what they do sexually.
8. Withdrawing before ejaculation (cumming) is a way for a sexual partner to
reduce the risk of transmitting HIV.
In this survey, we distinguish between CASUAL partners and REGULAR partners (boyfriend/lover). This section asks about your activities with recent sexual partners (casual and as a regular partner) and recreational drug use.

For each question, please tick the correct answer.

For each question, please tick the correct answer.

For each question, please tick the correct answer.

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For each question, please tick the correct answer.

For each question, please tick the correct answer.

For each question, please tick the correct answer.

For each question, please tick the correct answer.
44.) How many people do you know personally who have died from AIDS related illness

☐ More than 10
☐ 6-10
☐ Other
☐ None

☐ Yes ☐ No

45.) Have you received Pep in the last 6 months?

☐ Yes ☐ No

46.) Do you know anyone who has received Pep?

☐ Yes ☐ No

47.) Unsure / Don't Know

48.) How many of your close friends are HIV-positive?

☐ All ☐ Some ☐ None

49.) How many of your close friends are HIV-negative?

☐ All ☐ Some ☐ None

50.) How much of your free time do you spend with HIV-positive people?

☐ All ☐ Some ☐ None

This section asks about your experience with HIV testing and HIV positive people.
Please, hand this completed questionnaire
in the envelope to the RECEPTION STAFF.

Thank you for your time.

You have completed the survey.

SECTION 6.

This section will ask you a few questions about yourself.

SECTION 5.

Appendix 4.

54. What is your occupation?

☐ University or CAE
☐ Tertiary diploma or Trade Certificate / TAFE
☐ Year 12
☐ Less than or up to 2 years of high school / Year 10

53. What is the highest level of education you have had?

☐ Other
☐ Pensioner on social security benefits
☐ Student
☐ Unemployed
☐ Employed part-time
☐ Employed full-time

52. Are you (tick one only)

☐ Anglo-Australian
☐ Other (please specify)

51. What is your ethnic background? (e.g. Australian Aboriginal, Chinese, Vietnamese)

☐ Yes
☐ No

50. Are you of Aboriginal or Torres Strait Islander origin?

☐ Other (please specify)

49. What country were you born in?

☐ Australia

48. How old are you?

[ ] 50 - 59
[ ] 60 - 69
[ ] 70 - 79
[ ] 80 - 89
[ ] 90 - 99
[ ] 100 or older

For each question, please indicate your answer by ticking the appropriate box or filling in the gap.
Appendix 5: Ethics Committee approval letters for “HIV Superinfection Study”.
This is to certify that

Project No: 101/04

Project Title Case-Control Study of superinfection with HIV-1 among men who have sex with men (MSM)

Principal Researcher: Dr Christopher Fairley

Participant Information and Consent Form version 1.2 dated: May 2004

has been considered by the Ethics Committee and is APPROVED.

Approval date: 30/07/2004   Expiry date: 30/07/2006

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report every 12 months for the duration of the project (forms to be provided);
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

The Alfred Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

SPECIAL CONDITIONS

None

SIGNED: [Signature]  DATE: 30/07/04

Chair, Ethics Committee (or delegate)

Please quote Project No and Title in all correspondence

R. FREW
SECRETARY
ETHICS COMMITTEE
ALFRED ETHICS COMMITTEE

Request for Approval of Amendments

Alfred Project No: 101/04
Project Title: Case-Control Study of superinfection with HIV-1 among men who have sex with men (MSM)

Chief Researcher: Professor Christopher K Fairley

- What changes have occurred or are intended?
  Changes were made to the formatting of the questionnaire as well as some changes to the Section 1, such as wording changes and inclusion of some new questions. Additionally, we also included a completely new section (i.e. Section 4).

- Please explain the reason for these changes.
  These changes resulted after piloting our previous questionnaire with few patients.

- Do you believe these changes raise any ethical issues? Yes/No

1. Have you provided two (2) copies of this form? Yes/No

2. Have you provided two (2) copies of the sections of the most recently approved ethics application with all additions underlined and any deleted original text struck through, including the protocol if relevant, to which these amendments refer, and/or summaries of changes to the protocol? Yes/No

3. Do you believe the Plain Language Statement needs to be changed? Yes/No

A fee of $550 may be levied if the amendment was initiated by a commercial sponsor. In this instance, a tax invoice will be sent by The Alfred to the sponsor.

Did a commercial sponsor initiate this amendment? Yes/No

Project contact person:
Professor Christopher K Fairley
Melbourne Sexual Health Centre
580 Swanston Street, Carlton, VIC 3053

Chief Researcher’s Signature:
Professor Christopher K Fairley

Date: 12-11-04

Version: January 2004
Ethics Committee

Certificate of Approval of Amendments

This is to certify that amendments to

Project 101/04 Case-Control Study of superinfection with HIV-1 among men who have sex with men (MSM)

Chief Researcher: Dr Christopher Fairley

Study Questionnaire Version 1.3 dated: 1/10/2004

have been approved in accordance with your amendment application on the understanding that you observe the National Statement on Ethical Conduct in Research Involving Humans.

It is now your responsibility to ensure that all people associated with this particular research project are made aware of what has actually been approved and any caveats specified in correspondence with the Ethics Committee. Any further change to the application which is likely to have a significant impact on the ethical considerations of this project will require approval from the Ethics Committee.

Chair, Ethics Committee (or delegate) Date: 24/11/2004

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

The Alfred Ethics Committee is a properly constituted Human Research Ethics Committee operating in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).
To:
Kate Murphy
Executive Officer
Human Research Ethics
Melbourne Research and Innovation Office
The University of Melbourne
VIC 3010
Australia
Telephone: +61 3 83442073
Fax: +61 3 93476739

Date: 18th August, 2004

Dear Kate,

Subject: Registering studies approved by another Institution with MRIO.

My name is Mohsin M Sidat and I am a PhD Research Student (The University of Melbourne, student number 193667), based in Melbourne Sexual Health Center. Professor Christopher Fairley is my principal supervisor.

I have my second project entitled "Case-Control Study of superinfection with HIV-1 among men who have sex with men (MSM)" approved by the Ethics Committee of the Alfred Hospital (Project number 101/04).

I would like to register this my second research project with MRIO and, therefore, I am sending, attached to this letter, the ethics approval letter from the above mentioned Institution as well as the detailed protocol of the project, plain language statement, consent form and the questionnaire.

Yours Sincerely,

Mohsin M Sidat
23 August 2004

Professor C Fairley
Melbourne Sexual Health Centre, Public Health

Dear Professor C Fairley

Project Title: Case-control study of superinfection with HIV-1 among men who have sex with men (MSM) 101/04
Principal Investigator/s: Professor C Fairley & Mr M Sidat
Other Investigators: A Mijch, J Hoy & S Lewin
HREC Register No: 040586

I am writing to advise you that the above project has been registered at this University as approved by another institution. Please take note of our HREC reference number above.

Please also note that you will need to submit an annual report to the Human Research Ethics Committee at the end of 2004. Requests for annual reports will be sent out in December 2004.

Yours sincerely,

Kate Murphy,
Executive Officer,
Human Research Ethics

e-mail: k.murphy@unimelb.edu.au

c.c. Chair, DHEAG, Public Health
Mr Mohsin Sidat
Appendix 6: Plain language statement and consent form used for the “HIV Superinfection Study”.
1. Your Consent

You are invited to take part in this research project.

This research will contribute to the completion of a degree of PhD in Public Health by the student researcher Mohsin M Sidat.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the Statement. You may also wish to discuss the project with a relative or friend or your local health worker.

Once you understand what the project is about and if you agree to take part in it, you will be asked to complete a questionnaire and provide permission to have your previously collected blood samples analysed.

You will be given a copy of this Plain Language Statement to keep as a record, and a consent form to sign (yellow page).

2. Description of the Project

The purpose of this Project is to identify some of the reasons why some HIV positive men-who-have-sex-with-men (MSM) who have a sudden decline in their CD4 count and/or rise in their viral load.

About 60 HIV-positive MSM not on antiretroviral treatment in the past 2 years who show declines in their CD4 count and/or rise in their viral load will be invited to participate in this study. These 60 participants will be the called as CASES of this study and they will be identified by reviewing their medical records for CD4/Viral Load Count Profile. The characteristics of these men will be compared to 240 other participants who will constitute a CONTROL GROUP.

Eligible participants for this study will be invited by their attending Clinician. The participation in this study is voluntary and involves answering a questionnaire (attached) and allowing the Researchers to analyse stored blood samples (one recently collected and another collected about 2 or more years ago) to look for evidence of infection with a second HIV virus (this is called HIV
The reason for analysing blood samples is to determine whether or not HIV superinfection is associated with any particular behaviour (e.g. sexual or injecting drug use).

3. Possible Benefits
Participation may increase your knowledge and understanding about HIV superinfection.

4. Possible Risks
Answering the questionnaire may cause some anxiety. The questions ask about your sexual behaviour over the last 2 years and about injecting drug use.

If you become concerned about these issues please inform the Clinic staff who can arrange counsellors to discuss these issues with you.

5. Alternatives to Participation
Your participation in this study should be voluntary.

6. Privacy, Confidentiality and Disclosure of Information
Your participation in this study is confidential.

The questionnaire will be stored in a locked cabinet in the research unit at Melbourne Sexual Health Centre. If you are seen at the Melbourne Sexual Health Clinic for your regular HIV care, you should understand that the questionnaire will be kept separate from the clinic where your medical records are kept. All information in the questionnaires will remain confidential. No questionnaires will have your name on them. Following completion of the study all related documents or information will be archived indefinitely, in accordance with the Alfred Hospital guidelines.

7. Results of Project
The Results will be published in a medical journal but without any identifying information. If you would like a detailed report of this Project please indicate this to us on the consent form.

8. Further Information or Any Problems
If you require further information or if you have any problems concerning this project, you can contact the researcher Mohsin M Sidat by telephone on 03 9341 6247 or by e-mail: msidat@mshc.org.au
9. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

Name: Professor Christopher K Fairley
Position: Director, Melbourne Sexual Health Centre
Telephone: (03) 9347 0244

In the event that you have complaints about this study, and you are not satisfied that your concerns have been addressed, then you may contact:

Name: Ms. Rowan Frew
Position: Ethics Manager, The Alfred Hospital Research and Ethics Unit.
Telephone: (03) 9276 3848

10. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Melbourne Sexual Health Centre and The Alfred Hospital.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw.

11. Ethical Guidelines

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The Human Research Ethics Committee of The Alfred Hospital and Melbourne Sexual Health Centre has approved the ethical aspects of this research project.
I have read, or have had read to me, and I understand the Plain Language Statement (green pages) version 1.2 dated of May 2004.

I freely agree to participate in this project according to the conditions in the Plain Language Statement. I also authorize the Researchers to analyse stored samples of my blood for the purposes of the study as explained in the Plain Language Statement.

I have a copy of the Plain Language Statement to keep.

I am aware that all data obtained within this study will be kept indefinitely, in accordance with the Alfred Hospital guidelines. The Researchers has agreed not to reveal my identity and personal details if information about this study is published or presented in any public forum.

Participant’s Name (printed) .............................................................

Signature:                    Date:

Witness to Signature (printed) ..........................................................

Signature:                    Date:

Note: All parties signing the Consent Form must date their own signature.
Consent Form – Study version 1.2 / May 2004
Appendix 7: Questionnaire used for “HIV Superinfection Study”.
Complete this questionnaire, please follow the instructions in each section.

Participation in this project involves answering this questionnaire. To cells counts and/or increase in viral loads in the future.

information that can help to devise a prevention strategy to avert falls in these language statements (green pages). Findings of this study may provide and/or increase in their viral load that we cannot explain (as explained in Plane and understand why some people experience falls in their CD4 T-cell counts.

Thank you for participation in this project. Your participation is very important.
Please follow the instructions in each section.

Participating in this project involves answering this questionnaire. To cells counts and/or increase in viral loads in the future. Information that can help to devise a prevention strategy to avert falls in these language statements - green pages. Findings of this study may provide and/or increase in their viral load that we cannot explain (as explained in Plain to understand why some people experience falls in their CD4 T-cell counts.

Thank you for participating in this project. Your participation is very important.

Appendix 6:
### Part A: Sexual Relationships (including steady or non-regular partners)

For each question, please fill in the blank spaces and/or check the correct answer.

**In this survey we distinguish between Regular and Casual partners,**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many <em>regular</em> male partners have you had in the last 2 years?</td>
<td>None □ Some □ Don't know □ Unknown HIV-status □</td>
</tr>
<tr>
<td>2b. How many of these <em>regular</em> partners were HIV-positive?</td>
<td>None □ Some □ Don't know □ Unknown HIV-status □</td>
</tr>
<tr>
<td>3a. Have you had anal and/or sex without a condom with any of your male regular partners (who were/were not HIV-positive in the last 2 years)?</td>
<td>None □ Yes □</td>
</tr>
<tr>
<td>3. On average, how many months were you in a relationship without sex without a condom?</td>
<td>□ Some □ Please specify in numbers</td>
</tr>
<tr>
<td>3c. On average, how many months were you in a relationship without a condom?</td>
<td>□ Some □ Please specify in numbers</td>
</tr>
<tr>
<td>3d. On average, how many times you had anal intercourse?</td>
<td>□ Some □ Please specify in numbers</td>
</tr>
<tr>
<td>3e. On average, how many times you had vaginal sex?</td>
<td>□ Some □ Please specify in numbers</td>
</tr>
<tr>
<td>3f. On average, how many times you had oral sex?</td>
<td>□ Some □ Please specify in numbers</td>
</tr>
</tbody>
</table>

**Section 1: This section asks about your sexual practices with your partners.**
If none, then please go to question number 14, page 6.

6. How many CASUAL male partner(s) did you have in the last 2 years?

PART B: SEXUAL RELATIONSHIP WITH CASUAL PARTNER(S)

5. We are particularly interested in the 6 months before. Did you have more anal sex within condom with your regular partner(s) in this period than you had on average in the past 2 years? [ ] Yes [ ] No

4c. On average, how many months were you in a relationship when you were having anal intercourse without condom? [__] months (in numbers)

4d. On average, how many times you had anal intercourse without condom? [__] times (in numbers)

4b. On average, how many times you had anal intercourse without condom? [__] times (in numbers)

4a. Have you had anal sex without condom with any of your male regular partner(s) who was/were of unknown HIV-status in the last 2 years? [ ] Yes [ ] No

Appendix: ?
<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>6a. Have you had sex without a condom with any of your male casual partners (who was/were HIV-positive in the last 2 years)?</td>
<td>Don't know □</td>
</tr>
<tr>
<td>6b. How many of these casual partners were HIV-positive?</td>
<td>□</td>
</tr>
<tr>
<td>7a. How many times in the last 2 years, how many times you had anal intercourse?</td>
<td>None □</td>
</tr>
<tr>
<td>7b. On average, how many months were you in a relationship when you were having anal intercourse?</td>
<td>None □</td>
</tr>
<tr>
<td>7c. On average, how many months were you in a relationship when you were having anal intercourse?</td>
<td>None □</td>
</tr>
<tr>
<td>8a. Have you had sex without a condom? with any of your male casual partners (who was/were HIV-positive in the last 2 years)?</td>
<td>Don't know □</td>
</tr>
<tr>
<td>8b. How many of these casual partners were HIV-positive?</td>
<td>□</td>
</tr>
<tr>
<td>9a. How many times in the last 2 years, how many times you had anal intercourse?</td>
<td>None □</td>
</tr>
<tr>
<td>9b. On average, how many months were you in a relationship when you were having anal intercourse?</td>
<td>None □</td>
</tr>
<tr>
<td>9c. On average, how many months were you in a relationship when you were having anal intercourse?</td>
<td>None □</td>
</tr>
</tbody>
</table>
If you have never used injecting drugs, then please go to questions of Section 3 (page 6)

For each question, please indicate your answer by ticking the appropriate box or filling the gap.

### Section 2: The Following questions are about injecting drug use

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. How many times you had anal sex with your partner(s) in this period?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. How many times you had anal sex without condom?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>46. On average, how many times you were having anal insertive sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>72. How many different people who were HIV positive (below)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>73. How many different people who were HIV positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>74. Some - Please specify in numbers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75. Some - Please specify in numbers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>76. None - Please specify in numbers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15. During the last 2 years have you been away from your work for more than 7 days because of illness?

Section 3: This section will ask you few questions about your previous medical conditions.

14a. Sharing needles are not a problem if your viral load...
14b. I worry about injecting others by sharing needles.

14. Please indicate how you feel about the following statements:

- [ ] None of the above options apply
- [ ] Yes
- [ ] No
- [ ] I used the injecting equipment last
- [ ] The other person was also HIV-positive
- [ ] The person was my sexual partner
- [ ] The needle was disinfected and/or washed
- [ ] I was in a group
- [ ] We did not have access to other needles
- [ ] The person was HIV-positive
- [ ] The needle was disinfected and/or washed

13. The last time you shared injecting equipment which of the following describes the circumstances?

Appendix 7:
<table>
<thead>
<tr>
<th>Month/Year</th>
<th>Reason for Vaccination Received</th>
<th>Type of Vaccination Received</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If yes, please specify each vaccination you had and when did you have them (please write on the box below):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes □ No □</td>
<td></td>
</tr>
<tr>
<td>16. During the last 2 years have you received any vaccination?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes □ No □</td>
<td></td>
</tr>
<tr>
<td>17. During the last 2 years have you been diagnosed with Hepatitis B or Hepatitis C?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes □ No □</td>
<td></td>
</tr>
</tbody>
</table>

**Appendix**
20. You are concerned with becoming infected with HIV if engaged in unprotected sexual intercourse with a sexual partner who is HIV-positive or whose HIV-status is unknown to you:

- Strongly disagree
- Disagree
- Agree
- Strongly agree

20a. You believe that following infection with HIV can damage your health:

- Strongly disagree
- Disagree
- Agree
- Strongly agree

20b. You are concerned with becoming infected with HIV if engaged in unprotected sexual intercourse:

- Strongly disagree
- Disagree
- Agree
- Strongly agree

20c. You are concerned with becoming infected with HIV if engaged in unprotected sexual intercourse:

- Strongly disagree
- Disagree
- Agree
- Strongly agree

20d. Reinfected with HIV-1:

- Yes
- No

20e. You believe that the gap between someone who is HIV-positive and someone who is HIV-negative is too large:

- Yes
- No

For each question, please indicate your answer by clicking on the appropriate box or filling in the gap.

Section 4: This section asks you about your beliefs regarding HIV-1 reinfecion.
FOR YOUR PARTICIPATION IN THIS STUDY

THANK YOU

21. What is your occupation?

☐ University or CAE
☐ Tertiary diploma or trade certificate / TAFE
☐ Year 12
☐ Less than or up to 3 years of high school / Year 10

22. What is the highest level of education you have had?

☐ Other (please specify)
☐ Pensioner / social security benefits
☐ Unemployed
☐ Employed part-time
☐ Employed full-time

25. Are you: (tick one only)

☐ Anglo-Australian only
☐ Other

24. What is your ethnic background? (e.g. Australian Aboriginal, Dutch, Greek, Vietnamese, Lebanese, Chinese)

☐ Yes
☐ No

23. Are you of Aboriginal or Torres Strait Islander origin?

☐ Other (please specify)

22. What country were you born in?

☐ Australia

21. How old are you?

☐ years

For each question, please indicate your answer by ticking the applicable box, or filling the gap.

SECTION 5: THIS SECTION WILL ASK YOU A FEW QUESTIONS ABOUT YOURSELF.

Appendix 7:
Appendix 8: Ethics Committee approval letters for “Adherence Study”.
This is to certify that

**Project No:** 145/04

**Project Title** Qualitative study on adherence to highly active antiretroviral therapy (HAART)

**Principal Researcher:** Dr Jeffrey Grierson

**Participant Information and Consent Form version dated:** 1/10/2004

has been considered by the Ethics Committee and is APPROVED.

**Approval date:** 1/10/2004  **Expiry date:** 1/10/2006

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report every 12 months for the duration of the project (forms to be provided);
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

The Alfred Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

**SPECIAL CONDITIONS**

None

**SIGNED:** [Signature]

**DATE:** 1/10/06

Please quote Project No and Title in all correspondence

R. FREW
SECRETARY
ETHICS COMMITTEE
To:
Kate Murphy
Executive Officer
Human Research Ethics
Melbourne Research and Innovation Office
The University of Melbourne
VIC 3010
Australia
Telephone: +61 3 83442073
Fax: +61 3 93476739

Date: October 22, 2004

Dear Kate,

Subject: Registering studies approved by another Institution with MRIO.

My name is Mohsin M Sidat and I am a PhD Research Student (The University of Melbourne, student number 193667), based in Melbourne Sexual Health Center. Professor Christopher Fairley is my principal supervisor.

I have my third project entitled "Qualitative study on adherence to highly active antiretroviral therapy (HAART)" approved by the Ethics Committee of the Alfred Hospital (Project number 145/04).

I would like to register this third research project with MRIO and, therefore, I am sending, attached to this letter, the ethics approval letter from the above mentioned institution as well as the detailed protocol of the project, plain language statement, consent form and the questionnaire and the interview schedule.

Many thanks for your attention.

Yours Sincerely,

Mohsin M Sidat
1 December 2004

Professor C Fairley & Mr M Sidat
Department of Melbourne Sexual Health Centre, Public Health

Dear Professor C Fairley & Mr M Sidat

Project Title: Qualitative study on adherence to highly active antiretroviral therapy (HAART)
Principal Investigator/s: Professor C Fairley & Mr M Sidat
Other Investigator/s: Dr J Grierson
HREC Register No: 040856

I am writing to advise you that the above project has been registered at this University as approved by another institution. Please take note of our HREC reference number above.

Please also note that you will need to submit an annual report to the Human Research Ethics Committee at the end of 2004. Requests for annual reports will be sent out in December 2004.

Yours sincerely

Kate Murphy
Executive Officer,
Human Research Ethics

e-mail: k.murphy@unimelb.edu.au

c.c. Chair, DHEAG, Public Health
Mr Mohsin Sidat
Appendix 9: Plain language statement and consent form used for the “Adherence Study”.
1. Your Consent

You are invited to take part in this research project.

This research will contribute to the completion of a degree of PhD in Public Health by the student researcher Mohsin M Sidat.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the Statement. You may also wish to discuss the project with a relative or a friend or your local health worker.

Once you understand what the project is about and if you agree to take part in it, you will be asked to complete a brief questionnaire and to participate in an interview that will be at maximum 2 hours long. This interview will be tape-recorded.

You will be given a copy of this Plain Language Statement to keep as a record, and a consent form to sign (yellow page).

2. Description of the Project

The aim of this project is to understand the sociobehavioural issues related to being HIV-positive and taking antiretroviral medication as prescribed, as well as to understand how the experience of being HIV-positive and on Highly Active Anti-Retroviral Treatment (HAART) with its demands and complexities affects the behaviour to adhere or not to the medication.

For this study 30 to 40 participants will be interviewed, both with good and poor adherence to HAART. All the interviews will be audio-recorded and transcribed verbatim for further data analysis. All identifying data will be changed to maintain participant anonymity.

The participation in this study is voluntary and involves answering a brief questionnaire that will take about five minutes to complete and taking part in an interview lasting for a maximum of two hours.
The findings may help to identify issues related to poor adherence as well as what helps to improve adherence and assist in defining strategies to optimise adherence of patients to the challenging and life-long treatment that HAART represents to HIV-infected individuals.

3. Possible Benefits

Participation may help to improve your knowledge and understanding about HIV-infection and Highly Active Anti-Retroviral Treatment (HAART). Furthermore, it may also help to improve your understanding concerning the need to have above 95% adherence to HAART.

4. Possible Risks

Answering the questionnaire as well as taking part in an interview may cause some anxiety. If you become concerned about this issue when answering the questionnaire and/or during the interview counselling will be made available to help you by the Clinic Counsellors (two Counsellors are available at the Clinic).

5. Alternatives to Participation

Your participation in this study is voluntary.

6. Privacy, Confidentiality and Disclosure of Information

Your participation in this study is confidential.

The questionnaire as well as recorded tapes/transcripts will be stored in a locked cabinet in the research unit at Melbourne Sexual Health Centre. Because you are seen at the Melbourne Sexual Health Clinic for your regular HIV care, you are guaranteed that all study documents will be kept separate from the clinic where your medical records are kept. All information in the study documents will remain confidential. No questionnaires or transcribed interviews will have your name on them. Following completion of the study all related documents or information would be archived indefinitely, in accordance with the Alfred Hospital/MSHC guidelines.

7. Results of Project

The Results will be published in a medical journal but without any identifying information. If you would like a detailed report of this Project please indicate this to us on the consent form.

8. Further Information or Any Problems

If you require further information or if you have any problems concerning this project, you can contact the researcher Mohsin M Sidat by telephone on 03 9341 6247 or by e-mail: mswith@yahoo.com.au
9. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

Name: Professor Christopher K Fairley
Position: Director, Melbourne Sexual Health Centre
Telephone: (03) 9347 0244

In the event that you have complaints about this study, and you are not satisfied that your concerns have been addressed, then you may contact:

Name: Ms. Rowan Frew
Position: Ethics Manager, The Alfred Hospital Research and Ethics Unit.
Telephone: (03) 9276 3848

10. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Melbourne Sexual Health Centre.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw.

11. Ethical Guidelines

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The Human Research Ethics Committee of The Alfred Hospital and Melbourne Sexual Health Centre has approved the ethical aspects of this research project.
I have read, or have had read to me, and I understand the Plain Language Statement (green pages) of the above-mentioned project.

I freely agree to participate in this project according to the conditions in the Plain Language Statement. I have a copy of the Plain Language Statement to keep.

I am aware that all data obtained within this study will be kept indefinitely, in accordance with the Alfred Hospital/ MSHC (Melbourne Sexual Health Centre) guidelines. The Researchers have agreed not to reveal my identity and personal details if information about this study is published or presented in any public forum.

Participant's Name (printed) .................................................................

Signature: ....................................................... Date: ..................

Witness to Signature (printed) ..............................................................

Signature: ....................................................... Date: ..................

Please, note that if you would like a detailed report of this Project please indicate this by selecting the appropriate box: YES □ NO □

Note: All parties signing the Consent Form must date their own signature.
Appendix 10: Interview schedule used for “Adherence Study”.
QUALITATIVE STUDY ON ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL TREATMENT (HAART)

INTERVIEW SCHEDULE

First the signed Consent Forms will be collected from each participant. Secondly, the participants will be reminded of the aims of this research and instructions of how the interview will be conducted (including the use of tape-recorder). Finally, the tape-recorded interview will take place and following initial questions will be asked:

- When did you first commence HAART? (approximate time: month/year)
- How many different HAART regimens have you been on since you started? What were the circumstances around change of regimens?
- Why did you decide to start HAART?
  - Did anyone else help you to decide whether or not to start HAART?
  - What role did your clinician had in this decision?
  - What aspects did you take into account to decide?
  - In your view, how helpful has been HAART for your health?
- Have you been involved in any intervention or training at Melbourne Sexual Health Center to help you to adhere to your medication? If yes, what type of training or intervention? Was it helpful? If yes, in what extent? If no, why?
- Do you seek support from anyone (e.g. individuals, organizations, etc) to help you to improve your adherence to medication?
- Have you ever asked any one at the MSHC to help you in this issue? If yes, what type of help you asked for? Were you satisfied with the help provided by MSHC? How did the help provided by MSHC contributed for your adherence to HAART?
- Tell me/us about your experience with HAART? How HAART is experienced in your daily routine? How does HAART affect your life-style?
- In regard of adherence to HAART, tell me/us:
  - What difficulties do you have with adhering to HAART?
  - What helps in adhering to HAART?
  - What would you look from the MSHC or your clinician to help you in this regard?
- Would you like to say or comment on anything we have discussed in this interview? Have you any other comments that you wish to express here?

At the end of the interview the participant will be thanked and reminded that he/she can contact the research team or MSHC at any time and that he/she also will be contacted again to review the transcripts of the interview and that the brief report of this study will be posted to him/her (if he/she has expressed to have it).
Appendix 11: Invitation for clients attending Melbourne Sexual Health Centre to participate in an open non-randomized clinical trial named “Health Map”.
“Health Map” : A Road to Better Health

The use of HAART has transformed HIV-infection into a chronic, manageable disease. People living with HIV on HAART are now living longer. However, as with other chronic diseases, maximizing the chances of living longer and making the most of one’s physical and mental wellbeing requires taking charge of one’s own health issues. Taking into account some of the major issues regarded by HIV/AIDS experts as influencing the health & wellbeing of people on HAART, we have developed for this Referral Clinic a computer based program that we named “HEALTH MAP”.

The “HEALTH MAP” program will provide a printed report at the end, based on the answers given by you, with suggestions for health issues that you can address with our Nurses and/or Doctors here at the Referral Clinic, or you may even take the report elsewhere. The report is meant to be a guide or ‘map’ and we anticipate that it would help you to look for individually appropriate care and encourage you to be in charge of your health and wellbeing.

The “HEALTH MAP” will be a trial program that we expect to run between May to August 2006. If it succeeds in achieving its aims and perceived to be helpful to our clients then it will be introduced as part of a routine care at this Referral Clinic, here in Melbourne Sexual Health Centre.

Please, take part in this trial by asking one of our staff members at the reception desk. We estimate that the participation in this trial will take about 10 minutes (at most).
Coming Soon

For further information please speak with our nursing staff
Appendix 12: “Health Map” computer program development.
Appendix 12: “Health Map” computer program development.

The aim to develop “Health Map” was to assist PLWHA on HAART to eventually overcome dyslipidemias and other risk factors for heart disease without increasing their pill burden. Furthermore, it also aimed to be of assistance in increasing the motivation for keeping high levels of adherence to antiretroviral therapy (HAART). There were no similar programs reported in the currently available literature on HIV/AIDS care context.

The questionnaire for “Health Map” computer program was prepared after a literature review searching for simple tools assessing parameters such as self-efficacy to HAART; perceived stress levels and physical activity. Thus, below I explain the rationale for the use of different sets of assessment tools used to develop “Health Map” program preceded by the “Health Map” computer program window shots.

For each tool used in “Health Map” a system for reporting recommendations for participants was developed based on scoring system for each specific tool/sets of questions. For simplicity and convenience for reporting the system developed was restricted to only two possible answers: one recommending “action” and another just encouraging to keep same levels of activity.
Disclaimer
While considerable care has been taken in preparing this program, Bayside Health does not warrant that the information is necessarily appropriate for you. Before relying on the information, we recommend you discuss it with a doctor or a nurse, otherwise you take the risk that it does not fully reflect your medical condition.

Please provide your 6-digit unique Clinical Record Number (UR Number)

Start
ADHERENCE SELF-EFFICACY (questions 1 to 4):

Questions 1 to 4 will ask you to respond to statements about your anti-HIV medication:

1. You are able to take all your HIV-medication as directed.
   - Not at all sure
   - Somewhat sure
   - Sure
   - Extremely sure

2. You are able to take most of your HIV-medication as directed.
   - Not at all sure
   - Somewhat sure
   - Sure
   - Extremely sure

3. The HIV-medication is having a positive effect on your health.
   - Not at all sure
   - Somewhat sure
   - Sure
   - Extremely sure

4. Missed doses of HIV-medication will result in the virus becoming resistant to your HIV-medication.
   - Not at all sure
   - Somewhat sure
   - Sure
   - Extremely sure
Rationale: Several studies have shown that HAART self-efficacy is a reliable tool to predict HAART adherence (Chesney MA, 2000 #147). One study that was carried out in Melbourne Sexual Health Centre evaluating a tool (including anti-HIV medication self-efficacy tool) found that poor-self-efficacy was one of the best predictors of non-adherence (Wilson KJ, Doxanakis A, and Fairley CK (2004). Predictors for non-adherence to antiretroviral therapy. Sexual Health 1, 251 – 257). Thus, the anti-HIV medication self-efficacy tool used in Wilson’s KJ et. al. (2004) was adapted for “Health Map” by developing a scoring system to identify those with low self-efficacy.

ANTI-HIV MEDICATION SELF-EFFICACY QUESTIONS SCORING SYSTEM (S= score)
1. How sure are you that you are able to take ALL of your anti-HIV medications as directed?
   ○ Not at all sure  S=0
   ○ Somewhat sure  S=1
   ○ Sure  S=2
   ○ Extremely sure  S=3

2. How sure are you that you are able to take MOST of your anti-HIV medications as directed?
   ○ Not at all sure  S=0
   ○ Somewhat sure  S=1
   ○ Sure  S=2
   ○ Extremely sure  S=3

3. How sure are you that the anti-HIV medications are having a positive effect on your health?
   ○ Not at all sure  S=0
   ○ Somewhat sure  S=1
   ○ Sure  S=2
   ○ Extremely sure  S=3
4. How sure are you that missed doses of anti-HIV medications will result in the HIV becoming resistant?
   - Not at all sure  S=0
   - Somewhat sure   S=1
   - Sure            S=2
   - Extremely sure  S=3

RECOMMENDATIONS REPORTING SYSTEM:

If Score > 4: Congratulations, your answers to questions about anti-HIV medication show that you are confident in taking it.

If Score ≤ 4: Your answers to questions about anti-HIV medication show that you are less confident in taking it. We would recommend that you discuss this with your Doctor and/or Nurse.
NUMBER OF MISSED DOSES IN THE PAST 28 DAYS (QUESTION 5):

5. Type into the box how many doses of anti-HIV medication you have either completely or partially missed in the last 28 days:
RECOMMENDATIONS REPORTING SYSTEM:

IF “ZERO” DOSES MISSED:
Congratulations, you have reported missing none of your anti-HIV medication doses in the past 28 days. This is the most important thing you can do to prevent resistance developing.

IF ANY NUMBER OF DOSES MISSED:
You have reported missing ...... doses in the past 28 days. You should discuss this with one of the nurses or doctors in our clinic who have simple and practical tips that you may find useful. Please make a time to see them about it at the reception desk.
ABOUT A PILL-BOX AND ITS USEFULNESS (QUESTION 6):

6. Do you have a pill-box? (This is a Dosette with a separate chamber for each dose, so you know whether you have not taken this particular dose.)
   ☐ Yes
   ☐ No

If YES, how helpful is the pill box in enabling you to take your medication everyday as prescribed?

   ☐ Not helpful at all
   ☐ Somehow helpful
   ☐ Very helpful
**Rationale:** pill-box has proved to be a very useful tool for keeping track of anti-HIV medications taken daily and thus has an important impact on HAART adherence as shown in “Adherence Studies” that I have carried out as part of my thesis. Therefore, Melbourne Sexual Health Centre provides all its clients with free pill-box which can be collected from its pharmacy.

Thus, the recommendation provided in the printed report was only for those who said that they did not have a pill-box:

You reported not having a pill-box. We recommend that every client has one. Clients often find these surprisingly useful, if only to remind them whether they have taken a dose or not, when they can’t remember. They are available free of charge through pharmacy. Please, just ask for one at pharmacy.
Questions 7 and 8 will assess your knowledge about HIV/AIDS and anti-HIV medications:

7. Are you satisfied with what you know about?  
   | Adherence (taking treatment as prescribed) | Yes | Not Sure | No  
   | CD4 T cells counts |            |            |      
   | Lipodystrophy (body fat changes) |            |            |      
   | Nutrition / dietary advice |            |            |      
   | Side-effects of anti-HIV medications |            |            |      
   | Resistance to anti-HIV treatments |            |            |      
   | Risk factors for heart disease |            |            |      
   | Preventing HIV transmission |            |            |      
   | HIV superinfection |            |            |      
   | Community support (housing, employment Socializing, etc) |            |            |      
   | Sexual health and relationship issues |            |            |      

8. All the following statements about HIV and AIDS are TRUE. For each statement, please indicate whether you already knew this, you weren’t sure about it, you didn’t know about it.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Already knew</th>
<th>Didn’t know</th>
<th>Weren’t sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some anti-HIV medications can cause cholesterol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetectable viral load does not mean that HIV has been eradicated from the body</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug resistance is an important reason why HAART may fail</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HIV medications prevent HIV from damaging the immune system, and so prevent ill health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Engaging in unprotected sexual intercourse can put you at risk of HIV superinfection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking greatly increases the risk of heart disease</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Next button]
**Rationale:** Appropriate knowledge on HIV/AIDS as well as on anti-HIV medications is regarded of paramount importance for HIV-infected individuals on HAART to self-care, maintain optimal levels of HAART adherence and lead a healthier life-style.

Thus, the recommendation reporting was designed for two alternatives:

**IF THE CLIENT TICKED TO ALL “YES” OR “ALREADY KNEW” OPTIONS THEN:**
Congratulations, you have reported a very good level of knowledge of HIV/AIDS and anti-HIV medications.

**IF THE CLIENT TICKED TO ANY “NO” OR “DIDN’T KNOW” OR “WEREN’T SURE” OPTIONS THEN:**
(b) You have said that you are “not sure” or “don’t know enough” about the following issues:

*Listing of issues....*

Only those answered as “NO” OR “DIDN’T KNOW” OR “WEREN’T SURE”
It might be helpful to see one of the specialized nurses who work in the clinic. They have an educational program that they can work through with you. We also have lots of brochures and/or information about Organizations that can help with some of these issues.
Questions 9 and 10 will assess your physical activity:

9. How many times a week do you usually do 20 minutes or more of vigorous physical activity that makes you sweat or puff and pant (e.g. weight lifting, jogging, aerobics or fast bicycling)?
   - > 3 times/week
   - 1 - 2 times/week
   - None

10. How many times a week do you usually do 30 minutes or more of other moderate physical activity that increases your heart rate or makes you breath harder than normal (e.g. carrying light loads, bicycling at a regular pace or doubles tennis)?
    - > 5 times/week
    - 3 - 4 times/week
    - 1 - 2 times/week
    - None
Rationale: People living with HIV/AIDS (PLWHA) are now living longer and thus growing older. To prevent some age related diseases such as heart disease it is commonly recommended that people should regularly engage in physical activity. It has been shown that PLWHA and particularly those on HAART are more susceptible to develop heart disease. Thus, a simple tool to assess regular physical activity was used in order to identify those with low levels of regular physical activity and recommend accordingly for improvements. After searching the literature a simple tool for this purpose was found and used in “Health Map” (Marshall AL, Smith BJ, Bauman AE, and Kaur S (2005). Reliability and validity of a brief physical activity assessment for use by family doctors. British Journal of Sports Medicine 39, 294 – 297).

Questions scoring system:
9. How many times a week do you usually do 20 minutes or more of vigorous physical activity that makes you sweat or puff and pant? (e.g. weight lifting, jogging, aerobics or fast bicycling)
   a. > 3 times/week (SCORE=4)  b. 1 - 2 times/week (SCORE=2)  c. None (SCORE=0)

10. How many times a week do you usually do 30 minutes or more of other moderate physical activity that increases your heart rate or makes you breath harder than normal? (e.g. carrying light loads, bicycling at a regular pace or doubles tennis)
    a. > 5 times/week (SCORE=4)  b. 3 - 4 times/week (SCORE=2)
    c. 1 - 2 times/week (SCORE=1)  d. None (SCORE=0)
IF SCORE ≥ 4 THEN FOLLOWING RECOMMENDATION:
Congratulations, your physical activity assessment score shows that you have an acceptable level of physical activity. Please, keep it up.

IF SCORE < 4 THEN FOLLOWING RECOMMENDATION:
Your physical activity assessment shows a low level of physical activity. You may feel better if you increase your physical activity level. We have a Physical Fitness Consultant who is available free of charge and could help you with this. Please ask for our new brochure about exercise or get an appointment at the reception desk to see the Physical Fitness Consultant.
QUESTIONS ASSESSING PERCEIVED STRESS LEVELS (QUESTIONS 11 TO 14):

**Questions 11 to 14 will assess your perceived level of stress:**

11. In the past month, how often have you felt that you were unable to control the important things in your life?
   - Never or rarely
   - Sometimes
   - Often
   - Mostly or always

12. In the past month, how often have you felt confident in your ability to handle your personal problems?
   - Never or rarely
   - Sometimes
   - Often
   - Mostly or always

13. In the past month, how often have you felt that things were going your way?
   - Never or rarely
   - Sometimes
   - Often
   - Mostly or always

14. In the past month, how often have you felt difficulties were piling up so high that you could not handle them?
   - Never or rarely
   - Sometimes
   - Often
   - Mostly or always
**Rationale:** The use of this assessment tool was mainly because of the evidence from the literature that psychological factors (e.g. stress, depression) are related to poor self-care and poor-adherence to antiretroviral therapy among people living with HIV/AIDS. Thus, a validated tool to correlate HAART poor-adherence to psychological factors (e.g. Perceived Stress Measure) was used adapted from the article published by French T et. al. (French T, Weiss L, Waters M, Tesoriero J, Finkelstein R, and Agins B (2005). *Correlation of a Brief Perceived Stress Measure With Nonadherence to Antiretroviral Therapy Over Time.* Journal of Acquired Immune Deficiency Syndrome 38, 590 – 597.).

**Questions scoring system:**

11. **In the past month,** how often have you felt, that you were unable to control the important things in your life?
   - Never or rarely *(score=1)*
   - Often *(score=3)*

12. **In the past month,** how often have you felt, confident in your ability to handle your personal problems?
   - Never or rarely *(score=4)*
   - Often *(score=2)*

13. **In the past month,** how often have you felt, that things were going your way?
   - Never or rarely *(score=4)*
   - Often *(score=2)*

14. **In the past month,** how often have you felt, difficulties were piling up so high that you could not handle them?
   - Never or rarely *(score=1)*
   - Often *(score=3)*

   ○ Sometimes *(score=2)*
   ○ Mostly or always *(score=4)*
Range of score = 4 to 16

If Scores 4 to 10 then following recommendation to be reported:
Congratulations, the assessment of your stress level shows that you are coping very well, psychologically.

If Scores 11 to 16 then following recommendation to be reported:
The assessment of your stress level shows that you may be experiencing some psychological health problems and you might find a counselor helpful in overcoming them. We have two counselors at this clinic and you can see them free of charge. For more information regarding help and/or support for psychological health, please contact our reception desk.
Questions 15 to 24 will assess aspects of your clinical care:

15. Have you been fully vaccinated against Hepatitis A and B?
   - Yes
   - No
   - Not sure

16. In the past 12 months has your cholesterol been measured?
   - Yes
   - No
   - Not sure

17. In the past 12 months has your blood glucose (sugar) been measured?
   - Yes
   - No
   - Not sure

18. In the past 12 months has your blood pressure measured when you were seen by your doctor/nurse at this clinic?
   - Never
   - Sometimes
   - Always

19. Do you smoke presently?
   - Yes
   - No

Would you like to quit smoking?
   - Yes
   - No
Recommendations reporting system for questions 15 to 19:
IF (YES) TO Question 15 then OPTION (a) for recommendation and IF (NO/NOT SURE) TO Question 15 then OPTION (b) recommendation:
(a) Very good. You are fully vaccinated against Hepatitis A and B.
(b). You need to discuss with your doctor about getting vaccinated against Hepatitis A and B.

IF (NO) TO Question 19 then OPTION (a) for recommendation and IF (YES) TO Question 19 = OPTION (b) for recommendation:
(a) Congratulations, you answered that you are a non-smoker and this significantly reduces your risk of heart disease.
(b) You said that you are smoker and this increases your risk of heart disease,
(i) You expressed a wish to quit smoking. Please, ask the reception desk for information about the QUIT© Program. The clinic doctors and/or nursing team also offer services which might be useful to help you quit smoking.
(ii) You expressed no desire to quit smoking. Please, consider quitting smoking so that you can reduce your risk of heart disease.

There were no recommendations reported for questions 16, 17 and 18 (they were intended to prompt clients to ask their clinicians for the clinical processes assessed in these questions - e.g. ask for blood pressure control or for laboratory testing to measure blood sugar or cholesterol).
Questions assessing screening of sexually transmitted infections among men who have sex with men (questions 20 to 22):

Are you: (Questions 20 to 22 only applicable to male clients)
- Male
- Female

20. Have you had sex with any men in the past 12 months?
   - Yes
   - No (skip to 23)

21. Have you had swabs for sexually transmitted infections in the past 12 months?
   - Yes
   - No

22. Have you had any genital symptoms in the past 12 months such as:
   - Discharge from the penis?
   - Burning when passing urine?
   - Lumps or sores on the penis?
   - Or any sexually transmitted infection?
   - Yes
   - No
Rationale: these questions were included in “Health Map” because the current guidelines recommend for all self-identified men who have sex with men to be screened for sexually transmitted infections. These questions were adapted from “Check Your Risk” offered by Melbourne Sexual Health Centre at its website. These questions were thus only available for clients who were male and who had sex with other man (question 20).

The recommendations were made in the following way:
IF (NO) for Question 20 = No recommendation (skip to question 23)

The below recommendation appeared in the printed report only if:
The client has answered “NO” to Question 21 and/or “YES” to Question 22.
Recommendation provided in the report:
Please, consider having swabs for sexually transmitted infections.

There were no recommendations in the report for clients who answered “yes” to question 21 and/or had no symptoms of any sexually transmitted infections.
The following recommendation was provided in the report:
Your Body Mass Index (BMI) calculation result is ..... and the status is ......

The BMI calculator was prepared with the I.T. Department of Melbourne Sexual Health Centre. The report presented the BMI result and its interpretation (e.g. normal; overweight; and obese as commonly presented in BMI calculators).
24. Finally, would you like to know your present risk of heart disease?

- Yes
- No

The following recommendation was provided in the report if the client said “yes” only:
You expressed wish to know your heart disease risk. Thus, please see our Nursing staff.

**Rationale:** Individuals infected by HIV and on HAART are at additional risk of developing heart disease according to some studies. Therefore, it seemed relevant to include this parameter in “Health Map” program. However, for convenience reasons and because of the complexity of integrating a calculator for cardiovascular risk in “Health Map” clients who expressed to know their risk were referred to the Nursing staff. At Melbourne Sexual Health Centre there is already a very reliable cardiovascular risk calculator in MD software that is used to manage clients’ clinical data.
Appendix 13: An example of self-tailored recommendations report.
Disclaimer

While considerable care has been taken in preparing this program, Bayside Health does not warrant that the information is necessary appropriate for you. Before relying on the information, we recommend you discuss it with a doctor or a nurse, otherwise you take the risk that it does not fully reflect your medical condition.

Recommendations

The recommendations that are printed in this report are only intended to be a guide and were based upon the answers you gave. It is your decision which recommendation you follow. We’d recommend you discuss them with one of our Nurses and/or Doctors. This report contains medical information which your Doctor may find helpful.

1. Taking anti-HIV medications:
Your answers to questions about anti-HIV medication show that you are less confident in taking it. We would recommend that you discuss this with your Doctor and/or Nurse.
You have reported missing 2 dose(s) in the past 28 days. You should discuss this with one of the Doctors and/or Nurses in our clinic who have simple and practical tips that you may find useful. Please make a time to see them about it at the reception desk.

2. Knowledge of HIV/AIDS and anti-HIV medication:
You have said that you are “not sure” or “don’t know enough” about the following issues:

- Adherence (taking treatment as prescribed)
- CD4 T cells counts
- Lipodystrophy (body fat changes)
- Nutrition / dietary advice
- Side-effects of anti-HIV medications
- Resistance to anti-HIV treatments
- Risk factors for heart disease
- Preventing HIV transmission
- HIV superinfection
- Sexual health and relationship issues
- Some anti-HIV medications can cause cholesterol
- Undetectable viral load does not mean that HIV has been eradicated from the body
- Drug resistance is an important reason
- Anti-HIV medications prevent HIV from damaging the immune system, and so prevent ill health
- Smoking greatly increases the risk of heart disease

It might be helpful to see one of the specialised nurses who work in the clinic. They have an educational program that they can work through with you. We also have lots of brochures and/or information about organisation that can help with some of these issues.

3. Physical fitness:
Your physical activity assessment shows a low level of physical activity. You may feel better if you increase your physical activity level. We have a Physical Fitness Consultant who is available free of charge and could help you with this. Please ask for our new brochure about exercise or get an appointment at the reception desk to see the Physical Fitness Consultant.

4. Psychological health:
Congratulations, the assessment of your stress level shows that you are coping very well, psychologically.

5. Clinical care issues:
You need to discuss with your Doctor about getting vaccinated against Hepatitis A and B.
You said that you are a smoker and this increases your risk of heart disease. You expressed no desire to quit smoking. Please, consider quitting smoking so that you can reduce your risk of heart disease. Please, consider having swabs for sexually transmitted infections.
Your BMI is 27.78 and the status is overweight. You expressed wish to know your heart disease risk. Thus, please see our Nursing staff.

**SERVICES AVAILABLE**

Did you know about all of these extra services offered by this clinic? Some of them might be useful for you:

- Anti-HIV medication adherence support program
- Free pill-box availability at our pharmacy
- A number of pamphlets on issues which are relevant for people living with HIV which you can collect from our reception desk
- Physical fitness consultant
- Counselling service
- Service to help quitting smoking and also contacts of QUIT© program
- Diverse clinical and laboratory services to monitor your health
- Support for sexual health and relational issues
- Support for social issues (housing, employment, socialising, etc)

You might want to discuss the proposed recommendations with the Nurse/Doctor at this clinic. Please, feel free to ask for any further information you might need by contacting our Nursing Team personally or by phone (our phone number is 9341 6214).

Thank you for participating in this study. Click on the button below to close this page.

[Close] [Print]
Appendix 14: "Health Map" Evaluation Form
EVALUATION FORM

1. Are you:  □ male  □ female

2. You belong to which of the following age group:
   □ 20 – 30 years  □ 31 – 40 years  □ ≥ 41 years

3. Your computer knowledge or literacy is:
   □ Basic  □ Intermediate  □ Expert

4. How easy was the HEALTH MAP program?
   □ Very easy  □ Easy  □ Neither easy nor difficult

5. How useful would you consider the Health Map program to be for you?
   □ Very useful  □ Somehow useful  □ Useful
   □ Not useful  □ Not sure

6. If you were given a choice would you prefer to complete a questionnaire in:
   □ Electronic format  □ Paper format

7. Please, write below if you have any further comments/observations regarding Health Map program:

Many thanks for your participation
Appendix 15: “Health Map” website-version advertisement.
If you have HIV, use this site to guide you to get the most out of your visits to the doctor or other health care providers.

Health Map asks questions about your health and gives you a personal report, based on expert advice. This will direct you to websites chosen for your needs, as well as providing some facts and a “to do” list for your medical care.

Health Map is provided by Melbourne Sexual Health Centre and the Victorian AIDS Council, and funding from the Department of Human Services.
Author/s:
Sidat, Mohsin Mahomed

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Studies on prevention and management of HIV/AIDS in the era of highly active antiretroviral therapy (HAART)

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2007-03

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Studies on prevention and management of HIV/AIDS in the era of highly active antiretroviral therapy (HAART)

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